This file contains 120 unique comment letters of the 145 total comment letters received on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. For comment letters from individuals not representing organizations, CMS has removed the name, address, and contact information of the individual for privacy purposes. Any organization or academic institution has not been de-identified. CMS redacted a PowerPoint submitted as a comment letter from CiiTA, Inc. in its entirety as the PowerPoint included commercial proprietary and confidential material. Additionally, a single comment letter has been selected to represent any substantively duplicative comments (e.g., submitted as a part of a coordinated advocacy campaign).

CMS received two substantively duplicative letter campaigns. The comment letter shown on page two had 17 substantively duplicative comments. The comment letter shown on page 11 had 9 substantively duplicative comments.

June 28, 2024

Meena Seshamani, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Deputy Administrator and Director of the Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

Dear Deputy Administrator Seshamani:

Our organization's mission is to ensure access to high-quality health care and achieve health equity for the communities we serve.

Health centers strive to make medications affordable for all their patients. Because patients aged 65+ are the fastest growing patient population for health centers, we applaud CMS as it implements the Inflation Reduction Act (IRA) provisions to help decrease financial barriers for Medicare patients for prescription drugs and stand ready to partner with the agency. PETALUMA HEALTH CENTER, INC., however, has some concerns about how health centers will get access to 340B-priced drugs, especially with the rollout of the Medicare Transaction Facilitator (MTF), and how manufacturers will reconcile differences in the Maximum Fair Price (MFP) and the 340B price.

For over 30 years, the 340B program has been crucial to help safety net providers like health centers purchase outpatient medications at significantly reduced costs, enabling them to provide affordable discounted or free medications to uninsured and underinsured patients. By law and policy, health centers are required to invest every penny of 340B savings into activities that expand access to care for their patients. The 340B program generates savings that are reinvested in the health center to meet the unique needs of their communities, such as dental care, behavioral health, specialty care, translation services, food banks, housing support, and co-pay assistance programs. Health centers heavily rely on contract pharmacies to expand their community reach in providing their patients affordable, accessible medications. Additionally, health centers operate on razor-thin margins and cannot afford to lose access to 340B-priced medications. PETALUMA HEALTH CENTER, INC. supports the intent of the IRA as it lowers drug prices. We seek to provide constructive feedback on the effectuation of MFP, however, to ensure health centers' opportunities for participation in the 340B program remains intact and does not unduly burden our pharmacies, in particular contract pharmacies.

A summary of our comments is as follows:

- **PETALUMA HEALTH CENTER, INC. is concerned about the impact of 340B claims identification requirements when an entity purchases MFP priced medications prospectively.**
- **PETALUMA HEALTH CENTER, INC. recommends CMS create more flexibility to permit entities to identify 340B drugs through a retroactive process.**
- **PETALUMA HEALTH CENTER, INC. recommends CMS clarify if Option 2 of the housing of banking information on the MTF would allow the use of well-established processes for the reconciliation of payments, including a credit/rebill model to make covered entities whole and a process like Apexus' "Covered Entity Refund Service" if covered entities are overpaid.**

1455 N. McDowell Blvd., Ste D, Petaluma, CA 94954-6559
phone: 707.559.7500 • fax: 707.559.7707

- **PETALUMA HEALTH CENTER, INC. recommends utilizing field 545-2F in the National Council for Prescription Drug Programs (NCPDP) Adjudication responses to help identify claims that were reimbursed MFP based on the patient's eligibility for Medicare.**
- **PETALUMA HEALTH CENTER, INC. has significant concerns about health center pharmacies getting retrospective reimbursement (i.e., MFP rebates) and needing to pay a higher price for drugs upfront, given the thin financial margins health centers operate on.**
- **PETALUMA HEALTH CENTER, INC. strongly urges that CMS does not permit any other payer besides Medicare to provide MFP pricing.**
- **It is critical for the success of this program that CMS retain and exercise all enforcement authority related to 340B claim verification.**

I. **Comments around the Medicare Transaction Facilitator (MTF)**

PETALUMA HEALTH CENTER, INC. is concerned about the impact of 340B claims identification requirements when an entity purchases MFP-priced medications prospectively.

The current MTF transmittal seems to be based on the current prescription processing and flow logic, which is beneficial as it does not create an additional burden on the system. Claim information would be pulled from the switch and sent to the planned sponsor, which would then send the Prescription Drug Event data to the MTF to share with the manufacturer for reconciliation and rebate purposes. That said, the model shared does not illustrate the pathway for how it would handle a situation if an entity purchased the medication at the MFP price prospectively; further, it does not factor in the 340B process, which requires claims identifiers to be added on the front end. We request CMS clarify the following concerns:

1. How 340B claim identification would occur during the 14-day window through the MTF process if a health center purchased medications at the MFP price prospectively.

2. Whether there will be services to reconcile these payments or if health center pharmacies/contract pharmacies need to do this internally.
    - Pharmacy Services Administrative Organizations (PSAOs) could serve as partners to help facilitate this because nearly every pharmacy will have a central payment, and the PSAO will deposit the money into the health center's bank account.

3. If the MTF will provide contract pharmacies with the rebate directly or if the contract pharmacies have an obligation to share that with the covered entity that they contract with.
    - If a contract pharmacy contracts with multiple covered entities, this could be difficult and confusing to operationalize, especially on smaller, independent pharmacies. Health centers rely heavily on contract pharmacies to expand their service area and enhance patient convenience. Eighty-six percent of health centers utilize contract pharmacies, allowing them to serve hundreds of zip codes.[1] A claim indicator requirement could severely impact a pharmacy's desire to contract with a health center, given the anticipated burden of working with a claims indicator.

PETALUMA HEALTH CENTER, INC. recommends CMS create more flexibility to permit entities to identify 340B drugs through a retroactive process.

We believe most of the data processed through the MTF is reasonable; however, we have concerns about the use of the 340B Claims Indicator. Determining whether a prescription can and should be filled with a 340B purchased drug can be a

complicated, data-intensive process that often cannot be completed when the prescription is filled and the claim is submitted to the payer or at the point of sale. Point-of-sale identification for 340B drugs is difficult because it would require the pharmacy to resubmit claims that were classified incorrectly at the point-of-sale, leading to an increased administrative burden.

Under the 340B program, pharmacies have the discretion to use a variety of inventory models, including for tracking drugs at contract pharmacies. A covered entity will work with a third-party administrator (TPA) to implement a 340B drug inventory system for contract pharmacy arrangements, usually implementing the pre-purchased inventory model or the replenishment inventory model.[2] Both systems can run a compliant 340B program to avoid duplicate discounts but track inventory differently. Specifically, under the replenishment model, a contract pharmacy uses its non-340B purchased drugs when filling prescriptions on behalf of the covered entity. Because 340B eligibility is determined retrospectively in a replenishment model, most contract pharmacies do not know at the point of sale if the drug they are dispensing will ultimately qualify as a 340B drug and would have extreme difficulty implementing a point-of-sale modifier for 340B drugs. Additionally, even if a contract pharmacy uses the pre-purchase inventory model, that does not guarantee the pharmacy has 340B price drugs for all the health center patients' needs.

We request the ability for health center pharmacies to use both prospective and retrospective claim identification to accommodate all types of pharmacy models, which is currently how a model in Oregon functions. The state's retroactive 340B claims file process allows 340B covered entities to avoid duplicate discounts when contracting with retail pharmacies to dispense 340B-stocked medications to patients of the covered entity. Retroactively identifying which pharmacy encounter claims were filled with 340B drugs allows those claims to be excluded from the Medicaid Drug Rebate process by the Oregon Health Authority.[3] This clearinghouse model can enhance accurate claims identification while easing provider burden by minimizing disruptions to pharmacy workflow and allowing claim identification after submission, given the difficulty of placing a claims modifier on 340B drugs at the point of sale as mentioned previously.

PETALUMA HEALTH CENTER, INC. recommends CMS clarify if Option 2 of housing banking information on the MTF would allow the use of well-established processes for payment reconciliation, including a credit/rebill model to make covered entities whole and a process like Apexus' "Covered Entity Refund Service" if covered entities are overpaid.

It is essential CMS has a clear process in place for reconciliation payments as the number of drugs and manufacturers grow over time, if a rebate model must be used. While the manufacturer count is limited this year, more and more drugs will be added each year and be subject to negotiation; besides 10 this year, there will be 15 more in 2027, an additional 15 drugs in 2028, and 20 drugs in 2029, with a cumulative total of 60 drugs. While we do not believe a rebate model is in the best interest of health centers, given that health centers operate on financially thin margins, if CMS decides to utilize one of the options for housing banking information on the MTF, we recommend CMS use Option 2 but seek clarification on repayment methods.

Currently, there are already systems in place that health centers use to facilitate payments/rebates related to MFP and 340B pricing. However, current guidance on Option 2 is unclear whether when the MTF receives the aggregated refund amounts from participating primary manufacturers and passes through the refunds to participating dispensing entities, if this involves the collection and housing of new banking information from participating dispensing entities, or if the payments would go through already established payment channels, such as through Pharmacy Benefit Managers/PSAOs or through Apexus, as described in more detail below.

Instead of the MTF collecting banking information, PETALUMA HEALTH CENTER, INC. recommends CMS employ existing structures used to issue discounts and rebates. The rebates could be handled through the wholesaler rebate process, similar to chargeback or credit/rebills already in place with the 340B program. The wholesaler purchases the medication

at the full wholesale acquisition cost (WAC) on the front end of the transaction. Depending on the inventory account where a purchase is made, the appropriate pricing is extended by the wholesaler prospectively (in this case, the MFP), and the manufacturer, through the chargeback process, credits the wholesaler the difference between the WAC and MFP. In the chargeback model, the dispensers are able to purchase prospectively at the MFP and would not, as the smallest players in the system, have to bear the financial burden of sustaining the discounts for Medicare until they are made "whole" by a rebate. The credit/rebill process is also well established in the pharmacy industry, allowing a drug sold by a wholesaler on one account to be credited and reassigned to another account, for example, credit a WAC purchase and reassigning (rebill) as an MFP purchase.

Additionally, 340B covered entities are also used to mass repayment models from manufacturers to covered entity purchasers facilitated by the 340B Prime Vendor, Apexus. In this instance, HRSA requires manufacturers to refund covered entities on all drug overcharges and urges them to work in good faith with covered entities for repayments. HRSA expects repayment procedures to follow similar processes that align with standard business practice and be documented in the manufacturer's policies and procedures.[4] Facilitated by the 340B Prime Vendor, these rebates primarily take the form of credits to the wholesaler accounts where the purchases were made or checks sent directly to the entity, with neither requiring the housing of entity banking information. On the other hand, a model exists to facilitate entity repayments directly to manufacturers within the 340B program for 340B over-purchases, also facilitated by Apexus.[5] In this, the covered entity's over-purchased amount is paid back to the drug manufacturer, facilitated by Apexus. CMS could consider these well-established processes for the reconciliation of payments to run smoothly between covered entities and manufacturers while simultaneously protecting sensitive banking information from falling prey to bad cyber actors.

We are particularly concerned with Option 1, where the MTF collects banking information from participating dispensing entities and provides that information to primary manufacturers electing to receive such information to issue payment to those accounts. We harbor concerns about cyber security and sharing this sensitive information across numerous manufacturers. In 2023 alone, 725 healthcare data breaches were reported to the Department of Health and Human Services (HHS) Office of Civil Rights, which resulted in more than 133 million records being exposed or impermissibly disclosed. This year, a massive cyberattack was launched against Change Healthcare/Optum, subsidiaries of United Health Group, which impacted around 1 in 3 Americans' sensitive health information.[6] This attack has had and continues to have significant repercussions for health centers and our patients; 77% of health centers report that they were negatively impacted by the cybersecurity breach. Over 60% of health centers have patients who were impacted by a delay in access to care due to the inability to obtain prior authorization, service interruption, or going without needed medications. Seventy-two percent of health centers report that access to discounted medication or health care services has been affected, and one in five health centers have had over half of their revenue impacted by the breach. An average of 75% of health center patients have been directly affected by the breach.[7] We are concerned about the MTF's ability to protect this highly sensitive financial information given the realities of cyberattacks against the healthcare sector. Furthermore, as the number of manufacturers participating increases each year, this means an increased number of manufacturers will be accessing this highly sensitive financial information.

PETALUMA HEALTH CENTER, INC. recommends utilizing field 545-2F in the National Council for Prescription Drug Programs (NCPDP) Adjudication responses to help identify claims that were reimbursed MFP based on the patient being an eligible Medicare patient.

The NCPDP develops and promotes healthcare industry standards and business solutions in the drug supply chain through a multi-stakeholder forum that improves patient safety and health outcomes.[8] There is a field in Segment 25, 545-2F, of this NCPDP payer sheet that work in conjunction with the pharmacy software that can tell the dispensing

pharmacy who is actually paying the claim and what contract the reimbursement is based on.[9] There would be numerous positives if this or a similar process could be implemented for the MTF:

1. This would allow health center pharmacies to know which claims may need to have a payment rebate from the manufacturer to reduce the actual acquisition cost to the MFP.
2. The pharmacy could then track these claims or have a third party track them to ensure they received the proper retrospective payments.
3. This would also allow contract pharmacies to identify claims for CEs to capture (if 340B price is below MFP) without the contract pharmacy having to share payer information (BIN/GRP/PCN), which could be a massively cumbersome process.

If this was possible with Medicare, a similar setup could help identify Medicaid / Managed Care Organization (MCO) claims as well. If every claim had a response that identified it as being paid by Fee-For-Service/MCO, we could ensure no duplicate discounts occur due to unclear adjudications. If there was something in the NCPDP Response from the payor (Segment 25), the payor could be identified as a Medicaid MCO and then adhere to the proper requirements. This could be done in tandem if a patient modifier, such as N1, could be used. This could help with retrospective claim identification. However, in 2019, NCPDP convened a report that stated there was not a necessity for 340B batch processing.[10] PETALUMA HEALTH CENTER, INC. suggests CMS ask NCPDP to create a 340B batch processing opportunity where covered entities, like health centers, could voluntarily retrospectively identify these claims.

II. Access to the MFP

PETALUMA HEALTH CENTER, INC. has significant concerns about health center pharmacies getting retrospective reimbursement (i.e., MFP rebates) and needing to pay a higher price for drugs upfront, given the thin financial margins health centers operate on.

At 40.4, CMS guidance states that manufacturers can provide access to MFP to covered entities in one of two ways:

1. Prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP (Sections 40.4.1 and 90.2 draft guidance), or
2. Retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (section 40.4.3 draft guidance), which includes a 14-day prompt pay window after a verified dispense.

Many 340B covered entities, including health centers, operate with a physical inventory. They seek to ensure they have the medications their patients need, highlight any recurring inventory issues, reduce waste, and identify differences between inventory stock and actual stock.[11] Additionally, health centers operate on razor-thin financial margins while serving some of the most vulnerable, lower-income populations. Health center patients are four times more likely to have income at or below the Federal Poverty Level (FPL) and twice as likely to have income under 200% of FPL as compared to the U.S. population. Health center patients are also more than twice as likely to be uninsured as compared to the U.S. population. Around 11% of patients at a health center have Medicare, with over 4% being dually eligible for Medicaid as well.[12, 13]

Health centers provide healthcare services to all patients, regardless of their ability to pay, and evaluate patients, both those without insurance and those underinsured, on a sliding fee scale to help lower the cost they pay for services based on family size and income. Furthermore, health center entity-owned and contract pharmacies offer prescription assistance programs to help patients with lower incomes be able to afford their medications. Another example is copay assistance programs, which lower the copay patients see when acquiring their prescriptions at the pharmacy. Health

centers put their patients first, stretching their scarce federal resources as far as possible while discounting services to ensure healthcare remains affordable and accessible to all their patients. More than half of community health centers operate with margins below 5%, and 11 million patients were served by health centers operating with negative margins in 2022.[14] These facts show that forcing a rebate model would not be economically or financially feasible for health center pharmacies. All pharmacies, but especially the safety-net 340B covered entities, should have the opportunity to purchase MFP drugs prospectively at their discretion, not at the individual manufacturer's discretion.

PETALUMA HEALTH CENTER, INC. is also concerned about promptness of payment if health centers are paid retrospectively, which gives manufacturers 14 days to pay after a dispense is verified. Realistically, it will take much longer than 14 days for the health center pharmacy to receive any type of payment. When adding in the 30-day window for plan sponsor claim submission, it could be a total of 44 days before the pharmacy gets that rebate payment. As previously mentioned, it would be extremely difficult for pharmacies, both entity-owned and contracted, to continue to keep operations afloat, given the tight financial margins they operate within. We recommend CMS decrease the 30-day window for plan sponsors to submit claims to ensure safety net providers like health centers are not negatively impacted by delayed payments.

We encourage CMS to permit entity-owned pharmacies to have the option to buy drugs at MFP price prospectively from all manufacturers subject to negotiated prices. Health center pharmacies currently operate with physical inventory models for the 340B Program. Additionally, if a health center has a closed-door entity-owned pharmacy, then nearly all the drugs dispensed are 340B-eligible. Having the option to purchase at the MFP price in advance of dispensing and then being able to pass the cost directly along to Medicare, instead of purchasing at a higher price and operating at a loss until if and when a rebate is received, would be more financially viable for health centers serving our nation's most vulnerable populations. This model would also help alleviate the administrative burden on the health center from needing to track the receipt of MFP rebates from multiple manufacturers on what could become a daily basis.

PETALUMA HEALTH CENTER, INC. strongly urges that CMS does not permit any other payer besides Medicare to provide MFP pricing.

Referencing language on page 37, Section 40.4,[15] PETALUMA HEALTH CENTER, INC. is concerned about what this language construes because the manufacturers are only obligated to provide the MFP when the individual claim is eligible under specific Medicare plans and payment structures, as defined in the guidance. Pharmacies and health systems do not have a mechanism to compel manufacturers to provide the MFP pricing when they are filling prescriptions for commercial payers or Medicaid. However, the guidance could be interpreted as that they may be able to dispense medications at these rates to non-Medicare patients. The scope of the IRA is intended for Medicare patients; however, if CMS believes the MFP can extend beyond the Medicare patient population, the health centers should be able to use MFP drugs for their non-Medicare patients as well. We request CMS clarify which payers, if any, can provide MFP pricing.

III. CMS is Not Responsible for 340B

It is critical for the success of this program that CMS retain and exercise all enforcement authority related to 340B claim verification.

This guidance states at 40.4.2 (page 49) that "CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim", meaning that the identification of the claims at the pharmacy to CMS is now voluntary. This statement is further bolstered by the voluntary claims indicator section. The implication of voluntary claims identification is that individual manufacturers could create unique policies on how data is sent to them to

differentiate claims. This could be extremely administratively burdensome and confusing to health centers to adhere to different manufacturer policies, and overall hinder the process of getting their rebate, if eligible. It is essential that there is one clear, established set of rules as the future number of manufacturers and drugs covered under the IRA grows.

We have seen how varying manufacturer policies have been impacting 340B covered entities, as 36 manufacturers have restricted the distribution of 340B-priced medications to contract pharmacies (and in some recent cases, entity-owned pharmacies off-site), with some only unlocking 340B pricing when claims data are submitted and others not at all. Sixteen of these restrictions currently impact health centers. Numerous health centers that have chosen to submit data relay that having to comply with manufacturers' various policies, it is extremely burdensome, and time consuming, creating limited success in restoring 340B-pricing to contract pharmacies, despite their adherence. Additionally, there seems to be little enforcement mechanisms holding manufacturers accountable for ensuring rebates are given to health centers. It is for this reason that health centers have concerns about manufacturers appropriately extending both the statutorily required 340B and MFP discounts/rebates. With no agency as a clear arbiter for claims verification in the context of this guidance, this will be difficult for covered entities to navigate.

As CMS looks to clarify and bolster the Negotiation Program Complaints and Disputes process described at 90.2.2 in the guidance, we recommend the implementation of accountability measures for manufacturers if they do not pay covered entities, like health centers, their rebate. Currently as written, CMS states that manufacturers have to pay difference between MFP and 340B in a "timely manner" but offers no strict timelines or any consequences if there is delinquent payment. We understand that CMS is still looking at any limits on to what extent the agency can help facilitate private transactional disputes between manufacturers and covered entities; however, we implore the agency to detail more clearly how disputes can be resolved, and which governmental agency will be responsible for helping adjudicate any complaints related to the rebate process.

PETALUMA HEALTH CENTER, INC. appreciates the opportunity to comment on this draft guidance and looks forward to continuing to engage with CMS on this important issue. Health centers are eager to work in concert with CMS to implement provisions of the IRA and provide affordable medications to Medicare patients. If you have any questions, please contact Pedro Toledo, Interim Chief Executive Officer at pedrot@pheatlhcenter.org.

Sincerely,

Pedro Toledo, JD
Interim Chief Executive Officer

Appendix 1: NCPDP Payer Sheet
Appendix 2: Pharmacy Software Response

Appendix 1: NCPDP Payer Sheet

	Response Insurance Segment **Segment Identification (111-AM) = "25"**			**Claim Billing/Claim Rebill Accepted/Rejected**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
301-C1	GROUP ID			*Imp Guide:* Required if needed to identify the actual cardholder or employer group, to identify appropriate group number, when available. Required to identify the actual group that was used when multiple group coverages exist. *Payer Requirement:* (any unique payer requirement(s))
524-FO	PLAN ID			*Imp Guide:* Required if needed to identify the actual plan parameters, benefit or coverage criteria, when available. Required to identify the actual plan ID that was used when multiple group coverages exist. Required if needed to contain the actual plan ID if unknown to the receiver. *Payer Requirement:* (any unique payer requirement(s))
545-2F	NETWORK REIMBURSEMENT ID			*Imp Guide:* Required if needed to identify the network for the covered member. Required if needed to identify the actual Network Reimbursement ID, when applicable and/or available. Required to identify the actual Network Reimbursement ID that was used when multiple Network Reimbursement IDs exist. *Payer Requirement:* (any unique payer requirement(s))
568-J7	PAYER ID QUALIFIER			*Imp Guide:* Required if Payer ID (569-J8) is used. *Payer Requirement:* (any unique payer requirement(s))
569-J8	PAYER ID			*Imp Guide:* Required to identify the ID of the payer responding. *Payer Requirement:* (any unique payer requirement(s))

Appendix 2: Pharmacy Software Response

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TidalHealth

TidalHealth Peninsula Regional, Inc.

100 E. Carrol Street
Salisbury, MD 21801
O 410-543-7054
F 410-543-7485
TTY/TDD 410-543-7355

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

6/28/2024, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

We are writing to share our concerns regarding the Centers for Medicare & Medicaid Services' (CMS) May 3, 2024, draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. As a 340B hospital, we rely upon our 340B savings to provide vital care and services to our patients and community. Therefore, we are greatly concerned that the guidance, if implemented as proposed, would impermissibly interfere with hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on 340B hospitals, would recommend that 340B hospitals share their claims data directly with manufacturers, and would force hospitals to float greater drug costs until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price. In issuing the guidance, CMS has failed to meet its statutory obligation to ensure that 340B covered entities (CEs) receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

CMS does not provide a workable solution for hospitals to be able to use 340B drugs when a selected drug's 340B ceiling price is lower than its MFP. Instead, the guidance recommends that thousands of CEs, including hospitals, share claims data directly with each one of the hundreds of manufacturers that could become subject to MFP obligations. First, the process set up by CMS does not effectively permit CEs to use 340B-priced drugs when 340B is lower than MFP. CMS' proposal requires providers to purchase drugs at prices significantly higher than MFP and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"), impermissibly requiring that providers essentially float revenue to manufacturers. Applying this to 340B entities, CMS proposes that when the 340B price is lower than MFP, 340B entities append a modifier on the claim to identify the claim as 340B, which could allow the manufacturer to avoid making the default payment for those claims. Yet, CMS acknowledges that most CEs use a virtual inventory system in which 340B claims cannot be tagged until after the claim is submitted. That certainly is the case for our hospital. The virtual inventory model has been in use since 340B was enacted more than 30 years ago. It would be unworkable to expect these pharmacies to use a separate physical inventory of 340B drugs. Instead, CMS should develop a methodology that would enable CEs to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify 340B claims and withhold them from being

submitted to the manufacturer. This process has been used successfully for Oregon Medicaid for more than a decade.

Second, recognizing the problems with point-of-sale identification, CMS urges that CEs submit their 340B claims data directly to the manufacturers for drugs subject to the MFP, a chore that would involve thousands of CEs separately submitting data to potentially hundreds of manufacturers, each of which could have its own separate data requirements and processes.

While CMS does not mandate that CEs share data, the guidance sets up processes for manufacturers to use such data. We would strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies and believe that outcome is well outside CMS' statutory authority. It also directly conflicts with CMS' explicit authority in section 1193(d)(1) of the IRA to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price and, per sections 1193(a)(5) and 1196(b)**,** that process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of and separate from the government's stated process, especially when there could be thousands of different policies.

In addition, permitting each manufacturer to have its own methodology for nonduplication of 340B and MFP could create significant barriers to CEs accessing the lower of the 340B ceiling price or MFP and could be tremendously burdensome for CEs to manage. We are especially concerned because CMS provides no guidelines for the plans or criteria for how the agency will evaluate these plans, including what manufacturers are and are not permitted to do under them.

Absent evaluation guidelines and criteria for the manufacturers' nonduplication plans, a manufacturer might use a CE's NPI to assume all outpatient claims are 340B. Alternatively, a manufacturer might require CEs to submit large volumes of data to the manufacturer or its vendor in order to receive the 340B price or MFP as a refund. This would be at odds with the longstanding practice of CEs accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B programs. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices.

Additional concerns about manufacturers requiring covered entities to submit claims data directly to the company or its vendor include:

- It could be challenging for CEs, particularly small ones (e.g., rural hospitals), to navigate and manage a wide variety of manufacturer methodologies, especially as more drugs are selected in future years.
- It could be more challenging for CMS to monitor and ensure manufacturer compliance because the agency would have to understand, monitor, and enforce multiple nonduplication methodologies instead of a single methodology developed by the agency that all manufacturers must follow.
- Manufacturers could ask for a large amount of unnecessary claims data.
- The reporting methodology that a manufacturer requires CEs to use could be burdensome.
- Manufacturers might place unreasonable restrictions on the availability of the MFP or the 340B ceiling price (e.g., assurance of 340B compliance).
- There could be significant delays in CEs receiving payments from manufacturers.

Moreover, our hospital has extensive negative experience with sharing 340B claims data with manufacturers through their vendor ESP in connection with restrictions manufacturers put in place pertaining to the use of contract pharmacies in 340B. The process of obtaining and preparing 340B claims data for submission to ESP imposes a significant administrative burden on hospitals. Hospitals must download claims data reports from the portals of every 340B third-party administrator

(TPA) with which they contract and for every contract pharmacy arrangement administered by each TPA. There is wide variation around reinstatement of 340B pricing at hospitals' contract pharmacies after they have submitted claims data to ESP. Hospitals have reported that 340B pricing is made available for only some NDCs, but not all, and only at some contract pharmacy locations, but not all. Hospitals are forced to devote time and staff resources to follow up on notifications in ESP's portal that claims submissions are incomplete to ensure they do not lose 340B pricing, imposing a significant burden on hospitals. Many of these notifications are baseless and do not represent an actual issue with claims submissions.

TidalHealth Peninsula regional ([redacted]) and Nanticoke hospital ([redacted]) [redacted]. We are proving cares to high percentage of underserved population with high inflation, rising labor costs, and rising drug price. The manufacturer's new reporting requirement and data submission in the proposed CMS draft guidance would only exacerbate these challenges.

For these reasons, CMS should abandon its current proposal for the IRA's 340B provisions and develop a workable means for CEs to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP.

We also oppose the guidance's proposed implementation of MFP when it is lower than the 340B price. The guidance effectively prohibits use of 340B in those instances, expecting that hospitals would purchase drugs for 340B-eligible patients at a non-340B price, requiring safety-net hospitals to float more in drug costs. This would substantially disrupt hospitals' longstanding practice of purchasing and using 340B drugs for their patients, including their 340B-eliglble Medicare patients, and could have significant implications for their virtual inventory systems. Hospitals should be able to use 340B for all of their 340B-eliglible patients, as permitted under the 340B statute, which was not amended as part of the IRA. In addition, CMS should develop a clear process whereby manufacturers make CEs whole by providing the difference between the two price points.

Thank you for considering our comments. Please feel free to reach out to me if you have any questions or if we can provide any additional information.

Sincerely,

Dae H. Yim, PharmD, MBA, BCPS, 340B ACE
340B Coordinator
TidalHealth Peninsula Regional ([redacted])
100 East Carroll Street.
Salisbury, MD 21801
[redacted]

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Drug Price Negotiation Program (MDPNP) Draft Guidance

Dear Dr. Seshamani:

We, the undersigned organizations, represent the broad range of health care providers and programs that participate in the federal 340B Drug Pricing Program. We are writing to share our concerns regarding the Centers for Medicare & Medicaid Services' (CMS) May 3, 2024, draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. As 340B covered entities, we rely upon our 340B financial benefit to provide vital care and services to our patients and communities, consistent with Congress' intent for the program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Therefore, we are greatly concerned that the guidance, if implemented as proposed, would impermissibly interfere with covered entities' (CEs) ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on CEs, would recommend that CEs share their claims data directly with manufacturers, and would force CEs to pay higher prices higher than 340B until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price. By hindering CEs' ability to receive upfront 340B discounts, CMS' proposed approach would ultimately harm the patients and communities that benefit from CEs' use of the savings realized through these discounts. In issuing the guidance, CMS has failed to meet its statutory obligation to ensure that CEs receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

CMS proposes a process for implementing the MFP provisions for non-340B claims that essentially excludes CEs from accessing the lower of 340B or MFP, as they are required to be able to do under section 1193(d) of the Social Security Act (SSA). In recognition of this reality, CMS urges CEs and manufacturers to independently develop a solution that implements section 1193(d) for 340B claims. The proposed guidance directly conflicts with CMS's statutory responsibility to set standards that implement section 1193(d).

Therefore, we urge CMS to abandon the provisions in the guidance pertaining to 340B and develop a workable means for CEs to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP, or alternatively, require manufacturers to sell drugs at MFP. In addition, CMS should develop a methodology that would enable CEs to choose to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. CMS should also develop a clear process whereby manufacturers make hospitals whole by promptly providing the difference when a drug's MFP is lower than its 340B ceiling price or, as requested above, require manufacturers to sell drugs at MFP.

[1] H.R. Rep. No. 102-384, pt. 2 (1992).

For non-340B claims, the proposal would have the provider purchase drugs at prices significantly higher than MFP, which CMS believes will usually be at or around wholesale acquisition cost (WAC), and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"), unless the provider and manufacturer enter into an alternative agreement. Recognizing that a default payment should not be made for 340B claims because those drugs are priced below MFP, CMS proposes that manufacturers develop "deduplication" policies that would be subject to approval by CMS. CMS fails to delineate clear standards that CMS would use to support approval or denial. It appears that so long as manufacturers abide by their CMS-approved deduplication polices, those policies would apply to 340B claims regardless of whether they truly effectuated access to the lower of MFP or 340B and even if they included CE compliance with broad data-sharing requirements established by manufacturers. The only option for redress by CEs would be to complain to CMS and hope the agency would take action in some manner and timeframe that has not been clearly defined in the guidance.

Though CMS does not require that manufacturers follow any specific process for 340B claims, as it does for non-340B claims, it makes several suggestions:

1. Manufacturers could, but would not be required to, decline to pay a default payment on claims identified as 340B at the point of sale with a 340B modifier.[2] CMS acknowledges that 340B eligibility of most claims is determined after the point of sale.[3]

2. CEs could share 340B claims data with manufacturers. This would be a private arrangement between each CE and each manufacturer of drugs subject to the MFP and would take place completely outside of the process CMS is proposing for non-340B claims.[4] CMS proposes no standards or guidelines for how this process would work.

3. CEs could buy drugs at WAC, instead of the 340B price, receive the default payment and then, again under some undefined process, request that the manufacturer pay the difference between MFP and 340B.[5]

This suggested framework is problematic, unworkable, and inconsistent with CMS's statutory obligation under the IRA. First, a point-of-sale modifier for 340B claims is completely incompatible with the virtual inventory system used by the overwhelming majority of 340B pharmacies, in which 340B claims cannot be tagged until after the claim is submitted. The virtual inventory model has been in use since 340B was enacted more than 30 years ago. It would be unworkable to expect these pharmacies to use a separate physical inventory of 340B drugs.

We would strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies and believe that outcome is well outside CMS' statutory authority. It also directly conflicts with CMS' explicit authority in section 1193(d)(1) of the SSA to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price

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[2] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 –1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 49, 109 (May 3, 2024).
[3] *Id*. at 50. The National Council for Prescription Drug Programs (NCPDP), which developed the standard for point-of-sale identification of 340B claims, has stated it is impossible for the overwhelming majority of CEs to use point-of-sale modifier. National Council for Prescription Drug Programs, 340B Information Exchange Reference Guide 24 (June 2019), https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf.
[4] *Id.* at 46, 50, 109.
[5] *Id*. at 49.

and, per sections 1193(a)(5) and 1196(b)**,** and that the process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of and separate from the government's stated process, especially when there could be thousands of different policies. Furthermore, there is no language in the IRA's 340B provisions suggesting that manufacturers have any authority to create their own nonduplication methodologies.

Permitting each manufacturer to have its own methodology for nonduplication of 340B and MFP could also create significant barriers to CEs accessing the lower of the 340B ceiling price or MFP and could be tremendously burdensome for CEs to manage. We are especially concerned because the lack of guidelines suggests that there is no limit to the conditions a manufacturer could conceivably impose.

For example, a manufacturer might use a CE's National Provider Identifier to treat all outpatient claims as 340B, even if they are not. Alternatively, a manufacturer might require CEs to submit large volumes of data to the manufacturer or its vendor in order to receive the 340B price or MFP as a refund. This would be at odds with the longstanding practice of CEs accessing the 340B discount as a purchase price and would be highly disruptive to how CEs manage their 340B inventory and impose an impermissible financial burden on CEs, which would be required to purchase at a price significantly above 340B and wait to get paid at some undetermined point in the future by a manufacturer, essentially requiring public and nonprofit safety-net providers to float revenue to the manufacturer. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices. The IRA does not give CMS the authority to permit or encourage manufacturers to do so.

Additional concerns about manufacturers requiring covered entities to submit claims data directly to the company or its vendor include:

- It could be challenging for CEs, particularly small ones, to navigate and manage a wide variety of manufacturer methodologies, especially as more drugs are selected in future years.
- It would be impossible for CMS to effectively monitor and ensure manufacturer compliance because the agency would have to understand, monitor, and enforce multiple nonduplication methodologies.
- Manufacturers could ask for a large amount of unnecessary claims data.
- The reporting methodology that a manufacturer requires CEs to use could be extremely burdensome.
- Manufacturers might place unreasonable restrictions on the availability of the MFP or the 340B ceiling price (e.g., assurance of 340B compliance).

Moreover, our CEs have extensive negative experience with sharing 340B claims data through a vendor backed by manufacturers, 340B ESP, in connection with restrictions manufacturers are already putting in place limiting access to the use of contract pharmacies in 340B. Even though CEs submit data to a single vendor representing multiple manufacturers, drug companies impose different standards regarding whether and how they will use the data, resulting in significant and unpredictable variation around reinstatement of 340B pricing for contract pharmacies. CEs have reported that 340B pricing is made available for only some NDCs, but not all, and only at some contract pharmacy locations, but not all. CEs are forced to devote time and staff resources to follow up on notifications in 340B ESP's portal that claims submissions are incomplete to ensure they do not lose 340B pricing, imposing a significant burden on CEs. Many of these notifications are baseless and do not represent an actual issue with claims submissions.

For these reasons, CMS should abandon its current proposal for the IRA's 340B provisions and develop a workable means for CEs to continue purchasing at the 340B price without identifying a

claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP or, alternatively, require manufacturers to sell drugs at MFP. In addition, CMS should develop a methodology that would enable CEs to retrospectively submit 340B claims data to CMS' MTF and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. This process has been used successfully for Oregon Medicaid for more than a decade.

We also oppose the guidance's proposed implementation of MFP when it is lower than the 340B price. The guidance effectively prohibits use of 340B in those instances, expecting that CEs would purchase drugs for 340B-eligible patients at a non-340B price. This would substantially disrupt CEs' longstanding practice of purchasing and using 340B drugs for their patients, including their 340B-eliglble Medicare patients, and could have significant implications for their virtual inventory systems. It would also require CEs to pay a price higher than 340B until the manufacturer issues the refund at some undefined later point in time. CEs are entitled under the 340B statute to purchase and use 340B priced drugs for all of their 340B-eliglible patients and nothing in the IRA changes that obligation. *Instead, CMS should develop a clear process whereby manufacturers make CEs whole by providing the difference when the MFP is lower than the 340B ceiling price or, as already requested above, require manufacturers to sell drugs at MFP.*

* * *

Thank you for considering our comments. Please feel free to reach out to any of the contacts below if you have any questions or if we can provide any additional information.

Sincerely,

Advocates for Community Health
Ryan White Clinics for 340B Access
National Alliance of State & Territorial AIDS Directors
HIV Medicine Association
National Rural Health Association
America's Essential Hospitals
Association of American Medical Colleges
340B Health

Organizational Contacts

Stephanie Krenrich
Senior Policy President, Policy & Government Affairs
Advocates for Community Health
skrenrich@advocatesforcommunityhealth.org
202-738-6634

Michael D. Thompson
Managing Director
Ryan White Clinics for 340B Access
michael@rwc340B.org
850-391-5776

Emily McCloskey Schreiber
Senior Director, Policy
National Alliance of State & Territorial AIDS Directors
eschreiber@nastad.org
202-897-0078

Andrea Weddle
Executive Director
HIV Medicine Association
aweddle@idsociety.org
703-299-0200

Alexa McKinley Abel
Director of Government Affairs & Policy
National Rural Health Association
amckinley@ruralhealth.us
248-403-9090

Robert Nelb
Director of Policy
America's Essential Hospitals
rnelb@essentialhospitals.org
202-585-0127

Jonathan Jaffery
Chief Health Care Officer
Association of American Medical Colleges
jjaffery@aamc.org
202-741-0996

Maureen Testoni
President & CEO
340B Health
maureen.testoni@340Bhealth.org
202-552-5860

340B HEALTH

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Department of Health & Human Services
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Drug Price Negotiation Program (MDPNP) Draft Guidance

Dear Dr. Seshamani:

340B Health represents over 1,500 hospitals that participate in the 340B federal drug discount program. We are writing to share our concerns regarding the Centers for Medicare & Medicaid Services' (CMS) May 3, 2024, draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. 340B hospitals rely upon their 340B savings to provide vital care and services to our patients and community. Therefore, we are greatly concerned that the guidance, if implemented as proposed, would impermissibly interfere with 340B hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on hospitals, would recommend that hospitals share their claims data directly with manufacturers, and would force hospitals to pay prices higher than 340B until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price. In issuing the guidance, CMS has failed to meet its statutory obligation to ensure that hospitals receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

CMS proposes a process for implementing the MFP provisions for non-340B claims that essentially excludes most 340B hospitals from accessing the lower of 340B or MFP, as they are required to be able to do under section 1193(d) of the Social Security Act (SSA). In recognition of this reality, CMS urges hospitals and manufacturers to independently develop a solution that implements section 1193(d) for 340B claims. The proposed guidance directly conflicts with CMS's statutory responsibility to set standards that implement section 1193(d).

We urge CMS to abandon the provisions in the guidance pertaining to 340B and develop a workable means for 340B hospitals to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP. In addition, CMS should develop a methodology that would enable 340B hospitals to choose to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator

(MTF) and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. CMS should develop a clear process whereby manufacturers make hospitals whole by promptly providing the difference when a drug's MFP is lower than its 340B ceiling price.

I. The guidance fails to offer a workable way for hospitals to use 340B when a drug's 340B ceiling price is lower than its MFP

For non-340B claims, the proposal would have the provider purchase drugs at prices significantly higher than MFP, which CMS believes will usually be at or around wholesale acquisition cost (WAC), and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"), unless the provider and manufacturer enter into an alternative arrangement. Recognizing that a default payment should not be made for 340B claims because those drugs are priced below MFP, CMS proposes that manufacturers develop "deduplication" policies that would be subject to approval by CMS. CMS fails to delineate clear standards that CMS would use to support approval or denial. It appears that so long as manufacturers abide by their CMS-approved deduplication polices, those policies would apply to 340B claims regardless of whether they truly effectuated access to the lower of MFP or 340B and even if they included hospital compliance with broad data-sharing requirements established by manufacturers. The only option for redress by hospitals would be to complain to CMS and hope the agency would take action in some manner and timeframe that has not been clearly defined in the guidance.

Though CMS does not require that manufacturers follow any specific process for 340B claims, as it does for non-340B claims, it makes several suggestions:

1. Manufacturers could, but would not be required to, decline to pay a default payment on claims identified as 340B at the point of sale with a 340B modifier.[1] CMS acknowledges that 340B eligibility of most claims is determined after the point of sale.[2]

2. Hospitals could share 340B claims data with manufacturers. This would be a private arrangement between each hospital and each manufacturer of drugs subject to the MFP and would take place completely outside of the process CMS is proposing for non-340B claims.[3] CMS proposes no standards or guidelines for how this process would work.

[1] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 –1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 49, 109 (May 3, 2024).
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[3] *Id.* at 46, 50, 109.

3. Hospitals could buy drugs at WAC, instead of the 340B price, receive the default payment and then, again under some undefined process, request that the manufacturer pay the difference between MFP and 340B.[4]

This suggested framework is problematic, unworkable, and inconsistent with CMS's statutory obligation under the IRA. First, a point-of-sale modifier for 340B claims is completely incompatible with the virtual inventory system used by the overwhelming majority of 340B pharmacies, in which 340B claims cannot be tagged until after the claim is submitted. The virtual inventory model has been in use since 340B was enacted more than 30 years ago. It would be unworkable to expect these pharmacies to use a separate physical inventory of 340B drugs.

We would strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies and believe that outcome is well outside CMS' statutory authority. It also directly conflicts with CMS' explicit authority in section 1193(d)(1) of the SSA to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price and, per sections 1193(a)(5) and 1196(b)**,** and that the process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of and separate from the government's stated process, especially when there could be thousands of different policies. Furthermore, there is no language in the IRA's 340B provisions suggesting that manufacturers have any authority to create their own nonduplication methodologies.

Such a wholesale revision to how the 340B program has long operated would amount to an "implied repeal" generally disfavored by courts. Under the well-established canon of statutory construction that disfavors implied repeals, while a later enacted statute can sometimes modify or even abrogate an earlier statutory provision, implied repeals are disfavored and will not be inferred unless the legislative intent to repeal is clear and manifest. A court does not presume a statutory repeal unless the later statute expressly conflicts with the original act or unless such a construction is absolutely necessary to give any meaning to the later statute. Absent these limited circumstances, a statute addressing a narrow, precise, and specific subject is not overridden by a later enacted statute encompassing a more generalized spectrum.[5] The IRA contains no language suggesting that Congress intended for the Act to drastically alter how hospitals participate in 340B. In addition, as reflected by our proposed alternative polices described below, CMS could implement the IRA in ways that effectuate the law's 340B provisions while preserving how hospitals currently use 340B drugs for Medicare beneficiaries.

[4] *Id*. at 49.
[5] *See generally Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 662, 127 S. Ct. 2518, 2532 (2007).

Permitting each manufacturer to have its own methodology for nonduplication of 340B and MFP could also create significant barriers to hospitals accessing the lower of the 340B ceiling price or MFP and could be tremendously burdensome for hospitals to manage. We are especially concerned because the lack of guidelines suggests that there is no limit to the conditions a manufacturer could conceivably impose.

For example, a manufacturer might use a hospital's National Provider Identifier to treat all outpatient claims as 340B, even if they are not. Alternatively, a manufacturer might require hospitals to submit large volumes of data to the manufacturer or its vendor in order to receive the 340B price or MFP as a refund. This would be at odds with the longstanding practice of hospitals accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B inventory and impose an impermissible financial burden on 340B hospitals, which would be required to purchase at a price significantly above 340B and wait to get paid at some undetermined point in the future by a manufacturer, essentially requiring public and nonprofit safety-net hospitals to float revenue to the manufacturer. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices. The IRA does not give CMS the authority to permit or encourage manufacturers to do so.

Additional concerns about manufacturers requiring covered entities to submit claims data directly to the company or its vendor include:

- It could be challenging for hospitals, particularly small ones, to navigate and manage a wide variety of manufacturer methodologies, especially as more drugs are selected in future years.
- It would be impossible for CMS to effectively monitor and ensure manufacturer compliance because the agency would have to understand, monitor, and enforce multiple nonduplication methodologies.
- Manufacturers could ask for a large amount of unnecessary claims data.
- The reporting methodology that a manufacturer requires hospitals to use could be extremely burdensome.
- Manufacturers might place unreasonable restrictions on the availability of the MFP or the 340B ceiling price (e.g., assurance of 340B compliance).

Moreover, 340B hospitals have extensive negative experience with sharing 340B claims data through manufacturer vendor 340B ESP in connection with restrictions manufacturers are already putting in place limiting access to the use of contract pharmacies in 340B. Even though hospitals submit data to a single vendor representing multiple manufacturers, drugs companies impose different standards regarding whether and how they will use the data, resulting in significant and unpredictable variation around reinstatement of 340B pricing contract pharmacy. In addition to having varying standards, manufacturers will change standards without notice to hospitals, making it very challenging for hospitals to keep up with and comply with companies' polices in order to maintain access for 340B for contract pharmacies. Hospitals have reported that 340B pricing is made available for only some NDCs, but not all, and only at some contract

pharmacy locations, but not all. Hospitals are forced to devote time and staff resources to follow up on notifications in 340B ESP's portal that claims submissions are incomplete to ensure they do not lose 340B pricing, imposing a significant burden on hospitals. Many of these notifications are baseless and do not represent an actual issue with claims submissions.

For these reasons, CMS should abandon its current proposal for the IRA's 340B provisions and develop a workable means for hospitals to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP. In addition, CMS should develop a methodology that would enable hospitals to retrospectively submit 340B claims data to CMS' MTF and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer. This process has been used successfully for Oregon Medicaid for more than a decade.[6]

II. The guidance also fails to offer a workable way for hospitals to access a drug's MFP when the MFP is lower than the 340B ceiling price

We also oppose the guidance's proposed implementation of MFP when it is lower than the 340B price. The guidance effectively prohibits use of 340B in those instances, expecting that hospitals would purchase drugs for 340B-eligible patients at a non-340B price. This would substantially disrupt hospitals' longstanding practice of purchasing and using 340B drugs for their patients, including their 340B-eliglble Medicare patients, and could have significant implications for their virtual inventory systems. It would also require hospitals to pay a price higher than 340B until the manufacturer issues the refund at some undefined later point in time. Hospitals are entitled under the 340B statute to purchase and use 340B priced drugs for all of their 340B-eliglible patients and nothing in the IRA changes that obligation. *Instead, CMS should develop a clear process whereby manufacturers make hospitals whole by promptly providing the difference when the MFP is lower than the 340B ceiling price.*[7]

[6] For several years, Oregon Medicaid has used a proven model to identify 340B claims that relies upon covered entities or their contractors submitting at regular periods a file with 340B claim information directly to the state's Medicaid rebate vendor. The Oregon model demonstrates that 340B claim identification is achievable through retrospective file transfers and without manual application of 340B identifiers on claims. The rebate vendor matches the data in the file to other patient data to ensure the state excludes 340B claims from its Medicaid rebate requests to manufacturers. The Oregon model also improves compliance by decreasing the risk that the state does not get the 340B claim information it needs by removing Medicaid managed care organizations from the process. Oregon Health Authority, Retroactive 340B Claims File Instructions (Jan. 2, 2024), https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx.

[7] If CMS intends to prohibit hospitals from purchasing through 340B when the 340B ceiling price exceeds the MFP, that would effectively exclude such drugs from the 340B statute. We do not believe CMS has such authority to do so. We note, however, that if the IRA could be interpreted as granting CMS that authority, such drugs would no longer be subject to the provisions of the 340B statute since the hospital could not take advantage of a manufacturer's offer of the 340B price. 42 U.S.C. § 256b(a)(1). This would include the section of the 340B statute that prohibits many hospitals from purchasing covered outpatient drugs through their GPO, and such hospitals would be free to purchase those drugs through their GPO. 42 U.S.C. § 256b(a)(4)(L)(iii).

* * *

Thank you for considering our comments. We remain open to working with CMS to develop alternative methodologies and considering other methodologies that CMS is evaluating. Please feel free to reach out to me at maureen.testoni@340Bhealth.org or 202-552-5860 if you have any questions or if we can provide any additional information.

Sincerely,

Maureen Testoni

June 28, 2024

Dr. Meena Seshamani, M.D., Ph.D
Deputy Administrator and Director of the Center for Medicare
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Submitted via IRARebateandNegotation@cms.hhs.gov

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani,

The Association for Accessible Medicines (AAM) and its Biosimilars Council appreciates the opportunity to provide comments in response to the *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*.

AAM is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. The Biosimilars Council works to increase patient access to lifesaving, high-value biosimilar medicines.

Over the last ten years, generic and biosimilar medicines have provided more than $2.6 trillion in savings to U.S. patients and the healthcare system. In 2021 alone, these medicines provided more than $373 billion in savings, including more than $119 billion in savings for the Medicare program.[1] Because of their low cost and high value, generic and biosimilar medicines today account for more than 91% of all prescriptions dispensed in the US but only 18% of drug spending.

[1] AAM. (September 2022). "2022 Generic and Biosimilar Medicines Savings Report." Accessible at: https://accessiblemeds.org/resources/reports/2022-savings-report

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We are concerned by several key aspects of the approach outlined in the most recent drug negotiation Memorandum. These concerns, and suggested alternative approaches, are described below:

Section 70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect: CMS Should Determine Marketing Status of Generic Drugs or Biosimilar Biological Products Based on Marketing, Not Sales

CMS Should Determine Marketing Status Based on Marketing, Not Sales

The Inflation Reduction Act ("IRA") requires that a generic or biosimilar product be approved and *marketed* in order to make a determination regarding whether a product is considered single-source.

The IRA does not include a statutory definition of "marketing". For the 2027 initial price applicability year, CMS is proposing to use Part D Prescription Drug Event ("PDE") data for the 12-month period beginning January 16, 2024, and ending January 15, 2025 and AMP data with sales from December 1, 2023 and ending November 30, 2024 to assess whether a generic drug or biosimilar product meets the "marketing" requirement. CMS further states it will seek to determine that the manufacturer of the biosimilar or generic has "engaged in bona fide marketing."[2] AAM appreciates that the agency will be using a more expansive approach to determining if marketing has occurred, rather than relying on a single source of data, however we continue to be concerned that this approach is too narrow and is inconsistent with the statutory text of the IRA.

Sales Data is Insufficient to Identify Generic or Biosimilar Marketing, in part, due to Part D Policies that Limit Adoption of New Generics and Biosimilars

There are numerous barriers in place throughout Part D program design and the competitive landscape that initially limit volume for new generics and biosimilars as they enter a market. The proposed reliance on sales data as evidence of "marketing" ignores these market and policy realities that can delay generic and biosimilar adoption.

For instance, some generics and biosimilars may naturally face a slower adoption curve. These may reflect new competitors in chronic disease markets. Moreover, previous AAM research demonstrates how Part D formularies often delay coverage of "first generics"[3]. For example, despite an unprecedented number of product launches for adalimumab biosimilars with price reductions of more than 80 percent, biosimilars constituted only roughly 2 percent of total market share compared to the brand after a full year of competition.[4]

[2] Centers for Medicare and Medicaid Services (March 2023) Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (cms.gov) Accessible at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

[3]Association for Accessible Medicines (July 2021) New Evidence Shows Medicare Part D Plans Continue to Fail to Get New Generics to Seniors. Accessible at: https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf

[4]IQVIA, Adalimumab Biosimilar Tracking, Q1 Readout. Accessible at https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf

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Until CMS or the FTC act to eliminate anti-competitive rebate contracts that give maximum market power to high-cost, branded drugs, the use of this measure to determine if a biosimilar or generic launch meets the statutory marketing criteria is flawed.

Determining Marketing Status Based on Volume of Sales is Inconsistent with the IRA

To assess whether a generic or biosimilar meets the statutory requirement to be marketed, CMS uses PDE and AMP data to determine based on a 'totality of the circumstances' whether the generic or biosimilar has engaged in "bona fide marketing". However, the Congressional intent is clear in that the statutory text only requires a generic or biosimilar to be "marketed". It does not require that the generic or biosimilar have achieved a certain level of market penetration, either in the Medicare program or in the broader U.S. pharmaceutical environment. A requirement for "bona fide marketing" based on "the totality of the circumstances" is not found in the IRA text.

Rather than creating new standards that exceed the threshold established by Congress, CMS should follow the clear Congressional direction. This is not the first law enacted by Congress that is tied to the marketing status of a new generic or biosimilar. A similar requirement exists in the Food, Drug and Cosmetic Act for new generic medicines.

To implement this, the FDA has established a clear definition of commercial marketing. Under current law, first generic applicants must notify FDA of the date they commence commercial marketing. Although this definition is currently only needed for FDA purposes for generic drugs, it provides a model for CMS to follow for both generic and biosimilar products:

> **21 CFR 314.3(b)** *defines "commercial marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant."*

<u>AAM proposes that CMS define "marketed" consistent with FDA's definition of commercial marketing. A suggested adaptation to include biosimilars is:</u>

> <u>"Marketed means the introduction or delivery for introduction into interstate commerce of a generic or biosimilar drug".</u>

AAM further proposes that CMS create a pathway for generic or biosimilar manufacturers to certify to the agency that the generic or biosimilar is marketed consistent with the above definition. This certification could then be independently verified by CMS through industry sales databases as appropriate, and manufacturers would be responsible for certifying truthfully to CMS.

While we understand that CMS may be concerned about attempts to game the system, we believe the statutory language is clear and that such concerns are not supported by historical trends or currently available evidence. Generic and biosimilar manufacturers work aggressively to launch products quickly and successfully. During early years of the generic market, there were similar concerns that the Hatch-

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Waxman Act, which established the legal framework for generic manufacturers to allow their products to enter the marketplace, would incent generic manufacturers to manipulate their allowances by limiting the volume of products launched. But this has not been the case. Where pre-Hatch-Waxman only 35% of the top selling drugs not covered by patent had a generic available, they now represent 91% of all prescriptions dispensed.[5, 6]

Adopting this definition for the purposes of IRA implementation would ensure consistency and provide clear guidance to industry. This proposed approach would provide clarity and consistency to both CMS and industry in determining whether a generic or biosimilar has been marketed (and whether the reference drug is eligible for negotiation).

CMS Should Use Alternative Data Sources to Confirm Marketing and Sales

As noted above, we believe the statutory language is clear that the marketing determination does not allow for consideration of levels of adoption as a requirement. However, when verifying details of marketing through reporting generated by generic and biosimilar manufacturers, there may be no individual source that is sufficiently comprehensive. AAM urges CMS to clarify that the Agency will closely adhere to the statutory requirements outlined in the IRA with respect to making a determination of whether a product is a single-source drug and will not impose additional requirements related to market share minimums. Specifically, CMS should clarify that listing in pharmaceutical compendia or in Federal resources (NIH DailyMed), a certification of marketing from the generic or biosimilar manufacturer, or the presence of *any* sales of a biosimilar and generic drug in PDE files, AMP sales, and/or a real-time transaction data source will satisfy the IRA's statutory requirement to demonstrate that a generic or biosimilar has been marketed. We urge CMS not to continue using a different, more demanding standard than what is required by statute.

Section 30.3.1.2 High Likelihood - CMS Should Allow Biosimilars In Active Litigation To Receive The Two Year Delay

CMS states that it will consider the requirement that existing patents will not prevent a biosimilar from being marketed met if "one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product,"[7] there are no unexpired patents, or there is a signed legal agreement with the Reference Manufacturer in place when evaluating requests for delay from biosimilar manufacturers.

This approach is inconsistent with the statutory intent of the IRA biosimilar delay provision, and it will ultimately lead to less aggressive patent challenges. Patent litigation is inherently uncertain, fast-moving and should not be indicative of approval or marketing of a biosimilar. Under CMS' current standard, a biosimilar manufacturer that overwhelmingly establishes at trial that the relevant patents are invalid

[5] Silver R. A Wall Street Perspective on Generics (2007) GPhA Meeting, March 1-3, 2007. Accessible at: www.gphaonline.org/AM/CM/ContentDisplay.cfm?ContentFileID=593

[6] Association for Accessible Medicines (September 2022) The U.S. Generic & Biosimilar Medicines Savings Report. Accessible at: https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf

[7] CMS Guidance, Available here: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (cms.gov)

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and/or not infringed upon would be ineligible for the delay—even if the decision from the district court was a mere few days away. Moreover, multiple biosimilars on the market today have launched 'at risk' during ongoing litigation. This type of aggressive commercialization is a goal that CMS should seek to support.[8]

Not only is there a proven track record of biosimilars launching at risk, but in some cases, ongoing patent litigation may even be irrelevant to biosimilar launch. As an example, assume Reference Product A is approved for rheumatoid arthritis and Crohn's Disease, and a biosimilar applicant initially seeks approval for both indications. Even if litigation remains ongoing for the patent covering the Crohn's Disease indication, the biosimilar applicant could amend or supplement its 351(k) BLA to "carve out" that indication from its labeling, launching the product for rheumatoid arthritis only. Indeed, it is not uncommon for biosimilar applicants to add and remove indications as patent litigation evolves.

Furthermore, establishing a de facto standard that ongoing litigation disqualifies a biosimilar from receiving a two-year delay grants brand manufacturers too much control of the process, as they would have the ability to keep litigation active regardless of the willingness of a biosimilar manufacturer to launch at risk.

The IRA Includes Safeguards for Taxpayers if the Biosimilar Fails to Launch within Two Years

It is important to keep in mind that the IRA is intended to encourage generic and biosimilar competition, and that, furthermore, it provides a safeguard for situations in which a biosimilar delay is granted, but the product is not marketed. Under the IRA, if a delay is granted and a biosimilar is not subsequently marketed, a brand manufacturer will be required to pay a rebate for the years during which they would have provided access to a Maximum Fair Price (MFP). Accordingly, since there is a defined safeguard in place to protect the negotiation program and taxpayers if a biosimilar is not launched, it is appropriate to grant biosimilars with ongoing litigation but no adverse court decision eligibility to receive the two-year delay. Such an approach will reduce uncertainty for biosimilar manufacturers as they invest in development, increase competition, and reduce prices for patients and the Medicare Program.

AAM urges CMS to alter this standard to allow biosimilars with ongoing litigation but no adverse court decision to be eligible to receive the two-year delay. To support its determinations, CMS could permit or require biosimilar manufacturers to submit explanations detailing why market entry is likely. These could then be evaluated by the agency, rather than defaulting to an overly restrictive test that undermines biosimilar competition.

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry – CMS Should Make Determinations Regarding Successful Initial Delay Requests by January 15, 2026, Rather Than Late-2025

CMS requests comment on the appropriate date by which it should determine for applicability year 2028 whether each Biosimilar named in a successful Initial Delay Request for applicability year 2027 is licensed and marketed during the delay period. The agency indicates it is considering making the

[8] The following products were launched at-risk and are currently available on the market: Kanjinti (trastuzumab-anns) [July 2019], Inflectra (infliximab-dyyb) [November 2016], Fulphila (pegfilgrastim-jmdb) [June 2018], Mvasi (bevacizumab-awwb) [July 2019]

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determination by late-2025, however AAM believes this date should be as late as possible prior to the selection of products for applicability year 2028 to ensure the intent of the statute is achieved. Accordingly, AAM recommends the agency make this determination by January 15, 2026, to ensure that drugs marketed prior to the selection of the products for the 2028 applicability year are reflected in the CMS selection process. Additionally, AAM believes that the agency should promptly notify Biosimilar Manufacturers once a determination has been made that the product has been licensed and marketed during the initial delay period within three business days of the determination.

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry – CMS Should Commit to Providing Additional Transparency for Biosimilar Delay Requests

CMS has outlined a process and timeline for biosimilar delay requests, however there is still a lack of visibility for manufacturers into certain aspects of this process. CMS has committed to providing the reason for why a biosimilar delay request was unsuccessful directly to a manufacturer that submits a request. However, the agency has declined to publish a list of Biosimilar Manufacturers submitting an Initial Delay Request or CMS determinations in the process. AAM believes that CMS should commit to additional transparency around this process, including public information regarding these requests so that manufacturers and the public have a clear understanding of the delay process and how it is operating.

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027 – CMS Should Take Into Account Whether an Additional Moiety in a Fixed Combination Product is Contributing to the Product's Therapeutic Effect

Under the Draft Guidance, CMS proposes a blanket policy under which "fixed combination drugs" (i.e., those with two or more active moieties or ingredients) are excluded from aggregation with the same sponsor's single active moiety / single active ingredient products for purposes of identifying potential QSSDs. As a result, fixed combination drugs would not be subject to an MFP assigned to the QSSD for the single active moiety / single active ingredient, and the fixed combination drug could benefit from an additional 7- (drugs) or 11-year (biological products) period before they are eligible for selection. This approach, however, does not fully account for the fact that in certain instances, an active moiety / active ingredient in a fixed combination drug may not be contributing directly to the drug's therapeutic effect or the fixed combination drug may be comprised of two, previously approved active moieties / active ingredients with little patient benefit. CMS's proposed policy therefore offers a mechanism by which drug sponsors could more easily both evade negotiation and frustrate competition, providing an improper incentive to develop these types of fixed combination drugs. CMS should take this into account when evaluating these products for selection and reduce incentives for the creation of fixed combination drugs with minimal additional patient benefit.

Maximum Fair Price Process Transparency

As AAM has stated previously, we appreciate the guidance the agency has provided with respect to the CMS process and the calculation of the maximum fair price (MFP). However, we believe the agency should provide more transparency into the weighting of the different factors the agency is using to calculate the MFP. This transparency around calculation of the MFP is very important to AAM member

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companies, as the MFP process and anticipated MFP pricing is a critical factor in development decisions for generic and biosimilar products.

Overall, we encourage CMS to exercise flexibility and collaboration during the ongoing development and implementation of the program. We look forward to continuing to engage with HHS and CMS on improving competition, care, and access for America's patients.

Sincerely,

Craig Burton
Senior Vice President, Policy & Strategic Alliances
Executive Director, Biosimilars Council

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July 1, 2024

The Honorable Meena Seshamani
Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Re: **Medicare Drug Price Negotiation Program Draft Guidance**

Dear Dr. Seshamani:

AARP, which advocates for the more than 100 million Americans age 50 and over, appreciates the opportunity to comment on the May 3, 2024, draft guidance pertaining to the implementation of the Medicare Drug Price Negotiation Program (Negotiation Program) as part of the Inflation Reduction Act of 2022. AARP strongly supported giving Medicare the authority to negotiate lower prescription drug prices for older Americans and the multitude of other provisions in the new law that will help address high drug prices and related costs. Successful implementation of the Negotiation Program will help reduce prescription drug prices and costs and ensure that millions of older Americans are better able to access the prescription drugs they need at a price that they can afford.

AARP commends CMS for soliciting public input on this draft guidance and appreciates the agency's efforts to collect and include input from patients, caregivers, and health care providers in the Medicare drug price negotiation process. The first year implementing the Negotiation Program, currently underway, provided significant progress and learnings for future years. It is not fair or right to ask patients and taxpayers to continue paying for prescription drugs that have been priced based on what the market will bear. Above all, the needs of Medicare beneficiaries should remain paramount as the agency continues to implement the Negotiation Program. Below we offer more specific comments in response to the draft guidance.

Identification of Qualifying Single Source Drugs

AARP supports CMS' consistent application of the statutory definition of "qualifying single source drug" by using all dosage forms and strengths of drugs and biological products in identifying potential qualifying single source drugs. We also appreciate the agency's clear explanation of the statutory requirements for satisfying the definition of the term and the steps taken by the agency in accordance with those statutory requirements. We support strong program

integrity protections for the Negotiation Program and seek to ensure that, consistent with statute, the negotiation process captures as many high-cost drugs as possible. Equally important, AARP believes that CMS' approach will limit opportunities for drug companies to find ways to inappropriately exclude drugs that would otherwise be eligible for the Negotiation Program. This is essential for the many Medicare beneficiaries who rely on these drugs and have already faced excessively high prices for far too long.

Certain Orphan Drugs Excluded from Qualifying Single Source Drugs

Section 1192(e)(3)(A) of the Social Security Act (SSA) excludes certain orphan drugs from the definition of a qualifying single source drug that is eligible for negotiation. Specifically, the statute excludes a drug (1) that is designated under section 526 of the Federal Food, Drug, and Cosmetic Act as for only one rare disease or condition, and (2) for which the only approved indication (or indications) is for that disease or condition. The guidance provides that a drug that has orphan designations for more than one rare disease or condition will not qualify for this exclusion, even if the drug has not been approved for any indications for the additional rare disease or condition. The guidance further states that CMS will consider only active designations and active approvals when evaluating a drug for the exclusion. AARP strongly supports CMS' interpretation and policies as they will allow for more drugs to be eligible for negotiation and prevent big drug companies from gaming the system to keep prices high.

The Orphan Drug Act was designed to provide incentives to encourage drug manufacturers to develop medications for rare conditions for which there may be few, if any, treatments available. However, there is evidence that some manufacturers are gaming the Orphan Drug Act,[1] and many drugs with orphan drug designations generate significant revenue.[2] Researchers have projected that orphan drugs that could qualify for Medicare drug price negotiation will have earned billions of dollars in revenue before they became eligible for the negotiation process.[3] Further, expanding the orphan drug exemption under Medicare drug price negotiation could exempt anywhere from 10% to 25% of all Medicare prescription drug spending from negotiation,[4,5] a significant departure from the stated intent of the law.

AARP strongly supports innovation and wants to ensure our members can continue to benefit from innovative new drugs. However, AARP does not support any expansion of the orphan drug exclusion under the Negotiation Program. Expanding the scope of the exclusion is actually anti-innovation, as it effectively rewards drug manufacturers for obtaining multiple orphan drug designations for existing drugs rather than focusing their efforts on developing new drugs.

[1] https://kffhealthnews.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/; https://catalyst.nejm.org/doi/abs/10.1056/CAT.18.0032
[2] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01442
[3] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2811802
[4] https://www.congress.gov/118/meeting/house/116902/witnesses/HHRG-118-IF14-Wstate-KesselheimMDJDMPHA-20240229.pdf
[5] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2811802

Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

AARP continues to support CMS' approach to temporarily delay the selection of certain brand name biologic drugs for Medicare drug price negotiation. More specifically, we reiterate our strong support of CMS' approach to determining whether there is a high likelihood that a competing biosimilar will enter the market in the two years after a brand name biologic drug becomes otherwise eligible for negotiation. We believe that this approach will help curtail potential gaming of the system and incentivize the involved companies to ensure that competing biosimilars reach the market in a timely manner. AARP also supports CMS' efforts to create a meaningful threshold for "clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress… towards both such licensure and the marketing of such biosimilar biological product." These criteria will also help protect against potential gaming of the drug selection process.

Entrance into an Agreement with CMS and Alternatives

The 2022 prescription drug law links a manufacturer's voluntary participation in the Drug Price Negotiation Program (the Negotiation Program) to the manufacturer's voluntary participation in the Medicaid Drug Rebate Program, the Coverage Gap Discount Program (CGDP), and the Manufacturer Drug Discount Program (MDDP). If a primary manufacturer chooses to not participate in the Negotiation Program, it can submit notice to CMS and expedite its exit from the CGDP and Manufacturer Discount Program. AARP supports the agency's decision to automatically grant such requests upon receipt.

AARP also supports CMS' decision to only hold a related hearing on whether the primary manufacturer has rescinded its termination request before the effective date of the termination. This approach will help minimize confusion and potential gaming that could otherwise stem from the termination process.

If a primary manufacturer chooses to not participate in the Negotiation Program, this request should be shared expediently and publicly to help ensure that beneficiaries, caregivers, pharmacies, and other affected parties are aware of the drug manufacturer's decision not to participate in the Negotiation Program, as well as the larger implications of that decision.

Confidentiality of Proprietary Information: Supporting and Encouraging Further Transparency

AARP continues to support and strongly encourage transparency in all aspects of the Negotiation Program and especially throughout the negotiation process. AARP also appreciates CMS' stated goals of protecting the proprietary information of manufacturers and ensuring that manufacturers submit the information that is needed for the Negotiation Program, while also avoiding treating information that does not qualify for such protection as proprietary.

We continue to encourage CMS to consider, within the confines of the law, what is in the best interest of the Negotiation Program and the public when determining which information is

proprietary and to favor making relevant information publicly available whenever appropriate. This is especially important when the agency posts the Maximum Fair Price (MFP) negotiated for a selected drug and its justification. Transparency will instill confidence that the MFP represents the lowest price the agency is able to reasonably obtain and facilitate the public's understanding of how the MFP was reached. To that end, AARP supports the inclusion of high-level summary comments regarding manufacturer-submitted information determined to be proprietary into public documents discussing the MFP for a selected drug.

Termination of Agreement

AARP appreciates the detailed summary of the various options available to manufacturers with respect to participation in the Negotiation Program, including the statutory authority underlying such options. There are several points in the Negotiation Program process where a manufacturer can choose to continue to participate or opt out of the process. A manufacturer of a selected drug may choose not to participate in the Negotiation Program or may terminate its agreement to participate before or after agreeing to an MFP for its selected drug. They can also later choose to re-enter any applicable agreements.

AARP also agrees with the agency's decision to require that a manufacturer's termination notification include an attestation that the manufacturer does not intend, during the price applicability period, to enter into an agreement under the Medicaid Drug Rebate Program, CGDP, or MDDP, or to seek coverage of its drugs under the CGDP or MDDP. This ensures accountability and holds a manufacturer in violation of its termination notification (meaning the manufacturer will again be subject to the Negotiation Program requirements) if the manufacturer seeks to re-enter into the applicable agreements or to regain coverage of its drugs under the applicable programs during the price applicability period. The approach balances allowing manufacturers to re-enter applicable agreements under the Medicare and Medicaid programs while mitigating potential gaming of the process.

Other Provisions in the Agreement

AARP supports the agency's policy that the primary manufacturer of a selected drug remains responsible for all the terms of an agreement with CMS under the Negotiation Program even if the manufacturer transfers ownership of one or more new drug applications (NDAs)/biologics license applications (BLAs) of the selected drug. The primary manufacturer would remain responsible until they transfer all NDAs/BLAs of the selected drug to the acquiring entity and the entity assumes responsibility as the new primary manufacturer. AARP believes this approach will help minimize occurrences of primary manufacturers of selected drugs transferring ownership of a portion of NDAs/BLAs of the selected drugs for purposes of circumventing their responsibilities under the agreement.

Negotiation Factors and Consideration of Meaningful Information in Support of Factors

The guidance provides that CMS will consider information on evidence about therapeutic alternative treatments submitted by the primary manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers,

and other interested parties. AARP applauds CMS for including information submitted by beneficiaries and their caregivers. We believe the consideration of comprehensive and diverse data is necessary to ensure the integrity, completeness, and reliability of the data and evidence to be considered for the negotiation process to result in an appropriate MFP for a selected drug. AARP, therefore, also strongly supports and encourages CMS' collection of data and evidence from a broad range of experts and interested parties, and CMS' consideration of meaningful evidence to the greatest extent possible, including comparative effectiveness research. Use of drug value assessments will help ensure that Medicare pays more for drugs that offer high value to Medicare beneficiaries and less for drugs that do not.

AARP continues to recognize and support the statutory prohibition against using evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. AARP believes that there are measures that do not violate this prohibition and that non-discriminatory drug value assessments are an extremely valuable source of information, including for purposes of determining the MFP. We therefore strongly support the use of non-discriminatory drug value assessments and research in the negotiation process. AARP also supports CMS' intent to consider studies that clearly separate prohibited evidence from other evidence that is relevant to the negotiation process.

AARP supports the agency's efforts to improve data collection processes and strongly encourages CMS to develop guardrails to help ensure that such input is properly reviewed, meaningful, and useful to the process. We appreciate CMS' efforts to improve data collection, question format, and content received, including by potentially grouping the information and, to the extent practicable, focusing on patient and caregiver experience.

Similarly, AARP strongly supports the factors that CMS will take into account when reviewing literature and manufacturer submissions regarding alternative treatments. Specifically, we agree with the consideration of the source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternatives, whether the study has been through peer review, study limitations, the degree of certainty of conclusions reached, risk of bias, study time horizons, generalizability, study population, and relevance to the negotiation factors listed in section 1194(e)(2) of the Act. We believe these considerations by the agency will help to ensure the integrity of the data within the negotiation process.

AARP also supports the use of real-world evidence when considering therapeutic alternatives, specifically CMS' intent to consider such evidence relating to Medicare populations and patients with unmet needs, including individuals with disabilities and individuals with end-stage renal disease (ESRD). AARP is aware that many prescription drugs are not tested under real-world conditions prior to FDA approval and appreciates the potential usefulness of this data in the negotiation process, and notes that CMS' interest could help encourage more drug companies to engage in such research.

Supporting Caregiver Perspectives in Development of CMS' Initial Offer

AARP's research continues to highlight the importance of family caregivers and the challenges, including financial, they face in caring for the older adults in their lives.[6] We applaud CMS acknowledging the role of caregivers in the guidance, in which it proposes to add that the agency "may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug." AARP strongly supports CMS' proposal that relevant outcomes include information submitted by the public, including patients and caregivers, and from patient-focused events.

Supporting Additional Improvements in Patient-Focused Events

AARP strongly supports CMS' efforts to improve the design of the patient-focused listening sessions, including different formats that would permit discussion and clarifying questions from CMS, or focus groups with patients and caregivers. These changes would improve the agency's awareness of beneficiary and caregiver perspectives on the selected drugs.

Given that FDA's patient-focused listening sessions are not livestreamed, we believe it is appropriate for CMS to de-identify information from patients and caregivers in those sessions or related event summaries and transcripts. This could improve participation and increase the value and candor of insights provided to CMS through these forums. Such de-identification could be the default for certain forums or, alternatively, available as an option for patients and caregivers, upon request, to select at the time they participate or present. For the sake of transparency, AARP also strongly recommends that CMS consider appropriate conflict disclosures for any patient-focused listening sessions.

AARP also believes that general listening sessions organized around similar condition(s)/disease(s) will be more beneficial than drug-specific sessions. Such sessions will assist CMS in contextualizing the selected drugs, alternatives, and other medications (and their interactions) in ways that are important to patients, providers, pharmacists and caregivers.

Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

AARP supports agency efforts to verify that there is *bona fide* competition for a selected drug before it is removed from the selected drug list. Absent competition from another manufacturer of a generic or biosimilar version of a sole source drug, there is very little incentive for brand name drug manufacturers to lower the high prices of their products for Medicare beneficiaries. Thus, it is incredibly important to accurately and reliably determine when a selected drug is subject to meaningful competition, as prematurely removing it from the selected drug list could negatively impact Medicare beneficiaries' ability to afford needed drugs.

AARP is encouraged by CMS' proposal to look beyond information provided by the manufacturers regarding the availability of competing products for selected drugs and whether

[6] For example, see "AARP Research Insights on Caregiving," July 18, 2023, https://www.aarp.org/pri/topics/ltss/family-caregiving/aarp-research-insights-caregiving.html.

the drug is being actively marketed. We support CMS's proposal to look at the totality of the circumstances when a manufacturer asserts there is a competing product or products to ensure those competing products are *bona fide* competitors that Medicare beneficiaries can and do access. While considering prescription drug event data and average manufacturer price data is helpful, a more holistic approach to ensuring generic equivalents are available for use is necessary to prevent gaming by drug manufacturers.

Additionally, after a determination that a selected drug may be removed from the selected drug list, we strongly support regular and careful oversight of manufacturer practices to ensure that not only is such a competitor product available but that the manufacturer is in fact marketing the drug and beneficiaries have ready access to it. Strong oversight is one of the pillars of program integrity that will ensure the success of the Negotiation Program in lowering prices and costs of medicines for the Medicare program and its beneficiaries.

Part D Formulary Inclusion of Selected Drugs

When enacting the Part D program, Congress placed enormous importance on beneficiary access to covered Part D drugs. Section 1860D-4(b) of the SSA contains specific requirements for Part D sponsors in developing and applying formularies to the Part D plans they sell to Medicare beneficiaries. CMS has built on that framework through rulemaking to further ensure that seniors have access to those drugs and that plan practices, such as prior authorization or step therapy, do not unnecessarily restrict the availability of needed medications. It is critical that the agency continue to ensure that patients have appropriate access to the medications they need.

AARP strongly supports CMS' efforts to monitor plan practices and is encouraged to see the agency's commitment to ensuring plan sponsors are including selected drugs on the formularies with no undue restrictions that could unjustifiably impede access to such products. AARP also appreciates CMS' plan to follow-up with regular ongoing oversight activities.

We thank you for the opportunity to submit comment on the guidance for the Negotiation Program and continue to look forward to its full implementation. For decades, people in the United States have paid the highest prices in the world for prescription drugs – often three times higher than people in other countries. Successful implementation of the Negotiation Program will represent a major victory for older adults and their loved ones across the country who are struggling to afford needed prescription drugs. It will also help incentivize and appropriately reward the development of truly innovative products. AARP stands ready to assist in any way with these and other efforts to bring down drug prices and help older Americans afford the medications and treatments they need.

If you have any questions, please do not hesitate to contact me or Gidget Benitez on our Government Affairs team at gbenitez@aarp.org.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Affairs

July 2, 2024

Submitted via Electronic Filing: *IRARebateandNegotiation@cms.hhs.gov*

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 & Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 & 2027

Dear Dr. Seshamani:

AbbVie Inc. ("AbbVie") appreciates the opportunity to provide feedback on the May 3, 2024 memorandum issued by the Centers for Medicare & Medicaid Services ("CMS"), setting out the agency's draft guidance on how it intends to implement the drug price-control provisions of Sections 1191–1198 of the Social Security Act ("SSA"), as added by the Inflation Reduction Act ("IRA") for initial price applicability years ("IPAY") 2027 and for manufacturer effectuation of the "maximum fair price" ("MFP") in 2026 and 2027.

AbbVie is a biopharmaceutical company committed to discovering and delivering transformational medicines and products in key therapeutic areas, including immunology, oncology, neuroscience, and eye care. Innovation is the lifeblood of our company. Since AbbVie's launch in 2013, we have invested more than $63 billion in research to discover, develop, and deliver new medicines to patients. AbbVie has invested in the research and development needed for these innovative medicines and products that solve serious health issues, enhance people's lives today, and address tomorrow's challenges.

The IRA's unprecedented price-control provisions raise significant constitutional and rule-of-law concerns and threaten to impede the Biden Administration's own health care priorities with serious unintended consequences for innovation and for patient care.[1] In this context, it is especially important for CMS to remain within the bounds of authority prescribed by Congress and to implement the IRA's provisions with scrupulous regard for the limits of its authority and the bedrock requirements necessary to ensure reasoned decision-making and proper accountability. Unfortunately, CMS's IPAY 2027 draft guidance exacerbates many of the concerns from the IPAY 2026 guidance that depart from the statute and pose the greatest risk to innovation. Our comments on specific provisions of CMS's draft guidance are set forth below. AbbVie is also attaching, reiterating and incorporating by reference the comments it submitted on CMS's IPAY 2026 draft guidance. The comments below identify additional and new areas of concern and should be read to also include the comments AbbVie submitted to the IPAY 2026 draft guidance. CMS has never adequately responded to many of those comments and has not changed its guidance to comply with the law. We remain concerned that CMS is deviating from the statute

[1] Mary Caffrey, "How the IRA Has Unraveled the 'Biotech Social Contract,'" 12 *American Journal of Accountable Care* 57, 57-60 (2024).

and using guidance to impose regulatory requirements that are arbitrary and not adequately explained, and, in some cases, entirely outside the scope of CMS's authority or expertise. We respectfully urge CMS to reconsider the IPAY 2027 draft guidance and to respond meaningfully to feedback submitted.

I. CMS's Drug Selection Approach Violates Multiple Statutory Provisions

In the IPAY 2027 draft guidance, CMS deviates from the plain text of the statute to further expand upon its *ultra vires* definition of which products are subject to price controls. CMS not only departs from the IRA, but also from the science of drug development, to impose an ill-fitted definition that "bundles"—and treats as a single product—all of a drug sponsor's drug or biological *products* that *CMS alone* determines contain the same active moiety or active ingredient.[2]

A. CMS's Statements are Inconsistent in Identifying "Active Ingredient" and "Active Moiety," and Its Reliance on RxNorm is Problematic

CMS's statements are inconsistent and ill-defined regarding a pivotal determination in the "drug bundle" it devised—how it will identify a drug's active moiety or active ingredient. CMS first hinted at how it may identify active ingredient/moiety in the October 2023 FAQs for IPAY2026—after IPAY 2026 drug selection—when it stated that it used the "National Library of Medicine's RxNorm database to identify active ingredient(s) for *biological products*, and a combination of RxNorm and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file to identify active moiety(ies) for *small molecule drugs*."[3]

The current IPAY 2027 draft guidance is silent on this point. However, on page two of an obscure PDF file found within a zip folder on CMS's website,[4] CMS defines active ingredient and active moiety differently. In its MFP File Field Definitions, CMS identifies the "Active Ingredient Name" as the "RxNorm IN name associated with NDCs licensed by BLA" and "Active Moiety Name" as "UNII mapped through IN UNII for NDCs approved by NDAs/ANDAs."[5]

From last year to this year, CMS has changed how it identifies "active moiety" for small molecule drugs. And for biologics, CMS has updated its position by identifying a specific field, the "Ingredient"/IN field, within RxNorm to identify "active ingredient." Adding to the confusion, CMS refers to the "IN" field in RxNorm for both biologic products and small molecule products even though there are different "Active Ingredient" and "Active Moiety" fields and information available in RxNorm.

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[2] IPAY 2027 Draft Guidance ("Draft Guidance") § 30.1.
[3] https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-faqs-ipay-2026.pdf (emphasis added).
[4] *See* "MFP_File_Data_Draft_IPAY_2027_Guidance_Web_File_Structure_and_Definitions" located within the zip folder entitled "Proposed Maximum Fair Price File Layout and Definitions Document (ZIP) (May 3, 2024)" accessed at: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.
[5] In the definitions screenshot, the "IN name" is assumed to be the "Ingredient" field in RxNorm. "UNII" is the Unique Ingredient Identifier, which is a number assigned to an ingredient used in drug products and found on the FDA's Global Substance Registration System (GSRS).

CMS Statements	Source Used by CMS to Identify Active Ingredient (Biologics)	Source Used by CMS to Identify Active Moiety (Small Molecule Drugs)
October 2023 – IPAY2026 FAQs	RxNorm database	Combination of RxNorm and FDA's Active Ingredient-Active Moiety Relationship/Basis of Strength file
May 2024 – MFP File Field Definitions	RxNorm IN name	UNII mapped through IN UNII

Aside from failing to have a consistent approach for identifying "Active Ingredient" and "Active Moiety," CMS's reliance on RxNorm is deeply problematic and its method for doing so even more problematic. Relying on the "IN" field to identify active moiety or active ingredient can lead to inconsistent and, at times, inaccurate results that are contrary to science and determinations made by FDA as reflected in approval materials and labeling. Consider antibody drug conjugates ("ADCs"), therapeutic products consisting of a monoclonal antibody chemically linked to a small molecule drug, often a chemotherapy agent. In each of the examples in the chart below, the RxNorm "IN field" only identifies the antibody part of the larger ADC. Ignoring the chemotherapy drug component of an ADC is wrong as a scientific matter[6] and would erroneously aggregate biological products that have different active ingredients, in direct conflict with CMS's interpretation in its guidance (that AbbVie disputes) that only drug applications containing the same "active ingredient" from the same sponsor should be aggregated.

Proprietary Name	Non-Proprietary Name	RxNorm Ingredient (IN)
KADCYLA	ado-trastuzumab emtansine	trastuzumab
PADCEV	enfortumab-vedotin	enfortumab
ENHERTU	fam-trastuzumab deruxtecan	trastuzumab
TRODELVY	sacituzumab govitecan	sacituzumab
TIVDAK	tisotumab vedotin	tisotumab

In contrast, however, for other ADCs, the "IN" field appropriately matches the non-proprietary name of the molecule:

Proprietary Name	Core Non-Proprietary Name	RxNorm Ingredient (IN)
MYLOTARG	gemtuzumab ozogamicin	gemtuzumab ozogamicin
ADCETRIS	brentuximab vedotin	brentuximab vedotin
BESPONSA	inotuzumab ozogamicin	inotuzumab ozogamicin
LUMOXITI	moxetumomab pasudotox	moxetumomab pasudotox
POLIVY	polatuzumab vedotin	polatuzumab vedotin
ZYNLONTA	loncastuximab tesirine	loncastuximab tesirine
ELAHERE	mirvetuximab soravtansin	mirvetuximab soravtansin

[6] As FDA has explained, that agency "considers an antibody-drug conjugate to be a combination product composed of a biological product constituent part and a drug constituent part." *See, e.g.*, FDA, Questions and Answers on Biosimilar Development and the BPCI Act, Guidance for Industry (Sept. 2021) A.II.3, accessed at: https://www.fda.gov/media/119258/download.

There is no explanation for the inconsistent results across different ADCs. These examples illustrate the lack of transparency, predictability and consistency that results from relying on the "IN" field in RxNorm and the RxNorm database in general.

To the extent CMS maintains its approach, CMS should refer to a drug's nonproprietary name appearing in its FDA labeling and approval documents (typically the USAN as identified by FDA) to identify the active moiety for small molecules and active ingredient for biologics instead of relying on RxNorm and reconciling multiple, potentially conflicting, fields within that database. As part of the approval process, FDA determines the core nonproprietary name for the active ingredient(s) contained within a drug or biological product which generally reflects extensive scientific evaluation of the drug substance, such as the chemical structure and pharmacological properties of the molecule.[7] Among other things, a distinct core nonproprietary name should be dispositive that products contain *different* active ingredients, while a shared nonproprietary name can indicate that products contain the same or highly similar active ingredients. Accordingly, to the extent that CMS intends to continue its objectionable "bundling" of drug and biological products, AbbVie requests that in lieu of RxNorm, CMS update its guidance and the MFP File Field Definitions to reflect the nonproprietary name appearing in a drug's FDA product labeling when determining the "Active Ingredient Name" and "Active Moiety Name".

B. The Draft Guidance Departs Even Further from the Statute to Create an "Extra-Aggregation" Approach

The draft guidance aims to further extend CMS's already improper bundling approach by threatening to aggregate not only across distinct drug products and biological products but also across "non-identical names" reported "for the NDA [or BLA] holder."[8] First, we ask CMS to clarify exactly what it intends by this statement. It is unclear whether it plans to base its decision to aggregate across NDAs and BLAs to include NDA and BLA holders that are different entities, and/or whether CMS intends to base its decision to aggregate across different products marketed under different names. It is critical for CMS to provide transparency and clarity regarding what it intends to do, especially since it has already departed from the statute so drastically.

In any event, we are concerned by CMS's statement that it "*may* further investigate whether such NDAs [or BLAs] are held by the same entity,"[9] which seems to suggest an open-ended, standardless "investigat[ion]", without defining which "entities" will fall within the scope of the investigation.[10] It appears that CMS aims to grant itself unilateral authority to decide whether to investigate, without explaining the scope of the investigation or the factors the agency will consider in making its determination. Instead, CMS suggests only that it will consult sources "as CMS deems appropriate."[11]

We ask CMS to explain how this "extra-aggregation" approach (in addition to the overall approach) comports with statutory requirements. The IPAY 2027 draft guidance merely repeats the agency's contention from the IPAY 2026 guidance that its approach "aligns with" the IRA's "Use of Data" provision.[12] But that provision says *nothing* about aggregating data across "entities"

[7] *See generally, FDA Guidance for Industry, Nonproprietary Naming of Biological Products*, at 3-4 (Jan. 2017).
[8] Draft Guidance § 30.1.
[9] *Id.* (emphasis added).
[10] *Id.*
[11] *Id.*
[12] *Id.*

or across FDA applications.[13] Far from aligning with the IRA's Use of Data provision, CMS's approach conflicts with the statute and renders that provision a nullity.

Moreover, by neglecting to define "non-identical names" and "entity" in its broad approach to aggregating products, the agency leaves open the possibility that it will aggregate across distinct corporate actors. In particular, this extra-aggregation approach appears to conflict with CMS's guidance-created distinction between "Primary" and "Secondary" manufacturers. CMS is distinguishing between various types of manufacturers to argue that the agency will only "negotiate" with the "Primary" manufacturer. At the same time, CMS is proposing to aggregate across drug products and biological products and proposing to aggregate wholesale across "entities" with no limiting principle. The resulting dichotomy means that CMS is both expanding what it captures across entities and refusing to consider costs incurred by any entity other than the "Primary" manufacturers for the purposes of imposing an MFP. This approach is entirely unmoored from the statutory text and internally inconsistent with CMS's own proposed guidance.

Thus, we urge CMS to explain what it means by "non-identical names" and "same entity." We also ask CMS to explain what standards it will use to determine whether it will investigate, as well as standards for how it is defining "investigat[ions]," and "appropriate sources."

II. CMS's Creation of Primary and Secondary Manufacturer Definitions is Inconsistent with the Statute and CMS's Own Policies

In this draft guidance, CMS continues its extra-statutory creation of new legal entities—"Primary Manufacturers" and "Secondary Manufacturers." This artificial distinction is contrary to the statute, which specifically incorporates the pre-existing definition of "manufacturer" rather than allowing the agency to create a new one. CMS has not provided sufficient clarity as to how it will apply these new definitions or how these definitions will be reconciled with CMS's approach to identifying "manufacturers" in any other context. CMS may not redefine the definition of manufacturer, let alone in an inconsistent, results-oriented manner—leaving manufacturers and other stakeholders struggling to understand how CMS intends to apply the law.

A. CMS's Guidance Inexplicably Departs from the Settled Understanding of the Statutory Definition of "Manufacturer"

The IRA, Medicare Part B, and Medicaid Drug Rebate Program ("MDRP") statutes all define "manufacturer" to mean an entity that is engaged in "the production, preparation, propagation, compounding, conversion, or processing" or "packaging, repackaging, labeling, relabeling, or distribution" of prescription drug products.[14] But CMS's creation of "Primary" and "Secondary" manufacturers inexplicably differs from this definition and from CMS's own interpretations.

For example, under the MDRP, CMS deems the "manufacturer" to be the "entity that holds the [National Drug Code (NDC)] for a covered outpatient drug."[15] In May 2023, CMS issued a proposed rule that would include still more related entities in the definition of "manufacturer." The proposed rule would define the term to mean "that *all associated entities* of the manufacturer that sell prescription drugs, *including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies,*

[13] SSA § 1192(d)(3)(B) (instructing that *once* CMS has determined whether a drug or biological product is subject to price controls, CMS must *then* "use data that is aggregated across dosage forms and strengths of the drug").
[14] SSA § 1927(k)(5).
[15] 42 C.F.R. § 447.502.

divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement."[16] Under this approach, a "manufacturer" would include certain "affiliates" and "associated entities." As AbbVie explained in its comments on the MDRP rulemaking, even that proposed "manufacturer" definition is insufficiently specific for manufacturers to know if a separate corporate entity would constitute an "affiliate" or an "associated entity."[17]

Even within the purview of the "negotiation" program, CMS's new definition of manufacturer does not hold up. In pending litigation, for example, the Department of Health and Human Services ("HHS") and CMS have asserted that a "manufacturer" is *only* the specific corporate entity that holds the NDA(s) for a selected drug, even for entities with 100 percent common control and wholly-owned subsidiaries.[18] They likewise assert that under CMS guidance, "any obligations under this Program fall on the primary manufacturer alone, not any 'secondary manufacturer.'"[19] In contrast, this new draft guidance appears to suggest that CMS *would* consider affiliated corporate entities when determining the "manufacturer."[20]

B. CMS Inconsistently and Unpredictably Applies Its Primary Manufacturer Construct in the Draft Guidance

Through this draft guidance's approach to defining "manufacturer" as described above, CMS allows itself to cherry pick and choose when it can impose obligations or penalties on entities *other than* the Primary Manufacturer—in particular when other entities that meet the statutory definition of "manufacturer" with respect to a selected drug will be subject to the IRA's extreme penalties.

CMS's lawyers have suggested to courts that the IRA's price-control program is not coercive because "Primary" and "Secondary" manufacturers are to be treated as separate manufacturers, such that a Primary Manufacturer can leave the program and avoid price controls without penalties redounding to other entities that meet the statutory definition of "manufacturer" with respect to a selected drug. Likewise, HHS and CMS have insisted that under CMS guidance, "any obligations under this Program fall on the primary manufacturer alone, not any 'secondary manufacturer.'"[21]

In some places, CMS's draft guidance accords with this view. For example, in Section 40.1, CMS explains that it will enter into an "agreement" with the "Primary Manufacturer." That same section explains that a Primary Manufacturer can "terminat[e] … the Primary Manufacturer's applicable agreements under the Medicaid Drug Rebate Program, the CGDP, and the Manufacturer Discount Program."[22] However, *in other places* CMS's draft guidance suggests

[16] 88 Fed. Reg. 34238, 34292 (May 26, 2023) (proposed to be codified at 42 C.F.R. § 447.502) (emphasis added).
[17] AbbVie opposes the proposed definition of a "manufacturer," because it is inconsistent with the statute and conflicts with Congressional intent. *See* https://www.regulations.gov/comment/CMS-2023-0092-0116.
[18] *See, e.g., Chamber of Commerce v. Becerra*, Def. Mot. Dismiss (August 11, 2023) ("According to publicly available information, non-party Pharmacyclics—not AbbVie—appears to be the relevant manufacturer: Pharmacyclics holds all three NDAs for Imbruvica.").
[19] *Chamber of Commerce v. Becerra*, Def. Reply Supp. Mot. Dismiss (Sep. 8, 2023).
[20] For example, as mentioned above, section 30.1 implies CMS may investigate whether NDAs are held by the same entity for the purposes of identifying a potential qualifying single source drug. See also § 40.7 ("CMS recognizes that whether this transfer of ownership would have these impacts may depend on whether the transfer of the NDA(s)/BLA(s) was made to an entity that is not a related party (e.g., not treated as part of the same employer under subsections (a) and (b) of section 52 of the IRC of 1986) and complied with relevant principles of tax law."
[21] *Chamber of Commerce v. Becerra*, Def. Reply Supp. Mot. Dismiss (Sep. 8, 2023).
[22] Draft Guidance § 40.1.

otherwise. When describing the penalties associated with not signing the "agreement" before the deadline, the draft guidance switches to the term "manufacturer," creating uncertainty about whether CMS believes it could impose penalties on a non-Primary Manufacturer. Specifically, this draft guidance states that: "If the Agreement is not fully executed by February 28, 2025, then pursuant to 26 U.S.C. § 5000D(b)(1), a period will begin on March 1, 2025, during which *the manufacturer* could be exposed to potential excise tax liability."[23]

We urge CMS to provide clarification on the limitation or extension of this new "Primary Manufacturer" construct, including how it will apply this definition across the manufacturer specific factors and QSSD aggregation.

C. CMS Uses Its Primary Manufacturer Construct to Hide the True Impacts of the IRA's Price Controls and Limit Consideration of Manufacturer Costs

CMS likewise relies on its "Primary Manufacturer" definition to avoid accounting for substantial costs associated with drug development by truncating its cost analysis and resetting ledgers every time an NDA or BLA is bought or sold. By doing this, CMS allows itself to artificially depress the prices it imposes even beyond inadequate statutory ceiling prices and hide the true impact of the IRA's price controls.

For example, CMS is required to account for research and development recoupment in determining offers and counteroffers.[24] CMS's draft guidance recognizes that acquisition costs are crucial to determining whether a manufacturer has "recouped research and development costs."[25] In Appendix A of the draft guidance and in the IPAY 2026 ICR, CMS created categories of research and development cost data for manufacturers to report to CMS, but limits its consideration to only those costs incurred by the Primary Manufacturer. This means that CMS will disregard substantial research and development costs if a transaction or licensing arrangement is structured such that the NDA or BLA is held by a subsidiary (even if wholly owned), a commercialization partner, or a contract manufacturing organization. By creating novel definitions of "manufacturer" that are divorced from statutory text and long-held interpretation, CMS is able to cherry pick which costs it accounts for, including impractically limiting any analysis of investments and other cost incurred by entities other than the Primary Manufacturer. This, in turn, hides the true impact of the IRA, counter to the government's assertions that the burdens fall "on the primary manufacturer alone."[26]

CMS's inconsistent approaches hamper manufacturers' ability to make business decisions and have created confusion about who CMS views as the "manufacturer" under particular circumstances and with respect to particular statutory obligations and penalties. We ask CMS to clearly articulate how it interprets a "manufacturer" of a selected drug.

III. The "Negotiation" Process Is Not Designed to Result in a Genuine or Fair Negotiation or a Reasonable Price

A. CMS's Process Does Not Reflect a Robust or Realistic Negotiation

CMS fell short in its IPAY 2026 revised guidance in establishing any semblance of a genuine negotiation process. It dictated what materials could be shared; it artificially limited

[23] *Id.* (emphasis added).
[24] SSA § 1194(e)(1)(A).
[25] *Id.*; *see* Draft Guidance § 60.3; Appendix A.
[26] *Chamber of Commerce v. Becerra*, Def. Reply Supp. Mot. Dismiss (Sep. 8, 2023).

discussions and meetings; it precluded parties from providing relevant information; and it refused to respond adequately or in writing to parties' reasonable requests. The contract it seeks to impose is akin to a contract of adhesion, with CMS dictating its terms and manufacturers left with no option but to accept.

In this new draft guidance, CMS appears to be moving even further away from a meaningful process or affording manufacturers adequate procedures. While CMS says it is interested in providing "additional engagement opportunities for interested parties," it also suggests that it is interested in reducing the already limited number of meetings with pharmaceutical manufacturers and considering a change in format, potentially changing in-person meetings to paper submissions, to facilitate the process in a shorter timeframe.[27] In a process in which manufacturers already lack visibility to CMS's standards, methodologies and applications in making pricing determinations, this proposal only increases opacity.

Further, while AbbVie supports CMS's interest in seeking patient and other stakeholder input, we are concerned CMS will not be providing sufficient transparency with respect to the feedback it collects from patient-focused engagements or how such feedback will be considered in CMS's approach.[28] CMS suggests it will provide only redacted information to a Primary Manufacturer, and do so only "when feasible," providing no standards and no assurance of transparency for manufactures to consider and address such feedback to improve CMS's understanding.

B. CMS's Approach Fails to Identify Appropriate Therapeutic Alternatives and is Unnecessarily Opaque

During the price-setting process, and specifically to determine its initial offer and counteroffer(s), the IRA requires CMS to identify and consider "therapeutic alternatives" to the selected drug. To implement this requirement, CMS should develop clear, transparent guidance reflecting its approach for determining therapeutic alternatives, and should rely on substantiated evidence that manufacturers have had a chance to vet. Instead, CMS has further obscured its process for identifying therapeutic alternatives in this guidance.

The IPAY 2026 revised guidance stated that "[i]n all cases, CMS *will* select therapeutic alternatives based on clinical appropriateness."[29] CMS now states it "will *prioritize* clinical appropriateness in the selection of therapeutic alternatives."[30] In addition, CMS notes that only "[i]n cases where there are many potential therapeutic alternatives for a given indication of the selected drug" does CMS promise that it "may focus" on "therapeutic alternatives that are clinically comparable to the selected drug."[31] This language undercuts the statutory requirement and ensures arbitrary decision-making as it leaves CMS to identify therapeutic alternatives in a standardless vacuum. If CMS intends only to *prioritize* clinical appropriateness and will focus on clinically comparable alternatives only in some situations, in some cases, factors other than clinical appropriateness will drive CMS's selection of therapeutic alternatives.

CMS also appears to be muddying the relevance of various drugs' pharmacologic class in its determination of therapeutic alternatives. The IPAY 2026 guidance noted that CMS would

[27] IPAY 2026 Revised Guidance § 60.4.3.
[28] IPAY 2026 Revised Guidance § 60.4.
[29] IPAY 2026 Revised Guidance § 60.3.1 (emphasis added).
[30] *Id.* (emphasis added).
[31] *Id.*

"identify[] therapeutic alternatives within the same drug class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other drug classes."[32] We are concerned that CMS has revised its approach and come up with new rules, stating that it will "begin" with therapeutic alternatives that fall within the same drug class but "then also consider therapeutic alternatives in different pharmacologic classes" based only on CMS's review of "the sources noted."[33] CMS also states it "may" consult with FDA and/or with "clinicians, patients or patient organizations, and/or academic experts" in its exploration of therapeutic alternatives. But CMS does not provide any guidance as to when it intends to enter such consultations, how and on what criteria it intends to identify such experts, or what information it will share with manufacturers of selected drugs. This ambiguity and lack of transparency can only serve to make the process more arbitrary and inconsistent by obscuring CMS's process and leaving unfettered discretion for the agency to adopt whatever drugs it wishes as therapeutic alternatives, with no standards and no accountability. At minimum, CMS might consider seeking input, in a transparent manner, from healthcare provider advisory boards that fairly reflect the treating community and can provide input as to what drugs truly should be considered as therapeutic alternatives. CMS should also identify the sources it is relying on and allow "negotiating" manufacturers a meaningful opportunity to engage in discussion on the input.

CMS should clarify that the selection of therapeutic alternatives will be based exclusively on clinical appropriateness within the same class and mechanism of action, and will not consider the costs of therapy, including the MFPs of other drugs. Specifically, CMS should consider whether a potential therapeutic alternative is medically appropriate for the same group of patients as the selected drug, as supported by widely accepted and updated clinical guidelines, real-world practice, and evidence-based medicine. Likewise, CMS should clarify, and be transparent about, the data, information, and resources it uses to select therapeutic alternatives, which it should do from within appropriate drug classes. The IRA requires confidential treatment by CMS of information submitted "by a manufacturer to a selected drug that is proprietary information *of such manufacturer*."[34] But the agency has no justification for not sharing pertinent information about how CMS selected therapeutic alternatives, including what sources were used, what experts were consulted, and why CMS looked outside the relevant drug class, if indeed it did. Indeed, CMS's failure to share this information is on its face evidence that CMS is violating the basic requirements of reasoned decision-making. If CMS is applying a methodology for its determination behind the scenes, such methodology should be transparently communicated to manufacturers preparing for submissions and "negotiation" meetings.

C. The Draft Guidance Inappropriately and Opaquely Establishes New Factors for Setting an Initial Offer

When developing an initial offer, CMS suggests it can shortcut its own process by selecting therapeutic alternatives that have already been assigned an MFP in prior years. As in its earlier guidance, CMS states it will use the price of therapeutic alternative(s) to determine the starting point for developing the initial offer.[35] CMS now states, however, that it will consider for each therapeutic alternative covered under Part D, the lower of: (1) Part D total gross covered drug cost ("TGCDC") net of Direct and Indirect Remuneration ("DIR") and Coverage Gap Discount Program ("CGDP") payments; or (2) the "maximum fair price" for IPAY 2026 selected drugs, if

[32] IPAY 2026 Revised Guidance § 60.3.1.
[33] Draft Guidance § 60.3.1.
[34] SSA § 1193(c).
[35] Draft Guidance § 60.3.2.

applicable.[36] CMS then allows itself broad latitude to choose a starting point "within that range" if there are multiple therapeutic alternatives.[37]

First, we urge CMS to clarify how it intends to use these considerations in its calculations. Under both the IPAY 2026 guidance and the IPAY 2027 draft guidance, it is impossible for manufacturers to predict how CMS will determine initial offers for selected drugs. We support transparency and predictability in assessment methodology, and engagement of manufacturers by health technology assessment (HTA) authorities where there is a high-level of information sharing. We encourage CMS to look to and follow even the example of any HTAs around the world that have established consistent and transparent methodologies allowing manufacturers to enter conversations on the valuation of their products with a clear understanding and projection of the authorities' calculations.

Second, there is no statutory basis for the guidance's reliance on the price of therapeutic alternatives for CMS to determine—or seemingly drive—the starting point for developing its initial offer. Rather, when the statute directs CMS to evaluate therapeutic alternatives as one factor for purposes of determining an initial offer, it enumerates categories of evidence to be considered (i.e., therapeutic advance, prescribing information, comparative effectives, unmet medical needs) and never mentions the therapeutic alternatives' cost at all.[38] Nonetheless, CMS continues to build out extra-statutory and internally inconsistent constructs to create artificial leverage to depress initial offers in arbitrary and inconsistent ways.

Third, the pricing constructs CMS has created are arbitrary and unreasonable and will result in further depression in the starting point. The exclusion of DIR and CGDP from the therapeutic alternatives in the development of the starting point of the initial offer is inconsistent with the statutory direction for determining the ceiling price metric for the selected drug, which excludes only DIR.[39] Likewise, there is no statutory basis for considering the MFP of therapeutic alternatives at all when determining an initial offer and the approach risks creating a reference price system anchored to a single alternative versus the breadth of appropriate therapeutic alternatives the statute instructs CMS to consider (again, not for price), anchoring one manufacturer to the results of another manufacturer's "negotiation," and undermining the statute's provisions to consider time-on-market when determining these starting points.[40] For example, allowing the price imposed on a long-monopoly drug—with a lower statutory ceiling price—to depress the price for a more recently approved short-monopoly drug—with a higher statutory ceiling price—directly violates the balance the statute sought to incent innovation.

Along those lines, the statute unquestionably exempts from selection those drugs with generic or biosimilar competition, yet in the draft guidance, CMS seems to be affording itself the latitude (with clear incentive) to consider the price points of generics or biosimilars in the nebulous therapeutic class the agency will determine.[41] This is counterintuitive to the generic/biosimilar framework established under The Drug Price Competition and Patent Term Restoration Act and the Biologics Price Competition and Innovation Act, and unreasonably expands the range of the price control that can be set. It is inappropriate and inconsistent with the IRA's statutory history to

[36] *Id.*
[37] *Id.*
[38] SSA § 1194(e)(2).
[39] SSA § 1194(c)(1)(B)(i).
[40] *See* SSA § 1194(c)(3).
[41] Draft Guidance § 60.3.2.

use the price of a follow-on product to value an innovative medicine, either within or especially outside of the class of products.

D. The Draft Guidance Fails to Appropriately Consider Negotiation Factors

The IRA requires CMS to establish a "consistent methodology and process" for the consideration of the statutory negotiation factors, including certain manufacturer-specific data, during the negotiation process.[42] Specifically, for the purposes of determining offers and counteroffers, CMS must consider data submitted by manufacturers related to: (1) the manufacturer's research and development costs of the for the drug and the extent to which those costs have been recouped; (2) current unit costs of production and distribution of the drug; (3) prior federal financial support for the drug's discovery and development; (4) pending and approved patent applications and regulatory exclusivities; and (5) market data and revenue and sales volume data for the drug in the United States,[43] as well as evidence related to alternative treatments.[44] CMS must further consider evidence about alternative treatments to each selected drug.[45] Instead of a repeatable and transparent methodology, CMS obscures how it will weigh and consider these factors, resulting in a subjective and arbitrary framework for establishing an MFP.

1. CMS's view of therapeutic advance deviates from the statute's instruction and is inappropriately narrow

The statute requires CMS to consider the extent to which the selected drug represents a therapeutic advance compared to *existing* therapeutic alternatives.[46] Hence, when evaluating the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), CMS's findings should be driven by patient experience data and information, the potential for resolution of unmet medical needs, the unique characteristics or patient populations served, and the extent to which the selected drug represented a therapeutic advance *at the time of the drug's approval(s)*.[47] However, CMS's approach is flawed. After selecting therapeutic alternatives, CMS's draft guidance reflects its intent to use only those therapeutic alternatives *at the time the section 1194(e)(2) data is submitted* as the comparators to determine whether and the extent to which the selected drug represents a therapeutic advance.[48] Indeed, for first-in-class drugs, CMS suggests it will consider "other drugs [that] have become available since the selected drug's initial approval"[49] instead of considering alternatives that were "existing" at the time of approval. CMS's approach is contrary to the statute and ignores the scientific breakthroughs a selected drug may have represented at the time that drug was first approved.[50]

Additionally, CMS's approach causes the "alternative treatments" factors enumerated in the statute to collapse into a singular analysis. For example, the statute considers comparative effectiveness as a separate consideration from therapeutic advance, but by considering only the positioning of comparators at the time of drug selection, CMS allows itself to ignore that a drug represented a breakthrough in efficacy at the time of approval. To give effect to the word "existing,"

[42] SSA § 1194(b)(1).
[43] SSA § 1194(e)(1).
[44] SSA § 1194(e)(2).
[45] SSA § 1194(b)(2).
[46] SSA § 1194(e)(2)(A).
[47] *Id.*
[48] Draft Guidance § 60.3.3.1.
[49] *Id.*
[50] Draft Guidance § 60.3.3.

CMS must interpret "existing therapeutic alternatives" to reference a different time period than the other factors considered with regard to "therapeutic alternatives." CMS therefore should include in its therapeutic advance assessment only those therapeutic alternatives existing at the time of the selected drug's approval for its indication(s). CMS should not read the statute to render this word "superfluous, void, or insignificant."[51]

CMS's approach also undermines Congress's intent to encourage and reward "therapeutic advance" in the context of scientific breakthroughs, such as the discovery of first-in-class drugs. Even the legislative history of the IRA demonstrates Congress's intent to encourage and reward scientific breakthroughs.[52] The innovations that Congress protected in the statute occurred long before today. These discoveries happen early in drug development, most often, somewhere around when investigational new drug ("IND") and new drug applications ("NDA") are filed, when indications are approved and when FDA awards exclusivities and designations to applications. CMS must implement the therapeutic advance assessment consistent with Congress's intent to encourage and reward "new, truly valuable treatments," such as first-in-class medicines.[53] High levels of investment and risk are put into first-to-market products, and this point must be considered when CMS develops its initial offer. Factors such as breakthrough therapy designation, orphan designations, and other expedited approval programs, which are strongly probative of therapeutic advances, should be heavily weighted. Yet the guidance goes against the statute and reflects a missed opportunity for CMS to align the guidance with accepted drug development metrics.

2. *CMS should clarify how it intends to evaluate a selected drug's pending and approved patent applications and FDA exclusivities, applications and approvals to adjust CMS's preliminary price*

CMS is required to consider manufacturer-specific "[d]ata on pending and approved patent applications, exclusivities recognized by [FDA], and applications and approvals under section 505(c) of the [FDCA] or section 351(a) of the [PHSA]" for the selected drug.[54] Unlike for all other factors that are assessed independently, CMS states that this factor "will support CMS' consideration of 1194(e)(1) and 1194(e)(2) factors."[55] How CMS will apply this assessment, however, remains opaque.

With respect to the (e)(2) factors, CMS states that "patents and exclusivities may inform CMS' understanding … of whether the selected drug represents a therapeutic advance or meets an unmet medical need."[56] These innovative discoveries happen years before drug price negotiation and in the midst of drug development—as evidenced by the filing of INDs, NDAs, and patent applications and by the award of patents, exclusivities and approvals. Therefore, using

[51] *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001); *see also Elwell v. Oklahoma ex rel. Bd. of Regents of Univ. of Oklahoma*, 693 F.3d 1303, 1307 (10th Cir. 2012) ("[W]e are always hesitant to assume Congress included pointless language in its statutory handiwork."); *Sec. & Exch. Comm'n v. Stubos*, 634 F. Supp. 3d 174, 195 (S.D.N.Y. 2022) (rejecting interpretation that would require the court "to presume that Congress added the word 'pending' for no reason").

[52] *See, e.g.*, Press Release, Ron Wyden, *Wyden Releases Principles For Lowering Drug Prices for Americans* (June 22, 2021), *available at* https://www.finance.senate.gov/chairmans-news/wyden-releases-principles-for-lowering-drug-prices-for-americans ("Today's release reflects the core principles that will guide my work this summer: let Medicare negotiate, limit price gouging, provide relief to consumers at the pharmacy counter, ensure those with individual and employer insurance also benefit, and reward scientific research for those who are truly innovating.").

[53] Ron Wyden, Principles for Drug Pricing Reform (June 22, 2021) (emphasis added), *available at* https://www.finance.senate.gov/imo/media/doc/062221%20SFC%20Drug%20Pricing%20Principles.pdf.

[54] SSA § 1194(e)(1)(D).

[55] Draft Guidance § 60.3.4.

[56] *Id.*

patents, applications, exclusivities, and approvals awarded for past innovation to evaluate therapeutic advance and unmet medical need "as of the time the section 1194(e)(2) data is submitted" is impossible. By narrowly evaluating these (e)(2) factors only as of today, CMS undermines its statutory obligation to credit a drug with an exceptional innovation story with the upward adjustment that otherwise would have been awarded if patents, applications, exclusivities, and approvals had been evaluated independently. CMS should establish clear guidance on how patent applications, exclusivities, and applications and approvals informs its understanding of the other factors.

3. CMS is inappropriately considering patient assistance programs

CMS continues to inappropriately consider patient assistance programs when evaluating market data and revenue and sales volume data for a selected drug to assess the price of a selected drug for a plan. This draft guidance maintains the requirement that manufacturers report a "U.S. commercial average net unit price" both with and without manufacturer-run patient assistance programs, such as coupons, co-payment assistance, or free drug products.[57] These programs provide financial assistance directly to patients in order to reduce their out-of-pocket costs and thus are not price concessions to the plan.[58] Accordingly, it is inappropriate for CMS to require manufacturers to report patient assistance programs as part of the U.S. commercial average net unit price paid by a plan or use the data to assess net prices.

E. The Draft Guidance Impermissibly Threatens Disclosure of Confidential and Proprietary Information

In the IPAY 2026 draft guidance, CMS intended to bar manufacturers from disclosing "any information in the initial offer or any subsequent offer by CMS, the ceiling price contained in any offer, or any information contained in any concise justification provided with an offer," as well as "any information exchanged verbally during the negotiation period."[59] As we pointed out in our comment on that guidance, prohibiting manufacturers from disclosing information related to the process is arbitrary and unreasonable, and it violates the First Amendment as an impermissible prior restraint on speech.[60] CMS appeared to recognize as much, as it removed this mandate from the IPAY 2026 revised guidance.

Although the IPAY 2026 revised guidance and IPAY 2027 draft guidance do not explicitly impose mandatory non-disclosure requirements, CMS seeks to accomplish the same unconstitutional purpose, this time using the threat of disclosing confidential commercial and trade secret information to disguise its unreasonable restrictions on manufacturers' free speech. This draft guidance states that, if a manufacturer "discloses information that is made public regarding *any aspect* of the negotiation process prior to the explanation of the MFP being released by CMS, CMS reserves the right to publicly discuss the *specifics of the negotiation process* regarding that [manufacturer]."[61] CMS places no limits on the "specifics of the negotiation process" that CMS may disclose nor provides any explanation for what "any aspects" of the process will be

[57] Draft Guidance Appendix A: Market Data and Revenue and Sales Volume Data.
[58] *Pharmaceutical Research and Manufacturers of America vs. Becerra*, Civil Action No. 1:21-cv-1395 (CJN) (D.D.C. May 17, 2022) ("A manufacturer's financial assistance to a patient does not qualify as a price made available from a manufacturer to a best-price-eligible purchaser. Rather, a *manufacturer's financial assistance is available from the manufacturer to the patient*. And a patient is not a best-price-eligible purchaser.") (emphasis added).
[59] IPAY 2026 Draft Guidance § 40.2.2.
[60] *Nebraska Press Ass'n v. Stuart*, 427 U.S. 539, 559 (1976) (such restraints "are the most serious and the least tolerable infringement on First Amendment rights"); "*Org. for a Better Austin v. Keefe*, 402 U.S. 415, 419 (1971) (restraints of this type are subject to a "heavy presumption against [their] constitutional validity.").
[61] Draft Guidance § 40.2.2.

interpreted by the agency to mean. Rather than adopting a clear reciprocal disclosure principle, in which any responsive disclosure would be limited in scope to the specific information disclosed by the manufacturer, we are concerned that CMS is seeking to chill speech by reserving unfettered discretion to disclose any aspect of the "negotiation" process—including confidential, proprietary, and trade secret information unrelated to the information disclosed by the manufacturer. For example, a manufacturer that discloses non-confidential information about how CMS has conducted the process—information that is relevant to public oversight—faces the risk that CMS responds by disclosing all of the confidential and proprietary information that the manufacturer has been forced over its objections to turn over to CMS. Given the sensitive and valuable nature of that information, CMS's threatened disclosure effectively imposes the same gag order first proposed in the IPAY 2026 draft guidance.

CMS cannot accomplish by threat that which it cannot do by mandate. To protect manufacturers' confidential and proprietary information and avoid violating the First Amendment and requirements of reasoned decision-making, CMS should commit to a clear reciprocal disclosure principle in which the agency will commit to protecting confidential and proprietary information and will limit disclosure only to the specific information that the manufacturer has elected to make public.

IV. CMS Should Play a More Active Role in Creating a Policy Environment that Supports Successful MFP Effectuation, Manufacturers' Ability to Comply with the Law, and Patient Access to Selected Drugs through the Pharmacy Channel, which is the Crux of the Part D Program

AbbVie appreciates CMS's efforts to support the effectuation of the MFP and the inclusion of the Medicare Transaction Facilitator ("MTF"). However, the approaches outlined by CMS in the draft guidance would be subject to failure and not implementable for manufacturers for the following reasons:

- CMS contemplates an MFP effectuation process that would *de facto* require manufacturers and 60,000+ dispensing entities to negotiate refund calculations and payment distribution terms for MFP refunds when using a retrospective effectuation approach. We note that neither manufacturers nor pharmacies have the infrastructure to support this volume of negotiation or payment;

- CMS has elected not to play an active role in implementing the 340B nonduplication provision, which is essential to ensuring successful MFP effectuation and is a required part of CMS's role in implementing the program. This policy will delay payment and further exacerbate an already flawed approach;

- CMS proposes a 14-day prompt payment period for MFP refunds, when other federal programs where manufacturers make retrospective payments operate under at least a 37-day payment window. As we mentioned in previous comments, 14 days is an arbitrary number and is not feasible, particularly when manufacturers would need to, in addition to other data verification steps, secure 340B claim information—which CMS has inexplicably chosen to make voluntary for covered entities—to attempt to meet the statutory requirement of making the lesser of 340B ceiling price or MFP available to dispensing entities; and

- Under this proposal, pharmacies dispensing selected drugs would experience cashflow issues that would deter them from stocking selected drugs, likely resulting in patient access issues for these drugs.

For the reasons outlined above, AbbVie encourages CMS to explore more sustainable MFP effectuation options beyond the voluntary, MTF-facilitated payment Options 1 and 2 proposed in the draft guidance. Specifically, AbbVie suggests effectuation approaches where CMS or the MTF takes a more active role in ensuring dispensing entities are made whole timely for dispensing selected drugs and streamlines how dispensing entities accept these payments to ease the burdens placed on manufacturers of providing this volume of payments to dispensing entities.

We also urge CMS to adopt an effectuation approach where CMS plays an active role in implementing the 340B nonduplication provision, which we view as essential to ensuring successful MFP effectuation and part of CMS's role in implementing the program. The statute's use of the term "shall not be required" does more than delineate the responsibilities of manufacturers participating in both the Medicare Drug Price Negotiation Program ("MDPNP") and the 340B program; it also assigns to the agency, as the administrator of the MDPNP, a duty to ensure manufacturers are not subject to duplicative discounts under the MDPNP and 340B.

For the reasons set forth below, we urge CMS to adopt the following policies into MFP effectuation in issuing its IPAY 2027 revised guidance:

- Adopt an MFP effectuation approach that solves for or allows for commercial solutions to the complexities of making the MFP available to 60,000+ dispensing entities for dispensing selected drugs to MFP-eligible beneficiaries, including:
    - Making the payment facilitation function of the MTF mandatory for all parties, thereby aligning the function of the MTF more closely with the successful Third Party Administrator ("TPA") under the current CGDP;
    - Increasing the payment window from 14 days to at least 37 days to account for the challenges and complexities of the new MDPNP and to align with the timeline in other federal programs;
    - Prioritizing the calculation of *accurate* retrospective payments to dispensers by establishing transparency between dispensing entities and manufacturers on entities' acquisition costs; and
    - Taking an active role in preventing duplicate discounts between the MDPNP and the 340B program, by requiring dispensing entities to identify claims as 340B-eligible at the point-of-sale ("POS") using available 340B claims modifiers.
- Provide more information about the MTF and its functionality in a timely manner so manufacturers can create their MFP effectuation plans by the June 2025 deadline; and
- Reconsider the "non-appealable" nature of the proposed complaint and dispute resolution process, as well as CMS's proposal to defer to HHS's Health Resources and Services Administration's ("HRSA") Administrative Dispute Resolution ("ADR") process for 340B and MFP disputes, which is heavily biased against manufacturers.

A. CMS Should Adopt an MFP Effectuation Approach That Streamlines Payment of MFP Refunds to Pharmacies for Dispensing Selected Drugs to MFP-Eligible Beneficiaries

In the draft guidance, CMS contemplates an MFP effectuation process that would *de facto* require manufacturers and 60,000+ dispensing entities to negotiate refund calculations and payment distribution terms for MFP refunds when using a retrospective effectuation approach.[62] We note that manufacturers do not have the infrastructure to support this level of negotiation or payment, and doing so in time to create an effectuation plan by June 2025—and CMS suddenly moved up from December 2025—is not feasible. Given the lack of compliance requirements for dispensing entities with respect to diversion (i.e., the dispensing of a selected drug to, or on behalf of, an individual who is not an MFP-eligible individual), a prospective MFP effectuation where dispensing entities buy selected drugs at MFP is not an ideal option, thereby making the retrospective approach the most operational. However, as laid out, the retrospective option would still be significantly burdensome for manufacturers. AbbVie supports a more sustainable approach to MFP effectuation outlined below. In any scenarios for how this is resolved, CMS must be sure to not limit manufacturers' ability to find commercial solutions that could help address the numerous impediments to MFP effectuation that manufacturers face in meeting requirements under the statute and CMS guidance.

1. CMS should require all parties to use the MTF for data and payment exchange to ensure the smooth implementation of the MDPNP

CMS indicates that it is "considering how the MTF could offer some form of a voluntary payment facilitation functionality."[63] CMS is soliciting comments on two distinct payment facilitation options: (1) the first payment facilitation option allows the MTF to collect banking details from dispensing entities to share with Primary Manufacturers for direct payment, or (2) a second option that has the MTF handling aggregated refund amounts from Primary Manufacturers to distribute to dispensing entities.[64] CMS reiterates that while the Primary Manufacturer must participate in the data exchange functionality of the MTF, "any potential payment facilitation functionality of the MTF would be voluntary for dispensing entities and Primary Manufacturers…."[65]

AbbVie appreciates CMS's efforts to support the effectuation of the MFP, including bearing the full cost of standing up the MTF. We are perplexed, however, as to why CMS would invest its resources in the development of the MTF yet make its critical payment facilitation function voluntary for manufacturers and dispensing entities. CMS's experience with the TPA under the CGDP should have reinforced the need to mandate all parties involved to use the MTF as a central clearinghouse for both the data and payment functions necessary to effectuate the MFP.

There are over 60,000 pharmacies[66] for which manufacturers must provide access to the MFP. However, manufacturers have not historically had direct contractual relationships with retail

[62] Draft Guidance § 40.4.
[63] *Id.* § 40.4.4.
[64] *Id.*
[65] *Id.*
[66] Kelling, S. E., Rondon-Begazo, A., DiPietro Mager, N. A., Murphy, B. L., & Bright, D. R. (2022). A systematic review of the role of community pharmacists in vaccination services in low- and middle-income countries. *Journal of the American Pharmacists Association*, 62(6), 2151-2165. https://doi.org/10.1016/j.japh.2022.07.012.

pharmacies in the way that providing access to the MFP would require. Consolidating payment functionality in the MTF is therefore essential for successful MFP effectuation.

Dispensing entities would also benefit from a centralized payment functionality administered by the MTF. While there are comparatively fewer manufacturers of selected drugs, selected drugs are high-volume drugs. This means that pharmacies will need to process and reconcile a significant volume of selected drug prescriptions, which in turn could create cash flow problems as pharmacies will be required to float the difference between MFP and their acquisition cost until they receive payment from the manufacturer through a non-centralized process. This type of payment friction could discourage dispensing entities from stocking selected drugs, undermining CMS's goal of protecting access to selected drugs, as evidenced in the guidance through oversight of formulary placements to prevent discriminatory practices in formulary designs.[67]

Finally, for any payments that are made via the MTF, we ask CMS to institute a maximum time period for which the refund to dispensing entities needs to be made, especially since the manufacturer is the entity subject to civil monetary penalties if the payment is not made timely.

2. CMS should extend the prompt payment window from 14 days to at least 37 days to account for the challenges and complexities of implementing the novel and unprecedented MDPNP and align with other federal programs

As was the case for IPAY 2026, CMS proposes in the IPAY 2027 draft guidance that Primary Manufacturers must retrospectively provide reimbursement for the difference between the dispensing entity's acquisition cost and the MFP within 14 days.[68] In addition, CMS indicates that the 14-day prompt payment window would begin on the date the Primary Manufacturer receives the data report from the MTF verifying that a selected drug was dispensed to an MFP-eligible individual.[69]

AbbVie continues to strongly urge CMS to revisit the 14-day prompt payment window. Complying with a 14-day prompt payment period presents significant challenges, especially considering the novelty of the MDPNP. None of the parties currently have any implementation experience with a program of this nature, which could lead to unforeseen complications and delays, making the 14-day payment period particularly impractical during the first year of implementation. It is crucial to acknowledge the complexities that come with the introduction of a new program and the time it takes for all stakeholders to adapt. Therefore, expecting prompt payment within such a short timeframe is not a realistic expectation, especially in the early stages of the program's rollout. AbbVie urges CMS to increase the payment window to at least 37 days from the date the manufacturer receives the data, consistent with other federal drug discount programs (e.g., the MDRP and Part D CGDP).

Further, while CMS notes that the data report manufacturers receive from the MTF would include claims data that was dually verified by CMS and the MTF, manufacturers conduct many internal claims verification processes and business requirements that would be difficult to complete in the 14-day period. These processes include but are not limited to:

[67] Draft Guidance § 110.
[68] Draft Guidance § 40.4.3.
[69] *Id.* § 40.4.4.

- Manually importing invoices and checking the units and dollars as well as any data errors in the import file itself.

- Reviewing for duplicate claims and manually removing the erroneous claims.

- Independently investigating cases where necessary data components are not included.

- Performing manual reviews of the invoices versus prior quarter submissions to identify gaps.

- Validating the units by product. We have unit thresholds in place for several products, to make sure the invoicing is done accurately.

- Performing additional validations of the payment checking all the price and volume variances versus prior quarter and making sure that any large credits or variances for the claim are expected.

- Identifying and reviewing potential 340B duplicate claims. As discussed below, any attempt to identify 340B duplicate claims will be both incomplete and time-consuming given CMS's refusal to ensure that adequate, reliable 340B data is made available and covered entity's well-documented resistance to providing such data.

In the first year there is already a manufacturer with multiple products selected, it is therefore reasonable to expect that many manufacturers will eventually have multiple products in their portfolio that are selected drugs, thereby amplifying the resources necessary to validate claims within the specified time period.

While we advocate for manufacturers' need for additional time in the prompt payment window, we understand and agree with CMS's concerns around pharmacy cashflow as it relates to their dispensing of selected drugs. Under the draft guidance's proposed, it could take 45+ days for pharmacies to be made whole for dispensing selected drugs. This could result in a patient access issue whereby pharmacies choose not to stock selected drugs given the economic challenges of doing so. Failure to stock selected drugs could also lead to high risks of non-medical switching whereby providers will need to steer patients towards non-selected drugs because pharmacies choose not to stock selected drugs. As more drugs are selected each year, and more drugs in a therapeutic class are selected each year, patients could be switched to non-selected drugs in a class on an annual basis to solve for pharmacies not stocking selected drugs. We therefore suggest that CMS consider all ways it can limit the time in which pharmacies would be reimbursed for dispensing selected drugs, including shortening the current 30-day window for plans to submit prescription drug event ("PDE") records to seven days to ensure dispensing entities receive timely payment of MTF refunds, and requiring a 340B modifier on claims to limit the data verification that manufacturers require for data integrity in the prompt payment period.

As explained in greater detail below, these difficulties are exacerbated by CMS's intent not to take an active role in implementing the MDPNP's 340B deduplication provision, including CMS's decision not to require dispensing entities to apply a claims modifier that is used at the point-of-sale. Based on our experience with the 340B program's duplicate discount prohibition, the lack of a modifier will make it challenging for manufacturers to effectuate, much less timely effectuate, the MFP and may result in disputes with covered entities and others that introduce unnecessary complications in its execution. Without a specific mandate, pharmacies have limited

incentive to include the modifier on claims. To the extent CMS does not address our concerns in this area, it provides yet another reason for CMS to extend the 14-day prompt-pay window.

3. CMS should prioritize the calculation of accurate retrospective payments to dispensers, by establishing transparency between dispensing entities and manufacturers on entities' acquisition costs

CMS indicates that to calculate the retrospective MFP refund amount, the parties may use a reasonable, standardized pricing metric as the dispensing entity's acquisition cost in the MFP refund amount payment calculation. CMS proposes to set this pricing metric at the WAC as published in pharmaceutical pricing database compendia on the date of dispensing.[70] CMS refers to this amount as the "standard Default Refund Amount."[71]

AbbVie disagrees with using a standardized pricing benchmark as a proxy for the dispensing entity's acquisition cost. We anticipate that this approach may result in excessive reimbursements to pharmacies in most instances. For example, wholesalers already receive substantial markdowns from list prices, which they often use to give pharmacies a discount. A proxy price may thus be an overstatement of the pharmacy's acquisition cost and thus not an appropriate proxy. Even where the wholesaler markdowns are not transferred to pharmacies, using a proxy acquisition cost would create a duplicative financial burden for the manufacturer, who first offers a discount to the wholesaler, and subsequently to the pharmacy. We understand that CMS proposes using a proxy for acquisition costs because today, manufacturers do not have transparency into pharmacies' acquisition cost information. We encourage CMS to establish the transparency needed to facilitate retrospective MFP refund payment by manufacturers that is not based on a proxy that fails to account for other discounts that are provided through the supply chain (e.g., to wholesalers and dispensers). A "standardized refund amount" would systematically overcharge manufacturers and violate the statute. Transparency in acquisition costs could also help facilitate enforcement of the IRA's nonduplication provision in some contexts because it will provide transparency into a dispenser's acquisition cost at a 340B discount. In instances where the MFP is lower than the 340B ceiling price for a given drug, CMS should clarify that a manufacturer's payment obligation is only the 340B ceiling price (actual acquisition cost) minus the MFP.

Further, given that it is not unusual for some independent and long-term care pharmacies to buy drugs above proxy prices, they would be disadvantaged by using a proxy as the metric for acquisition costs. Given the recent concerns that independent pharmacies have voiced on their reimbursement and cashflow as a result of recent regulatory DIR changes,[72] this would exacerbate these issues for this important pharmacy type and potentially impact patient access if these pharmacy types are concerned that their reimbursement would not support profitable participation in the Medicare Part D program.

For these reasons, we believe the MTF must establish transparency between manufacturers and dispensing entities as it relates to the acquisition costs of the drug unit to the dispenser, and dispensing entities should be required to submit that information to the MTF. We

[70] *Id.* § 40.4.3.
[71] *Id.*
[72] Kaiser Family Foundation Health News. "Biden Plan to Save Medicare Patients Money on Drugs Risks Empty Shelves," June 11, 2024.

also understand the pharmacies may consider acquisition cost information proprietary, so we advocate for data privacy standards to keep that information safeguarded and used only for purposes of effectuating the MFP.

4. CMS should take an active role in preventing duplicate discounts between the MDPNP and the 340B program by requiring dispensing entities to prospectively identify 340B prescriptions

SSA section 1193(d)(1), as added by the IRA, exempts manufacturers from providing access to the MFP to covered entities when the 340B ceiling price is lower than the MFP for a given selected drug. While SSA section 1193(d)(2) requires manufacturers to provide access to the MFP if it is lower than the 340B ceiling price, this provision further requires that the MFP be offered in a "nonduplicated amount." The purpose of these "340B nonduplication provisions" is to ensure manufacturers are not subject to duplicate discounts under the MDPNP and the 340B program. In the IPAY 2027 draft guidance, CMS proposes that Primary Manufacturers may avoid duplication of discounts between the MFP and 340B ceiling price by identifying claims from the data elements transmitted by the MTF that are 340B-eligible and for which the 340B ceiling price is lower than the MFP.[73] However, CMS will not require dispensing entities to identify claims as 340B-eligible at POS using available 340B claims modifiers.[74] CMS instead expects Primary Manufacturers and covered entities to separately determine whether a prescription is 340B-eligible.

Experience has shown that covered entities will not voluntarily cooperate with manufacturers to identify 340B units and implement the 340B nonduplication statutory requirement. This is demonstrated by HRSA's inability to effectuate the 340B statute's prohibition on duplicate discounts between the 340B program and the MDRP in the absence of a required claims modifier. Particularly in the absence of adequate federal regulation and oversight, covered entities have little motivation to avert the occurrence of double discounts, as this can be contrary to their own financial interests to the extent it results in the covered entity's loss of a 340B discount in favor of a rebate to the state Medicaid agency or other private payer, including Medicare Part D plans. Meanwhile, the growing size of the 340B program, due in part to the widespread and growing use of contract pharmacies, complicates manufacturers' ability to prevent and identify such duplicate discounts.

Indeed, according to government oversight agencies, all of these factors have resulted in a significant number of duplicate discounts under the 340B program.[75] In 2018, the U.S. Government Accountability Office ("GAO"), finding that HRSA does not have the ability to ensure compliance with the nonduplication of 340B and Medicaid rebates,[76] made recommendations that HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs and incorporate an assessment of covered entities'

[73] Draft Guidance § 90.2.
[74] *Id.* § 40.4.2.
[75] U.S. Government Accountability Office, "340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement," GAO Report No. GAO-20-212 (2020); "State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs," OIG OEI-05-09-00321 (June 2011), https://oig.hhs.gov/documents/evaluation/2889/OEI-05-09-00321-Complete%20Report.pdf.
[76] U.S. Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO Report No. GAO-18-480 (June 2018), https://www.gao.gov/products/gao-18-480.

compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been HHS agreed with these recommendations. While HHS agreed to these recommendations, as of now, it has not taken steps to implement them. To fully implement these recommendations, HRSA needs to communicate to covered entities how they are to prevent duplicate discounts under Medicaid managed care and assess the potential for these duplicate discounts as part of its audits. Until these recommendations are fully implemented, HRSA will not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers will continue to be at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions. CMS must take steps to avoid a similar situation under the MDPNP.

We further disagree that CMS is permitted to take a passive approach to implementing the 340B nonduplication provision. The language in SSA section 1193(d)(1) expressly states that manufacturers are not required to offer both the MFP and the 340B ceiling price for the same unit of a given selected drug under certain circumstances, and section 1193(d)(2) requires that even where access to the MFP is required it must be done in a "nonduplicated amount." Not only is the proper implementation of this provision necessary to ensure the proper functioning of the MDPNP as contemplated by Congress, given its placement in section 1193 of the Act, the 340B nonduplication provision is incorporated into the Medicare Drug Price Negotiation Program Agreement to which CMS is a party. Accordingly, while it is primarily the manufacturer's obligation to offer the MFP for its selected drugs, CMS is responsible for ensuring the manufacturer is not subject to duplicate discounts in doing so. It would be arbitrary and capricious and contrary to the statute for CMS to finalize a policy under which a manufacturer must pay an MFP rebate by the close of a prompt MFP payment window, on pain of a civil monetary penalty, where the manufacturer does not have the data necessary to determine whether the unit is not subject to the 340B price.

In limited circumstances where manufacturers have been able to obtain data from covered entities, the data applied to only a subset of 340B claims and proved to be incomplete, untimely and often inaccurate. Moreover, a growing number of states have passed or are considering legislation that would hinder manufacturers' ability to obtain necessary data from covered entities to confirm the 340B eligibility of prescriptions.[77]

By failing to mandate a 340B claim modifier at POS, CMS is making it virtually impossible for manufacturers to meet their statutory obligation to make the lesser of 340B ceiling price and MFP available within any prompt-pay period. MFP refund eligibility would be reasonably known as of a point in time (i.e., when the MTF sends the claim to the manufacturer); however, claims are often retroactively claimed as 340B in absence of a POS modifier at any point after POS, including years later. Therefore, manufacturers are *de facto* in a situation where they might be required to provide the MFP within the prompt pay period if there is no claim modifier of information on 340B eligibility during the prompt pay period.

CMS can undertake this responsibility and significantly mitigate the risk of duplicate discounts between the MFP and 340B ceiling price by requiring that pharmacies and other dispensing facilities identify 340B prescriptions, ideally at POS. More specifically, CMS should impose requirements on Part D plans regarding the types of claims that they may adjudicate. CMS currently requires Part D plan sponsors to reject a pharmacy claim for a Part D drug unless

[77] States May Consider 340B Legislative Proposals in 2024, Avalere (December 1, 2023), https://avalere.com/insights/states-may-consider-340b-legislative-proposals-in-2024. In 2024 alone, bills with data sharing prohibitions have been passed in MS, MO, SD and VT and are under consideration in AZ, CT, DE, FL, ID, IL, MA, OH and RI.

the claim contains the active and valid National Provider Identifier of the prescriber, thereby establishing precedent that CMS can stipulate that certain data be included on claims submitted by pharmacies.[78]

The 14-day prompt payment standard also provides an independent basis for CMS to require a 340B claims modifier on dispensing entity claims. The statute requires that Part D plan sponsors pay "clean claims" submitted by pharmacies within 14 days of receipt.[79] The statute defines a "clean claim" as a claim that has no "defect or impropriety (including any lack of any required substantiating documentation)…."[80] In the context of selected drugs, the lack of a 340B claims modifier is a "defect" that prevents the claim from being a "clean claim" subject to the prompt payment standard. This would strongly encourage dispensing entities to include the 340B claims modifier, and it would facilitate implementation of the MDPNP.

It also bears noting that CMS requires all 340B covered entities that submit separately payable Part B drugs and biologicals to report modifier "JG" or "TB" on claims for drugs acquired through the 340B program.[81] CMS is also considering how to enforce the identification of 340B drugs for Part D inflation rebates, which needs to be in place by January 2026.[82] The IPAY 2027 draft guidance notes that the National Council for Prescription Drug Programs has introduced a data field to mark a claim as 340B-eligible.[83] CMS should require that dispensing entities complete this data field to facilitate the enforcement of the 340B nonduplication policy, in a similar vein to the agency's actions regarding Part B inflation rebates.

Without POS identification, the 340B and MDPNP programs become more complex as manufacturers have to piece together fragmented data from various sources to verify that a given prescription is truly 340B-eligible. Often, manufacturers do not have the complete data needed to accurately determine their financial responsibilities, resulting in duplicate discounts. Not requiring POS identification for purposes of nonduplication in the context of MFP would also be inconsistent with CMS's implementation of other IRA provisions, including the inflation rebates.

Further, in the instance where CMS adopts an effectuation approach where the agency initially pays the MFP refund to dispensing entities, and the prompt pay period for refunds from manufacturers to dispensing entities becomes less relevant, it remains advantageous for CMS to require a 340B claims modifier as it is imperative that CMS, as a steward of taxpayer dollars, is not overpaying for drugs that dispensing entities are classifying as 340B for Medicare Part B and Part D.

In short, we recognize that historically CMS has opted not to mandate the inclusion of 340B claims modifiers on submitted claims and left this deduplication issue to be sorted out between manufacturers and covered entities. But this decision has been a policy preference rather than a constraint on the agency imposed by law. As mentioned earlier in this letter, the governing statute expressly grants CMS the power to determine the criteria for a "clean claim." In

[78] 42 C.F.R. § 423.120(c)(5)(i).
[79] SSA § 1860D-12(b)(4).
[80] *Id.* at § 1860D-12(b)(4)(A)(ii).
[81] "Medicare Part B Inflation Rebate Guidance: Use of 340B Modifier", CMS MLN4800856 (December 2023), https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf.
[82] Medicare Part D Inflation Rebates Revised Guidance, CMS (December 14, 2023), https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.
[83] Draft Guidance § 40.4.2, at FN 52.

the process of implementing the MDPNP, CMS possesses the authority to stipulate that a "clean claim" must incorporate the 340B claims modifier for selected drugs.

B. CMS Should Provide More Information About the MTF and Its Functionality in a Timely Manner So Manufacturers Can Create Their MFP Effectuation Plans by the June 2025 Deadline (Section 90.2.1)

As laid out in this letter, the novelty and complexity of MFP effectuation will necessitate time and information for manufacturers to adequately prepare their plans to make the MFP available. AbbVie desires further clarification on the following elements of the MFP effectuation plan:

- **Data privacy and security.** The draft guidance outlines requirements for how manufacturers will ensure that their process for making the MFP available will comply with all applicable data privacy and security laws, regulations, policies, and CMS requirements. But CMS does not elaborate on how the MTF will comply with any security restrictions that manufacturers use to safeguard data. If manufacturers are required to engage with the data transmission functionality of the MTF, CMS should outline their approach to data privacy and security related to collecting, holding, and, if applicable, sharing interested parties' financial and securities information for purposes of MTF payment facilitation.

- **Level of detail in MFP Effectuation plans.** In the draft guidance, CMS lays out at a high level the elements that manufacturers should include in their effectuation plans, one of which is "calculation of refund amounts for reimbursements not consistent with the Standard Default Refund Amount."[84] Is the intent that manufacturers have the details of reimbursement included in the MFP effectuation plans? For instance, is the manufacturer to include how they will determine the refund amount for all 60,000+ pharmacies? In the guidance, CMS notes, "if the Primary Manufacturer and a dispensing entity agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost (e.g., WAC as used in the Standard Default Refund Amount), as opposed to the dispensing entity's actual acquisition cost for that particular unit of the selected drug, then CMS will consider a retrospective refund paid pursuant to that calculation to be sufficient for the Primary Manufacturer to meet its obligation to make the MFP available to the dispensing entity." Understanding that some pharmacies would not want to be reimbursed using WAC, in the absence of acquisition cost-based refunds, we believe this to mean that would necessitate manufacturers negotiating these terms with dispensing entities *prior* to submission of our effectuation plan. If so, manufacturers will need the revised guidance in a timely manner to support the negotiation that will be needed for the 60,000+ dispensing entities, to provide that level of detail in their effectuation plans.

- **Publishing MFP Effectuation plans.** CMS notes in the draft guidance its plans "to promote transparency and preparedness for MFP effectuation among pharmaceutical supply chain entities, CMS intends to publish these plans on the CMS IRA website and will redact proprietary information in those plans."[85] AbbVie encourages CMS to include any "best in class" information on creative ways that manufacturers may be effectuating

[84] *Id.* § 90.2.1.
[85] *Id.*

MFP as proprietary information and therefore redact that information before publishing the effectuation plan publicly.

C. CMS Should Reconsider the "Non-Appealable" Nature of the Proposed Complaint and Dispute Resolution Process and CMS Deferring to HRSA ADR Process Which Is Heavily Biased Against Manufacturers (Section 90.2.2)

AbbVie supports CMS's proposal that the MTF implement a dispute resolution process through which manufacturers can challenge initial determinations of a claim's validity. In the draft guidance, CMS states they will, "consider a dispute to be a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an MFP refund). A dispute will warrant CMS review and issuance of a non-appealable finding and will be assessed based on available relevant factual information."[86] However, AbbVie disagrees with the "non-appealable" nature of this process, which will not afford adequate process to manufacturers when disputes in a new system arise.

Further, as it relates to disputes of 340B non-duplication with MFP, CMS notes, "if a dispensing entity believes that certain dispenses should have been purchased at the 340B ceiling price and the Primary Manufacturer did not make the 340B ceiling price available, then the dispensing entity would be able to utilize Health & Human Services enforcement mechanisms outside of the complaint and dispute process described in section 90.2.2 of this draft guidance to pursue corrective action in order to receive the 340B ceiling price." AbbVie assumes the "enforcement mechanisms" refer to the ADR process under HRSA, which many manufacturers have commented is biased towards covered entities.[87] Given this, it is unlikely that manufacturers can trust they will be given a fair, reasonable assessment of 340B duplication claims. CMS itself has responsibility for ensuring nonduplication and for resolving disputes that arise from the MFP effectuation system it designs.

V. CMS's Proposed Guidance Confirms that Participation in the IRA Program is Not Voluntary and CMS Does Not Intend to Implement a Meaningful "Negotiation" Process

CMS's draft guidance confirms that participation in the IRA's price-control process is not voluntary, and that CMS does not intend to implement any meaningful negotiation process or to adopt constitutionally adequate procedures.

The agency is not even attempting to "negotiate" a fair price. Instead, as noted above, CMS's draft guidance reflects the exercise of a clear regulatory function, seeking to impose new requirements on certain targeted manufacturers, including changing statutory definitions and requiring manufacturers to disclose confidential and proprietary business information that is not required to be disclosed under the statute. CMS's new draft guidance confirms that CMS is not looking to reach agreement on a "maximum fair price," but rather to impose a price of its own choosing and then to force manufacturers into saying that they agree that the imposed price is both fair and the lowest maximum price. Indeed, manufacturers are compelled to take that position even if the price imposed does not allow a reasonable return on their investment and is far below the fair prices that have been paid in the past.

[86] *Id.* § 90.2.2.

[87] Manufacturers have criticized the alternative dispute resolution process for its panel composition bias and the absence of mechanisms providing detailed transactional data necessary for accurate problem assessments, among other issues.

CMS's new draft guidance does nothing to ameliorate or change the fact that the IRA price-control process is both legally and economically coercive. As CMS well knows, no manufacturer can afford to withdraw *all* of its products from Medicare and Medicaid or pay the draconian penalties that the statute imposes. Patients depend on manufacturers' products, and manufacturers are in no position to deny millions of patients access to life-saving medications. Moreover, because the government has taken control of the market, preventing manufacturers from selling their products to that market is not a special governmental benefit that CMS may hold hostage, to be ransomed only by waiver of manufacturers' constitutional rights.[88]

Sincerely,

Hayden

Hayden Kennedy
Vice President, Global Policy & U.S. Access Strategies
On behalf of AbbVie Inc.

[88] *See Horne v. Dept. of Agric.*, 576 U.S.351, 366 (2015).

June 25, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: Medicare Drug Price Negotiation Draft Guidance

Dear Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to offer comments on the recently issued "Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027." ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions, which will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN is keenly interested in how implementation of the new prescription drug negotiation program will impact cancer patients. We shared our initial thoughts with CMS in our letter of April 2023[1] and the following comments build upon those observations.

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

The orphan drug exclusion from negotiation was clearly meant to preserve incentives for drug development for rare diseases, for which many cancers qualify. Unfortunately, several aspects of the proposed guidance run counter to that intent. The current policy of multiple designations rather than multiple approvals causing ineligibility for the orphan exemption was clearly a drafting mistake per Congressional authors. While CMS may believe that it does not have latitude to remedy this error, it is within CMS' power to fix the starting point for the negotiation timeline when a previously exempt orphan drug loses its exemption with a subsequent approval. In the proposal, the starting point would be the original approval date, but we request that CMS use the date of the loss of orphan negotiation exclusion, i.e. the date of the first subsequent approval.

[1] https://www.fightcancer.org/policy-resources/acs-can-comments-rx-negotiation-implementation.

40.4 Providing Access to the MFP in 2026 and 2027

CMS states that any Primary Manufacturer of a selected drug that participates in the negotiation program must provide access to the Maximum Fair Price (MFP) to MFP-eligible individuals as well as pharmacies, mail order services, and other dispensing entities. CMS further states that MFP-eligible individual's cost-sharing will be based on the negotiated price which cannot exceed the MFP plus any dispensing fees for such drug. This is to ensure that beneficiaries have access to the MFP at the point-of-sale.

In ACS CAN's April 2023 letter to CMS, we urged the agency to ensure that Medicare enrollees realize the savings related to drugs that are the subject of negotiation and in no case pay more out-of-pocket for a drug that is subject to negotiation than they were paying previously. We support the CMS proposal to make the MFP available to eligible individuals and further request that CMS perform an end-of-the-year evaluation of whether, and to what extent, beneficiary savings were achieved.

We also urge CMS to include in your public education materials information for beneficiaries about the MFP and what they can expect at the point of sale – including information about where to direct questions.

60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

CMS states that to consider comparative effectiveness between a selected drug and its therapeutic alternative(s), it will identify outcomes – including patient centered outcomes – to evaluate for each indication of the selected drug. When reviewing such information CMS will not use Quality Adjusted Life Years (QALYS) or evidence that treats extending the life of an individual who is elderly, disabled, or terminally ill as lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Further, CMS notes that it may consider outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes. CMS may also consider the caregiver perspective to the extent that it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.

ACS CAN supports comparative effectiveness research because it provides clinicians with information regarding the relative clinical effectiveness of a given intervention and potential differences in side effects. We support CMS' decision to not use evidence in a manner that treats extending the life of any individual as lower value than the life of another individual; this includes QALYs.

ACS CAN strongly opposes the use of QALYs to determine whether to provide coverage or to set patient cost-sharing for a given treatment. Doing so fails to consider the value an individual may place on the quality of life provided to them for a given treatment. For some cancer patients, medication therapy may not be curative but may provide additional years of life that are valuable to the individual.

As CMS examines the effectiveness and clinical benefit between a selected drug and its therapeutic alternatives, we ask you to consider that in oncology there are very few drugs that are truly equivalent with respect to the FDA-approved label indication and the scientific evidence supporting the efficacy of a given drug. Cancer is not a single disease, and the efficacy of drugs is not the same across all cancer patients. Therefore, we urge you to consider the real-world use of a particular medication across all types and subtypes of a disease for purposes of determining whether a drug has a therapeutic alternative.

ACS CAN also supports the use of both patient-reported outcomes and patient experience data. Patients have first-hand knowledge of the effectiveness of a treatment as well as the impact on quality of life. We support CMS considering health outcomes such as cure, survival, progression-free survival, or improved morbidity when comparing the selected drug to therapeutic alternatives. We also support CMS considering whether a selected drug fills an unmet medical need such as treating a disease or condition in cases where extremely limited or no other treatment options exist as this is particularly important for cancer patients.

60.4 Negotiation Process

CMS is proposing several opportunities to further engage patients in the negotiation process. We appreciate the agency's commitment to ensuring that patients have the chance to share their perspectives – including potential impact – of the new negotiation program.

Listening Session Improvements

ACS CAN participated in the first round of listening sessions held in the fall of 2023. While the sessions provided a forum for sharing information, the format was limiting and failed to provide an opportunity for actual dialogue with CMS. We support the agency's proposal to consider changing the format of future events.

Earlier this year ACS CAN, along with 16 other patient advocacy groups, participated in a discussion hosted by the National Health Council about improving patient engagement in the negotiation program going forward. Groups reached consensus on several recommendations for improving the listening sessions. These included:

- **Host an educational webinar in advance of any listening sessions.** CMS should educate patient groups, patients, and stakeholders on how sessions will be structured and what the agency is looking for in the sessions.
- **Clarify how CMS will select speakers.** CMS should be transparent about its strategy in selecting speakers.
- **Enhance dialogue-based engagement.** CMS should hold listening sessions with smaller groups of patients, with opportunities for dialogue. There is a need for greater collaboration between patients and CMS, but CMS should also properly prepare advocacy groups and patients for what will be asked of them during such a session.
- **Allow speakers more time.** At least five minutes would allow for more thorough testimony. Also, a timer should be added to the Zoom screen to allow speakers to manage the pacing of their comments.
- **Allow for data submissions after the listening sessions.** CMS should allow for limited written supplements to speakers' remarks for a short period after the sessions.
- **Restructure the required disclosures.** The CMS introduction stated whether the speaker disclosed a conflict, refused to disclose or had no conflicts. For those who did disclose conflicts, there was no description of the nature of such conflict. The disclosure should be presented in a less direct manner, for instance a link on the website associated with the listening session, and CMS should include how such a disclosure or nondisclosure affects (or does not affect) the patient testimony and why the disclosure is needed.

- **Report on how the patient engagement information and qualitative data was incorporated into negotiations**. At the end of a negotiation cycle, CMS should report, in the aggregate, on how the information gathered specifically from the listening sessions and the qualitative data it received was used.
- **Increase ways for patients to engage.** CMS should provide additional mechanisms for speakers to submit their testimonies, including written statements or recordings, and provide more advance notice of listening sessions. Patient organizations need enough time to identify relevant patients and/or conduct surveys to bring quantitative data to CMS.

Other Ways of Engaging Patients

Beyond formalized listening sessions, we support CMS trying different avenues for engaging patients – including the roundtable sessions and focus groups proposed in the guidance. ACS CAN suggests that CMS consider hosting some informal discussions with patients directly affected by the drugs identified for negotiation to provide CMS with an opportunity to hear first-hand patients' experience with the medications (including the extent to which a given medication has minimized possible side effects) medications, and their questions and concerns about the negotiation process. In turn, CMS could share with patients how the drug was chosen, what the expectations are for lower patient costs, how the patient can insure they realize savings, and where to report any issues that arise.

Patient Education

Whenever there is a major change in the Medicare program, beneficiaries are inundated with information – and misinformation – about the potential impact. It is critical that CMS provide beneficiaries with clear and accurate information about negotiation – what it will mean for them, any expected changes the beneficiary should anticipate, and where to go with questions. There were valuable lessons learned from the enactment of the Medicare prescription drug benefit that can be applied to the new negotiation program. These include:

- **Work directly with patient advocate and Medicare beneficiary organizations**: These groups work with beneficiaries and patients daily and know the best ways to communicate with their memberships. These groups are also experienced at communicating complicated information in a manner that is easily understood by the average consumer. We urge you to ask these groups to provide input on material development and to review materials before they are made available to beneficiaries.
- **Consider a wide range of information dissemination**: While social media offers a quick and inexpensive way to communicate information, many Medicare beneficiaries and patients still use more traditional means including newspapers, television, local libraries, direct mail, and organizational newsletters. Further, they rely on trusted sources including physicians, pharmacists, places of worship, service organizations, barbershops, clubs, and membership organizations. CMS should consider some of these options for dissemination of information.

90.2.2 Negotiation Program Complaints and Disputes

CMS proposes to establish a centralized two-track system to address complaints and disputes related to MFP availability. One of the tracks will be for complaints from manufacturers and the other for both the

public as well as Primary Manufacturers and dispensing entities. CMS anticipates that the types of complaints it may get include reports that the MFP was not made available to beneficiaries.

We support CMS making available a system that provides an avenue for beneficiaries to direct complaints about the operation of the new negotiation system. We urge you to provide clear direction for beneficiaries on how to use the system including the types of complaints most appropriate to send through the system. We also urge you to establish a maximum allotted time for resolution of complaints brought by beneficiaries.

110. Part D Formulary Inclusion of Selected Drugs

CMS indicates that it is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage certain drugs by placing these drugs on less favorable tiers, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries. To that end, CMS intends to monitor Medicare Part D plans' compliance with all applicable formulary requirements and use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

ACS CAN strongly supports CMS monitoring plan formularies to determine the extent to which plans are using more utilization management tools for negotiated or non-negotiated drugs, which can hinder access to these medications. ACS CAN is concerned about the extent to which beneficiaries could be steered towards specific drugs. For cancer patients who have found a particular drug that works for treating their cancer, being steered towards another – potentially less effective drug – could be detrimental. Medicare Part D is administered entirely through private plans which have a financial incentive to steer beneficiaries toward the lowest price drug the plan can negotiate. To the extent that providers have a choice of drugs to prescribe (e.g., several drugs available in the same therapeutic category and class) the Part D plan could steer beneficiaries toward the negotiated drug and may impose barriers (such as more rigorous prior authorization or step therapy requirements) on non-negotiated drugs.

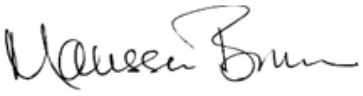
We also urge CMS to be rigorous in its review of plan formularies' use of utilization management tools for all drugs within a category and class for which there is an MFP drug. In a recent paper, ACS CAN engaged Avalere to conduct an analysis to understand the extent to which step therapy restrictions exist for certain drugs that treat breast cancer (cyclin-dependent kinase 4 and 6 (CDL 4/6) inhibitors).[2] While none of the plans examined explicitly required step therapy in their formulary design, Avalere evaluated the detailed restrictions policies and found that many plans included step therapy requirements embedded within their prior authorization requirements, with step edits dependent on patient characteristics of treatment choice. A rigorous review of the utilization management tools will help to ensure transparency of potential barriers for patient access.

[2] American Cancer Society Cancer Action Network. Step Therapy in Medicare Part D Oncology Drugs. May 2024. Available from https://www.fightcancer.org/sites/default/files/acs_can_part_d_formulary_analysis_final.pdf.

Conclusion

Thank you for the opportunity to comment on the new guidance for the prescription drug negotiation program. If you have any questions or need additional information, please feel free to contact me directly or Kirsten Sloan, Managing Director, Public Policy at Kirsten.Sloan@cancer.org.

Sincerely,



Marissa Brown
Senior Vice President
American Cancer Society Cancer Action Network

American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to share our feedback on the Centers for Medicare & Medicaid Services' (CMS) draft guidance on the Medicare drug price negotiation program. The AHA supports the intended goals of the Inflation Reduction Act (IRA) to lower the exorbitant costs of drugs in the U.S. However, the agency's proposal to effectuate this policy in a retrospective manner is problematic and may undermine the very goals Congress and the agency have of lowering drug prices for patients and providers.

The agency's proposed retrospective refund process is complex, burdensome and would be operationally unworkable, particularly with respect to the critical 340B Drug Pricing Program. We are deeply concerned that such an elaborate process would put providers in the position of chasing rebates and 340B discounts from drug manufacturers instead of requiring manufacturers to make the lower negotiated prices available upfront, just as the 340B program currently works. In addition, given the implications for the 340B statute, which the Health Resources and Services Administration (HRSA) has interpreted through agency guidance as a prospective discount program, there are significant questions about the draft guidance's retrospective approach. **Therefore, we urge the agency to finalize a process that ensures *prospective* access to the maximum fair price (MFP) and 340B price for all dispensing entities furnishing selected drugs to eligible Medicare patients. In addition, we urge the agency to impose strict accountability measures to ensure drug manufacturers are complying with the law.**

OPERATIONAL CONCERNS WITH CMS' PROPOSAL

The agency's retrospective approach is unnecessarily complex and operationally challenging, which will add substantial costs to providers as they would need to build the infrastructure necessary to chase rebates from drug manufacturers. The imposition of new costs on drug purchases directly undermines the intent of the IRA. In addition, the retrospective approach could fundamentally change the 340B program, which would strip vital resources from providers caring for the most vulnerable communities.

Transmission of data and other sensitive information. In section 40.4.1 of the draft guidance, CMS discusses the role of the Medicare Transaction Facilitator (MTF) in transmitting data between covered entities and manufacturers. The AHA appreciates CMS' commitment to limiting the type and amount of data and other sensitive information that would be made available to manufacturers for purposes of carrying out the program. However, we do not believe the proposed retrospective processes provide adequate safeguards to ensure the protection of private or otherwise sensitive information shared by eligible Medicare patients and dispensing entities. Instead, we urge CMS to consider a prospective approach with a more robust role for the MTF such that sensitive information, like a patient's personally identifiable information, or a dispensing entity's banking information, is not made available to the manufacturer or any other entity. The MTF could act as a clearinghouse to facilitate both pricing verification and payment between dispensing entities and manufacturers, which would better protect against the sharing of sensitive data across multiple stakeholders. Recent data breaches of third-party vendors in the health care industry, such as the Change Healthcare cyberattack, underscore the importance of limiting any unnecessary transfer of sensitive data. **We believe the MTF would be best positioned to evaluate data submitted by covered entities, plans and manufacturers and share only that information which is absolutely necessary for purposes of effectuating the program.**

Implications for 340B program operations. The 340B program is a critical resource for participating hospitals and other covered entities to stretch their resources to maintain, improve and expand access to care for the patients and communities they serve. The program relies on the ability of participating entities to purchase covered outpatient drugs at an *upfront* discounted price which enables the entity to generate price savings that is used to support a range of patient programs and services such as behavioral health, medication-assisted treatment and diabetes education. Simply put, any retrospective model to accessing the 340B discounted pricing would jeopardize the ability of 340B covered entities to support access to these important patient programs. This is for two reasons. First, as noted above, drug manufacturers have a history of avoiding payment of 340B discounts. A retrospective approach would give them a new, complex administrative process through which to avoid paying such discounts. Our concerns are not unfounded given that drug companies and their vendors have explored such efforts in the past, and Congress, in a bipartisan manner, has written to

the Health and Human Services (HHS) Secretary to disallow such an approach.[1] Second, the costs of administering such a program would effectively deplete a portion of the savings — shifting dollars meant for patient programs to third party technology companies and other administrative actors.

A retrospective 340B rebate model would mean covered entities would not be able to purchase covered outpatient drugs at the 340B price at the point of sale. Instead covered entities would be required to purchase these drugs at a much higher price and wait for a refund. This would require hospitals and their 340B third-party administrators (TPAs) to completely change their 340B operations and would create devastating cash flow issues, including for many hospitals that continue to operate under substantial financial strain. Further, this would require the 340B covered entity or its TPA to transmit sensitive claims data to each drug manufacturer (of which there are many) creating unnecessary burden and cost to the covered entity, and which can be used by the drug manufacturer for their own financial advantage. Finally, we believe a retrospective process would create an administrative nightmare for covered entities and for HRSA. 340B covered entities that have not received refunds from manufacturers could choose to seek relief through the 340B administrative dispute resolution (ADR) process as an instance of a manufacturer overcharge. As a result, the 340B ADR process could be inundated with such requests for administrative review, creating uncertainty for covered entities, manufacturers and the government.

STATUTORY CONCERNS WITH CMS' PROPOSAL

The IRA includes several provisions authorizing the HHS Secretary to establish a drug price negotiation program ("the program") under which the Secretary enters into agreements with manufacturers to negotiate lower prices for certain prescription drugs on behalf of individuals enrolled in the Medicare program. The agency's draft guidance seeks to effectuate the program through a series of complex processes with which we have concerns. Chief among these is that the two processes the agency proposes to effectuate the MFP are retrospective and unfairly disadvantage providers and other entities who care for Medicare patients in favor of drug manufacturers who are the entities responsible for setting high drug prices.

CMS makes clear that the statute directs the manufacturer, not the agency or the HHS Secretary, to make the MFP available to all dispensing entities for selected drugs. We agree. However, the statute does recognize the HHS Secretary's administrative responsibilities for the purposes of administering the program.[2] These responsibilities include entering into agreements with manufacturers, selecting negotiation-eligible drugs, publishing the MFP for selected drugs, and engaging in other administrative duties, including conducting oversight and enforcement requirements under the

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[1] https://calhospital.org/wp-content/uploads/2020/11/201113_final_340b_hhs_letter.pdf
[2] See section 1196 of the Social Security Act (42 U.S.C. 1320f-5).

program.[3] In addition, the statute directs the HHS Secretary to establish procedures to ensure the MFP of a drug is applied *before* ". . . any coverage or financial assistance under other health benefit plans or programs that provide coverage or other financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals . . . and any other discounts."[4] We believe these administrative requirements are best satisfied through a process that ensures prospective access to the MFP. At the very least, the statute does not prohibit the HHS Secretary from establishing a prospective approach. In fact, CMS acknowledges in this draft guidance that manufacturers may meet their statutory responsibilities either prospectively, by ensuring the acquisition cost paid by a dispensing entity is no more than the MFP, or retrospectively, by reimbursing a covered entity for the difference between such entity's acquisition cost and the MFP. Yet, in this draft guidance, the agency only proposes a retrospective process.

The agency's retrospective process also appears to conflict with the 340B program. The IRA requires that drug manufacturers allow dispensing entities that participate in the 340B program access to the lower of the 340B price or the MFP for selected drugs.[5] However, the 340B statute authorizes the Secretary to enter into pharmaceutical pricing agreements (PPA) with manufacturers where the amount paid by 340B covered entities to the manufacturer to acquire a covered outpatient drug does not exceed the 340B ceiling price.[6] HRSA's long-standing guidance interpreting its responsibilities under the 340B statute sets up a process that allows 340B covered entities to purchase covered outpatient drugs at an *upfront* discounted price.[7]

We cannot conceive of a process where there could be retrospective access to the MFP but prospective access to the 340B price while still complying with the statutory requirements under both the IRA and 340B statutes. It appears that the agency cannot either since it does not provide for such a process in its draft guidance. We believe the only way to protect upfront access to the 340B price while also ensuring that 340B covered entities have access to the lower of the 340B price or the MFP is to effectuate a prospective process. **Therefore, we urge CMS to finalize a prospective process that aligns with HRSA's historic interpretation of the 340B statutory requirements and balances the interests of Medicare patients, dispensing entities and manufacturers under the program.**

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[3] See section 1191(a) of the Social Security Act (42 U.S.C. 1320f).
[4] Section 1196(a)(1) of the Social Security Act (42 U.S.C. 1320f-5(a)(1)).
[5] See section 1193(d) of the Social Security Act (42 U.S.C. 1320f-2(d))
[6] See section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)(1)).
[7] Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27289, 27291 (May 7, 1993); Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110, 25113 (May 13, 1994).

PROPOSED APPROACH ENSURING PROSPECTIVE ACCESS TO MFP AND 340B PRICING

Given the concerns outlined above, we urge the agency to adopt an approach that ensures *prospective* access to the MFP for any dispensing entity furnishing drugs to an eligible Medicare patient. In the case of a dispensing entity that is eligible and participating in the 340B program, we ask the agency to ensure that the 340B entity retains its ability to access the upfront 340B discounted price. We propose one such process the agency could implement that would achieve these goals, is operationally feasible, and adheres to the statutory requirements, including the need to protect against the 340B nonduplication provision in section 1193(d)(1) of the Act.

Purchasing at the prospective MFP or 340B price. Under our proposed approach, any dispensing entity would have prospective access to the MFP price when purchasing a selected drug for any eligible Medicare patient. Any dispensing entity participating in the 340B program, would retain its ability to purchase a selected drug at the 340B price for all eligible Medicare patients. This would likely require dispensing entities to maintain separate inventories for these selected drugs. Dispensing entities, particularly those that participate in 340B, already operate separate 340B and non-340B inventories for their drugs either through separate physical inventories or through a virtual replenishment model facilitated by a TPA. Since the statute requires the HHS Secretary to publish the list of selected drugs far in advance of the applicability period, we presume that it would not be too burdensome for dispensing entities to establish a separate physical or virtual inventory for these drugs and could be facilitated by their TPAs, if necessary.

MTF facilitates data verification. Upon purchase of the drug, the dispensing entity would submit the claim to the plan sponsor via the same process the agency lays out in the draft guidance. If a selected drug is purchased at the MFP and it is approved by the plan sponsor, no further action is needed by the MTF or the manufacturer. For a selected drug purchased at the 340B price, the 340B covered entity or its TPA would submit to the MTF a batch datafile that contains only necessary data elements for each 340B-eligible drug claim.[1] The necessary data elements would include whether a selected drug was purchased at the prospective 340B price or MFP and an indicator noting whether the MFP is higher or lower than the 340B price for that drug. Since current regulations allow only the 340B covered entities, drug manufacturers, and HRSA to have access to proprietary 340B pricing data, the MTF would need one of these parties to notify them as to which price, 340B or MFP, is lower. We propose that the covered entity or its TPA could accommodate this with the ability of the manufacturer to verify the information later. Once the batch datafile is received by the MTF, it could reconcile the data elements against the prescription drug event (PDE)

[1] This process is similar to the "Oregon model" employed by the State of Oregon to protect against the 340B statutory prohibition of a drug being subject to both 340B discounted pricing and a Medicaid rebate. www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx

data submitted by the plan sponsor to verify that the claim was approved by the plan, is an eligible 340B claim, and flag claims where the MFP for the selected drug Is lower than the 340B price. For any claim where the 340B price is lower than the MFP, the MTF could notify the dispensing entity that no further action is needed. This would allow the dispensing entity or its TPA to ensure proper inventory management.

MTF facilitates refund payments from manufacturers to dispensing entities. If the MFP is lower than the 340B price for the selected drug, the MTF should then transmit to the manufacturer only the data required to verify the pricing. It is important that the MTF limits the ability of the manufacturer to receive data that is beyond the scope of effectuating the MFP and that could be used by the manufacturer for its own financial advantage. Upon receipt of the data elements from the MTF, the manufacturer would have a 14-day timeframe, as proposed in section 40.4 of the agency's draft guidance, to verify the pricing data and direct the MTF to facilitate payment to the dispensing entity. In order for the MTF to facilitate *timely* payment, we propose that dispensing entities share banking information only with the MTF. At the same time, we propose the MTF require each drug manufacturer to submit funds necessary to process any required refunds for the difference between the 340B price and MFP in a non-interest-bearing escrow account to be held by the MTF. The concept of CMS facilitating an escrow account is not without precedent as the agency uses escrow accounts in managing refunds under the Medicare shared savings program.[8] Upon manufacturer verification of pricing or the 14-day timeframe, whichever occurs sooner, the MTF should be automatically authorized to deduct the appropriate amount from the manufacturers escrow account and issue payment to the dispensing entity. We believe this ensures both timely payment and minimizes burden for dispensing entities by not requiring them to share banking information with multiple manufacturers. As a final step, the MTF would notify the dispensing entity that the MFP price of the drug has been verified by the manufacturer and a refund has been issued so that the covered entity and/or TPA can ensure proper inventory management under a physical or virtual replenishment model.

ACCOUNTABILITY MEASURES TO ENSURE COMPLIANCE

In addition to the concerns outlined above, we believe that the proposed mechanisms to oversee and enforce the requirements of the program are insufficient and fail to conform with the specific penalties for noncompliance.[9] For example, in section 100.1 of the proposed guidance, CMS states that it may impose a civil monetary penalty in the event that a primary manufacturer does not make the MFP for a selected drug available to an MFP-eligible individual (or a covered entity providing such a selected drug to such an individual). However, the statutory language does not provide the HHS Secretary with discretion in applying a civil monetary penalty. Rather, the language expressly requires

[8] https://www.cms.gov/files/document/2021-05-27-medicare-shared-savings-program.pdf
[9] See section 1197 of the Social Security Act (42 U.S.C. 1320f-6).

the HHS Secretary to apply a very specific civil monetary penalty in such a situation. We believe that statutory compliance and the integrity of the program can only be protected with clear and consistent enforcement of such rules. As written, the proposed guidance unnecessarily increases the risk of noncompliance and diminishes both the value and impact of both the drug negotiation and 340B programs. We urge CMS to establish a more robust oversight and enforcement mechanism that conforms with the requirements set forth in the statute.

In conclusion, we appreciate the opportunity to provide feedback to the agency on this critically important program. It is of utmost importance to us that the agency effectuates a policy that balances the interests of dispensing entities, manufacturers, the government, and most importantly, the Medicare patients who stand to benefit from access to lower cost drugs. We believe that the only way these interests can be achieved is through a process that ensures prospective access to the MFP and 340B price for a selected drug. We welcome the opportunity to discuss our comments or any other aspects of this important program in more detail.

Sincerely,

/s/

Ashley Thompson
Senior Vice President, Public Policy Analysis and Development

601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

July 2, 2024

Dr. Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program Draft Guidance

Submitted via email to: IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

AHIP appreciates the opportunity to provide feedback on the Draft Guidance on the Medicare Drug Price Negotiation Program issued May 3, 2024 (the Guidance). AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone.

Part D plan sponsors negotiate lower costs with drug manufacturers and pharmacies to provide seniors and people with disabilities robust access to prescription drugs and help minimize the premium impacts associated with high and escalating drug prices. Our attached comments address provisions of the Guidance related to the ability of Part D sponsors to ensure competition, choice, and affordability. We also highlight provisions that present operational challenges to Part D plan sponsors in their administration of the Part D benefit.

We support CMS's position to not implement explicit tier placement or utilization management requirements for selected drugs. This approach will help ensure Part D plan sponsors can deploy proven and effective negotiation and formulary tools to promote access, affordability and clinical efficacy for Part D beneficiaries. However, our comments raise significant concerns with a potentially complex new infrastructure described in the Guidance to facilitate pharmacy access to selected drugs at the maximum fair price (MFP) that raises the prospect of shorter submission deadlines for reporting Part D drug claim data. We caution this will likely require more retroactive claim adjustments and create operational challenges for the supply chain.

Thank you again for the opportunity to offer comments on the Guidance. We look forward to continuing to work with CMS for the benefit of enrollees in the Part D program.

Sincerely,

Mark Hamelburg
Senior Vice President, Federal Programs

AHIP Detailed Comments on Medicare Drug Price Negotiation Program Draft Guidance

40.2.2 Data and Information Use Provisions and Limitations

CMS indicates that a Primary Manufacturer may choose, at its discretion, to publicly disclose information regarding its ongoing negotiations with CMS. However, CMS underscores that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation. CMS warns that Primary Manufacturers should consider the antitrust implications of information exchanges concerning confidential and strategic business negotiations.

AHIP Comments: We encourage CMS to recognize in the final guidance that manufacturer disclosure of information relating to MFP negotiations could negatively impact negotiations involving other Part D drugs and negotiations for drugs in other markets. We are concerned, for example, that selective or otherwise improper releases of information could influence negotiations in a way that increases beneficiary, employer, and taxpayer costs. CMS should highlight the antitrust implications for consumers in all markets that might be negatively impacted by such releases. CMS should also consider adopting policies relating to confidentiality of negotiations that limit potential anti-competitive impacts.

40.4 Providing Access to the MFP in 2026 and 2027

Section 1193(a) of the Social Security Act requires a Primary Manufacturer to provide dispensing entities with access to the MFP for a selected drug dispensed to an MFP-eligible individual. CMS states that access to the MFP must be provided by a Primary Manufacturer in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP, or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. For 2026 and 2027, CMS will use a Medicare Transaction Facilitator (MTF) to verify that a selected drug was dispensed to an MFP-eligible individual. Generally, in cases involving retrospective reimbursement, CMS will require payment to the dispensing entity within 14 calendar days of when the MTF sends the verification data to the Primary Manufacturer.

AHIP Comments: AHIP members have significant operational concerns with the retrospective reimbursement option. The MTF is an entirely new infrastructure that requires systems and operational updates and potentially new data connections along the supply chain. In addition to the complexities such a new system could create, we are concerned that the MTF's reliance on Part D prescription drug event (PDE) reports could present significant operational challenges because CMS is suggesting new processes to account for claim adjustments, resubmissions, deletions, corrections and the potential for shorter PDE submission timelines. Further comments on these issues are included in section 40.4.1.

Accordingly, we believe the prospective option should be the preferred approach. However, we encourage CMS to share additional details and parameters regarding the prospective option and work with stakeholders including Part D sponsors and PBMs to minimize operational challenges.

For example, if the MTF process is implemented, CMS could require that a "report with payment-related data" from a Primary Manufacturer to the MTF be shared with a Part D sponsor/PBM when it indicates access to the MFP has been provided prospectively.

40.4.1 Medicare Transaction Facilitator Data Facilitation

CMS outlines that the data exchange component of the MTF, in which all Primary Manufacturers would be required to participate, would involve both the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of payment-related data elements from the manufacturer for selected drugs. Once the data has been verified by the Part D plan sponsor and Drug Data Processing System (DDPS), the MTF will make claim-level data elements available to the Primary Manufacturer to notify them that the selected drug was dispensed to an MFP-eligible individual, which would trigger the start of the 14-day prompt payment window for effectuating the MFP of the selected drug.

CMS states that it is evaluating whether the current 30-day window for Part D plans to submit PDE records should be shortened to seven days. CMS is also considering how to address claim adjustments and reversals, recognizing that they could occur after the 14-day MFP payment window has concluded.

AHIP Comments: Shortening PDE submission windows would create significant administrative and operational burdens and complexities in Part D. It would also have the unintended consequence of causing more PDE reversals, further complicating the MTF process. For example, a Part D plan may receive a claim triggering the seven-day PDE submission requirement when a pharmacy dispenses a drug, which is when the pharmacy creates a patient-specific amount of the prescribed drug that is ready for patient pick up. We understand that a patient generally has 10 to 14 days to pick up the prescription, depending on pharmacy practice. If the patient does not pick up the drug, the dispense is reversed by the pharmacy. If CMS requires that PDE records be transmitted prior to the customary patient pick up window, more post-PDE submission reversals will occur than we see today.

We urge CMS not to shorten the PDE submission timeline. If it does move forward with such a proposal, the new timeline should be as close as possible to the current timeline to ensure more accurate PDE data and to minimize PDE reversals. Regardless, CMS will need to clearly lay out how reversals and other corrections are going to be addressed.

110 Part D Formulary Inclusion of Selected Drugs

In general, Medicare Part D plans are required to include covered Part D drugs that are selected drugs on Part D formularies. Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2027, CMS states that formularies must include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. CMS also indicates that for contract year 2027, it will not impose explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies. However, CMS states that it will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs

on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

As part of the contract year 2027 Part D formulary review and approval process, CMS states that it will expect Part D sponsors to provide a reasonable justification to support a submitted plan design that includes any of the practices noted above during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements. CMS states that it will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D sponsor only if the plan benefit package complies with those requirements.

AHIP Comments: We support CMS not implementing explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies for 2027. This decision is consistent with the Inflation Reduction Act not specifying how selected drugs are required to be included on Part D formularies. In addition, not all selected drugs and drug classes will present Part D sponsors and their Pharmacy & Therapeutics (P&T) committees with the same formulary considerations and might not warrant the same formulary placement in all situations. While plan formularies are required to include all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect, selected drugs may not be the clinically preferred treatment in all indications. Given that negotiation eligibility is based, in part, on the time a drug has been on the market, many of the negotiated drugs may be older and no longer be the preferred standard of care or the best option for new patient initiation.

Inappropriate tier placement or other requirements could also unduly impact formulary, rebate and other negotiations pertaining to non-selected Part D drugs.[1] When Part D sponsors are able to leverage CMS-negotiated prices to increase rebates on other therapeutically similar products for preferable formulary placement, beneficiaries and taxpayers will see lower overall Part D drug spending. [2] And as more drugs become subject to negotiation over time, multiple drugs within a therapeutic class may have negotiated prices; the manufacturers of these drugs may be willing to offer additional price concessions for preferred relative formulary placement, reducing overall Part D drug spending.

We recommend that CMS provide additional guidance in connection with these formulary requirements. CMS should clarify whether the clinical justification process it referenced would

[1] CBO and MedPAC reports have outlined how limiting formulary flexibility and tools impacts the ability of Part D sponsors to negotiate rebates and can contribute to higher net prices. See https://www.cbo.gov/system/files/2022-01/57050-Rx-Spending.pdf and https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_reporttocongress_sec.pdf.

[2] See CBO analysis at https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf, stating that "the availability of maximum fair prices for some drugs would prompt manufacturers of competing products to offer prescription drug plans greater discounts than they would in the absence of negotiation."

apply in instances where a selected drug may not be preferred for a certain indication rather than be non-preferred for all indications. In addition, we encourage CMS to reiterate the flexibilities Part D sponsors have to include a selected drug in a certain tier for one condition and then in a different tier for a different condition, based on input from P&T committees, scientific evidence, and pharmacoeconomic considerations.

Further, we request that CMS provide additional guidance pertaining to how the clinical justification process would apply in cases where the MFP of a selected drug is higher than the net price of non-selected drugs. More preferential formulary placement of selected drugs in these circumstances would have the potential to impact beneficiary premiums.

In future guidance, we also encourage CMS to propose for comment the criteria it will use for the clinical justification process. Transparency and standardization in CMS evaluations of clinical justifications associated with formulary placement of selected drugs versus non-selected drugs will help ensure consistency in its formulary review and approval process.

Importantly, the Guidance (in Section 60.6) reiterates the statutory requirement that CMS publish, by November 30, 2025, the MFP for each selected drug for initial price applicability year 2027 for which CMS and the Primary Manufacturer have reached an agreement on an MFP. Given the formulary inclusion requirement and other provisions (e.g., a Part D plan's negotiated price for a selected drug cannot exceed the MFP plus any dispensing fee), it is critical that CMS meet this publication deadline so Part D plans can appropriately operationalize these provisions and incorporate them into dispensing entity negotiations and bid development for 2027.

In addition, while the Guidance (also in Section 60.6) stipulates that CMS will publish on the CMS website when a drug is no longer a selected drug and the reason for that change, we encourage CMS to also promptly notify Part D plan sponsors, such as through an HPMS memo, when the formulary inclusion requirement no longer applies to a previously selected drug.

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

July 1, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program Draft Guidance - Patient/Caregiver Involvement

Dear Dr. Seshamani,

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiAiArthritis diseases, shares CMS's goal of lowering patient out-of pocket costs so that they can more easily maintain their health. We are the only patient organization in the world focusing solely on this group of diseases, whose leadership consists of those diagnosed with or caring for persons with our diseases, and who specialize in designing innovative, patient-inspired solutions.

We appreciate CMS' willingness to include patient, caregiver, and patient organization suggestions as you update and begin to finalize guidance for the Medicare Drug Price Negotiation. Through our participation in the process, as both an organization and as patients, we have recognized areas that could benefit from improvement. Thank you for this opportunity to provide the following recommendations.

Listening Sessions

Recruitment. AiArthritis, as an organization who connects patients/care partners to opportunities to have a voice in matters that impact their health, is excited about the evolving landscape to bring more people with lived experience to the conversation. In saying this, our organization is led by those affected by these diseases, so we also understand challenges associated with inviting community participation (i.e., they may feel uncertain they are answering the question correctly, uncertain how their perspectives will be interpreted, not fully clear of the purpose for participation/broader issue, fine line between wanting help developing speaking points and feeling 'scripted'). While this is not usually the case with experienced advocates, who are used to speaking publicly, there is a push to bring additional patients 'to the table,' including those who historically are not accustomed to sharing their stories or perspectives.

Furthermore, robust data requires minimum participation from a variety of groups, including subgroups. For example, people who have a diagnosis of Rheumatoid Arthritis will experience different systems, disease progression, and complications (like comorbidities – heart disease,

dual diagnosis, Alzheimer's disease). This is, in part, due to disease heterogeneity and, as such, varied responses to the same treatment. When the data from a statistically significant diagnosis demographic is not available, the analysis and information extracted from it may be limited.

Listening Session Recruitment - What Worked. AiArthritis staff spent several hours day and night working on peer-to-peer recruitment, created associated education ("the why you should participate/what is this anyway"), and promised guidance to those unsure what to say if they were selected. As a result of these efforts, AiArthritis successfully recruited 7 or the 16 people selected for the Enbrel session and 4 of the 11 people selected for the Stelara session. Of those people, 40% (both sessions) have never spoken publicly or had experience being a Patient Advocate (PA).

Listening Session Recruitment - What Needs Improvement. It was extremely difficult recruiting patients who are not experienced PA's. While AiArthritis was successful in recruiting non-PA's, we struggled finding diverse pools of respondents who represented various disease subgroups and other demographics.

- **Lack of clarity and understanding breeds silence**. Given no one fully understood how the Listening Sessions would run, in addition to drug price negotiations being a new topic, developing education to help patients/caregivers understand it was near impossible.
- **Recruiting for patient/caregiver participation was tasked largely to Patient Organizations (POs).** CMS has the database of people who utilize their services. Why can't CMS help with recruitment and outreach?

Recruitment recommendations and opportunities. Agencies, like CMS, who are conducting drug price reviews, should be required to dedicate a percentage of time towards recruiting participants.

Given future recruitment will require approaching patients/caregivers who may never have contributed perspectives, associated education about why this is being done – as well as potential consequences – should be included.

Listening Session Preparation - What Worked. AiArthritis led patient/peer education meetings to first explain to patients/caregivers what this is about and then we helped them figure out how to prepare their testimonies if they chose to participate. We refrained from calling any discussions "training," as we *did not craft their statements or actions*. Instead, we held patient-peer conversations, letting patients/caregivers tell us their stories about the treatment, access, and affordability. As they did so, we alerted them how to translate those stories into bulleted points that can be captured in a 2-3 minute window.

For example, a patient may say, “I couldn’t access my Stelara for three months,” which often is not due to affordability, but rather due to insurance protocols, like step therapy, prior authorization, or accumulator programs. Without the help of a patient organization to help the patient/caregiver understand what is causing their struggle (access, affordability, manufacturer, payer, etc.) stories could be misunderstood and the points patients wanted CMS to know could have been incorrectly expressed. This demonstrates the value - and the much needed inclusion of Patient Organizations - as part of this process.

Listening Session Preparation - What Needs Improvement. Email notification to participate – 4 day turn around to accept. Notifications of acceptance to speak at a Listening Session had an extremely quick turn around time to accept the invitation. Not all people check emails daily. AiArthritis spent hours trying to notify potential patients/caregivers selected to check their emails, including spam.

The HIPPA and media form were difficult to download, complete, and resubmit (not patient friendly). One document was in Word and had severe formatting issues. Another was a PDF. After identifying patients/caregivers who were invited to speak, our organization had to personally assist half a dozen who either did not have the computer software to pull up a PDF form or did not have a printer to print, write, and scan.

Listening Session Participation - What Worked. While we have heard from some viewers and participants who felt 3 minutes was not enough time to speak, all those who participated that AiArthritis recruited did express they felt this was ample time. They felt prepared and that their answers were to the points they most wanted to say.

However, they did all say (me included) they would prefer to have been able to follow up with CMS on those statements, gain feedback, and be permitted to continue a two-way conversation so they could be certain CMS understood their point of view. *This has become more important since the emergence of Prescription Drug Affordability Boards (PDABs), as the Colorado PDAB members have repeatedly misinterpreted patient comments and testimony.* [1]

Listening Session Participation - What Needs Improvement.

- **Better screening of participants.** In one of the Listening Sessions a researcher spent his entire time talking about Amgen and patent extensions.
- **Not enough people were chosen to speak; or more likely, not enough people applied to speak**. As mentioned previously, without a diverse and plentiful pool of participants, the validity of the data collected is limited.
- **Not enough Medicare/Medicaid patients/caregivers participated.** We feel the patients on the Enbrel and Stelara Listening Sessions did a great job explaining how their disease impacts their lives and the importance of accessing and affording the

[1] AiArthritis - Tiffancy Westrich-Robertson.pdf

biologic that works best for them. However, most patients who are not on government plans do not have issues affording their treatments – thanks to manufacturer copay assistance programs. Given these programs are not available to those on government plans, a deeper dive into their affordability should have been a priority.

- **Prior knowledge of what data points will be analyzed could improve content focus.** If the patients/caregivers do not know what points from their testimony is being applied to the decision making, it is difficult to craft responses in a way that will generate meaningful information. Additionally, a patient who does not want to lose access to their treatment, and then does as a result of the Listening Sessions/something they potentially said (or did not say), can have negative after effects on their mental health.

Listening session participation recommendations and opportunities. Given public speaking is a known fear for most, consider hosting private Listening Sessions, including the option for patients to participate off camera. This could improve participation, particularly as many patients are private about their experiences and would not be comfortable having their stories and struggles visible to the public.

Consider hosting several small, breakout meetings with both PO and Patient/Caregiver representatives present. These should be both separate and collaborative. Add alternative methods of participation, like enlisting moderators to host conversations with various demographics (heavily including those on Medicare). Also, consider polling Medicare beneficiaries who are on the 10 drugs (perhaps in mailers, email outreach, etc.)

We hope CMS will communicate how data collected from patients was or is intended to be used, including citing data to justify decisions.

Associated Surveys

While most people seemed to focus on the Listening Sessions, there was an associated survey option for patients/caregivers and patient organizations to participate as well. However, this was extraordinarily difficult, particularly if the participant was part of a patient organization AND a patient - as the patient testimony portion disappeared on the form if “patient organization” was chosen.

Surveys - What Worked. Until we know how many participated and completed the surveys and how the content collected will be used, we cannot comment on ‘what worked.’

Surveys - What Needs Improvement. The webform was simply too complex.

- The site itself was difficult to navigate, the answers cannot be saved, and the site could time out before answers had been completed.
- The instructions and questions were written at an advanced level.

- The answers had to be written first into a document and then copied and pasted to ensure not to exceed the maximum word count. Also, not all patients/caregivers have access to a program that enables them to pre-type their answers, or may not even have a computer.
- Option for Patient Organization or Patient/Caregiver, not both. AiArthritis leadership are people with diseases that can be treated by both Enbrel and Stelara. However, to also include the voice of the patient perspective, they had to go back in and start over. More concerning, however, is the missed opportunity for the same leaders who had never been on either and, therefore, preferred to complete Q 31 on behalf of all persons in our community who were not participating in the Listening Sessions nor did not feel comfortable navigating or completing the survey option.

Survey recommendations and opportunities. CMS should invest in various methods of survey/data collection, including an easy-to-use online option. Forms used for input submissions should be simplified, both in terminology and methodology.
CMS should consider recruiting patients during the development of questions to identify potential issues prior to publication. Patients can identify potential issues that a person not living with the condition would not realize. AiArthritis is willing to assist with questions and other methodology review.

In closing, I would like to extend gratitude again on behalf of AiArthritis, and all persons living with our diseases, for this opportunity to participate in your review process and to provide comments that we hope can help as you evolve it. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Tiffany Westrich-Robertson
Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
AiArthritis (International Foundation for Autoimmune & Autoinflammatory Arthritis)

July 2, 2024

SENT VIA EMAIL

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the opportunity to provide feedback on the Medicare Drug Price Negotiation Program and applaud CMS for its commitment to actively engage patients, caregivers and providers throughout the implementation of the IRA. Aimed Alliance urges CMS to consider the following recommendations to ensure the listening sessions are genuine, inclusive, and effective.

I. Introduction

While we appreciate the inclusion of patient listening sessions in the negotiations, there are a few areas we suggest addressing to ensure future success. Previous sessions were marked by strict time requirements and a lack of guidance, which likely hindered participants' ability to provide meaningful and relevant contributions. Additionally, there was a lack of diversity, which may have resulted in a limited range of perspectives being considered. Furthermore, all listening session spots were not filled, indicating a potential lack of awareness among stakeholders of these opportunities. Addressing these issues is crucial to ensuring that future listening sessions are more inclusive, genuine, and fully attended, thereby enriching the quality of feedback and fostering a more comprehensive understanding of patients' needs and concerns.

II. Guidance on Listening Sessions

To ensure that listening sessions are beneficial to CMS, it is essential to provide clear guidance on the types of information that are most useful to CMS. This guidance should outline the specific objectives of the listening sessions, clarify the type of feedback CMS is seeking, and explain how this feedback will be utilized in decision-making processes. Such clarity will enable participants to tailor their contributions effectively to meet CMS's needs, fostering more productive and focused discussions.

III. Promoting Diversity Through Varied Times and Formats

To promote diversity and inclusivity in participation, we recommend offering listening sessions at various times and in different formats, while also permitting the submission of pre-recorded materials. This approach will accommodate the schedules of a wider range of participants, including patients, caregivers, providers, and health data experts. This will also help ensure those with childcare, caregiving, or other responsibilities can share their comments and experiences with CMS.

Additionally, we support CMS's consideration of interactive sessions that encourage discussion and allow CMS to ask clarifying questions, rather than hosting listen-only events. We also support combining events for medications that treat similar conditions or diseases, rather than holding separate events for each drug. Providing a variety of session formats will help maximize participation, ensure that a broader spectrum of voices are heard, and facilitate a more comprehensive exchange of ideas.

IV. Allowing Patient Advocates to Speak

We strongly encourage CMS to allow patient advocates to speak on behalf of their respective disease communities. Many patients may find it difficult to speak out about their personal health issues due to stigma, emotional distress, or other barriers. Patient advocates, and advocacy organizations, are well-versed in the challenges and needs of their communities which can provide valuable insights and articulate the collective experiences and concerns of patients. This approach can enhance the quality of the feedback CMS receives and ensure that the perspectives of those most affected by the issues are adequately represented, while also preventing the burden of providing these insights from falling solely on individual patients.

V. Conclusion

We support CMS's efforts to engage with stakeholders for the successful implementation of the IRA. We appreciate the opportunity to provide input on this matter and look forward to participating in listening sessions that are genuine, inclusive, and effective in gathering valuable feedback to inform healthcare decisions.

Thank you for considering our comments.

Sincerely,

Ashira Vantrees
Counsel

Alliance FOR AGING RESEARCH
Catalyzing Innovation for Healthy Aging

1700 K Street, NW | Suite 740 | Washington, DC 20006
T 202.293.2856
www.agingresearch.org
@Aging_Research

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191- 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Dr. Seshamani,

The Alliance for Aging Research ("Alliance") appreciates the opportunity to review and comment on the Medicare Drug Price Negotiation Program (MDPNP) Draft Guidance for 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity.

The Alliance appreciates CMS's willingness to revisit and solicit comment on several key areas, including the patient-focused engagement process and the grouping of qualifying single source drugs. We also strongly believe that CMS must, and has legal authority to, be more proactive in establishing expectations and guardrails to prevent inappropriate or excessive applications of utilization management.

30.1.1 Qualifying Single Source Drugs

CMS has chosen to combine all indications, dosage forms, and strengths of a medication together as one "drug" for the purpose of applying the MFP. The Alliance has concerns about the downstream impacts of this decision on areas of medical research. For example, the

manufacturers of some glucagon-like peptide 1 (GLP-1) agonists are currently in clinical trials for conditions that are very different from their originally approved indication of diabetes, such as Alzheimer's disease and slowing the progression of kidney disease. The difference in patient population and condition is significant, requiring separate clinical trials and substantial investment. However, if a drug in the future is subject to the current QSSD grouping guidelines, there will be greatly reduced incentives to perform these types of additional research, leaving potentially very meaningful treatments unexamined. Further, Medicare's negotiated price for a qualifying single source drug (QSSD) may or may not incorporate costs associated with additional research and development of a drug with an existing approved FDA indication.

While we have the greatest concern about the above potential application of the statute, there are also concerns about whether the QSSD structure excessively disincentivizes research into distinct formulations or routes of administration. CMS should assess whether these advances represent clinical improvements (based on better efficacy due to the method of action, or due to ease of administration that improves adherence, for example) that improve outcomes and/or quality of life.

The Alliance asks CMS to explore with the wider patient community and other subject matter experts the degree to which application of an MFP on a QSSD constitutes a deterrent for investment and research into novel indications. We hope manufacturers and pharmaceutical companies will continue investing significantly in novel areas regardless of CMS policy, but we are cognizant of real-world considerations and are concerned about the unnecessary risks the current formulation of the QSSD policy raises for the development of novel uses of therapeutics. Over time, this policy could impact patients in nearly every disease area, including areas with significant unmet need.

60.3 Issues Resulting from CMS' Lack of Transparency About Methodology and Potential Use of Discriminatory Metrics

Currently, there is little to no publicly available information on the process and methodology used by CMS as they negotiate prices. However, CMS is a public agency – not a private payer – and there is little need for a similar level of secrecy or guarding of "trade secrets" around methodology. There is material public interest in how CMS is establishing the MFP, given that millions of beneficiaries take the medicines subject to negotiation and there may be resultant impacts - positive or adverse – that result as negotiated prices take effect in 2026. We encourage CMS to change course and publicly release information on the methodology used to establish the MFP and price negotiation. Further, releasing this information will encourage drug manufacturers to collect relevant data, either during the clinical trial process or through real-

world data collection, to provide a robust base of information on factors likely to be considered in Medicare negotiations in the future.

There is also interest in ensuring that metrics assessed as discriminatory are not used in price negotiation. While CMS has noted that they will not be using the quality adjusted life year (QALY) to set the MFP, there have been explicit mentions of other equally discriminatory metrics in guidance. In the June 2023 Revised Direct Negotiation Guidance, CMS noted that many commenters recommended metrics such as the equal-value of life years (evLY) gained – which was developed and is calculated in part by using the QALY[1] - or the Health Years in Total metric and then responded, "CMS will review cost-effectiveness measures and studies that use such measures for initial price applicability year 2026 to determine if such measures are permitted under section 1194(e) of the Act."[2] The public is not able to know the degree to which this research was conducted or the implications it had on the initial prices the Agency proposed. This is especially notable given the finalization of the updated final rule on Section 504 of the Rehabilitation Act, which confirmed that agencies under the umbrella of the Department of Health and Human Services cannot use metrics that discount the value of life extension based on disability.[3]

Further, methods for the underlying data collection used to complete the QALY, evLY, and similar analyses are incomplete and immature. At present, these analyses rely solely on clinical trial data, which typically include exclusion criteria that disqualify individuals from participating in a trial based on comorbidities, age, and other factors. As a result, clinical trial data often reflects a population that differs significantly from real-world users, meaning that any calculations of evLY are not representative of a drug's entire intended user base. Negotiated drugs are not new to the market, and so CMS should not be relying primarily on preclinical data, but rather should incorporate analysis of real-world data and real-world evidence.

CMS must be transparent about data collection and analysis in calculating the MFP, as well as the role of the engagement sessions, so that stakeholders can have meaningful engagement, including around the methodology the agency chooses to deploy.

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[1] O'Day, Ken and Dylan J. Mezzio. "Demystifying ICER's Equal Value of Life Years Gained Metric." Value & Outcomes Spotlight. https://www.ispor.org/publications/journals/value-outcomes-spotlight/vos-archives/issue/view/overcoming-vaccine-hesitancy-injecting-trust-in-the-community/demystifying-icer-s-equal-value-of-life-years-gained-metric

[2] Centers for Medicare and Medicaid Services. "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026." 30 Jun 2023. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf

[3] Department of Health and Human Services. "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance." Federal Register Vol. 89, No. 91. https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf

60.4 Negotiation Process (and Improvements to the Patient-focused Engagement Process)

The Alliance appreciates and acknowledges the proposed effort that CMS is making to improve the format of the listening sessions and the overall patient engagement process. In the first round of negotiation, the listening sessions and patient engagement processes fell short of expectations for participants and, we suspect, did not produce highly useful information for CMS. There are three overarching reasons for this: 1) The format of the listening sessions and requested written comments from beneficiaries, physicians, and manufacturers were intimidating and unapproachable for broad audiences; 2) CMS did not clearly communicate the purpose or importance of participating in the listening sessions, including what the agency hoped to learn during the sessions; and 3) the listening sessions were a one-way conversation that did not allow for discussion, or any acknowledgement by participating CMS staff that they were "listening." Below, we outline broad principles for improving this process. The Alliance also recommends that CMS consider the National Health Council's report, "Amplifying the Patient Voice: Roundtable Recommendations on CMS Patient Engagement"[4] and the Innovation and Value Initiative's report, "Ensuring Equity in Implementation of IRA Drug Price Negotiations"[5] that outline recommendations, including contributions from the Alliance and the wider patient advocacy community.

1. **Clear Communication of Purpose and Meaningful Incorporation of Findings:** There are significant opportunities for CMS to improve communications regarding the purpose and the importance of patient participation in these sessions. CMS should explicitly articulate the goals of the sessions and what the Agency hopes to gain from them, as well as what type of data or information on the patient experience might be useful. For example, CMS may note that the goal of the sessions to understand which endpoints are most significant to patients and how these could influence pricing methodology.

   It is crucial to avoid assuming that beneficiaries inherently understand the value or purpose of their participation. CMS should provide comprehensive information on what is expected from participants, the type of information sought, and how the data coming out of that will be used in the negotiation process. Clear, detailed explanations will encourage more informed and willing participation.

[4] National Health Council. "Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement. March 2024. https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[5] Innovation and Value Initiative. Policy Symposium: Ensuring Equity in Implementation of IRA Drug Price Negotiations. Dec 2023. https://thevalueinitiative.org/wp-content/uploads/2024/04/2023-IRA-Policy-Symposium-Proceedings-Report_FINAL.pdf

CMS should use the data (both empirical and anecdotal) collected from the listening sessions into the setting of the MFP, and there should be greater transparency into how patient perspectives are being assessed. In addition to clinical factors, a drug's value should reflect the broad array of benefits important to patients, caregivers, and society. This means not only soliciting patient and provider input in a systematic way, but also establishing a process for this input to be quantified when setting an MFP.

2. **Inclusivity and Representation:** CMS should ensure diverse representation of patients during patient engagement sessions. It is essential to identify and reach out to groups that were underrepresented or absent in initial sessions. Specifically, CMS should coordinate with the Office of Minority Health, as well as organizations involved in outreach to underserved communities of color and rural communities to enhance participation from these demographics.

3. **Adequate and Transparent Time Allocation:** The current format, which allots only three minutes per speaker, is insufficient for patients and advocates to thoroughly discuss important outcomes and provide supporting data. Extending the time allocated for each participant will allow for more meaningful contributions. If CMS carries forward last year's format, CMS should consider adopting a visible countdown timer during sessions, similar to the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices public meetings. This transparency would allow both speakers and listeners to monitor their progress.

4. **Accommodation for Disabilities:** During the sessions, CMS must ensure appropriate accommodations for individuals with disabilities. Participants should have the support they need to ensure they can participate meaningfully in the process, including additional speaking time for those who have disabilities that impact their ability to communicate. CMS must adhere to basic principles of patient engagement by providing necessary accommodations for all participants.

5. **Improved Notification and Timing:** The timing and method of notifying selected speakers also need improvement. Last year, the agency extended the deadline for sign up, but began selecting and notifying (on October 13th, 2023) participants before the extended deadline had lapsed (on October 15th, 2023). Further, selected participants were emailed on October 13th and told they needed to complete all relevant forms and submit to CMS by October 17th – only four days, inclusive of weekend days, following receipt of the notification message.

CMS should include a more generous notification and response period to ensure participants have ample time to prepare regardless of format. Further, if the agency hosts hybrid or in-person opportunities, reasonable lead time should be provided to allow participants to make cost-effective travel arrangements.

6. **Fair Disclosure Standards:** In the previous round, CMS required groups that receive funding from pharmaceutical companies – regardless of amount – to submit a disclosure in their request to participate in the listening session. However, this question singles out funding from one sector while ignoring the financial interests of other stakeholders (such as insurers, PBMs, or funders such as Arnold Ventures) that may have financial or ideological incentives to participate in the stakeholder process. We encourage CMS to either eliminate this question or broaden it to provide transparency regarding financial support of participating groups.

7. **Handling HIPAA Concerns:** CMS should address HIPAA concerns more flexibly. For instance, at least one participant from an advocacy organization was unable to discuss their caregiving experience without written power of attorney for a deceased family member. CMS should streamline processes to allow meaningful discussions without imposing excessive bureaucratic requirements.

CMS has asked for specific feedback on the potential discussion format and information administration proposals in the guidance. We recommend that CMS implement discussion-based formats for future patient-focused engagement sessions. These formats are significantly more welcoming to participants, as they allow for informal exchanges rather than requiring specific, prepared remarks. They also allow participants to answer questions and gain some understanding of how their contributions are being considered by the Agency.

During the previous listening sessions, the livestreamed format has also been noted as a barrier to patient and patient advocacy group participation. To balance the need for privacy and transparency, CMS should instead produce anonymized summaries to be posted publicly after the session. This approach, following Chatham House Rules, ensures that participants can speak freely without fear of attribution, encouraging more candid and valuable feedback. CMS should further consider a mix of hybrid and in-person meetings to encourage more widespread participation and enable a more conversational tenor where possible. As a supplement to hybrid and in-person meetings for those unable to participate at the scheduled time, CMS should offer alternative options to provide testimony. This flexibility would broaden participation and capture diverse perspectives that might otherwise be missed.

Sessions should also be organized based on condition or therapeutic area, rather than by a specific drug. Organizing sessions around a specific therapeutic puts participants in the position of "defending" or "attacking" a certain brand of drug, as opposed to speaking more broadly about the landscape of treatments available and relevant patient-centered endpoints. It is often preferable to speak about clinical need, therapeutic alternatives, and relevant data holistically for relevant drugs, rather than either focusing only on a single drug or, alternatively, repeating the same information across multiple sessions. This will allow the Agency to collect more comprehensive feedback and have a clearer picture of patient experiences across different treatments.

CMS can continue to improve patient engagement by adopting best practices from organizations like the Food and Drug Administration and the Patient-Centered Outcomes Research Institute. These organizations have developed effective two-way discussion formats, often incorporating both in-person and virtual participation options. CMS could also look to international examples, such as the European Medicines Agency, for innovative patient engagement strategies. Further, the National Health Council has developed a number of tools to advance patient engagement and experience mapping.[6] CMS has the chance to lead by example as more research and payer groups work to include the patient perspective in their models and assessments.

110. Formulary Inclusion of Selected Drugs and Resulting Incentives for Increased Abuse of Utilization Management Techniques

A recent report from the Government Accountability Office (GAO) found that, "Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates."[7] As a result, plans are at risk of losing significant rebate revenue when CMS sets a maximum fair price (MFP) for the drugs selected for negotiation. At the same time, plans are facing a significant increase in financial liability in the catastrophic phase of the benefit as a result of the Part D redesign, and constraints on premium growth through 2029. All of these factors will drastically increase incentives for plans to find levers by which to control their growing costs, including by narrowing formularies, adopting more rigorous utilization management strategies like prior authorization or step therapy, or promoting drugs other than those CMS has selected for negotiation. As a result, beneficiaries face a growing risk of

[6] National Health Council. Capturing and Including the Patient Voice. https://nationalhealthcouncil.org/issue/patient-engagement/
[7] Government Accountability Office. "Medicare Part D: CMS Should Monitor Effects of Rebates on Drug Coverage and Spending." 19 Sep 2023. https://www.gao.gov/assets/gao-23-107056.pdf

burdensome or clinically inappropriate utilization management requirements, potential treatment delays, or loss of coverage altogether.

We support CMS's acknowledgement of these factors and stated concern that sponsors may be "incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers … or by applying utilization management that is not based on medical appropriateness."[8] We also believe that the draft guidance's reiteration of existing rules regarding formulary placement and tiering, as well as noting specific behaviors related to the placement of drugs selected for negotiation, is a good first step.[9]

However, given the high stakes for beneficiaries, the agency should go further. Increased application of UM – particularly when not clinically appropriate - puts patients at risk of delayed care and life-threatening adverse outcomes. For example, step therapy protocols require beneficiaries to take (often a series of) less expensive and potentially less efficacious medications first. In this case, beneficiaries must fail to show the desired clinical improvement before becoming eligible for coverage for the medication their physician or medical provider initially prescribed.

Further, many beneficiaries may have selected their current plan because it resulted in the lowest out-of-pocket (OOP) cost burden.[10] However, given the new OOP cap on beneficiary costs in Part D, changes to plans' benefit parameters may result in a different plan having lower expected OOP costs. As a result, more beneficiaries are expected to switch plans in 2025 than in a typical year. However, when beneficiaries switch plans, they may be required to go through their new plan's UM structure (or, to have the process knowledge and capability to file for an exception with their new plan) to maintain continued access to drugs on their care plan. This is particularly problematic with step therapy, where a beneficiary may be required to stop their current medication and go back to take a medicine they have previously taken but that has not worked. These scenarios are likely to be seen in the real-world, given the increased "churn" in MA plan enrollment and projected expansion in UM protocols following from plans' increased liability in the catastrophic phase of the benefit.

[8] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. Sec. 110. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf
[9] Ibid.
[10] Gretchen Jacobson, Faith Leonard, Elizabeth Sciupac, and Robyn Rapoport. "What Do Medicare Beneficiaries Value About Their Coverage?" 22 Feb 2024. https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage

As mentioned above, CMS has recognized the importance of these issues but has thus far declined to take important steps to strengthen formulary standards, increase transparency, and strengthen oversight. While CMS asserts that the agency "does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS's revised guidance for … 2026 are warranted," we disagree. The agency should not wait until harmful behavior is observed – especially when the impact on beneficiaries would not be evident in data patterns until significantly later - in order to take action. Post hoc changes once harms are already being experienced by beneficiaries are not appropriate, given that interruptions or delays in access can, in some cases place beneficiaries at risk of delayed care that can result in irrevocable loss of function or adverse outcomes.

We encourage CMS to take the following actions (as proposed in a report developed by Manatt, with support from the Alliance, and released on June 26, 2024) to protect beneficiaries, all of which the agency should be able to do with existing regulatory authority. The recommendations[11] from Manatt include:

1. *Require that drugs selected for negotiation—for which CMS has established a maximum fair price—be given preferred formulary status, without utilization management.* Current CMS rules only encourage placement of drugs selected for negotiation on preferred tiers with limited utilization management, by requiring plans to submit a clinical justification if they attempt otherwise. However, this provides no guarantees, and it would have CMS resource implications for reviewing each submitted justification. Moreover, CMS's guidance on reviewing clinical justifications is vague. Instead, CMS could adopt a blanket rule protecting drugs selected for negotiation. This could be supported by CMS's authority to disapprove plan designs likely to discourage enrollment. A plan tiering design that steers beneficiaries away from drugs selected for negotiation and towards drugs not selected with higher out-of-pocket costs to the beneficiary is likely to discourage enrollment of beneficiaries who need a particular drug that has been selected for negotiation. CMS could also justify this by setting reasonable minimum standards for plans.

   CMS could also give additional guidance on the clinical justifications it will require for non-preferred treatment or utilization management of drugs selected for negotiation. This guidance could address more directly what a might constitute a valid justification.

[11] Manatt Health. "Patient Impact of the Inflation Reduction Act Administrative Options to Address Changed Incentives for Formulary and Utilization Management." June 2024. https://www.manatt.com/Manatt/media/Documents/Articles/AAR-Patient-Impact-of-the-IRA_2024-06_d.pdf

2. *Adopt a public "watchlist" for specific adverse formulary decisions that CMS will not approve, to keep PDP sponsors from excessive narrowing of formularies.*

   When CMS disapproves a formulary design or utilization management practice, it could do more than simply require the sponsor to correct it. Instead, CMS could publicly announce to all sponsors that it has identified that specific practice as an issue, and that it will be on the lookout for it going forward. This could create clarity for plans and discourage the submission of similar plan designs. It could also give CMS an opportunity to demonstrate that the agency is being proactive in addressing noncompliance with formulary requirements. PDP sponsors who repeatedly submit formularies that require correction could be required to implement a corrective action plan to better consider their formularies before submission.

3. *Commit additional resources to formulary reviews so as to identify access issues before such issues can harm beneficiaries.*

   The importance of protecting beneficiaries through the first few years of IRA's implementation suggest CMS should devote additional resources specifically to formulary reviews and PDP sponsor monitoring. The IRA appropriates $341 million to CMS to implement the IRA's Part D improvements. It would be prudent to devote some of those funds to expand the teams and tools used for the ordinary annual formulary review process and Part D plan monitoring functions.

4. *Explicitly and publicly identify more situations where plans must cover more than two drugs per category or class to ensure that formularies provide adequate coverage of drugs commonly used by beneficiaries.*

   Current CMS policy is that it follows "widely accepted treatment guidelines" and "general best practice" to determine whether a formulary has adequate coverage. It also published a list of commonly prescribed drug classes in 2010 for use in formulary reviews. This guidance is vague and out of date. Instead, CMS could publish more detailed lists of key areas where it demands adequate coverage on formularies, including specific minimum numbers and types of medications.

5. *Improve plan transparency so beneficiaries can more easily see when drugs have utilization management restrictions.*

   Beneficiaries shopping for coverage may struggle to easily identify when a plan they are considering has a utilization management restriction for a drug they take. Likewise, they

may not know to look and see if a plan disfavors drugs selected for negotiation. CMS could adopt rules and improve transparency of this information by including it prominently in the Medicare Plan Finder and make specific utilization management policies easily searchable and accessible. Likewise, CMS could place a flag in the Plan Finder on plans that disfavor drugs selected for negotiation, to alert beneficiaries in advance.

6. *Enforce minimum payment rates to pharmacies, to prevent sponsors from diverting patients away from community pharmacies.*

   CMS could ensure broad access to covered Part D drugs at beneficiaries' chosen pharmacy by requiring that PDP sponsors pay at least the pharmacy's acquisition cost for covered drugs. While CMS ordinarily does not "interfere" in the negotiations between plans and pharmacies, this could be construed as falling within CMS's authority to set "reasonable and relevant" reimbursement terms plans must meet to satisfy the "any willing pharmacy" rule.

7. *Actively monitor appeals, grievances and exception requests filed by beneficiaries with their plans, to have near real-time view of access issues.*

   CMS could closely monitor rates of beneficiary appeals of coverage denials, complaints to plans about coverage and exception requests for coverage of drugs not on formulary or for preferred status of a non-preferred drug. Upticks in these processes could be leading indicators of specific problems on specific plan formularies that CMS could act on quickly. CMS currently collects this data on a quarterly basis, and perhaps not in sufficient detail to identify specific drug products or policies that trigger additional appeals. By increasing the pace and detail of this collection, CMS could improve its visibility and act more quickly. Additional regular audits of plans would demonstrate situations where plans are inadequately processing and reviewing appeals and exceptions. Publication of this data and CMS's enforcement activity could demonstrate that the agency is acting proactively.

8. *Improve appeals and grievance processes, to reduce the burden of challenging a plan's coverage decision.*

   CMS might also consider taking steps to improve the efficiency of the appeals process to relieve patients and providers of the burden of filing an appeal or a formulary or tiering exception request. These processes are the best immediate mechanism available to beneficiaries facing challenges with coverage or authorizations, and having

them run smoothly is an important protection for 2025 and beyond. For example, CMS could consider requirements for seamless electronic prior authorization, appeals and exception requests. CMS could also ensure that beneficiaries are aware of these processes through better communication and education on rights to appeal or request an exception. Finally, CMS could make exception requests easier to obtain, such as by adopting a presumption in favor of granting an exception. This would support a reduction of administrative burden, as data has shown that millions of prior authorization requests are submitted annually, with most appeals of prior authorization denials being overturned.

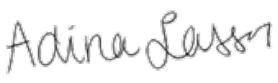
9. *Adopt new actuarial equivalence tests to more accurately and quantitatively track whether plan sponsors are offering sufficient coverage of drugs selected for negotiation.*

   To protect beneficiaries in 2025, CMS could improve the sensitivity of its actuarial equivalence test to protect against adverse formulary tiering of drugs selected for negotiation. Beginning in 2026, CMS could separately test the actuarial equivalence of out-of-pocket costs of drugs selected for negotiation to ensure that sponsors are actually offering an actuarily equivalent benefit for these drugs. In so doing, CMS will likely prevent PDP sponsors from quietly inflating the out-of-pocket costs for drugs selected for negotiation through inferior formulary tiers.

Conclusion

Thank you for the opportunity to provide input and comment on the draft guidance. The Alliance remains hopeful that CMS will put patient care and experience at the forefront of the negotiation process. Should you have any questions, please contact Adina Lasser, Public Policy Manager, at alasser@agingresearch.org.

Sincerely,



Michael Ward
Vice President of Public Policy and Government Relations

Adina Lasser
Public Policy Manager

July 2, 2023

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 2124401850

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

On behalf of the Alliance for Patient Access (AfPA), thank you for the opportunity to comment on the draft guidance for implementation of the Initial Price Applicability Year 2027.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making, promote personalized care and protect the provider-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials.

We are pleased to see that CMS is committed to implementing the prescription drug negotiation law with the goal of transparency and engagement. As such, our comments will primarily focus on the agency's process for engaging patients in its decisions. Patients with chronic diseases, and their healthcare providers, have valuable experiences that can inform CMS decisions, including on decisions such as a treatment's clinical effectiveness, unmet need and therapeutic alternatives.

Patient Listening Sessions

CMS must strive to ensure meaningful patient and provider input and provide advance explanation of how that input will be incorporated in the drug price review.

During the first round of drug price negotiations, CMS held a single listening session for each of the 10 selected medications, a recognition of the importance of lived experience with the medications and the conditions they treat. CMS is to be applauded for taking this step but must improve on the process for future years.

To ensure input in the public listening sessions is meaningful and can drive informed policymaking, CMS should:

- Clearly identify what qualitative and quantitative information is being sought and how CMS intends to incorporate it into the negotiation process
- Report on how past patient input was used in the maximum fair price determinations, allowing participants to better tailor their input
- Clearly identify who can participate and how they will be chosen

- Ensure diversity of speakers to better represent the Medicare patient population
- Structure the listening sessions such that they are interactive, with CMS participation and the opportunity for questions and responses
- Provide further advance notice of the sessions
- Allow for additional methods of providing input such as recordings and written statements
- Establish a methodology for how qualitative patient experience data will be incorporated, developed with input from the patient community, allowing for better input going forward

We are pleased that CMS is seeking input to better bring together stakeholders, including patients, beneficiaries, caregivers, and consumer and patient organizations, to share patient-focused feedback with CMS on patient experiences with the conditions or diseases treated by the selected drugs as well as therapeutic alternatives to the selected drugs. By implementing the above principles, CMS will benefit from better input and gain insights to help evaluate the value and benefit to Medicare beneficiaries.

Formulary Design

Medicare patients can only benefit from the therapies chosen for negotiation if they are available on formulary without significant utilization management barriers and with reasonable cost sharing.

CMS has stated that Part D plans will be required to include selected drugs on their formularies, as required by statute. Importantly, CMS provided that the formulary requirement extends to all dosage forms and strengths to which the MFP applies.

We are pleased that CMS is explicitly recognizing its statutory obligation to monitor Medicare Part D plans' compliance with all applicable formulary requirements. To that end, we applaud CMS for proposing to use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

Specifically, as part of the contract year 2027 Part D formulary review and approval process, CMS will expect Part D sponsors to provide a reasonable justification to support the submitted plan design that includes any of the practices noted above during the annual bid review process. CMS will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D sponsor only if the plan benefit package complies with those requirements.

We recognize that CMS does not yet have the data needed to determine if formulary design is leading to increased access barriers for beneficiaries for the negotiated medicines. We urge CMS to be proactive in gathering this information and ensuring access is not impacted.

Conclusion

As CMS continues to implement the drug pricing negotiation authority provided by the Inflation Reduction Act, decisions will be improved by robust patient and provider input. Implementing an improved input process, providing clear direction about what qualitative and quantitative information is most valuable, and how CMS is incorporating that information in the price determination will help beneficiaries have a meaningful role. Finally, ensuring that formulary design does not limit access will be increasingly important.

Thank you for the opportunity to provide this input on this important matter. AfPA supports efforts to include the patient and provider voice.

Sincerely,

Josie Cooper
Executive Director
Alliance for Patient Access

The Alliance for Transparent and Affordable Prescriptions (ATAP) Action Network thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide feedback on the ongoing implementation of the Medicare Drug Price Negotiation Program (MDPNP).

ATAP was created in 2017 with a mission to address prescription drug costs and patient access to affordable treatment by regulating PBM practices and reforming the drug industry through educational outreach and grassroots advocacy initiatives at both the state and federal levels. Driven by the reality that many patients struggle to afford their medications, the physician and patient advocacy organizations joined to expose the abusive practices of PBMs.

As we have previously communicated to the agency, we are concerned that the MDPNP will have unintended consequences for formulary design in Medicare prescription drug coverage. The *Inflation Reduction Act* requires that Part D plans cover drugs with a maximum fair price (MFP) established pursuant to the MDPNP. Presumably, the goal of this coverage requirement was to maximize the number of beneficiaries who can access the lower pricing and thus benefit from lower cost-sharing. However, the statute does not prohibit utilization management on MFP drugs, nor does the statute specify where an MFP drug must be placed on formulary. As we've seen in the commercial market, "coverage" becomes an empty word when the covered medication is subject to Kafkaesque utilization management protocols that render it functionally non-covered. We have seen patients "whipsawed" back and forth on different medications within a plan year, depending on a given medication's profitability for the PBM/plan.

Since brand drugs that have generic or biosimilar competition are not eligible for the MDPNP, this issue will become especially important for disease states in which much of the competition is among brands. If drugs A, B, and C all treat rheumatoid arthritis, but only drug A has an MFP, the PBMs may prefer options B and C because these promise greater income potential in terms of percentage-based price concessions.

Monitoring for PBM/insurer misbehavior and correcting after the fact will not sufficiently protect beneficiaries. In fact, this behavior already occurs today: investigative reporting and data analysis continues to confirm that medications with higher list prices are frequently preferred on formulary. Recent examples include:

- A research letter published in JAMA compared the formulary coverage of adalimumab biosimilars under Medicare Part D plans to coverage of the highest-priced reference product Humira. The results revealed that Humira had a coverage rate of over 98%. One biosimilar, Hyrimoz, priced at only 5% less than the reference product, had a coverage rate of 26%. Interestingly, the biosimilars with the lowest prices – 85% less than the reference product – had the lowest coverage rates, at less than 5% coverage in Part D plans. This clearly indicates

the existence of the perverse incentive to prefer higher-priced products, including in Part D plans.[1]

- An investigation by the *New York Times* found that, "the largest P.B.M.s often act in their own financial interests, at the expense of their clients and patients. Among the findings: P.B.M.s sometimes push patients toward drugs with higher out-of-pocket costs, shunning cheaper alternatives."[2]
- Similarly, Drug Channels reviewed biosimilar insulin coverage and found that patients whose plans use a certain PBM "will be prevented from getting the biosimilar version with the low list price. They will instead be pushed toward the high-list/high-rebate version."[3]
- In its review of formularies, Endpoints News found that several PBMs had preferred coverage of a $10,000 brand drug while its $450 generic was not covered at all.[4]
- Of particular relevance to CMS, this is happening in Medicare Part D as well: a study found that the largest PBMs and insurers were driving Medicare beneficiaries who needed a drug for multiple sclerosis to the $8,275 brand rather than the $184 generic.[5]

In the context of the MDPNP, this preexisting dynamic means that beneficiaries may be pushed to high list price options over MDPNP options. **To ensure that the statutory coverage requirement realizes its full potential, we urge CMS to (1) require that drugs subject to MFPs are covered at the lowest cost-sharing tier and (2) prohibit or at least curtail utilization management on these drugs**. The stated goal of utilization management is to drive down costs, but the establishment of an MFP will greatly reduce the need to control costs via utilization controls on selected drugs. A regulatory prohibition on utilization management for MFP drugs should not result in increased costs. In fact, such a prohibition could result in prescribers and patients choosing MFP options over non-MFP options when clinically appropriate, driving program spend towards the lowest-cost option and maximizing the reach and impact of the MFP program in Medicare.

In closing, we want to reiterate our appreciation for the opportunity to provide input as CMS implements this new, complex program, and we hope that you will consider us a resource on the issues discussed herein.

Sincerely,

Angus B. Worthing, MD, FACP, FACR
President
ATAP-Action Network

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[1] *JAMA Network*, Formulary Coverage of Brand-Name Adalimumab and Biosimilars Across Medicare Part D Plans (June 6, 2024).
[2] *New York Times*, The Opaque Industry Secretly Inflating Prices for Prescription Drugs (June 21, 2024).
[3] *Drug Channels*, Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices – And What That Means for Humira (November 9, 2021).
[4] *EndPoints News*, When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system (February 18, 2022).
[5] *Drug Topics*, US Drug Prices Distorted to Favor Pharmacy Benefit Managers (March 22, 2022).

AMCP
Optimizing medicine.
Improving lives.

July 2, 2024

Meena Seshamani
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Deputy Administrator Seshamani:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the Medicare Drug Price Negotiation Program Draft Guidance.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

We commend the Centers for Medicare & Medicaid Services (CMS) for its continued efforts to enhance patient access to affordable medications while ensuring the sustainability of the Medicare program. We would like to address several key aspects of the draft guidance and offer our recommendations to refine the approach and address potential concerns.

Section 40.4.1 Medicare Transaction Facilitator Data Facilitation

AMCP supports the implementation of the Medicare Transaction Facilitator (MTF) data exchange process to facilitate the exchange of data and payment between pharmaceutical supply chain entities. Effective data management and protection of sensitive information exchanged between Primary Manufacturers and dispensing entities will be vital to the success of this process.

CMS noted that it is evaluating whether the current 30-day window for plans to submit prescription drug event (PDE) records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. AMCP recommends continuing with the 30-day window because such an abbreviated timeline would not be feasible and will likely lead to an increase in the volume of invalid PDEs. PDE processing times may vary by plan sponsor and,

currently, there are claims that must be reversed and reprocessed with the 30-day turnaround time. Shortening this time frame would likely lead to an increase in these reversals. CMS should also consider that it if decides to shorten the window, plan sponsors will need additional implementation time in which to revise turn-around time agreements and ensure that internal processes can meet this timeline.

Section 40.4.2 Nonduplication with 340B Ceiling Price

For drugs subject to the 340B ceiling price, CMS should implement robust mechanisms to prevent duplication of benefits and ensure that the Maximum Fair Price (MFP) is applied appropriately without overlapping with 340B discounts. Clarifying documentation requirements for 340B eligibility will facilitate compliance, promote fair pricing practices, and reduce potential abuses.

Section 40.4.3 Retrospective Refund Amount to Effectuate the MFP

Despite the 14-day prompt pay window for retrospective refunds of the difference between the acquisition cost and the maximum fair price (MFP), AMCP is concerned that pharmacies may end up waiting longer for manufacturer refunds. AMCP believes that such a true-up could potentially take 4-6 weeks instead of the required 14 days. AMCP is hopeful that the use of the MTF to facilitate payments will help to ensure that payments are timely and this concern may be moot, but nonetheless urges CMS to consider whether additional guardrails may alleviate this potential problem.

Section 50.2 Evidence About Therapeutic Alternatives for the Selected Drug

AMCP applauds CMS for seeking to include more real-world evidence (RWE) as it looks at therapeutic alternatives. CMS is required to consider the extent to which the selected drug represents a therapeutic advance and the extent to which the selected drug and the therapeutic alternatives address unmet medical needs. CMS must also consider the FDA-approved prescribing information for the selected drug and therapeutic alternatives, and evidence on the comparative effectiveness of the selected drug and its therapeutic alternatives. RWE offers additional context and is becoming increasingly important in evaluating the safety and effectiveness of medications. It is important to acknowledge the importance of facilitating the advancement and use of systematic approaches to collecting and utilizing patient outcomes to more consistently inform regulatory decision-making.

AMCP supports CMS' approach to aligning the value of selected drugs with meaningful therapeutic alternatives. In the guidance, CMS states that it will prioritize research and real-world evidence relating to Medicare populations, such as individuals with disabilities, patients with end-stage renal disease (ESRD), and Medicare-aged populations. Therapeutic alternatives can serve as a useful benchmark and guide the decision-making process, helping to meet medical needs and assuring clinical effectiveness. CMS' robust approach to assessing therapeutic alternatives, including considering a variety of patient-centered factors, supports value for patients. AMCP also believes that CMS should work toward including non-pharmacological therapeutic alternatives that are documented and in line with clinical guidelines.

Section 60.4 Negotiation Process

AMCP supports dialogue, including CMS' ability to ask clarifying questions, during the patient listening sessions and urges that CMS continue to learn from the listening sessions it has already conducted. During those prior sessions, some of the speakers had "canned" talking points, with some speakers addressing more than one listening session with identical presentations. Many of the patients appeared to represent trade associations or pharmaceutical-backed patient advocacy groups. AMCP recommends that speakers be vetted in advance or be required to disclose any potential conflicts of interest. AMCP also encourages CMS to actively recruit patient participants from underrepresented groups to ensure that the listening sessions include diverse perspectives. AMCP believes the ability to attend as an observer via livestream is valuable, allowing real-time transparency into CMS' processes, and encourages CMS to continue to conduct patient listening sessions publicly.

Conclusion

We appreciate the opportunity to provide feedback on the draft guidance. We believe that our recommendations will help enhance the effectiveness of the Medicare Drug Price Negotiation Program, ensuring fair pricing, fostering competition, and improving patient access to essential medications.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing collaboration with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer

July 01, 2024

Via Email: IRARebateandNegotiation@cms.hhs.gov and Meena.Seshamani@cms.hhs.gov and U.S. Mail
Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-01850

Re: Medicare Drug Price Negotiation Program

Dear Deputy Administrator Seshamani:

AACE would like to contribute some comments and recommendations to CMS for consideration in the upcoming Negotiation Program.

The American Association of Clinical Endocrinology represents a global, inclusive community of more than 5,700 endocrine-focused clinical members, affiliates and partners from every walk of professional life. Our mission is elevating the practice of clinical endocrinology to improve global health. Our vision is achieving healthier communities through endocrine innovation, education, and care.

AACE has been on the forefront for advocating for affordable medications for patients. Drs. Irl Hirsch and Guillermo Umpierrez have testified before Congress, on behalf of AACE, about the cost and access to insulin. We advocate for increased access to the most appropriate medications for our patients as recommended by their endocrinologists and/or health care clinicians.

Though the Inflation Reduction Act is well-intentioned, implementation will require the avoidance of collateral pain points to the public and simultaneously harm to successful American manufacturing and innovation. We encourage the agency to examine the report from USC – Schaeffer Center White Paper, titled, "Mitigating the Inflation Reduction Act's Adverse Impacts on the Prescription Drug Market."[i]

AACE believes in removing barriers to equity, physician engagement in customized therapeutic choices, and transparency of estimating the value of a particular drug.

Equity: Ensuring equitable access to medications is paramount to safeguarding the health and well-being of all patients, especially those from underserved and vulnerable communities. Any policy on drug price negotiation must avoid exacerbation of existing disparities in healthcare access and outcomes.

Physicians' Ability to Practice Evidence Based Medicine: Physicians and other healthcare clinicians require the flexibility to prescribe medications based on their patients' individual medical needs without undue restrictions imposed by formulary limitations. Limiting physicians' access to a comprehensive

range of medications could compromise patient care and outcomes, particularly for those with complex medical conditions requiring specialized treatments.

Patient Access to Affordable Medication: DRug affordability remains a critical concern for patients nationwide. While addressing the cost of drugs is necessary, it is equally essential to ensure that any negotiated prices result in tangible savings for patients. Drug price negotiations should not create barriers for patients to receive the affordable and appropriate medications. Care must be taken not to negatively impact other patients who are not taking any of the drugs on the negotiated list.

Public Transparency: Transparent processes in drug price negotiation are essential to foster public trust and accountability. It is crucial that the methodologies and outcomes of these negotiations are made accessible to the public, including how negotiated prices are determined and how savings are passed on to patients.

In implementing drug price negotiation policies, we urge the Department of Health and Human Services to prioritize patient-centered principles that safeguard equity, preserve physician autonomy in prescribing decisions, and enhance patient access to affordable medications. Transparency and collaboration with healthcare stakeholders, including patient advocacy groups and physicians, are essential in developing policies that effectively balance affordability with patient care quality and innovation.

We support:

1) Greater transparency with stakeholders and focus on value/price determination rather than the price alone.
2) The need for more useful data on cost-effectiveness to improve decision-making.
3) Greater public awareness of the role of PBM's, inflation rates and Medicare regulations in pricing decisions.
4) Greater efforts to improve health literacy of the public to help them better understand their drug coverage plans.
5) Appropriate adjustment of pricing and inflation rebate penalties if real-world evidence, new clinical trial data or new indication approvals demonstrate increasing value of a drug post-approval.

We laud CMS for doing what's best for our patients and what's fair to all the stakeholders.

Sincerely,

AACE
American Association of Clinical Endocrinology

Susan Samson, PhD, MD, FRCPC, FACP, FACE
ssamson@aace.com
https://www.aace.com/

President, American Association of Clinical Endocrinology
Elevating the practice of clinical endocrinology to improve global health

[i] Goldman, D., Grogan, J., Lakdawalla, D., Liden, B., Shafrin, J., Than, K.S. and Trish, E., 2023. Mitigating the Inflation Reduction Act's adverse impacts on the prescription drug market. *Schaeffer Center White Paper Series*.

American Pharmacists Association

June 24, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

The American Pharmacists Association (APhA) is pleased to submit the following comments on the "Medicare Drug Price Negotiation Program Draft Guidance," for implementation of the Negotiation Program for initial price applicability year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Sections 40.4 Providing Access to the MFP in 2026 and 2027 and 90.2 Monitoring of Access to the MFP in 2026 and 2027

Section 40.4 of the guidance states "CMS requires that the Primary Manufacturer establish safeguards to ensure that entities dispensing drugs to MFP-eligible individuals—including pharmacies, mail order services, and other dispensing entities—have access to the MFP for the selected drug in accordance with section 1193(a) of the Act and as further described in this section and section 90.2 of this draft guidance. CMS defines "providing access to the MFP" as ensuring that the net amount paid by the dispensing entity for the selected drug is no greater than the MFP."

Section 90.2 further states "[c]onsistent with section 40.4 of this draft guidance, the Primary Manufacturer may make MFP available, including to 340B covered entities and their contract pharmacies consistent with section 40.4.2 of this draft guidance, by: (1) using retrospective reimbursement to issue refunds to dispensing entities as required to ensure the MFP is made available to dispensing entities, (2) providing access to the MFP through prospective sale of selected drugs at prices no greater than the MFP, or (3) using some combination of these two approaches."

CMS issued initial guidance in March 2023, solicited feedback through a request for information (RFI) on the Medicare Transaction Facilitator (MTF) and issued a June 2023 memorandum (updated guidance).

CMS clarified in section 40.4 of its revised guidance "that it intends to engage with an MTF to facilitate the exchange of data between pharmaceutical supply chain entities to help effectuate access to the MFP through a retrospective refund model. CMS is also exploring allowing the use of a standardized refund amount from the manufacturers to the pharmacies under a retrospective refund model and confirms it will require the use of a 14-day prompt pay standard for the refund from manufacturers to pharmacies and other dispensing entities to reimburse dispensing entities for passing through the MFP."

As such, there are currently two proposed payment facilitation options. The first has the MTF collecting dispensing entities' banking information and providing it to manufacturers. The second has the MTF receiving aggregated refund amounts from manufacturers and passing them through to dispensing entities, including pharmacies.

Implementing MFP without hurting pharmacies

Recently, expert analysis has confirmed that both models present challenges for pharmacies.

APhA agrees that "CMS should monitor pharmacy participation in Medicare by region and plan for safeguards should participation decline in response to how manufacturers provide access to MFP."

In addition, CMS should also increase/require enhanced dispensing fees from Part D plans to cover the increase in operating costs for pharmacies to manage inventory and generate the reporting necessary to manufacturers under both options. In particular, if pharmacies are also subject to manufacturer audits. If a manufacturer chooses to provide the pharmacy with access to the drug at MFP, then the pharmacy will only make gross from the dispensing fee – which is not standard and is negotiated across health plans. Accordingly, APhA respectfully recommends that CMS require a dispensing fee at a minimum of ($11.29/Rx).

Stakeholders have called for CMS to use a publicly available pricing benchmark, such as wholesale acquisition cost (WAC), or an estimate of the manufacturer's list price for a drug to wholesalers or direct purchasers that does not include discounts or rebates to facilitate MFP calculations. However, manufacturers in the future may engage in different WAC pricing

strategies or wholesalers may also change their discounting. Therefore, CMS would need to revise a "WAC – MFP" if pharmacies do not receive 4-5% off of WAC discounts.

As APhA has recently emphasized to CMS, current underwater payment rates by PBMs received through Pharmacy Services Administration Organizations (PSAOs), currently at a minimum 3% below cost on dispensing brand medications, have only led to increased pharmacy closures (January 2014 to March 2024 data) and are already jeopardizing Part D plans' ability to meet Part D pharmacy access requirements. Given the consolidation in the PBM marketplace and the potential for discrepancies in pharmacy MFP payments, "[i]f plans fail to provide sufficient fees, pharmacies might leave their network or close…," which "would destabilize the market and interrupt beneficiary access."

APhA also strongly urges CMS to avoid scenarios under a retrospective reconciliation option that mimics the current situation with direct and indirect remuneration fees (DIR) fees, which according to CMS increased by more than 107,400 percent from 2010-2020, that are facilitated by pharmacy benefit managers (PBMs) under Part D that would leave "pharmacies holding the risk for payment discrepancies and delays."

Addressing PBM DIR fees

The Inflation Reduction Act (IRA) is clear that pharmacies are not to be reimbursed below the MFP for negotiated drugs. However, APhA is concerned that pharmacies will be reimbursed below the MFP if DIR fees from PBMs are assessed on these drugs. Pharmacy reimbursement should cover acquisition cost plus margin plus and include a commensurate professional dispensing fee (currently, PBMs pay community pharmacies dispensing fees far below the actual cost to dispense - as low as $0).

Pharmacies are already facing significant cash flow concerns in Medicare Part D and failing to establish protections against DIR fees on MFP drugs or to ensure appropriate pharmacy dispensing fees and prompt payment to pharmacies (as required by the IRA) would exacerbate those concerns. **Accordingly, CMS needs to issue guidance that ensures Part D plans and PBMs cannot pay pharmacies at less than that MFP and that PBMs cannot assess pharmacy DIR fees on MFP drugs.**

Thank you for the opportunity to submit comments. The IRA grants CMS flexibility in the rulemaking processes in the first years to adjust the MFP. APhA stands ready to assist CMS in taking proactive steps to monitor pharmacy participation, appropriately adjust dispensing fees, and identify additional pharmacy safeguards to ensure an MFP that does not hurt community

pharmacies and seniors to lose access to Part D plans due to noncompliance with federal pharmacy access standards. If you have any questions or would like to speak further with APhA experts about these requests, please contact me at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

From: Conwell Hooper <conwell@americansenioralliance.com>
Sent: Friday, June 28, 2024 4:40 PM
To: CMS IRA Rebate and Negotiation
Subject: Medicare Drug Price Negotiation Program Draft Guidance

Categories: Comments

American Senior Alliance Statement on Access to Treatments and Medicare Drug Price Negotiation Program (MDPNP)

At the American Senior Alliance, we recognize that access to treatments is not just important—it is essential for improving the quality of life for our nation's seniors.

Effective treatments can alleviate debilitating pain, enhance daily living, and even save lives. However, policies affecting access to these treatments, such as changes in formulary incentives, must prioritize the needs and voices of those who are most impacted: the patients.

We firmly believe that healthcare policies should be centered around the patient, not driven solely by financial considerations. This is why it is crucial for patient perspectives to be integrated throughout the Medicare Drug Price Negotiation Program (MDPNP).

As the MDPNP enters its second cycle of treatment selection and negotiation, we call on the Centers for Medicare & Medicaid Services (CMS) to ensure that patients have a meaningful seat at the table.

Last year, numerous patients and patient organizations provided valuable input through written comments and participation in listening sessions. While we appreciate these opportunities, many patients felt their voices were not fully heard and that they had more to contribute. Concerns about privacy also deterred some patients from sharing specific details about their health, hindering their full and honest participation in the negotiation process.

To address these issues, we urge CMS to improve and expand the opportunities for patient engagement. By fostering greater dialogue, input, and participation from all voices, we can ensure that healthcare policies truly reflect the needs and rights of our senior citizens.

The American Senior Alliance stands ready to support and amplify the voices of seniors to protect the treatments and services they have rightfully earned.

Thank you for your consideration.

All my best wishes,

Conwell

Conwell Hooper

Executive Director
American Senior Alliance
225 Peachtree Street NE
Suite1430 | South Tower
Atlanta, GA 30303
404-475-2566
www.americanseniorallliance.com
Like Us on Facebook
Follow Us on Twitter

July 2nd, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244-8013

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

On behalf of the American Society of Consultant Pharmacists (ASCP) membership, we are pleased to submit the following comments to the Center for Medicare and Medicaid Services' (CMS) on the draft guidance related to the implementation of the *Inflation Reduction Act* (*IRA*.)

ASCP urges CMS to implement the Medicare Drug Price Negotiation Program in a manner that does not harm long-term care pharmacies nor the patients under their care. 42 C.F.R. 483.45 requires long-term care facilities to provide or obtain routine and emergency medications in a timely manner. Long-term care pharmacies fulfill this requirement for a facility and provide critical services to facility staff, residents and caregivers. Unreasonable and delayed reimbursement payments threaten the viability of long-term care pharmacies, the services they offer and ability of patients and facilities to access needed medications.

In our following comments, ASCP outlines four policy provisions CMS should consider regarding the proposed guidance to strengthen the guidance and ensure unfettered patient access to needed medications from pharmacies.

Maximum Fair Price (MFP) and Pharmacy Reimbursement

ASCP requests that CMS confirm MFP is the ingredient costs - The *IRA* equates MFP with ingredient costs because the law requires manufacturers to make selected drugs available for purchase by pharmacies at MFP.

Per this statutory definition, **ASCP believes that the *IRA* requires Part D Plan (PDP) sponsors to reimburse pharmacies at MFP for ingredient costs, plus a fair and reasonable dispensing fee with no extraction of further concessions**. In writing the *IRA*, Congress treated MFP as ingredient costs and uses a singular definition throughout the *IRA*.

Furthermore, CMS must ensure that payment for MFP drugs is reasonable and relevant. PDP sponsors/PBM reimbursement should not be lower than the MFP and should include compensation for the professional dispensing fee, in line with Medicare fee-for-service.

In the IRA language, Congress does not provide PDP sponsors authority to extract "concessions" for MFP drugs. Therefore, ASCP requests that CMS clarity that PDP sponsors should reimburse

pharmacies at ingredient costs plus a reasonable dispensing fee. Since the Secretary is negotiating the price of MFP drugs, PBMs should have no role in their pricing.

Finally, ASCP urges CMS to take all necessary steps to ensure PBMs and Plans cannot impose any pharmacy price concessions that ultimately reduce patience access to MFP drugs. It is clear that Congress intended the *IRA* to extract price concessions from manufacturers, not providers or pharmacies. Attempts to reimburse pharmacies less than MFP are counter to the Congressional intent.

Prompt Payment to Pharmacies

Per 42 C.F.R. 423.520, PDP sponsors are required to promptly pay pharmacies within 14 days after receiving a clean, electronic Part D claim. ASCP stresses that pharmacies operate within thin margins and must receive prompt payment, within 14 days, to ensure continued operation and patient access.

Currently, CMS allows a 30-day window for PDP sponsors to submit completed prescription drug event (PDE) records to the Drug Data Processing System (DDPS). We urge CMS to reduce this window to 7 days to facilitate prompt payment to pharmacies. **CMS should ensure that under no circumstances does payment to a pharmacy exceed the existing 14-day prompt pay requirement.**

Pre-Funding Medicare Transaction Facilitator (MTF)

ASCP believes that CMS has the authority to direct manufacturers to prefund the MTF. We believe the agency should use its authority to require prefunding, which will assist in expediting payment to pharmacies.

While CMS has the authority to direct manufacturers to prefund the MTF; it has no such authority related to pharmacy prefunding. Thus, we do not believe CMS should effectively require pharmacies to prefund the MTF. Additionally, ASCP supports MTF functionality option 2 as it provides CMS with more standardization.

Identification of 340B Claims

ASCP supports the voluntary status assigned to the MTF claim-level data element for 340B the claim indicator. We remind CMS that it is infeasible to proactively or retroactively identify these claims.

Thank you in advancing for considering our comments in your final rulemaking. Please contact James Lewis at jlewis@ascp.com with any questions or for additional information. As always, ASCP and our members stand ready to assist CMS with our experience and expertise in improving the lives and health of older Americans.

Sincerely,

Chad Worz, PharmD, BCGP, FASCP
Chief Executive
American Society of Consultant Pharmacists (ASCP)

Greg Portner
Senior Vice President

Global Government Affairs & Policy
601 Thirteenth Street, NW
Suite 1100 North
Washington, DC 20005
Phone: 202.585.9649
Email: gportner@amgen.com
www.amgen.com

June 28, 2024

VIA ELECTRONIC DELIVERY
IRARebateandNegotiation@cms.hhs.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act (SSA) for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure:

Amgen Inc. (Amgen) appreciates the opportunity to submit comments on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the SSA for IPAY 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027 posted on the Centers for Medicare & Medicaid Services (CMS) website on May 4, 2024 (IPAY 2027 Draft Guidance).

Amgen is committed to using science and innovation to dramatically improve people's lives, improving access to drugs and biologics (collectively, "drugs," consistent with CMS's convention), and promoting high-quality care for patients. Amgen develops innovative medicines as well as biosimilar biological products. Thus, our interest is to ensure a robust market for, and improve patient access in the United States to, both innovative and biosimilar biological products.

We are pleased to provide CMS with feedback on certain aspects of the implementation of the Drug Price Negotiation Program (DPNP) for IPAY 2027. However, Amgen remains concerned that the government price controls on certain medicines provided to Medicare beneficiaries under the guise of price "negotiation" under the Inflation Reduction Act of 2022 (IRA) are stymieing biopharmaceutical innovation at precisely the time when the world needs more new medicines to treat an aging population. This government price setting is forcing biopharmaceutical companies to stop pursuing research and development (R&D) on many new drugs. Companies are having

to rethink how and where they invest in medical innovation, with the government essentially picking winners and losers by discouraging the development of some types of treatments for certain patient populations. Though we also continue to believe the IRA is unlawful, we submit these comments as part of our ongoing commitment to patients and in an effort to bring to CMS's attention the myriad problems the IRA contains and creates.

Biopharmaceutical innovation is key to improving public health and people's lives. We encourage CMS to consider the impact on innovation as well as the impact on biosimilars and patient access as it develops guidance for this and other IRA-related programs.

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G. CMS should permit appeals as part of the complaints and disputes resolution process and clarify additional aspects of such process. (Section 90.2.2)

IV. RECOMMENDATIONS REGARDING FORMULARY ACCESS UNDER PART D (SECTION 110)

A. CMS should take additional steps to ensure broad beneficiary access to selected drugs under Medicare Part D in IPAY 2026 and future payment years. (Section 110)

V. RECOMMENDATIONS REGARDING THE PRICE SETTING FACTORS

A. CMS should limit mandatory disclosures to information necessary to administer the DPNP. (Section 60.3, Appendix A)

I. RECOMMENDATIONS REGARDING THE SPECIAL RULE TO DELAY THE SELECTION OF A BIOLOGIC FOR PRICE SETTING ON ACCOUNT OF ANTICIPATED BIOSIMILAR MARKET ENTRY (SECTION 30)

Section 1192(f) of the Social Security Act (SSA) establishes a "Special Rule" which permits CMS to delay selection of a reference biologic for price setting for up to two years under certain circumstances:

(1) The reference biologic that would be selected for price setting but for the requested delay must be an extended-monopoly drug.[1]

(2) A manufacturer that intends to market a biosimilar of the reference biologic must request the delay before what would otherwise be the reference biologic's selected drug publication date.[2]

(3) CMS must determine that there is a "high likelihood" that the biosimilar will be licensed and marketed within two years of what would otherwise be the reference biologic's selected drug publication date.[3]

(4) Certain disqualifying circumstances must not be present.[4]

If CMS determines that the high likelihood test is met, a first year of delay is granted. For a second year of delay, the biosimilar manufacturer must submit a second delay request before the selected drug publication date that follows what would otherwise have been the reference biologic's selected drug publication date.[5] If CMS finds that the high likelihood test does *not* continue to be met, including if the "significant amount of progress" requirement is not met, then the reference biologic is selected for price setting, and its manufacturer must pay a specified rebate.[6] If the test *does* continue to be met, a second year of delay is granted.[7] If the biosimilar has not come to market by the end of the second year of delay, the reference biologic is selected for price setting, and its manufacturer must pay a specified rebate.[8] If, instead, the biosimilar comes to market by the end of the first or second year of delay, the reference biologic becomes ineligible for selection for price setting.

As discussed in more detail below, to support effective implementation of the delay scheme, CMS should:

- Take care in implementing the Special Rule to protect against disrupting a healthy biosimilar market.
- Afford relief with respect to the Special Rule's timing requirements.

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[1] SSA § 1192(f)(1)(A).
[2] *Id.* § 1192(f)(1)(B)(i)(1).
[3] *Id.* § 1192(f)(1)(A).
[4] *Id*. § 1192(f)(2)(D).
[5] *Id.* § 1192(f)(1)(B)(i)(II).
[6] *Id*. § 1192(f)(2)(B)(ii).
[7] *Id*. § 1192(f)(2)(B)(iii).
[8] *Id*. § 1192(f)(2)(C).

- Clarify that the high likelihood test, including the clear and convincing evidence standard, can be met in any of a number of ways, including provision of patent office decisions and attestation by the manufacturer.
- Clarify what CMS views as an agreement that incentivizes a biosimilar manufacturer to request a delay and that indication carve-outs are permissible as part of a settlement.
- Publish a preliminary selected drug list that biosimilar manufacturers may use to assess the need to apply for a delay.
- Establish the above requirements for IPAY 2027 and future payment years.

These measures would offer predictability and certainty in the biosimilar delay process and thus help preserve a robust biosimilar market that could generate savings for the Medicare program and its beneficiaries; help streamline the CMS process for reviewing and approving delay requests; and ensure that the selection of drugs for price setting remains focused on products without anticipated competition.

A. CMS Should Take Care in Implementing the Special Rule to Protect Against Disrupting a Healthy Biosimilar Market (Section 30)

It is critical that CMS adopt these recommendations to ensure a robust biosimilar market. The introduction of biosimilar competition to the marketplace has created an estimated cumulative $24 billion in savings over the past seven years[9] and has potential to create an estimated $181 billion in additional savings over the next five years.[10] CMS has taken welcome steps to support investment in biosimilars, for example, through its current Medicare Part B coding policy. CMS's willingness to take a flexible approach to implementation of the biosimilar delay provisions and to communicate such approach to stakeholders would greatly boost biosimilar manufacturers' confidence that a viable marketplace for biosimilars will continue in the United States.

The Special Rule includes timing requirements for completion of activities that pose significant challenges given the operational realities facing biosimilar manufacturers, like Amgen. For example, the Special Rule requires that a request for a delay be submitted by the "selected drug publication date" of the reference product, which can be as soon as 11 years after Food and Drug Administration (FDA) approval of the Biologics License Application (BLA) of the reference product and therefore prior to the expiration of the 12-year data exclusivity period for reference biologics. Furthermore, the Special Rule requires that FDA have accepted or approved the BLA of the biosimilar before granting a request for delay.

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[9] Association for Accessible Medicines. 2023 US Generic and Biosimilar Medicines Savings Report, Page 27. September 6, 2023. Retrieved from: accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.

[10] IQVIA. Biosimilars in the United States 2023-2027, Page 29. January 31, 2023. Retrieved from: www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2023-2027.

Where a biologic is selected for price setting soon after its eligibility for selection, a biosimilar manufacturer ordinarily would not submit a BLA before the delay request submission deadline because the Biosimilar User Fee Act (BsUFA) date will not fall until after the expiration of regulatory exclusivity. And biosimilar development typically takes a number of years between initiation of development and submission of a BLA to FDA. Given the lead time for the development of biosimilars, it will be difficult or even impossible to accelerate clinical trials and other development milestones in response to the Special Rule. Biosimilars are expected to take between eight to ten years to bring to market at a cost of between $100 million and $200 million.[11] Considering that a reference product can be selected as soon as 11 years after FDA licensure, this leaves only a year or two of sales of the innovator product for a biosimilar manufacturer to evaluate before deciding whether to begin development of a competing product, in order to fall within the time frame of the biosimilar delay requirements. Moreover, it becomes difficult for the biosimilar manufacturer to predict the financial forecasting and planning because the parties do not know whether the reference biological manufacturer's product will be subject to the MFP or whether the two manufacturers will reach a settlement allowing the biosimilar to come to market and what the terms of that agreement will be (e.g., the licensed entry date). This uncertainty is likely to result in development of fewer biosimilars.

As discussed in Section II(A) below, CMS's "bona fide marketing" standard creates additional uncertainty that is making manufacturers more cautious when investing in biosimilars. Newly launched biosimilars face an uncertain uptake trajectory, especially under the pharmacy benefit where rebate dynamics create incentives for pharmacy benefit managers (PBMs) to favor products with higher list prices. Biosimilar manufacturers have no way of knowing whether a biosimilar currently in development will satisfy the vague standard of "bona fide marketing." Rather than pursuing flexibility to encourage biosimilar development in light of the challenges created by the DPNP, CMS has layered on an additional extra-statutory barrier to biosimilar entry through the "bona fide marketing" standard.

Our following slate of biosimilar delay recommendations is designed to ensure a robust biosimilar market.

B. CMS Should Afford Relief with Respect to the Special Rule's Timing Requirements (Section 30.3)

1. *Preview of Potential Selected Drugs*

Requests for delay must be submitted prior to the selected drug publication date.[12] Under the IPAY 2027 Draft Guidance, however, biosimilar manufacturers would continue to have to prepare these requests well before they know whether a particular reference biological product will be selected. These requests for delay will require time and resources for biosimilar manufacturers

[11] Amgen Biosimilars, The Potential Benefits and Advantages of Biosimilars, https://www.amgenbiosimilars.com/bioengage/value-of-biosimilars/potential-benefits-advantages-of-biosimilars#:~:text=Biosimilars%20are%20expected%20to%20take%208%20to%2010,prices.%20Biosimilars%20introduce%20competition%20into%20the%20healthcare%20system. (last accessed Jun. 9, 2024).
[12] SSA § 1192(f)(1)(B).

to prepare, possibly for multiple products, which will be unnecessary if the reference drugs are not likely to be selected. Accordingly, Amgen recommends that CMS publish a list of reference biological products likely to be selected ahead of the selected drug publication date, so that biosimilar manufacturers have reasonable advance notice to prepare a request for delay. We ask that this list be published by November 15, preceding the selected drug publication date to allow biosimilar manufacturers time to prepare a delay request if appropriate.

2. *Submission Deadlines*

Setting the deadline for receipt of an application requesting a delay needlessly far in advance of the selected drug publication date exacerbates the timing issues discussed in Sections I(A) and II(B). Therefore, CMS should make the application deadline align as closely as possible with the selected drug publication date. We appreciate the agency's proposal to align applications more closely with publication of the selected drug list but request that the agency further extend submissions to the January 15 preceding the selected drug publication date.

In addition, CMS proposes that a biosimilar's application for licensure must be "accepted for review or approved by the FDA no later than January 15, 2025" for a delay request to be approved.[13] We appreciate the agency's recognition that more time may be needed to allow for acceptance of the BLA by FDA, and we support this proposal.

C. CMS Should Expand Options for Demonstrating that Patents Related to the Reference Drug are Unlikely to Prevent the Biosimilar from Being Marketed (Section 30.3)

The proposed standard for demonstrating that patents related to the reference drug are unlikely to prevent a biosimilar from being marketed can be nearly impossible to meet for biosimilar manufacturers. CMS proposes to continue to use the standard it adopted for IPAY 2026, which requires that: "1) there are no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar; 2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or 3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before February 1, 2027…."[14]

This standard can be met if there are no unexpired patents, but that is not often the case. Where there is at least one unexpired patent, this standard creates a "catch 22" for biosimilar manufacturers due to the timing of the FDA BLA approval process and patent litigation, in combination with the IRA limitation that CMS cannot grant a delay request if more than one year has elapsed since FDA approval of the biosimilar and marketing has not commenced.

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[13] Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 § 30.3.1 (May 3, 2024) (IPAY 2027 Draft Guidance).
[14] *Id.* § 30.3.1.2.

The FDA typically approves BLAs approximately one year after submission. On the other hand, patent litigation typically begins around 10 months after a BLA is filed and lasts 2.5 to 3 years or even longer. A biosimilar applicant cannot count on obtaining a patent settlement or a court decision in time or guarantee that no potentially relevant patents will issue by the delay request deadline. The delay request deadline may occur before the parties have completed the patent exchange process under the Biologics Price Competition and Innovation Act (BPCIA), which includes the sharing of patent information between the parties that could be used as factor in assessing what settlement terms may be reasonable based on the patent landscape. Additionally, the parties may want to assess information obtained during discovery and briefing, as well as consider initial decisions by the patent office or courts to evaluate possible settlement terms. The existing option of obtaining a court decision to submit as evidence for the delay request is difficult to satisfy due to the length of time litigation takes. It is difficult to predict ahead of time how long litigation will take (and whether a decision could be obtained by the deadline) because the timing depends on a number of factors such as the forum, number of patents, complexity and number of disputed issues, availability of dates in the judge's calendar for pre-trial hearings and trial, and the length of time after trial for the judge to issue a decision. Trial dates can also be delayed. Thus, court decisions are typically issued after the delay request deadline.

Therefore, if a biosimilar manufacturer waits to launch its biosimilar until litigation is resolved (either through a court order or settlement agreement), more than one year likely will have passed between FDA approval and marketing of the biosimilar and the biosimilar will be ineligible to request a delay.

The other option would be for a manufacturer to launch "at risk," that is, despite litigation or potential for litigation. However, in this case, the manufacturer could not provide CMS with court decision or settlement agreement to satisfy the proposed guidance.

Due to this uncertainty regarding whether the criteria can be satisfied, Amgen recommends that CMS consider patent office decisions, such as Inter Partes Review or Post Grant Review decisions, as an alternative criterion. These patent office decisions take 18 months to be issued and thus are faster than court decisions.

While this new criterion is desirable for the additional flexibility it provides biosimilar applicants, it will not be available in all cases. Only certain arguments can be raised in patent office proceedings and for some arguments such as non-infringement, a biosimilar applicant will have to wait for a court decision, which is unlikely to be issued by the deadline. In addition, new patents may issue shortly before the delay request deadline so there would not be 18 months to obtain a decision before the delay request deadline. Thus, Amgen also recommends that the biosimilar manufacturer be able to certify that, to the best of its knowledge, no valid patents will be infringed once the biosimilar is launched. This new criterion allows the biosimilar manufacturer to rely on its assertion that patents are believed to be invalid, unenforceable, or not infringed. Some foreign agencies allow the biosimilar applicant to rely on such a certification to obtain regulatory approval.

Accordingly, we ask that CMS revise its standard as follows. New text as compared to existing criteria in support of this standard is shown in italics, bold, and double underline.

- [O]ne or more court ***or patent office*** decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar;

  or

  [T]he Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar before February 1, 2027, without imposing improper constraints on the Biosimilar Manufacturer.

  or

  The Biosimilar Manufacturer certifies that, to the best of its knowledge, there are no valid patents that will be infringed upon once the biosimilar is launched.

CMS should include these additional options for demonstrating a high likelihood for the initial delay determination given the difficulty and unpredictability of being able to satisfy the existing criteria.

D. CMS Should Establish Standards for Second Year of Delay in its IPAY 2027 Guidance for Future Program Years (Section 30.3)

Amgen thanks CMS for "soliciting comment regarding the types of documentation and information that may constitute 'clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress . . . towards both . . . licensure and the marketing of such biosimilar biological product' under section 1192(f)(2)(B)(i)(II) of the Act to inform CMS's policy development for this issue."[15] However, we urge CMS to consider the following information as presumptively supporting the clear and convincing evidence standard for a second year of delay in its final IPAY 2027 guidance, so that biosimilar manufacturers can plan ahead for future delay requests. Specifically,

CMS should find that a biosimilar manufacturer that meets the following criteria has satisfied the test for a *second* year of delay:

a) If the BLA for the biosimilar was pending review during the first year of delay:

   (i) FDA has since approved the BLA for the biosimilar; *or*

   (ii) The first cycle of review remains ongoing, i.e., FDA's BsUFA date has not yet occurred; *or*

   (iii) FDA has issued a complete response letter to the biosimilar manufacturer denying the BLA for the biosimilar but, as of the time CMS is assessing eligibility for a second year of delay, the biosimilar manufacturer has resubmitted the BLA for the biosimilar; *or*

[15] *Id.* § 30.3.1.

(iv) The biosimilar manufacturer's disclosures to investors or filings with the Securities and Exchange Commission (SEC), such as Forms 10-K or 10-Q, indicate that it plans to market the biosimilar within the requisite time frame; *or*

(v) The manufacturing schedule for the biosimilar submitted to FDA indicates that commercial lots of the biosimilar are expected to be produced within the requisite time frame; *or*

(vi) Agreements filed with the Federal Trade Commission (FTC) or the Department of Justice (DOJ) do not bar the biosimilar manufacturer from marketing the biosimilar within the requisite time frame.

Amgen urges CMS to adopt these criteria when considering a request for a second year of delay to help enable biosimilar competition, as intended under the statute.

E. CMS Should Clarify What It Believes Constitutes an Agreement That Incentivizes a Biosimilar Manufacturer to Request a Delay (Section 30.3)

By statute, a request for delay of selection of the reference biologic may not be granted if, based on certain information,[16] a reference biologic manufacturer and a biosimilar manufacturer have entered into an agreement that incentivizes or requires the biosimilar manufacturer to make such a request.[17] The statute also clearly directs CMS to consider agreements between the reference biologic manufacturer and biosimilar manufacturer in determining whether to delay selection of the reference biologic.[18] Amgen appreciates CMS's acknowledgement in the IPAY 2027 Draft Guidance that an agreement between a reference biologic manufacturer and a biosimilar manufacturer "that permits the Biosimilar Manufacturer to [timely] market the Biosimilar before February 1, 2027," simultaneously (a) is not necessarily an agreement incentivizing a delay and (b) can constitute clear and convincing evidence that the high likelihood test is met.[19] If CMS had alternatively suggested that the mere existence of such an agreement disqualifies a biosimilar manufacturer from requesting a delay, it would have nullified the statutory instruction to consider such agreements when determining whether to authorize a delay. It is a long-held principle that a statute should *not* be interpreted in a manner that renders statutory text inconsequential.[20]

CMS should clarify the circumstances under which it will determine an agreement between a reference biologic manufacturer and a biosimilar manufacturer to impermissibly incentivize a delay request. Notably, CMS intends to require a biosimilar manufacturer that requests a delay

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[16] *SSA* § 1192(f)(1)(B)(ii)(I)(bb) ("[A]ll agreements related to the biosimilar biological product filed with the [FTC] or the [DOJ] pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," which includes agreements between "brand name drug companies" and "generic drug applicants").
[17] *Id.* § 1192(f)(2)(D)(iv).
[18] *Id.* § 1192(f)(1)(B)(ii)(I)(bb), (2)(B)(i)(II), (3)(B).
[19] IPAY 2027 Draft Guidance § 30.3.1.2.
[20] *United States v. DBB, Inc.*, 180 F.3d 1277, 1285 (11th Cir. 1999) ("A statute should be 'interpreted so that no words shall be discarded as meaningless, redundant, or mere surplusage.'") (internal citations omitted).

to certify that it has not entered into a disqualifying agreement,[21] on pain of potential "liability, including under the False Claims Act."[22] Yet CMS has provided only that an agreement may not "impos[e] improper constraints on the Biosimilar Manufacturer" and has offered no clearer guidance for manufacturers.[23] So that manufacturers can make informed decisions about the agreements into which they enter, Amgen urges CMS to further explain what it believes constitutes an agreement that incentivizes a biosimilar manufacturer to request a delay.

In addition, with respect to CMS's statement that an agreement that "directly or indirectly restricts the quantity of the Biosimilar that may be sold in the United States over a specified period of time" is a disqualifying agreement,[24] the agency should clarify that it will not consider a patent litigation settlement that provides a "date certain" for when a biosimilar may come to market to be such an agreement. Such a limitation does not limit the quantity of the biosimilar that may be sold but rather only the time frame in which it may be sold. And it will be clear from the terms of the agreement whether the restriction will lift within the requisite two-year period in which the biosimilar must come to market.

Lastly, we urge CMS to clarify that in order for CMS to grant an Initial Delay Request, the patent settlement for the Biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval. In particular, a patent settlement for an indication that is not limited in quantity for that indication is not a disqualifying agreement even if the settlement does not cover other indications (such as if the biosimilar applicant only obtains regulatory approval for some indications approved for the reference product and thus only has a patent settlement for the indications for which the biosimilar applicant is approved). This would be consistent with CMS's policy that the licensure application for the biosimilar does not need to include all of the dosage forms, strengths, and indications for which the Reference Drug has received approval.[25]

F. CMS Should Clarify Terms Implementing the Special Rule (Section 30.3)

In its discussion of the Special Rule's initial delay request provisions, the IPAY 2027 Draft Guidance refers multiple times to the "reference product included in the Reference Drug."[26] This phrase is confusing, particularly given that it is not consistent with terminology used by FDA and understood by regulated industry. CMS should clarify the meaning of this phrase to facilitate understanding and implementation of the Special Rule.

It appears that CMS intends for "reference product" to refer to the presentations (e.g., dosage form, strength, route of administration) that serve as a biosimilar's "reference product(s)" in the biosimilar's marketing application. Indeed, several statements in the IPAY 2027 Draft Guidance suggest CMS is adopting a presentation-by-presentation interpretation of the term "reference

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[21] Small Biotech Exception and Biosimilar Delay Information Collection Request Forms for Initial Price Applicability Year 2027, Part 2 § 2, Question 7.
[22] *Id.* at Part 2 § 4.
[23] IPAY 2027 Draft Guidance § 30.3.1.2.
[24] *Id*. § 30.3.1.1.
[25] *Id.*
[26] *Id.* § 30.3.1.2.

product."[27] Such an interpretation would be consistent with FDA's approach toward interchangeability designations for biosimilars, under which FDA has taken the position that a biosimilar's "reference product" is determined on a presentation-by-presentation basis.

If this understanding of CMS's intention is correct, we urge CMS to replace the phrase "reference product included in the Reference Drug" with "presentation included in the Reference Drug" in the final guidance. If this is not CMS's intent, we ask that CMS clarify the meaning of "reference product included in the Reference Drug" in its final guidance.

II. RECOMMENDATIONS REGARDING THE MARKETING OF GENERICS AND BIOSIMILARS (SECTIONS 30.1, 70, AND 90.4)

A. We Urge CMS to Move Away from its "Bona Fide" Marketing Standard (Sections 30.1 and 90.4)

We urge CMS to adopt the "start marketing date" published in the National Drug Code Directory to determine the date a drug is "marketed." This would align CMS policy with both the statutory language of the IRA as well as FDA's jurisdiction under the Food Drug and Cosmetics Act, which is triggered by the introduction of a product into interstate commerce. This is the right policy for both legal and policy reasons.

As Amgen, the Pharmaceutical Research and Manufacturers of America (PhRMA), and many others have pointed out, the "bona fide" marketing standard is incompatible with the clear language of the statute. We refer to Amgen comments on the IPAY 2026 draft guidance and PhRMA's comments on the IPAY 2026 and IPAY 2027 draft guidances for additional discussion.

Setting aside the very serious legal problems with CMS's definition, as a policy matter it creates an unnecessary barrier to a robust biosimilar marketplace. As we have emphasized in other sections of these comments, predictability is essential when biosimilar manufacturers make decisions to invest in clinical trials and commercialization activities. The "bona fide" marketing standard is entirely undefined. In fact, in the IPAY 2026 final guidance, CMS rejected requests that it establish specific market share or other objective requirements to define the market date and instead stated it would look at the "totality of the circumstances."[28] Such a "we know it when we see it" standard is impossible for a biosimilar manufacturer to plan against.

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[27] Id. § 13.1 ("*If any strength or dosage form of a potential qualifying single source drug is the listed drug or reference product*, as applicable, for one or more generic or biosimilar products that CMS determines are approved or licensed, as applicable, and marketed based on the process described in this draft guidance, the potential qualifying single source drug will not be considered a qualifying single source drug for initial price applicability year 2027.") (emphasis added); *id.* § 60.7 ("… if CMS determines that at least one generic drug or biosimilar biological product satisfies the following criteria: (1) it is approved under section 505(j) of the FD&C Act *with at least one dosage form and strength of the selected drug as the listed drug or licensed under section 351(k) of the PHS Act with at least one dosage form and strength of the selected drug as the reference product*….") (emphasis added).

[28] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 §§ 30, 70 (Jun. 30, 2023) (IPAY 2026 Final Guidance).

It is also premature to adopt this policy. Based on statements in the IPAY 2026 Final Guidance, we understand CMS's concern to be that a manufacturer might "launch into the market a token or de minimis amount of a generic drug or biosimilar for the selected drug and the manufacturer of that selected drug could claim that the MFP should no longer apply."[29] This hypothetical concern is not consistent with Amgen's experience.

Any arrangement that CMS might view as problematic is already regulated by the FTC, which has the statutory authority and expertise to investigate and challenge conduct that it believes is anticompetitive. As noted above, agreements between brand and biosimilar drug manufacturers regarding the manufacturing, marketing, and sale of biosimilar versions of reference drug products must be filed with the FTC and the DOJ. The same is true for agreements between brand-name drug manufacturers and generic drug applicants. Thus, federal antitrust agencies, which have the statutory authority, experience, and expertise to assess the merits of competition involving biosimilars and generics are best positioned to perform this assessment. With respect to marketing by manufacturers of biosimilars or generics that are not subject to agreements with brand-name manufacturers, there would be no reason for such manufacturers to go through the time and expense of the FDA approval process and launch of their products but to compete vigorously in the marketplace.

Contrast the FTC's authority with the limited tools CMS has at its disposal. CMS's sole unique tool is to review Medicare claims data, but such data could suggest low utilization for any number of reasons, including PBM "rebate walls," initially slow uptake by prescribers, and data lags, that do not involve intentional "token or de minimis" launches. In the IPAY 2027 draft guidance, CMS indicates that it will also review "licenses or other agreements" that may limit availability of generic drugs or biosimilars, but such reviews are squarely within the expertise of FTC and outside of CMS's expertise.[30]

If, despite marketplace incentives to compete and FTC's oversight, CMS sees the types of behavior it is worried about, it may be appropriate for CMS to take policy action. But we urge CMS not to create a barrier to biosimilar entry based on an entirely hypothetical and, in our view, unrealistic risk.

B. CMS Should Remove a Drug from the Selected Drug List Where a Generic or Biosimilar Is Timely Marketed After the End of the "Negotiation Period" But Before an MFP Takes Effect (Section 70)

Amgen urges CMS to interpret the IRA to allow a reference product to exit the program if a generic or biosimilar product is marketed after the "negotiation period" but before the start of the IPAY. Such reading aligns with the statutory definition of a "qualifying single source drug" (QSSD)—a threshold requirement for a drug to be subject to price setting. The statute defines a QSSD "with respect to an [IPAY],"[31] indicating that a product's status as a QSSD must exist as of the first day

[29] *Id.* at Summary of Public Comments.
[30] IPAY 2027 Draft Guidance § 70, 90.4.
[31] SSA § 1192(e)(1).

of the IPAY, not just at the selected drug publication date, as CMS suggests in Section 70 of the IPAY 2027 Draft Guidance. Had Congress intended QSSD status to be assessed only as of the selected drug publication date, it would have said so. Thus, a product that has become multisource before the IPAY should not be subjected to price setting.

This view also comports with the definition of "price applicability period," which means, "*with respect to a qualifying single source drug*, the period beginning with the first IPAY with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug."[32] This reference to QSSD status signals that a product that has gone multisource and hence no longer meets the QSSD definition should not be subject to a price applicability period. Moreover, as the statute and CMS's Figure 1 show, only products that are QSSDs may be negotiation-eligible drugs. Where a product is no longer a QSSD, it cannot, by definition, be considered a negotiation-eligible drug or a selected drug.[33]

Amgen's position aligns with subsection (c)(1) in section 1192 and its use of the phrases, "with respect to an [IPAY]" and "with respect to such year" in paragraph (1).[34] This phrasing supports the conclusion that "negotiation-eligible" status (and, hence, QSSD status) must remain in place as of January 1 of the IPAY for subsection (c)(1) to apply to the drug. Thus, this provision speaks to the exit process for drugs that remain a QSSD and selected drug on the first day of the IPAY and then experience generic or biosimilar competition. Paragraph (2) "clarif[ies]" the application of paragraph (1) to a specific time period when various tasks otherwise would need to be performed by both CMS and the manufacturer, i.e., during the "negotiation period."[35] The provision does not address what happens if the generic or biosimilar is marketed after the "negotiation period," as there is no "negotiation process" to which the manufacturer is subject, and thus no need for a clarification that the process must stop. Paragraph (2)'s styling as a "clarification" shows that the statutory terms referenced in subsection (c) must be given full effect in subsection (c)(1). In other words, it does not change the fact that the statute defines QSSD "with respect to an [IPAY]."

This position is grounded in sound policy. Congress crafted the IRA to provide for price setting for *single source* products. CMS's current position undermines this intent by applying MFPs to products that are already multisource. This position thereby directly undermines generic and biosimilar competition and incentives for pursuing approval of such products. For generic and biosimilar companies, developing and marketing generic and biosimilar products within the time frames under the law is already challenging. The processes necessary to market a generic or biosimilar product can be complex, and there are many steps that are not solely in control of the generic or biosimilar sponsor, including FDA review timelines. The price-controlled MFP may go into effect before such companies are ever able to market their products and may set a price below the level of economic viability. CMS's position compounds this problem by essentially providing that generic or biosimilar marketing in the last thirteen months before the IPAY does not trigger exit from the program. In other words, a generic or biosimilar company that brings its

[32] *Id*. § 1191(b)(2) (emphasis added).
[33] *Id*. §§ 1192(c) (defining "selected drug"), 1192(d) (defining "negotiation-eligible drug").
[34] *Id.* § 1192(c)(1).
[35] *Id.* § 1192(c)(2).

products to the market during these thirteen months will nevertheless be forced to compete with an MFP.

Amgen therefore urges CMS to revise the proposal in the IPAY 2027 Draft Guidance to provide that a reference product exits the DPNP if generic or biosimilar marketing occurs after the "negotiation period" but before the IPAY. CMS also should amend the table on page 105 of the IPAY 2027 Draft Guidance as follows:

Date on which CMS determines that a generic drug or biosimilar is approved and marketed	**Result with respect to selected drug for the DPNP Program**
The date that the selected drug list for initial price applicability year 2027 is published through ~~November 1, 2025~~December 31, 2026 (which includes the Negotiation Period for initial price applicability year 2027)	Selected drug remains a selected drug for IPAY 2027, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2028
~~November 2, 2025~~January 1, 2027 through March 31, 2027	Selected drug remains a selected drug and MFP applies for IPAY 2027; selected drug ceases to be a selected drug on January 1, 2028.
April 1, 2027 through March 31, 2028	Selected drug remains a selected drug and MFP applies for IPAY 2027 and calendar year 2028; selected drug ceases to be a selected drug on January 1, 2029.

III. RECOMMENDATIONS REGARDING THE PROVISION OF THE MFP (SECTION 40)

Amgen appreciates the opportunity to comment on the proposed MTF, both as to its role as a data facilitator to support validation of eligibility for the MFP and as to its potential role as a payment facilitator to support the effectuation of the MFP. We strongly support establishment of an MTF to facilitate effectuation of MFP and to minimize the operational burden of program administration for both manufacturers and pharmacies. The MTF is essential to streamline processes needed for timely provision of MFP discounts to pharmacies. We offer the comments below to ensure a workable framework for MFP effectuation.

A. CMS Should Allow for Additional Mechanisms to Validate Eligibility for the MFP and Allow Additional Time to Process Payment, Including Where There Have Been Adjustments to a Previously Filed Claim (Section 40.4.1)

1. *MTF Claim-Level Data Elements*

Amgen generally supports the proposed list of claims-level and other data elements that the MTF would provide to manufacturers to validate eligibility for the MFP. Providing these data to manufacturers would help them verify eligibility for the MFP, beyond the validation conducted by Part D plan sponsors and the Part D Drug Data Processing System (DDPS), and consistent with

all applicable legal requirements such as those under the Sarbanes-Oxley Act.[36] Contrary to CMS's assertion, the proposed validation mechanisms alone do not obviate the need for manufacturers to also perform some measure of validation of eligibility for the MFP.[37]

To support manufacturer validation of eligibility for the MFP, Amgen asks that CMS consider one of two approaches:

- Provide deidentified beneficiary data to manufacturers, both for MFP eligibility validation purposes and because neither the DDPS nor the Part D plan sponsor appear to verify whether there are duplicate claims for the MFP. Use of a deidentified Medicare beneficiary identifier (which could be randomly generated by the MTF and unique to each beneficiary) would allow manufacturers to eliminate duplicate MFP claims while still protecting against privacy concerns.
- In the alternative, require the MTF to further validate eligibility for the MFP by (1) eliminating duplicate MFP claims and (2) redressing any clear error arising from the validation efforts of the DDPS and the Part D plan sponsor before the MTF notifies the manufacturer of any liability for an MFP rebate. In the IPAY 2027 Draft Guidance, neither the DDPS nor the Part D plan sponsor appear to verify whether there are duplicate claims for the MFP, and the MTF appears to play no role in otherwise validating eligibility for the MFP.

CMS should also regularly audit and otherwise monitor claims submitted to the MTF, publicly report any uncovered duplication and other error rates, and mandate corrective action, as warranted.

2. *Prompt MFP Payment Window*

CMS is proposing that manufacturers must "provide access to *[sic]* MFP and transmit reports with payment-related data within [a] 14-day prompt MFP payment window."[38] The shortness of this window is not mandated by statute, and Amgen has a number of concerns related to the volume of claims that manufacturers would have to process within such window.

First, according to the IPAY 2027 Draft Guidance, "CMS is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds."[39] CMS should recognize the negative impact that shortening the window would have on the volume of MTF data adjustments during and after the prompt MFP payment window (because the Part D plan may not have the opportunity to accurately validate the MFP in the first instance). CMS should not shorten the 30-day window for plans to submit PDE records.

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[36] Sarbanes-Oxley Act of 2002, Pub. L. 107–204 (Jul. 30, 2002), https://www.govinfo.gov/content/pkg/COMPS-1883/pdf/COMPS-1883.pdf (last accessed June 14, 2024.)
[37] IPAY 2027 Draft Guidance § 40.4.1.
[38] *Id*.
[39] *Id*.

Second, Amgen is concerned that a 14-day prompt MFP payment window is insufficient to process and pay MFP rebates even if there is no subsequent adjustment to MTF data. For just one selected drug for IPAY 2026, average daily Part D claims were nearly 52,000 in 2022 based on an analysis of the Part D drug spending dashboard, which would have yielded the same number of MFP rebates. Amgen is not aware of any other federal drug discount or rebate program with such a short payment processing time frame.[40] We urge CMS to extend this window to 30 days instead.

In addition, Amgen asks CMS to permit manufacturers and dispensing entities to agree to a prompt MFP payment window where the manufacturer chooses to offer the MFP through its own chosen process instead of through the MTF payment facilitation process. For example, if a manufacturer were to receive claims-level data shortly after a drug is dispensed, it may be able to effectuate the MFP more quickly and before receiving data from the MTF. The manufacturer could then still use the MTF data to verify the initial data and effectuate an MFP refund within a prompt MFP payment window tied to the date of receipt of data from the MFP.

Finally, the IPAY 2027 Draft Guidance is internally contradictory as to whether the prompt MFP payment window begins on the date the MTF "transmits" the data (see page 40 of the IPAY 2027 Draft Guidance) or the date of "receipt" of the data by the manufacturer (see page 42). CMS should clarify that the prompt MFP payment window begins on the date that the data are received by the manufacturer so that manufacturers are not penalized by any lag in transmission. For comparable reasons, CMS should clarify that the window ends on the date on which the manufacturer transmits the payment (as opposed to the date on which the pharmacy receives the payment.

3. *Transmission of MTF Data to Manufacturers*

CMS seeks comment on the frequency with which the MTF should transmit data to manufacturers of selected drugs. Given the challenges we anticipate with the 14-day prompt payment window (outlined above), we ask that CMS establish a policy for less frequent data transmissions. Specifically, the MTF should transmit data to manufacturers no more frequently than every two weeks. Less frequent data transmissions are necessary both to ensure the MTF can appropriately validate and process data received from pharmacies and that manufacturers can complete data validation and 340B deduplication to ensure prompt and accurate payments to pharmacies.

[40] For example, manufacturers have 38 days to pay discounts under the Coverage Gap Discount Program and Manufacturer Discount Program (starting in 2025). CMS, Medicare Coverage Gap Discount Program Technical Guide, 9 (Aug. 2021), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Coverage_Gap_Discount_Program_Technical_Guide_08.2021.v1.pdf; CMS, Medicare Part D Manufacturer Discount Program Final Guidance § 80.2.3 (Nov. 17, 2023), https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf. Although there is a 14-day prompt pay requirement in Part D, it is specific to reimbursement from Part D plans to pharmacies, not rebates from manufacturers to pharmacies. 42 C.F.R. § 423.520(a)(1)(i).

4. *Adjustments to MTF Data*

Amgen encourages CMS to specify that any adjustments to the MTF data that occur within a prompt MFP payment window restart that window. Restarting this window would be consistent with the requirements governing the reimbursement window between Part D plans and pharmacies.[41] Any adjustments beyond the prompt MFP payment window should be treated as credits or debits against future MFP payments to the pharmacy at issue, except in the limited circumstances where a credit or debit would not be reasonable (as where a pharmacy stops dispensing a drug), in which case CMS should require the manufacturer or the pharmacy, as appropriate, to make the other party whole.

B. CMS Should Require the Use of 340B and Non-340B Modifiers to Avoid MFP/340B Ceiling Price Duplicate Discounts, Supported by a Clearinghouse and a Claw Back Mechanism, and Adopt a Policy of Non-Enforcement Where 340B Eligibility Cannot Be Timely Validated (Section 40.4.1)

1. *Deduplication of 340B-Eligible and MFP-Eligible Units*

By statute, a manufacturer of a selected drug cannot be required to offer both the MFP and the 340B price on the same unit and instead is required only to offer the lower of these two prices.[42] Amgen continues to urge CMS to mandate use of 340B and non-340B modifiers (as applicable) to identify 340B-eligible and 340B-ineligible units on any claim submitted for reimbursement as a condition precedent to the start of the prompt MFP payment window as well as a condition of Part D reimbursement. [43] These data would serve to help identify 340B-eligible and 340B-ineligible units on any claim submitted for reimbursement under Part D in order to facilitate deduplication. CMS has already adopted 340B modifiers (but not non-340B modifiers) with respect to Part B units, for which, effective January 1, 2024, all 340B covered entities that submit Part B claims must use specified claims modifiers to identify 340B units.[44] The contemplated 340B and non-340B modifiers would be included in the claims-level data provided by the MTF to the manufacturer. These modifiers would help ensure that manufacturers do not provide the MFP on any units identified as 340B-eligible where the 340B ceiling price is lower than the MFP.

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[41] 42 C.F.R. § 423.520; s*ee also* 76 Fed. Reg. 54,600, 54,613 (Sep. 1, 2011) ("If the sponsor does not provide notice to the submitting pharmacy of any defect or impropriety in the resubmitted claim within 10 days of the sponsor's receipt of such claim, the resubmitted claim is deemed to be a clean claim and must be paid consistent with the timeframes specified in § 423.520(a)(1) (within 14 days of the date on which a resubmitted electronic claim is received and within 30 days of the date on which a nonelectronically resubmitted claim is received).").

[42] SSA § 1193(d).

[43] CMS has authority to require the appropriate use of these modifiers as a condition of Part D reimbursement. To appropriately implement Part D inflation rebates under section 1860D-14B of the SSA, CMS needs to be able to identify whether a Part D unit of a selected drug is subject to the MFP or the 340B price to determine whether the unit should be excluded from such rebates. See SSA § 1860D-14B(b)(1)(B). CMS may condition payment of a clean claim on the appropriate use of these modifiers. See, e.g., SSA § 1860D-12(b)(3)(D) (general authority to add Part D contract terms); see also §§ SSA 1102(a), 1871(a) (general rulemaking authority).

[44] CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers (Dec. 20, 2022), *available at* https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.

Because covered entity compliance with the use of the modifiers may not be unfailing, Amgen further supports the use of a neutral clearinghouse to help validate 340B eligible units and avoid MFP-340B duplication.[45] The clearinghouse could further help CMS by identifying 340B-eligible units for purposes of other programs, including the exclusion of such units from the Part D inflation rebate calculation.

In addition, it is imperative that CMS provide for an enforceable claw back mechanism by which a manufacturer can readily recover the MFP should a covered entity receive a lower 340B ceiling price on the same unit after the payment of the MFP.

Deduplication is most likely to be successful if enabled by the agency measures described above, i.e., the 340B and non-340B modifiers and the clearinghouse.[46]

2. *Non-Enforcement where 340B Eligibility Cannot be Timely Validated*

In the IPAY 2027 Draft Guidance, CMS states that it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP" and is not requiring pharmacies to submit data to manufacturers to support validation of eligibility for the 340B ceiling price so that manufacturers can police duplication instead.[47] Given CMS's lack of support for deduplication of the MFP and the 340B ceiling price, and the challenges of identifying 340B units on account of the 340B replenishment model, CMS should not pursue an enforcement action against a manufacturer if the manufacturer, despite good faith efforts, cannot timely identify whether the 340B ceiling price might instead be due on a given unit because data are insufficient to determine whether the unit is or is not a 340B unit.

With respect to units dispensed under 340B contract pharmacy arrangements, the 340B ceiling price (if lower than the MFP) would be owed to the 340B covered entity and the MFP (if lower than the 340B ceiling price) would be owed to the 340B contract pharmacy.[48] With no claw back mechanism in place for manufacturers to recover an MFP paid to a 340B contract pharmacy, if it is ultimately determined that the unit is instead subject to 340B pricing, it is essential that manufacturers are able to validate eligibility of a given unit for the 340B ceiling price before paying the MFP. Under the 340B replenishment model, 340B covered entities determine only after a unit was dispensed whether the individual to whom the unit was dispensed was a 340B "patient," in which case the 340B covered entity later purchases a replacement unit at the 340B ceiling price. Thus, it necessarily will take considerable time to validate eligibility of a given unit for the 340B

[45] A 2023 report by IQVIA found that use of the Part B 340B modifier across a variety of 340B covered entities was limited with a particular lack of compliance by rural referral centers and sole community hospitals. R. Martin et al., IQVIA. Can 340B Modifiers Avoid Duplicate Discounts in the IRA? IQVIA (Feb. 2023), *available at:* https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[46] *See* IPAY 2027 Draft Guidance § 40.4.2.
[47] *Id.* § 40.4.1 (specified 340B indicators in the PDE record "may be *voluntarily* applied to a Part D claim by the dispensing entity") (emphasis added).
[48] *See* Public Health Service Act § 340B(a)(1); SSA § 1193(a)(3).

ceiling price and therefore also to determine whether the MFP or the 340B ceiling price is due on that unit.

Amgen further notes that it is not possible for a manufacturer to "promptly provide to the 340B covered entity dispensing the 340B drug the difference between the MFP . . . and the 340B ceiling price,"[49] as suggested by CMS in the IPAY 2027 Draft Guidance. As noted above, the 340B ceiling price is paid to the 340B covered entity and the MFP to the 340B contract pharmacy; thus, no true-up to either entity could help a manufacturer satisfy its obligation to offer the lesser of the MFP or the 340B ceiling price to the entity to which such pricing is owed.

C. CMS Should Specify That Payment of the Standard Default Rebate Amount (SDRA) Is a True Default (Section 40.4.3)

Amgen supports CMS's proposal to define the SDRA as the difference between the wholesale acquisition cost (WAC) and the MFP for the selected drug, and to make it an option for a manufacturer that owes the MFP. However, CMS should specify that, where opted by a manufacturer, the SDRA serves as a true default measure of the MFP rebate amount due for a selected drug so that there is certainty that payment of the SDRA is sufficient, absent affirmative notice from the pharmacy that it is not, within 30 days of payment of the SDRA. As pharmacy acquisition costs are typically lower than WAC, using the SDRA as a true default would ensure that the obligation to pay the MFP is fully satisfied.[50]

Amgen also urges CMS to clarify that the MFP rebate amount can never be higher than the SDRA, including where acquisition costs are higher than WAC, despite the statements in the IPAY 2027 Draft Guidance that "the [SDRA] may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug" and "payment of the [SDRA in such cases] would not be sufficient to make the MFP available to the dispensing entity…."[51] It may be the case that pharmacies sometimes purchase drugs at a price higher than WAC; however, where that purchase is made through wholesalers and distributors, the costs above WAC are not representative of a price offered by the manufacturer in the market. Rather, the costs reflect upcharges by the wholesalers and distributors. If CMS were to require manufacturers to pay an MFP rebate that covers these additional costs, it would not only impose on manufacturers an obligation that exceeds that specified in the law but also create adverse incentives for pharmacies and others in the pharmaceutical supply chain to increase profits by artificially inflating acquisition costs and thus MFP rebate amounts.

For example, prior to January 2024, Part D plan sponsors were permitted to agree to a Part D negotiated price with pharmacies that was higher than the final payment from the Part D plan sponsor to the pharmacy, thus artificially inflating the amount of the Coverage Gap Discount Program (CGDP) discount and the beneficiary coinsurance amount, which are calculated as a

[49] IPAY 2027 Draft Guidance § 40.4.2.
[50] *See* NADAC Equivalency Metrics, Myers and Stauffer, (Mar. 25, 2024), *available at:* https://www.medicaid.gov/medicaid/prescription-drugs/downloads/retail-price-survey/nadac-equiv-metrics.pdf.
[51] IPAY 2027 Draft Guidance § 40.4.3.

percentage of the Part D negotiated price. CMS has since prohibited this practice.[52] The Brookings Institute similarly has observed that vertical integration "permits [Medicare Advantage (MA)] plans to circumvent regulations aimed at constraining the profits that can be earned from the MA program."[53] Specifically, "a vertically integrated MA plan can move profits from the MA plan to the related business. This increases the MA plan's [medical loss ratio (MLR)] without reducing the parent company's profits, weakening the MLR constraint."[54]

To address these concerns, and should CMS nevertheless require the MFP rebate to be based on an amount greater than WAC, the following steps should be taken:

- Provide a non-exhaustive list of documentation that a manufacturer may require a pharmacy to submit to the manufacturer where the manufacturer pays an MFP rebate amount other than the SDRA, including documentation as to the acquisition costs of the pharmacy (net of price concessions) (but without detail as to the pharmacy's specific reimbursement contracts and other arrangements).
- Where the MFP rebate requested is in excess of the SDRA because the acquisition costs were in excess of WAC, require pharmacies to certify to the government that they are not receiving remuneration or anything else of value in exchange for the excessive acquisition costs.
- Monitor the number/percentage of pharmacies claiming acquisition costs above WAC and, if CMS notices an increasing trend in these arrangements, publicly report on it so that policymakers and stakeholders can take remedial steps as appropriate.

D. CMS Should Adopt Option 2 of the MTF Payment Facilitation Options and Clarify Conditions of Participation for Manufacturers and Pharmacies (Section 40.4.4)

1. *Options for MTF Payment Facilitation*

Amgen thanks CMS for considering two ways in which the MTF could help facilitate the payment of MFP rebates by manufacturers to pharmacies. Using the MTF to facilitate payment of MFP rebates could be invaluable to streamlining the MFP rebate process given the over 60,000 pharmacies in the United States.[55] Of CMS's two proposed options, Amgen encourages CMS to adopt Option 2, supplemented by the use of pharmacy bank account information in the claims-level data submitted to manufacturers to help ensure that the effectuation of the MFP rebate payment goes smoothly.

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[52] 87 Fed Reg 27,704, 27,847 (May 9, 2022).
[53] Frank RG, Milhaupt C. Related businesses and preservation of Medicare's Medical Loss Ratio Rules. *Brookings*, (Jun. 2023), *available at* https://www.brookings.edu/articles/related-businesses-and-preservation-of-medicares-medical-loss-ratio-rules/.
[54] *Id*.
[55] Lucas A. Berenbrok, et al., Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-sectional Analysis, 62 J. of the Ame. Pharmacists Ass'n. Vol 6 (Jul. 12, 2022), *available at:* https://www.japha.org/article/S1544-3191(22)00233-3/fulltext.

2. *Non-standard MFP Rebate Amounts*

In the IPAY 2027 Draft Guidance, CMS states that "[a] dispensing entity could work directly with a manufacturer outside of the MTF to establish an adjusted refund amount based on the dispensing entity's acquisition costs."[56] To avoid the risk of confusion over when manufacturers can use the MTF to facilitate payment, CMS should clarify that manufacturers can participate in any MTF payment facilitation process, even where the manufacturer and the pharmacy have separately agreed to an MFP rebate amount other than the SDRA.

Further, CMS should specify that a manufacturer will not be held responsible for failing to meet the prompt MFP payment window if the MTF payment facilitation process fails to timely transmit payment of any MFP rebates. This failure could occur, for example, if a pharmacy provides incorrect bank account information.

3. *Pharmacy Participation in the Manufacturer's Elected Payment Option*

CMS should specify that manufacturers can meet their obligation to provide access to the MFP by establishing a single process of making the MFP available to pharmacies. The manufacturer's chosen approach could be addressed in the effectuation plan submitted to CMS.[57] Given the 60,000+ pharmacies in the United States, CMS should further specify that participation in the MTF payment facilitation process, as elected by the manufacturer, is, by default, mandatory for pharmacies.[58] This approach would be similar to the approach to paying pharmacies under Part D, where Part D plan sponsors must pay most categories of network pharmacies for electronic, clean claims within 14 days (with a longer payment window for non-electronic claims) and pharmacies have to participate as an in-network pharmacy if they wish to benefit from the prompt payment period.[59]

If CMS does not adopt the above approach, manufacturers should be obligated to offer at most one additional MFP effectuation option to pharmacies, and CMS should expressly provide that manufacturers need only honor the payment effectuation options set forth in its MFP effectuation plan.

E. CMS Should Not Permit Participating Pharmacies to Opt Out of the Medicare Transaction Facilitator (MTF) Payment Facilitation Process Before the End of Each Calendar Year (Section 40.4.4)

To the extent that CMS allows pharmacies to opt out of the MTF payment facilitation process (see Section III(D) above), CMS should not finalize its proposal that a pharmacy that participates in

[56] IPAY 2027 Draft Guidance § 40.4.4.
[57] *See* id. § 90.2.1.
[58] We note that the number of days in the prompt MFP payment window is a product of CMS guidance and is not in statute.
[59] SSA § 1860D–12(b)(4)(B), 42 C.F.R. § 423.520. If CMS allows pharmacies to opt out of the MTF payment facilitation process, CMS should require those that do so to notify manufacturers and provide contact and bank account information/provide for a process to notify manufacturers and provide contact and bank account information through the MTF.

the MTF payment facilitation program may opt-out of that program on at least 90 calendar days' advance notice.[60] Instead, pharmacies that have chosen to participate in the MTF payment facilitation program should not be permitted to opt out before the end of a calendar year. This approach would help provide certainty to manufacturers as to how they are to effectuate payment while preserving flexibility for pharmacies by still permitting them to change their election from one year to the next.

F. CMS Should Not Post Manufacturer MFP Effectuation Plans on a Public Website and Should Propose an Information Collection Request (ICR) on Information to Be Collected with Respect to These Plans (Section 90.2.1)

1. *Confidentiality*

CMS should not finalize its proposal to post manufacturer MFP effectuation plans on a public website. CMS appears to expect manufacturers to provide detailed information about their MFP effectuation plans, which may necessitate the inclusion of proprietary and otherwise confidential business information. CMS intends to try to redact such information; however, that redaction may not be sufficient, particularly given the broad audience that would be able to view the plans. Under the statute, CMS is obligated to keep manufacturer-submitted information confidential for use only by CMS and the Comptroller General.[61] To help preserve the confidentiality of MFP effectuation plans, CMS should both work cooperatively with the manufacturer to redact confidential information in the plans and disclose the plan only to a more limited group of stakeholders, namely those in the drug supply chain. This approach would balance the need for transparency with doing more to protect manufacturers' confidential information.

2. *Information included in MFP Effectuation Plans*

CMS should specify and limit the level of detail that manufacturers must include with respect to each MFP payment effectuation approach. CMS should propose an ICR with respect to these plans as soon as possible, to be finalized no later than one year before the start of IPAY 2026.

G. CMS Should Permit Appeals as Part of the Complaints and Disputes Resolution Process and Clarify Additional Aspects of Such Process (Section 90.2.2)

Amgen appreciates CMS's stated intent to establish a complaints and disputes resolution process for the DPNP and urges the agency to follow through on such intent in line with the following comments.

[60] IPAY 2027 Draft Guidance § 40.4.5.
[61] SSA § 1193(c).

1. *Dispute Process*

CMS should adopt an internal agency appeals process, similar to that to be used under the Manufacturer Discount Program in 2025, with three levels:[62]

- The manufacturer or pharmacy files a complaint or dispute with CMS.
- If the manufacturer or pharmacy disagrees with CMS's decision, it can appeal the decision to an Independent Review Entity (IRE).
- If a manufacturer or pharmacy disagrees with the IRE's decision, it can appeal to the CMS Administrator, who will issue a final decision.

To minimize excessive appeals, CMS could also develop reasonable aggregation parameters.

2. *Timing*

CMS should establish clear deadlines for the dispute and complaint resolution and appeals process comparable to those under the Manufacturer Discount Program:[63]

- *60 days to file a complaint.* Manufacturer complaints or disputes would need to be filed within 60 days of receipt of claims-level data from the MTF. Pharmacies would have 60 days to file from the date an MFP rebate is due.
- *60 days for CMS to issue its decision.*
- *30 or 90 days to appeal the decision to the IRE*. Manufacturers and pharmacies would have 30 days from the date of CMS's decision to appeal or 90 days from the date of the complaint if CMS has failed to timely render a decision.
- *90 days for the IRE to issue its decision.*
- *30 days to request review by the CMS Administrator*.
- *90 days for the CMS Administrator to issue his or her final decision*.
- *90 days for the parties to take corrective action*.

3. *Enforceable MFP Claw Back Mechanism*

To account for circumstances in which it is determined through the dispute resolution process that an MFP rebate was paid on an MFP ineligible unit, it is imperative that CMS establish an enforceable MFP claw back mechanism through which a manufacturer can readily recover the MFP rebate. By statute, the MFP rebate is due only on units dispensed to MFP-eligible individuals.[64] Thus, a manufacturer may need an enforceable claw back mechanism in the event that a duplicate discount was inappropriately paid.

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[62] CMS, Medicare Part D Manufacturer Discount Program Final Guidance (Nov. 17, 2023), *available at:* https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.
[63] *Id.*
[64] SSA § 1193(a)(3).

4. *Other*

CMS should further:

- C*larify who can be an appropriate party to a dispute or complaint.* For example, if a Part D plan sponsor submitted the wrong claims-level data to the MTF for transmission to the manufacturer, then the dispute should be handled between the pharmacy and Part D plan sponsor per the terms of their contract—not the manufacturer.
- *Clarify that stakeholders, including pharmacies, should engage in good faith efforts to resolve a complaint or dispute before filing a complaint with CMS.* Good faith efforts will be particularly significant in the early years of the program when stakeholders may be working through a particular category of dispute for the first time.

IV. RECOMMENDATIONS REGARDING FORMULARY ACCESS UNDER PART D (SECTION 110)

A. CMS Should Take Additional Steps to Ensure Broad Beneficiary Access to Selected Drugs Under Medicare Part D in IPAY 2026 and Future Payment Years (Section 110)

The IRA amended the Medicare Part D statute to require Part D plans to cover each selected drug.[65] The IRA also created an exception to the Part D statute's "noninterference" clause to allow CMS to require "a particular formulary" "as provided under section 1860D-4(b)(3)(I)" (i.e., to effectuate the coverage requirement for selected drugs).[66]

In its IPAY 2027 Draft Guidance, as well as in the IPAY 2026 Final Guidance, CMS states that it will require Part D plan sponsors to submit justification for any of the following formulary actions:

1. Placement of selected drugs on non-preferred tiers;
2. Placement of a selected drug on a higher tier than non-selected drugs in the same class;
3. Utilization management or step therapy requiring use of an alternative brand drug prior to a selected drug; or
4. More restrictive utilization management for a selected drug compared to a non-selected drug in the same class.[67]

We remained concerned that reviewing plan restrictions on a case-by case basis is insufficient oversight to protect beneficiaries who rely on selected drugs. If CMS is only considering restrictive formulary designs individually, there is a risk that broader market-wide trends of restricting access to specific selected drugs may be missed. While the IRA generally requires Part D plans to cover all selected drugs, the DPNP inherently creates financial incentives for plans to nevertheless impose restrictions on meaningful access to those therapies. Under the DPNP, point-of-sale

[65] *Id.* § 1860D-4(b)(3)(I).
[66] *Id.* § 1860D-11(i).
[67] IPAY 2026 Final Guidance § 110; IPAY 2027 Draft Guidance § 110.

(POS) prices for selected drugs under Part D will be lower than they were previously to reflect the lower MFP pricing plus any dispensing fee that may apply. Historically, stakeholders have expressed concern that Part D plans exhibit a preference for drugs with higher prices and, thus, higher rebates. When POS prices for selected drugs decrease, Part D plan sponsors and their PBMs may favor other drugs in the selected drug's class with higher prices in order to access higher rebates and administrative fees. As a result, Part D plan sponsors may choose to place selected drugs on tiers with higher cost-sharing or more burdensome utilization management requirements to encourage patients to prefer higher-cost alternatives, with more substantial rebates and fees, instead. For these reasons, experts have warned that a selected drug's maximum fair price—particularly in conjunction with the price pressures imposed on plans under the IRA's Part D redesign provisions—is likely to increase negative formulary treatment of selected drugs.[68]

A Part D plan could reasonably interpret the ambiguity in CMS's current guidance as permitting the use of elevated cost-sharing and/or burdensome utilization management requirements for selected drugs to "continue to manage costs." We are particularly concerned about plan restrictions in light of broader Part D formulary trends and the pressure on Part D plans as they implement benefit redesign and take on a greater share of catastrophic costs. A recent study in *Health Affairs* found that Part D plans have increased restrictions such as prior authorization, step therapy, and formulary exclusions from 2011 to 2020. Specifically,

- Increased Restrictions: The proportion of non-protected-class compounds facing restrictions rose from an average of 31.9% in 2011 to an average of 44.4% in 2020.
- Formulary Exclusions: Exclusions of brand-name-only compounds surged, with 44.7% excluded by 2020.
- Utilization Management Tools: PBMs used tools like prior authorization and step therapy more liberally to control costs, which can delay or deny access to prescribed medications.
- Impact by Drug Type and Cost: Restrictions were more common for brand-name-only compounds. For instance, in 2020, 68.4% of brand-name-only compounds were either excluded or subjected to prior authorization/step therapy.[69]

The Office of Inspector General (OIG) has also found that Part D patients may face "avoidable extra steps" that delay patient care, including unapproved utilization management requirements, prior authorization, and step therapy. In instances where patients appealed coverage denials, 73% of initial denials were overturned.[70] These restrictions place an undue burden on patients that have real consequences for continuity of care, clinical outcomes, and quality of life.

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[68] *See, e.g.*, Cathy Kelley, *Medicare Part D Redesign Could Expand Rebate-Driven Formulary Exclusions In Program*, CITELINE (Jan. 26, 2023), https://pink.citeline.com/PS147634/Medicare-Part-D-Redesign-Could-Expand-Rebate-Driven-Formulary-Exclusions-In-Program; Cathy Kelley, *Medicare-Negotiated Drugs May Not Get Favorable Coverage In Part D: Will CMS Intervene?*, CITELINE (Apr. 16, 2024), https://pink.citeline.com/PS150091/Medicare-Negotiated-Drugs-May-Not-Get-Favorable-Coverage-In-Part-D-Will-CMS-Intervene.

[69] Joyce, G., Blaylock, B., Chen, J., Van Nuys K. "Medicare Part D Plans Greatly Increased Utilization Restrictions On Prescription Drugs, 2011–20." *Health Affairs* 43, no. 3 (March 2024). https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00999

[70] *Id.* at 14.

Such a result would subvert the purpose of the DPNP. Specifically, such access barriers to selected drugs could render meaningless the requirement that a selected drug that has competition in a particular category or class be covered. It would also undermine the efforts CMS has expended to engage in a lengthy, time-intensive process to determine an MFP for each selected drug. Moreover, to the extent plans place drugs on tiers with higher cost-sharing obligations, CMS will not achieve the President's stated promise of reducing beneficiary out-of-pocket for selected drugs in IPAY 2026.[71]

Formulary placement alone is insufficient to protect beneficiary access to selected drugs under Part D. The DPNP could create the unintended consequence of increasing barriers to access of selected drugs for beneficiaries and could distort competition among Part D drugs. CMS should take additional steps to ensure broad beneficiary access to selected drugs under Part D.

To preserve the purpose of the DPNP, selected drugs should be placed on formulary in a no less favorable position than other treatments for the same conditions and than prior to becoming selected. Additionally, CMS should make clear to Part D plan sponsors that utilization management requirements, including prior authorization and step therapy, should not be more restrictive than the terms of a selected drug's FDA-approved label, to help preserve patient access to these therapies. Part D plans sponsors should not be permitted to restrict beneficiary access to selected drugs through step-edits or other forms of utilization management in favor of non-selected drugs.

We strongly urge CMS to adopt these measures in final guidance applicable to IPAY 2026, IPAY 2027, and future price applicability years. We also note that CMS has not yet issued proposed rulemaking for the MA and Part D programs for CY 2026, and such rulemaking offers additional opportunity for CMS to clarify obligations of Part D plans with respect to ensuring access to selected drugs through a notice and comment process.

V. RECOMMENDATIONS REGARDING THE PRICE SETTING FACTORS

A. CMS Should Limit Mandatory Disclosures to Information Necessary for Price Setting (Section 60.3, Appendix A)

We urge CMS to limit the burden of data production imposed on manufacturers of selected drugs. Under section 1193(a)(4) of the SSA, manufacturers must submit to CMS "information that the Secretary requires to carry out" price setting for a selected drug. Under section 1194(a)(2)(A) of the SSA, this information must be submitted less than 30 days after CMS identifies a product as a selected drug (that is, the period between February 1 and March 1).

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[71] *See* The White House, FACT SHEET: Biden-Harris Administration Announces First Ten Drugs Selected for Medicare Price Negotiation (Aug. 29, 2023), https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-negotiation/ ("Medicare drug price negotiation will result in lower out-of-pocket costs for seniors and will save money for American taxpayers.").

Amgen's subsidiary Immunex Corporation ("Immunex") has first-hand experience with this process. Anticipating that the Immunex product Enbrel would be selected for IPAY 2026, Immunex began work on data production in Spring 2023, and it was still a challenge to submit all data by the October 2, 2023, submission deadline. Although Immunex did not track hours attributable to IRA data collection, we estimate that at least 1,000-2,000 staff hours were required to assemble and submit the information. It would have been impossible to assemble this data within 30 days.

Furthermore, we do not understand how much of the information could have been of use to CMS in its price setting exercise. For example, CMS required manufacturers to report research and development (R&D) costs broken down into five categories. Immunex records did not break out costs in this way, so Immunex had to develop assumptions to satisfy the CMS reporting requirements. But for price setting purposes, CMS's final IPAY 2026 guidance stated that it would consider adjusting the initial offer price upward or downward based on whether the manufacturer has recouped its total R&D costs, which suggests the five categories were irrelevant. CMS could limit the burden on manufacturers by simply requiring them to attest whether R&D costs had been recouped.

Another example is federal financial support. An objective indicator of federal financial support is a patent application containing a Government Interest Statement. Instead of relying on information that a manufacturer can find through a search of patent applications (which is a significant burden in itself), CMS also required manufacturers to report tax credits or other types of funding that are insufficient to result in a Government Interest Statement. Manufacturers do not track this information in any organized way and have to assess what level of diligence is appropriate. Imposing this kind of burden on manufacturers seems arbitrary and unnecessary, especially when it is unclear to what degree CMS is using, or should use, such information to establish prices of selected drugs.

We have provided only two examples, but there are many more. We urge CMS to engage with manufacturers so both sides can better understand the types of information CMS "requires" for price setting and how manufacturers can provide this information as efficiently as possible and within 30 days after the selected drug publication date.

* * * * *

We appreciate CMS's consideration of these comments. Please do not hesitate to contact Yola Gawlik at (202)-320-1159 or ygawlik@amgen.com if you have any questions.

Sincerely,

Greg Portner
Senior Vice President
Global Government Affairs & Policy

June 27, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Administrator Brooks-LaSure:

Arnold Ventures welcomes the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the following guidance issued on May 3, 2024:

- *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*

Arnold Ventures is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. We work to develop evidence to drive reform across a range of issues including health care, education, and criminal justice. Our work within the health care sector is driven by a recognition that the system costs too much and often fails to adequately care for the people it serves.

We want to thank you and CMS staff for your important and expeditious work implementing the prescription drug provisions of the Inflation Reduction Act (IRA). We recognize the difficulty of the task you face. We appreciate the opportunity to provide comments on the draft guidance. This letter provides comments on the following sections of draft guidance:

- *Section 30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry*
- *Section 40.2.1 Confidentiality of Proprietary Information*
- *Section 40.4 Providing Access to the MFP in 2026 and 2027*
- *Section 60.3 Methodology for Developing an Initial Offer*
- *Section 70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect*

30.3.1 Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

CMS will allow a biosimilar manufacturer to apply to delay negotiations for brand-name biologics that are selected for negotiations (that are extended monopoly drugs) if the biosimilar manufacturer can demonstrate that there is a high likelihood of entry within 2 years. We strongly support the following policies outlined in CMS's draft guidance:

- Negotiations would not be delayed unless the biosimilar manufacturer can demonstrate (1) that existing patents are unlikely to block biosimilar entry, and (2) operational readiness to market the biosimilar.
- CMS must evaluate any agreements between the brand-name manufacturer and the biosimilar manufacturer and refuse to grant a delay request if the biosimilar manufacturer

has entered into an anti-competitive agreement with the brand-name manufacturer of the selected drug (such as an agreement that would restrict the quantity of the biosimilar product sold in the US).

40.2.1 Confidentiality of Proprietary Information

CMS will protect the confidentiality of proprietary information during the negotiation process and when publishing an explanation of how it determined the MFP. Under current law, the nonfederal average manufacturer price (Non-FAMP) is proprietary. The Non-FAMP will likely be the basis for the ceiling price under negotiations for many drugs. When CMS publishes its explanation of the MFP at the individual drug level, the Secretary may not be able to publicly disclose whether the MFP is below the ceiling price because the Non-FAMP is proprietary.

If CMS is in fact unable to report whether the MFP is below the ceiling price for a selected drug, we recommend that CMS report, in the aggregate, how many of the drugs selected for negotiations in that year have an MFP below the ceiling price.

In addition, to increase price transparency and to better inform the public about the outcomes of drug price negotiations, Arnold Ventures recommends that Congress enact legislation to make both the Non-FAMPs and the average manufacturer prices (AMPs) publicly available. Both prices are average transaction prices that are close to the actual amounts paid by providers to manufacturers and wholesalers for prescription drugs. They do not include rebates negotiated between manufacturers and health plans/pharmacy benefit managers.

Making these prices public would improve price transparency and help to inform the reimbursement amounts paid by employers and health plans to providers and pharmacies. This recommendation is similar in practice to the current policy of making the ASPs publicly available for Medicare Part B drugs on the CMS website.

40.4 Providing Access to the MFP in 2026 and 2027

Medicare Transaction Facilitator (MTF).

Manufacturers must provide pharmacies with access to the MFP after the selected drug has been dispensed to a Medicare beneficiary. To assist with this process, the guidance proposes that a MTF perform two functions:

1. Facilitate the exchange of data between Part D plans, CMS, and manufacturers so that manufacturers can be informed of the amount of the selected drug dispensed to Medicare beneficiaries at the pharmacy level.
2. Assist in making pharmacies whole when payments are provided by the manufacturer to the pharmacy retrospectively.

We do not support CMS's proposal to form a direct financial link between individual pharmacies and brand manufacturers by facilitating the exchange of bank account information between these parties. Manufacturers do not currently have direct financial relationships with most pharmacies in the United States. Instead, CMS could encourage manufacturers to make the MFP available to pharmacies through a chargeback system that can be administered by wholesalers or other actors in the supply chain. Such an approach would not require the exchange of bank account information between pharmacies and manufacturers.

Manufacturer reimbursement to pharmacies for selected drugs.

We do not recommend that CMS have manufacturers reimburse pharmacies at the Wholesale Acquisition Cost (WAC) less the MFP for selected drugs. Instead, we recommend that CMS use a standard metric that is tied to a transaction price that is closer to pharmacy acquisition costs. Research has found that the WAC is 4 to 7 percentage points above what pharmacies are paid for Part D drugs—which also means that it exceeds the pharmacy acquisition cost by a significant amount on average.[1]

There are two related dynamics of concern when using the WAC as the standard form of reimbursement that would make competition inequitable between selected and non-selected drugs.

1. Manufacturers would earn less than the MFP on sales of selected drugs to Medicare beneficiaries, while pharmacies would earn more on selected drugs than non-selected drugs.[2] This means that pharmacy markups would be higher for selected drugs and the manufacturer would cover that additional cost, not Medicare.
2. It is possible that manufacturers could increase the WAC without increasing pharmacy acquisition costs to increase the profitability to pharmacies of dispensing their selected drugs.[3] This does not occur now for brand-name drugs partly because PBMs rather than manufacturers help to determine how much pharmacies get paid for dispensing brand-name drugs. But under the draft guidance, the manufacturer directly effects how much pharmacies get paid for dispensing selected drugs (by reimbursing the pharmacy the difference between the WAC set by the manufacturer and the MFP).

60.3 Methodology for Developing an Initial Offer

We strongly support this decision to include DIR as well as manufacturer Coverage Gap Discount Program discounts when estimating the net Part D price of therapeutic alternatives—which informs the initial offer price. We also recommend that in future years, manufacturer discounts under the Part D redesign be included (in addition to DIR) when calculating the net Part D price of therapeutic alternatives.

We strongly support CMS's decision to consider generic and biosimilar drugs as therapeutic alternatives to a selected drug. We believe that generic and biosimilar drugs can be cost effective alternatives to brand-name medications in the same therapeutic class.

70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

In determining whether bona fide generic or biosimilar entry has occurred, CMS will consider whether an agreement exists between the generic or biosimilar manufacturer and the brand

[1] CBO has found that the WAC is about 4 to 7 percentage points above the total amount that Part D plans pay pharmacies for brand-name drugs on average. https://www.cbo.gov/publication/56978 (see Table 2).
[2] For further discussion of this and other issues involved in effectuating the MFP see Mattingly, Esterly and Kaltenboeck: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2818378
[3] The potential incentive to increase the gap between the WAC and the pharmacy acquisition cost would be greater for selected drugs in competitive therapeutic classes with a large Medicare Part D market share.

manufacturer of the selected drug that restricts the quantity of generic/biosimilar drugs that can be sold in the US.

Given the prevalence of anti-competitive agreements between brand-name and generic manufacturers, we strongly support this policy.[4]

Conclusion

Arnold Ventures is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook, Ph.D. with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures and Mark E. Miller, Ph.D., Executive Vice President of Health Care at Arnold Ventures.

Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller at mmiller@arnoldventures.org with any questions. Thank you again for the opportunity to comment and for your important work to lower prescription drug prices for the Medicare program and its beneficiaries.

Sincerely,

Andrea Noda

[4] https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf

July 2, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request.

ASHP is pleased to submit our comments on the Centers for Medicare & Medicaid Services' (CMS) draft guidance regarding the implementation of the drug pricing provisions of the Inflation Reduction Act (IRA) in Medicare Part D. ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients.

ASHP appreciates the opportunity to comment on the draft guidance and we look forward to providing additional feedback as the agency further refines the drug price negotiation framework. As a general matter, **we urge the agency to implement the IRA drug pricing provisions in a manner that does not create new administrative costs for pharmacies or disrupt established workflows**. Our specific feedback on the proposed structure for the negotiated drug price framework is as follows:

- **Retrospective Access to Maximum Fair Price (MFP) Will Increase Costs for Pharmacies:** In the draft guidance, CMS proposes two options for payment facilitation, both of which are retrospective. As ASHP has stated in previous comments, a retrospective payment model is unworkable because it places undue administrative and financial burdens on providers, particularly for 340B covered entities. Under a retrospective rebate model, pharmacies will be forced to purchase Selected Drugs at prices significantly higher than Maximum Fair Price (MFP) and finance these inflated purchase prices until a retrospective rebate is provided. This will substantially increase the actual cost for pharmacies to purchase these medications and undermines the cost-saving intent of the IRA. These inflated carrying costs will be most severe for pharmacies affiliated with 340B covered entities that already have access to discounted medications under the 340B program. **Instead of finalizing either of its proposed options for access to MFP, we urge CMS to move to a prospective model crafted from elements of the MFP models CMS outlines in the draft guidance.**

  The simplest way of facilitating this system would be to provide prospective access to the MFP price at the time of purchase. With both MFP and 340B prices available, 340B covered entities could then select the 340B price for all eligible patients. Many covered entities already maintain separate 340B and non-340B inventories, either through physical separation of products or via third-party administrator (TPA) facilitated virtual replenishment. Allowing prospective access to both MFP and 340B prices would likely significantly reduce the burden of identifying and remedying duplicate discounts versus a retrospective model built on a refund system.

We support CMS's proposal that the Medicare Transaction Facilitator (MTF) receive and dispense aggregated payments. However, under our proposed prospective payment system, the occurrence of duplicate discounts with the 340B program would likely be limited. Given the smaller volume of claims, we propose that the MTF facilitates refund payments from covered entities to manufacturers when duplicate discounts are identified. The retrospective model proposed by CMS would require providers to wait for refunds from manufacturers, resulting in providers effectively subsidizing the costs of these medications, which runs counter to the IRA's key purpose – reducing the cost of medications. Requiring manufacturers, rather than providers, to carry costs until MFP can be trued up may also incentivize manufacturers to provide timely access to MFP and 340B prices. Further, this better aligns with existing systems for identifying and refunding duplicate discounts under the 340B program. This will require integration of TPAs with MTF, which we will address in more detail below.

- **An MTF That Is Independent of Manufacturers Should Facilitate Data Verification and Payments:** To build a prospective model outlined above, the MTF would also need to facilitate data verification. At the time of purchase, the covered entity would submit the claim as CMS as proposed. For drugs purchased at MFP, the MTF will need to take no additional action. However, for drugs purchase at the 340B price, the MTF will likely need to integrate or communicate with a covered entity's TPA. The TPA would submit the required data elements for each 340B claim to the MTF. Because current regulations limit access to proprietary 340B pricing data to covered entities, manufacturers, and the Health Resources and Services Administration (HRSA), the MTF could not make an independent determination of whether the MFP was higher or lower than the 340B price. However, the covered entity or TPA could provide the information with downstream manufacturer verification. The MTF could then verify 340B claims and flag claims where the MFP is lower than the 340B price. For claims where the 340B price is lower than the MFP, the MTF could notify the covered entity that the claim has been completed, allowing covered entities to properly manage inventory.

  As noted above, we prefer a framework with an independent MTF facilitating payments and other transactions. Specifically, we have serious concerns with providing claims and payment information directly to manufacturers. Claims data is proprietary, and once turned over to manufacturers, providers would have little control over how the data is used or stored. Claims data turned over to manufacturers, rather than an independent MTF, could also be used for manufacturer sales and marketing activities that would further contribute to escalating drug spending. An MTF-centric model would provide greater transparency for providers as well as increased CMS oversight, providing a higher degree of accountability and comfort than would likely be the case for manufacturer-specific communication. Further, a system where providers interact directly with manufacturers for the purposes of purchasing a single, or at best, a few drugs, fractures the system, creating new administrative burdens and introducing new security weaknesses. An independent MTF with significant CMS oversight, as well as buy-in from and engagement with manufacturers and providers, will be critical to successful implementation of the IRA's drug pricing provisions.

- **Integrate the MTF with TPAs to Avoid Disrupting 340B Claims:** In order to facilitate transactions efficiently, the MTF should be able to integrate with TPAs. The guidance does not directly address this issue, beyond stating that CMS "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g.,

wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price." However, TPAs are an intrinsic element of the 340B process – accounting for 340B claims within the IRA process will require engagement of TPAs. Many covered entities rely on TPAs for compliance assistance with HRSA and manufacturer 340B audits, as well as 340B program integrity requirements. Rather than duplicating these efforts, we urge CMS to integrate TPAs with the MTF to identify 340B claims without requiring new modifiers and to utilize existing processes for IRA compliance to the greatest extent possible.

- **Establish a Firm Time Limit for Adjudicating and Paying Claims:** In addition to ensuring appropriate oversight of, and transparency around, the interaction of MFP and 340B, CMS must establish a time limit of claims payment. Currently, there is no prompt payment requirement under CMS's proposed model. As such, providers are at significant risk of financial loss. This risk is further exacerbated by the fact that it is unclear whether HRSA or another entity will be responsible for disputes related to 340B that arise within the MFP context. To address these issues, **we urge CMS to convene another listening session focused on the interaction of 340B and MFP.**

As noted above, TPA integration with the MTF would also facilitate a prospective payment model. TPAs could assist the MTF in verification of the 340B claims and determination of whether 340B or MFP is the lower price for a given claim. Further, TPAs' understanding and engagement in 340B audits for duplicate discounts could also be utilized by the MTF in the IRA context, avoiding the need for creating a retrospective system of payment which could undermine the 340B program. We are concerned that a retrospective system opens the door to manufacturers using the determination of whether MFP or 340B prices apply as a pretext for limiting or delaying payment to covered entities. CMS should clarify that the statutory requirement that manufacturers provide access to MFP to 340B covered entities without any duplicate discounts does not mean that manufacturers can delay providing access to 340B pricing.

Again, we urge that for the purposes of addressing any duplicate discounts between MFP and 340B pricing, covered entities will provide any required refund to manufacturers rather than vice versa. This process could look similar to 340B audits, with a preference for the MTF to facilitate these processes. Allowing manufacturers to individually audit providers creates serious concerns around transparency and oversight and will almost certainly result in additional administrative and financial burdens, straining safety-net providers.

Thank you for your consideration of our comments. We continue to support CMS's efforts to create a workable IRA framework, and we stand ready to assist the agency in any way possible. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

Jillanne Schulte Wall

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

Association of Black Cardiologists, Inc.
2400 N Street, NW
Suite 200
Washington, DC 20037
(800) 753-9222
www.abcardio.org

ABC MISSION:
To promote the prevention and treatment of cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

July 2, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD21244-1850

Sent electronically to IRARebateandNegotiation@cms.hhs.gov

Re: **Comments on Medicare Drug Price Negotiation Program and Implementation of the Inflation Reduction Act**

Dear Administrator Brooks-LaSure:

On behalf of the Association of Black Cardiologists (ABC), we appreciate the opportunity to comment on the Medicare Drug Price Negotiation Program and Implementation of the Inflation Reduction Act guidance. While we support the efforts of CMS to ensure access to affordable medications through the Medicare Drug Price Negotiation Program (MDPNP) and other provisions of the Inflation Reduction Act (IRA), we have concerns and recommendations to ensure these initiatives genuinely benefit all patients without unintended negative consequences.

About ABC

Founded in 1974, the ABC is a nonprofit organization dedicated to eliminating the disparities related to cardiovascular disease and achieving health equity such that all people can live long, healthy lives. Membership is open to all interested in the care of people with or at risk of cardiovascular disease including health professionals, lay members of the community (Community Health Advocates), corporate and institutional members. Today, the ABC's public and private partnerships continue to increase the impact in communities across the nation.

The Association of Black Cardiologists, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Part D Formulary Inclusion of Selected Drugs

Overall, the ABC is concerned that the MDPNP and changes under the IRA could lead to increased utilization management practices, such as prior authorization and step therapy, as well as alterations in formularies, tiering, and patient cost-sharing, which may ultimately create barriers to care.

We are pleased that CMS acknowledges these concerns and plans to review formularies and monitor Part D plans for these practices. However, the potential for Part D plans to restrict access to medications underscores the vital role of CMS in protecting beneficiaries.

To protect beneficiaries, CMS should specifically consider the following:

- Establish and enforce clear guidelines that limit the excessive and inappropriate use of utilization management practices.
- Create a system for continuous monitoring of changes in these policies and their impacts on beneficiaries.
- Implement a structured process that facilitates input from beneficiaries and patient organizations on Part D formulary design, cost-sharing, utilization management, and appeals.

Moreover, it is crucial to incorporate diversity and equity considerations in these safeguards to assure that subgroups are not selectively impacted. CMS should ensure that these protections are applied equitably across all demographic groups, particularly focusing on populations that historically face greater barriers to accessing healthcare, such as racial and ethnic minorities, low-income individuals, and those living in underserved areas.

Patient Engagement in the Negotiation Process

We appreciate CMS's efforts to enhance patient engagement through patient listening sessions and other methods. To improve patient engagement for initial price applicability year (IPAY) 2027 and facilitate meaningful interactions between CMS and the beneficiary community, we offer the following suggestions:

- ***Types of Information***: CMS should communicate the specific types of information it seeks from the beneficiary community during patient listening sessions which will help participants prepare more effectively and provide relevant insights to CMS.
- ***Use of Information***: CMS should clearly communicate the objectives of patient engagement opportunities and how beneficiary input will be used throughout the negotiation process. This transparency will build trust and incentivize greater participation.
- ***Format of Patient Engagement***: Provide advanced and clear notifications about the format of engagement sessions and allow sufficient time for participants to prepare and share their experiences, which will enhance the quality of input received.
- ***Multiple Methods of Engagement***: Explore various methods of obtaining beneficiary input, such as smaller group sessions, roundtable discussions, focus groups, and the ability to submit information post-session. This approach will ensure diverse and representative participation.
- ***Participant Selection***: Clearly communicate the process for selecting participants and allow input from patient organizations to ensure diversity and representation.

Additionally, we urge CMS to prioritize equity in patient engagement efforts by ensuring that the voices of historically marginalized and underserved communities are adequately represented. This includes providing accommodations for individuals with disabilities, language barriers, or other barriers that might prevent them from participating fully in these sessions.

Excluding the Utilization of Quality-Adjusted Life-Years in the Negotiation Process

We commend CMS for explicitly stating that it will not use Quality-Adjusted Life Year (QALY) metrics in the negotiation process. However, we remain concerned about the potential inadvertent use of QALY-based analyses. CMS should provide clarity on how QALY metrics will be excluded from evidence analysis and highlight when and how these metrics are removed from consideration. A rigorous process is necessary to ensure that evidence is not bias against elderly, disabled, or terminally ill patients as well as those who may be disproportionately affected by health disparities.

Off-Label Use of Drugs

The guidance also addresses the off-label use of drugs, emphasizing the need to ensure that such use does not inadvertently lead to coverage denials or restrictions. While the MDPNP focuses on negotiated drugs, it is crucial that patients continue to have access to medications deemed medically necessary and prescribed by their physicians.

To address this, CMS should:

- Ensure that the negotiation process and subsequent formulary designs do not inadvertently limit access to medications that are deemed medically necessary.
- Implement guidelines that protect the availability of approved medications and prevent utilization management practices from creating barriers to access.
- Continuously monitor and assess the impact of the negotiation process on the availability of medications prescribed outside of the approved indications to ensure patients receive the best possible care.

Conclusion

We appreciate the opportunity to provide feedback on this important guidance. Please feel free to reach out to Levather N. Johnson at lnjohnson@abcardio.org with any questions or concerns. We look forward to working with you on these crucial issues.

Sincerely,

Paul Underwood, MD
Chair, ABC Board of Directors

July 2, 2024

VIA Electronic Filing – *IRARebateandNegotiation@cms.hhs.gov*

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for the Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Deputy Administrator Seshamani:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS, the Agency) *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (Guidance or the Guidance) which CMS released on May 3, 2024.

Astellas is a Japanese-based pharmaceutical company with its US headquarters in Northbrook, Illinois. Our more than 3,000 employees in the United States are dedicated to improving the health of individuals by developing and marketing treatments for unmet medical needs in the therapeutic areas of oncology, women's health, ophthalmology, urology, cardiology, infectious disease, and immunology.

Astellas supports the comments of our trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), and we share PhRMA's concern that the Guidance, if finalized, would heighten the substantial risks already posed by the drug pricing provisions of the Inflation Reduction Act (IRA): curbing biopharmaceutical innovation and eroding patients' access to new therapies. We write separately to emphasize a few points of particular importance about suggestions to help mitigate the risks associated with the initial Guidance. We urge CMS to work to implement the IRA's drug price-setting provisions in a way that mitigates the IRA's risks to patients, without departing from the statute's text.

Our specific comments on the Guidance can be summarized as follows:

1. CMS should enhance transparency around the drug selection process and release Medicare spending data quarterly.
2. CMS' treatment of medicines containing the same active ingredient or moiety as one drug under the Program discourages the development of new dosage forms and formulations.
3. CMS should not disproportionately weigh federal financial support in developing MFP offers.

Astellas
2375 Waterview Drive; Northbrook, IL 60062

4. CMS should not penalize manufacturers for patents and exclusivities.
5. CMS should defer to experts in determining therapeutic alternatives, and publicly identify all therapeutic alternatives considered when setting the MFP.
6. CMS should revise the Guidance to remove a selected drug from the program after the "negotiation" period if a generic or biosimilar is approved and marketed before the start of the IPAY.
7. The concept of "Bona Fide Marketing" is inconsistent with the IRA and should be removed from the Guidance.

CMS should enhance transparency around the drug selection process by releasing Medicare spending data quarterly.

The lack of transparency and predictability surrounding the IRA's "negotiation" program remains a significant challenge. For IPAY 2026, publicly available Medicare Part D spending data (accessible through the annual Medicare Dashboard) proved to be an unreliable indicator of which drugs would be selected for negotiation. For IPAY 2026, the reference period used to determine the 10 drugs selected for price setting was from June 1, 2022, to May 31, 2023. The only publicly available data to potentially indicate what drugs might be selected was the 2021 Dashboard data, which showed Part D spending from January 1, 2021, to December 31, 2021. This data set captured Medicare spending that began **17 months** before the end date of the IPAY 2026 reference period. Medicare Part D spend during the 12-month IPAY 2026 reference period for HALF of the 10 drugs selected grew between 63% and 136% from the 12-month period captured in the 2021 Dashboard.[1] The lack of transparency and predictability creates unnecessary uncertainty for manufacturers.

For IPAY 2027, the reference period used to determine the 15 drugs selected for price setting will be November 1, 2023, to October 31, 2024. The latest publicly available data to potentially indicate what drugs might be selected is the 2022 Dashboard data, which shows Part D spending from January 1, 2022, to December 31, 2022. This data set will capture Medicare spending beginning a full **22 months** before the end date of the IPAY 2027 reference period, creating even more uncertainty and less predictability than the prior cycle. Astellas believes CMS should release Medicare spending data quarterly to provide greater public visibility into the selection process.

CMS' treatment of medicines containing the same active ingredient or moiety as one drug under the Program discourages the development of new dosage forms and formulations.

CMS' interpretation of "Qualifying Single Source Drug" (QSSD) for the purposes of price setting under the IRA is untethered from the statute and will stifle the development of innovative and lifesaving treatments. CMS' overly broad approach treats new dosage forms and formulations containing the same active ingredient or moiety as the same drug, even if the drug was approved under a different marketing application. As a result, biopharmaceutical companies will have to reconsider the economic feasibility of investing in new dosage forms, jeopardizing the development of these critical treatments moving forward.

[1] 2021 Medicare Part D Dashboard

Astellas
2375 Waterview Drive; Northbrook, IL 60062

Whether improving adherence for vulnerable patient populations or providing new options for an entirely different disease or patient population, post-approval R&D that leads to new dosage forms and formulations provides meaningful treatment advances for patients.

Unfortunately, the first set of drugs selected for price setting demonstrates CMS' disregard for the value these medicines provide and for the patient populations that rely on these treatment advances. While CMS was permitted to select 10 drugs for price setting, CMS adopted an overly broad interpretation of QSSD to sweep in an expansive range of dosage forms and formulations, including those submitted under entirely different marketing applications. The selection of these drugs, for which the government-set price will go into effect in 2026, sends a clear signal discouraging any future research on improved dosage forms and formulations to meet unmet needs for various patient populations, including patients outside of Medicare.

Given the IRA's price-setting framework and CMS' treatment of new dosage forms and formulations under the framework, the economic incentives driving investment in these types of dosage forms and formulations will be significantly limited moving forward as they may be swept into government price setting shortly after reaching the market. Astellas urges CMS to require that to be included in a QSSD, each individual drug product or biological product must be approved or licensed (1) under the same NDA or BLA, either as part of the original application or under a supplement to such application, and (2) at least seven years or 11 years (as applicable) before the selected drug publication date.

CMS should not disproportionately weigh federal financial support in developing offers.

As noted above, the Guidance provides that CMS will consider "the extent to which the Primary Manufacturer benefitted from Federal financial support" and "may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from federal sources." Other than referring to "the extent to which the Primary Manufacturer benefitted from Federal financial support," the Guidance does not discuss how much weight CMS might give to prior Federal financial support. Federal financial support may be early in the discovery phase and eclipsed by ongoing investment in a product. We recommend that CMS look at Federal financial support in the context of the total R&D costs incurred for the selected drug and consider – at most – a proportional adjustment in the preliminary price. For example, if prior federal financial support represented 1% of the total investment required to develop a new drug, to the extent CMS considers adjusting the preliminary price downward as a result of such funding, it should do so in a proportional manner by adjusting the preliminary price downward by no more than 1%.

CMS should not penalize manufacturers for patents and exclusivities.

As currently proposed, CMS "intends to consider the length of the available patents and exclusivities before the drug may no longer be single source" and may consider adjusting the preliminary price downward if the drug has patents and exclusivities that will last for a number of years. We strongly believe this proposal is ill-advised, and we urge CMS to refrain from penalizing manufacturers for patents and exclusivities.

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Patents and exclusivities encourage and incentivize research and development and other investment in new drugs and therapies. Post-approval R&D that could result in additional patients and exclusivities can improve patients' lives via meaningful improvements in existing therapies. Instead of undermining manufacturers' intellectual property rights and reducing motivation to improve existing therapies and/or develop groundbreaking therapies, CMS should take exactly the opposite approach. The important role of patents in promoting scientific advancement is long-established and recognized on our Constitution. Article I of the U.S. Constitution provides for Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[2] By proposing to adjust a preliminary price downward because a product has available patent rights and exclusivities, CMS would penalize manufacturers for innovation and – again – undo incentives that Congress created intentionally and for important reasons. Intellectual property rights have helped to fuel the country's leadership in global innovation for over 200 years and by using those rights as a trigger to reduce the preliminary price of a selected drug, CMS would be directly diminishing the value of those intellectual property rights. This would set a troubling precedent -- contravening long-standing policies stated in our Constitution to promote intellectual property rights and spur scientific advancement.

To encourage future research and innovation, and to ensure that development continues to take place domestically, CMS should reconsider its Guidance and instead should adopt a policy of rewarding innovation and adjusting the preliminary price upward for a selected drug with unexpired patents or exclusivities.

CMS should defer to experts in determining therapeutic alternatives, and publicly identify all therapeutic alternatives considered when setting the MFP.

In determining the therapeutic alternatives to a selected drug, CMS should rely on clinicians with disease-specific expertise, manufacturers, patient groups, and independent, widely respected experts. These groups are best positioned to know which products are potential therapeutic equivalents to a selected drug that are appropriate for consideration. For example, when CMS identifies therapeutic alternatives to a selected cancer drug, CMS should consult oncologists, the NCCN Drug and Biologics Compendium, and relevant manufacturers of oncology drugs. Moreover, to ensure transparency, and to allow for feedback from clinicians with disease specific and other relevant expertise, including manufacturers and independent, widely respected experts, CMS should publicly identify all therapeutic alternatives to a selected drug as early as possible in the process. Given the specialized knowledge and experience required to identify appropriate therapeutic alternatives to oncology drugs in particular, CMS should ensure that it will receive input from all relevant stakeholders in a timely manner, and that it structures its MFP-setting process so as to create multiple opportunities for stakeholders with expertise to provide feedback to CMS on therapeutic alternatives.

CMS should revise the Guidance to remove a selected drug from the program after the "negotiation period" if a generic or biosimilar is approved and marketed before the start of the IPAY.

[2] U.S. Constitution, Article I, Section 8, Clause 8.

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Under the IRA, a selected drug will not be subject to an MFP if CMS determines that the generic or biosimilar for the product is approved and "marketed" before the end of the statutory "negotiation period."[3] Given the obvious purpose of this provision—to take out of the MFP program drugs and biologics that face competition from a generic or biosimilar before their MFPs take effect, as they no longer represent "qualifying single source drugs"— CMS should also remove a selected drug from the MFP program if marketing of the approved generic or biosimilar begins after the "negotiation period" ends but before the start of the IPAY (i.e., between August 1, 2024 and December 31, 2025, for IPAY 2026). Congress intended that the program allow for price setting for single-source products. If CMS does not remove a selected drug from the program even in a case where a generic drug or a biosimilar is approved and marketed before MFPs take effect (at the start of the IPAY), this could have the unintended effect of forcing a generic drug or a biosimilar to compete with an MFP-priced listed or reference product for a year—distorting competition and undermining the program. The MFP may set a price below the level of economic viability for the generic or biosimilar competitor and undercut the ability of the generic or biosimilar to establish a stable footing in the marketplace. We urge CMS to remove a selected drug from the MFP program if a generic or biosimilar for the drug is approved and marketed at any point prior to the start of IPAY, even if marketing of the generic or biosimilar product begins after the statutory "negotiation period" has ended.

The concept of "Bona Fide Marketing" is inconsistent with the IRA and should be removed from the Guidance.

CMS has imposed an extra-statutory "bona fide marketing" standard, entirely of its own invention, that would leave significant ambiguity as to whether it will be possible to avoid price setting even when there is a marketed generic or biosimilar. Astellas opposes CMS' extra-statutory concept of "bona fide marketing." Section 1192(e)(1) of the SSA defines a qualifying single-source drug (QSSD) as a drug product "that is not the listed drug for any [generic] drug that is approved and marketed under section 505(j)" of the FDCA and a biological product "that is not the reference product for any [biosimilar] biological product that is licensed and marketed under section 351(k)" of the PHSA. Similarly, section 1192(c) provides that a product ceases to be a "selected drug" beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one generic drug or biosimilar biological product "is approved or licensed (as applicable)" and "is marketed pursuant to such approval or licensure."

The Guidance refers to "bona fide marketing," stating that CMS "will consider a generic drug or biosimilar to be marketed when the totality of the circumstances, including the data specified below, reveals that the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar."[4] The Draft Guidance also states that "[t]he determination whether a selected drug should not be subject to the negotiation process and ultimately removed from the selected drug list" will depend upon evidence that "reveals that the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing of that drug or product."[5] Furthermore, even after CMS determines that a potential QSSD will not be considered a QSSD or that a selected drug has ceased to be a selected

[3] See SSA § 1192(c)(2).
[4] Draft IPAY 2027 Guidance, at 11.
[5] Draft IPAY 2027 Guidance, at 103.

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drug, CMS "will monitor whether meaningful competition continues to exist in the market by ongoing assessments of whether the manufacturer of the generic drug or biosimilar is engaging in bona fide marketing."[6]

The addition of the term "bona fide" adds an extra-statutory limitation and is at odds with the ordinary meaning of "marketed." CMS' approach also is inconsistent with other provisions of the IRA, where Congress expressly imposed volume-based requirements for marketing purposes. Finally, the statute does not permit CMS to monitor for "bona fide marketing" after it determines that a product is not a QSSD or has ceased to be a selected drug.

The ordinary meaning of "marketing," which is the way "marketing" is used in the pharmaceutical sector specifically, does not support CMS' narrowly focused approach. For example, Merriam-Webster's Dictionary defines marketing as "to expose for sale in a market."[7] In a Supreme Court case interpreting the meaning of "marketing" when the term was undefined in a statute, the Court looked to the "ordinary meaning" of the term and concluded that "[m]arketing ordinarily refers to the act of holding forth property for sale, together with the activities preparatory thereto…The word does not require that the promotional or merchandising activities connected with the selling be extensive."[8] Thus, when "marketing" is undefined, the Court simply requires the product to be "for sale."[9]

These definitions also reflect the generally accepted, ordinary meaning of "marketed" in the context of a pharmaceutical product, and, consequently, the meaning of "marketed" that Congress intended in the context of the IRA. For instance, the ordinary meaning of "marketing" is consistent with FDA's conception of marketing under section 505(j) of the FDCA, which is relevant given that the IRA's statutory QSSD and selected drug definitions reference a generic drug "marketed under section 505(j)."[10] In the context of 180-day exclusivity for first generic applicants, the FDCA provides that FDA shall not make effective a subsequent generic application until "180 days after the date of the first commercial marketing of the drug…by any first applicant."[11] In regulations, FDA defines the term "commercial marketing" (a term that is narrower than "marketing") as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except…for investigational use or transfer of the drug product to parties identified in the ANDA for reasons other than sale."[12] Similarly, for purposes of implementing section 506I of the FDCA concerning required notifications to FDA about the marketing status of a product,[13] FDA considers a

[6] Draft IPAY 2027 Guidance, at 115.
[7] "Market." Merriam-Webster.com, https://www.merriam-webster.com.
[8] *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179, 187 (1995)
[9] *Id.* ("One can market apples by simply displaying them on a cart with a price tag; or market a stock by simply listing it on a stock exchange; or market a house (we would normally say 'place it on the market') by simply setting a 'for sale' sign on the front lawn. Indeed, some dictionaries give as one meaning of 'market' simply 'to sell. ' See, *e.g.,* Oxford Universal Dictionary 1208 (3d ed. 1955); Webster's New International Dictionary 1504 (2d ed. 1950).").
[10] SSA § 1192(e)(1)(A)(iii); *see also id.* SSA § 1192(c)(1)(A)(i).
[11] FDCA § 505(j)(5)(B)(iv)(I).
[12] 21 C.F.R. § 314.3.
[13] Section 506I requires NDA and ANDA holders to provide written notification prior to withdrawing an approved product from sale and if the drug will not be available for sale within 180 days of the date of approval.

Astellas
2375 Waterview Drive; Northbrook, IL 60062

product's marketing status to depend on whether a product is distributed by the application holder, i.e., whether the product is available for sale.[14]

In contrast, the Guidance imposes an extra-statutory limitation on what qualifies as marketing of a generic or biosimilar biological product for purposes of the QSSD definition and for determining whether a product ceases to be a selected drug or otherwise is no longer subject to the price-setting process or to an MFP. In the IPAY 2026 Initial Guidance's "Appendix C: Definitions for Purposes of Collecting Manufacturer-Specific Data," CMS defined "marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product."[15] Perhaps recognizing the tension between this definition and its extra-statutory "bona fide marketing" concept, CMS deleted this definition from the IPAY 2026 Revised Guidance and the new Draft Guidance, both of which instead refer to "[m]arketing costs" as "expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion."[16] Astellas opposes the extra-statutory "bona fide marketing" standard and advises CMS to remove it from the Guidance.

* * *

We thank CMS for the opportunity to comment on this very important matter. We hope that CMS will take our feedback, as well as that of PhRMA, into consideration as it revises the Guidance to ensure it conforms with the statute and ultimately provides the best environment for patients to access novel medicines.

Sincerely,

Christie Bloomquist,
Vice President, Government Affairs & Policy
Astellas Pharma US, Inc.

[14] FDA. (August 3, 2020). Guidance for Industry: Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format. Available at: https://www.fda.gov/media/120095/download
[15] Initial IPAY 2026 Guidance, at 82.
[16] Revised IPAY 2026 Guidance, at 194; Draft IPAY 2027 Guidance, at 131.

Astellas
2375 Waterview Drive; Northbrook, IL 60062

BY ELECTRONIC SUBMISSION VIA
IRAREBATEANDNEGOTIATION@CMS.HHS.GOV

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani,

AstraZeneca appreciates the opportunity to submit comments in response to the above captioned guidance (the "Draft Guidance") setting forth the Centers for Medicare & Medicaid Services' (CMS') proposed policies for implementing the Medicare Drug Price Negotiation Program (the "Negotiation Program") for initial price applicability year (IPAY) 2027.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas: Oncology, Cardiovascular, Renal & Metabolism (CVRM) and Respiratory & Immunology. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

Our key areas of focus can be summarized as follows:

1. **AstraZeneca appreciates that CMS is considering ways to update its policies for the selection of therapeutic alternatives for selected drugs, but believes CMS' proposed changes would result in a wholly inappropriate definition of therapeutic alternative.** AstraZeneca urges CMS to maintain and expand upon the policy it finalized for IPAY 2026, under which CMS selects only the "most clinically comparable" therapeutic

alternatives. In the Revised Guidance for IPAY 2027, CMS should more objectively describe its process for selecting therapeutic alternatives to increase predictability and transparency. Below, AstraZeneca outlines five principles for the appropriate selection and assessment of therapeutic alternatives that would improve the appropriateness and transparency of CMS' process for selecting therapeutic alternatives.

2. **AstraZeneca remains highly concerned that patient access to selected drugs through Part D plans may be impacted by maximum fair price ("MFP") implementation. Therefore, AstraZeneca urges the agency to provide additional formulary guidance and oversight of these potential challenges to ensure that patients are entitled to open access to selected drugs.**
3. **AstraZeneca reiterates our concerns regarding the ambiguity around the exemption of orphan drugs from the Negotiation Program.** We urge CMS to support orphan drug development and access to innovative treatments for rare disease patients by clarifying that, in the context of an orphan drug, the 7- or 11-year pre-negotiation period is tolled while an orphan drug qualifies for the exclusion.
4. **AstraZeneca appreciates CMS' commitment to improving the process of soliciting input from patients and patient advocacy organizations. AstraZeneca encourages CMS to expand stakeholder engagement efforts, in addition to the methods used for IPAY 2026.** Moreover, we recommend much greater clarity around listening sessions, and greater transparency around how CMS uses patient input. This would help patients and patient representatives provide more meaningful feedback to the agency that would better inform the Negotiation Program.
5. **AstraZeneca believes the proper implementation and functioning of the Medicare Transaction Facilitator (MTF) will be essential to the success of the Negotiation Program, and our comments below provide several recommendations for how CMS can successfully implement the MTF, including:**
    - General design considerations for the MTF, such as the recommendation that it be a single entity, as independent from the pharmaceutical supply chain as possible, and open to continuous operational improvements, especially in the early years of implementation.
    - Encouraging the implementation of CMS' proposal for the MTF as processing payments from the manufacturer through the facilitator to the dispensing entity. Further, our comments note that **participation in the MTF as a payment facilitator should be mandatory** for dispensing entities.
    - Specific details on the data fields that AstraZeneca believes are necessary for successful MFP implementation.
    - Concern that CMS does not contemplate MTF involvement in de-duplication of 340B discounts.
    - The impracticability of CMS' proposed 14-day prompt pay window.
    - Recommendations for the appropriate calculation and processing of MFP refunds.
    - Improvements to strengthen the dispute resolution process contemplated for the MTF.

I. Principles for Selection of Therapeutic Alternatives and Assessing Clinical Benefit

For the purposes of selecting therapeutic alternatives for IPAY 2027, the Draft Guidance states that "the term 'therapeutic alternative' may refer to one or more therapeutic alternative(s) or a subset of therapeutic alternatives that are clinically comparable."[1] By contrast, the IPAY 2026 revised guidance had stated that "therapeutic alternative" may refer to "a subset of the most clinically comparable therapeutic alternatives."[2]

This proposed change is a significant and dramatic departure from CMS' existing definition that could easily result in the agency arbitrarily identifying inappropriate therapies as "therapeutic alternatives" for selected drugs. CMS should not expand its definition for therapeutic alternatives and should instead focus on identifying the most clinically comparable products.

The selection of appropriate, clinically comparable therapeutic alternatives is vital to determining an appropriate MFP. The choice of therapeutic alternatives should be solely driven by clinical appropriateness—informed by current treatment practices among a relevant patient population—selected from potential comparators with the same treatment modality and from within the same class, rather than be dictated by cost or any other concerns or implicit goals. For drugs with multiple indications that span different diseases and patient populations, CMS should consider all indications holistically and avoid selecting comparators that are only relevant for a subset or single indication of the selected drug.

A therapy that is "clinically comparable," but not in the subset of "most clinically comparable," is likely to lack the safety, efficacy, and other clinical benefits of the selected drug such that it is a "therapeutic alternative" for that drug. Consideration of only the most clinically comparable alternatives is thus necessary to align with the statute's clear references to "therapeutic alternatives." Limiting therapeutic alternatives to those drugs that are "most clinically comparable" is also essential to recognize the value of novel treatments so as not to reverse the incentives that currently encourage innovation and access for patients. These incentives depend on rewarding advances in clinical outcomes and other considerations (such as total cost of care savings, value to special populations, and improvements to health equity). These incentives would be disrupted were CMS to set the MFP for selected drugs by starting with a comparison to products that may treat the same disease but not in clinically comparable ways.

Furthermore, the terms CMS has chosen to use in describing the process for selecting therapeutic alternatives, including "clinically comparable" and "subset" continue to be ambiguous and prone to subjective interpretation. CMS should more objectively describe its process for selecting therapeutic alternatives to increase predictability and transparency. This would allow all stakeholders (e.g., patient advocacy groups, clinician professional societies, guideline writing organizations) to provide CMS the most relevant comments, data, and analyses to inform negotiations. Specifically for manufacturers of selected drugs in IPAY 2027, CMS should communicate which therapeutic alternatives it believes to be in-scope early in the negotiation process. This would allow manufacturers to provide the most relevant data (e.g.,

[1] Draft Guidance at 81.
[2] *Id.* at 145.

clinical trial, real-world evidence, health economic modelling) to support CMS' clinical assessment.

AstraZeneca supports a framework for assessment of clinical value that considers the following five core principles. CMS' process for selecting therapeutic alternatives would benefit from adopting the below principles, which provide more reliable, transparent, and appropriate selection and assessment of therapeutic alternatives.

1. The process of clinical value assessment should be transparent. Using scientific principles, consistent methodology, and appropriate evidence, various stakeholders should be able to come to similar conclusions.

2. While adhering to consistent methodology, clinical value assessments should consider contextual factors associated with the disease in question. For instance, clinical trials for rare disease treatments may be non-comparative and often use endpoints that are not specifically developed to capture the full impact of the rare disease or its treatment. In the area of oncology, cancer is not one disease but rather a cohort of related diseases that requires a range of treatments with different goals and outcomes that can vary over the course of the disease. Relevant trial endpoints therefore also vary according to cancer type (e.g., solid or blood cancers) and staging (I-IV), intent of treatment (e.g., curative vs. palliative) and feasibility, which is the likelihood of capturing relevant endpoint data (e.g., tumor growth and spread, quality of life assessments from people with cancer) within time and cost constraints. The process CMS outlines for selecting therapeutic alternatives would benefit from recognizing the significant differences inherent in assessing products from a given therapeutic area.

3. Appropriate therapeutic alternatives must be assessed based on clinical, not economic, factors. Therapeutic alternatives should be licensed and approved for the disease in question and there should be sufficient data to make a valid assessment of each alternative's clinical value feasible. For many diseases, especially rare diseases, there may be only one appropriate therapeutic choice.

4. The perspective of clinical value assessment should be multifaceted and inclusive of factors related to health equity. The assessment must include not just short-term efficacy endpoints used in clinical trials, but safety, long-term health outcomes, patient experience factors such as route and frequency of administration, impacts on population health equity, health system resource use, and societal impacts outside the healthcare system as well. For instance, a study conducted by the EveryLife Foundation concluded that 55 percent of the total burden of rare diseases is experienced outside of the healthcare system—and these impacts are still very much part of the lived experience of rare disease patients.

Health equity deserves additional consideration. The Centers for Disease Control and Prevention defines health equity as "the state in which everyone has a fair and just opportunity to attain their highest level of health," and CMS has identified advancing health equity as one of its six strategic pillars. Health equity is an important consideration across disease areas: a study in the *Journal of the American Medical Association* found in disadvantaged neighborhoods, a lack of physicians and healthcare resources, weak referral systems, poor social support networks, and barriers to travel for initial and ongoing care negatively impact outcomes for

people with cancer.[3] Health equity is also important in chronic diseases, where socioeconomic, occupational, and environmental factors, as well as access to healthcare, impact prevalence and outcomes in different patient groups. Given the importance and priority of health equity, CMS should consider opportunities to incorporate a health equity lens when conducting the clinical value assessment, such as particularly considering the value of the therapy to underserved populations or for conditions that disproportionately affect underserved populations.

5. Data used to inform a clinical value assessment will need to come from a wide variety of sources. Appropriate data sources should include, but should not be limited to, clinical trials, patient registries, and other real-world data. Patient registries and other real-world data have been important sources of data to demonstrate the certain kinds of treatments that are hard to evaluate in clinical settings. Real-world data are also needed to assess some endpoints not easily measured in clinical trial settings, such as caregiver burden and non-medical costs. Data collected from patients via patient-reported outcomes (PROs) including quality of life, should be routinely and consistently incorporated into value assessments, along with the value components that are already used relating to safety and efficacy.

I. Increasing Guidance and Oversight on Formulary Placement of Selected Drugs.

Section 1198(b)(3)(E) of the Social Security Act (the "Act") requires that Part D plan sponsors include selected drugs on their formularies. AstraZeneca remains concerned that CMS has not provided adequate guidance and guardrails for the implementation of this requirement in the Draft Guidance. AstraZeneca and CMS share the goal of ensuring access and affordability for patients, and without further action from the agency, patients may face substantially increased cost-sharing to remain on drugs they are currently taking if those drugs are selected drugs.

CMS has stated it will monitor formulary compliance among health plans, but more detail on the agency's implementation of this guarantee is necessary to ensure both fair implementation of the MFP and appropriate access to selected drugs for Medicare beneficiaries. As CMS is aware, perverse incentives in the drug pricing ecosystem could result in selected drugs in competitive classes (especially those priced below the ceiling price) being disadvantaged in formulary placement versus products that do not have MFPs and therefore have higher prices from which Part D plans can negotiate rebates. The uncertainty in this space is only heightened because implementation of MFPs will occur concurrently with the IRA's Part D program redesign.

Formulary placement is a critical factor in patient access, not least because it can have a substantial impact on patient cost-sharing. One survey found that patients face an average of a $47 copay or 21 percent coinsurance for preferred brand drugs, versus an average of 46 percent coinsurance for non-preferred drugs—a more than doubling in potential average cost-sharing.[4] If a plan moves a drug from preferred to non-preferred status, cost-sharing would likely increase

[3] Cheng E, Soulos PR, Irwin ML, et al. Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients with Nonmetastatic Common Cancers + Supplemental content. *JAMA Network Open*. 2021,
[4] https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2024-a-first-look-at-prescription-drug-plan-availability-premiums-and-cost-sharing/

for many beneficiaries, patient access would decrease (or patients would effectively be forced into non-medical switching), and non-adherence would increase.

In the absence of direct oversight and intervention by CMS, AstraZeneca is concerned that selected drugs could be subject to adverse tiering, resulting in higher patient copayments and/or formulary-driven switching, increased utilization management, or other reductions in beneficiary access. Unfortunately, such developments would thwart the intent of the Negotiation Program by threatening access to selected drugs, while undermining the competition within the Part D program that has made the program a success. Ultimately, CMS should ensure patients are receiving the full benefit of the MFP and not subject to any additional barriers imposed by payers.

Currently, Medicare beneficiaries have excellent access and experience few barriers to many of the ten drugs selected for IPAY 2026, in part because of deep rebates negotiated by manufacturers to ensure low-cost patient access. CMS must ensure that the Negotiation Program does not create unintended consequences, such as increased utilization management requirements, that may reduce patient access. In other words, while the Medicare program may save money through the implementation of IPAT 2026, patients would not directly benefit. Third-party experts have already raised concerns about these challenges,[5] and evidence for these concerns is already becoming apparent. For example, AstraZeneca has been made aware that some Part D plans are negotiating formulary placement for 2025 with the goal of setting a baseline standard for 2026. AstraZeneca urges CMS to monitor these developments that will begin to affect patient access for selected drugs in 2026.

In addition, CMS should implement additional safeguards to protect patient access to selected drugs, both through more detailed guidance on prohibited practices and more oversight of plan practices, including in the development of formularies for plan years 2025 and 2026. While we appreciate that CMS is generally prohibited from enforcing a particular formulary on plans, Congress created an express exemption from this "non-interference" provision to ensure coverage of selected drugs, and it is essential that such coverage be meaningful. We further note that CMS has extensive experience with providing guidance to Part D plans on appropriate patient access protections, and the agency should take similar steps here to ensure that Part D plans are on notice that any policies that reduce access to selected drugs are prohibited and will be subject to enforcement by CMS.

II. Improving Implementation of the Orphan Drug Exclusion

In the Draft Guidance, CMS proposes to make no changes from the policies regarding the orphan drug exclusion under section 1192(e)(3)(A) of the Act. The agency interprets the exclusion as applying to a drug or biological product that must (1) be designated as a drug for only one rare disease or condition under section 526 of the Food, Drug & Cosmetic Act (FDCA) and (2) be approved by the FDA only for one or more indications within such designated rare

[5] Kelly C. Medicare Part D Redesign Could Expand Rebate-Driven Formulary Exclusions in Program. The Pink Sheet. January 26, 2023. https://pink.pharmaintelligence.informa.com/PS147634/Medicare-Part-D-Redesign-Could-Expand-Rebate-Driven- Formulary-Exclusions-In-Program

disease or condition. CMS states it will then use the FDA's Orphan Drug Product designation database and approvals on the FDA website to identify a qualifying orphan drug.

In its IPAY 2026 revised guidance, CMS stated it is "considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development."[6] Developing drugs for orphan diseases and rare cancers is exceedingly challenging. Most importantly, 95 percent of rare diseases lack an FDA-approved treatment.[7] One top FDA official has noted that IRA implementation carries the risk of discouraging development of drugs for rare diseases.[8] AstraZeneca therefore encourages CMS to consider how it can implement the IRA's orphan drug exclusion in a manner that encourages the continued development of orphan therapies, consistent with the intent of the Orphan Drug Act.

A. CMS should state that the 7- or 11-year period that must elapse before a drug or biological can be subject to negotiation should begin on the date a drug loses eligibility for the orphan drug exclusion.

In passing the IRA, Congress included orphan drugs as one of just three exclusions from the QSSD definition, evincing a clear intent to preserve Congress' longstanding support and incentives for drugs treating small patient populations, namely populations of fewer than 200,000 patients. Unfortunately, the approach CMS plans to continue using in implementing this exemption fundamentally undermines rare disease drug development.

As discussed above, pursuant to section 1192(e) of the Act, a drug can only be classified as a QSSD (and hence be subject to negotiation) once "*at least 7 years...since the date of such approval [under section 505(c)]*" or "*at least 11 years...since the date of such licensure [under section 351(a)]*" have elapsed. The orphan drug exclusion provides that: "[T]he term 'qualifying single source drug' does not include any of the following . . . [a] drug that is designated as a drug for only one rare disease or condition under section 526 of the [FDCA] and for which the only approved indication (or indications) is for such disease or condition."[9]

Under CMS's revised guidance for IPAY 2026 and the Draft Guidance, a drug that initially qualifies for the orphan drug exclusion would lose this exclusion—and could potentially be classified as a QSSD—following the receipt of a new orphan designation or the approval of a new orphan indication for a distinct disease or condition for that active ingredient or active moiety. Setting aside our deep concerns regarding CMS's policy of aggregating all products with a single active ingredient or active moiety into a single "drug" for purposes of identifying QSSDs, AstraZeneca strongly disagrees with CMS that the 7- or 11-year pre-negotiation period should commence upon the date of the original approval.

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[6] Draft Guidance at 10.

[7] https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf

[8] https://insidehealthpolicy.com/daily-news/cber-s-tierney-ira-could-impact-rare-disease-small-molecule-development

[9] *See* SSA § 1192(e)(3)(A).

Instead, AstraZeneca continues to urge CMS to clarify that the pre-negotiation period for a qualifying orphan drug begins only upon the date a drug loses eligibility for the orphan drug exclusion. The orphan drug exclusion constitutes a threshold exclusion from the definition of a QSSD.[10] It must follow from this structural placement that the 7- or 11-year pre-negotiation period that would otherwise apply to a QSSD is *tolled* until the first day after the orphan drug no longer meets the requirements of the orphan drug exclusion. (Consider, by contrast, the small-biotech exclusion, which was specifically inserted as an exclusion to the definition of a "*negotiation-eligible drug*" under section 1192(d)(2) of the Act.)

Any other approach would defeat the intent of excluding relevant orphan drugs from the QSSD definition, including the statutory sub-elements. For instance, under CMS' proposed interpretation of the IRA's orphan drug exclusion, the 2018 approval of LYNPARZA for metastatic breast cancer likely would have resulted in the loss of the orphan drug exclusion for LYNPARZA all the way back to 2014 when the product was originally approved for advanced ovarian cancer, in effect ignoring the fact that LYNPARZA had qualified for the exclusion for those first four years and negating the protection the exclusion was meant to provide.

By issuing guidance that sets forth the interaction between the orphan drug exclusion and the QSSD definition in this way, CMS will be following the plain text of the statute. More broadly, CMS would be interpreting the Negotiation Program in a way that supports and safeguards the important progress the ODA has achieved in sharing the benefits of medical innovation with patients with orphan diseases.

B. Alternatively, CMS should carve out the original orphan drug exclusion-eligible indication when a product becomes QSSD eligible.

Under the Draft Guidance, as noted above, a drug that initially qualifies for the orphan drug exclusion would lose such exclusion, and potentially be classified as a QSSD, following the approval (with respect to the same active moiety) of a new orphan designation or the approval of a new orphan indication for a distinct disease or condition. In the case of a drug that initially qualifies for the orphan drug exclusion from inclusion in a QSSD as outlined above, CMS should carve out the original approval(s) that qualified for the orphan designation of the active moiety or active ingredient (and associated Total Expenditures) from the resulting QSSD, such that the QSSD includes only the subsequent or supplemental approvals of the active moiety or active ingredient that never qualified for the orphan drug exclusion.

As also above, pursuant to section 1192(e), "the term 'qualifying single source drug' does not include. . . [a] drug that is designated as a drug for only one rare disease or condition under section 526 of the [FDCA] and for which the only approved indication (or indications) is for such disease or condition." By carving out the initial exclusion-eligible use of the product,

[10] *See id.* ("Exclusions.—In this part, the term [QSSD] does not include any of the following...(A) Certain Orphan Drugs.")

CMS can preserve the intent of Congress to protect the development of orphan drugs while maintaining the ability to negotiate expanded uses of the same active moiety or ingredient.

III. Improving Patient Input Opportunities

In the Draft Guidance, CMS notes that it "intends to improve upon the design of the patient-focused listening sessions from initial price applicability year 2026,"[11] including the possibility of discussion among speakers or specific questions being asked of patients.

AstraZeneca appreciates CMS' commitment to improving the process of patient-focused listening sessions to provide a broader array of patient perspectives and feedback to inform the Negotiation Program. The possibility of more structured formats for patient listening sessions—such as specific questions posed by CMS to patients and patient representatives, as well as discussions among speakers—holds promise for soliciting patient perspectives from a broader, more diverse group of affected stakeholders. AstraZeneca recommends that CMS develop these options as additions to, and not as a replacement for, opportunities for patients and patient representatives to present their own perspectives.

AstraZeneca echoes both the short- and long-term recommendations for patient input generated by a roundtable hosted by the National Health Council following the IPAY 2026 listening sessions.[12] We recommend that CMS work with patient groups, manufacturers, and other stakeholders to develop an appropriate set of questions or topics that would provide the most productive ways to solicit patient perspectives in any additional, new listening sessions. Patient groups' input would benefit from a greater understanding of how their qualitative input is specifically being used to guide CMS' assessment of selected drugs and the quantitative process of developing an MFP. In the short-term, that means more meaningful communication from CMS around the perspectives they wish to hear from patients; in the long term, it should include the development of a more rigorous methodology for how to solicit and consider patient perspectives.

We also note that the National Health Council roundtable found that patients and other stakeholders (such as caregivers, family members, providers, or patients who formerly used a selected drug) were often not aware of the patient listening sessions or how they could easily contribute to them. Therefore, we encourage CMS to consider ways in which third parties, such as patient or provider organizations or manufacturers, may be able to act as a conduit for gathering patient perspectives to ensure CMS has the broadest, most diverse possible input.

IV. Successfully Implementing the Medicare Transaction Facilitator

In the Draft Guidance, CMS sets forth several parameters and functions for the Medicare Transaction Facilitator (MTF). AstraZeneca believes the proper implementation and functioning of the MTF will be essential to the success of the Negotiation Program and provides the following recommendations for how CMS can implement the MTF.

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[11] Draft Guidance at 89

[12] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

At the outset, AstraZeneca urges CMS to move as quickly as possible in identifying an appropriate entity to serve as MTF, in order to accelerate the process of developing MTF capabilities and providing for communication between the MTF, manufacturers, and dispensing entities. The sooner CMS announces the selection of an MTF entity, the sooner that the entity, manufacturers, and dispensing entities can begin developing processes for the vital work of payment facilitation beginning in 2026.

A. General Design Considerations

AstraZeneca makes the following recommendations regarding the general design of the MTF role:

- **The MTF should be a single entity.** AstraZeneca appreciates that the MTF will be tasked with a wide array of functions requiring different operational capabilities, but believes that housing the MTF functions within a single entity will provide for the best performance by the entity and the most efficient experience for manufacturers, plans, pharmacies, and other entities interacting with the entity.
- **The entity selected to provide the MTF functionality should be as independent from the pharmaceutical supply chain as feasibly possible.** While AstraZeneca recognizes it may not be possible to select an entity with no connection to the existing pharmaceutical supply chain (given the capabilities and experience required), CMS should endeavor to select an entity that does not provide services like those provided by any parties that are central to the drug price negotiation ecosystem (such as manufacturers or drug plans).
- **As part of the MTF's initial year of operation, CMS should set forth specific metrics for assessing the entity's functionality, with plans for continuous assessment** of the entity's functionality and annual opportunities to modify the entity's operations, including through the addition or subtraction of capabilities. Assessing the functionality of the MTF and any necessary changes should be an element of the guidance development for IPAY 2028 and future rulemaking for the Negotiation Program.
- **The implementation of the MTF should allow for flexibility in manufacturer adoption and compliance**, given the extremely compressed timeframe in which all parties are tasked with setting up processes for MFP effectuation. A significant amount of time and effort will be necessary for manufacturers to establish the connections and agreements necessary to exchange data with a new supply chain entity, the MTF, and CMS should provide flexibility for this process, given the delays that have already occurred in MTF development and implementation.

B. Options for Payment Processing Facilitation

In the Draft Guidance, CMS presents two proposed options for facilitating payments between manufacturers and dispensing entities: one in which the MTF simply facilitates sharing

banking information between the manufacturer and the dispensing entity and one in which actual payment passes from the manufacturer to the dispensing entity through the MTF itself.[13]

AstraZeneca recommends that CMS choose the second option in implementing the MTF, which would provide a significantly more seamless way to effectuate the MFP. Further, participation in the MTF as a payment facilitator *should be mandatory* for dispensing entities. Such an expectation for dispensing entities would not impose a significantly increased burden over CMS' proposed alternative, in which participating dispensing entities would be required to furnish the MTF with banking information regardless.

A mandatory MTF that provides actual facilitation of payments, rather than merely facilitation of data exchange, is essential to reliable availability of the MFP for dispensing entities. Especially if CMS adopts a relatively short prompt payment timeframe, the only operationally feasible way to achieve this goal is to require the MTF to facilitate the exchange of both data *and* payment.

CMS has the clear legal authority to ensure that the MTF is mandatory for dispensing entities through authorities under the Part D statute. Under Section 1860D-12(b)(3)(D) of the Act, CMS has general authority to add Part D contract terms, as well as general rulemaking authority under Sections 1102(a) and 1871(a). CMS could therefore require, as a matter of contracting with Part D plans, that plan sponsors ensure dispensing entities with which they contract are participating in the MTF as a payment facilitator. It cannot be overstated how essential the MTF will be to successful implementation of access to the MFP and a seamless experience for MFP-eligible patients, and AstraZeneca urges CMS to recognize that this will not be possible without mandatory MTF participation for manufacturers and dispensing entities.

Further, making the MTF into a true payment facilitator, mandatory for both parties, would help to address the possibility of concerns around dispensing-entity non-compliance, a risk that CMS does not adequately address in the Draft Guidance (focusing instead on manufacturer compliance alone). Further, it would help simplify compliance for both manufacturers and dispensing entities, by creating the possibility for CMS to establish a form of safe harbor for manufacturers and dispensing entities that participate in the MTF and reasonably rely on the MTF for purposes of MFP effectuation.

C. Details on Data Fields

Successful MFP effectuation will require a substantial amount of data. Specifically, because manufacturers have a legal obligation to ensure access to the MFP, it is essential for manufacturers have clear claims-level visibility into the claims for which MFP pricing—greater than the visibility that manufacturers currently have in the Coverage Gap Discount Agreement today. This need for data is elevated by the statutory 340B de-duplication requirements, as discussed below. AstraZeneca recommends that the MTF entity be able to aggregate Part D pharmacy dispensing data and issue claims/invoices to manufacturers with at least the following data fields, which represent the minimum data necessary to ensure that manufacturers can verify MFP eligibility for each unit of a selected drug dispensed:

[13] *Id.* at 53, Section 40.4.4.

- **NDC-11**
- **MFP Per Unit**
- **Record Type**
- **Plan ID Code**
- **Plan Name**
- **Pharmacy ID (NABP # or NPI #)**
- **Total Quantity**
- **Unit of Measure (EA, ML, GM)**
- **Rebate**
- **Days Supply**
- **Prescription Number**
- **Date of Service**
- **Paid Date (date the Part D plan paid the pharmacy)**
- **Fill Number**
- **Record Purpose Indicator (R, M)**
- **Rebate Per Unit Amount**
- **Requested Rebate Amount**
- **Formulary Code**
- **Claim Number**
- **Number of Prescriptions**
- **Site of dispensing**
- **340B Modifier**
- **Part D contract ID**
- **De-identified Part D Beneficiary ID**
- **Prescriber NPI (PDE Field Name)**
- **Claim Status (whether the claim was paid or reversed)**
- **340B Clearinghouse Determination**
- **340B Ceiling Price (received from Clearinghouse)**
- **Pharmacy Actual Acquisition Cost**

The above data will be necessary for manufacturers to validate claims at a claim-by-claim level and provide for effective implementation of MFP.

Among these fields, AstraZeneca particularly encourages CMS to prioritize the inclusion of a 340B Modifier to ensure non-duplication of the MFP and the 340B ceiling price (as discussed further in the next subsection). Further, CMS should require that the data submitted to the manufacturer comply with the standard NCPDP format to allow the manufacturer to process the data for verification.

D. MTF Involvement in 340B De-Duplication

AstraZeneca is disappointed that, in the Draft Guidance,[14] CMS has suggested that the agency does not plan to assist with the de-duplication of 340B-eligible and MFP-eligible claims, a process that is required by the IRA statute. Without effective methods to de-duplicate discounts and avoid duplicate discounts in the first place, implementation of MFP will be extremely logistically challenging for manufacturers.

As an initial step to effective de-duplication, it is essential that CMS require covered entities to use a 340B claims modifier (e.g., through the MTF or to a 340B clearinghouse). In order to perform effective de-duplication, the MTF must be able to identify 340B claims to determine whether an MFP discount is due before the manufacturer is invoiced by the MTF. While we recognize CMS may have concerns about whether the agency has the statutory authority to require the inclusion of a 340B modifier by covered entities, the agency has broad authority under §1860D-12(b)(3)(D) of the Act to develop contract terms with Part D plans. This authority would permit CMS to, for instance, require Part D plans to require the use of 340B claim modifiers by their network pharmacies that are affiliated with 340B covered entities.

AstraZeneca continues to consider various approaches and methods that we believe may be helpful to de-duplicating discounts and plans to continue to provide input on this issue to CMS as the MTF development process proceeds.

E. 14-Day Prompt Pay Window

While AstraZeneca appreciates the additional details CMS has begun to provide about MFP effectuation, for drug manufacturers, it is impossible as a practical matter to implement a 14-day prompt pay window for MFP, as CMS suggests in the Draft Guidance.[15] Numerous steps are necessary to process the data received by manufacturers, including but not limited to validating the product name and NDC, the prescription number, the length of the supply, and various pharmacy details, while also ensuring that duplicate claims are avoided. In AstraZeneca's experience, 14 days is a far shorter period than the time in which 340B claims are typically reconciled, and it is far less than the time window provided to managed care plans for the identification of 340B claims. A much more appropriate, and time-tested, option would be to use the 38-day period used for reimbursement under the Coverage Gap Discount Program. By adopting this window, CMS would be using a standard that all the relevant entities have demonstrated is feasible, rather than creating an unrealistic and potentially risky timeframe for a new, complex, and untested process.

For the prompt pay window to be effective, CMS should provide further clarity on how it will be defined. As an initial matter, the prompt pay window should be defined as beginning from the date that the manufacturer receives the appropriate data from the dispensing entity necessary to process the claim. For instance, CMS should clarify that the prompt pay window begins from the date that a manufacturer receives the appropriate data from the MTF, rather than the day that the MTF transmits the data. While these dates may not necessarily differ, challenges do arise in the transmittal of data, and we recommend that CMS clarify that the date beginning the 14-day prompt pay window is the date the manufacturer receives the data from the MTF.

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[14] *Id.* at 48-49.
[15] *Id.* at 37.

AstraZeneca also recommends that any dispute initiated under the dispute resolution process discussed by CMS in Section 90.2.2 of the guidance result in a halt to the tolling of the 14-day prompt pay window.

F. Processing and Calculating MFP Refunds

In Section 40.3.4 of the Draft Guidance,[16] CMS discusses considerations for implementing the option of making the MFP available through retrospectively providing reimbursement to the dispensing entity within the prompt pay window. We appreciate that CMS recognizes the difficulty in calculating an appropriate refund amount, due to the difficulty of determining a dispensing entity's acquisition cost.

Given this challenge, CMS has acknowledged that most stakeholders have indicated they would prefer the use of a standardized amount to determine the refund owed, such as a percentage of Wholesale Acquisition Cost (WAC). However, dispensing entities generally can purchase drugs at a price somewhat lower than WAC. Therefore, AstraZeneca encourages CMS to set the Standard Default Refund Amount for Part D as the lesser of WAC minus the MFP of the selected drug *or* the manufacturer-contracted price minus the MFP. This would provide a standardized option for ease of administration while also ensuring that manufacturers are not required to provide a greater refund than that actually owed.

Further, given the potential shortcomings of the standardized amount, we also recommend that CMS establish a safe harbor for efforts to provide access to the MFP through a retrospective refund of a different amount than the standardized amount. The agency could make this available in cases where the manufacturer has maintained documentation justifying the refund amount and how it meets the manufacturer's obligation to make the MFP available.

G. Dispute Resolution Process

In Section 90.2.2 of the Draft Guidance, CMS discusses potential parameters for an MTF complaint and dispute process.[17] AstraZeneca appreciates CMS' efforts to outline this process and recommends that the potential functionality be enhanced by providing a mechanism for clawing back MFP in cases where the MFP discount was inappropriate.

AstraZeneca appreciates that such a clawback mechanism, while important to providing practical resolution of disputes, may be somewhat complex to develop, but multiple potential options may be feasible. In cases where a manufacturer has identified an error in the provision of MFP or the calculation of the refund amount, it may be possible for manufacturers and dispensing entities to work together on the manufacturer simply receiving a refund on the overpaid amount. Other possibilities exist, however: Rather than a direct clawback, a manufacturer could receive a credit on a future unit of the drug so that a manufacturer can offer a discount less than MFP. A variety of such mechanisms are possible for resolving disputes, but guidance from CMS will be necessary for manufacturers and dispensing entities to feel confident

[16] *Id.* at 50 ff.
[17] *Id. a*t 113 ff.

that such mechanisms are compliant with their respective obligations. Regardless, some level of guidance from CMS regarding the actual financial settlement of disputes will be important to the functioning of any dispute resolution process.

V. Conclusion

AstraZeneca is grateful for the opportunity to submit comments regarding the Draft Guidance and looks forward to continuing to engage with CMS as it implements the Negotiation Program for IPAY 2026, IPAY 2027, and beyond.

Sincerely,

Sarah C. Arbes
Head of Federal Affairs and Policy

Via Electronic Submission

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

July 2, 2024

Brian Nagle
Head of Federal Gov't Affairs
for Healthcare and Policy
801 Pennsylvania Avenue NW
Washington, D.C. 20004

Tel. +1 202.756.3779
Brian.Nagle@bayer.com

www.bayer.com

Subject: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Dr. Seshamani,

Bayer US ("Bayer") appreciates the opportunity to offer its input to the Centers for Medicare and Medicaid Services (CMS) initial memorandum issued May 3, 2024, regarding the drug price setting program implementing provisions of the Inflation Reduction Act.

Bayer is a global enterprise with core competencies in the life science fields of health care and agriculture with nearly 25,000 employees in 300 sites across the United States. Our products and services are designed to benefit people and improve their quality of life. At the same time, we aim to create value through innovation and are committed to the principles of sustainable development and to our social and ethical responsibilities as a corporate citizen.

As we noted last year in our comments,[1] many unanswered questions regarding the Inflation Reduction Act (IRA) persist as we look to the new draft guidance for Initial Price Applicability Year (IPAY) 2027. We urge CMS to make

[1] Nagle B. Bayer Letter to CMS Deputy Administrator Meena Seshamani. Subject: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments. April 14, 2023.

every effort to balance the near-term implications on patient care with the longer-term impact on future pharmaceutical innovation.

The implications of this program on the future of innovation in the United States cannot be overstated. Thus, we continue to urge CMS to use its administrative discretion under the statute to ensure the program is implemented in a manner that avoids unintended consequences and preserves innovation for critical medical conditions. This includes new treatments for patients with cancer or rare medical conditions as well as for patients with chronic diseases for which new medical treatments are needed.

The enactment of Medicare Part D in 2003 ushered in an era of meaningful gains in life expectancy and quality of life for older Americans. Yet today's Medicare patients continue to face unmet medical needs. With more than 400 medicines under development for leading chronic diseases impacting older Americans, it is vital that implementation of the IRA's negotiation provisions enables such innovation to continue.[2]

We address several topics of particular importance to Bayer in this letter. The comments are offered in the hope of ensuring better access to important new treatments to patients.

Comment Overview: Following is a summary of our feedback provided in this document.

Requirements for Manufacturers of Selected Drugs

I. **Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026: Confidentiality of Proprietary Information (40.2.1; 50.1; Appendix A):** We support CMS using Exemptions 3 and 4 of the Freedom of Information Act (FOIA) related to confidential information from manufacturers. Each manufacturer should be allowed to designate its information as confidential to the extent that it cannot legally be found publicly. In addition, the guidance should not override the full range of other potentially applicable privacy and confidentiality laws, including but not limited to the Trade Secrets Act and the Tax Reform Act.

II. **Requirements for Manufacturers of Selected Drugs: Providing Access to the MFP in 2026 and 2027 (40.4):** CMS lays out requirements for manufacturers to ensure the MFP for a selected drug is available to pharmacies, mail order services, and other dispensers with respect to MFP-eligible individuals under Part D under the 14-Day Prompt MFP Payment Window. We still have concerns under the current process the 14 days do not begin until the claim is verified and adjudicated as a "clean claim." As we previously commented in our April 14, 2023 letter, we recommend that CMS use an approach similar to the Medicare Part D Coverage Gap discount program.

[2] PhRMA. Fact Sheet: *Addressing the Unmet Medical Needs of Older Americans.* Accessed June 25, 2024 at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/A-C/Addressing-the-Unmet-Medical-Needs-of-Older-Americans-2.pdf

Negotiation Factors

III. **Manufacturer-Specific Data (50.1; 60.3.4; Appendix A):** We offer several recommendations pertaining to data for research and development (R&D) costs, information on pending and approved patent applications, and tax credits.

IV. **Manufacturer-Specific Data: Evidence About Therapeutic Alternatives for the Selected Drug (50.2):** We restate our recommendations for the determination of a therapeutic advance based on examples from the Food and Drug Administration, the Medicare New Technology Add-on Payment (NTAP) and guidelines from the National Comprehensive Cancer Network (NCCN). We believe this can serve as a useful benchmark in establishing therapeutic advances.

Negotiations

V. **Negotiation Process (60.4)**: We continue to support the approach of allowing up to 3 manufacturer meetings with CMS as part of the negotiation process. The opportunity for dialogue should not be diminished. Furthermore, we support efforts to improve the approach to receiving input from patients as part of the negotiation process via patient-focused events. Any such meetings should continue to be public and livestreamed.

Compliance and Penalties

VI. **Manufacturer Compliance and Oversight (90):** We appreciate that CMS is attempting to establish a robust and fair process for reporting of violations. We believe CMS should go through a notice and comment rulemaking process to establish the reporting of violations and a process for dispute resolution.

VII. **Civil Monetary Penalties (100):** The guidance in Section 100 addresses the Civil Monetary Penalties (CMP) set forth in section 1197 of the SSA (the Program-related CMPs). CMS provided the "procedures" CMS intends to follow to impose these CMPs on manufacturers. We believe that CMS can only implement these CMPs in a manner that conforms to the statute through a notice and comment rulemaking process.

Formulary Inclusion of Selected Drugs

VIII. **Formulary Inclusion of Selected Drugs (110):** We find growing concern about patient access to needed medications, necessitating a review and improvement of existing formulary review standards on the part of CMS. The requirement for formulary coverage of selected medications under the statute is important. However, inclusion on a formulary does not necessarily ensure access to the selected medications. This impacts not only the selected medication but also other products in the same therapeutic class that may be considered therapeutic alternatives.

# # #

Requirements for Manufacturers of Selected Drugs

I. Requirements for Manufacturers of Selected Drugs for Initial Price Applicability Year 2026: Confidentiality of Proprietary Information (40.2.1; 50.1; Appendix A)

As flagged in our comments last year, section 1193(c) of the Inflation Reduction Act (IRA) specifies Congress' intent to protect from public release any confidential information provided by manufacturers to HHS in the context of maximum fair price negotiations. The statute provides the following:

> (c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (*as determined by the Secretary*) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

We are pleased CMS notes its intention to treat specific information as proprietary, with a reference to Exemptions 3 and/or 4 of the Freedom of Information Act (FOIA).[3]

We also support the CMS list of information that constitutes specific information as proprietary:

> "…if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer. Specifically, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue and sales volume as proprietary, unless information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available." [4]

While this description is helpful, we continue to believe manufacturers should have the opportunity to designate its own information as proprietary or confidential, requiring CMS to prove why the information should be made publicly available. We strongly encourage CMS to clarify and affirm that nothing in the guidance shall override the full range of other potentially applicable privacy and confidentiality laws.

In addition to FOIA, the Trade Secrets Act is a criminal statute that prohibits government disclosure of information that "concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any

[3] United States Department of Justice. *What are the 9 FOIA Exemptions?* Accessed June 5, 2024 at: https://www.justice.gov/d9/what_are_the_9_foia_exemptions.pdf

[4] Seshamani M. *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.* May 3, 2024. (see page 33).

income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association."[5] The Tax Reform Act also establishes confidentiality of tax returns and return information, with few limitations.[6]

Manufacturers have a long track record of information sharing with the US Food and Drug Administration (FDA) that continues to serve as a reasonable model. With the FDA, a manufacturer can designate part or all the information it provides as proprietary and is therefore exempt from public disclosure.[7] Such a designation is made at the time of the data submission or within a reasonable time thereafter. The FDA initiates a regulatorily-defined process for determining whether the information, indeed, falls within an exemption upon receipt of information designated as confidential.[8]

While information in the hands of FDA tends to be clinical in nature, and more likely to become public over the normal course of a drug's patented lifecycle, CMS is requesting detailed, research, operational and sales data that have never been requested prior to the IRA or made public. For example, under R&D expenses, CMS mentions personnel expenses (compensation), which is proprietary. Unit costs of production and distribution would not be the type of information that FDA requests, but it goes to the very heart of business strategy and cost allocations and would never be appropriate for public release. In some cases, the public release of information could violate a manufacturer's agreement with a supplier, such as the price paid for raw ingredients or contracted packaging and shipping costs.

Should CMS decide to proceed with the guidance as currently drafted, we would raise an additional concern about the lack of protections for some of the data in non-proprietary categories identified by CMS, such as tax credit information included in the definition of prior federal funding. This information is not public per the Tax Reform Act. Unless CMS can clearly articulate why it would be lawful to make such data publicly available, this information should be protected from public release.

II. Requirements for Manufacturers of Selected Drugs: Providing Access to the MFP in 2026 and 2027 (40.4)

Our comments focus on the 14-day prompt MFP payment window (40.4.1), the 340B nonduplication provisions (40.4.2), the Standard Default Refund Amount (40.4.3), and options for Medicare Transaction Facilitator (MTF) payment facilitation (40.4.4).

14-Day Prompt MFP Payment Window (40.4.1): As we stated in our prior comments, the 14-day deadline for ensuring dispenser access to the MFP may be achievable if the deadline occurs after the claim is verified and adjudicated as a "clean claim" prior to adjusting the payment. However, as described in the draft guidance, we still have concerns with manufacturers' ability to

[5] 18 U.S.C. § 1905 (2023) Accessed June 28, 2024 at: https://www.law.cornell.edu/uscode/text/18/1905
[6] 26 U.S.C. § 6103 (2023) Accessed June 28, 2024 at: https://www.law.cornell.edu/uscode/text/26/6103
[7] 21 C.F.R. 20.61. Accessed June 28, 2024 at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.61
[8] 21 C.F.R. 20.61. Accessed June 28, 2024 at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=20.61

meet the deadline given the large volume of claims that are anticipated for each drug. As described, the system would apparently result in a 14-day clock starting every single day, creating huge administrative and logistical problems for purposes of compliance. CMS should seek to limit the number of submissions manufacturers receive on a monthly basis. This will be especially important when considering submissions that may not take advantage of the Standard Default Refund Amount (SDRA – see below).

We continue to believe that the method currently used to operate the Medicare Part D coverage gap (created under provisions implementing the Patient Protection and Affordable Care Act (ACA) in March 2010) is an effective model that CMS should consider.[9] We provided additional background on this program in our submission to you on April 14, 2023.

Nonduplication with 340B Ceiling Prices (40.4.2): We were concerned to see that "…CMS will not, at this time, assume responsibility for deduplicating discounts between 340B ceiling and MFP." We believe, in this situation, that a clearinghouse and mandatory claims modifiers would clearly assist in the deduplicating process. Even when claims modifiers were mandated for the Medicare Part B program, an analysis by IQVIA found that for rural referral centers (RRC) and sole community hospitals (SCH), modifiers were used only 61% of the time.[10] These findings further support the need for a clearinghouse to assist in the deduplication process.

Retrospective Refund Amount to Effectuate the MFP (40.4.3): We support CMS adopting a Standard Default Refund Amount (SDRA) that is a function of the wholesale acquisition cost (WAC) and the MFP. While this may be the predominant approach used to calculate the refund amount, alternative approaches using the actual acquisition cost presents significant challenges.

As we previously stated, the actual acquisition cost (AAC) for an individual prescription is hard to track and is currently unknown to entities outside the pharmacy. Pharmacies typically purchase medicines from multiple wholesalers at different prices depending on mark-ups, and the quantity purchased can vary significantly. Individual prescriptions can be comprised of a quantity taken from bottles purchased from different wholesalers at different prices depending on the available inventory at the pharmacy. Because of this, only the dispensing pharmacy would be able to know the AAC for a prescription dispensed to an MFP-eligible beneficiary.

Manufacturers have no control over the mark-ups a dispenser may pay as part of the distribution network. Those charges are within the purview of the dispenser and its wholesaler or other distributor based on charges for a service. We are also concerned that such an approach could raise concerns about potential efforts to maximize refund amounts running the risk of manufacturers paying artificially inflated MFPs, compromising the integrity of the program. If this approach is used, CMS should create safeguards to prevent inappropriate activity in the program, including standards for dispensers seeking an alternative approach to the SDRA.

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[9] Social Security Act § 1860D-14A. Accessed March 31, 2023 at: https://www.ssa.gov/OP_Home/ssact/title18/1860D-14A.htm

[10] Martin R, Karne H, Duffy J. "Can 340B Modifiers Avoid Duplicate Discounts in the IRA?" *IQVIA White Paper.* Copyright 2023. Accessed June 5, 2024 at: https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.

MFP Payment Facilitation (40.4.4): CMS presented two options for payment facilitation. We support Option 2 in which the MTF would be responsible for passing through funds from the Primary Manufacturer to dispensing entities. This option could be modified to allow for the sharing of dispenser bank information to assist in instances where a manufacturer and a dispenser pursue a separate program outside of the SDRA approach.

Negotiation Factors

III. Manufacturer-Specific Data (50.1; 60.3.4; Appendix A)

In our prior comments from April 14, 2023, we provided extensive comments pertaining to the collection of manufacturer-specific data. We provide a summary here of those relevant comments for IPAY 2027.

CMS notes that the Primary Manufacturer must report manufacturer-specific data by March 1, 2025, including any Secondary Manufacturer data. Key factors to be reported, also included for IPAY 2026, are:

- R&D costs for the selected drug and the extent to which the costs have been recouped;
- Current unit costs of production and distribution of the selected drug;
- Prior Federal financial support for novel discovery and development of a selected drug;
- Data on pending and approved patent applications, exclusivities recognized by the FDA; and
- Market data, revenue and sales data in the United States.

In addition, Appendix A provides additional information about the types of information that will be expected early in the MFP negotiation process.

Research and Development Costs: The challenges for provision of data are especially important as it pertains to research and development (R&D) costs. A submission of this type raises multiple questions as to how to account for the R&D costs for a specific drug and other drugs over time. While requirements for submission should be limited to specific costs for an individual drug, CMS should give manufacturers latitude to provide and for CMS to consider other costs related to R&D.

We observe that R&D costs related to new indications or formulations under development but not yet approved seem to be excluded from consideration. However, this research may have a significant impact on how patients use and benefit from these treatments. Since the MFP will apply to any new indication or formulation approved after the MFP has been set, those R&D costs, if known at the time, should be considered in the R&D cost calculation.

Pending and Approved Patent Applications: We appreciate the additional clarity the new draft guidance provides concerning the definition of relevant patents and patent applications. In one respect, however, the definition remains overbroad and deserves further revision. CMS

considers relevant patents and patent applications to include "[a]ll patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant."[11] This may be justified where the Primary Manufacturer is involved in a joint venture or where related patents are held by a federal agency as the result of a research collaboration with the Primary Manufacturer. However, it also broadly sweeps in all patents and patent applications from third parties that have no relationship with the Primary Manufacturer. CMS should clarify that only data about patents and patent applications from third parties that have a business relationship with the Primary Manufacturer related to the selected drug should be submitted.

We are pleased that the guidance no longer indicates that CMS intends to consider adjusting the preliminary price downward if a selected drug has existing patents and exclusivities. We support CMS instead using this information to inform its consideration of whether a selected drug represents a therapeutic advance or meets an unmet medical need.

Tax Credits: We are concerned about the inclusion of tax credits in the definition of federal financial support. First, tax return information is confidential under the Tax Reform Act and should not be requested by CMS. Additionally, these credits exist for public policy reasons. Congress wanted to incentivize behaviors that drive innovation for manufacturing in the United States. Conversely, if tax information is going to be used as a rationale to drive down CMS's offered prices (thus, inflating the federal support factor), tax payments of all types (global, U.S., tariffs, state and local, user fees, the ACA industry fee) clearly are operational costs and should be deducted from any revenue calculation.

IV. Manufacturer-Specific Data: Evidence About Therapeutic Alternatives for the Selected Drug (50.2)

IPAY 2027 guidance lays out the consideration of evidence about treatment alternatives to the selected drug, including:

- Whether a selected product represents a therapeutic advance compared to the therapeutic alternatives;
- Evaluation of FDA-approved prescribing information among comparable products;
- Comparative effectiveness research, inclusive the of the implications for "specific populations"; and
- The extent to which a treatment addresses an unmet medical need.

Therapeutic Advance: CMS includes a definition of a "therapeutic advance" as follows:

> "A selected drug may be considered a therapeutic advance when evidence indicated that the selected drug represents a substantial improvement in outcomes compared to

[11] Appendix A: Definitions for Purposes of Collecting Manufacturer-Specific Data, "Patents, Exclusivities, and Approvals."

the selected drug's therapeutic alternative(s) for an indication(s). In cases where there is no therapeutic alternative, a selected drug may be considered a therapeutic advance when there is a substantial improvement in outcomes for the condition or disease state treated by the selected drug. CMS will consider the extent to which a selected drug represents a therapeutic advance.

We appreciate having a better sense of how CMS will consider a therapeutic advance. However, the approach, as described, is highly subjective. While maintaining a certain degree of flexibility in the assessment, we had previously recommended 3 options for the consideration that may at least serve as a set of minimum benchmarks for consideration. Those recommendations included the following:

> Food and Drug Administration: The FDA sets forth important criteria for the determination of fast-track approvals, breakthrough therapy, accelerated approval and priority reviews.[12] These determinations may serve as a minimum threshold for therapeutic advances.
>
> Furthermore, newer medications in a treatment class may offer critical advances in therapy regarding the adverse event profile, ease of administration (e.g., oral versus intravenous) or impact on a patient's quality of life or overall survival. All of these must be considered in the evaluation of a therapeutic advance.
>
> New Technology Add-on Payment (NTAP): The Medicare Inpatient Prospective Payment System (IPPS) includes an approach for a new "add-on payment" for "new technologies" known as the NTAP.[13] This may present another set of considerations for the determination of a therapeutic advance or achieving an unmet medical need. As noted in the related regulations, the medical service or technology must demonstrate a substantial clinical improvement over new technology.
>
> NCCN Guidelines: The National Comprehensive Cancer Network (NCCN) utilizes a distinct process for the evaluation and development of recommendations for interventions to prevent, diagnose and manage cancers at their different stages.[14] The approach uses a careful analysis of available evidence about various treatments for cancer and preferences for approaches to treatments. As part of the process, the quality of the evidence and the consensus of panels reviewing the evidence come together to assess the level of appropriateness for a treatment for a specific type of cancer.
>
> For example, the highest NCCN rating among four levels is Category 1, which is granted to those for which there is high-level evidence and a uniform NCCN consensus

[12] U.S. Food and Drug Administration. *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review.* Content current as of June 12, 2023. Accessed June 28, 2024 at: https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review

[13] Centers for Medicare and Medicaid Services. *New Medical Services and New Technologies: Overview of the New Technology Add-on Payment.* Accessed June 28, 2024 at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech

[14] National Comprehensive Cancer Network. *Development and Update of Guidelines.* Accessed June 28, 2024 at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines

on the appropriateness of the intervention.[15] The next level – Category 2A – represents treatments, based on lower-level evidence, that have a uniform NCCN consensus based on appropriateness of the intervention. These two categories must reach an 85% majority support among the panelists for a treatment to achieve one of these ratings. Furthermore, NCCN includes categories of preference in their reviews. The three categories are: 1) Preferred intervention; 2) Other recommended intervention; and 3) Useful in certain circumstances.[16] Designations at the Category 1 or Category 2A levels could serve as a benchmark for oncology medications when considering a therapeutic advance.

Unmet Medical Need: Concerning the determination of an unmet medical need, we call your attention to the FDA guidance document that defines an unmet medical.[17] Specifically, this includes treatments receiving fast track designation, breakthrough therapy designation, accelerated approval or priority review designation. As the FDA notes, the four programs "…are intended to facilitate and expedited development and review of new drugs to address unmet medical need in the treatment of a serious or lifethreatening [sic] condition…"[18]

Each of these assessments represent examples of important evaluations that influence the use and access to treatments for patients. They serve as a minimal basis for measures of assessing a therapeutic advance or unmet medical need. However, these should not be the only factors CMS considers. Other considerations should include factors such as reducing adverse events and reducing broader health system costs by keeping patients out of hospitals or other institutions. CMS should also consider the impact on efforts to advance health equity.

Negotiations

V. Negotiation Process (60.4)

Patient-Focused Events: We appreciate CMS seeking to improve upon the patient-focused listening experience from last year. CMS should provide an assessment of how they considered the input received to inform the price setting process.

The suggestion to eliminate livestreaming the meetings concerns us. We believe that including more meaningful input from patients during this process can help to inform CMS and

[15] National Comprehensive Cancer Network. *Development and Update of Guidelines.* Accessed June 28, 2024 at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines
[16] National Comprehensive Cancer Network. Development and Update of Guidelines. Accessed June 28, 2024 at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines
[17] US Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). Center for Biologics Evaluation and Research (CBER). *Guidance for Industry – Expedited Programs for Serious Conditions – Drugs and Biologics.* May 2014 – Procedural. OMB Control No. 0910-0765. Accessed June 11, 2024 at: https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf
[18] US Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research (CDER). Center for Biologics Evaluation and Research (CBER). *Guidance for Industry – Expedited Programs for Serious Conditions – Drugs and Biologics.* May 2014 – Procedural. OMB Control No. 0910-0765. Accessed June 25, 2024 at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics

their decisions. In addition, representatives of various patient advocacy organizations appeared enthusiastic about sharing their stories to help improve access to needed treatments. Significantly limiting the time available to patients may have led to limited participation in the sessions.

Meetings Between CMS and Manufacturers: We were pleased to see that CMS adopted an approach to allow up to three meetings between manufacturers and CMS. While we understand there may be challenges in accommodating such an approach as the program grows, we believe it is essential to reserve these meetings to assist in the facilitation of a proper process.

Compliance and Penalties

VI. Manufacturer Compliance and Oversight (90)

As we previously commented to CMS in our letter of April 14, 2023, we appreciate that CMS is looking to establish a robust and fair process for reporting of violations. We believe CMS should go through a notice and comment rulemaking process to establish the reporting of violations and a process for dispute resolution.

Among the issues that must be addressed through this process are: (1) equal access to the process by all parties; (2) competence and independence of the investigators receiving and acting on the reported violations; (3) clear parameters of what can be reported as violations; and (4) a defined process for how a report should be received, handled, communicated, and resolved. As the reported violations may result in non-compliance and potential Civil Monetary Penalties (CMP), a robust dispute resolution process and fair hearing process must be established. We strongly encourage CMS to do this through the notice and comment rulemaking process.

VII. Civil Monetary Penalties (100)

We refer you back to our comments from April 14, 2023. As we noted, the guidance in Section 100 addresses the Civil Monetary Penalties (CMP) set forth in section 1197 of the SSA (the Program-related CMPs). CMS provided the "procedures" CMS intends to follow to impose these CMPs on manufacturers. We believe that CMS can only implement these CMPs in a manner that conforms to the statute through a notice and comment rulemaking process. Section 1197 authorizes extraordinarily high CMP penalties equal to $100 million for each item of false information and $1 million per day for failing to provide the information required under section 1193(a)(4) warrant notice-and-comment rulemaking prior to Agency implementation.

Due to the complexities and many ambiguities that exist in the program, implementation gaps and shortcomings may cause undue harm to a manufacturer and lead to unfair administration of the determination of a violation and resulting penalties. Thus, a more detailed process is needed.

We believe the rulemaking process should address the following issues:

(1) Scope: Specific identification by CMS of violations that would qualify for a Section 1197 CMP and the amounts that correspond to the specific violation;

(2) Transparency: Detailed procedures for the determination of violations and imposition of the Section 1197 CMPs; and

(3) Review and Appeal Process: Clear process for reviewing and appealing a Section 1197 CMP to provide the manufacturer due process and ensure fairness.

VIII. Part D Formulary Inclusion of Selected Drugs (110)

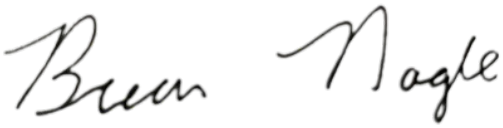
We continue to hear growing concern about patient access to needed medications. The requirement for formulary coverage of selected medications under the statute is important. However, inclusion on a formulary does not necessarily ensure access to the selected medications. This impacts not only the selected medication but also other products in the same therapeutic class that may be considered therapeutic alternatives.

Patients that rely on the Medicare program should have access to appropriate care. The implications of emerging formularies and utilization management should be addressed by CMS. To that end, we strongly recommend CMS strengthen its formulary standards when considering the inclusion of medications on a Part D formulary by a plan and the related access to treatments overall.

# # #

Again, Bayer appreciates the opportunity to offer these recommendations and hopes to continue its engagement with CMS as the program is implemented.

Sincerely,



Brian Nagle
Head of U.S. Federal Government Affairs
Healthcare and Policy
Bayer

BlueCross BlueShield Association

750 9th Street, N.W.
Washington, D.C. 20001
www.bcbs.com

July 2, 2024

Meena Seshamani, M.D., Ph.D
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Dr. Seshamani:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) draft guidance on the Medicare Drug Price Negotiation Program (MDPNP) issued on May 3, 2024.

BCBSA is a national federation of independent, community-based and locally operated BCBS companies (Plans) that collectively cover, serve, and support 1 in 3 Americans in every ZIP code across all 50 states and Puerto Rico. BCBS Plans contract with 96% of hospitals and 95% of doctors across the country and serve those who are covered through Medicare, Medicaid, an employer, or purchase coverage on their own.

BCBSA appreciates CMS publishing revised guidance for Initial Price Applicability Year (IPAY) 2026 and is eager to work with CMS as it implements the MDPNP for IPAY 2027 and effectuates Maximum Fair Prices (MFPs) in 2026 and 2027. We recognize success for this program is dependent on the partnership between CMS, health plans, pharmacies, and other entities in the prescription drug supply chain, and we look forward to supporting this program's launch. We thank CMS for consideration of BCBSA's comments, and we look forward to future collaboration on Inflation Reduction Act (IRA) implementation. We have summarized our detailed comments below.

Detailed Recommendations on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Section 40. Requirements for Manufacturers of Selected Drugs

- *40.4 Providing Access to the MFP in 2026 and 2027.* As described in CMS' draft guidance, drug manufacturers must offer access to the MFP either prospectively or retrospectively. Under prospective effectuation, pharmacies would purchase drugs based on MFP and manage that inventory separately from drugs not sold at the MFP. Pharmacies could also use retrospective effectuation where they would purchase a drug based on Wholesale Acquisition Cost (WAC) and the Medicare Transaction Facilitator (MTF) would be used to ensure that manufacturers pay pharmacies the difference between WAC and MFP. BCBSA appreciates CMS' efforts to provide dispensers access to the MFP through prospective or retrospective effectuation.
    - *Recommendation:* BCBSA recommends CMS provide incentives for prescription drug manufacturers to provide the MFP prospectively to dispensers instead of retrospectively to easily facilitate MFP access and reduce administrative burdens associated with claims processing. Additionally, if CMS opts to finalize its provisions on retrospective effectuation, BCBSA encourages the agency to use a single MTF to ensure efficiency and reduce costs.
- *40.4.1 Medicare Transaction Facilitator Data Facilitation.* Currently, plans must submit Prescription Drug Event (PDE) data within 30 days of dispensing to CMS. However, under CMS' draft guidance, plans would be required to submit PDE to the agency within seven days of dispensing. BCBSA appreciates CMS' work to effectuate MFPs for negotiated drugs but encourages CMS to modify its data submission timeframes.
    - *Recommendation:* BCBSA recommends that CMS revise its guidance to allow plans to submit PDE data to CMS within 14 days of dispensing for selected drugs instead of the proposed seven days. Additionally, the modified PDE data submission timeframe should only apply to claims for selected drugs and all other claims should be subject to the current 30-day timeframe.

Section 110. Part D Formulary Inclusion of Selected Drugs

In its draft guidance, CMS indicates that all dosage forms and strengths of negotiated drugs must be covered on Part D formularies, but Part D sponsors may place them on preferred or non-preferred formulary tiers or impose utilization management practices based on medical appropriateness. CMS also noted that it will perform oversight to ensure beneficiary access to negotiated drugs.

- BCBSA appreciates the consistency from the IPAY 2026 final guidance to the IPAY 2027 draft guidance on the formulary inclusion for selected drugs given the Part D program has not yet had experience with coverage of selected drugs. As noted, a Part D sponsor's pharmacy and therapeutics (P&T) committee will be responsible for evaluating the clinical profile of all drugs, selected and non-selected drugs, using the standards in

place prior to enactment of the IRA, with the statutory requirement to cover all selected drugs on Part D formularies.

- For instances when a Part D sponsor places a selected drug on a non-preferred tier after a recommendation from a P&T committee, an enrollee would still have access to that therapy as a covered drug. Even if there is higher cost-sharing with the selected drug, enrollees would have financial support from the Medicare Prescription Payment Plan, the $2,000 cap on out-of-pocket costs, and other changes to the Part D program that support patient access to selected drugs and all other covered Part D drugs.
    - *Recommendation:* BCBSA supports CMS maintaining the existing Part D formulary review standards that permit "Part D sponsors to use formularies and tiered cost sharing in their benefit design, subject to certain limitations, and requires them to have a cost-effective drug utilization management program that includes incentives to reduce costs when medically appropriate." The current statutory and regulatory structure allows sponsors to rely on an independent P&T committee – a multidisciplinary expert group that is comprised of external doctors, pharmacists, and other health care professionals – to review medications based on current evidence-based medicine and decide which drugs to include on the formulary. The clinicians serving on a P&T committee play a critical role in effective formulary management and provide consistent, uniform, and equitable drug coverage to meet members' clinical needs. The P&T committee structure is well suited for the nuance of drug coverage and tier placement of selected and non-selected drugs alike.

We thank CMS for consideration of our comments, and we look forward to future collaboration on IRA implementation. If you have any questions or want additional information, please contact Paul Eiting at paul.eiting@bcbsa.com.

Sincerely,

Kris Haltmeyer

Vice President, Policy Analysis

Office of Policy & Advocacy

Biotechnology Innovation Organization
1201 New York Avenue NW
Suite 1300
Washington, DC, 20005
202-962-9200

June 28, 2024

VIA ELECTRONIC DELIVERY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

The Biotechnology Innovation Organization (BIO) appreciates this opportunity to comment on the draft guidance regarding the Drug Price Negotiation Program ("DPNP") under the Inflation Reduction Act of 2022 (IRA) issued by the Centers for Medicare & Medicaid Services (CMS or Agency) on May 3, 2024 (Draft Guidance).[1]

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than thirty other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay the onset of such diseases, or prevent them in the first place. As a result, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO's members include biologic and vaccine manufacturers, which have worked closely with stakeholders across the spectrum, including the public health and patient advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

At the outset, we believe it is critical to underscore our views on the IRA. We have long supported a Medicare Part D out-of-pocket cap and the ability for patients to spread these costs throughout the year. We will continue to engage with the Agency on these important patient protections, with the aim of ensuring that the maximum number of Medicare beneficiaries benefit from them. However, patient out-of-pocket burden will never be truly addressed unless the broken rebate system – which fuels high drug spending without passing down savings to patients – is addressed. Pharmacy benefit managers (PBMs) continue to leverage their size and

[1] CMS, "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" (May 3, 2024), *available at* https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

market influence at the expense of vulnerable patients. For instance, it is evident that the DPNP may result in plans and PBMs implementing more restrictive formularies, increased utilization management practices, such as prior authorization and step therapy, and other tactics to delay or deny access to essential treatments. BIO urges CMS to take necessary steps to protect patient access to needed therapies and implement robust monitoring against plan or PBM tactics that may create undue burden on patients. We look forward to continued engagement with you on these critical issues.

In addition, we reiterate our concerns about the significant, negative impacts the DPNP is having on companies' investments in research and development for new treatments and cures, particularly for rare, hard-to-treat disease and conditions with high unmet need. Patients win when a vibrant biopharmaceutical sector is valued and where a range of innovators, from smaller start-ups to more established companies, are encouraged to invest in that next cure or advancement in treatment. Unfortunately, the price controls and other troubling polices included in the IRA are stifling this research and collaboration, putting beneficiary access to future treatments at risk. We continue to urge CMS to put these patient access considerations first and foremost – not only as it works to improve this proposed guidance based on stakeholder feedback – but also in its ongoing implementation of
the DPNP.

Further, we reiterate what BIO and our members have long argued – that the underlying structure of the DPNP, as set forth by the statute and implemented by CMS, is legally flawed. In view of the punishing penalties for non-compliance, and the general inflexibility of the process for product selection and maximum fair price (MFP) determination, these legal flaws cannot be fully overcome through guidance. Notwithstanding the fact that none of these comments can resolve the more fundamental legal infirmities of the overall program, we provide in our comments several suggestions for CMS to consider as it implements this program. This includes ensuring the process for determining the MFP is transparent, predictable, fair, and patient-focused as possible. CMS must provide accountability to stakeholders and better clarify how it will consider and utilize the broad set of information it collects and reviews related to the statutory factors. Further, we continue to urge CMS to use its discretion to emphasize factors that are critical for patients, specifically those related to clinical benefit and unmet medical need and to de-emphasize manufacturer-specific data elements such as cost of production and research and development costs, and to take steps to protect patient access to all medically necessary therapies, including selected drugs.

Finally, it is both in the Agency's interests and the public's interest to ensure that the MFP is effectuated properly. Ensuring consistently proper and timely effectuation of the MFP poses a daunting operational challenge, accordingly, it is essential for CMS to establish a high-functioning MTF that provides for both necessary data exchange and effective and efficient MFP payment facilitation.

Our more detailed comments follow.

<u>Qualifying Single Source Drugs (Section 30.1)</u>: BIO urges CMS to reconsider its approach to identifying a qualifying single source drug and its dosage forms and strengths by reference to common active moiety (drugs) or common active ingredient (biologics), and instead identify such a drug and its dosage forms and strengths by reference to unique New Drug Applications (NDAs) and Biologics License Applications (BLAs).[2]

In the Draft Guidance, CMS proposes that—as it did in the revised guidance for initial price applicability year (IPAY) 2026—it will treat products as the same qualifying single source drug where, for drug products, they share the same active moiety or, for biological products, they share the same active ingredient, and the same manufacturer holds all applicable NDAs or BLAs.[3] This policy is irreconcilable with the statute.

The statute requires products to be treated as the same qualifying single source drugs only where they share the same NDA or BLA. This necessarily follows from the plain text of section 1192(e)(1). The term "qualifying single source drug" is statutorily defined for products approved under an NDA by reference to whether seven years has elapsed since "such approval;"[4] likewise, the term is statutorily defined for products licensed under a BLA by reference to whether eleven years has elapsed since "such licensure."[5]

Congress's use of "such licensure" and "such approval" is intentional and unambiguous and must be given effect. Congress used this language to denote that a qualifying single source drug is determined by reference to a distinct approval or licensure—i.e., a distinct NDA or BLA. CMS has no authority to re-write the plain language of the statute by inventing an ultra vires policy of grouping together drugs based on their active moieties or active ingredients for the purposes of determining qualifying single source drugs. Where "Congress has been unambiguous, neither the Agency nor [a] court may diverge from that intent."[6]

Although the plain language of the statute is dispositive, BIO notes that other canon of statutory construction confirm Congress's unambiguous intent to distinguish qualifying single source drugs based on distinct NDAs or BLAs.[7] Of particular note, the statute defines "qualifying single source drug" by express reference to the Food, Drug, and Cosmetics Act (FDCA) and the Public Health Service Act (PHSA). It is well understood that a statute should be interpreted in the manner "most compatible with the surrounding body of law into which the provision must be integrated."[8]

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[2] For a discussion of the related and equally critical concern with CMS's "bona fide marketing" standard, please see the discussion below.
[3] Draft Guidance at 8.
[4] Social Security Act (SSA) § 1192(e)(1)(A).
[5] *Id.* § 1192(e)(1)(B).
[6] *Cabazon Band of Mission Indians v. Nat'l Indian Gaming Comm'n*, 827 F. Supp. 26, 29 (D.D.C. 1993), *aff'd*, 14 F.3d 633 (D.C. Cir. 1994). In addition, with respect to a Medicare Part D drug, a qualifying single source drug is statutorily limited to a product that is a "covered Part D drug." SSA § 1192(e)(1). In turn, a "covered Part D drug" is statutorily defined in relevant part by cross-reference to section 1927(k)(2). *Id.* § 1860D-2(e)(1). And, like section 1192(e)(1), section 1927(k)(2) distinguishes among products by reference to approvals or licensures. *See also* SSA § 1104 ("The right to alter, amend, or repeal any provision of this Act is hereby reserved to the Congress.").
[7] *See Chevron v. Nat'l Res. Def. Council*, 467 US 837, 843 n.9 (1984) (in addition to the plain text, the traditional tools of statutory construction are used to ascertain the intent of Congress).
[8] *Green v. Bock Laundry Machine Co.*, 490 U.S. 504, 528 (1989) (Scalia, J., concurring); *cf. Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (under the rule of *in pari materia*, it is generally "assume[d] that whenever Congress passes a new statute, it acts aware of all previous statutes on the same subject").

CMS should therefore look to the well-established framework under the FDCA and PHSA for distinguishing among products. Under this framework, drug and biological products generally may be marketed only if approved or licensed by the Food and Drug Administration (FDA),[9] and manufacturers seeking such approvals or licensures must meet stringent requirements bearing on safety, effectiveness, and other considerations.[10] In implementing this framework, FDA has spoken directly to the circumstances under which a change to an existing product is so significant that it yields a new product warranting a new NDA or BLA, as well as the circumstances under which a change to an existing product is not.[11] It is manifestly reasonable and appropriate to rely on such FDA standards here, such that a product approved or licensed under a new NDA or BLA is a distinct qualifying single source drug.

There would be immeasurable benefits to giving effect to the statute as written and, as Congress intended, adopting FDA's application-based framework for distinguishing among products (as opposed to maintaining CMS's wholly invented, statutorily unmoored scheme for doing so). First, and most critically, doing so would avoid exacerbating the disincentive to develop next-generation therapies inherent in the DPNP to the point of suffocating all such innovation, to the detriment of patients in need. The sheer breadth of CMS's "qualifying single source drug" definition—which amalgamates drug products by common active moiety and biological products by common active ingredient—is already negatively impacting real-world drug development compared to the pre-IRA policy landscape. In a recent study published by Avalere, researchers explored six case studies of different products approved for chronic disease, rare disease, or cancer, finding that the risk of selection shifts manufacturer evaluations on whether to continue research and investments into those products.[12] This subsequent shift in investment strategies has significant implications for patient access to new treatments and affects all patient populations, including those with rare, serious conditions and/or unmet need. It is evident that CMS' "qualifying single source drug" definition leaves no incentive for therapeutic advancement and will continue to have significant, negative impacts on innovation for years to come.

Biopharmaceutical innovation is incremental, relying on sustained and continuous improvements to molecules, pathways, and modes of administration to achieve maximum clinical benefit for patients. Researchers cannot take significant leaps and develop new active moieties or active ingredients with each generation of treatment. By combining drugs at the active moiety or active ingredient level, CMS is harming investments into new therapies, including for orphan and other hard-to-treat diseases. For the sake of pharmaceutical and biotechnology innovation, and patient access to needed therapies, CMS's current framework cannot stand.

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[9] 21 U.S.C. § 355(a); 42 U.S.C. § 262(a)(1)(A).

[10] 21 U.S.C. § 355(c), (d); 21 C.F.R. §§ 314.105, 314.125 (NDA requirements); 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. §§ 601.2(a), 601.4(a) (BLA requirements).

[11] FDA, Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), *available at* https://www.fda.gov/media/72397/download. For example, a new active ingredient (e.g., a different salt, ester, or complex of an approved moiety) should be approved under a new application. *Id.* at 3. In contrast, a new strength generally should be approved under a supplement. *Id.* at 4. The same is true for a new container size or package type of the same indication and route of administration. *Id.* Certain changes in dosage form and route of administration should be approved under a supplement, but others should be approved under a new application. *Id.* at 3.

[12] "An Assessment of Regulatory Interpretation of Qualifying Single Source Drugs in Medicare Negotiation." Avalere. April 22, 2024.

Second, an application-based framework would create an easily administrable bright line rule based on a familiar standard, to the benefit of both CMS and manufacturers. A bright line rule would enable CMS to more readily identify relevant dosage forms and strengths for purposes of aggregating Medicare expenditures and applying the MFP.[13] And a bright line rule would enable manufacturers to more confidently track the seven- or eleven-year "qualifying single source drug" clock, and thereby make more informed decisions about research and development.

For these reasons, BIO strenuously disagrees with CMS's approach to identifying a qualifying single source drug by reference to common active moiety (drugs) or common active ingredient (biologics). Both law and policy dictate that a qualifying single source drug be identified by reference to its NDA or BLA.

Notably, it necessarily follows from the identification of a qualifying single source drugs by reference to its NDA or BLA that the dosage forms and strengths of such a drug (across which Medicare expenditures are aggregated and the MFP is applied) also must be identified by reference to the NDA or BLA of the drug. With respect to a qualifying single source drug, the statute requires CMS to aggregate Medicare expenditures "us[ing] data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug."[14] Similarly, with respect to a qualifying single source drug that is a selected drug, the statute requires CMS to "establish[] . . . procedures to compute and apply the maximum fair prices across different strengths and dosage forms of [the] drug and not based on the specific formulation or package size or package type of such drug."[15] Accordingly, Medicare expenditures are to be aggregated, and the MFP is to be applied, across only dosage forms and strengths of the qualifying single source drug. As set forth above, a qualifying single source drug must be identified by reference to its NDA or BLA; it necessarily follows that the dosage forms and strengths of such a drug also must be identified by reference to the NDA or BLA of the drug.[16]

It is imperative that CMS abandon the approach set forth in the Draft Guidance—under which Medicare expenditures are aggregated, and the MFP is applied, across dosage forms and strengths of products that share the same active moiety (drugs) or the same active ingredient (biologics)—and instead specify that, for purposes of aggregation of Medicare expenditures and application of the MFP, dosage forms and strengths are also identified by reference to the NDA or BLA of the qualifying single source drug, consistent with the requirements of the statute.[17]

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[13] *See* SSA §§ 1192(d)(3)(B), 1196(a)(2).
[14] *Id.* § 1192(d)(3)(B).
[15] *Id.* § 1196(a)(2).
[16] The references to "formulations" in the statutory text do not change the analysis. In context, such formulations are plainly limited to formulations of the dosage forms and strengths of the qualifying single source drug. *See, e.g.,* A. Scalia & B. Garner, *Reading law: The interpretation of Legal texts* 199, 203-132–33 (2012) ("[T]he verb to include introduces examples, not an exhaustive list."). We note that formulations of dosage forms and strengths may be approved under the same NDA or BLA. *See* FDA, Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees 3–4.
[17] Regardless of the "qualifying single source drug" definition adopted by the Agency, CMS must consistently apply such definition. As such, if CMS were to maintain that products that share the same active moiety (drugs) or the same active ingredient (biologics) are the same qualifying single source drug, BIO agrees that the market entry of a generic or biosimilar to any such product would disqualify all such products from treatment as a qualifying single source drug. *See* Initial Guidance at 10. Any other approach would be irreconcilable with CMS's stated "qualifying single source drug" definition. *See, e.g.*, *Nat'l Credit Union Admin. v. First Nat. Bank & Tr. Co.*, 522 U.S. 479, 501–02 (1998) (a basic canon of interpretation is that similar or identical language "be accorded a consistent meaning").

<u>Orphan Drug Exclusion (Section 30.1.1)</u>: BIO urges CMS to clarify the scope of the orphan drug exclusion in a manner that maximizes protections for orphan drugs. **Specifically, CMS should clarify that, where an orphan drug loses eligibility for the orphan drug exclusion, the seven- or eleven-year "qualifying single source drug" clock runs from *the date on which the drug lost eligibility for the exclusion*. CMS should also enable manufacturers to submit evidence that an indication aligns with an orphan drug designation to account for situations where CMS is unable to determine eligibility for the orphan drug exclusion based on a review of FDA's orphan drug databases**.

Clarifying that the seven- or eleven-year clock starts on the date a drug loses eligibility for the orphan exclusion would help maximize protection for orphan drugs. Absent such clarification, an orphan drug that loses eligibility for the orphan drug exclusion could be virtually immediately subject to selection for negotiation, simply because it was designated as an orphan drug for a second rare disease or condition or because an indication was approved for a second rare disease or condition. CMS's implementation of the orphan drug exclusion would thereby disincentivize progress in rare disease drug development, which is often predicated upon identification of promising new uses of existing therapies. CMS should act to avoid such a result, as it would further disincentivize developers of orphan drugs from investing in treatments for a second rare disease. It would also circumvent the clear intent of Congress, which established the orphan drug exclusion as an exception to the QSSD definition. Accordingly, our interpretation of the statute is that, for so long as a drug qualifies for the orphan drug exclusion, the product is entirely exempt from the QSSD definition and all of its sub-elements. Thus, the 7- or 11-year "pre-negotiation" period that would otherwise apply to a QSSD is tolled until the first day after the orphan drug no longer qualifies for the orphan drug exclusion.[18] Any other interpretation would contradict the intent of excluding eligible drugs from the QSSD definition and negatively impact on drug development decisions for rare disease treatments.

In addition, CMS should create a process that enables manufacturer to provide evidence that an indication falls within an orphan drug designation, where such fact is not ascertainable from FDA databases alone. In many cases, CMS will be able to readily determine whether a drug meets such criteria using publicly available information. This is because FDA maintains various databases containing relevant information.[19] But there are situations where an approved indication falls within the scope of an orphan drug designation but there is no corresponding grant of orphan exclusivity.[20] In such situations, CMS cannot rely on FDA's databases, because those databases principally track orphan exclusivity, rather than orphan drug designation.[21] CMS has stated it will "consult with" FDA as needed; but we believe such discretionary consultation is insufficient. In particular, CMS should clarify that acceptable evidence that an indication falls within an orphan drug designation could include written communication with FDA, whether pre- or post-approval and other sources of data provided by the manufacturer.

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[18] See SSA § 1192(e)(3)(A) ("Exclusions.—In this part, the term [QSSD] does not include any of the following…(A) Certain Orphan Drugs.")

[19] Such databases include FDA's orphan drug designation/exclusivity database, the drugs@FDA database, and the Approved Drug Products with Therapeutic Equivalence Evaluations publication (Orange Book).

[20] There are various circumstances where this can arise. For instance, it can occur in certain circumstances where an orphan drug is approved for the same indication as a previously approved drug, but is not clinically superior to the previously approved drug. In such circumstances, although the indication falls within the scope of the orphan designation, it does not qualify for orphan exclusivity.

[21] Orphan exclusivity is, in itself, irrelevant for purposes of the orphan drug exclusion. The orphan drug exclusion is unambiguously based on whether all indications of a drug with a single orphan drug designation fall within the scope of that designation. It is therefore immaterial whether the drug also has (or had) orphan exclusivity.

Implementing the above recommendations is necessary to mitigate the risk that the DPNP will deter the development of orphan drugs to treat those suffering from rare diseases. It is also fully consistent with long-standing Congressional policy favoring protection of orphan drugs. Such policy dates back to the early 1980s, when Congress enacted the Orphan Drug Act of 1983 to create various incentives to encourage and facilitate the development of new orphan drugs.[22] In keeping with Congress's long-held policy of protecting orphan drugs, CMS should make every effort to ensure that it does not hamper orphan drug innovation as it implements the DPNP and its orphan drug exclusion.

By definition, orphan drugs target diseases affecting less than 200,000 people in the United States.[23] As such, such drugs are particularly susceptible to the chilling effect of factors that discourage research and development. On average, the development of a single drug takes anywhere from ten to fifteen years and costs upwards of $2.6 billion in research and development[24]—and the development of an orphan drug, often takes even longer and costs even more. Limited patient populations make it inherently more challenging for the developers of orphan drugs to recoup this investment, especially because orphan drug developers are overwhelmingly small emerging companies: Start-ups and emerging biotechnology companies are responsible for fully 85% of all orphan-designated products in development.[25]

It is vitally important that CMS take special steps to protect development of and access to orphan drugs. The stakes could not be higher for patients. There are over 10,000 known rare diseases, and approximately thirty new ones are identified each year.[26] While each rare disease affects only a relatively small number of patients, collectively, over thirty million Americans are affected by a rare disease, with an estimated cost to society in excess of $1 trillion annually.[27] Further, 95% of rare diseases currently have no approved medical treatment.[28] According to a 2020 IQVIA/National Organization for Rare Diseases report examining trends in rare disease innovation, "there are [only] 447 drugs with orphan-only indications, with 104 drugs approved for two or more orphan indications."[29] As such, there is a pressing need to maintain strong incentives for continuing orphan drug development.

Small Biotech Exception (Section 30.2.1): BIO continues to urge CMS to establish a dispute resolution process in implementing the small biotech exception.

We appreciate the ongoing engagement with the Agency regarding the process for applying for and receiving the small biotech exception. This exception provides critical protection and recognizes that small biotech manufacturers with a single product that represents much of their

[22] *See* Orphan Drug Act, Pub. L. No. 97-414, §§ 1, 2, 96 Stat. 2049, 2049–51 (1983), *as amended by* Pub. L. 98-551, 98 Stat. 2815, 2817 (1984).
[23] 21 C.F.R. § 316.10(d)(8)(ii).
[24] T. Sullivan, A Tough Road: Cost to Develop One New Drug Is $2.6 Billion, Policy & Med., https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html (Mar. 21 2019).
[25] D. Thomas & C. Wessel, *2019 Emerging Therapeutic Company Trend Report, BIO Industry Analysis* 40 (2019), *available at* http://go.bio.org/rs/490-EHZ-999/images/BIO%202019%20Emerging%20Company%20Trend%20Report.pdf.
[26] Smith CIE, Bergman P, Hagey DW. Estimating the number of diseases - the concept of rare, ultra-rare, and hyper-rare. iScience. 2022 Jul 1;25(8):104698.
[27] S. Garrison, et al., *The Economic Burden of Rare Diseases: Quantifying the Sizeable Collective Burden and Offering Solutions*, Health Affairs Forefront, https://www.healthaffairs.org/do/10.1377/forefront.20220128.987667/ (Feb. 1, 2022).
[28] Nat'l Insts. of Health, *Delivering Hope for Rare Diseases* 1 (Jan. 2022), *available at* https://ncats.nih.gov/files/NCATS_RareDiseasesFactSheet.pdf.
[29] IQVIA, *Orphan Drugs in the United States* 7 (Dec. 2020), *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-rare-disease-innovation-and-cost-trends-through-2019/orphan-drugs-in-the-united-states.pdf.

Medicare revenue would be disproportionately impacted by the DPNP, which could have an immediate impact on the ability of such manufacturers to invest in future research and development—in particular, in areas that predominantly affect the Medicare population.

We continue to urge the Agency to establish a dispute resolution process where a manufacturer can respond to and appeal a negative determination by CMS—similar to the process that has been instituted for the specified small manufacturer phase-in under the Medicare Part D benefit redesign. Specifically, the small biotech manufacturer should have the opportunity to provide additional data or other information to the Agency to support its application for the small biotech exception.

We also recommend CMS initiate the small biotech exception ICR process earlier in the year, to allow sufficient time for a dispute resolution process to conclude *prior* to the February 1 deadline for CMS to select drugs for negotiation. Per the Draft Guidance, small biotech exception eligibility determinations are rendered after publication of the selected drug list. Initiating the small biotech exception process earlier would allow sufficient time for a robust dispute resolution process. And we note that such an approach is consistent with the flexibilities afforded under the revised Part D Manufacturer Discount DPNP, where CMS provided an opportunity for manufacturers to obtain a preliminary determination regarding their eligibility for phased-in discounts as specified manufacturer or small specified manufacturer.

We also continue to urge CMS to be flexible in its implementation of the exception, particularly given the small number of companies that are eligible for the exception. For example, if CMS determines that information submitted by the small biotech manufacturer is incomplete or unclear, we urge CMS to engage in a dialogue with the manufacturer to resolve any outstanding issues. We appreciate the Agency's consideration of these recommendations, which would help mitigate uncertainty for small biotech companies.

Selection of Drugs for IPAY 2027 (Section 30.3): BIO continues to recommend that, well in advance of the selected drug publication date, CMS should notify each manufacturer of each drug that it intends to select for the DPNP and afford each such manufacturer a reasonable opportunity to dispute the propriety of each such intended selection.

The process for selecting a drug for the DPNP is complex. Eligibility for selection is based on multiple factors, including whether a sufficient number of years have elapsed since approval or licensure;[30] whether a generic or biosimilar has come to market;[31] whether the drug is eligible for the orphan drug exclusion;[32] whether the drug is a plasma-derived product;[33] whether the drug is a small biotech drug;[34] whether Medicare expenditures are sufficiently low to disqualify the drug from selection;[35] and whether Medicare expenditures are sufficiently high to qualify the drug for selection.[36] Manufacturers of selected drugs are also required to generate a significant amount of information in a short period of time.

[30] SSA § 1192(e)(1).
[31] *Id.*
[32] *Id.* § 1192(e)(3)(A).
[33] *Id.* § 1192(e)(3)(C).
[34] *Id.* § 1192(d)(2).
[35] *Id.* § 1192(e)(3)(B).
[36] *Id.* § 1192(d)(1).

The intricate nature of the selection process presents an inherent risk of a selection error. Notably, if a selection error were identified after the selected drug publication date, CMS would de-select the erroneously selected drug but could not select a substitute. By statute, for a given IPAY, starting with IPAY 2027, all drugs must be selected by February 1 of the year that is two years before the IPAY.[37]

CMS can readily mitigate this concern by adopting a process for soliciting feedback from manufacturers of potential selected drugs before the selected drug publication date. Specifically, CMS should make Medicare expenditure data publicly available for the selection years. CMS should then provide notice to each such manufacturer at least thirty days in advance of the selected drug publication date. CMS should afford the manufacturer at least fourteen days to identify to the Agency any basis on which the manufacturer believes the drug is not, in fact, eligible for selection. Such a pre-selection process would serve an important role in identifying selection errors and further the Agency's interests in transparency, efficiency, and informed decision-making.

In addition to providing advance notice to each manufacturer of a drug that the Agency intends to select, CMS should provide advance notice to each manufacturer of at least each of the next five drugs that would be selected if one or more drugs that the Agency intends to select were found to be ineligible for selection. Doing so would promote efficiency by giving each such manufacturer the same opportunity to engage with the Agency regarding potential selection errors. And doing so would impose no additional burden on the Agency because CMS is already required to identify the top fifty qualifying single source drugs by Part D expenditures and, starting with IPAY 2028, the top fifty qualifying single source drugs by Part B expenditures.[38]

In addition, in advance of the deadline by which a biosimilar manufacturer must request a delay in the selection of a reference biologic for negotiation, CMS should enable such biosimilar manufacturer to ascertain whether the reference biologic is among the drugs that the Agency intends to select (or one of at least the next five drugs in line for selection). This would reduce the burden on biosimilar manufacturers as well as the Agency by eliminating the submission of biosimilar delay applications that prove to be unnecessary.

<u>Delayed Selection and Anticipated Biosimilar Entry (Sec. 30.3.1)</u>: BIO makes a number of recommendations to enhance the implementation of the process by which a biosimilar manufacturer may request a delay in the selection of a reference product for negotiation, including requirements for meeting the "high likelihood" determination for the first year of a delay request.

With respect to the timing of a delay request, under the Draft Guidance, CMS notes that it expects an Initial Delay Request to be submitted to CMS by "mid-December 2024," in advance of the February 1, 2025 selected drug publication date.[39] CMS also states that it intends to permit a biosimilar manufacturer to update the Agency on the status on its FDA application for licensure through January 15, 2025.

[37] *Id.* §§ 1192(e), 1192(a); *see also id.* § 1191(d)(1) (September 1, 2023, for IPAY 2026).
[38] *See id.* § 1192(d)(1).
[39] Draft Guidance at 17.

An accurate "high likelihood" determination reduces administrative burden. If CMS makes an erroneous determination based on outdated or incomplete information, the Agency will be required to administer the payment of a rebate by the reference biologic manufacturer. To ensure that CMS adjudicates a delay request based on the most mature information possible, for the first year of a delay request, CMS should (1) set the delay request submission deadline as close as reasonably possible to the selected drug publication date and (2) permit broad supplementation of a timely request with late-breaking information or otherwise for good cause. Information bearing on the expected timing of licensure and marketing often rapidly changes. The expected timing of market entry can fluctuate based on a range of factors, including FDA communications regarding the BLA and changes to the manufacturer's production or distribution arrangements. In order for CMS to make an informed determination regarding eligibility for delayed selection, it is vitally important that the Agency rely on the most recently available information that bears on the likelihood of market entry within the requisite time period.

In addition, CMS should provide notice of its delay request determination in advance of the selected drug publication date and establish a dispute resolution process. Under the Draft Guidance, CMS will not inform a biosimilar manufacturer of an unsuccessful delay request until after the selected drug publication date.[40] This effectively means that the biosimilar manufacturer will have no opportunity to dispute the determination. The Agency instead should provide preliminary notice of an unsuccessful delay request in advance of the selected drug publication date and establish a process by which the biosimilar manufacturer can dispute an erroneous determination. The Agency should also inform the reference manufacturer that a biosimilar pause review has been triggered. BIO recommends that CMS provide both notices at least fourteen days in advance of the selected drug publication date and afford the biosimilar manufacturer at least seven days to dispute the determination.

CMS should also accept and consider all information that the biosimilar manufacturer determines relevant to determining eligibility for delayed selection.[41] As noted above, there are countless factors that can affect the expected timing of licensure. It follows that CMS should not artificially limit the information that it considers in determining eligibility for delayed selection. Accordingly, it is vital that CMS enable the biosimilar manufacturer—the party closest to the information—to submit all information that it determines relevant to the initial year delay request.

There is clear statutory authority to enable the biosimilar manufacturer to submit such information. The statute provides that the biosimilar manufacturer must submit "information and documents necessary for [CMS] to make [the delayed selection determination], as specified by [CMS] . . . ."[42] In addition, the statute provides that, after CMS has reviewed the delay request, the biosimilar manufacturer must submit "any additional information and documents requested by [CMS] necessary to make [the delayed selection determination]."[43] CMS therefore has discretion to consider a broad range of information in support of the initial year delay request.

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[40] *Id.* at 24.

[41] *See* SSA § 1192(f)(1)(B)(ii)(I)(aa) ("information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary"), (II) ("additional information and documents requested by the Secretary necessary to make determinations under this subsection").

[42] SSA § 1192(f)(1)(B)(ii)(II). The statute goes on to specify that such information "includ[es]" the information specified in section 1192(f)(1)(B)(ii)(III). *Id.*

[43] *Id.* § 1192(f)(1)(B)(ii)(II).

The Agency should exercise such discretion and request submission of all relevant information as determined by the biosimilar manufacturer. Doing so would help ensure that CMS has the most pertinent information, as the biosimilar manufacturer is the entity best situated to identify the information that bears on the initial year delay request.

Notably, CMS also has clear legal authority to consider all such information submitted in the request in making a "high likelihood" determination. Section 1192(f)(3) sets forth a set of circumstances under which CMS must find a high likelihood of timely market entry—based on a limited set of enumerated information and documents, including information and documents described in section 1192(f)(1)(B)(ii)(III) (subclause (III)).[44] Critically, section 1192(f)(3) cannot be interpreted to set forth the only set of circumstances under which CMS may find a high likelihood of timely market entry. The broader structure of section 1192(f) makes clear that Congress intended that the full range of relevant information and documents be considered by CMS, not only the limited set of information and documents enumerated in section 1192(f)(3). This is because section 1192(f)(1)(B)(ii)(I)(aa) (subclause (I)(aa)) clearly requires the biosimilar manufacturer to submit information and documents necessary to rendering the "high likelihood" determination—"includ[ing]" (but not limited to) the information and documents described in subclause (III).

The necessary implication is that there is information and documents—beyond the information and documents described in subclause (III)—which are also "necessary" to rendering the "high likelihood" determination in the initial year request. While the information and documents described in subclause (III) are accounted for in section 1192(f)(3), the remaining information and documents described in subclause (I)(aa) are not—despite being "necessary" to rendering the "high likelihood" determination. Thus, if section 1192(f)(3) were the only set of circumstances under which CMS may find a high likelihood of timely market entry, the language in subclause (I)(aa) requiring broad submission of pertinent information and documents beyond those in subclause (III) would be rendered a nullity.[45] Because the information and documents described in subclause (I)(aa) serve no other statutory purpose, the only way to give meaning to the entirety of subclause (I)(aa) is to assign it its most natural meaning: Information and documents described in subclause (I)(aa) are "necessary" to rendering the "high likelihood" determination and, thus, CMS may consider all such information and documents submitted in rendering such determination. Accordingly, section 1192(f)(3) does not set forth the set forth the only set of circumstances under which CMS may find a high likelihood of timely market entry.

There is every reason to think that Congress intended for CMS to consider all relevant evidence in rendering the "high likelihood" determination. Any other interpretation of the statute would yield an absurd result. Through subclause (I)(aa), Congress clearly granted CMS broad discretion to consider information and documents "necessary" to rendering the determination. If CMS were to refuse to consider such information, it would be tantamount to the Agency acknowledging that it is rendering the determination without considering information and documents that the Agency itself has concluded is essential to doing so. It is hard to imagine more arbitrary and capricious governmental decision-making.[46] Accordingly, CMS should

[44] *Id.* § 1192(f)(3).
[45] *See Duncan v. Walker*, 533 U.S. 167, 175 (2001) (a statute is not to be interpreted in a manner that renders any provision a nullity or otherwise meaningless).
[46] *See* 5 U.S.C. § 706(2)(A).

request all information that a biosimilar manufacturer concludes supports a "high likelihood" determination and consider all such information in rendering such determination.

And as we noted in previous comments on the Initial Guidance for IPAY 2026, we appreciate CMS's confirmation that an agreement between a biosimilar manufacturer and a reference biologic manufacturer that permits the biosimilar manufacturer to market the biosimilar is not necessarily an agreement that incentivizes the biosimilar manufacturer to request a delay. But we ask for clarification on the circumstances under which CMS will find a disqualifying agreement to exist. BIO recommends that an agreement should only be disqualifying when it explicitly requires submission of a delay request.

We also request that CMS consider outlining in the final IPAY 2027 guidance any standards the agency is considering for second year delay requests. Such information is critical so that biosimilar manufacturers can plan for future delay requests. As a threshold matter, we encourage CMS to consider how to reduce burden on biosimilar manufacturers by only requiring submissions when new information or evidence is available. Further, there are instances that CMS should recognize that presumptively support the clear and convincing evidence standard for a second year of delay. For example, CMS could make a determination that a biosimilar manufacturer that meets the following requirements satisfies the test for a second year of delay. Specifically, if the BLA for the biosimilar was pending review during the first year of delay, any of the following could suffice:

- FDA has since approved the BLA for the biosimilar; *or*
- The first cycle of review remains ongoing, i.e., FDA's BsUFA date has not yet occurred; *or*
- FDA has issued a complete response letter to the biosimilar manufacturer denying the BLA for the biosimilar but, as of the time CMS is assessing eligibility for a second year of delay, the biosimilar manufacturer has resubmitted the BLA for the biosimilar; *or*
- The biosimilar manufacturer's disclosures to investors or filings with SEC, such as Forms 10-K or 10-Q, indicate that it plans to market the biosimilar within the requisite time frame; *or*
- The manufacturing schedule for the biosimilar submitted to FDA indicates that commercial lots of the biosimilar are expected to be produced within the requisite time frame; *or*
- Agreements filed with FTC or DOJ do not bar the biosimilar manufacturer from marketing the biosimilar within the requisite time frame.

<u>Confidentiality and Data Use (Sections 40.2.1 and 40.2.2):</u> BIO acknowledges CMS's stated confidentiality policy but recommends that CMS establish more fulsome safeguards to ensure that the Agency is adequately protecting the confidentiality of all proprietary information submitted to CMS under the DPNP. CMS should also establish a process to enable manufacturers to review a draft of the explanation of the MFP in advance of its publication and raise concerns about disclosure of confidential information.

The statute imposes a clear confidentiality requirement: "Information submitted to . . . [CMS] . . . by a manufacturer of a selected drug that is proprietary information of such manufacturer (as

determined by . . . [CMS]) shall be used only by . . . [CMS] or disclosed to and used by the Comptroller General of the United States for purposes of carrying out [the DPNP]."[47] Congress imposed this confidentiality requirement for good reason. The statute mandates that manufacturers of selected drugs submit highly sensitive information—including, among other things, information regarding Non-Federal Average Manufacturer Price (Non-FAMP), research and development costs, production and distribution costs, and revenue and sales volume data.[48] It would be deeply disruptive to commercial markets if such proprietary information were disclosed or used in violation of the confidentiality requirement. Indeed, the Draft Guidance acknowledges the "highly sensitive" nature of information to be submitted under the DPNP.[49] In principle, BIO is encouraged that CMS continues to state that it "will implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, including Exemptions 3 and/or 4 of [the Freedom of Information Act (FOIA)]."[50] That said, we continue to believe there is a pressing need for more detailed specification as to how the Agency will safeguard confidential commercial information to ensure that the statute's robust confidentiality requirement is fully honored.

BIO therefore asks CMS to more fully specify the controls and safeguards that it will implement. We urge CMS to ensure that such controls and safeguards maximize the protection of confidential commercial information to be submitted under the DPNP. This would be fully consistent with the approach taken in other areas of federal law and policy, which have long given special consideration to such highly sensitive information. For nearly forty years, the Supreme Court has made clear that commercial trade secrets are a "property right [] protected by the Taking Clause of the Fifth Amendment."[51] Likewise, Congress has repeatedly made clear its expectation that commercially sensitive information be appropriately safeguarded. For example, even beyond FOIA's long-standing protection of "trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential,"[52] the Defend Trade Secrets Act prohibits the "misappropriation" of trade secrets through public disclosure and established a private cause of action to enable affected parties to sanction such misappropriation.[53]

We also request that CMS confirm that it will ensure protections comparable to, not only those under FOIA, but also those under government price reporting law and policy. In developing the DPNP, Congress did not intend to disrupt the confidentiality requirements under other federal law and policy.[54] CMS's confidentiality policy should thus maintain the confidentiality of information protected against disclosure under all other federal law and policy. For example, under the Medicaid Drug Rebate Program (MDRP), "information disclosed by manufacturers . . . under [MDRP] . . . is confidential and shall not be disclosed by [CMS] . . . in a form which discloses the identity of a specific manufacturer . . . [or] prices charged for drugs by such manufacturer . . . ."[55] Similarly, Medicare Act provides that "[Average Sales Price (ASP)]

[47] SSA § 1193(c).
[48] *Id.* §§ 1193(a)(4), 1194(e)(1).
[49] Draft Guidance at 33.
[50] *Id.*
[51] *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1004 (1984).
[52] 5 U.S.C § 552(b)(4); 45 C.F.R. § 5.31(d).
[53] 18 U.S.C. § 1839(5)(B)(ii)(II).
[54] *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 662 2d 467 (2007) ("[R]epeals by implication are not favored" and will not be presumed unless the "intention of the legislature to repeal [is] clear and manifest.").
[55] SSA § 1927(b)(3)(D) (subject to certain limited exceptions).

information disclosed by manufacturers . . . is confidential and shall not be disclosed by [CMS] in a form which discloses the identity of a specific manufacturer . . . or prices charged for drugs or biologicals by such manufacturer . . . ."[56] Likewise, the 340B Drug Pricing Program (340B Program) generally prohibits disclosures of information submitted by manufacturers under the program.[57] Where confidential commercial information is protected against disclosure under these or any other federal programs, CMS should safeguard such information against disclosure to at least the same extent.

In addition, CMS should implement robust storage and access controls and safeguards to protect the confidentiality of sensitive information. Confidentiality requirements are only as meaningful as the data privacy and security protections that are implemented to safeguard sensitive information against inadvertent or malicious[58] improper disclosure. Accordingly, CMS should implement robust systems and protocols, including by ensuring that all proprietary information stored in the Health Plan Management System (HPMS) and in electronic communications with the Agency is secure and accessible only to CMS staff and only where there is a legitimate programmatic need for access to such information.

In doing so, CMS should look to the safeguards it has already established under MDRP. Under MDRP, CMS has implemented a system with numerous privacy and security protections to safeguard sensitive product and pricing data submitted by manufacturers. For example, the online interface allows a manufacturer to view its pricing data, such as its Baseline Average Manufacturer Price (AMP) data, while disallowing states, which do not have a programmatic need to view such information, from doing likewise.[59] CMS should ensure that similar controls are in place with respect to HPMS, given CMS's use of that system.

CMS should also specify how it will maintain the confidentiality of the subset of information that is required to be submitted via e-mail or Box. With respect to e-mail, CMS should explain, among other things, how it will enforce access security controls. With regard to Box (a third-party commercial platform), BIO asks CMS to specify how submitted information will be kept confidential, including as against misuse by Box personnel.

Finally, CMS should establish a process to enable manufacturers to review a draft of the explanation of the MFP in advance of its publication and raise concerns about disclosure of confidential information. By statute, CMS is required to publish an explanation of the MFP.[60] Such publication inherently poses heightened risk of disclosure of confidential commercial information. BIO appreciates that CMS intends to make only high-level comments regarding submitted data and refrain from sharing proprietary information.[61] But this is insufficient to safeguard against inadvertent disclosure of confidential commercial information. Accordingly, BIO asks that the manufacturer be given an opportunity to review the intended explanation in advance of publication, as well as an opportunity to raise concerns. Such precaution is well

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[56] *Id.* § 1847A(f)(2)(D) (subject to certain limited exceptions).
[57] Health Res. & Servs. Admin., General Instructions for Completing the Pharmaceutical Pricing Agreement 7 (2019), *available a*t www.hrsa.gov/sites/default/files/hrsa/opa/pharmaceutical-pricing-agreement-example.pdf.
[58] Malicious third-party cyber activities have increasingly targeted the federal government—in, part, because its databases are repositories of significant amounts of sensitive information. *Cf.* David E. Sanger, *Russian Hackers Broke into Federal Agencies, U.S. Officials Suspect*, N.Y. Times, https://www.nytimes.com/2020/12/13/us/politics/russian-hackers-us-government-treasury-commerce.html.
[59] CMS, *Medicaid Drug Programs User Manual* 1 (Nov. 3, 2021).
[60] SSA § 1195(a)(2).
[61] Draft Guidance at 33.

warranted here, given Congress's special emphasis on the need for safeguards with respect to the public explanation of the MFP, as evidenced by its specific cross-reference to the statute's confidentiality requirement.[62] Further, the explanation of the MFP at a high level is appropriate as it should not be used, for example, as medical guidance for practitioners or beneficiaries.

DPNP Factors (Section 50) and Process (Section 60): As set forth in previous comments to the Agency, BIO strongly urges CMS to emphasize factors that are most important to patients—those related to clinical value and unmet need—and to de-emphasize manufacturer-specific data elements such as cost of production and research and development costs. Further, CMS must clarify how it will evaluate the evidence it receives from stakeholders and how such evidence will be considered in identifying therapeutic alternatives and setting the MFP. BIO also urges CMS to ensure that the process for determining the MFP is predictable, transparent, and allows for meaningful engagement and dialogue with manufacturers and other key stakeholders, particularly the patient community.

We understand that the IRA requires CMS to consider factors under both section 1194(e)(1) and section 1194(e)(2) but it does not specify how CMS should weigh the factors. We continue to recommend that CMS de-emphasize the manufacturer-specific data under section 1194(e)(1) and focus on the factors that matter most to patients—those that are focused on clinical value and unmet need. In addition, we ask that CMS expressly allow manufacturers to use reasonable assumptions (with accompanying justifications) regarding the manufacturer-specific data that they submit. We understand that CMS intends to improve upon the collection process, question format, and content received through the "Negotiation Data Elements and Drug Price Negotiation Process Information Collection Request (ICR)" for IPAY 2027 that CMS intends to release for comment in summer 2024. We appreciate CMS' commitment to improve upon the data collection process for all stakeholders and look forward to providing more detailed comments as part of the ICR process; we also refer CMS to our previous comments on the IPAY 2026 initial guidance and ICR for IPAY 2026.

CMS should expand its definition for unmet medical needs to include both clinical and non-clinical benefits to better encompass patient, caregiver, and society value. For instance, it is important that CMS considers a patient and caregiver's mental and social well-being, improvement or maintenance of quality of life, improvements in clinical/disease outcomes, sustainable costs for patients, including both cost of treatment and cost of ancillary services, and other measurements of value. CMS should also consider and prioritize high quality, robust real-world evidence (RWE), evidence provided by clinicians with the necessary expertise, as well as evidence submitted by manufacturers—which have a vast depth and breadth of clinical and scientific expertise regarding their marketed therapies.

It is equally critical that CMS is transparent in its approach in determining therapeutic alternatives to selected drugs, including by (1) providing to the manufacturer of the selected drug a written justification of such determination that shows that the determination was primarily driven by clinical guidelines and patient need as opposed to cost, (2) allowing the manufacturer a meaningful opportunity to object to such determination, including by submitting data and other

[62] SSA § 1195(a)(2); *see also id.* § 1193(c).

information in support of such objection, and (3) meaningfully considering any such objection before making a final determination. And, we also note that regarding the development of the initial offer, we strongly disagree with CMS' proposal to consider total gross covered drug costs (TGCDC) *net of Coverage Gap Discount Program (CGDP) payments* when identifying the prices of therapeutic alternatives.[63]

CMS should also be transparent and provide sufficient detail regarding how evidence was used to inform the identification of therapeutic alternatives for a selected drug, as well as the establishment of the starting point, preliminary price, the initial offer, and the response to any counteroffer, including what evidence was most impactful in CMS's analysis and why. It is important that the development of the initial offer and CMS's review of evidence should be patient-centered and focus on health equity and reducing disparities. To that end, we strongly support CMS's confirmation that evidence that uses discriminatory considerations such as quality-adjusted life years (QALYs) will not be considered. We note that other measures that have often been promoted as alternatives to QALYs—such as the Equal Value of Life Years Gained (evLYG)—are also problematic as they limit the value of interventions that both extend life and improve the quality of life—and CMS should similarly reject them. In reviewing the evidence, CMS should recognize both the current and future value of therapies and remain flexible to keep pace with innovations in science and technology. Further, evidence regarding a therapy should be viewed in the context of its benefits to the Medicare program, as well as the overall health care system.

We ask that CMS provide manufacturers with robust detail regarding its analysis of evidence throughout the process and provide manufacturers with opportunities for discussion and dialogue. CMS should also provide a line of sight into its assessment of the evidence for the broader stakeholder community, so as to ensure appropriate transparency and accountability not just to manufacturers but also to Medicare beneficiaries, providers, and other key stakeholders.

It is vital that, in setting the MFP, CMS impose on itself bright-line limitations that mitigate the negative effects of the DPNP and the MFP on patient access and on therapeutic innovation. Setting higher MFPs for products that have advanced patient care and address unmet medical need will help maintain investment in assets and clinical programs that show scientific promise and address needs not served by current therapies. BIO asks CMS to commit to a policy where it will not set the MFP below a price shown to imperil patient access (or below the MFP ceiling, if higher than such price). This should include, for example, not setting the MFP below the ceiling price until thirteen years post FDA-approval for small molecule drugs; during any year of the price applicability period into which patent protection extends; and for any vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC).

[63] From the Initial Guidance: CMS indicates that, in identifying the prices of therapeutic alternatives for purposes of developing the initial offer, it will use "*the lower of Part D total gross covered drug cost (TGCDC) net of DIR and [Coverage Gap Discount Program (CGDP)] payments . . . for the therapeutic alternative(s),* and/or the Average Sales Price (ASP) for the therapeutic alternative(s) that is covered under Part B, or the MFP for initial price applicability year 2026 selected drugs that are therapeutic alternatives to determine a starting point for developing an initial offer . . . ." (emphasis added).

Further, CMS should allow for meaningful engagement between CMS and manufacturers for purposes of setting the MFP. BIO continues to be concerned that the Agency is arbitrarily limiting the number of meetings – specifically proposing to reduce the number of meetings. BIO does not support CMS' suggestion to further reduce the number of meetings for IPAY 2027. Instead, BIO encourages CMS to (1) enable real dialogue between the parties throughout the process and (2) specify that, where CMS rejects a counteroffer, additional meetings, beyond those contemplated by CMS, may be held without limit where both parties agree to them. In addition, the manufacturer should more generally be permitted to supplement its timely submission where a post-submission development arises or there otherwise is good cause. The statute generally requires the manufacturer to submit specified information by March 1 of the year that is two years before the applicable IPAY. Inevitably, there will be situations where information relevant to the process arises after the submission deadline has passed. Such late-breaking developments will often be completely unforeseeable at the time of submission but highly relevant to the setting of the MFP. The potential scenarios are virtually limitless: For example, new therapeutic alternatives may come to market; production costs may shift due to ingredient shortages or supply chain issues; or new comparative effectiveness studies may become available. Ultimately, more liberally permitting the manufacturer to supplement its timely submission where there is good cause will help ensure that the MFP is set based on the best available information.

CMS should also provide a *meaningful* justification of its initial offer and its response to any counteroffer and afford the manufacturer a meaningful opportunity to comment on the response once the MFP is set. As noted above, Congress intended for the MFP to be set via "negotiation," meaning a bilateral "discussion or process of treaty" between the parties "aimed at reaching an agreement about a particular issue."[64] Open dialogue is vital and critical to CMS' ability to determine the MFP in a manner that reflects the statutory DPNP factors, as required by law. To this end, BIO asks CMS to specify that its initial offers and its responses to any counteroffers include *meaningful* explanations of how the Agency arrived at the offer or response, including by explaining how the offer or response is supported by the statutorily enumerated factors and any other information upon which the Agency relied, and how the Agency considered and weighted such factors and information.

We also strongly support CMS's efforts to improve upon the patient-focused listening sessions that were held for IPAY 2026. It is essential that policymakers prioritize understanding patient needs and perspectives when measuring the value of drugs and therapeutic alternatives. Innovative treatments help patients address significant unmet needs, improve quality of life for patients, provide a meaningful improvement over the current standard of care, including for patients who face health disparities, and offer significant benefits to the broader ecosystem and society at large. Unfortunately, CMS has not been able to capture the true value of drugs and therapeutic alternatives through their current process of combining listening sessions by drug class. Each drug and patient experience for that drug is unique, and by combining condition or disease areas, CMS is failing to acknowledge the heterogeneity in treatment effects.

It is important that CMS effectively captures the patient experience by collecting data that truly matters to patients, including treatment adherence and patient-reported outcomes. We agree

[64] Oxford English Dictionary, Definition of Negotiation, https://www.oed.com/view/Entry/125879?redirectedFrom=negotiation#eid.

that an approach that allows for discussion among a range of stakeholders and where CMS may ask clarifying questions (as opposed to just "listening"), such as roundtable discussions or focus groups, would much better serve the patient community and all other parties that have interest in the process.

CMS should also clarify, well in advance of any stakeholder engagement processes, what information it seeks from speakers and how such information will be used in determining the MFP. For instance, CMS could outline in more detail what types of data it is seeking on patient experience and therapeutical alternatives, so that patients can provide relevant and targeted information. CMS should also share—at a high level—how information from patient-focused listening sessions and stakeholder-submitted information was used in determining the MFP. CMS should also take steps to enhance dialogue between patients and CMS, perhaps through smaller group sessions, as well as increase ways for a range of stakeholders to engage with the Agency, such as through written statements or recorded testimonies, as not all patient advocates are comfortable speaking in a public setting. And CMS should seek to engage speakers from diverse backgrounds and perspectives. We also believe it is incumbent upon CMS to work with patient organizations to monitor program impact and access to necessary treatments. Continued engagement with the patient community is instrumental to adapt the program to changing circumstances and reinforce CMS' commitment to patient-centered care.

Removal from the Selected Drug List—CMS's "Bona Fide Marketing" Standard (Section 70): CMS must abandon its bona fide marketing standard. CMS' creation of a new "standard" for determining the date of marketing of a generic or biosimilar is incompatible with the statute and contrary to sound public policy. **The starting point for that definition should be the plain English meaning of the word "to market."**[65]

The statute anchors multiple important provisions to either (1) the date on which a generic or biosimilar is marketed or (2) the date on which CMS determines that a generic or biosimilar is marketed.

With respect to the former date, a drug or biologic may be selected for the DPNP only if, by the selected drug publication date, it is a qualifying single source drug—which excludes a drug or biologic with respect to which a generic or biosimilar is marketed.[66] In addition, a biologic subject to a delay in selection for the DPNP is rendered ineligible for selection if a biosimilar is marketed by the date that is two years what otherwise would have been the selected drug publication date.[67] And a biologic may not be subject to such a delay if more than one year has passed since the biosimilar was licensed and the biosimilar is not marketed.[68]

With respect to the latter date, most notably, a selected drug ceases to be subject to the MFP at the start of the year that is "at least 9 months after the date on which [CMS] determines that at

[65] *Marketed,* Merriam-Webster Dictionary (11th ed. 2003). Merriam Webster defines this as "to expose for sale in a market; sell," and defines "on the market" as "available for purchase."
[66] SSA § 1192(e)(1)(A)(iii); (B)(iii). The statute refers to a generic or biosimilar that is both approved or licensed and marketed. We focus only on the latter because the date of marketing should never fall before the date of approval or licensure.
[67] *Id.* § 1192(f).
[68] *Id.* § 1192(f)(2)(D)(iii).

least one generic or biosimilar has been marketed."[69] In addition, a drug or biologic ceases to be subject to the DPNP if, before the end of the period, CMS determines that a generic or biosimilar has been marketed;[70] and a manufacturer of a selected drug subject to an ongoing excise tax ceases to be subject to such penalty on the date on which CMS determines that a generic or biosimilar has been marketed.[71]

In either case, the determination of the date of marketing of a generic or biosimilar is of enormous consequence throughout the program. CMS has stated its intent to continue to use an ill-defined and incomplete—and unlawful—process to make what is in fact an entirely straightforward determination. CMS's approach is deeply problematic and inaccurate for myriad reasons. Foremost is that the bona fide marketing standard is contrary to the plain language of the statute: CMS's standard is not rationally related to the actual date of marketing. As a definitional matter, marketing is "[t]he act[] . . . of bringing or sending a product or commodity to market."[72] As such, once the "action of buying or selling" has occurred, a product has necessarily been "marketed." i.e., **sold.**[73]

CMS itself has long recognized that the date on which a product is "marketed" is an objective point-in-time determination of the date on which it is made available for sale in the commercial marketplace—including in the course of implementing other provisions of the IRA as well as under the Part D program, which will source the data on which CMS intends to rely in effectuating its bona fide marketing standard. CMS determines when a product is "marketed" for purposes of the IRA's Part D inflation rebates by reference to the "market date" that the manufacturer must report under MDRP.[74] In turn, under MDRP, CMS has long defined the "market date" of a product by reference to the date on which the product entered commercial distribution, consistent with the plain language definition of "marketed."[75] And, under the Part D program, which will source the PDE data on which CMS intends to rely (in part) in effectuating its bona fide marketing standard, CMS has recognized that the date on which a product is "release[d] onto the market" triggers certain coverage-related obligations[76]—which by necessary implication means that CMS will have already recognized that a product has been released onto market by the time such coverage-related obligations yield PDE data showing utilization of the product.

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[69] *Id.* § 1192(c)(1).
[70] *Id.* § 1192(c)(2).
[71] Internal Revenue Code (IRC) § 5000D(b)(1)(B).
[72] Oxford English Dictionary, Definition of Marketing, https://www.oed.com/view/Entry/114186?rskey=36dfg4&result=2&isAdvanced=false#eid.
[73] *Id.*
[74] CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of SSA, and Solicitation of Comments, § 40.3 (Feb. 9, 2023), *available at* https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf; FDA, National Drug Code Directory (July 22, 2022), *available at* https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory#:~:text=Marketing%20start%20date%20is%20the,no%20longer%20in%20commercial%20distribution. With respect to the IRA's Part B inflation rebate, CMS determines when a product is "marketed" by reference to the "date of first sale" that the manufacturer must report for ASP purposes, which likewise is an objective point-in-time determination. CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments, § 50.3 (Feb. 9, 2023), *available at* https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.
[75] 83 Fed. Reg. 12,770, 12,784 (Mar. 23, 2018) (MDRP National Rebate Agreement); *see also* 42 CFR 447.502.
[76] CMS requires that Part D plan sponsor pharmacy and therapeutics committees "make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and . . . make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met." Prescription Drug Benefit Manual, ch. 6 § 30.1.5.

CMS may not supplant wholesale the statute's objective point-in-time "marketed" standard with an extra-statutory standard based on the Agency's subjective judgment of sufficiency of utilization.[77] Such judgment is immaterial to whether a product is in fact marketed—i.e., is available to be bought and sold in the commercial marketplace.

Notably, Congress well knows how to statutorily impose a "bona fide" standard in the drug pricing context. Congress expressly established such a standard when amending the MDRP statute in 2010 to specify that only "bona fide" service fees are exempt from the calculation of AMP.[78] By contrast, Congress chose not to establish such a bona fide standard here. "[W]here Congress knows how to say something but chooses not to, its silence is controlling."[79]

CMS's extra-statutory bona fide marketing standard has vast legal implications. For example, as noted above, the date on which CMS determines that a generic or biosimilar has been marketed determines when the MFP terminates.[80] As such, through the bona fide marketing standard, CMS is effectively claiming for itself limitless discretion to prevent the MFP from timely (if ever) terminating, notwithstanding the fact that a generic or biosimilar has in fact come to market, based on the Agency's subjective assessment of whether PDE and AMP data show that the generic or biosimilar is utilized sufficiently.

Such policies are completely untethered to anything in the text or structure of the statute and run directly contrary to Congress's intent to allow market-based competition to govern where a generic or biosimilar has come to market to compete with a drug or biologic.[81] The Agency's approach is therefore patently unlawful. "[N]either federal agencies nor the courts can substitute their policy judgments for those of Congress."[82] CMS's effort to do so here is "effectively the introduction of a whole new regime of regulation," which "is not the one that Congress established."[83]

The Agency's unlawful standard also necessarily yields an inaccurate determination of when a generic or biosimilar was marketed. Many Part D plan sponsors will not add a newly approved drug to their formulary until the 180-day mark, and, thus, the first six months following the market entry of the drug will necessarily reflect only very limited uptake.[84] And some plan sponsors may choose not to add the drug to their formulary at all. In addition, even where plan sponsors add the drug to their formulary, widespread uptake of a new product does not occur overnight. After a new product is made available for sale, providers and patients typically transition to such product gradually as they become increasingly familiar with its benefits relative to pre-existing alternatives.[85] Such a product is in fact marketed during this uptake period, but CMS's standard ignores this fact and focuses instead on whether the product is adequately

[77] It is unclear, for example, whether CMS expects a generic or biosimilar to capture and maintain a certain percentage of the market.
[78] SSA § 1927(k)(1)(B)(i)(II) (as amended by Pub. L. No. 111–148, § 2503(a) (2010)).
[79] *Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 789 F. 3d 1206, 1217 (11th Cir. 2015).
[80] SSA § § 1192(c)(2).
[81] *See, e.g.,* SSA § 1192(c)(1).
[82] *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 176 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000).
[83] *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 114 (1994).
[84] While plan enrollees may access a non-formulary drug via an exceptions process, access may not be immediate under such process; moreover, exception processes typically yield only a very small volume of utilization.
[85] *See* A. Lubby, Factors affecting the uptake of new medicines: a systematic literature review, 14 BMC Health Services Research 469 (2014) (describing the various factors that affect early uptake of new medicines).

utilized, in contravention of the statutorily mandated standard.[86] Such shifts in utilization patterns over time do not mean that the market is not working as intended.

The Agency compounds these concerns with its intent to continue to review data only once per month for purposes of determining when the MFP terminates.[87] The Agency's approach virtually always ensures that there will be a lag between the actual date of marketing and the date of CMS's determination. This poses a significant concern with respect to when the MFP terminates. If there is a lag of even a single day between the actual date of marketing and the date of CMS's determination, a selected drug can be subject to the MFP for a full additional year. For instance, if a generic or biosimilar is in fact marketed on March 31 but CMS's determination of this fact is deferred until April 1, the selected drug is subject to the MFP for a full year longer than if CMS's determination had not been deferred.

Additionally, as CMS evaluates whether a biosimilar is marketed, we urge CMS to clarify that a biosimilar must not carry all of the indications of the reference product to be considered marketed for purposes of the DPNP. This understanding aligns with the long-standing FDA practice in which generic and biosimilar products are not required to carry every indication of their brand or reference product in order to gain FDA approval and subsequently enter the market. Any other interpretation of marketing for biosimilars would falsely and erroneously impose an MFP on a reference product with biosimilar or generic competition, creating undue harm to the biosimilar marketplace.

It is imperative that CMS abandon its unlawful and ill-advised standard and instead adopt as its standard the "market date" reported under MDRP. The MDRP "market date" standard should be used for identifying *both* the date on which a generic or biosimilar is marketed *and* the date on which CMS determines that a generic or biosimilar has been marketed.

Under MDRP guidance, "market date" is "the earliest date the drug was first marketed under the application number by any labeler."[88] Manufacturers report this date when reporting MDRP pricing data. As such, the MDRP "market date" is a familiar construct to both CMS and manufacturers, and carries the additional benefit of ensuring consistency across MDRP and the DPNP. And, unlike the "date of first sale" used for ASP reporting purposes, the MDRP "market date" is available for generics and biosimilars without regard to whether they are subject to ASP reporting.[89]

It is particularly critical that the Agency equate the date on which CMS determines that a generic or biosimilar has been marketed with the MDRP "market date" because, as noted above, the difference of a single day in the date of CMS's determination can result in the MFP being extended for a full additional year. Failing to do so would have a dramatic chilling effect on the

[86] Other examples of deficiencies in CMS's approach include circumstances where low utilization is driven by uncontrollable factors such as supply shortages.
[87] Initial Guidance at 62.
[88] CMS, MDRP Data Guide § 5.15 (Apr. 2022).
[89] The "date of first sale" is reported only for products subject to ASP reporting, and thus may not be available for all generics and biosimilars whose marketing is implicated by the DPNP. By contrast, the "market date" reported under MDRP is more broadly reported and is thus the superior metric to use. *See* CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments, (Feb. 9, 2023), https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.

development of generics and biosimilars. Manufacturers would be seriously disincentivized against investing in the development of such products if there is a risk that they would be forced to compete with the MFP for an unduly extended period of time. This, in turn, would defeat Congress's objective of encouraging the development of generic and biosimilar market competitors.

For all of these reasons, we strongly oppose CMS's extra-statutory bona fide marketing standard, and strongly urge CMS instead to adopt the MDRP "market date" as a uniform standard for identifying both the date on which a generic or biosimilar is marketed and the date on which CMS determines that a generic or biosimilar has been marketed. And if there are instances where, for example, a manufacturer is not participating in the MDRP, a manufacturer should be afforded an opportunity to provide CMS input as to whether a generic is marketed or not.

Finally, we note our concern that CMS proposes to continue to monitor whether a generic or biosimilar continues to be "marketed" even after a determination has been made. We strongly urge CMS to abandon this approach – there is simply no basis for this ongoing "monitoring" – it was not contemplated by the IRA and is not supported by the statute.

Interaction Between Inflation Rebates and Selected Drugs (Section 120): **There is no reason for the application of inflation rebates to selected drugs.**

A manufacturer should not be obligated to pay an inflation rebate on a selected drug because Medicare expenditures on a selected drug are already constrained by the maximum fair price.[90] By statute, the Part B inflation rebate calculation is based in relevant part on the amount by which "106 percent of the amount determined under paragraph (4) of [section 1847A(b) of the SSA] for [a part B rebatable drug] during the calendar quarter . . . . exceeds . . . the inflation-adjusted payment amount . . . for such part B rebatable drug during the calendar quarter."[91]

Importantly, the circumstances under which an amount is "determined" under paragraph (4) is dictated by section 1847A(b)(1) (paragraph (1)).[92] Specifically, paragraph (1) dictates a payment amount of, "in the case of a single source drug or biological . . . , 106 percent of the amount determined under paragraph (4) *or* in the case of such a drug or biological product that is a selected drug . . . , with respect to a price applicability period . . . , 106 percent of the maximum fair price . . . applicable for such drug and a year during such period."[93]

In other words, the payment amount for a selected drug is determined under paragraph (1), and such payment amount is determined without regard to paragraph (4). Rather, it is only the payment amount for a non-selected drug that is determined under paragraph (4).

It necessarily follows that the Part B inflation rebate calculation has no application to a selected drug. With respect to such a drug, there is no amount "determined under paragraph (4)," and therefore Part B inflation rebates have no applicability. Thus, with respect to a selected drug,

[90] *Id*. §§ 1847A(b)(1)(B); 1860D-2(d)(1)(D).
[91] SSA § 1847A(i)(3) (emphasis added).
[92] *See id*. § 1847A(b)(1).
[93] *Id*. § 1847A(b)(1)(B) (emphasis added).

Medicare is shielded from the increase in expenditures occasioned by a price increase that outpaces inflation that an inflation rebate is intended to address. Medicare does not need to be made whole on account of such a price increase, and, thus, no inflation rebate should be due.

Formulary Access (Section 110): BIO asks that CMS clarify how it will ensure robust beneficiary access to needed therapies, including selected drugs, and institute safeguards that ensure diversity across formularies to meet patient needs.

CMS should act to mitigate any way in which the MFP process results in narrower formularies and otherwise provides fewer choices to patients. In addition, CMS should monitor plan coverage and tiering design, clinical appropriateness of utilization management policies, cost-sharing levels, and patient out-of-pocket exposure. BIO encourages CMS to redouble its oversight of formulary requirements and to strengthen its policies regarding Part D coverage determinations and appeals as well as tiering exceptions.

Manufacturer Effectuation of the MFP in 2026 and 2027

As we set forth below, because ensuring consistently proper and timely effectuation of the MFP poses a daunting operational challenge, it is essential for CMS to establish a high-functioning MTF that provides for both necessary data exchange and effective and efficient MFP payment facilitation.

Effective and efficient MFP payment facilitation. With respect to CMS's proposed MFP payment facilitation options, biopharmaceutical manufacturers generally have neither the functional expertise nor the operational systems to carry out MFP payment to the tens of thousands of dispensers that will be required to effectuate the MFP—let alone the capacity to do so in myriad ways, at the whim of each such dispenser. Therefore, it is essential, not only that CMS finalize payment of the MFP through the MTF as an MFP payment option, but also that CMS clarify that a manufacturer will not be found to have failed to provide access to the MFP where a dispenser declines to accept payment of the MFP through the MTF where the manufacturer has elected such MFP payment option. At the same time, while we expect biopharmaceutical manufacturers to rely heavily on the MTF as the vehicle for paying MFP rebates, we support flexibility that enables each manufacturer to pay the MFP in an alternative manner.

It is critical that the Agency recognize that ensuring consistently proper and timely MFP effectuation will be challenging for biopharmaceutical manufacturers, absent robust support from the MTF, and absent the ability to elect a uniform approach. Providing access to the MFP will come at a significant cost—both financial and operational—especially for high-volume products. Despite the best efforts of manufacturers to consistently and correctly fulfill their obligation to provide access to the MFP, insufficient support from the Agency will inhibit fully successful MFP effectuation. It would be a monumental undertaking for a manufacturer to establish direct payment relationships with a large number of dispensers, and ensuring consistent compliance and payment accuracy across such a vast network would be virtually impossible if each dispenser could dictate a different mode of payment.

It is both in the Agency's interest and in the public's interest to ensure that MFP effectuation is properly implemented. Even assuming CMS finalizes the proposed MFP payment option of paying the MFP through the MTF, the proposed voluntary nature of a dispenser's participation in the MTF payment option is extremely problematic and will lead to a highly fragmented system where manufacturers will be practically unable to ensure consistently proper and timely

effectuation of the MFP. Our comments below set forth the necessary preconditions to ensure consistent and correct MFP effectuation.

Necessary data exchange. With respect to CMS's proposed prompt MFP payment window, in light of the statutory directive that a unit of a selected drug is subject only to the lower of the MFP or the 340B price, the clock may not start until the manufacturer receives all of the data necessary to ascertain whether the unit is or is not a 340B unit—and therefore whether there is or is not an obligation to pay a MFP rebate. To incentivize timely receipt of such data, CMS should, both as a condition of the start of the clock and as a condition of Part D reimbursement, require the appropriate use of Medicare claims modifiers (or comparable indicators) that show whether the unit has or has not been determined to be 340B-eligible. In addition, where the unit has been determined to be 340B-eligible and the 340B price is lower than the MFP, additional information will be necessary to effectuate the 340B price: whether the 340B price has already been provided on the dispensed unit and, if not, whether the 340B price is to be provided via a 340B rebate on the dispensed unit or the 340B price on a replenishment unit. Furthermore, to prevent double dipping on the same unit, it will be necessary for any replenishment order of a selected drug to be accompanied by data linking the replenishment unit to the dispensed unit and showing whether either the MFP or a 340B rebate has already been provided on the dispensed unit.

BIO notes that this comment letter applies strictly to MFP effectuation with respect to dispensers, consistent with the scope of CMS's proposed guidance; CMS should seek feedback on MFP effectuation with respect to providers and supplies, which raises distinct considerations, through a separate process.

Role of the MTF

We appreciate the opportunities CMS has provided for our members to provide input to the Agency regarding implementation of the DPNP, including CMS's Request for Information on the MTF and ongoing stakeholder calls. As we have stated in previous comments, BIO supports CMS's recognition that, due to the real risk of MFP diversion as well as MFP-340B duplication, a manufacturer should be permitted to fulfill its obligation to pay the MFP via rebates and, with respect to such rebates, CMS's intention to contract with an MTF for IPAY 2026 and beyond.

As we largely noted in our response to the Request for Information on the MTF, the MTF should (1) transmit a batch submission of claim files once every two weeks (fourteen days) or longer to the Primary Manufacturer, given operational complexities; (2) ensure that MFP-340B duplicate discounts are avoided (see discussion below for further detail); (3) validate MFP eligibility based on clean claims data; (4) calculate manufacturer reimbursement amounts for differences between MFP and 340B (see discussion below for further detail); (5) create, maintain, and provide manufacturers with access to a database of pending and finalized MFP rebate claims and associated claims data, so that manufacturers can verify MFP eligibility within any prompt MFP payment window; (6) facilitate MFP payments from manufacturers to dispensers as the default MFP payment option, with the ability for a manufacturer to opt out and instead receive banking information from the MTF and pay the MFP on its own (see discussion below for further detail); and (7) establish a robust MFP dispute resolution process, with a bona fide ability for manufacturers to recoup the MFP where it is determined that the unit is not MFP-eligible (see discussion below for further detail).

It is also essential that the selected MTF entity does not have any line of business that could create a conflict of interest, such as serving as a PBM.

In addition, is important for CMS to recognize that manufacturers need appropriate time after MTF selection to establish data connections, agreements, and mechanics for data exchange between parties.

Also, CMS's current timeline indicates that manufacturers are losing approximately six months to develop an MFP effectuation plan, which must be submitted by June 1 of the year before the applicable IPAY. CMS should provide greater clarity around the MFP effectuation plan review process, including under what scenarios a plan could potentially be rejected. It is critical that CMS provide not only clear guidance but also enhanced flexibility with respect to the review process in the first few years of the program. The initial years of MTF effectuation should be treated as if it were a pilot program, with flexibility for manufacturers to adjust their MFP effectuation plans along the way as necessary.

Options for MTF Payment Facilitation

CMS proposes two options for facilitating MFP payment between manufacturers and dispensing entities: Under option one, the MTF facilitates the sharing of banking information between the manufacturer and the dispensing entity, and, under option two, payment passes from the manufacturer to the dispensing entity through the MTF.

BIO recommends that option two, where the MTF facilitates payments from manufacturers to dispensers, be the default MFP payment option, but that a manufacturer should have the ability to opt out. In other words, manufacturers and dispensers would be automatically predisposed to participate in option two, but a manufacturer could choose to opt out of such MTF-facilitated MFP payments. A manufacturer that opts out should then automatically receive banking information from the MTF to facilitate the manufacturer making MFP payments on its own.

Because most manufacturers are not practically able to establish direct payment relationships with such a high volume of dispensers, the ability to rely on the MTF to facilitate MFP payments (option 2) is imperative. At the same time, an "opt-out" (option 1) would allow some manufacturers the flexibility to arrange for MFP payment in an alternative way.

BIO requests that CMS finalize MFP payment facilitation as described above.

Separately, BIO strongly objects to CMS's proposal that dispensers' participation in MTF payment facilitation will be voluntary, with no consequence for non-participation. Such voluntary participation by dispensers in the MTF would create extreme fragmentation, complexity, and operational difficulty and cost. Instead, where a manufacturer elects to use the MTF to effectuate MFP payment, CMS should incentivize bilateralism by specifying that the Agency will find a manufacturer to have fulfilled its obligation to provide access to the MFP where the manufacturer elects a CMS-established MFP payment option, including where a dispenser refuses to accept MFP payment via such option.

In the event that a dispenser does not honor a manufacturer's election to participate in the MTF payment facilitation option, MTF effectuation will be unfeasible. Allowing each dispenser to choose how it will receive an MFP rebate would create a chaotic landscape with potentially thousands of different payment effectuation approaches. This fragmentation would create confusion, increase administrative burden, and raise operational costs for manufacturers as they navigate numerous and incompatible payment schemes. The sheer number of pharmacies alone, approximately 70,000, that bill under Medicare Part D shows how it would be virtually

impossible, financially and operationally, for manufacturers to administer bespoke payment mechanisms. Absent the ability of a manufacturer to elect a uniform MFP payment approach, the MFP effectuation is, as a practical matter, severely undermined; a “wild west” of MFP payment approaches is unsustainable. And, as the number of selected drugs grows each year, the potential MFP payment approaches incumbent on a manufacturer could grow exponentially, further straining operational capacity.

In light of CMS’s proposed MFP payment facilitation options as well as the potential for an excessive number of alternative payment approaches demanded by dispensers, a manufacturer that elects to utilize a CMS-approved payment facilitation option should be granted an enforcement safe harbor for its good faith effort to effectuate the MFP (i.e., it should be found to have fulfilled its obligation to provide access to the MFP) where a dispenser refuses to accept MFP payment through such option. Providing a safe harbor would allow a manufacturer to rely on a CMS-approved payment facilitation option to fulfill its legal obligation to provide access to the MFP without fear of incurring a CMP if a dispensing entity declines to participate in such option. In establishing this safe harbor, CMS would clarify that the Agency will not penalize a manufacturer for the refusal of a dispensing entity to participate in a CMS-approved payment facilitation option.

MTF Data Exchange

For 2026, CMS intends for the MTF to facilitate the exchange of data between manufacturers and dispensing entities to support authentication of an MFP-eligible claim. Primary Manufacturers would be required to participate in the MTF data exchange, regardless of how the Primary Manufacturer effectuates the MFP (prospectively or retrospectively).

BIO urges CMS to work closely with manufacturers to ensure that all appropriate data fields are provided for in the MTF data exchange so that the MFP eligibility of each unit can be fully validated, which includes, but is not limited to, determination of whether the unit is also 340B-eligible and which price point (MFP or 340B) is lower (see discussion below for further detail). These data fields could expand on existing fields utilized under the Coverage Gap Discount Program (CGDP). Ultimately, it is essential that Primary Manufacturers be given all data necessary to confirm MFP eligibility, and that such data are thoroughly and meticulously scrubbed for inaccuracies, errors, potential fraud, and other concerns. As we have commented in the past, we encourage CMS to work with manufacturers and others to update the data elements list as the MTF process evolves.

MFP-340B Non-Duplication

Currently, the lack of mechanism to prevent both MFP and 340B discounts on the same drug unit is concerning as the MFP and the 340B discount are expected to be effectuated through post-transaction adjustments, with patient eligibility unclear at time of dispensing. We continue to be deeply concerned that without robust data capture and timely determination of 340B status, duplication of 340B and MFP discounts will become pervasive and persistent. While we appreciate CMS’ acknowledgment of the critical role that data will play in properly effectuating deduplication, we firmly believe that 340B covered entities must be required to identify 340B and MFP-eligible prescriptions at the point of sale (or very soon thereafter) in order to ensure that 340B sales and units are excluded from government price calculations. CMS should prioritize enabling MFP-340B non-duplication, such that a manufacturer is not, contrary to statute , forced to provide both the MFP and a 340B discount on the same unit of a selected drug, instead of only the lower of the two. This “deduplication” provision is critical to ensuring the

340B and MFP programs operate harmoniously and do not inadvertently expand manufacturer liability under either program.

With respect to CMS's proposed prompt MFP payment window (see discussion below for further detail), it is critical to recognize that, in light of the statutory directive that a unit of a selected drug is subject only to the lower of the MFP or the 340B price, the clock may not start until the manufacturer receives all of the data necessary to ascertain whether the unit is or is not a 340B unit—and therefore whether there is or is not an obligation to pay a MFP rebate. Thus, CMS should ensure that the proposed codes denoting circumstances in which the Standard Default Refund Amount is not paid encompass a circumstance in which payment is not made for lack of all data necessary to ascertain whether the unit is or is not a 340B unit.

As noted above, to incentivize timely receipt of such data, CMS should, both as a condition of the start of the clock and as a condition of Part D reimbursement, require the appropriate use of 340B/non-340B Medicare claims modifiers (or comparable indicators) that show whether the unit has or has not been determined to be 340B-eligible. (CMS already requires the use of a 340B modifier on Part B claims.) These data would then be included in the claims data supplied by the MTF to the manufacturer. In addition, where the unit has been determined to be 340B-eligible and the 340B price is lower than the MFP, additional information will be necessary to effectuate the 340B price: whether the 340B price has already been provided on the dispensed unit and, if not, whether the 340B price is to be provided via a 340B rebate on the dispensed unit or the 340B price on a replenishment unit. Furthermore, to prevent double dipping on the same unit, it will be necessary for any replenishment order of a selected drug to be accompanied by data linking the replenishment unit to the dispensed unit and showing whether either the MFP or a 340B rebate has already been provided on the dispensed unit.

As we have noted previously to CMS, the potential for MFP-340B duplication is not merely a theoretical concern. And, in contrast to the DPNP, the 340B Program features a statutory audit right, a statutory dispute resolution mechanism, and agency authority to impose sanctions, including termination of access to the 340B price. Yet even this constellation of statutory safeguards against Medicaid-340B duplicate discounts has proven deeply inadequate to prevent such duplicate discounts. Further, allowing covered entities to voluntarily disclose 340B and MFP eligibility as CMS proposes in this draft guidance, means they can choose not to provide this data to manufacturers. This, in turn, means covered entities would be able to demand both the 340B discount and the MFP discount in clear violation of the deduplication provision of the IRA.

Further, as a part of the Medicaid Drug Rebate Program (MDRP), standard government price refiles can occur up to twelve quarters or three years after date of dispensing, which could potentially impact 340B prices due to rounding or other corrections. Manufacturers should not be liable for recalculating the discount amounts (using the lower of MFP or 340B price) based off of these government pricing refiles that could change the 340B price.

Ideally, CMS would create a 340B claims clearinghouse to identify units subject to a 340B discount. This could be a source of data for manufacturers that are ensuring MFP-340B non-duplication, as well as for CMS in identifying 340B units for purposes of Part D inflation rebates. Moreover, the clearinghouse could enable the MTF to itself ensure MFP-340B non-duplication.

14-Day Prompt MFP Payment Window

The Draft Guidance indicates that Primary Manufacturers must ensure that they provide dispensing entities of a selected drug with access to the MFP within 14 calendar days (14-day prompt MFP payment window) of the MTF sending/the manufacturer receiving data from the MTF verifying that the unit was dispensed to an MFP-eligible individual.

BIO is deeply concerned that the proposed 14-day prompt pay window does not provide enough time for manufacturers to process all MFP rebate claims accurately and thoroughly to ensure compliance with program standards. As noted above, managing relationships with approximately 70,000 dispensing entities requires substantial resources, time, and coordination, which presents significant logistical and administrative challenges. The complexity of ensuring consistent compliance and payment accuracy across such a vast network of dispensing entities implicates all MFP rebate claims, including those involving 340B units. The proposed 14-day timeline is far shorter than the period during which 340B claims are typically identified for a typical contract pharmacy and covered entity. Additionally, the 14-day window is far shorter than that provided to process managed care plan rebates, which is at least 30 days on average.

CMS should provide for a longer prompt pay timeline similar to that under the Coverage Gap Discount Program, which is 38 days. It is critical that the prompt pay window be lengthened so that manufacturers can effectively make the determination of MFP eligibility, including by determining of whether the 340B price applies instead, and otherwise scrubbing for duplicative or errant MFP rebate claims. The process for manufacturers to scrub data to process the claim is arduous and involves not only verifying patient eligibility, but also verifying the quantity is correct and that each claim is unique and is not duplicative of another claim. Accordingly, the proposed 14-day window is insufficient and would create significant operational challenges for manufacturers, which must conduct intensive MFP rebate claim validation.

BIO also requests that CMS clarify whether any prompt pay window starts on the date on which the data are sent to the manufacturer, or from the date on which the data are received by the manufacturer. In the Draft Guidance, “sent to” and “received by” are seemingly used interchangeably; however, it is possible that data will not be received on the same date on which they are sent. CMS should confirm that the prompt pay window starts on the date of manufacturer receipt of the data. In addition, CMS should confirm that the prompt pay window ends on the date of manufacturer transmission of payment, not the date of dispenser receipt of payment.

Within any prompt pay window, BIO requests that the MTF transmit files containing the claims-level data elements to manufacturers on a bi-weekly basis, i.e., once every 14 days, or longer, given operational complexities. Any transmission of data shorter than this frequency could create the risk of duplicate discounts by providing insufficient time for 340B identification and associated chargeback.

As noted above, even with a lengthening of the prompt pay window, absent use of 340B/non-340B claims modifiers, there will likely be a significant lag in time before MFP-340B duplication can be adjudicated. As also noted above, by law, any prompt pay window cannot start until the manufacturer has all data necessary to validate MFP eligibility—including data necessary to adjudicate MFP-340B duplication. “While CMS proposes that manufacturers pay the MFP and, later, where the unit is determined to be 340B-eligible and the 340B price is lower than the MFP, simply pay the difference between the 340B price and the MFP, its proposal fails to recognize that, where a 340B contract pharmacy arrangement is concerned, it is unclear whether the MFP will be claimed by the pharmacy and the 340B price will be claimed by the covered entity, i.e., whether there can be no offsetting of the MFP paid to the pharmacy against the 340B price to

be paid to the covered entity, as they are distinct entities. Where a contract pharmacy arrangement is concerned, such offsetting is workable only if the MFP will be payable to the covered entity, not the pharmacy."

Moreover, CMS has proposed no means for a manufacturer to reclaim the MFP from the pharmacy in such a circumstance. For these reasons, CMS's proposal does not obviate the need to toll the start of any prompt pay window until the manufacturer has all data necessary to adjudicate MFP-340B duplication.

Monitoring of Access to the MFP in 2026 and 2027

BIO continues to note our concern with the proposal to hold a Primary Manufacturer responsible for submitting applicable information concerning a Secondary Manufacturer, which poses significant confidentiality concerns, particularly with the effectuation of the MFP. A Primary Manufacturer has no inherent legal authority to compel a Secondary Manufacturer to act or not act, including to share information on acquisition prices or other claims level data or maintain National Drug Code (NDC) lists. Further, it would be fundamentally unfair and legally problematic for CMS to threaten a Primary Manufacturer with significant civil monetary penalties (CMPs) for failure to do the impossible. We note that this same concern pervades the Draft Guidance, given the numerous contexts in which CMS proposes to hold a Primary Manufacturer responsible for the action or inaction of a Secondary Manufacturer.

Standard Default Refund Amount

BIO is concerned that setting the Standard Default Refund Amount at the Wholesale Acquisition Cost (WAC) minus the MFP of the selected drug would not be an accurate reflection of costs when effectuating the MFP, particularly when the actual acquisition price is above WAC. Often, cumulative markups within the supply chain result in the actual acquisition price being significantly higher than the WAC. Instead, BIO recommends that manufacturers should have the option to provide instead the manufacturer-contracted price (i.e., the actual acquisition price, less any cumulative markups within the supply chain) minus the MFP.

We are also concerned that manufacturers may be held liable and subject to CMPs if the standard default amount is deemed to be incorrect, even if the manufacturer provided a good faith effort to make the MFP available based on the WAC as calculated by the manufacturer. Meanwhile, there is no mechanism that manufacturers can use for MFP recoupment or any guarantee that dispensing entities will return funds to manufacturers in the event of overpayment. Accordingly, we request that manufacturers be given a safe harbor for its good faith effort to make the MFP available to the dispensing entity, irrespective of the choice to use a standard default refund amount or a refund of a different amount and be given the opportunity to correct that amount without fear of incurring CMPs.

Dispute Resolution

BIO appreciates CMS's recognition of the need for an MFP dispute resolution process. Especially if CMS finalizes a prompt MFP payment window, it is imperative that, at the core of this process, CMS establish an enforceable mechanism for MFP recoupment where, post-MFP payment, it is determined that the unit is not in fact MFP-eligible, as well as an enforceable mechanism for 340B recoupment where, post-340B payment, it is determined that the unit is MFP-eligible. This mechanism should at the very least allow for manufacturers to receive direct

repayments. In addition, there could also be an option for overpayment of MFP to be treated as a credit toward future MFP discounts.

At a minimum, CMS should expressly clarify that a manufacturer risks no CMP or other penalty if it offsets the amount owed against any future discounting owed to the dispenser. To elaborate, CMS provide explicit guidance on adjustments and reversals of the MFP, including but not limited to instances where a dispenser stops dispensing the selected drug, and instances where the application of the MFP has terminated. A mechanism for necessary adjustments and reversals of MFP should, at a minimum, allow for manufacturers to receive direct repayments. In addition, there could also be an option for overpayment of MFP to be treated as a credit toward future MFP discounts.

Finally, especially if CMS does not establish an enforceable recoupment mechanism, it is critical that CMS provide that initiating a dispute resolution proceeding halts the running of any prompt MFP payment window.

BIO appreciates this opportunity to provide feedback to CMS on the Draft Guidance. We look forward to continuing to work with the Agency on these important issues. Should you have any questions, please do not hesitate to contact Crystal Kuntz at 202-962-9200 or ckuntz@bio.org.

Sincerely,

/s/
Crystal Kuntz
Senior Vice President, Health Policy & Research

/s/
Jack Geisser
Senior Director, Healthcare Policy, Medicaid, and State Initiatives

Biocom California

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted electronically

Dear Administrator:

Biocom California appreciates the opportunity to offer comments on the draft guidance for the second cycle of negotiations for the Medicare Drug Price Negotiation Program ("MDPNP") issued by the Centers for Medicare and Medicaid Services (CMS)[1].

Biocom California is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,800 members dedicated to improving health and quality of life, Biocom California drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates over $414 billion in annual economic output, supports 1.24 million jobs, and produces $128.6 billion in labor and sole proprietor income [2].

While Biocom California supports the Inflation Reduction Act's (IRA) establishment of a $2,000 cap on out-of-pocket patient spending and the restructuring of the Medicare Part D benefit program, we have continuously raised strong concerns about the MDPNP provisions which have already had a negative impact on biotechnology innovation. We believe that the IRA does not balance promoting patient affordability and the role of the biomedical community in bringing innovative medicines to market. As the advocate for California's life science sector, we understand the importance for stakeholders to inform and guide the implementation of the MDPNP for initial price applicability year (IPAY) 2027 and we offer our comments below:

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf
[2] Biocom California 2024 Economic Impact Report Databook. https://www.biocom.org/eir/.

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

The guidance states that CMS will identify a potential qualifying single source drug by "all dosage forms and strengths of the drug with the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs." For biological products, CMS will consider "all dosage forms and strengths of the biological product with the same active ingredient and the same holder of a Biologics License Application (BLA) inclusive of products that are marketed pursuant to different BLAs."

Biocom California disagrees with CMS's approach to identifying a qualifying single source drug and its dosage forms and strengths by its common active moiety and common active ingredient for drugs and biologics, respectively. Instead, we suggest that CMS identify drugs and their dosage forms and strengths by referencing an NDA or BLA. The Food and Drug Administration's (FDA) application-based framework should act as a reference and be adopted such that a product approved or licensed under a new NDA or BLA (as opposed to a product approved or licensed under a supplement to an existing NDA or BLA) is a distinct qualifying single source drug. Utilizing this framework to distinguish products would be consistent with industry practice and incentivize innovation; unlike CMS's current definition of a "qualifying single source drug" which combines drug products by common active moiety and biological products by common active ingredient. Furthermore, utilizing FDA's application-based framework would enable CMS to more easily identify relevant dosage forms and strengths when aggregating Medicare expenditures and this would allow manufacturers to track the seven- or eleven-year "qualifying single source drug" clock more readily.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

CMS explains that certain orphan drugs will be excluded when identifying qualifying single source drugs: "CMS will exclude a drug or biological product that is designated as a drug for only one rare disease or condition under section 526 of the [Food, Drug, and Cosmetics] FD&C Act and for which the only approved indication (or indications) is for such disease or condition." The limited scope of the orphan drug exclusion risks disincentivizing orphan drug research and development (R&D) and will impact a manufacturer's decision to continue R&D to expand a drug's indications to include additional rare diseases. **Biocom California urges CMS to consider the scope of the orphan drug exclusion in a manner that maximizes protections and continues to support and incentivize the development of orphan drugs and rare disease R&D.**

Additionally, in situations where an approved indication falls within the scope of an orphan drug designation but there is no corresponding orphan exclusivity, CMS cannot rely on FDA's databases as they track orphan exclusivity, rather than a designation, to determine eligibility for orphan drug exclusion. We appreciate that the agency "will consult with FDA as needed, including to determine whether a drug is designated for, or approved for indications for, one or more rare disease(s) or condition(s)." **However**, **Biocom California also suggests that CMS establish a process that enables manufacturers to submit evidence demonstrating that an indication falls within an orphan drug designation in situations where the agency is unable to determine eligibility for the exclusion based on FDA's databases.**

Lastly, Biocom California asks CMS to clarify that, where an orphan drug loses eligibility for the orphan drug exclusion, the seven- or eleven-year "qualified single source drug" clock runs from *the date on which the drug lost eligibility for the exclusion*. An orphan drug that loses eligibility for the orphan drug exclusion due to an expansion of indications for a second rare disease could be immediately eligible for negotiations. **This would further disincentivize drug developers from investing in rare disease R&D and we ask CMS to clarify these details in order to mitigate the risk that the MDPNP will deter necessary orphan drug development.**

30.2.1 Exception for Small Biotech Drugs

Per the IRA, a drug is exempt from negotiation for initial price applicability years 2026, 2027, and 2028 if the drug meets the exception for small biotech drugs ("Small Biotech Exception"). "To identify and exclude such small biotech drugs, CMS will consider whether, for dates of service in calendar year 2021, the Total Expenditures under Part D for the qualifying single source drug: (1) were equal to or less than one percent of the Total Expenditures under Part D for all covered Part D drugs; and (2) were equal to at least 80 percent of the Total Expenditures under Part D for all covered Part D drugs for which the manufacturer of the qualifying single source drug had a [Coverage Gap Discount Program] CGDP Agreement in effect during 2021."

The Small Biotech Exception is a critical protection that recognizes the need for small biotech drugs to be exempt from negotiation. Biocom California asks CMS to make the Small Biotech Exception permanent and we encourage the agency to develop a dispute resolution process that enables manufacturers to respond to and appeal a negative determination. As part of this process, CMS should engage in a dialogue and small biotech companies should have the opportunity to provide additional data to support their application for the exception before CMS provides a final determination.

40.2.1 Confidentiality of Proprietary Information

CMS explains that it "will implement a confidentiality policy that is consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of [the Freedom of Information Act] FOIA, and that strikes an appropriate balance between: (1) protecting the highly sensitive information of manufacturers and ensuring that manufacturers submit the information CMS needs for the Negotiation Program, and (2) avoiding treating information that does not qualify for such protection as proprietary. Thus, for initial price applicability year 2027, CMS will treat information on non-FAMP [non-Federal average manufacturer price] as proprietary."

The guidance states that R&D costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue and sales volume data will be considered proprietary. Conversely, data on prior Federal financial support, approved patent applications, exclusivities, and FDA applications and approvals will be considered non-proprietary since this data is publicly available. **Biocom California acknowledges and agrees with the information that will be considered proprietary versus non-proprietary. However, we believe there is a need for CMS to further explain how it intends to protect a manufacturer's confidential information and establish more robust safeguards to ensure that the agency is adequately handling proprietary information submitted as part of the process. We suggest that CMS focus on developing data privacy and security protection protocols that include robust storage and controls that limit access to confidential information to CMS staff on a "need-to-know" basis.**

Furthermore, "CMS is required to publish the explanation of the MFP [maximum fair price] by March 1, 2026, for initial price applicability year 2027…. In this public explanation and any other public documents discussing the MFP, CMS will make public the…data submitted by the Primary Manufacturer and the public that are determined to be non-proprietary, but will not include any protected health information (PHI) or personally identifiable information (PII)." **Biocom California appreciates CMS's discretion to not disclose PHI/PII, however, the possibility of inadvertently disclosing confidential information is possible. In order to avoid such a disclosure, we suggest CMS allow manufacturers the opportunity to review a draft explanation of the MFP prior to its publication and dispute any confidentiality concerns. This will ensure that manufacturers are comfortable with the information disclosed and no proprietary information is inadvertently released.**

40.4 Providing Access to the MFP in 2026 and 2027

In section 40.4, CMS details the ways in which a Primary Manufacturer may provide access to the MFP by either "(1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP…or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP…" The agency intends to engage a Medicare Transaction Facilitator (MTF) to "facilitate the exchange of data between pharmaceutical supply chain entities to support the verification that the selected drug was dispensed to an MFP-eligible individual."

We support the establishment of the MTF to facilitate the effectuation of the MFP and to minimize the operational burden of program administration for both manufacturers and pharmacies. The MTF is essential to streamline processes needed for the timely provision of MFP discounts to pharmacies. As CMS finalizes functionality for the MTF, we offer the following recommendations:

- In addition to the data elements outlined in the proposed guidance, **we recommend that CMS require the use of 340B and non-340B modifiers (as applicable) to identify 340B-eligible and 340B-ineligible units on any claim submitted for reimbursement as a condition precedent to the start of the prompt MFP payment window as well as a condition of Part D reimbursement.** By statute, a manufacturer of a selected drug cannot be required to offer both the MFP and the 340B price on the same unit and, instead, is required only to offer the lower of these two prices. 340B modifiers are needed to facilitate non-duplication of MFP and 340B discounts.
- Of CMS's two proposed options, **we encourage CMS to adopt Option 2 (*MTF Pass Through of Primary Manufacturer Funds to Dispensing Entities)***, supplemented by the use of pharmacy bank account information in the claims-level data submitted to manufacturers to help ensure that the effectuation of the MFP rebate payment goes smoothly.
- CMS seeks comment on the frequency with which the MTF should transmit data to manufacturers of selected drugs. **We ask that CMS establish a policy that the MTF should transmit data to manufacturers no more frequently than every two weeks**. Less frequent data transmissions are necessary to ensure that 1) the MTF can appropriately validate, and process data received from pharmacies and 2) manufacturers can complete data validation and 340B deduplication to ensure prompt and accurate payments to pharmacies.

We believe that CMS should also dedicate resources to educating beneficiaries about the MFP and patient smoothing. The IRA does not comprehensively account for beneficiary education and the impact of the final results of negotiation on patient out-of-pocket costs. To ensure that patients have a clear understanding of their costs, we encourage CMS to provide resources for comprehensive beneficiary education about the results of the negotiations so that they may accurately understand their out-of-pocket costs at the pharmacy counter.

Similarly, the Medicare Prescription Payment Plan, or the aspect of the program that allows patients to spread their $2,000 out of pocket maximum over the course of a year, is voluntary and beneficiaries must re-enroll in the program annually. It is critical that its availability and benefits are clearly conveyed to Medicare beneficiaries, especially those facing increased prescription drug costs. Additionally, significant outreach and robust education efforts, including collaboration with pharmacies on educating beneficiaries, will be necessary to increase beneficiary enrollment into the program since it is currently an opt-in benefit. By providing educational resources, CMS can ensure that all Medicare beneficiaries can access the benefits of the Medicare Prescription Payment Plan.

50. Negotiation Factors and 60. Negotiation Process

Section 50.1 of the guidance outlines the selected drug data factors to be reported by the Primary Manufacturer to CMS by March 1, 2025. These elements include 1) R&D costs and the extent to which those costs have been recouped; 2) current unit costs of production and distribution averaged across the Primary and any Secondary Manufacturers; 3) Federal financial support for the drug's novel therapeutic discovery and development; 4) data on pending and approved patent applications, exclusivities recognized by the FDA, and FDA applications and approvals; and 5) market data, revenue, and sales volume data for the selected drug in the United States for the Primary and Secondary Manufacturers.

While we appreciate CMS outlining the exact manufacturer-specific data required, it is unclear what the agency's expectations are regarding data quality and how it intends to assess these factors without standardizing each element. **In an effort to provide clear data that aligns with the relevant information CMS requires, we suggest that the agency allow manufacturers to 1) submit the information which they believe is most relevant and aligns with these required elements and 2) provide a justification for the manufacturer-specific data they submitted.**

As noted in section 50.2, CMS will "consider evidence about alternative treatments to the selected drug, as available, including:

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy."

Furthermore, in section 60.3 *Methodology for Developing an Initial Offer*, when developing a starting point for the initial offer, CMS proposes to identify therapeutic alternatives for the selected drug and will use the lower of Part D total gross covered drug cost (TGCDC) net of Coverage Gap Discount Program (CGDP) payments for the therapeutic alternative(s), and/or the Average Sales Price (ASP) for the therapeutic alternative(s) that is covered under Part B, or the MFP for IPAY 2026 selected drugs that are therapeutic alternatives. Then, the agency will evaluate the selected drug and adjust the starting point using the negotiation factors to determine the initial offer price. This will also include the extent to which the selected drug and its therapeutic alternative(s) address an unmet medical need, the selected drug's impact on specific populations, and the extent to which the selected drug represents a therapeutic advance as compared to its therapeutic alternatives.

Biocom California disagrees with CMS's proposal to consider the TGCDC net of CGDP payments when identifying the prices of therapeutic alternatives and we urge the agency to reconsider this approach.

When developing an initial offer, we support prioritizing factors which are most important to patients such as factors related to clinical value and unmet need and de-emphasizing manufacturer specific data elements such as cost of production and research and development costs. Ensuring such evidence is appropriately weighted in the MFP will more appropriately reward products that have enhanced patient care and will help maintain the investment in promising R&D and clinical programs.

Biocom California also encourages an approach that places a greater emphasis on a range of high-quality robust evidence, including real-world evidence (RWE), and prioritizes information submitted by clinicians and manufacturers with clinical and scientific expertise in their therapeutic areas.

Additionally, **Biocom California supports an open and transparent dialogue between CMS and the Primary Manufacturer when determining the MFP.** We ask CMS to provide manufacturers with details regarding the agency's evaluation of evidence related to therapeutic alternatives and MFP-setting, and to discuss this analysis with manufacturers. **We also suggest the agency consider circumstances when drugs should be priced as close as possible to the MFP ceiling in order to avoid imperiling patient access.** Setting higher MFPs for products that have advanced patient care and address unmet medical needs will help maintain investment in assets and clinical programs that show scientific promise and address needs not served by current therapies.

Lastly, to facilitate a transparent process, we ask CMS to provide 1) a <u>meaningful</u> justification of its initial offer, 2) its response to any counteroffer, and 3) afford the manufacturer a legitimate opportunity to comment on the response before the MFP is set. As part of this justification, we would ask the agency to provide a rationale as to how it arrived at the offer or response, including an explanation of how the decision is supported by the factors, how those factors were considered and weighted, and any additional information that was utilized as a part of the decision. Disclosing the basis of an offer or response would promote a robust and effective dialogue that informs more targeted discussions during the process.

<u>70. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect</u>

CMS discusses that a drug will be removed from the selected drug list and no longer subject to the negotiation process when the agency determines that "(1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference-listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar under section 351(k) of the PHS [Public Health Service] Act that identifies as its reference product a product that is included in the selected drug; and (2) the generic drug or biosimilar, as applicable, is marketed pursuant to such approval or licensure." CMS will consider an approved generic drug or licensed biosimilar biological product to be marketed when the totality of the circumstances, including prescription drug event (PDE) and average manufacturer price (AMP) data, demonstrate that the generic drug or biosimilar manufacturer is engaging in bona fide marketing.

Biocom California disagrees with the agency's use of "bona fide marketing" as this is a subjective assessment and we urge the agency to abandon "bona fide marketing." Instead, we suggest that CMS consider a product's market date as the date on which a generic or biosimilar is marketed <u>and</u> the date on which CMS *determines* that a generic or biosimilar has been marketed. Per CMS's Medicaid Drug Rebate Program (MDRP) Data, "market date" is defined as "the earliest date the drug was first marketed under the application number by any labeler[3]. The MDRP "market date" is a familiar term for both CMS and manufacturers and would allow for a consistent application and less burdensome adoption of this standard as part of the MDPNP.

Furthermore, the use of PDE data raises timing concerns as there will be a delay between the actual date of marketing and the date of CMS's determination that a product has been marketed since some time is required for sales to be reflected in this data. Lastly, when a new product is available and actively marketed, it takes time for the widespread adoption of the product by providers and for patients to transition to the generic or biosimilar. During this uptake period, this information will not be immediately reflected in the PDE data once a generic or biosimilar is on the market.

[3] CMS, MDRP Data Guide § 5.15 (Apr. 2022).

110. Part D Formulary Inclusion of Selected Drugs

Research has demonstrated that Part D formularies have already become more restrictive over the past decade[4]. CMS indicates it "…is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.[5] However, the IPAY 2027 draft guidance does not identify the specific steps CMS will take to strengthen its formulary oversight to ensure that beneficiaries have access to selected drugs. Absent clearer guidance from CMS, we are concerned that beneficiary access will deteriorate as the MDPNP is implemented.

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. Please contact Biocom California's Regulatory Policy Manager, Zoe Bilis, at zbilis@biocom.org for additional information or questions. We look forward to continuing to work with you on this matter.

Sincerely,

Joe Panetta
President and CEO
Biocom California

[4] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999

[5] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Biosimilars FORUM

July 2, 2024

SUBMITTED ELECTRONICALLY

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Biosimilars Forum Comment on "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027"

I. Introduction and Background

The Biosimilars Forum ("The Forum") appreciates the opportunity to comment on CMS's "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" ("Draft IPAY 2027 Guidance").

The Forum is a non-profit organization with the mission to educate stakeholders on the value of biosimilars and advance biosimilars in the United States with the intent of expanding access to biological medicines and improving health care. Our members represent the majority of companies with the most significant U.S. biosimilars development portfolios and experience in the U.S market.[1] The Forum is a voluntary group working on a consensus basis to develop policy positions to ensure the United States has a competitive, safe, and sustainable biosimilars market, providing more options to patients and physicians. Further, the Forum provides evidence-based information to inform and support public policies that encourage access to and awareness and adoption of biosimilars. The Forum respectfully submits these comments.

Biologics play a critical role in the treatment of many serious illnesses, ranging from cancers to gastrointestinal disease to genetic disorders. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") established section 351(k) of the Public Health Service Act, which provides an abbreviated licensure pathway for biosimilar (including interchangeable biosimilar) products.[2] Biosimilars cost about 30% less than the originator products they reference and have the potential to save $133 billion by 2025. Since the first biosimilar was approved just under ten years ago, these safe and effective medicines have generated substantial savings.

[1] Unless indicated otherwise, the term "biosimilar" includes interchangeable biosimilars.
[2] Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010).

On August 16, 2022, President Biden signed the Inflation Reduction Act ("IRA") into law.[3] The IRA creates a price-setting framework for certain "selected" drug and biological products.[4] In March 2023, CMS published its draft guidance, "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" ("IPAY 2026 Draft Guidance"). The Forum submitted comments, noting the potential difficulties for biosimilars that were created by CMS's interpretations in the IPAY 2026 guidance. When CMS finalized its IPAY 2026 guidance in June 2023, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026" ("IPAY 2026 Revised Guidance"), we were disheartened to see that the agency had not substantially modified that guidance in response to our comments.

Likewise, when CMS issued its Draft IPAY 2027 Guidance on May 3, 2024, we noticed that the agency is carrying through many of the problematic policies and interpretations—policies and interpretations that will hinder biosimilar development and patient access to these important medicines. Consistent with the Forum's comments on the IPAY 2026 Draft Guidance, we wish to further comment on a number of topics. In particular, the Forum continues to be concerned that CMS's guidance approach is imposing obligations on biosimilar manufacturers that are more onerous than those the statute permits. These policies will artificially capture reference products even after biosimilars have been approved and launched, therefore undermining biosimilars' ability to successfully gain market share. In addition, CMS's implementation of the Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry ("Biosimilar Special Rule") substantially nullifies biosimilars' opportunity to avail themselves of that provision, frustrating Congress's objective in preserving this vital route for biosimilar competition. All of this will chill biosimilar development and reduce affordable options.

II. Discussion

In enacting the IRA, Congress recognized both that biosimilar competition is crucial to lowering healthcare costs and maintaining a robust marketplace, and that imposing price controls on biological reference products had the potential to disincentivize biosimilar development—in particular by unduly capturing reference products that already faced (or were about to face) biosimilar competition. The statute thus contains, on its face, several indicators of Congressional intent to avoid capturing reference products and stymying biosimilar competition, including the following:

- CMS is precluded from imposing price controls on a reference product for which there is an approved and "marketed" biosimilar;[5]
- If a selected drug is relied on as a reference product for an approved and marketed biosimilar, CMS must de-select that reference product during a 9-month off-ramp period specified in the statute;[6] and

[3] Pub. L. No. 117-169, §§ 11001-11003, 136 Stat. 1818, 1833-62 (2022).
[4] *Id.*
[5] 42 U.S.C. § 1320f-1(e)(1)(B)(iii).
[6] *Id.* § 1320f-1(c)(1).

- Inclusion of the "Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Entry" (also referred to as the "Biosimilar Special Rule") in the IRA to minimize the impact on biosimilars.[7]

Unfortunately, the Draft IPAY 2027 Guidance ignores these requirements, imposing increasingly broad and *ultra vires* obligations on biosimilar and reference product manufacturers alike. This, broadening the scope of biological products that are captured and potentially diminishing the number of such products that are available to become reference products for biosimilar development while simultaneously diminishing the utility of the Biosimilar Special Rule. Despite numerous comments on this topic in response to CMS's IPAY 2026 Draft Guidance, CMS's new draft guidance still does not include any salient information on the deselection process for reference products based on biosimilar marketing. Instead, CMS again improperly ties deselection exclusively to the negotiation timeline, ignoring Congress's direction that reference products should be off-ramped 9 months after biosimilar marketing. Notwithstanding the prospect of biosimilar competition well before commencement of the relevant IPAY, and well before the statutory de-selection date, CMS sets biosimilars up to have to launch against MFPs dictated by impossibly low statutorily-mandated ceiling prices and MFPs that CMS has determined to be even lower than such ceiling prices. CMS and the Biden Administration have expressed support for the development and launch of biosimilars and should reconsider these positions in its final guidance to allow for the continued momentum of biosimilar adoption.

A. CMS Must Only Select Qualifying Biological Products for Price Controls and Timely De-Select Reference Products After a Biosimilar is Marketed

Instead of continuing to take positions that seek to destabilize and undermine the biosimilar industry, CMS can—and should—structure its implementation of the IRA's statutory mandates with an understanding that biosimilar competition is critical to a robust marketplace, not only for price and competition reasons but also for patient choices, shortage mitigation, and even to enhance innovation building on the analytical techniques harnessed first by biosimilars.

First, CMS should revise its guidance to be true to the long-standing definition and understanding of the term "marketing." CMS's *ultra vires* "bona fide" marketing definition renders the IRA process opaque for biosimilar manufacturers and runs directly contrary to Congress's instruction that multi-source products must not be subjected to the IRA's price controls.

Second, CMS should hew to the IRA's timeline for reference product de-selection based on biosimilar launch. The IRA requires a biosimilar to have been marketed by the end of the negotiation period in order for the reference product to avoid publication of an MFP, but the statute also clearly calls for *de-selection* of a reference product if a biosimilar has launched at least 9 months prior to the start of the subsequent IPAY.[8] For purposes of IPAY 2027, this means that the MFP should not apply to a selected drug if a biosimilar is licensed and marketed by March 31, 2026. CMS's guidance takes the myopic view first articulated in its IPAY 2026 Revised Guidance, that a biosimilar must have launched (and ostensibly attained "bona fide marketing" status) by the end of the negotiation period in order to avoid having an MFP implemented for the its reference

[7] *Id.* § 1320f-1(f).
[8] *Id.* § 1320f-1(c)(1).

product.[9] Here too, CMS should revise its position to avoid penalizing biosimilars and to follow statutory requirements.

i. CMS Should Eliminate the Ultra Vires "Bona Fide Marketing" Requirement

Several of the IRA's critical provisions are conditioned on when a biosimilar is "marketed." This includes whether or not a biological product is a "qualifying single source drug" ("QSSD")—it cannot be if it is the reference product for a licensed and marketed biosimilar[10]—whether a selected drug will continue to be negotiation eligible,[11] and whether a selected drug can remain a selected drug.[12] The language of each of these provisions in the IRA is clear: they refer, without caveat or limitations, to whether the biosimilar is "marketed" which has an established meaning that has been clearly defined by the Department of Health and Human Services.[13]

CMS must recognize the term "marketed" in the IRA as it appears in the statute, as it has long been understood, and as defined in FDA's regulations in the context of drugs and biological products—as the introduction or delivery for introduction of a product into interstate commerce.[14] Indeed, when a biosimilar is launched, the biosimilar faces the regulatory obligations associated with a "marketed" product, as well as the business realities of gaining traction in the marketplace for that product. There is not another point in time after launch at which "marketed" starts to mean something more.

Despite the clear regulatory definition of "marketing" as "introduction or delivery for introduction into interstate commerce,"[15] CMS's draft guidance continues to seek to impose an extra layer of obligation on biosimilars to show not only that the product is physically available for procurement and administration but also that such marketing is "bona fide." CMS states that it intends to consider a biosimilar to be marketed when the "totality of the circumstances . . . reveals that the manufacturer of that . . . licensed biosimilar is engaging in bona fide marketing."[16] And then, CMS also notes, it will continue to "monitor" the biosimilar marketing to ensure that it continues to meet whatever arbitrary standards CMS imposes.[17] This is troubling as CMS has given itself unfettered discretion to prevent the MFP from ever terminating—even if a biosimilar has indeed come to market.

It is important for CMS to acknowledge the commitment of the members of the Biosimilars Forum to developing and marketing lower cost biosimilars. Development of a biosimilar requires extensive scientific evaluations over 7-9 years and hundreds of millions of dollars. This does not include the cost of commercializing a new biosimilar in the U.S. or successfully navigate the patent

[9] Draft IPAY 2027 Guidance § 70.
[10] 42 U.S.C. § 1320f-1(e)(1)(B)(iii).
[11] *Id.* § 1320f-1(c)(2).
[12] *Id.* § 1320f-1(c)(1).
[13] *See, e.g.*, Medicaid Drug Rebate Data Guide for Labelers § 4.15; 21 C.F.R. § 314.3.
[14] *See, e.g.*, 21 C.F.R. § 314.3(b)(defining "commercial marketing" for generic drugs as "introduction or delivery for introduction into interstate commerce"); *see also* Medicaid Drug Rebate Data Guide for Labelers § 4.15.
[15] 21 C.F.R. § 314.3(b)
[16] Draft IPAY 2027 Guidance § 30, at 11.
[17] Draft IPAY 2027 Guidance § 90.4, at 115.

challenges in order to launch. The decision to develop and market a biosimilar is a very serious decision our members do not take lightly. To spend significant resources over multiple years with the possibility of launching in an unstable marketplace due to CMS misinterpretation of Congressional intent and how our market works with terms such as "bona fide marketing" is of grave concern.

The subjective "totality of the circumstances" standard has significant consequences for the prospect of biosimilar competition. Notwithstanding the actual date of marketing for a biosimilar, it can take weeks, months, or even longer before a fully licensed and marketed biosimilar passes CMS's arbitrary and as-yet undefined threshold. Educating patients and physicians takes time, particularly as many are new to biosimilars. This process is further complicated by misinformation about biosimilars and rebate traps that frustrate biosimilar uptake. CMS should abandon this "bona fide marketing" concept. At a minimum, the agency needs to provide clear standards for biosimilar developers and competitors as to what will define "totality of the circumstances" and "bona fide marketing."

CMS's "bona fide marketing" requirement creates an unstable future in which to develop and market a biosimilar in the US. It creates more artificial delay—and can result in price negotiation of a reference product regardless of biosimilar competition and without consideration of the time and resources it took to develop and launch that biosimilar. What is more, because CMS is considering all dosage forms and strengths of a biological product with the same active ingredient to be a single biological product for purposes of its selections, a "selected drug" may consist of a dozen or more products, with different indications and presentations. A biosimilar applicant may seek approval a subset of a reference product's approved conditions of use (*e.g.*, due to patents or regulatory exclusivity). CMS's extra statutory requirement that any biosimilar marketing be "bona fide" under a "totality of circumstances" approach could impose a higher standard that the biosimilar must satisfy in the context where reference products are aggregated for purposes of selection. The new draft guidance is as unclear on this point as was the IPAY 2026 Revised Guidance: we still do not know at what point the aggregated biological products might still be selected even though a biosimilar is licensed and marketed.

Without certainty as to when, or even whether, our member companies can meet this subjective standard, the Forum is concerned that CMS's interpretation will chill biosimilar development and its promise of increased access and lower drug prices. For the IPAY 2027 guidance and beyond, the Forum therefore requests that CMS abandon this artificial construct, which is untethered to the statute and harmful to the biosimilars industry and instead adopt a definition of "marketed" as it was used in the statute, consistent with the long-standing regulatory definition of that term, *i.e.*, as the introduction or delivery for introduction of a product into interstate commerce.[18]

ii. CMS's Guidance Should Include Processes for Reference Product De-Selection, Including De-Selection Based on Biosimilar Marketing after the Start of the Negotiation Period

[18] In addition, as discussed in the Forum's comments on the IPAY 2026 Draft Guidance, CMS should consider marketing based on real-time information (*e.g.,* transaction data at the point of use) to avoid making critical decisions based on outdated statistics like PDE data.

CMS's guidance fails to provide adequate processes or information implementing the IRA's requirements regarding de-selection of reference products based on biosimilar marketing. Instead, CMS focuses almost exclusively on the timing for removal of a reference product from negotiation, as it did in its IPAY 2026 guidance. The Forum urges CMS to provide clarity on the de-selection process, in particular. Effectuation of this "off-ramp" will be critical to providing stability to biosimilar manufacturers, in particular those that are planning to launch biosimilars to reference products that were selected by CMS for IPAY 2026 and that will be selected for IPAY 2027.

The Forum urges CMS to revisit its thinking in its Draft IPAY 2027 Guidance, and to give meaning to the statutory provision stating that if a biosimilar is approved and marketed by March 31 of any given year, *i.e.*, 9 months prior to the commencement of the following IPAY, its reference product will cease to be a selected drug for that IPAY.[19] For a drug initially published on the selected drug list for IPAY 2027, if a biosimilar were approved and marketed by March 31, 2026, CMS should clarify that drug would cease to be a selected drug and no MFP would *apply* for IPAY 2027. This interpretation is consistent with the statutory text, which seeks to impose prices only on qualifying *single source* drugs. Please clarify in guidance which definitions of date(s) CMS will abide by, as this directs the biosimilar industry in our decisions on our ability to develop, receive FDA approval, navigate patent challenges, and launch our biosimilars within CMS requirements.

Contrary to CMS's assertions, a more conservative reading is not mandated by the text or structure of the IRA. Nowhere does the IRA authorize—or even suggest—that CMS can impose an MFP on a biological product that does not meet the QSSD definition. To the contrary, *only* QSSDs are subject to price controls. And, the statute expressly ties the QSSD definition to the initial price applicability year.[20] We note that the Guidance's reference to section 1192(c)(2) of the IRA cannot salvage this interpretation. Section 1192(c)(1) describes the circumstances during which a selected drug will (or will not) remain a selected drug. Section 1192(c)(2), itself billed as a "clarification," merely conveys *additional* circumstances during which a selected drug will remain a selected drug. CMS, however, would have this "clarification" impose draconian consequences on selected reference biological products with biosimilar competitors that launch 9 or more months before January 1, 2027 but after the close of negotiation—an unsupportable reading of that text.

B. CMS Should Maximize the Utility of the Biosimilars Special Rule

Under the Biosimilar Special Rule, CMS must delay selection and negotiation of a reference biological product upon a request that demonstrates a "high likelihood" that a biosimilar referencing such product will be approved and marketed within a specified time period.[21] CMS's new draft guidance largely reiterates the agency's guidance on these provisions from the IPAY 2026 guidance. Although CMS received a number of Special Rule delay requests for IPAY 2026, the agency did not grant any requests, did not explain the rationale for the rejection, nor even make public the identity of the reference products for which requests were not granted. The result is that the Forum's members remain in the dark about the operation of the Special Rule provisions and

[19] 42 U.S.C. § 1320f-1(c)(1).
[20] *See* Inflation Reduction Act § 1192(e)(1); *see also id.* § 1191(b)(2).
[21] *See* 42 U.S.C. § 1320f-1(f)(1)(A).

how CMS intends to implement them. Again, we urge CMS to provide industry with greater transparency on detailed requirements and the agency's rationale.

The Biosimilar Special Rule aims to maintain the incentives for biosimilar companies to continue to invest significant resources in biosimilar development, notwithstanding the negotiation framework introduced under the IRA. The Forum urges CMS to interpret this rule to provide maximum flexibility—and hence maximum opportunity for biosimilar competition, patient access, and healthcare savings—not to continue its opaque and unduly conservative guidance approach.

i. Timeline for CMS Engagement and Delay Requests Should Be Earlier and More Transparent

For IPAY 2026, CMS denied biosimilar applicants any process or opportunity for engagement prior to the deadline for submitting the Initial Delay Request. In its Draft IPAY 2027 Guidance, CMS proposes to follow the same process: setting a deadline of December 2025 for Special Rule delay requests without providing any insight into the products for which such requests may be needed. Requiring a biosimilar manufacturer to effectively guess which reference biologic may be selected for negotiation and thus whether to submit a delay request is unreasonable and inefficient. We urge CMS to revisit the delay request process, allowing for earlier and more open communication with biosimilar companies, with appropriate confidentiality safeguards, to better understand whether a reference biologic is likely to be selected and where the biosimilar manufacturer is in the development process, to more accurately gauge whether the likelihood of approval is "high" and what a launch timeline, assuming licensure, looks like well in advance of the selected drug publication date for that IPAY.

Congress recognized the importance of biosimilar competition in increasing access to affordable medications with its enactment of the Biosimilar Special Rule, and early engagement will make the Biosimilar Special Rule framework more meaningful and predictable, while ensuring continued development of and investment in biosimilars. Indeed, CMS has recognized the need for biosimilar applicants to have sufficient opportunity to provide CMS with information during the Initial Delay Request process, but in order to fulfill that important objective, additional discourse and transparency is needed. To that end, the Forum requests that CMS begin discussions with biosimilar applicants significantly in advance of the publication of the selected drug list and not limit conversation with applicants thereafter. Likewise, CMS should establish a dispute resolution process under which the agency provides notice of an unsuccessful request under the Special Rule, and the biosimilar applicant is afforded the opportunity to dispute that decision.

ii. CMS Should Give Meaning to the Special Rule Delay's "Significant Amount of Progress" Requirement in the Second Year

The new draft guidance solicits comment regarding the types of documentation and information that may constitute "'clear and convincing evidence, the manufacturer of [the] biosimilar biological product has made a significant amount of progress . . . towards both such licensure and the marketing of such biosimilar biological product'" for the second year of delay under the Special

Rule.[22] In order to give meaning to this provision, however, CMS must first stop equating *high likelihood* of licensure and marketing with licensure and marketing itself.

Indeed, the requirement for this showing itself is evidence that the original showing of "high likelihood" is not supposed to equate to licensure and marketing; if it were, there would be no progress left for a biosimilar applicant to show. Yet, because of CMS's overly restrictive view of "high likelihood," it is unclear what a biosimilar applicant *could* provide to show a significant amount of progress. With respect to progress toward licensure, if the application is *approved*, then there is nothing to show. Even if a BLA has just been submitted (such that it could be filed but not approved in the first year of the delay), that BLA would be pending by the time of the subsequent delay request. With respect to progress on the marketing side, CMS is already requiring certainty of marketing in the first delay year by requiring that the patent field has already been cleared. There is, simply, nothing else to provide. In other words, CMS's stringent approach effectively nullifies the "significant amount of progress." It is incompatible with the structure of the Special Rule Delay—and demonstrates how overreaching CMS's approach to high likelihood is.

iii. CMS Should Stop Equating "High Likelihood" With Certainty of Licensure

The Forum requests that CMS reconsider the criteria for high likelihood of licensure and marketing laid out in the draft guidance in order to maximize the utility of the Biosimilar Delay and to avoid stymying biosimilar competition.

Under the statute, there must be a "high likelihood" of licensure within *two years* of the relevant selected drug publication date (*i.e.*, for IPAY 2027, February 1, 2027). Under the timeline laid out by CMS's guidance is that in order to demonstrate high likelihood of licensure, a biosimilar BLA must be filed by FDA, or approved, no later than January 15, 2025; this means that a 351(k) BLA must be submitted to FDA no later than November 2024.

The Forum urges CMS to reconsider this timeline in its revised guidance. FDA review of a biosimilar BLA takes one year from the time of submission. Thus a biosimilar BLA can be approved, and the biosimilar licensed by February 1, 2027 as long as the BLA is submitted by February 1, 2026—more than a year later from CMS's November 2024 deadline. Simply stated, by restricting eligibility for the Biosimilar Special Rule to biosimilar manufacturers with a filed or approved 351(k) BLA, CMS truncates that *two-year* period for demonstrating high likelihood of licensure to a *one-year* period.

What is more, CMS's approach cannot be squared with the PHS Act's regulatory exclusivity provisions, which block FDA from approving a biosimilar for *12 years* after approval of a reference product.[23] To help illustrate, a reference product approved in January 2014 would be eligible for drug selection on February 1, 2025 for IPAY 2027. Under CMS's interpretation, a biosimilar applicant must submit its 351(k) BLA no later than November 2024, meaning that FDA review would conclude in November 2025. However, a biosimilar to that reference product *could not be approved* until after January 2026 at the earliest (or June 2026 if a pediatric exclusivity extension attaches)—well-after the one-year review period for the application. This

[22] Draft IPAY 2027 Guidance § 30.1.1, at 20.
[23] 42 U.S.C. § 262(k)(7).

is particularly problematic for biosimilars given that a reference product may be selected for negotiation prior to the expiration of that reference product's exclusivity period.

Equating "high likelihood of approval" with approval itself reads "high likelihood" out of the statute; it also ignores these deadlines. And it leaves biosimilar applicants stuck between a rock and a hard place, with CMS requiring approval early enough to trigger the Biosimilar Special Rule, but not so early as to face the statute's preclusion from eligibility for such delay if more than a year elapses between licensure and marketing (a *very* common occurrence in practice given the duration of time it takes to get through the patent dance).

To maintain the viability of the Biosimilar Special Rule and consistent with our previous comments, we suggest that CMS clarify in its guidance additional circumstances under which the agency can determine there exists a high likelihood of licensure. This should be done in conjunction with FDA, which has a good earlier sense of metrics that can gauge likelihood of licensure, such as whether the biosimilar manufacturer has had a successful Biological Product Development (BPD) Type 4 Meeting (i.e., a pre-BLA meeting).

iv. CMS Should Stop Equating "High Likelihood" With Certainty of Marketing

The Forum similarly requests that CMS reconsider its criteria for demonstrating high likelihood of biosimilar marketing, as the criteria in the draft guidance are irreconcilable with the statutory language and do not reflect the patent litigation process and timeline for biosimilars.

As set forth in the Draft IPAY 2027 Guidance, to demonstrate a high likelihood for Initial Delay Requests for IPAY 2027 under the Biosimilar Special Rule, the applicant must demonstrate clear and convincing evidence that the biosimilar will be marketed before February 1, 2027. Referencing sections 1192(f)(1)(B)(ii)(I)(bb) and (III) of the IRA, CMS further states that the biosimilar manufacturer must demonstrate "both (1) that patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed" (under CMS's criteria, which effectively require certainty, not likeliness, that patents will not preclude marketing); and "(2) that the Biosimilar Manufacturer will be operationally ready to market the Biosimilar."[24] CMS believes that evidence showing that a biosimilar meets these two requirements is necessary to establish clear and convincing evidence that the Biosimilar will be marketed. Section 30.3.1 of the Draft IPAY 2027 Guidance describes the information CMS may consider (in addition to the required information) in determining whether a biosimilar meets the statutory threshold for delay.

But CMS fails to acknowledge that there are alternative, objective factors that provide good barometers of high likelihood of marketing while also preserving the functionality of the Biosimilar Special Rule—which CMS's requirements do not do. We suggest that CMS consider any one of the following as clear and convincing evidence of a high likelihood of marketing. These options are tailored to achieve the Congressional intent of the rule while fostering continued development of biosimilars.

- A copy of a notice of first commercial marketing pursuant to 42 U.S.C. § 262(l)(8), which the biosimilar applicant must provide to the reference product sponsor no later than 180 days before the date of first commercial marketing;

[24] Draft IPAY 2027 Guidance § 30.3.1.2, at 25.

- An attestation that, for any ongoing patent litigation, the court has issued neither a preliminary injunction nor a permanent injunction preventing launch by the date that is two years after the selected drug publication date;
- Public statements from the biosimilar manufacturer that it is planning for biosimilar launch before the date that is two years after the selected drug publication date (*e.g.*, press statements, excerpts from investor relations reports or meetings, and public statements from a corporate director). These statements could also be accompanied by an attestation signed by the General Counsel and/or Chief Executive Officer. The fiduciary obligations biosimilar companies owe to their shareholders ensure accountability, providing a preexisting check against self-serving statements;
- Public statements from the reference product sponsor that it is planning for biosimilar launch before the date that is two years after the selected drug publication date (*e.g.*, in disclosures to the United States Securities and Exchange Commission);
- Biosimilar market entry forecast by an industry-leading analytics firm, such as IPD Analytics. These firms prepare data-driven forecasts of anticipated market entry based on tracking litigation and mapping out the patent landscape; or
- An executive summary of a law firm's assessment of the asserted patents' invalidity and non- infringement.

It is imperative that CMS's policy provide consistent and meaningful application of the Biosimilar Special Rule going forward. Adoption of any of these objective measures will help ensure innovation is not stifled due to a moving target or subjective decisions.

Depriving biosimilars of the necessary time to secure approval and launch will result in delayed price decreases and decreased competition. Biosimilar entry can facilitate price erosion, ensuring patients have access to less expensive, safe, and effective medicines sooner. And, it results in fewer options overall, increasing risk of shortage and decreasing options for patients and healthcare providers. More broadly, undermining the utility of the Special Rule, particularly in conjunction with CMS's collapsing of the minimum statutorily provided period before applicability of the MFP, will deter biosimilar development.

v. Need for Increased Transparency

In order to have a clear understanding of how CMS is managing the negotiation program (including selection of products for negotiation and timely deselection of products from the selected drug list), the Forum requests additional information and transparency from CMS. This includes making available the data on which CMS intends to rely in determining whether any given biological product will be considered a qualifying single-source drug or negotiation-eligible drug well in advance of the selected drug publication date; timely publishing a list of all reference products for which biosimilar applicants submitted delay requests (including those that were denied); and, if CMS continues to implement its bona fide marketing requirement, publishing the criteria CMS intends to use to evaluate bona fide marketing and any data on CMS's tracking of bona fide marketing.

III. Conclusion

The Forum remains gravely concerned that as drafted, the Draft IPAY 2027 Guidance raises significant issues that are likely to stifle the biosimilar industry, directly contrary to Congress's intent. The current biosimilars market is difficult. Recently launched biosimilars did not gain significant percentages of the market quickly, and excess ASP erosions, while emblematic of competition, are unsustainable. If CMS does not ensure a robust off-ramp for reference products, and if the Biosimilar Special Rule does not provide a workable pathway for granting a delay, then our members will continue to reconsider their development programs.

Given this landscape, our chief concern is that CMS has established an arbitrary and subjective decision-making regime that is inconsistent with the statute and introduces substantial uncertainty into the industry. CMS's use of a "totality of the circumstances" approach will result in reduced biosimilar development because it creates a moving target and does not guarantee that a reference product will be properly excluded from that IPAY—a necessary outcome to promote biosimilar competition and adoption as intended by Congress. As a result, CMS's implementation of the IRA may ultimately prolong high healthcare costs and reduce patient access to more affordable medicines. This can be remedied by adopting the recommendations the Forum put forth in this comment, as well as our previous comments, and in general, by engaging in a more collaborative and transparent negotiation and application process with manufacturers concerning the Biosimilar Special Rule.

Respectfully submitted,

Juliana M. Reed
Executive Director
The Biosimilars Forum

Boehringer Ingelheim USA
Corporation
900 Ridgebury Road
Ridgefield CT 06877

Via Electronic Mail - *IRARebateandNegotiation@cms.hhs.gov*

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Seshamani:

Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) welcomes the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS or the Agency) *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (Draft Guidance).[1] Boehringer adopts and incorporates by reference the comments submitted on the Draft Guidance by the Pharmaceutical Research and Manufacturers of America. We offer the following comments to elaborate and expand on certain issues raised in the Draft Guidance.

Boehringer is a leading research-driven biopharmaceutical company committed to innovation in areas of high unmet medical need. Jardiance® (empagliflozin), one of Boehringer's products, was a selected drug for initial price applicability year (IPAY) 2026. Accordingly, Boehringer has a significant interest in CMS's implementation of the Inflation Reduction Act (IRA). While Boehringer supports the goal of ensuring patient access to affordable, life-enhancing medicines, it has significant concerns relating to aspects of the Draft Guidance, including but not limited to the proposed procedures and deadlines associated with providing beneficiaries access to the MFP.[2]

1. **For IPAY 2026, CMS Should Provide Manufacturers of Selected Drugs Additional Flexibility to Implement a Process to Ensure Access to Drugs at the MFP**

Throughout the Draft Guidance, CMS reiterates that failure to provide access to the MFP may be grounds for the imposition of civil monetary penalties (CMPs). Specifically, CMS notes that CMPs could be imposed on a manufacturer if it fails to (1)

[1] Available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[2] Boehringer has filed a lawsuit challenging the "Drug Price Negotiation Program" in the U.S. District Court for the District of Connecticut. *See Boehringer Ingelheim Pharm., Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:23-cv-01103 (D. Conn. Filed Aug. 18, 2023). Boehringer reserves all of its rights with respect to such litigation.

register with the Medicare Transaction Facilitator (MTF) or meet the data exchange requirements,[3] (2) provide access to the MFP to beneficiaries and transmit reports with payment-related data with regard to the claim identified in the MTF data within the 14-day prompt pay window,[4] or (3) make the MFP available to a dispensing entity or provide the report with payment-related data to the MTF within the 14-day prompt MFP payment window.[5]

Since IPAY 2026 will be the first time any manufacturer must implement a system to provide access to the MFP, Boehringer is concerned that there are likely to be glitches or failures outside the control of any party. To avoid penalizing a manufacturer for an error outside its control, Boehringer asks that CMS publicly commit to not imposing CMPs for any good faith errors or technical problems that may otherwise temporarily prevent a manufacturer from adhering to the guidance.

2. **CMS Should Extend the Deadline for Manufacturers to Submit Their Plans to Provide Access to the MFP At Least to September 2025**

In the Draft Guidance, CMS requires "that a Primary Manufacturer submit its plan for making the MFP available, including its process for deduplicating 340B covered units . . . for the selected drug, in writing to CMS at least seven months before the start of the first initial price applicability year for the selected drug."[6] As a result, manufacturers would have to finalize and submit a plan for Jardiance® no later than June 1, 2025. This represents a significant change from the CMS's guidance for IPAY 2026, where CMS required that a Primary Manufacturer "submit its process for making the MFP available . . . at least 30 days before the start of the [IPAY]," i.e., by December 2, 2025.[7]

Boehringer is concerned that the new proposed timeline for submitting a plan to make the MFP available will be difficult to comply with and unnecessarily short. Since IPAY 2026 is the first time any manufacturer will have to implement a system to provide access to the MFP, there are likely to be multiple challenges to implementing such a system. As the June 1, 2025 deadline is not required by statue, Boehringer asks that CMS provide manufacturers additional flexibility to fully vet the proposed system. As a result, CMS should delay the submission deadline until September 1, 2025 at the earliest.

3. **CMS Should Commit to Using Existing Authority to Ensure that Medicare Beneficiaries Have Access to Selected Drugs**

CMS notes that it "intends to continue the formulary inclusion policies described" in the 2026 Revised Guidance.[8] Nevertheless, CMS states that it "does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS' revised guidance . . . are warranted."[9] Boehringer reiterates its concern that Part D plans will unfairly disadvantage selected drugs through unfavorable formulary placement, increased cost sharing, or additional utilization management. Such actions could make access to the selected drugs more difficult for Medicare beneficiaries which, in turn, could lessen any potential cost savings from the Program.

Boehringer asks that CMS commit to using its existing authority to ensure that selected drugs are placed on the most favorable formulary tier afforded any brand name drug in the therapeutic class, but at a minimum, on the formulary tier and level of cost sharing

[3] Draft Guidance at 39.
[4] *Id.* at 42.
[5] *Id.* at 43.
[6] *Id.* at 110.
[7] Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 at 127.
[8] Draft Guidance at 121.
[9] *Id.*

predating selection, and without stricter utilization management requirements, unless related to clinical safety or product label limitations. **Boehringer believes that two sections of CMS's regulations, which address access to covered Part D drugs and CMS's review and negotiation of Part D plan bids, provide existing authority to impose such a requirement on Part D plans. These regulations (1) require adequate coverage of Part D drugs most commonly needed by Medicare patients,[10] (2) authorize CMS to reject bids that would substantially discourage enrollment,[11] and (3) authorize CMS to decline bids that would significantly increase cost sharing and decrease benefits.[12]** Given this existing authority, CMS should communicate its intention to enforce access requirements for selected drugs to Part D plans before IPAY 2026 MFPs are finalized without having to wait and see how Part D plans choose to cover and govern access to selected drugs.

* * *

Thank you for considering these comments and those submitted by PhRMA. If you require any additional information or have questions, please contact Michael Penn, Head of Public Policy at (203)791-6680 or michael.penn@boehringer-ingelheim.com.

Sincerely,

Bridget Walsh
Vice President
Government Affairs & Public Policy
Boehringer Ingelheim Pharmaceuticals, Inc.

Christine Marsh
Senior Vice President
Value & Access
Boehringer Ingelheim Pharmaceuticals, Inc.

[10] *See* 42 C.F.R. § 423.120(b)(2)(iii).
[11] *See* 42 C.F.R. § 423.272(b)(2)(i).
[12] *See* 42 C.F.R. § 423.272(b)(4).

Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY to: IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: "Medicare Drug Price Negotiation Program" Guidance for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the "Maximum Fair Price" (MFP) in 2026 and 2027

Dear Dr. Seshamani,

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 ("Guidance")*.[1]

At BMS, we are inspired by a single vision—transforming patients' lives through science. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

BMS supports Medicare policies that promote beneficiary access to new and effective medical treatments and help ensure Medicare patients benefit from the innovation that defines the U.S. health care system. That is why we do not support the so-called Medicare "negotiation" policies contained in the *Inflation Reduction Act (IRA)*. We are extremely concerned by the impact that these policies will have on clinical research in addition to current and future innovation for patients. For these reasons, BMS has filed a federal lawsuit asking a court to declare the IRA unconstitutional. BMS believes that, in the absence of full repeal of the IRA's drug pricing provisions, significant clarity and reforms are necessary in several critical areas. Although our comments are designed to help CMS in these areas as it implements the process that Congress established in the IRA, nothing we say in this comment letter should be construed as suggesting that CMS can cure the constitutional flaws in the statute that Congress wrote. The IRA compels manufacturers to

[1] CMS, "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" (May 3, 2024), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

express "agreement" that there is a "negotiation," and that the resulting government-mandated price is the "maximum fair price" ("MFP"). But as we have noted in our litigation, there are no true negotiations or agreements involved, and the price is not fair.

The IRA will have vast ramifications for patients, providers, manufacturers, and other stakeholders across the country. BMS is concerned that CMS' implementation of the IRA could have sweeping negative repercussions with respect to Medicare beneficiary access to needed medicines, and, indeed, for all patients. It is vital for CMS to give meaningful consideration of and response to stakeholder feedback on its proposals, particularly as the Agency begins to finalize details on effectuating the MFP in the marketplace.

BMS appreciates the opportunity to provide the following comments on the Guidance. We intend our input to help CMS improve transparency and clarity of the IRA's negotiation program. Our recommendations reflect and are driven by our deep expertise in pharmaceutical innovation, delivery and supply chain, and access, as well as our experience with the IRA to date,[2] and we offer them to help mitigate against the negative consequences the Guidance would have on innovation and, most importantly, patients.

Key comments include:

- **Identification of Selected Drugs:** While BMS appreciates the opportunity to comment on Section 30, as we were unable to do in IPAY 2026 when CMS did not accept comments, we oppose CMS' broad interpretation of a qualified single source drug (QSSD) and its introduction of the extra-statutory "bona fide" marketing construct. We are concerned with how narrow policies related to biosimilars and orphan indications will impact current and future innovation and patient access to medicines. We urge CMS to be targeted, flexible, and lawful in its approach to identifying QSSD for the purposes of drug selection.
- **Requirements for Manufacturers of Selected Drugs:** Despite CMS' intent to create a Medicare Transaction Facilitator (MTF) that could effectuate the MFP by January 1, 2026, BMS has serious concerns with CMS' proposed approach due to various operational complexities. These include but are not limited to significant financial and operational burdens on manufacturers, lack of accountability and transparency across the supply chain, and complexity related to CMS' obligation not to require unlawful 340B program duplication. We hope to work with the Agency to ensure operational success, but in the absence of additional Agency action to remedy these serious concerns, CMS should provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance and ensure efficient operationalization of the MFP.
- **Negotiation Factors and Negotiation Process:** BMS appreciates that CMS is seeking to incorporate lessons learned on the negotiation factors and process from IPAY 2026. Just as CMS has learned from the IPAY 2026 process, so too have stakeholders, including manufacturers—and it is critical for CMS to apply those learnings to IPAY 2027 and make meaningful, positive changes. We note that the current process is not sufficient to address (to the extent possible under the IRA) the full value of a selected medicine. For factors that are not tied to the value a selected medicine offers to patients, caregivers, providers, and the Medicare program, we strongly urge CMS to only collect essential information for determining the MFP but to do so in the most effective and accurate way possible. And importantly, we continue to ask the Agency for the maximum level of flexibility and transparency in implementing this process, especially in the early IPAYs. BMS strongly supports CMS' efforts to directly and actively solicit patient-focused input from patients, beneficiaries, caregivers, and consumer and patient organizations, but CMS must make significant improvements in order for the process to be more meaningful, comprehensive, transparent, deliberative, and relevant to understanding a medicine's value.

[2] In general, we refer CMS to BMS' comments in response to the "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" Draft Guidance, released on March 15, 2023 (hereinafter referred to as the "IPAY 2026 comments").

- **Part D Formulary Access:** BMS remains concerned with how onerous formulary management policies may impede access to care, particularly in light of IRA "negotiation." We are disappointed with CMS' passive approach to "monitoring" Part D plans' compliance with existing formulary requirements, and we implore the Agency to preemptively modernize and strengthen CMS' current formulary review standards for a post-IRA era. Given the negative downstream consequences that negotiation will have on the Part D program, including on plan dynamics and increased utilization management (UM), we urge CMS to critically examine these impacts and prioritize shared decision-making between patients and providers, not health plans, on appropriate treatment plans.

Section 30 – Identification of Selected Drugs for IPAY 2027

BMS appreciates the opportunity to provide comments on Section 30 of this Guidance. We remain disappointed that CMS did not solicit or accept comments on Section 30 in IPAY 2026. Although we understand such comments were not considered for IPAY 2026, BMS nonetheless submitted to CMS extensive feedback on Section 30. We hope the Agency contemplates such feedback from both IPAYs 2026 and 2027 when incorporating lessons learned and changes to the Guidance based on these comments. As we noted in our IPAY 2026 comments, had CMS allowed for a comment period, the Agency would have been in the position to consider feedback on critical issues related to IRA implementation from BMS and other relevant stakeholders. We appreciate the opportunity to submit comment that CMS has now solicited and to provide thoughts on these important topics below.

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

CMS states that it will identify "qualifying single source drugs" (QSSDs) at the active moiety/active ingredient level. As BMS noted in our IPAY 2026 comments, that approach is contrary to and beyond the scope of the IRA statute, creating unnecessary confusion in the face of statutory clarity, and departing from well-established means of identifying products. The statute makes no mention of active moiety or active ingredient, and CMS' proposal undermines incentives for innovation in a way that will be detrimental to future innovation and patient access to crucial medicines.

Alternatively, CMS could consider an approach that would be consistent with the statute. For example, CMS may identify QSSDs by reference to a distinct New Drug Application (NDA) or biologics license application (BLA), aggregate relevant program expenditures across dosage forms and strengths within each distinct NDA or BLA, and apply the MFP across dosage forms and strengths specific to each such NDA or BLA. This approach would maintain consistency with the Food and Drug Administration's (FDA's) well-established approval framework for NDAs and BLAs.

Approximately half of all indications and three-quarters of industry-funded clinical trials are a result of post-approval activity, and many post-approval clinical trials and indication approvals occur after or near drug selection and MFP effectuation dates.[3] **We implore CMS to update its approach to identifying QSSDs to not only be consistent with the statute and current standards, but to better preserve the balance of incentivizing innovation for patients.**

Relatedly, BMS has serious concerns with CMS' policy to consider a generic drug or biosimilar product to be "marketed" when the "totality of the circumstances"—a standard so vague that it amounts to no standard at all—reveals whether a manufacturer is "engaging in bona fide marketing."[4] Those serious concerns are doubled by CMS' suggestion that it will continue to "monitor" marketplace sales to evaluate whether there is "meaningful competition"[5] from a generic or

[3] Grabowski, H., & Long, G. (2024). Post-approval indications and clinical trials for cardiovascular drugs: some implications of the US Inflation Reduction Act. Journal of Medical Economics, 27(1), 463–472. https://doi.org/10.1080/13696998.2024.2323903.
[4] CMS, IPAY 2027 Draft Guidance, p. 11.
[5] *Id.* at 115.

biosimilar, in determining whether a selected drug remains eligible to be negotiated. "Bona fide marketing" and "meaningful competition" are not phrases or concepts included in the statute, and CMS' attempt to create such standards is *ultra vires*, demonstrated by the following points:

- Under the statute, a selected single source product can no longer be defined as a "selected drug" after the Secretary's determination that at least one generic drug or biosimilar has been approved or licensed, as applicable, and "is marketed pursuant to such approval or licensure."[6] Although Congress gave the Secretary responsibility for the *determination* that such approval or licensure and marketing has occurred, the statute's plain words establish the objects of that determination.
- At a threshold level, negotiation applies only to a *single source* product, meaning that if a *different* source exists (*i.e.*, a generic or biosimilar), the product categorically cannot come from a single source. Further, the plain meaning of the statutorily unqualified term "marketed" reveals that Congress did not contemplate extra-statutory concepts related to degree of utilization or "meaningful" competition.
- Both CMS and FDA have long determined a product to have been marketed based on a point-in-time standard. For instance, CMS has long used this concept in the Medicaid Drug Rebate Program (MDRP), where "market date" has been defined in Guidance to mean "the earliest date the drug was first marketed under the application number of any labeler,"[7] and where "marketed" is defined under the National Drug Rebate Agreement to mean the date on which the product was first "available for sale by a manufacturer in the states."[8] Congress would have understood this common-sense, established approach in drafting the IRA provisions.

Interposing subjective, indefinite criteria in the determination of when a generic is "marketed" is inappropriate, subject to abuse, *ultra vires*, and inconsistent with the terms of the statute. It also risks introducing a number of practical complexities and drawbacks, including unnecessary lag with respect to termination of MFP and concomitant adverse effects on generic/biosimilar competition which could jeopardize future savings, contrary to what Congress has sought to promote.

BMS therefore supports CMS taking a position that aligns with the "market date" reported under the MDRP because it presents an established, uniform standard that would help ensure that manufacturers are not inappropriately subject to selection, negotiation, application of an MFP, or an excise tax. Adopting this standard would also help ensure clarity and consistency in the identification of these key dates under Medicare negotiation. BMS urges CMS to use this standard for identifying both: (1) the date on which a generic or biosimilar is first marketed; and (2) the date on which CMS determines that to be the case (which, ideally, should be the same as the actual marketing date to prevent complexities involving potential inappropriate delay in removal from negotiation or MFP applicability). This approach would also support CMS' objective to encourage meaningful competition by providing predictability for generic and biosimilar manufacturers who would otherwise be concerned about their product's ability to compete with a selected drug's MFP.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

BMS remains concerned about how the IRA could risk undermining the patient-centric incentives at the core of the Orphan Drug Act (ODA). In the last 40 years, the ODA framework has supported the development, approval, and distribution of products that meet pressing, often unmet, public health needs, and otherwise might not ever be available. Historically, companies have launched their products in smaller indications that often impact the rare disease

[6] *Id.* at 102.
[7] CMS, MDRP Data Guide § 5.15 (Apr. 2022).
[8] National Drug Rebate Agreement § I(l), 83 Fed. Reg. 12,770 (Mar. 23, 2018).

community; and the IRA may shift incentives such that companies will now prefer to launch indications that have greatest economic value and impact.

With respect to orphan drug exclusions, CMS' interpretation of the statute is overly narrow and short sighted with respect to research and development (R&D) incentives created under the ODA. Under CMS' current approach, an orphan drug will be vulnerable for negotiation as soon as it receives an additional orphan designation, disincentivizing manufacturers from conducting further research on more than one rare disease. Additionally, relying on the databases mentioned in the Guidance may not always provide an accurate reflection of whether a drug's indication falls within the scope of the orphan drug designation. CMS should adopt practices consistent with statutory requirements, and should allow manufacturers to present evidence to support their claims while also evaluating orphan designation at the time of selection (and not looking to any previous designation that has been withdrawn). **Furthermore, to maximize patient benefit and preserve incentives for manufacturers to develop future therapies for rare diseases, CMS should consider clarifying that the "clock" for identifying QSSD status of an orphan drug starts when it loses its status as an excluded orphan drug, not from the date of the earliest approval of the active moiety. Additionally, BMS recommends CMS apply the Orphan Drug Exclusion on an indication-specific basis, not a product-specific basis.**

30.3 Selection of Drugs for Negotiation for Initial Price Applicability Year 2027

To ensure a fair and lawful drug selection process, CMS should be mindful that it does not have the authority to redefine which drugs qualify for selection, as this power has not been delegated by Congress. There continues to be an inherent risk that CMS could engage in *ultra vires* selection of a drug, such as publishing a drug statutorily ineligible for selection, or take action that raises constitutional concerns related to equal protection given to the selection of drugs for particular manufacturers. The Agency could mitigate against such risks by engaging with stakeholders to confirm that its approach comports with the statute and the discretion granted to the Agency under the statute. Further, the Agency should provide advance notice to applicable manufacturers of drugs *anticipated* for selection and offer those manufacturers the opportunity to raise concerns before ultimate selection.

The Agency could also consider, among other measures: (1) providing at least one quarter of such advance notice to manufacturers of drugs anticipated for selection; (2) providing the same such advance notice to the manufacturers of the next five drugs (should drugs anticipated for selection be determined ineligible); and (3) providing biosimilar manufacturers the opportunity to inquire as to whether a particular reference biologic is among the drugs anticipated for selection. If advance notice conflicts with CMS' final determination of delay for certain biologics, CMS could explain in such advance notice that a delay request has been submitted and is being actively considered.

30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2027

BMS remains concerned with CMS' proposed timeline for the biosimilar special delay request. Currently, manufacturers of biosimilar products will have to proactively submit their delay request prior to the selected drug publication date, forcing both biosimilar and branded manufacturers to speculate on which reference products will be selected for negotiation. The uncertainties imposed by this timeline can lead to inefficiencies, administrative burden, and operational challenges for the biosimilar manufacturer and undermine CMS' objective of bolstering competition and bringing biosimilars to the market more swiftly.

In implementing the requirements for granting an initial delay request for a biosimilar manufacturer, BMS believes CMS should set a deadline as close as reasonably possible to selection to help ensure the best available information for consideration of the request, whereas the date established creates a very tight timeframe that could result in critical information not being considered. The Agency could also notify the reference biologic manufacturer of a request and subsequently delay selection while the Agency evaluates all information submitted, while also providing notice of

determination in advance of the selected drug publication date, allowing the biosimilar manufacturer to bring any error or other concern to CMS' attention before such date.

Additionally, CMS should clarify what constitutes an agreement that incentivizes a biosimilar manufacturer to request a delay, and which agreements could disqualify the reference biologic from being eligible for the delay. CMS should not presume that the existence of an agreement between a biosimilar manufacturer and a reference biologic manufacturer necessarily incentivizes the biosimilar biological manufacturer to request a delay. CMS refers to the statutory unavailability of a delay request where an agreement exists between a biologic manufacturer and a biosimilar manufacturer that imposes "improper constraints"[9] on the biosimilar manufacturer but does not identify the contours of such an agreement that would give rise to such improper constraints in the view of the Agency. Consistent with the statute, the Agency should determine an agreement is disqualifying *only* when the agreement explicitly requires submission of an initial delay request. As the Agency recognizes, certain agreements could inform whether "high likelihood" exists of biosimilar entry in a specified period. Presuming "improper constraints" in an agreement, rather than looking to the language of the contract itself, risks nullifying the statute's contemplation of these other agreements informing "high likelihood" determinations.

30.3.1.2 High Likelihood

BMS encourages CMS to reasonably make a "high likelihood" determination based on the best available information and consider further information that could help inform whether high likelihood exists (*e.g.*, FDA's views of data and information submitted in the BLA, FDA communications about BLA status, the biosimilar manufacturer's production and distribution arrangements and progress, and information the biosimilar manufacturer concludes to be relevant to the determination). The statute permits the Agency to consider such other information and could also permit a biosimilar manufacturer's supplementation through a timely request based on recent information or otherwise for good cause.

BMS seeks to clarify what constitutes clear and convincing evidence that a biosimilar will be marketed within the required period of time and would note that CMS should specify how it intends to apply this term, so that biosimilar manufacturers are on notice as to the standard that such submissions must satisfy and thereby can make informed decisions as to whether to make such a submission and, should they choose to do so, include the information needed to satisfy that standard. CMS should precisely define what clear and convincing evidence that a biosimilar will be marketed within the required time frame means in the specific context of the biosimilar delay provision. CMS' explanation of clear and convincing evidence should include examples of circumstances in which CMS will and will not grant a delay request. There is a range of information that informs whether there is a high likelihood that a biosimilar will be licensed and marketed within the specified period. Biosimilar manufacturers are in the best position to determine which information may be relevant to that determination—and there is no one-size-fits-all approach to identifying the types of information that will help CMS determine whether to grant any particular request for a delay. A precise definition will increase transparency with respect to how CMS intends to approach delay requests, helping reduce the likelihood of biosimilar manufacturers or CMS investing in delay requests that are unlikely to succeed.

Section 40 – Requirements for Manufacturers of Selected Drugs

40.4 Providing Access to the MFP in 2026 and 2027

BMS appreciates CMS' proposal to utilize an MTF overseen by CMS to carry out critical front- and back-end functions of MFP effectuation. **While we believe that CMS has the opportunity to be efficient in implementing MFP effectuation by utilizing an MTF service provider, CMS must make several key changes to ensure operational success by January 1,**

[9] CMS, IPAY 2027 Draft Guidance, p. 25.

2026. In the absence of CMS' action on these critical topics, BMS urges CMS to allow manufacturers to have the highest degree of flexibility in IPAYs 2026 and 2027 to compliantly effectuate the MFP. This is particularly important as manufacturers are the only party facing civil monetary penalties (CMPs) and must comply with statutory requirements.

As a general matter, we note it is extremely important that the selected MTF service provider must be a separate and independent stakeholder and should have no pre-existing or future conflict of interest with stakeholders (*e.g.*, payers and/or Pharmacy Benefit Managers, or PBMs), nor be able to gain competitive advantage due to its role as MTF.

While the MTF process could potentially ease the burden on all stakeholders, including manufacturers, BMS notes that in its current state, the MTF would fall short of this goal. MFP effectuation will come at a significant financial and operational cost to manufacturers, particularly for high volume, high value products. For example, despite both the Part D plan sponsor and CMS' Part D Drug Data Processing System (DDPS) verifying claims, based on BMS' real-world experience with claims verification, manufacturers will need to engage in a third verification to ensure the data of MFP-eligible individuals are scrubbed to remove duplicative, non-compliant, previously discounted claims as well as to ensure appropriate patients are receiving MFP-eligible products, which adds significant financial and operational complexity. And manufacturers will need to pass data from the MTF to a manufacturer-verified vendor who will scrub according to the manufacturer's data standards, internally verify, and then move to pay appropriate claims. Operationalizing the coordination of up to three vendors will be costly and burdensome, but furthermore, will be significantly challenging to complete within 14 days. BMS is also concerned with the lack of standard payment amount outlined in the Guidance. Without standard payment amounts and mandatory participation by dispensing entities, it will require manufacturers to have a specific payment amount and arrangement, via separate contracts, with each pharmacy, which would be an incredible, if not impossible, burden. In addition, we strongly oppose CMS' proposal to require manufacturers to submit MFP effectuation plans by June 1, 2025—the IPAY 2026 Guidance finalized a date of December 2, 2025, and the loss of approximately six additional months to evaluate and validate a compliant plan will further increase costs and complexities.

For these reasons and other reasons highlighted further below, we consider it to be vital that CMS give manufacturers flexibility in the MTF process, particularly in the first few years of effectuation, and mandate that a manufacturer cannot be expected to reimburse higher than Wholesale Acquisition Cost (WAC), as acquisition cost is not public and subsequent transactions occur between dispensing entities and other stakeholders, which can lead to a different non-public acquisition cost that is unavailable to manufacturers. We hope to work with the Agency to ensure operational success, but in the absence of additional Agency action to remedy these serious concerns in advance of January 1, 2026, and to help ensure a transparent and administratively efficient operationalization of the MFP, CMS should provide flexibility for manufacturers to establish the appropriate data sets, timeframes, and processes to support compliance. This approach should achieve a result that could be more easily adjusted over time than a solely CMS-directed mechanism and would relieve the Agency from complex administrative responsibilities.

We provide feedback on specific elements of the MTF process below and look forward to working with CMS to refine this process in advance of January 1, 2026.

- 40.4.1 MTF Data Facilitation:
  As CMS itself states: "CMS may revisit the data flow for such years in the future and anticipates technical specifications to evolve as development of the MTF's data functionality moves through acquisition and information system development."[10] So, too, should CMS allow manufacturers to maintain flexibility in their approaches for IPAYs 2026 and 2027. Manufacturers, as well as other stakeholders in the system, will need to

[10] *Id.* at 39.

set up new, complex systems and processes to operationalize MFP effectuation, so we urge the Agency to give all stakeholders flexibility during implementation.

In general, and as we discussed in our IPAY 2026 comments, it is BMS' strong belief that CMS should lengthen the 14-day prompt MFP payment window, given the new processes that need to be developed to facilitate compliant MFP effectuation, including the additional 340B program complexity and reduced timeframe for developing an MFP effectuation plan. At a minimum, we ask CMS to allow manufacturers electing to provide MFP refunds outside the MTF payment facilitation process the flexibility to agree with dispensers on a payment timeline that is still compliant with the statute and also in line with standard business practices—in other words, BMS is asking CMS to confirm that the 14-day prompt payment window, if finalized contrary to feedback as to its infeasibility, should *only* apply to manufacturers who utilize the MTF payment facilitation process. To the extent possible, we urge CMS to aid in effectuating the MFP by utilizing an approach similar to the Coverage Gap Discount Program (CGDP), where the Agency would pass through MFP refund amounts at the time of claim adjudication. This would not only support manufacturers as we review claim-level data from the MTF and make payments more in line with standard business practices but also ensure dispensers receive prompt payment of MFP refunds. We look forward to working with the Agency further on this topic.

CMS further justifies this 14-day payment period by stating "because MFP eligibility status [will be] twice validated before the data elements are sent from the MTF to the Primary Manufacturer, the data elements will have been verified as involving a selected drug that was dispensed to an individual who is MFP-eligible."[11] Based on our significant experience with transaction processing, we note that CMS' assessment is incorrect. Currently, manufacturers must validate data from health plans and other entities to ensure proper identification of duplicate claims, fraud, etc. Without requirements for Part D plans to verify data, the compliance risk is even more heightened for manufacturers when effectuating and providing the MFP—meaning it is imperative that manufacturers separately validate MTF-related claims data. Despite CMS' intentions, this will still place an incredible financial and operational burden on manufacturers. **Therefore, we ask CMS to lengthen the 14-day prompt MFP payment window, or at a minimum, allow manufacturers who do *not* utilize the MTF payment facilitation process to agree with dispensers on an acceptable and compliant payment timeline.**

As CMS acknowledges, there will be an "anticipated high volume of claims for selected drugs."[12] To that end, we note that the voluntary nature of dispensing entities' participation in the MTF effectuation model will be incredibly challenging. Manufacturers will be required to maintain separate contracts with separate payment rates for each dispensing entity. As discussed in 40.4.3 and 40.4.5, BMS strongly encourages CMS to standardize the payment amount for the Standard Default Refund Amount at WAC and make it a true default payment option and require that dispensing entities accept payment by the manufacturer's preferred option. To ease additional burden, manufacturers should not be required to inform the MTF of payment if a different vendor is being used.

BMS appreciates CMS' consideration of minimum necessary claim-level data elements that the MTF will send to a manufacturer. We note that many of these data elements are necessary data elements, including but not limited to elements that identify the provider, plan benefit package, and Part D beneficiary. If possible, BMS asks CMS to be more prescriptive on and clarify the purpose of each element; for example, the stated purpose of several data elements is similar, if not the same, as others. While we appreciate the consideration of a minimum necessary dataset, we urge CMS to give manufacturers flexibility to establish the appropriate data sets and

[11] *Id.* at 42.
[12] *Id.* at 43.

processes. Given the individual product and channel, as well as standard business practices, manufacturers are best-suited to determine which claim-level data elements are necessary and sufficient. Should the Agency choose not to give manufacturers this flexibility, we ask CMS to work closely with industry to refine this list in the near term and over time. BMS also strongly opposes CMS' proposal to allow the 340B Claim Indicator to be reported as voluntary by the dispensing entity, and we opine further on that topic in 40.4.2.

Regarding the Payment Elements List, BMS asks CMS to create an additional payment element, "Amount of MFP Refund Payment/Adjustment Due." We also note that a distinction is needed between the basis of the MFP discount/refund determination and actual remittance of MFP discount/refund amount.

- 40.4.2 Nonduplication with 340B Ceiling Price:
BMS appreciates the opportunity to provide comments on how manufacturers make MFP available in a nonduplicated amount to the 340B ceiling price, but we are disappointed that CMS has not proposed a more thoughtful approach on how to operationalize the nonduplication provision nor provide adequate specificity to effectuate it. Clarity from CMS is essential on this topic, as the appropriate application of MFP depends upon the 340B status of the patient. The IRA statute and "agreement" also make plain that the manufacturer *shall not be required* to provide a 340B discount lower than the MFP, but shall be required to provide 340B discounts only in a non-duplicated manner. Adequate transparency is essential for CMS to oversee and enforce compliance of this requirement to safeguard the manufacturer's non-duplicated provision of the MFP and 340B discounts. In the absence of operationalizing a system, CMS should require that the MTF pass along all data fields requested by the manufacturer to facilitate the manufacturer's ability track duplicate discounts. Accurate and robust data collection is essential to the integrity of both the 340B program and IRA implementation. The current proposed data fields are insufficient and do not allow enough information for manufacturers to de-duplicate the claims, making a requirement for the MTF to share requested data with manufacturers essential.

  CMS notes that payment must be passed through to the dispensing entity within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual, yet fails to acknowledge that the current timeframe for 340B determination is open-ended (*i.e.*, there is no standard, defined payment window), and is therefore incompatible with the 14-day prompt payment timeline, ultimately resulting in disorderly MFP extension and CMS enforcement. Currently, covered entities assert that they have an unlimited amount of time to comb through claims, retroactively identify 340B "patients," and issue chargebacks to manufacturers. Multiple third-party administrators have identified this as a profit center and created a business model around identifying 340B claims for covered entities. This model is another way businesses profit from the 340B program and makes it extremely difficult to know and verify if the patient served was actually a 340B patient, by any definition.

  BMS notes the importance of establishing clear determination of both the 340B and MFP status on claims before being submitted to a manufacturer for settlement. This will significantly reduce administrative burden and facilitate processing within the timeframes specified in the Guidance and will help ensure consistency with statutory non-duplication requirements. CMS must support transparent data submission and validation, including requiring key data elements of covered entities needed to facilitate the identification of 340B claims and the prevention of duplicate discount occurrence. CMS should, for example, mandate the use of modifiers, with accountability for covered entities to provide such modifiers, as an approach to identifying claims on which a 340B discount is owed. **In the absence of Agency action to establish an effective method for identification, BMS asserts that manufacturers will need to develop their own processes for deduplication, despite not being required to carry this burden by statute, and CMS must give manufacturers the flexibility to establish such**

processes. CMS should also require Part D plans to establish procedures to identify 340B units of negotiated drugs to assist in this process.

CMS reminds manufacturers that it is their responsibility to "ensure that the appropriate price concession is honored,"[13] but that does not account for the obligation of CMS under the IRA "agreement" not to require manufacturers to engage in duplicated discounts. Further, by making the 340B Claim Indictor voluntary for dispensing entities, the Agency gives these manufacturers little-to-no recourse to properly effectuate the MFP and account for nonduplication. While not sufficient on its own to ensure compliance, BMS strongly urges CMS, at a minimum, to make the 340B Claim Indicator mandatory. CMS has already recognized the importance of claims data in publications regarding Medicaid and 340B, and these recommendations are also germane for Medicare. As we noted in our IPAY 2026 comments, we agree with CMS' specific statements and suggest CMS apply its own guidance for the MFP: "When states provide claims level data to manufacturers, we would expect there to be a reduction in number of disputes due to more accurate information being provided.... Manufacturers likely need claims level data for true invoice validation purposes… [and] If claims level data is provided, this may reduce the state's administrative burden and expense of researching manufacturer dispute issues."[14] Additionally, the statute clearly states that manufacturers must provide access to the MFP based upon MFP-eligible individuals, and data would support that provision.

Incomplete data inputs lead to incomplete outcomes, and voluntary processes that allow partial data submissions or rely on inaccurate input data ultimately do not provide the needed transparency. CMS should acknowledge that addressing these transparency challenges in a manner that ensures visibility of the MFP validation data is critical to successful MFP operationalization. It would also be helpful for CMS to clarify that a final 340B eligibility determination at the point-of-sale aligns with CMS' 340B modifier mandates, which would help resolve the current MFP-340B complexity.

BMS is disappointed that CMS is choosing not to assume responsibility for deduplicating discounts between the 340B ceiling price and MFP but empathizes with how arduous that process would be for the Agency, or for any stakeholder including a manufacturer, to deduplicate claims, particularly with incomplete data. **In the absence of Agency action, and in light of the vast complexity of the 340B program, CMS should expressly acknowledge that manufacturers may establish, receive, review, and as necessary, audit MFP validation data to ensure manufacturers have provided MFP access in accordance with the statute, and require the MTF to submit to manufacturers any data requested necessary for deduplication.** In addition, we ask that manufacturers that demonstrate a good faith effort to provide covered entities with the lesser of the 340B ceiling price or MFP should be held harmless from CMPs and other enforcement mechanisms. Without this CMS support, the statute cannot be faithfully implemented, and manufacturers will be left in an impossible position of not knowing how to comply with the statutory requirements, all while under the threat of penalty for perceived non-compliance.

- 40.4.3 Retrospective MFP Refund Amount:
  We thank CMS for acknowledging the "significant challenges that manufacturers and dispensing entities face in attempting to establish a reliable acquisition cost for a selected drug that could be used to determine the difference between the MFP and the dispensing entity's acquisition cost."[15] **Despite CMS' proposal to create a Standard Default Refund Amount, which we appreciate is intended to approximate the acquisition costs of**

[13] *Id.* at 48.
[14] CMS, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" (Jan. 2020), *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_107.pdf.
[15] CMS, IPAY 2027 Draft Guidance, p. 50.

dispensing entities and streamline MFP effectuation, without solidifying the Standard Default Refund Amount as a "true default," and thus standardizing the payment amount, it still places an incredible burden on manufacturers. Manufacturers will essentially have a separate payment amount with each dispensing entity, and each entity will require a separate contract to ensure compliance—which could require manufacturers to enter into tens of thousands of contracts for this process.

Even more critical is that manufacturers do not control acquisition costs; acquisition costs are determined by transactions between wholesalers/distributors and pharmacies. We are concerned that there could be perverse incentives for other stakeholders to increase acquisition costs significantly above WAC if manufacturers were to be held accountable for the difference. In consideration of that risk and the challenges manufacturers would face in trying to effectuate acquisition costs for individual pharmacies, CMS should acknowledge that manufacturer participation in the MTF option and provision of the Standard Default Rebate Amount on claims provided by the MTF will satisfy manufacturer obligations under the IRA. **At a minimum, CMS must ensure that manufacturers would never be responsible for reimbursing on a cost greater than WAC. Accordingly, we also urge CMS to standardize the payment amount for the Standard Default Refund Amount at WAC.**

- 40.4.4 Options for MTF Payment Facilitation:
  BMS appreciates CMS' proposal to create a voluntary payment mechanism through the MTF to connect manufacturers and dispensing entities in order to provide the MFP via retrospective refund per the statutory requirements.

  In general, BMS supports Option 2, where the MTF receives aggregated refund amounts from the manufacturer and passes those refunds through to dispensing entities. We note that, with modification, Option 2 would function most similarly to the current CGDP, where an end-to-end transaction system has been efficient and effective for all stakeholders. CMS could, for example, add dispenser bank account information to the MTF data fields to aid in payment facilitation. Importantly, we ask CMS that manufacturers not be held responsible should the MTF fail to make timely payments (*e.g.*, if a dispenser has not provided accurate bank account information).

  BMS thanks CMS for proposing that utilizing the MTF for payment facilitation is an optional endeavor, and we stress that this flexibility is critical for MFP effectuation. While the choice to engage in a payment facilitation method is, and should be, optional, we ask CMS to clarify that should a manufacturer choose to participate in the MTF payment process, dispensers should be required to accept payment via this method. Conversely, if a manufacturer chooses to utilize an alternative process, the dispenser must agree to accept payment through those terms.

- 40.4.5 MTF Dispensing Entity Participation Requirements:
  As noted throughout our Section 40 comments, CMS' proposed MFP effectuation model will place a tremendous burden on manufacturers to compliantly provide the MFP to dispensing entities. To reiterate, it will be incredibly challenging, if not impossible, for manufacturers to participate in compliant MFP effectuation while dispensing entity participation remains voluntarily. **We ask CMS to revise its policy, such as through requiring dispensing entities to accept payment in the way that a manufacturer directs (whether through the MTF or through some other means) and by standardizing the payment amount that a manufacturer provides to dispensing entities.** Unless CMS provides additional clarity and certainty on this topic, manufacturers must have flexibility in implementing an MFP effectual model for January 1, 2026.

Section 50 – Negotiation Factors

BMS appreciates that CMS is seeking to "incorporate lessons learned pertaining to the collection process, question format, and content received from respondents for [IPAY] 2026."[16] Just as CMS has learned from the IPAY 2026 process, so too have stakeholders, including manufacturers—and it is critical for CMS to apply those learnings to IPAY 2027 and make meaningful, positive changes. While BMS understands that CMS will release the Negotiation Data Elements and Drug Price Negotiation Process Information Collection Requests (ICRs) at a later date, the following comments in Sections 50 and 60 are intended to provide CMS with preliminary feedback in advance of those ICRs based on our experience with the process and content, including questions and formats. We thank CMS for its willingness to update the negotiation factors process and look forward to commenting on the ICRs.

In general, however, an ICR is not an adequate mechanism for providing public input and dialogue on the important process of determining the wide range of data and metrics that CMS will use in MFP-decision making. Furthermore, the current process is not sufficient to address the full value of a selected medicine. **For factors that are not tied to the value a selected medicine offers to patients, caregivers, providers, and the Medicare program, we strongly urge CMS to only collect information that is essential in determining the MFP but to do so in the most complete and accurate way possible. And importantly, we continue to ask the Agency for the maximum level of flexibility and transparency in implementing this process, especially in the early IPAYs.**

50.1 Manufacturer-Specific Data

BMS remains concerned with both the scope and burden of information CMS will require as part of the ICR submission. For example, manufacturers will have exceedingly short timeframes for completing and submitting the data submission—which could require multiple individuals compiling complex data sources and then submitting in a form acceptable to CMS for submission. This is especially burdensome for manufacturers that may have more than one product on the selected drug list. Even for the appropriate data elements that manufacturers can provide, the breadth of information coupled with the strict timelines will make the burden exceptionally high. And without clear instructions and guidance from CMS on how to answer intricate questions, manufacturers may make reasonable assumptions with their submissions that are not consistent with how other manufacturers may interpret their obligation, thus creating an inequity in how CMS views this information to determine an MFP. There may also be information to which manufacturers do not reasonably have access or cannot provide with reasonable efforts, further driving inequities across data submissions and subsequent evaluations. And many of the requested data, such as government price reporting information, are already available to CMS, while others are publicly available, creating additional and unnecessary burden on manufacturers.

Importantly, CMS' requested costs do not accurately portray the cost of innovation or reflect the cost of getting a selected drug to patients—and oftentimes, drug development and delivery is significantly more costly than what CMS' requested costs portray. For example, no other health technology assessment (HTA) process in the world includes supply side factors (*e.g.*, R&D costs, public funding) to determine the value of a product and/or to inform price considerations. **BMS strongly urges CMS to place a lesser emphasis on factors such as R&D recoupment and more emphasis on the selected drug's therapeutic and clinical attributes, which is the true measure of innovation. The manufacturer-specific data elements are also not reflective of the realities of supplying product to the market, as channel complexities, access, and additional costs are not accounted for in the submission. To the extent possible, we urge CMS to account for these measures by providing an opportunity to submit a more complete view of the drug development and delivery process; and if CMS cannot commit to these updates, then BMS urges CMS to considerably de-emphasize the magnitude of adjustment based on manufacturer-specific data.**

[16] *Id.* at 65.

BMS also asserts that only information germane to determining an MFP for the Medicare market should be included in the manufacturer's submission (*i.e.*, commercial and/or non-Medicare government pricing information should not form the basis of a Medicare price). And practically speaking, only information that is currently available via standard price reporting conventions should be included in the manufacturer's submission (*i.e.*, CMS' proposed "Manufacturer Net Part D Price" is not a standard metric that is reported anywhere throughout the federal programs, is an inappropriate attempt to aggregate price concessions from supply chain entities across the pharmaceutical supply chain, and should also not form the basis of a Medicare price). The IRA statute only refers to the submission of a manufacturer's non-FAMP, and not the other pricing metrics in the current ICR, and BMS urges CMS to remove these extraneous reporting requirements. We also ask CMS to only finalize submission requirements that are essential for operationalizing the negotiation process and to do so in the least burdensome way possible.

50.2 Evidence About Therapeutic Alternatives for the Selected Drug

BMS supports CMS issuing a new ICR to "improve upon the collection process, question format, and content received."[17] As noted in our previous comments, we continue to urge CMS to deeply consider a robust body of information when assessing a selected drug's impact on unmet need and therapeutic advance. This holistic consideration should go beyond rigid health care costs and health outcomes to consider the impact of medicines on society—such as improvements to patients' and caregivers' lives, efficiency and quality in the health care system, and equity across populations.

While we have been encouraged that CMS appears receptive to a broad and holistic view of value, we remain deeply concerned with the significantly limited opportunity proposed for manufacturers to share evidence about alternative treatments. As CMS seeks to improve upon this process, we urge the Agency to continue to review experienced HTA markets, and leverage greater flexibilities related to in-market value assessments, such as unlimited word counts on dossiers, transparency in the decision-making process, and more opportunities for an information exchange. Other countries have adopted a more collaborative approach with manufacturers and have implemented key procedural elements, such as structured scoping phases, indication-specific assessments, traceability of outcomes, and structured patient involvement to promote a cooperative process. CMS must demonstrate fluidity in these areas, especially where other markets with longstanding assessment processes offer cooperative procedural elements.

We also believe it is critical for CMS to consider a variety of perspectives throughout the data submission and review process, and are pleased to see that CMS is seeking to "improve the data collection process with information more closely aligned to a respondent's area of expertise."[18] As we encouraged CMS to do in our IPAY 2026 comments, the Agency should consider an appropriate forum and method for different stakeholders to provide input, rather than using a single submission format for all stakeholders. If CMS attempts to continue to use a single set of questions to collect feedback from a variety of stakeholders, we urge the Agency to provide transparency and explicit rationale for decision making. Moreover, BMS recommends the Agency adopt a structured and transparent consultation process where relevant stakeholders are permitted to provide input in a format most suited to their expertise. We opine further on stakeholder involvement elsewhere in these comments.

BMS also seeks to provide feedback on some select topics below related to the negotiation factors:

- Cost-Effectiveness Measures: BMS appreciates CMS' commitment to ensuring that it not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value, which also includes excluding Quality-Adjusted Life Years (QALYs) from the assessment. While new methods like generalized cost-effectiveness analysis (CEA) are being

[17] *Id.* at 69.
[18] *Id.*

explored to account for differential value of health improvement in different contexts, there is no consensus yet on the ability of these methods to adequately address health equity considerations for special populations. For example, while Equal Value of Life Years Gained (evLYG) has gained traction in limited academic settings, most methodological and ethical limitations of the QALY still apply to the evLYG and could be used to limit patient access by utilizing value-for-money comparisons to arbitrary thresholds. Further, CMS has not sought public comment from patients and other stakeholders on willingness to pay and appropriate cost-effectiveness thresholds for IRA assessments in general. Therefore, BMS strongly recommends that CMS not anchor value assessments for selected drugs on CEA. Any consideration of CEA should merely be a part of a broader and holistic assessment of value and should only be used for a positive, upward adjustment for a selected drug.

- Research Relating to Specific Populations: In the Guidance, CMS indicates that priority will be given to studies focusing on special populations (including individuals with qualifying disabilities, patients with End-Stage Renal Disease [ESRD], and Medicare-aged populations) over studies for which these populations were not the primary focus. While BMS agrees that benefits and risks to these special populations are critical to assess, depending on the size of the special population relative to the overall patient population, there may be numeric differences in outcomes for a selected drug compared to its therapeutic alternative that are not statistically significant (or may not be replicable in a similar population). We recommend that CMS consider subgroup/population analysis as a core assessment with safety and efficacy and that evidence from these studies be considered of equal priority to evidence from larger studies that are better powered to draw comparative effectiveness conclusions. We also encourage CMS to consider evidence in other subpopulations, including patients with comorbidities and different ethnicities, when data is available, and ask that CMS require submitters to speak to the quality of evidence and/or be prepared to assess that quality during the Agency's internal review process.
- Addressing Unmet Medical Needs: BMS urges CMS to take a broad, holistic view of unmet medical need. As CMS will assess medications in the middle of their life cycles, BMS recommends that unmet need be considered from initial approval to the time of assessment. Additional value should be particularly considered for those medications that treat serious medical conditions, including those that make incremental steps toward curative goals or significantly reduce the risk of adverse events compared to alternatives. For example, comparative effectiveness evidence in difficult-to-treat or underserved populations can demonstrate that a selected medicine address an unmet medical need. Further, unmet need should be viewed from the perspective of patients and providers. Unmet need should accordingly encompass a spectrum of characteristics, such as: alternative dosing regimens; route of administration; reduction of side effects; and shorter treatment periods.

Section 60 – Negotiation Process

As with our Section 50 comments, we thank CMS for planning to release the Negotiation Data Elements and Drug Price Negotiation Process ICRs at a later date and offer the following comments in advance of those ICRs based on our experience with the negotiation process. We thank CMS for its willingness to update the negotiation process and look forward to commenting on the ICRs.

60.1 Establishment of a Single MFP for Negotiation Purposes

BMS understands CMS' desire to convert utilization across a medication's dosage forms and strengths into a consistent 30-day equivalent supply. While this methodology may yield a meaningful metric for certain Part D drugs which are exclusively in tablet form, taken at a consistent rate through the entire course of therapy, not approved for varying regimens to treat different indications, and not prescribed uniquely to each patient based on their own individual body weight or other personal characteristics, it is important for CMS to recognize that many products do not meet all of these criteria, which will preclude establishment of a single price that can be applied meaningfully to all NDCs. In addition, there are other notable challenges with using a 30-day equivalent supply for pricing, including: weight-based

dosing, dosing variation across indications, and dosing titration/loading doses/changes in dosing over course of treatment. And treating supplies for less than 30 days as 30-day supplies is erroneous and creates inconsistency across different dosing regimens.

The issues in calculating a 30-day equivalent supply mentioned above would also preclude meaningful comparisons to therapeutic equivalent products in many cases. For instance, many products are prescribed in combination with other drugs, which may be produced by other manufacturers. In this situation, comparisons of one manufacturer's drug to a single drug from another manufacturer would be further obscured, as neither reflects a complete course of therapy, and neither can simply be substituted for the other within that course of therapy.

Given the significant limitations of the 30-day equivalent methodology, BMS also strongly urges CMS to consult manufacturers on the methodology to be used for a selected drug at least prior to the "initial offer," but ideally closer to drug selection, to better ensure any limitations are appropriately addressed and accounted for in the initial offer. With greater information, and in consultation with the manufacturer, CMS would be able to gain a better understanding of the drug's usage and determine how to make meaningful comparisons to therapeutic equivalents.

60.3 Methodology for Developing an Initial Offer

- Identification of Therapeutic Alternatives: BMS supports CMS' decision to consider FDA-approved resources when identifying indications for a selected drug as well as the body of information that will be considered (manufacturer/public data, clinical guidelines, peer reviewed studies) when identifying therapeutic alternatives. **As CMS prepares to examine a large volume of evidence across multiple indications and multiple therapeutic alternatives within each indication and conduct several simultaneous assessments, BMS strongly recommends that CMS plan for additional, early dialogue with manufacturers, who have the most expertise with the selected drug, or at minimum, issue advance notice about the possible selection and the therapeutic alternatives that are likely to be considered by the Agency.** Importantly, therapeutic alternatives should be selected based on clinical appropriateness and not narrowed based on least costly alternatives. BMS also requests the opportunity to submit comparative effectiveness evidence data after CMS has identified indications and therapeutic alternatives. Relatedly, and as a practical matter, BMS cautions CMS on the usage of off-label therapeutic alternatives, as well as those in different pharmacologic classes; CMS must prioritize the most appropriate therapeutic alternatives and seek input from manufacturers and other stakeholders on these alternatives through a separate scoping process before comparative effectiveness evidence is submitted to focus those submissions on only prioritized alternatives, reducing burden to both manufacturers and CMS. In ex-U.S. countries, value assessments are typically conducted for a single indication and pricing and access mechanisms are subsequently applied behind the scenes to account for the differential benefit of each indication. But these mechanisms often have data collection and financial flow issues. CMS should expect similar operational challenges to translate varying indication values to a single MFP—for example, oncology therapies can have dozens of indications, and the value story across these indications is unique given unique patients' needs; and for fixed-dose combinations, as well as single agents used in combination, value assessments have additional complexity. **The consequences of inaccurate value determination can lead to restricted patient access. To prepare for this unprecedented task within a short amount of time with essentially no framework or examples on which to rely, BMS recommends that CMS plan for additional consultation with stakeholders. To do so, BMS requests that CMS issue additional guidance, as well as allow for a scoping meeting, prior to the evidence submission for a complex situation like medicines being used in combination.**
- Starting Point for Initial Offer: BMS opposes CMS' proposal to consider CGDP payments—and MFPs, when applicable—in using therapeutic alternatives as the starting point for the initial offer. We note that CGDP

payments are not a standard metric that is reported anywhere throughout the federal programs and can be highly variable depending upon the mix of drugs a patient is taking, and therefore, should not form the basis of a Medicare price.

- Adjusting the Starting Point Based on 1194(e)(2) Factors: To ensure the proper consideration of information between a selected drug and alternatives, manufacturers should have insight into CMS' literature review and the opportunity to comment on the accuracy of the proposed value capture. **When considering evidence about alternative treatments and added benefits of a selected medicine, BMS also encourages CMS to consider several critical elements in order to capture the full- and long-term value of a treatment, including: health outcomes, both from clinical trials and real world evidence, medical association guidelines, and health equity and subpopulation benefits. Equally important is an emphasis on health outcomes and benefits, including but not limited to reduction in burden to the health care system, patient preferences, treatment adherence, and scientific spillover. Non-clinical benefits should be weighted heavily when determining the starting point for the MFP offer.** Also, important to consider is situations in which medicines treat conditions with a limited number of treatment alternatives, as well as the innovation and societal progress that is achieved in treating serious medical conditions, including incremental success achieved to address unmet needs and provide hope for patients.
- Analysis for Selected Drugs with Therapeutic Alternatives: BMS urges CMS to clearly state how the Agency came to a determination that a selected drug did or did not represent a therapeutic advance or address an unmet medical need. While we support driving towards patient-centered outcomes, CMS should provide more transparency into how qualitative considerations translate into an adjustment to the starting point.
- Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data: For reasons mentioned elsewhere, CMS should place lesser emphasis on manufacturer-specific data, particularly in early years based on inconsistencies in submissions and use of inappropriate price comparators and until CMS can alleviate patient access concerns.

60.4 Negotiation Process

BMS strongly supports CMS' efforts to directly and actively solicit patient-focused input from patients, beneficiaries, caregivers, and consumer and patient organizations as it implements IPAY 2027. While we appreciate that CMS held patient-focused listening sessions at the start of the IPAY 2026 negotiation process, we believe there are significant improvements that can be made to future patient-focused events. BMS encourages CMS to make the process more meaningful, comprehensive, and deliberative by taking the following actions:

1. Clarify the appropriate participants and establishing clear intentionality and purpose for the listening sessions to increase transparency.
2. Revamp the structure of the listening sessions to better support meaningful bi-directional engagement with participants.

To demonstrate the entire community perspective, CMS should clarify the appropriate participants and purpose of these sessions. BMS strongly believes that the sessions be open to not just patients but also caregivers, health care providers, disease-specific organizations, and other stakeholders who serve as patient advocates or are experts in issues such as health equity. CMS should provide more structured discussion topics to help participants prepare. This could include the purpose of these listening sessions as well as how the information will be used by CMS during the negotiation process. More fully understanding how their perspective will be used can help participants more meaningfully prepare and share their personal experiences. Perhaps CMS could host an interactive webinar in advance of the patient-focused listening sessions that outlines the process and expectations. This would give potential participants a chance to ask questions and gain more insight into what CMS is seeking during the patient-focused events. In previous sessions, CMS required

disclosure of conflicts, but it was unclear why these disclosures were required and what type of disclosures were appropriate to report. Moreover, while participants were required to disclose funding from pharmaceutical companies as a potential conflict, they were not required to report funding from other parties. As such, CMS should require and publish disclosures for all reported conflicts, including those from participants who might represent biased views of health plans and payers.

BMS believes that the structure of the listening sessions can be greatly improved to better support a meaningful conversation with participants. For example, CMS should remove any ambiguity in the speaker selection process. During the IPAY 2026 sessions, it was unclear how CMS selected speakers if there were more than 20 speakers registered for a listening session. Listening sessions should also support bi-directional feedback. With this in mind, CMS should consider events that are not listen-only but instead encourage discussion and dialog among speakers and with CMS. These steps would promote participants to more freely share their personal experiences and allow the Agency to show its active engagement and consideration of feedback from stakeholders. CMS should also prioritize creating an environment that is supportive of feedback. For example, the Agency should build in more flexibility for length of statements from participants and giving extra time as needed. We also urge CMS to continue with drug-specific sessions instead of combining sessions for drugs that treat similar conditions or diseases; separate sessions for each drug are essential in order to highlight different lived experiences that would be lost in broader discussions, and CMS would also be failing to acknowledge the heterogeneity in treatment effect by combining condition or disease areas. Finally, CMS should make the entire listening session process as transparent as possible, for example, by sharing the transcripts after the events in a more timely manner and articulating clearly how it will incorporate patient and caregiver experiences into its decision-making process and pricing methodology for selected drugs.

We are encouraged that CMS intends to improve upon the design of the patient-focused listening sessions from IPAY 2026 and would strongly urge CMS to take stakeholder feedback into account as it revamps this process. It is important to mitigate barriers to participation for the patient and caregiver community so they can fully share their unique expertise and perspectives on the value of medicines. Their firsthand experiences with selected drugs will be invaluable as CMS proceeds with the negotiation process.

60.4.1 Provision of an Initial Offer and Justification

It is critical for manufacturers to understand the context and basis for the MFP offer. **To increase transparency and further CMS' two-way dialogue with a manufacturer of a selected drug, we continue to urge the Agency, as we did in our IPAY 2026 comments, to consider releasing a confidential report for the manufacturer alone alongside the initial offer and justification to better inform a manufacturer's "counteroffer" and subsequent data submissions.** Given the anticipated submissions from members of the public, including academic experts and clinicians, CMS will have a significant amount of information on a selected drug, as well as latitude in determining what is included in an initial concise justification. Manufacturers are unlikely to have enough context to effectively address potential evidence gaps in the initial offer, which would impact manufacturers' abilities to craft an appropriate, evidence-based counteroffer. We therefore ask the Agency to provide a confidential report to manufacturers with details on the Agency's assessment of a selected product, as well as the evidence which was deemed relevant and appropriate from stakeholder submissions. The concise justification and report should, at a minimum, include the following information: (1) evidence sources CMS considered, including third-party assessments the Agency may have formally or informally considered; (2) how each factor was weighted in CMS' MFP determination; (3) how patients and other stakeholders engaged in the process and influenced CMS' decision-making; (4) benefits and impacts that CMS considered; and (5) how CMS came to determine therapeutic advance and unmet need.

60.4.2. Required Components of a Counteroffer

BMS reiterates that if CMS does not provide a meaningful justification in the initial offer, then it is impossible for manufacturers to provide a meaningful justification in the counteroffer. We urge CMS to provide a more complete and meaningful initial offer and justification to improve the counteroffer process. This should include a more formulaic approach to how CMS weighted each factor to give manufacturers more transparency and predictability in the process and for the future.

60.4.3 Negotiation Process After Manufacturer Counteroffer

BMS has serious concerns with CMS' process for interfacing with manufacturers of selected drugs. As set forth in the Guidance, manufacturers may have only up to three meetings with CMS—all occurring after the initial MFP is set by the Agency. While we agree with CMS that meetings occurring after CMS rejects a manufacturer's counteroffer is necessary and will allow for a more efficient and effective process, starting meetings only *after* rejection of the manufacturer counteroffer is too late. In our vast experience negotiating with states and payers, CMS' process is highly unusual and arbitrary, and we would encourage CMS to allow for more meaningful dialogue with manufacturers throughout the process, including through appropriate flexibility to have as many meetings as necessary and not place arbitrary limitations on meetings.

We strongly disagree with CMS' assertion that the selection of 15 drugs, or more in the future, "may present challenges" that would warrant the Agency to allow for *less* meetings with manufacturers than in previous years,[19] especially in light of the fact that the current meeting structure is already counter to standard negotiations. CMS incorrectly proposes an "either-or" approach in the Guidance—three meetings *or* "an additional written offer to be made in lieu of one or more meetings"—when, at a minimum, CMS should be suggesting an "and" approach—three meetings *and* additional written offers, as appropriate.

BMS strongly believes that CMS should meet with the manufacturer of a selected medicine at multiple points during the negotiation process to allow manufacturers to address questions and provide additional commentary on the value of these medicines, and we note that three meetings, at a minimum, are necessary to thoroughly discuss the value of a selected medicine. In addition, without CMS abiding by standard rules of negotiation to which we are bound with other payers and in other markets, it is increasingly difficult for manufacturers to adequately prepare for ongoing negotiations with CMS and to come to a shared understanding on the mutual value that these drugs bring to the Medicare program. CMS should maintain the minimum three meeting standard and seek to enhance the negotiation process by being an active participant and clearly communicating next steps in the process. This could, for example, be through an updated offer or counteroffer from CMS directly after a negotiation meeting so that both the manufacturer and the Agency are aligned on their shared understanding of value and are well prepared for the next step (*i.e.*, another meeting) in the negotiation process. As CMS refines and further standardizes its process, BMS strongly believes that the Agency should be able to increase transparency and certainty in the negotiation process by maintaining three meetings, updating the offer after each meeting, and clearly communicating next steps to manufacturers.

Section 90 – Manufacturer Compliance and Oversight

90.2 Monitoring of Access to the MFP in 2026 and 2027

In general, we refer CMS to our comments in Section 40 which discuss many concerns with CMS' MTF proposal and how manufacturers will effectuate the MFP—including, but not limited to, the significant financial and operational burden, interaction with dispensing entities, and 340B program complexity. We also recognize that CMS intends to release an

[19] *Id.* at 94.

ICR for manufacturer plan submissions, and BMS looks forward to this additional comment opportunity to highlight concerns and offer solutions to ensure operational success in advance of January 1, 2026.

- Manufacturer Plans for Effectuating the MFP: BMS strongly opposes CMS' policy change that manufacturers must submit effectuation plans for ensuring MFP availability to CMS by June 1, 2025, which is approximately six months earlier than CMS' finalized timeline of December 2, 2025 in the IPAY 2026 Guidance. **While we recognize that CMS created the MTF process to ease operational concerns, and also acknowledge an earlier deadline will allow for CMS to better evaluate a manufacturer's effectuation plan, BMS implores CMS to give manufacturers additional flexibility, either with the elements of the effectuation plan, the timeline, or both.** Given the many operational concerns we have highlighted, BMS notes that it will be very challenging, if not impossible, for manufacturers to submit a plan by June 1, 2025. We are also seeking guidance from CMS on how the voluntary nature of dispenser participation in the MTF payment process will align with a manufacturer's obligation to submit detailed requirements on making the MFP available to each dispenser. As discussed in Section 40, we urge CMS to mandate dispensing entity participation in the MTF process and also work with manufacturers to reduce burden. In addition, we ask CMS *not* to publicly post manufacturer plans online, regardless of whether proprietary information is redacted—CMS should limit the distribution of a manufacturer's plan to stakeholders (*e.g.*, dispensing entities) on a need-to-know basis. For example, we note that a manufacturer's process for deduplicating 340B claims is proprietary information and should be redacted from the written MFP effectuation plans which CMS intends to publish.
- Negotiation Program Complaints and Disputes: BMS thanks CMS for seeking to create a two-track dispute functionality within the MTF and complaint process to aid in compliance and operationalization. We ask CMS to further refine this process by establishing a formal appeals process for disputes to provide additional guardrails and recourse for manufacturers. In addition, we ask CMS to clarify that if a claim is going through the dispute process that the obligation for manufacturers would be essentially "frozen" until after CMS makes a determination—and relatedly, that once CMS makes a determination, the 14-day prompt payment window would then restart. Finally, CMS must ensure that dispensers/other stakeholders engage in good faith efforts with manufacturers to resolve MFP disputes prior to submitting complaints through CMS' formal process.

90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

As we did in our IPAY 2026 comments, BMS strongly opposes CMS' extra-statutory notion of "bona fide" marketing and the Agency's continued monitoring for whether "robust and meaningful competition" exists in the market for a given drug. This approach is found nowhere in the statute and would violate the statute's clear command as to exclusion from drug selection and MFP application.

The IRA "negotiation" framework applies only to a single source product, meaning that if a different source exists (*i.e.*, a generic or biosimilar), the product categorically cannot come from a single source. Further, the plain meaning of the statutorily unqualified term "marketed" reveals that Congress did not contemplate extra-statutory concepts related to degree of utilization or "meaningful" competition.

BMS therefore supports CMS taking a position that aligns with the "market date" reported under the MDRP because it presents an established, uniform standard that would help ensure that manufacturers are not inappropriately subject to selection, negotiation, application of an MFP, or an excise tax. Adopting this standard would also help ensure clarity and consistency in the identification of these key dates under Medicare negotiation.

BMS urges CMS to use this standard for identifying both: (1) the date on which a generic or biosimilar is first marketed; and (2) the date on which CMS determines that to be the case.

Section 100 – Civil Monetary Penalties

As we noted in our IPAY 2026 comments, while dictated by statute, the CMPs associated with the IRA negotiation framework are virtually unparalleled in magnitude and strongly warrant CMS implementing special safeguards against erroneous and inappropriate application. BMS thanks CMS for providing manufacturers with notice of any preliminarily identified deficiency and urges the Agency to give at least 30 days to cure such deficiency before any sanction is imposed. In addition, CMS should provide manufacturers with a reasonable opportunity to dispute CMS' findings prior to the imposition of any sanction to better ensure that sanctions are not imposed based on legal or factual errors by the Agency. We refer CMS to our IPAY 2026 comments for further details.

Section 110 – Part D Formulary Inclusion of Selected Drugs

BMS agrees with CMS that the statute requires a selected drug, for which an MFP is in effect, to be covered on all Part D formularies. **We note that it is critical for CMS to recommend, and health plans to design, formularies that promote beneficiary access to *all* medicines, both MFP and non-MFP medicines.**

BMS shares CMS' concern that "Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying UM that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."[20] However, BMS disagrees with CMS' assertion that the Agency does not have sufficient information to determine whether changes to its formulary inclusion policies are warranted at this time despite current trends in UM and the Agency's own recognition of multiple IRA-mandated changes to the Part D program taking effect, including MFP implementation and Part D redesign, that are expected to impact beneficiary access to both MFP and non-MFP medicines.

BMS remains concerned with how onerous formulary management policies may impede access to care, particularly in light of negotiation, and we are disappointed with CMS' passive approach to "monitoring" Part D plans' compliance with existing formulary requirements. We implore the Agency to preemptively modernize and strengthen CMS' current formulary review standards for a post-IRA era. Given how negotiation may have downstream consequences for the Part D program, including on plan dynamics and increased UM, we urge CMS to critically examine these impacts and prioritize shared decision-making between patients and providers, not health plans, on appropriate treatment plans.

In general, BMS supports public policies that ensure that health plan UM techniques follow clinical guidelines, provide timely and transparent responses to patients, and allow for physician/patient choice based on individual patient medical needs and desired outcomes. While UM techniques, such as step therapy and prior authorization policies, are purportedly designed to manage drug costs, these UM practices can lead to medication adherence issues, delayed access to care, and negative health outcomes for patients. Delays in effective treatment can increase costs to the health care system and cause patients to suffer unnecessarily.[21] Excessive UM hurdles can also increase administrative burden, diminish clinical autonomy, lower job satisfaction, and exacerbate feelings of burn-out for health care providers.[22]

[20] *Id.* at 122.

[21] *See* Strand V, Tundia N, Song Y, Macaulay D, Fuldeore M. Economic Burden of Patients with Inadequate Response to Targeted Immunomodulators for Rheumatoid Arthritis. J Manag Care Spec Pharm. 2018 Apr;24(4):344-352 *and* Avalere Health, Step Therapy Can Lead to Higher OOP Costs for Crohn's Disease Patients (October 2020), available at https://avalere.com/insights/step-therapy-can-lead-to-higher-oop-costs-for-crohns-disease-patients.

[22] AMA, 2021 AMA prior authorization (PA) physician survey, available at https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

UM techniques also disproportionately impact communities of color, further exacerbating existing health disparities. In a survey of over 3,600 patients, majorities of Hispanic Americans (64%) and Black Americans (55%) report being subject to at least one UM barrier to accessing medicines, compared to 44% of White Americans.[23] Many physicians of color also recognize the impact of UM on their minority patients; in a survey by the Association of Black Cardiologists, physicians agree "very much" that prior authorization contributes to delays in care (61%), higher patient confusion (50%), increased medication discontinuation (45%), reduction in medication adherence (32%), and worse outcomes (16%).[24]

While not contemplated in this Guidance, we also urge CMS to think critically about how Part D redesign will affect patient access to MFP and non-MFP medicines. In fact, BMS asserts that reforms to UM are even more critical in light of Part D redesign. For these new Part D redesign changes to produce the desired outcome for enhanced patient access, the Part D program must maintain its competitive, market-based structure. As health plans assume significantly greater liabilities as a result of the IRA, BMS is concerned they may employ more aggressive UM techniques to restrict patient access to medically necessary care. This concern is further validated by payer responses to actions they may take due to Part D redesign. Among the respondents, payers reported more frequently requiring step edits (87%), increasing scrutiny for formulary exceptions (83%), and increasing use of prior authorizations (70%).[25] Historically, plans have used creative formulary design, onerous prior authorization schemes, and step therapy delays to limit plan liabilities, all of which adversely affect enrollees' access to medicines. This point is underlined when we consider recent research from the American Cancer Society Cancer Action Network (ACS CAN) highlighting the impact of UM in cancer and that many Part D plans embedded step therapy within their prior authorization criteria to obscure CMS' formulary review process and pose additional barriers to patient access.[26] BMS is concerned that without appropriate guardrails and patient protections against UM, many of these trends may be exacerbated under the new Part D benefit design, which would run counter to the intent of the redesign policy.

BMS remains disappointed that CMS did not propose additional beneficiary safeguards considering longstanding issues of beneficiary access related to certain practices by plans and PBMs. We ask CMS to convey more strongly to plans the necessary expectation that they do not engage in measures to disadvantage selected drugs and ensure their formulary placement decisions are clinically-driven rather than financially-driven. We appreciate CMS using its formulary review process "to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive UM (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class."[27] However, CMS should also assess any instances where beneficiary cost-sharing increases for selected drugs within the same tier such as due to a shift from a copay to coinsurance design for that tier. For example, a selected drug may be placed on Tier 3, the preferred brand tier, but the plan could still shift the design of Tier 3 from copay to coinsurance thus increasing beneficiary out-of-pocket costs and limiting access to the selected drug. We encourage CMS to promote greater transparency and plan accountability by

[23] PhRMA, "Covered By Insurance But Still Exposed: Barriers to Care for Insured Americans," *available at* https://phrma.org/-/media/Project/PhRMA/PhRMAOrg/PhRMA-Org/PDF/P-R/PES-Report-2_final.pdf.
[24] Association of Black Cardiologists, "Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients" (2019), *available at* http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.
[25] Magnolia Market Access, "Inflation Reduction Act of 2022: Payer Insights Survey" (2023), *available at* https://www.magnoliamarketaccess.com/wp-content/uploads/MAG_Gathering_early_perceptions_of_payer_response_to_the_Inflation_Reduction_Act_of_2022.pdf.
[26] ACS CAN, "Step Therapy in Medicare Part D Oncology Drugs," available at https://www.fightcancer.org/sites/default/files/acs_can_part_d_formulary_analysis_final.pdf.
[27] CMS, IPAY 2027 Draft Guidance, p. 123.

committing to public reporting on the occurrence of all the above instances in approved formularies for selected drugs. This reporting should be in addition to publishing data on formulary, tiering, and UM exception requests for selected and non-selected drugs including actual numbers and rates of approvals, denials, and appeals of exception requests. These measures will help ensure that there is a robust assessment of Part D formularies so that MFP products have medically appropriate access vis-à-vis non-MFP products, and that patient access is not impeded due to potential consequences of payer UM techniques.

Without clear guidance protecting beneficiary access to medicines, BMS is concerned that negotiation in the Part D program will have the unintended consequence of altering formulary dynamics that result in narrower formularies with increased formulary exclusions and adverse tiering with more medicines, including those with an MFP, being placed on a higher cost-sharing tier. These changes may put patients at greater risk of experiencing non-medical switching, also referred to as "PBM Prescribing," which occurs when plans or PBMs exclude a medication from formulary or adversely increase the cost-sharing tier, forcing patients, who already stable on their doctor prescribed medication, to switch to an alternative medication for non-clinical reasons. These non-clinical decisions, as a result of new financial incentives, can have vast impacts on the government, and most importantly, on patients. We urge CMS to continue to monitor unintended consequences of the IRA as the Agency seeks to implement negotiation and Part D redesign.

To understand the effect that non-medical switching has on patients, the American Society for Preventive Cardiology conducted a national survey of cardiovascular patients on blood thinners which found that non-medical switching can have a significant impact on a patient's overall health and quality of life.[28] Additionally, 1 in 5 patients reported stopping taking their blood thinner altogether, which is particularly dangerous for this patient population as several common blood thinners have FDA black box warnings against premature discontinuation due to the risk of thrombotic events.[28,29] The patient survey findings echo a recent Xcenda claims-based case study assessing the impact of formulary exclusions on health care costs and outcomes which found that patients on a cardiovascular therapy had higher rates of hospitalization (+51%) and outpatient emergency department visits (+29%) during the 6-month period post-formulary exclusion relative to the 6-month period prior to the exclusion.[30] In addition to formulary exclusions, non-medical switching can also occur due to adverse tiering. A nationwide claims data study analyzing the impact on Medicare beneficiaries facing a tier increase from Tier 3 to Tier 4, an increase in OOP costs from $54/month to $135/month, while taking apixaban, an oral anticoagulant (OAC), found that among the 96% of patients who remained on the same plan, 12.4% switched to another OAC while 30.1% discontinued treatment on all OACs thus placing the discontinuers at a 2-3 times increased risk of ischemic stroke.[31,32] To mitigate the dangers of non-medical switching, we urge CMS to strengthen beneficiary protections and review formulary/tiering exceptions and appeals processes including ways to streamline and simplify those processes to ensure patients who are stable on their current medication can remain on their provider prescribed medication without disruption.

[28] American Society for Preventative Cardiology, "The Impact of Non-Medical Switching on Patients Taking a Blood Thinner" (Aug 2022), *available at* https://www.aspconline.org/wp-content/uploads/2022/08/ASPC-NMSBloodThinner-SurveyReport-August2022.pdf
[29] Prescribing Information. Eliquis (apixaban). Xarelto (rivaroxaban). Pradaxa (dabigatran).
[30] Xcenda, "Assessing the impact of formulary exclusion on healthcare costs and outcomes for patients on therapy for certain chronic conditions" (May 2023), *available at* https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_formularyexclissue-brief_may2023.pdf.
[31] Deitelzweig S et al. Payer formulary tier increases of apixaban: how patients respond and potential implications. Curr Med Res Opin. 2023 Aug;39(8):1093-1101. doi: 10.1080/03007995.2023.2232636.
[32] García Rodríguez LA et al. Discontinuation of oral anticoagulation in atrial fibrillation and risk of ischaemic stroke. Heart. 2020 Dec 11;107(7):542–8. doi: 10.1136/heartjnl-2020-317887.

BMS urges CMS to critically consider the potential downstream impacts of government negotiation on Part D plan dynamics and patient access. We assert that it is necessary for the Agency to contemplate these issues further in the revised IPAY 2027 guidance and future rulemaking processes.

Beyond the IPAY process, BMS urges CMS to continuously and actively monitor the impact of IRA on patient access and affordability. For example, there is a possibility that patient utilization of prescription drugs may increase due to the Medicare Part D redesign component of the IRA which includes a cap of $2,000 on beneficiaries' out-of-pocket costs and the option for beneficiaries to spread these costs over the plan year using the Medicare Prescription Payment Plan (MPPP). BMS strongly urges CMS to track changes in utilization as these could change Part D market dynamics and could lead to increased formulary management over time resulting in higher patient cost sharing, and other UM-related patient access issues.[33] Moreover, since participation in the MPPP is voluntary, we urge CMS to consider the perspectives of the advocacy community, support more flexibility in the program, and ensure that adequate guidance is available to beneficiaries to help them make educated decisions regarding enrollment in the MPPP.

Other Considerations – MFP Spillover Risks

BMS believes, and the statute requires, that the MFP be available to Medicare-eligible beneficiaries only, given that this policy is a Medicare policy intended to reduce prescription drug costs for Medicare patients. **We continue to remain highly concerned with how the scope of the MFP could potentially be expanded beyond the intended Medicare market ("spillover") and reiterate key themes from our IPAY 2026 comments below.**

The MFP risks spillover beyond Medicare in two ways: (1) diversion, where Medicare patient status is not established at purchase, risking MFP discount diversion to ineligible individuals; and (2) unintended reimbursement consequences, when commercial payers may seek to adjust to MFP-based reimbursement for non-MFP-eligible individuals and/or providers are reimbursed at the lower MFP payment rate (and not at Average Sales Price, or ASP), thus compromising patient access to therapies. And even if providers *are* reimbursed at ASP, if MFP is included in ASP, providers will be at risk of increased financial burden for using a negotiated Part B product. Spillover risk is also present at the state level.

We refer CMS to Sections 40 and 90 of our comment letter for our proposed solutions to mitigate diversion, but note that CMS must also address work to address unintended reimbursement consequences. We encourage the Agency to work with Congress to mitigate spillover effects, particularly in advance of IPAY 2028.

- Unintended Reimbursement Consequences: BMS is concerned that due to financial and operational challenges related to utilizing MFP products, unintended reimbursement consequences will likely occur, resulting in treatment switches to non-MFP products, which could also jeopardize patient access to medicines. We look forward to reengaging the Agency on this topic to ensure that providers remain financially whole, and patients receive the medicines that they need.
- Rationale for Exclusion of MFP Units from ASP Calculation: To protect patient access to critical medicines in non-Medicare markets, BMS urges CMS to exclude MFP units from the definition of "unit" for purposes of the ASP calculation. Although Medicare reimbursement for an MFP-eligible Part B medicine will not be based on ASP, non-Medicare payers commonly rely on ASP as a metric for setting reimbursement rates for such drugs. BMS is highly concerned that due to this dynamic, over time, the MFP will increasingly lower the ASP, and as a result, ASP-based reimbursement rates of non-Medicare payers will be increasingly insufficient to make providers whole for their acquisition cost of the selected drug. It is critical that CMS act to exclude MFP units from ASP to protect patient access to critical medicines in non-Medicare markets. Fortunately, CMS has clear authority to

[33] Hayden, "IRA: Patient Access to Therapeutic Options," available at https://haydencg.com/ira-patient-access-to-therapeutic-options/.

avoid this serious concern by excluding MFP units from ASP.[34] The statute expressly delegates broad authority to CMS to define "unit" for ASP purposes—and, notably, the legislative history of the statute reveals that Congress specifically intended the exclusion of "those sales that do not reflect market prices" from ASP.[35] Had Congress wanted the MFP to be included in ASP, it would have expressly done so. BMS asserts that CMS should exclude MFP units from ASP.

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BMS appreciates the opportunity to comment on the Guidance. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Caroline Tucker, Director, Executive Branch Strategy, at caroline.tucker@bms.com.

Sincerely,

/s/

Amy Demske
Executive Director, U.S. Policy & Executive Branch Strategy
U.S. Policy & Government Affairs & Policy Communications

[34] The ASP statute, *see* SSA at § 1847A(b)(2)(B), defines "unit" for ASP purposes to mean: "[W]ith respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section."

[35] *See* H.R. Rep. No. 108-391, at 587-88 (2003), *reprinted in* 1808 U.S.C.C.A.N. 1954-55.

Center on Health Policy at BROOKINGS

July 1, 2024

Dr. Meena Seshamani

Director, Center for Medicare

Center for Medicare & Medicaid Services

Dear Dr. Seshamani,

Thank you for the opportunity to comment on the Medicare Drug Price Negotiation Program Draft Guidance issued on May 3, 2024. In what follows, we comment on several proposed provisions of the guidance, including some of those where comments were specifically requested. Our comments are organized into four groupings: 1) competitive entry standards; 2) payment and price components; 3) negotiation factors; and 4) negotiation process.

1. *Competitive Entry Standards*

The draft guidance sets forth a process for the Centers for Medicare & Medicaid Services (CMS) to assess whether generic or biosimilar competition has been established, which is relevant both for determining a drug's eligibility for selection into the negotiation program and for determining when a drug will be removed from the selected drug list. The guidance describes a holistic assessment of whether a generic or biosimilar is engaging in "bona fide" marketing. We recognize the challenges of trying to determine how the market will evolve.

The elements of information set forth in Section 30.1 (particularly on pages 10-12) and in Section 70 are generally sensible. In addition to the sources of information listed on page 11, CMS should be mindful of erroneous reporting of information in the U.S. Food and Drug Administration (FDA) Orange Book. There have been numerous examples of invalid and expired patent being reported in the Orange Book that would cloud assessments of whether entry is even possible. The discussion of information to be examined includes agreements between a generic manufacturer and the Primary Manufacturer of a selected drug. We suggest that specific attention be given to settlement agreements of patent litigation and discussion of expected and realized competition in Primary Manufacturer 10K and 10Q filings with the Securities and Exchange Commission (SEC). Bona fide entry of biosimilars involves similar issues. It is important to recognize that the Purple Book has less complete information to inform an analysis of bona fide marketing than the Orange Book and is likely equally prone to errors. That may result in distorted assessments of whether market entry by the biosimilar is likely.

The biosimilar delay portion of the negotiation program in Section 11002 of the IRA allows for a potential delay in selection of a biological product for negotiation if the Secretary determines that

there is a "high likelihood" that a biosimilar for that biologic would be licensed and marketed within two years of the relevant date. The process by which CMS will determine whether there is a "high likelihood" of such licensure and marketing is detailed in Section 30.3.1 of the draft guidance. Section 30.3.1.2 of the draft guidance, referencing section 1192(f)(3)(B) of the Social Security Act, identifies SEC filings and comparable communications with shareholders of privately held companies as relevant in determining whether the "high likelihood" threshold is met. We would suggest that CMS also obtain data from the FDA and private vendors to track progress of clinical trials involving potential biosimilar entrants in assessing the likelihood of timely launch and marketing. While the statute requires CMS to obtain data on manufacturing schedules, private vendors and the FDA also receive data on the progress of clinical trials and details on potential risks that may be relevant to assessing the likelihood of launch. Examining the timing and details of patent settlement agreements should also be incorporated into the assessment. Finally, monitoring bona fide marketing should involve monitoring of agreements between pharmacy benefit managers (PBMs) and manufacturers. This may be important because such agreements may serve to limit the ability of a biosimilar product to effectively penetrate the market.

In assessing an Initial Delay Request from a biosimilar manufacturer, the draft guidance sets out the conditions that a written agreement that permits the biosimilar manufacturer to market the biosimilar before February 1, 2027, would need to meet to constitute support for an application (Section 30.3.1.2). We would suggest that as a complement to the review of a written agreement CMS also examine the biosimilar manufacturer production plans, that they are required to obtain, to ensure that no tacit agreement on volume of production has been made in connection to the written agreement.

If, after consideration of all the listed sources, there is residual uncertainty regarding whether the biosimilar is going to be launched and bona fide marketed in the required time frame, we suggest that CMS adopt a presumption to resolve this uncertainty against the applicant, declining to remove the relevant biologic from the list of negotiation-eligible drugs. Otherwise, there is the real possibility of a sham launch.

2. *Payment and Price Components*

We identify several issues regarding the primary manufacturers whose products are selected for the negotiation program and the elements that will be considered in constructing the initial offers.

- Prescription drug markets are dynamic. Thus, price levels depend on a variety of market conditions that can change in significant ways over time. Given that there is a notable time lag between the time at which drug prices are negotiated and the date that the maximum fair price (MFP) applies, much can change. This means that the marketplace for a negotiated drug may look quite different on the day the MFP goes into practice from when it was negotiated. CMS should anticipate changes to the structure and conduct in the market in developing its stance on individual drug negotiations.
- The guidance in section 60.5.1 describes procedures for addressing how new formulations and dosage forms of negotiated drugs with an MFP and new drug applications (NDAs) or biologics license applications (BLAs) will be incorporated into the pricing scheme. The guidance proposes to identify comparable NDAs and BLAs and

project volume to rescale prices. The guidance does not explain in detail how CMS proposes to identify what drugs are comparable. Similarly, for cases without a comparable NDA or BLA, an imputation will be implemented. The guidance offers only minimal information on any principles guiding the imputation. One approach might assign the existing weighted average price for a period of at least one year. That would be followed by a rescaling.

- The guidance defines a method for calculating retrospective refunds to pharmacies in Section 40.4.3, on pages 50-51. The refund uses wholesale acquisition cost (WAC) to estimate the pharmacy acquisition cost. The Congressional Budget Office has provided evidence that WAC typically exceeds what Medicare Part D plans pay pharmacies.[1] Since WAC is a list price and not a transaction price, manufacturers control the size of the refunds given to pharmacies. While in many cases the ability to steer prescriptions by pharmacies is quite limited (e.g., many retail pharmacies) that may be less so in the case for pharmacies connected to vertically integrated health care organizations (e.g., some retail pharmacies, mail order- and specialty pharmacies). Thus, pharmacies would have an incentive to favor negotiated drugs. The net impact for consumers and Medicare spending would depend on the alternatives available and their prices. An acquisition cost measure that is not controlled by manufacturers and more reflective of transaction prices may be preferable. Alternative metrics might include national average drug acquisition cost (NADAC), average sales price (ASP) (when available), and federal supply schedule prices. These metrics attempt to reflect transaction prices and are less able to be controlled by manufacturers.
- In considering facilitation of payments to pharmacies, the guidance offers two options for doing so in Section 40.4.4, page 53. Option 1 establishes a direct financial link between the manufacturer and the dispensing pharmacy. It also has the potential to provide proprietary data about the pharmacies to the manufacturers. In effect, the financial links creates new risks from the facilitation of coordination between pharmacies and manufacturers. For example, agreements between manufacturers and PBMs (owners of mail order and specialty pharmacies) can facilitate limited entry arrangements related to both generic and biosimilar marketing. This is especially the case with specialty pharmacies and mail order pharmacies. CMS notes that Option 1 facilitates more efficient payment of pharmacies. Option 2 retains a more arm's length relation of manufacturer and pharmacy. The downside risks associated with coordinated conduct and reduced competition may make Option 2 worth pursuing.
- Weighting prices: CMS interprets Section 1196(a)(2) of the statute as calling for negotiation of a single price per drug product (based on active ingredient or moiety). This requires developing a weighting scheme to arrive at a single weighted average price. Creating that weighted average requires information on volume of sales for individual formulations and dosages plus information about the relative prices across dosage forms and strengths. The guidance proposes using WAC to construct the relative price weights (page 98). As noted earlier, WAC is a list price controlled by manufacturers. It would be preferable to base the aggregation and eventual disaggregation on something close to transaction prices such as Medicare net prices.

[1] Congressional Budget Office, A Comparison of Brand-Name Drug Prices Among Selected Federal Programs, September 2021; Table 2 provides the comparisons between various Medicare prices and WAC.

Since the aggregation would be done by applying ratios CMS would not be revealing any individual product net prices.

- New dosages, strengths, and formulations. As new products within a defined drug with an MFP enter the market, the guidance does not fully articulate the process for recalculating the weighted average prices under the negotiated MFP. While we propose that re-weighting use net prices, a related question is how long the new product should be on the market to ensure the market has adjusted to it and adequate data exist prior to the re-weighting calculations being made.
- The guidance does not offer sufficiently complete direction related to combination products. We are concerned with the potential for strategic development of combination products. For example, an easy way to create a product hop that might affect the construction of MFPs that would be to continue to produce the original negotiated drug and add a component that will make it a combination drug, but the combination would not be significantly different from the original. The guidance should add some additional direction about how combination products will be treated.
- Section 1860D-4(b)(3)(I) of the statute requires that Part D plans include on their formularies all selected drugs for which a negotiated MFP is in effect. In section 110 of the draft guidance, CMS is not establishing any substantive requirements about placement within formularies (page 121-123). CMS recognizes the potential to disadvantage drugs via formulary placement and application of utilization management techniques. The draft guidance notes that CMS will monitor formulary arrangements and may take enforcement actions if drugs with an MFP are disadvantaged. It should be recognized that doing so is costly and complex and may be less effective than establishing some directive for formulary placement and the application of utilization management mechanisms. This issue is in part evidenced by a recent finding that CMS does not use information on rebates and information on gross to net price gaps to monitor formulary practices in Part D.[2] CMS could stipulate that the negotiated drug be placed on the formulary in a favorable tier unless it can demonstrate to CMS that there is a therapeutic alternative with a lower price than the negotiated drug.

3. *Negotiation Factors*

In developing initial offers, Section 60.3.4 of the draft guidance discusses how CMS will use the 5 elements of manufacturer-specific data to adjust the preliminary price. The draft guidance identifies a variety of considerations for the five elements, and it highlights that the five elements will be viewed in their totality. However, it is unlikely that as a matter of economics, public education, or program management each of the five elements should be given equal weight. Some guidance on elements of most import would provide greater understanding and potentially greater credibility to the development of price offers.

Some specific comments on individual elements.

- Research and Development (R&D) Costs: There are a variety of complex accounting issues in making estimates of R&D spending attributable to a specific product. There are

[2] See U.S. GAO, CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, September 2023, GAO-23-105270

difficult allocation assumptions related to so-called joint costs that must be made in such an exercise. The guidance set out on pages 127-129, does not provide direction on how this might be done. That means the results reported to CMS will depend on such assumptions and those assumptions can be based on strategic considerations related to the negotiations. It is likely that the intent of the provision was for CMS to be aware of the investments that a manufacturer has made in developing a drug to calibrate what might represent a fair return on investment. That intent is not well served by being permissive about assumptions made by a party to the negotiations.

- The guidance notes that CMS will use R&D costs along with revenues, including global revenues, to assess whether R&D costs have been recouped (page 87). The guidance states that if they have not been recouped, CMS might consider adjusting its preliminary price upward. Using a recoupment of costs standard is a complicated matter. That is because price adjustments would have to make judgements about the duration of time the drug in question would continue to be a sole source product and the expected volume of sales during that time. Furthermore, one might want to consider the reasons why costs were not recouped. Some guidance on how such information would be obtained and used would be important to outline.
- Federal financial Support for Drug Development. Existing evidence shows that nearly all prescription drugs have some federal financial support in their history.[3] Thus, if the point is to determine the extent to which taxpayers have a claim on the surplus produced by these drugs, then the level of federal support and where in the process it took place is relevant and those data should be collected.
- There are a variety of circumstances that would arise with respect to the market context where the range of possibilities with respect to therapeutic alternatives differ substantially. In considering alternatives that serve as a starting point for negotiations drugs that are lower priced that are therapeutic alternatives will give CMS the greatest leverage in the negotiations.

4. *Negotiation Process*

The draft guidance document solicits comments on the number of meetings and other communication there should be between CMS and manufacturers (Section 60.4). One of the most fundamental features of negotiation is communication and research has shown that face to face contacts and less constrained exchanges of views yield more satisfactory outcomes. This is especially true in circumstance where the issues and alternative views of the problems are complex and the markets in question are dynamic. Prescription drug markets have those attributes. Moreover, there are lots of intangible issues and important assumptions made by both sides in making formal price proposals. Understanding of those issues benefits from situations where there is free give and take. Given concerns aired by various stake holders about the degree to which the IRA negotiation are true negotiations, we support CMS continuing to hold up to

[3] Zhou EW, Jackson MJ, Ledley FD. Spending on phased clinical development of approved drugs by the US National Institutes of Health compared with industry. JAMA *Health Forum*. 2023;4(7):e231921. doi:10.1001/jamahealthforum.2023.1921

three negotiation meetings with each Primary Manufacturer. We support this in full recognition of the compressed schedule.

Thank you once again for the opportunity to comment on this critically important draft guidance document. We hope that you find these comments helpful to your work on this policy.

Sincerely,

Richard G. Frank
Senior Fellow, The Brookings Institution

Gerard F. Anderson
Professor, Johns Hopkins University

July 2, 2024

Meena Seshamani, MD, PhD
Deputy Administrator and Director
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: *Medicare Drug Price Negotiation Program Draft Guidance*

California Life Sciences (CLS) appreciates the opportunity to comment on the recent guidance by CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.* CLS welcomes the chance to provide feedback on the implementation of the Medicare Drug Price Negotiation Program (MDPNP) and to highlight key considerations when implementing the law. CLS appreciates the steps the agency has taken to establish a dialogue with key stakeholders about the negotiation program and other elements of the Inflation Reduction Act (IRA), but we have significant concerns about the effects the implementation of this law will have on California's life sciences ecosystem and our companies' abilities to bring new, lifesaving medicines to patients.

CLS is proud to represent more than 1,200 companies and organizations across California and to advocate for the whole breadth of our state's life sciences sector, with membership spanning biotechnology, biopharmaceutical, medical device and technology, diagnostic companies, venture capital firms, and research hospitals and universities. California's life sciences industry generates more than 1.1 million direct and indirect jobs[i] and over $472 billion in economic output for our state on an annual basis,[ii] and our members drive innovations in patient care and save lives nationally.

The process of therapeutic development is a high risk and long-term endeavor. Life sciences leaders are inspired to take on this challenge by their desire to improve the lives and health of patients and their communities. CLS strongly supports policies that both uphold the scientific enterprise and ensure that these products are affordable and accessible to all.

The Initial Price Applicability Year for 2027 (IPAY27) Draft Guidance dictates how CMS will implement the MDPNP, which will have significant impacts on the future of Medicare, patients, access to medicines, and the future of the life sciences ecosystem. We are hopeful that CMS will incorporate the meaningful feedback provided by industry, patient groups, providers, and others on the IPAY27 Draft Guidance.

CLS is deeply concerned that the seismic shift, caused by the CMS price setting authority in the IRA, will drive us away from the current market-based systems that underpin both Medicare Part D and Medicare Part B and will erode patient access as well as undermine continued biopharmaceutical innovation. Unfortunately, the IPAY27 Draft Guidance only serves to reinforce and increase our concerns. Please see the below considerations for CMS to consider before finalizing the IPAY27 Draft Guidance.

Qualifying Single Source Drug (QSSD)

CLS is disappointed to see that CMS maintains a broad definition of QSSD, inclusive of New Drug Applications (NDAs) and Biological Licensing Agreements (BLAs) with the same active

SACRAMENTO
1201 K Street, Suite 1010
Sacramento, CA 95814
P 916 226 9957

SAN DIEGO
9605 Scranton Rd. Suite 120
San Diego, CA 92121
P 858 551 6677

SOUTH SAN FRANCISCO
685 Gateway Blvd. Suite 100
South San Francisco, CA 94080
P 650 871 3250

LOS ANGELES
605 E. Huntington Dr., Suite 103
Monrovia, CA 91016
P 858 551 6677

WASHINGTON, DC
1200 G Street, NW, Suite 725
Washington, DC 20005
P 202 743 7566

moiety or ingredient held by the same NDA/BLA holder. CLS remains concerned about the continued use of an extremely broad approach to identifying selected drugs, stating that any form of a drug from the same manufacturer with the same active moiety or active ingredient will be swept into the definition of a QSSD. This means that a drug approved only a year ago by the Food and Drug Administration (FDA) could be subject to price-setting even if it has a different trade name and if the new drug represents a significant advancement for patients. CMS' overly broad interpretation of the statute will have serious and negative effects on innovation intended to improve patient lives.

However, CLS strongly supports CMS' continued treatment of fixed combination drugs with distinct combinations of active moieties or active ingredients as distinct QSSDs. Specially, as under the IPAY26 guidance, the IPAY27 Draft Guidance proposes that if a selected drug is "a fixed combination drug with two or more active moieties/active ingredients," then "the distinct combination of active moieties/active ingredients will be considered as one active moiety/active ingredient for the purpose of identifying potential qualifying single source drugs" This approach is consistent with the QSSD statutory definition, which limits a QSSD to a drug approved under a NDA or BLA and uses the terms "drug product" or "biological product." Fixed dose combination drugs are not merely changes in the "dosage form" or "dosage strength" of an existing drug. Rather, they include the addition of an entirely different molecular entity and constitute distinct drugs that involve significant alterations from existing products. Not only is treating fixed combination drugs as distinct QSSDs consistent with the IRA, but it is supported by the clinical benefits brought to patients.

Generic and Biosimilar Competition

A robust market for generic and biosimilar drugs provides patients, Medicare, and other payers with significant savings, while encouraging ongoing therapeutic innovation. Safeguarding the incentives for generic and biosimilar development is vital for CMS to maintain long-term savings for the Medicare program and the health care system broadly.

While most brand medicines with an approved competitor are exempt from price setting, the timing for selection in the law predates the typical timeline for generic and biosimilar competition. CLS is concerned that in the Draft Guidance, CMS states it will look at specified data in Medicare and Medicaid to evaluate if a competitor is engaged in "bona fide marketing" – a concept nowhere in the statute and that ignores the reality that insurers and PBMs decide what medicines are covered. This standard for determining the date of marketing of a generic or biosimilar is incompatible with the statute and contrary to sound public policy. CLS disagrees with CMS's plan to use this concept to determine if a marketed generic or biosimilar "counts" as a competitor and encourages CMS to abandon its bona fide marketing standard. As a result, marketed generics or biosimilars will be forced to compete against medicines with government-set prices, significantly reducing the incentive to bring them to market. It is imperative that CMS abandon this standard and instead adopt as its standard the "market date" reported under the Medicare Drug Rebate Program (MDRP). The MDRP "market date" standard should be used for identifying both the date on which a generic or biosimilar is marketed and the date on which CMS determines that a generic or biosimilar has been marketed.

Further, to enhance the process for a biosimilar manufacturer to request a delay in the selection of a reference product for negotiation, CLS recommends including meeting the "high likelihood" determination. CLS encourages CMS to make a determination of "high likelihood" based on the most up to date and complete information and believes CMS has

the statutory authority for broad discretion in specifying that the manufacturer can submit all relevant information. To ensure that CMS decides a delay request based on the most mature information possible, CMS should set the delay request submission deadline as close as reasonably possible to the selected drug publication date and permit broad supplementation of timely request with late-breaking information or otherwise good cause. Information on the expected timing of licensure and marketing often rapidly changes and may fluctuate based on a range of factors. For CMS to make an informed determination regarding eligibility for delayed selection, it is vital that the Agency rely on all of the most recent available information that bears on the likelihood of market entry within the requisite time period.

Furthermore, CLS recommends that CMS provide notice of its delay request determination in advance of the selected drug publication date and establish a dispute resolution process. As it is currently laid out in the Draft Guidance, CMS will not inform a biosimilar manufacturer of an unsuccessful delay request until after the selected drug publication date.[iii] This eliminates the ability for a manufacturer to dispute the determination. CLS encourages CMS to provide a preliminary notice of an unsuccessful delay request in advance of the selected drug publication date and establish a process by which the biosimilar manufacturers can dispute an erroneous determination.

Small Biotech Exemption (SBE)

CLS continues to urge CMS to establish a dispute resolution process for the implementation of the small biotech exception. In recognition of the potential hardships to small and emerging companies who likely do not have significant reserves or multiple products on the market or in the pipeline, the IRA exempted small biotech drugs from negotiation until 2029. We urge CMS to continue to engage stakeholders regarding the SBE so that the exemption is workable for the small companies it was created to support.

First, CLS believes it is imperative that CMS implement a predictable and transparent process for small biotech manufacturers applying for this exemption. This includes a clear process for how to apply for an exemption, appropriate timelines to submit information, consistent criteria for evaluating submissions, and timely and clear notification if a drug meets or does not meet the SBE requirements.

Second, we ask that CMS provide flexibility in its discussions with the companies and maintain a dialogue with companies throughout the process to ensure complete and accurate data submissions. Additionally, if a drug has received an SBE, and the manufacturer's circumstances have not changed in a material way, the manufacturer should not have to re-apply in subsequent years. We also believe that CMS must protect the confidentiality of the proprietary information that is submitted by a manufacturer.
As stated above, of utmost importance to CLS members is for the Agency to establish a dispute resolution process where a manufacturer can respond to and appeal a negative determination by CMS—similar to the process that has been instituted for the specified small manufacturers phase-in under the Medicare Part D benefit redesign. Specifically, the small biotech manufacturer should have the opportunity to provide additional data or other information to the Agency to support its application for the small biotech exemption.
We also encourage CMS to initiate the SBE Information Collection Request (ICR) process earlier in the year, to allow sufficient time for a dispute resolution process to conclude prior to the February 1 deadline for CMS to select drugs for negotiation. Per CMS's IPAY 2027 Negotiation Guidance, SBE eligibility determinations are rendered after publication of the

selected drug list. Initiating the SBE process earlier would allow sufficient time for a robust dispute resolution process.

Orphan Drug Exclusion

Recognizing the unique challenges in orphan drug research and development, and the significant unmet medical need for rare disease patients, Congress created an exemption for orphan drugs from the MDPNP. The law says that CMS must exclude from negotiation a drug "for only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition" (Section 1191(e)(3)(A)). However, CLS remains concerned that the exemption is insufficient and, while well intentioned, undermines the long-standing incentives for orphan drug development as laid out in the Orphan Drug Act. The current Draft Guidance exempts only orphan drugs with one disease or condition and therefore could limit opportunities for additional research and development for indications to other rare diseases. Most of the research and development in additional therapeutic areas happens years after a drug is approved. But if the drug receives an additional orphan designation, it is no longer exempt and therefore we are concerned that companies will no longer have the incentive or the ability to invest further in these products. Another area we believe needs clarification is when the timeline for negotiation eligibility would begin for a product that no longer qualifies for an orphan exemption. The Draft Guidance indicates that the eligibility timeline would be based on the date of approval for the first approved indication, not approval for the additional indication.

CLS urges CMS to clarify the scope of the orphan drug exclusion in a manner that maximizes protections for orphan drugs that patients desperately rely on. We believe that CMS should clarify that the eligibility for the selection clock only begins for an orphan drug upon approval for another non-orphan indication.

Furthermore, CLS requests additional clarification around how "disease or condition" will be defined for the exemption and criteria that CMS will use to determine "conditions" from separate "indications." In addition, CMS should create a process that enables manufacturers to provide evidence that an indication falls within an orphan drug designation, where such fact is not ascertainable from FDA databases alone.

Maximum Fair Price (MFP) Considerations and Price Setting Methodology Factors

The IRA statute directs the Secretary to develop and use "a consistent methodology and process that aims to achieve the lowest [MFP] for each selected drug," which must include consideration of certain specified manufacturer-specific factors, factors related to therapeutic alternatives, and the statutory ceiling price. CLS remains concerned that the agency has not articulated a "consistent methodology," as required by the IRA. Furthermore, we feel that the agency should better explain how it will weigh the factors it intends to use to set prices, including how the agency will incorporate patient and caregiver experiences.

The process for setting the ceiling price and MFP can have significant impact on the investment in future therapeutic research and development. CLS continues to encourage CMS to consider the importance of driving value for patients in limiting the negotiation program's impact on the sector. A drug should be valued for its elements over the lifetime of its use, rather than at the moment in time that CMS offers the MFP. CLS encourages CMS to establish MFPs at the ceiling price for selected products that address unmet needs or significantly advance patient care. Setting higher MFPs for these products will help maintain

investment in assets and clinical programs that show scientific promise and address needs not served by current therapies.

CLS strongly encourages CMS to emphasize negotiation factors that are most important to patients—those that are related to clinical value and unmet need—and to de-emphasize manufacturer specific data elements such as cost of production and research and development costs. CLS is supportive of CMS considering additional steps to further standardize submitted information, facilitate a better understanding of the solicited information and reduce reporting burden. One way CMS can improve consistency of information submitted is to provide more detail on the definition of the manufacturer specific conditions, including to utilize a more robust definition of unmet medical need. If CMS must consider manufacturer-specific data, CLS wants to ensure that a robust, comprehensive set of information submitted by manufacturers— with necessary supplemental material—will be accepted and considered.

CLS also believes that CMS should ensure an inclusive definition of costs – for example, research and development costs should include research costs of failures where a drug did not come to market, the cost of ongoing studies, acquisition costs for both marketed and failed drug candidates, and partnering and licensing agreements. Implementing an MFP that is reflective of the complete costs of bringing a product to market will be critical to ensure companies have the ability to continue to invest in new innovation.

As the top ranked state in National Institutes of Health funding, CLS is also concerned about the requirement for CMS to consider the use of prior federal funding in the calculation of MFP. If this could further lower the price ceiling, it may discourage the use of federal funds for drug research moving forward. The inclusion of prior federal funding in the calculation may also cause hesitation to invest in companies that have used such funds, particularly as there is a lack of clarity in what constitutes prior financial support. We urge CMS to ensure a balanced approach to including the use of federal funds that will not undermine the future of public-private partnerships. Additionally, we believe CMS's suggestion that tax credits should be included into the calculation, goes against their intended purpose of advancing medical innovation and seems punitive, particularly for small and emerging companies.

Therapeutic Alternatives

CLS encourages CMS to clarify how it will evaluate the evidence about alternative treatments by different stakeholders and how different evidence will be considered in setting the MFP. CLS looks forward to the forthcoming data elements Information Collection Request (ICR) to ensure the collection process, question format, and content received is clear and accessible for all stakeholders to provide feedback on.

Manufacturer Engagement

CLS has serious concerns with CMS' process for interfacing with manufacturers of selected drugs. In the IPAY27 Draft Guidance, CMS has also proposed an abbreviated and restrictive negotiation process by setting a maximum of meetings, and only one at the request of the manufacturer. As set forth in the Guidance, manufacturers may only have up to three meetings with CMS – all occurring after the initial MFP is set by the Agency. While we agree with CMS that meetings occurring after CMS rejects a manufacturer's counteroffer is necessary and will allow for a more efficient and effective process, starting meetings only *after* rejection of the manufacturer counteroffer is too late. In the vast experience that CLS members have in negotiating with states and payers' the process CMS has implemented and

proposed in the IPAY27 guidance is unusual and arbitrary. Given the importance of these negotiations and the complexity of the data, we believe it is important to have a more flexible and meaningful process. We encourage CMS to allow for more meaningful dialogue with manufacturers throughout the process such as appropriate flexibility to start the dialogue with a manufacturer sooner, have as many meetings as necessary and not place arbitrary limitations on meetings and engagements.

CLS strongly disagrees with CMS' assertion that the selection of 15 drugs, or more in the future, "may present challenges" that would warrant the Agency to allow for *less* meetings with manufacturers than the previous years, especially in light of the fact that the current meeting structure is already counter to standard negotiations. CMS incorrectly proposes an "either-or" approach in the Guidance – three meetings OR "an additional written offer…" – when, at a minimum, CMS should be suggesting an "and" approach – three meetings *and* additional written offers, as appropriate.

CLS encourages CMS to make changes to achieve a more meaningful process, not just with the number of meetings, but with the frequency. CLS strongly believes that CMS should meet with the manufacturer of a selected medicine at multiple points during the negotiation process to allow manufacturers to address questions and provide additional commentary on the value of these medicines. Further, the manufacturer should generally be permitted to supplement its timely submission where post-development submission development arises, or there is otherwise good cause.

Another change CMS can make is to align with the standard rules of negotiation that manufacturers are bound by with other payers and in other markets. That way it is less difficult for manufacturers to adequately prepare for ongoing negotiations with CMS and to come to a shared understanding of the mutual value that these drugs bring to the Medicare program. This could, for example, be through an updated offer or counteroffer from CMS directly after a negotiation meeting so that both the manufacturer and the Agency are aligned on their shared understanding of value and are well prepared for the next steps in the negotiation process.

Finally, CLS remains concerned with the opaque nature of CMS' price-setting process. In the Draft Guidance, CMS reaffirmed that it will not disclose information about how it will set medicine prices until months after these decisions are made. CLS is concerned with the premature nature of the IPAY27 initial guidance, and the timelines set forth within related to the explanation publication and drug selection. The IPAY27 drug selection process begins prior to the required date of publication of the IPAY26 MFP explanations. Those explanations are to include, at a minimum: 1) therapeutic alternative(s) for each indication and how they were selected; 2) how each factor was weighed; 3) data and analysis CMS developed and considered supporting each factor, including evidence provided by third parties engaged formally or informally by CMS; 4) benefits and impacts considered; and 5) stakeholders, and other government agencies and organizations CMS engaged, formally or informally, in the process and how their input factored into the Agency's decision-making. The explanations of the MFP provide all stakeholders with the necessary insights into program implementation and the potential impact on patients. For this reason, we ask that CMS adhere to good governance standards and delay the IPAY27 selection process until after the explanations are made public for the previous IPAY selected drugs. The current sequence of events leaves manufacturers in the dark as they head into future negotiation cycles, hindering meaningful manufacturer engagement.

Stakeholder Engagement

CLS is pleased to see CMS acknowledge that there is an opportunity to improve patient engagement throughout the process for determining the MFP. CLS urges CMS to take steps to ensure this process is predictable, transparent and allows for meaningful engagement with key stakeholders, particularly the patient community. CLS strongly supports CMS's efforts to improve upon the patent-focused listening sessions that were held for IPAY2026.

We agree that an approach that allows for bidirectional engagement, allows discussion among a range of stakeholders and that allows CMS to ask clarifying questions, would be much more effective in leveraging the expertise from the patient community. CMS should also clarify the questions that they want answered, rather than leaving it vague and unclear, and allow patients and stakeholders more time to share their perspectives. CMS should also consider alternative ways to enhance dialogue between patients and the Agency, such as smaller group sessions, and find ways to engage with speakers from diverse backgrounds and perspectives. It may also be impactful to hold patient engagement events outside of those that require public speaking and use formats such as roundtables and focus groups. CLS also encourages CMS to not place arbitrary restrictions around stakeholder engagement, rather, continuously engage with relevant patients, patient representatives, or clinicians throughout its decision-making process. Finally, CMS should share—at a high level—how information from patients and stakeholders was used in determining the MFP.

Part D Access

The IRA made the most significant changes to Medicare Part D since its inception. CLS strongly believes that CMS should take appropriate action to proactively protect beneficiaries from anticipated harm, including worse access to medicines and more restrictive formularies. In the Draft Guidance CMS has recognized the importance of these issues but declined to take important steps to strengthen formulary standards and oversight. CLS is concerned that because of CMS' continued inaction, many seniors will likely face disruptions and barriers to accessing the medicines they need. CLS encourages CMS to clarify how it will ensure robust beneficiary access to needed therapies, including selected drugs, and institute safeguards that ensure diversity of formularies to meet patient needs.[iv] CMS should act in ways that mitigate narrower formularies and fewer choices as a result of the MFP process. CLS also encourages CMS to monitor plan coverage and tiering design, clinical appropriateness of utilization management policies, cost-sharing levels, and patient out-of-pocket exposure.

Conclusion

CLS remains concerned about the significant and potentially negative impacts the MDPNP will have on companies' investments in research and development, which in turn will harm beneficiary access to future treatments and cures, particularly for rare, hard-to-treat diseases and those areas with high unmet need. We continue to urge CMS to consider these impacts as the agency works to finalize this Draft Guidance based on stakeholder feedback.

CMS can mitigate harm to patients through a thoughtful and stakeholder-informed approach to implementation. We hope that CMS will consider the risks of the drug price negotiation program to patient access and future innovation. CLS welcomes any questions and further discussion on the topics above, and you can contact me at bfisk@califesciences.org.

Sincerely,

Brent Fisk

Brent Fisk
Senior Vice President, Government Relations & External Affairs
California Life Sciences

[i] https://www.califesciences.org/california-life-sciences-sector-report/
[ii] https://www.califesciences.org/california-life-sciences-sector-report/
[iii] *Id.* at 24.
[iv] Patient Impact of the Inflation Reduction Act. https://www.manatt.com/insights/white-papers/2024/patient-impact-of-the-inflation-reduction-act June 26, 2024.

June 27, 2024

Submitted via email to IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Seshamani,

As an organization representing cancer patients, survivors, and caregivers, the Cancer Support Community (CSC) would like to thank you for the opportunity to provide feedback and recommendations on the Centers for Medicare & Medicaid Services' (CMS) draft guidance on the Medicare Drug Price Negotiation Program, implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. Our comments focus on creating an infrastructure for patient engagement and increasing patient protections against inappropriate uses of utilization management practices.

CSC is an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones. As the largest provider of social and emotional support services for people impacted by cancer, CSC has a unique understanding of the cancer patient experience. In addition to our direct services, our Research and Training Institute and Cancer Policy Institute are industry leaders in advancing the evidence base and promoting patient-centered public policies.

Section 60. Negotiation Process
We commend Congress and the Administration for enacting policies to increase affordable access to lifesaving and life-enhancing care, such as the Medicare Drug Price Negotiation Program (MDPNP). However, we share the concerns of many stakeholders that some of these policies may have unintended consequences on patients and overlook the perspectives of those most affected. We strongly advocate for patients and caregivers to have a significant role in shaping patient-centered clinical benefit in the MDPNP and led the development of consensus-based *Principles for Patient-Centered Engagement When Implementing the Medicare Drug Price Negotiation Program* that can be used as CMS continues to implement the MDPNP and other similar policies.

We believe that CMS has the opportunity to mitigate these possible unintended consequences by creating an infrastructure to collect and implement patient and caregiver feedback in the negotiation process and throughout the MDPNP implementation process. The needs of patients and caregivers will change over time, and two individuals may experience the same events in entirely different ways, this is why we need a system that acknowledges and responds to these truths and gives patients the opportunity to share their care preferences, impacts on quality of life, and what they value in regard to their treatments and outcomes.

CSC appreciates CMS' intention to improve upon and expand the patient-focused listening sessions. We urge CMS to take steps to ensure that these sessions adequately represent the broad and diverse range of both patient and caregiver perspectives that will be impacted by the MDPNP, as the time-consuming nature, symptom burden, and side effects of cancer treatment often make caregivers a necessity. For instance, CSC captures caregiver insights in our Cancer Support Community's Cancer Support Source-Caregiver (CSS-CG) survey that could also help to inform clinical benefit in the MDPNP. To this end, we highlight the need for continued opportunities for patients and caregivers to share their experiences and values as not all patients and caregivers will be able to participate in these sessions, and as spoken to above, their needs will likely change over time, supporting the need for continuous engagement.

Our patient-centered principles, linked above, outline how CMS can successfully and comprehensively engage patients and their needs. These principles provide insight into areas such as collecting and incorporating meaningful data and real world-evidence, diversifying outreach, and engagement to different patient populations, and defining clinical benefit around patient reported outcomes and experiences. One example, outlined in our principles, of how CMS can improve engagement with patients and caregivers, is to collect and incorporate meaningful data and real world evidence that amplifies patient values and input into the negotiation process to define clinical benefit and determine the maximum fair prices of each drug. This data collection, for each drug in the negotiation process, should include patient reported outcomes, evaluations around endpoints, patient experience data, impact on quality of life, and models that capture the dynamic and varied preferences of patients.

CMS should also facilitate a 2-way dialogue throughout the listening session process, offering a concrete list of areas on which they are seeking feedback, including disease- or drug-specific questions, prior to the listening session. For example, CMS should share potential therapeutic alternatives and ask for patient and provider perspectives to ensure optimal feedback. To the extent feasible, CMS should also share data sources under consideration prior to the listening session so patients are able to provide feedback on the patient-centricity and relevance of the source.

CSC commends CMS for requesting comments on the format and methods to mitigate barriers to participation of patients and other interested parties in the patient-focused listening sessions. CMS proposes combining drugs that treat like-conditions into sessions instead of the current drug-specific session model. If the purpose of stakeholder engagement in these events is to gather patient value on a specific drug, CSC strongly urges CMS maintain the format of drug-specific events, as patients value the impact of drugs differently.

Finally, in the draft guidance, CMS set the deadline to publish a narrative explanation of the negotiation process and additional information that led to the decision of the maximum fair price more than three months after the deadline of publishing the maximum fair prices for each prescription drug. CSC has concerns with this approach. To increase transparency, we recommend that CMS articulates how patient experiences and perspectives were incorporated into the price setting process when the decision is announced/released.

110. Part D Formulary Inclusion of Selected Drugs

CSC shares the agency's concerns that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. We call on CMS to ensure that Part D sponsors' use of utilization management techniques, such as prior authorization and step therapy, follow clinical guidelines, provide timely and transparent responses to patients, and leave medical decisions up to provider expertise and patient choice based on individual needs and desired outcomes. We, therefore, urge CMS to establish a feedback mechanism to monitor inappropriate use and overutilization of these cost control tools and their effect on patient access to life saving care and life enhancing care. CSC has discussed the possible unintended consequences of increased utilization management practices as a result of IRA implementation and how to mitigate the negative impacts on patients.

Conclusion

CSC appreciates the opportunity to comment on CMS' draft guidance on the Medicare Drug Price Negotiation Program (the "Program") for Initial Price Applicability Year (IPAY) 2027. We look forward to continuing our strong partnership with CMS to ensure that all Medicare beneficiaries, including patients impacted by cancer, have access to affordable lifesaving and life enhancing care. If you have any questions or need additional information, please contact me at dsekoni@cancersupportcommunity.org or (202) 659-9707.

Sincerely,

Daneen G. Sekoni, MHSA

Vice President, Policy & Advocacy

CMS is faced with conducting a form of multi-criteria decision analysis (MCDA) in its development of initial price offers. MCDA is defined as, "an umbrella term to describe a collection of formal approaches which seek to take explicit account of multiple criteria in helping individuals or groups exploring decisions that matter."[1] In its latest draft guidance, CMS reaffirms that it will use a qualitative approach rather than "a more thoroughly pre-specified quantitative approach" to adjust the starting point for an initial price offer. However, CMS need not choose between either a qualitative or a "thoroughly pre-specified quantitative" approach. Instead, CMS could draw on aspects of both qualitative and quantitative MCDA without adopting a thoroughly pre-specified quantitative approach.

For instance, CMS will consider "[o]utcomes such as changes in symptoms or other factors that are of importance to patients" when reviewing the clinical benefit of the selected drug and its therapeutic alternative(s). It may help CMS to know which outcomes are most important to patients (and how these preferences may vary across different diseases and patient groups). By using established preference elicitation techniques during the patient-focused listening sessions, CMS could quantify the relative importance to patients of different outcomes. We have outlined how to conduct such preference elicitation exercises in recent publications.[2,3] More importantly, we have used these methods to assist the Colorado Prescription Drug Affordability Review Board in determining its priorities for selecting drugs that will be subject to price caps.[4] This exercise was conducted in under three hours and can be repeated on a regular basis as needed. The quantitative weights/priorities identified in such an exercise could then be used as guides to inform CMS' adjustment of the starting point without needing to be algorithmically incorporated in a "pre-specified" manner. CMS could also consider convening a group of patients, caregivers, and their representatives to deliberate and decide on the benefit of a selected drug (versus its therapeutic alternatives) in terms of its impact on outcomes of importance to patients, especially when there is a lack of high-quality, published evidence on a selected drug for these outcomes. The quantitative weights described above could be used to support these deliberations as well, again in a non-algorithmic or "pre-specified" manner. We have previously argued that such weights, even if not algorithmically incorporated into decision-making, may help to reduce the cognitive burden of deliberation, mitigate the effects of anchoring or recency bias, or provide tangible evidence to participants that their voices were heard and counted.[2,3] A second potential benefit of identifying and transparently reporting these weights are the precise signals they would send to manufacturers and researchers regarding what clinical evidence is most important to generate.[2] Sending such signals may be especially important for incentivizing investment in evidence generation regarding patient experience, where there are likely to be significant gaps in the published literature.

CMS also states its intention "to improve upon the design of the patient-focused listening sessions from initial price applicability year 2026 and is soliciting comments from interested parties on event format, scope, and logistics." Our suggestions above to 1) quantitatively elicit preferences from patients regarding which "factors a patient cares about most when assessing the value of a drug" and to 2) allow a group of patients and caregivers to deliberate and decide on a selected drug's benefit in terms of the patient experience represent two ways CMS could improve upon its patient-focused listening sessions. We also recommend that CMS consider excluding potential participants from these listening sessions who are associated with patient advocacy organizations that receive significant funding from drug manufacturers. Manufacturers already have several opportunities to provide their perspective throughout the drug price negotiation process. Finally, we support CMS' willingness to include discussion between speakers at these patient-focused events, especially if CMS were to also adopt some form of preference elicitation exercise or allow for decision-making in these sessions. When eliciting preferences, it is important that these preferences be informed and well-considered. Allowing for discussion between participants can promote view sharing and may lead participants to revise their own views in response to new information or arguments.[5,6] **Figure 1** below represents one way that qualitative deliberations among clinical and patient experts, informed by quantitative criteria weights, could be used to inform CMS' process of determining a starting point for price negotiations.

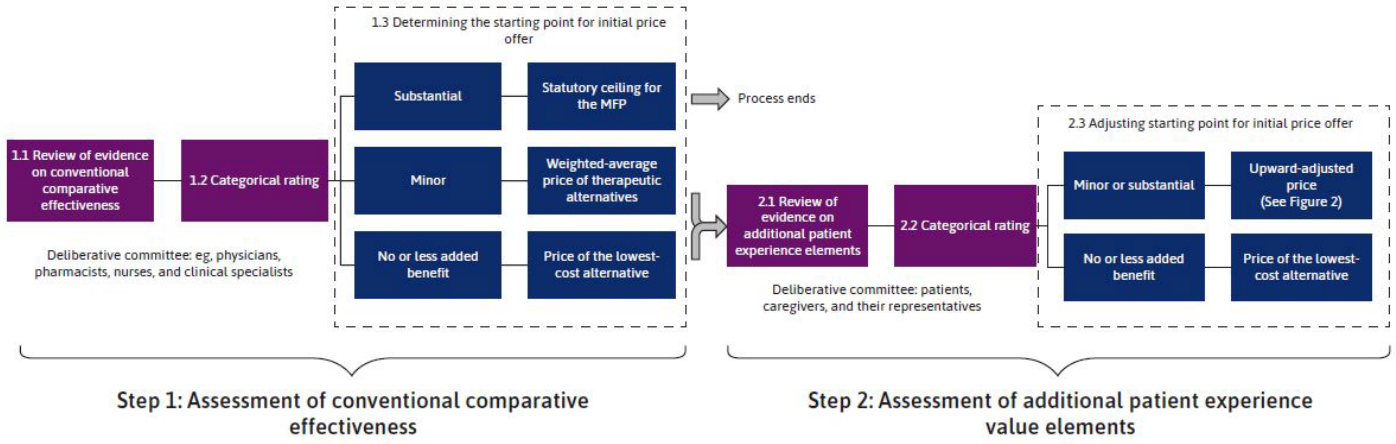
Thank you for this opportunity to comment on the second cycle of negotiations for the Medicare Drug Price Negotiation Program.

Best regards,

Michael J. DiStefano, PhD
Antal Zemplenyi, PhD
R. Brett McQueen, PhD

Center for Pharmaceutical Outcomes Research
Skaggs School of Pharmacy and Pharmaceutical Sciences
University of Colorado Anschutz Medical Campus

FIGURE 1 Roadmap Describing the 2-Step Approach for Assessing the Overall Clinical Benefit of a Selected Drug Compared With Its Therapeutic Alternatives



MFP = maximum fair price.

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U.S. Chamber of Commerce

1615 H Street, NW
Washington, DC 20062-2000
uschamber.com

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024)

Dear Deputy Administrator Seshamani:

The U.S. Chamber of Commerce ("the Chamber") Global Innovation Policy Center ("GIPC") once again urges the Centers for Medicare and Medicaid Services ("CMS" or the "Agency") to re-evaluate the approach taken in the Agency's Draft Guidance, which proposes to implement the second year of the Medicare Drug Price Negotiation Program ("Program") established by the *Inflation Reduction Act* ("IRA"). The Chamber supports efforts to ensure every American has equitable access to life-saving medicines at fair market prices, from diabetes and weight loss drugs to new diagnostics and therapeutics combating some of the world's most debilitating diseases. However, we firmly believe that the Program itself, the steps taken thus far in implementing the Program, and the contemplated next steps of implementation are damaging the present and future of life-science innovation, which could curb positive health outcomes for Americans now and in the future.

Reducing barriers to access has long been a health policy priority and focus for Congress and the business community. The Chamber supports efforts to help mitigate obstacles to life-saving medicines but government price setting will create additional access challenges for Americans. The Chamber has significant concerns about the permanent effect this program will have on innovation. Though the detriment of these policies to the economy is wide-ranging, we have focused our comments on three primary areas:

1. **The impact of price controls on life-science innovation and patient access.**
2. **The significant definitional overreach of the IRA.**
3. **The implementation process and so-called "negotiation" provisions lack transparency.**

These concerns (which are illustrative, and do not represent the entirety of the problems inherent in the Program or in its past or proposed implementation) are outlined in more detail below.[1]

[1] As CMS is aware, the Chamber and other parties have challenged the Program in federal court as unconstitutional on several grounds. The fundamental legal defects in the Program further support the conclusion that CMS should reconsider the approach

I. The IRA's price controls negatively impact life-science innovation, thereby depriving American patients of access to new life-saving medications.

Congress and the business community both share in the goal of reducing barriers to patient access. The Chamber supports appropriate, effective efforts to help mitigate obstacles that patients might face in accessing and affording life-saving medicines. However, government price setting will create additional significant access challenges for American patients. A June 2023 study estimated that the IRA could, over a 10-year period, result in a reduction of 40% in approvals from the Food and Drug Administration ("FDA"). In addition, studies also show that price controls limit clinical research in cutting edge therapies, resulting in a reduction for some treatments and cures by as much as 75%.[2]

Analysis and experience in other countries also demonstrates that market-restrictive policies like the IRA's price controls deter future innovation, inhibit patient access, and limit patient choice. A 2024 study from the Chamber comparing the IRA to policies in countries shows that the IRA will result in 29% to 44% fewer products for American patients [3]. These estimates are in line with other research conducted on the potential impact of the IRA on life sciences research and development. For example, prior to the enactment of the IRA's price controls, out of 104 new oncology products released globally, 80% were approved by the FDA and made available in the U.S., while only 58% of those new medicines were similarly available in Europe. Likewise, while U.S. patients benefit from faster access to therapies, in several benchmark countries, approvals can be lengthy-an average of 133 days in Germany and up to 500 days in Spain [4].

Government intervention in the market's establishment of prices undermines the innovation ecosystem that has enabled the U.S. to become one of the most inventive countries in the world. Moving forward in this second round of so-called "negotiations," decisionmakers must consider the implications of the IRA's price controls on patients. Failure to do so will jeopardize U.S. leadership on biopharmaceutical innovation and access to treatments. The ability of American patients to access life-saving innovations in a timely manner depends on it.

II. CMS' definition of a Qualifying Single Source Drug represents a significant **overreach and is overbroad.**

As in previous guidance, CMS has improperly expanded the definition for medications subject to the IRA's "negotiation" process by identifying multiple drugs as negotiation-eligible based on their molecule, including newer drugs that would not otherwise qualify for "negotiation" on their own under the statute. This action greatly increases the therapies

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set forth in the Draft Guidance. The Chamber respectfully submits that even if the Program were lawful (which it is not), sound policy would require CMS to change its proposed approach to implementation as these comments suggest.

[2] *From Innovation Oasis to Research Desert How Price Controls Imperil American Medical Innovation and the Search for Cures,* December 11, 2023, available at https:// www.uschambe r.com/intellectual-property/ne w-study- forecasts-devastating-imoact-on-patients-and-medical-science-from-g overnment-orice-controls.

[3] *The True Cost of Price Controls: Patient Access Report 2024,* January 31, 2024, available at GIPC-2024-Patient-Access-Reoort.odf (uschamber.com)

[4] *Id.*

detrimentally affected by price controls. By grouping these therapies together at the active-ingredient or moiety level, the guidance significantly reduces the incentives for future research into how these lifesaving medications can be improved. This overly broad definition is contrary to the IRA requirement that a medicine be approved for a specified number of years, and it will negatively impact the many patients who benefit from ongoing research into a molecule.

CMS has also improperly expanded the definition of a qualified medicine by creating a "bona fide marketing" standard, where the Agency will determine whether there is "meaningful competition" from a generic or biosimilar to determine whether a selected medicine remains eligible for "negotiation." The plain text of the IRA does not include a bona fide marketing standard, and accordingly CMS should remove this construct from the guidance. If there is *any* generic or biosimilar competition, then CMS must remove a selected medicine from negotiation because that medicine would no longer be a "qualifying single source drug" (QSSD). This overly broad concept will inappropriately allow CMS to continue implementing price controls on medicines that should no longer be subject to them.

III. The entire "negotiation" process lacks transparency and accountability.

Dubbed as a voluntary "negotiation"[5], the implementation process selected by this Agency has provided limited opportunities for stakeholder input. The Agency has held inappropriately constrained listening sessions as part of the 'negotiation' process, where feedback has been limited to feedback from patients only; patients were cut off from speaking and were selected to participate in an unclear way. Additionally, it should be emphasized that there is minimal public information on many key aspects of the entire "negotiation" and "agreement" process, further supporting the conclusion that this is not a negotiation at all, but rather a one-sided scheme for mandating prices. Given the impact that price controls will have on patient access and patient choice, the Agency should revise its implementation guidance to provide greater transparency and opportunities for public review and engagement.

IV. Conclusion

Implementation of the IRA's price controls poses a real threat to America's future as the world's leading life-science innovator. Additionally, arbitrary price controls, once implemented, will lead to patients waiting longer to receive, and having reduced access to, new medicines. The Chamber opposes misguided, market-restrictive, and legally defective efforts that limit patient access and choice and undermine the living life-science innovation ecosystem. If the Agency elects to ignore these impacts on American patients and, instead, moves forward with the IRA's implementation, it should at least revise this guidance to reduce definitional overreach and ensure an open, public, fully transparent "negotiation" process.

[5] In reality, this entire process is nothing but the result of government coercion. True negotiation occurs when private actors freely negotiate in good faith to reach a mutually agreeable price. The process outlined by CMS isn't negotiation in the true sense of the word but is instead an arbitrary, government compelled price setting process. Continuing to dub this process a "negotiation" ignores the reality of the legal and practical power of the government to set a price and compel a manufacturer to accept it.

Sincerely,

Tom Quaadman
Executive Vice President
Center for Capital Markets Competitiveness
U.S. Chamber of Commerce

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Electronically Submitted via
IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani,

We are patient organizations who collectively represent a wide range of patients living with chronic diseases. For patients, access to treatments is critically important. Treatments can improve daily life, minimize debilitating pain and extend or save lives. However, policies that may affect access to treatments, such as changing incentives for including a treatment on a formulary, mean that patient who would be most affected by the change should have the greatest voice in the matter. We strongly believe that health care policies should be patient-centered, not simply made based on financial considerations. **That is why we believe that patient voices must be included throughout the process of the Medicare Drug Price Negotiation Program (MDPNP).**

As the MDPNP enters its second cycle of treatment selection and negotiation, we urge CMS to ensure patients have a seat at the table. Last year numerous patients and patient organizations provided input on treatments selected for negotiation through written comments and participating in listening sessions. While we appreciate CMS providing these opportunities, many patient voices felt they had more to contribute to this process but lacked the opportunity to be fully heard. Additionally, patients were concerned that the process was lacking in privacy and therefore were not comfortable going into specific details about their health. These factors deterred patients from participating fully and honestly in the negotiation process. **We urge CMS to both improve and expand these opportunities to foster greater dialogue, input, and participation from all voices.**

We offer three recommendations:

1) **Requirements for written comments should be less structured to allow a wider range of comments.** Please understand that each patient's story, experience and ability vary widely. The written comment process in the first negotiation cycle was cumbersome, time consuming and forced comments into pre-determined and awkwardly defined frameworks. This resulted in advocates feeling their input was not valued, with important points being

left out because there was not a clear avenue to fully express them, and discouraged patients from participating at all due to the complexity of the process

2) **Listening sessions should promote dialogue between CMS and stakeholders.** The listening sessions conducted in the first cycle were an important opportunity to provide direct feedback to CMS; however, the lack of dialogue and overly rigid structure diminished their usefulness and the perception that the comments were "heard." In future listening sessions, we recommend a roundtable style that allows stakeholders to directly engage with each other and CMS – this will help elucidate patient concerns. CMS should also consider having separate roundtables for different stakeholder types – patients, their advocates, providers, and others – to give stakeholders more comfort in expressing their views by having a less intimidating forum. We do not believe that any voices should be diminished through this process and increased engagement from all stakeholders will only help elevate the primacy of the patient in this process. Additionally, CMS should consider offering both virtual and in-person options, holding regional discussions using its regional staff around the country, and varying the times that sessions are held to accommodate time zones and work schedules of the varied stakeholders CMS seeks to engage. Further, offering recorded and non-recorded options may help even more patients feel comfortable providing feedback.
3) **Beyond the listening sessions, patients should be consulted throughout the negotiation process.** Patients have a clear interest in ensuring that the negotiation process does not have unintended consequences, such as losing access to treatments because of changes in formulary coverage for both negotiated and non-negotiated treatments. CMS should regularly convene meetings with patient organizations and other stakeholders to brief them on the negotiation process, hear feedback and concerns about access to treatments, and provide a means to resolve and address those concerns. Access to treatment and medication is paramount for patients – the potential for new barriers to access, like greater prior authorization requirements, step therapy, or other hurdles, must be zealously guarded against as a negative consequence of the negotiation process.

We look forward to engaging with CMS as the second cycle of negotiation moves forward.

Should you have any questions or comments, please contact Liz Helms, Founder and Director, CCPA at lizh@chroniccarealliance.org. Thank you for your time and attention to these critical issues.

Sincerely,

Chronic Care Policy Alliance

AiArthritis

Albie Aware Breast Cancer Foundation

Alliance for Aging Research

American Senior Alliance

Arizona Chronic Care Together (ACT)

Axis Advocacy

Bay Area Cancer Connections

California Access Coalition

California Black Health Network

California Chronic Care Coalition

California Health Collaborative

California Hepatitis C Task Force

Carrie's TOUCH

Chronic Disease Coalition

Healthy Men Inc.

HIV+Hepatitis Policy Institute

Looms For Lupus

Neuropathy Action Foundation

Nevada Chronic Care Collaborative

Partnership to Fight Chronic Disease

The National Puerto Rican Chamber of Commerce

Chronic Care Policy Alliance

State Advocates Working Together to Bridge the Gaps in Chronic Care

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Electronically Submitted via
IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani,

The Chronic Care Policy Alliance (CCPA) is a network of state and regional advocacy organizations advancing public policy that improves the lives of those living with chronic conditions and diseases. In recent years, CCPA has advocated in the interests of these patients for issues related to prescription treatment access and reducing out-of-pocket costs under the Inflation Reduction Act (IRA), as well as through supporting efforts to ensure patients benefit at the pharmacy counter, by urging reforms for Pharmacy Benefit Managers and supporting prohibiting copay accumulator programs within insurance plans, that drive up out-of-pocket costs for patients.

CCPA appreciates CMS releasing a draft Guidance Memorandum for the 2026 Program Year of the Medicare Drug Price Negotiation Program (MDPNP). We were pleased to comment on last year's draft guidance and are grateful that CMS took some of CCPA's comments to heart, by adding opportunities for patient input through written comments and listening sessions. While not all of our concerns were addressed and improvements to the patient input process are greatly needed, we hope to contribute to continued improvement of the MDPNP that supports patient-centered health care policies and patient access to treatments.

1. Ensuring Patients Have a Seat at the Table and Patient Voices Are Heard

Recently, CCPA joined with 21 other patient organizations in sending a letter to CMS outlining how patients can be more involved in the negotiation process, including by broadening the written comments and listening sessions, as well as engaging in ongoing dialogues with patient organizations. We incorporate those recommendations here by reference and our letter is attached.

As with the implementation of any new program, there are lessons learned from the first year that can support improvements in subsequent years. As noted in the stakeholder letter, the rigid structure of the written comments and narrow focus of the listening sessions left many patients and

patient advocates feeling that they were not fully heard. We hope that CMS will strive to address this in future opportunities for patient input.

Regarding the specific patient-focused events referenced in Section 60.4, CCPA welcomes this focus on patient input and hopes CMS will implement an "all of the above" strategy to hear from patients and all stakeholders in as many forums and events as possible. Recognizing that many patient organizations are state-based (and not based in the Washington, DC region), providing options for virtual participation is important. It is also important to seek out and include groups beyond only large national organizations, as smaller advocates have real contributions to make but not the same ability or resources to track and engage with all federal policymaking opportunities. To that end, CMS should consider hosting virtual and in-person events to accommodate patient advocates around the country. CMS could host regional events using its local staff. Providing both recorded and non-recorded opportunities to speak will also give more patients greater comfort in commenting and expressing themselves without fear of overexposing their personal information or making themselves a focal point for a topic. Recognizing that many patients and providers may not have flexibility in their work schedules or the ability to take time off during the typical office hours, we also encourage CMS to vary the times of day that events are held to accommodate these limitations and encourage more robust participation from patients and physicians alike – those with the real-world knowledge about the use and importance of the medications under review.

Additionally, CCPA supports allowing dialogue and discussion between participants and CMS, to promote greater understanding and appreciation of different perspectives. One option may be to host roundtables for different types of stakeholders – patient groups, providers, and others – so that similar stakeholders can offer their perspectives together, without feeling intimidated by other stakeholders. For example, the discussion a patient advocate forum would be much different than the likely more scientific and medically focused discussion a group of physicians and other providers would have. CCPA supports expanded discussions with any patients living with disease or conditions of the medications under review, rather than limiting or putting emphasis on those that are currently receiving the individual treatment, since there is a high likelihood of patients having used or needing that particular treatment in the future. All groups and voices, regardless of their background, mission, or perspective, should have a seat at the table. We hope all stakeholders will focus on evaluating the arguments presented, as we collectively strive to achieve our shared goal of improving patient care.

2. Valuing All Patients

As noted in the draft Memorandum in Section 50.2, the law prohibits CMS from using research that "treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill." CCPA and other advocates have long opposed efforts to value some patients over others – whether that is in the form of Quality Adjusted Life Years (QALYs) or metrics, all patients deserve to be treated fairly, equally, and with respect to their needs and wishes. We appreciate CMS making clear in its Memorandum that this data, in accordance with the law, will not be included, and encourage CMS to further protect against similar quality metrics that would have the same harmful impact on patients. **CCPA urges CMS to find all possible avenues for further strengthening these protections for patients as it considers multitudes of research and data on treatments.**

Additionally, in looking at comparative effectiveness research, CCPA urges CMS to see patients as unique individuals, and not an aggregated group. A treatment that works for many patients may not work for others or might be the only option that works for another – aggregating many patients undermines the value a treatment provides to each individual. Because of this, we believe that comparative effectiveness research may not be the right means of assessing value, and we encourage CMS to hear from patients on the unique value a medication provides to them, in supporting their wellbeing and quality of life, and making judgments of value based on those individual stories. Patients fear that this process will result in them losing access to their preferred medications, especially if plans prioritize negotiated products over non-negotiated products. Incorporating individual patient experiences into a product's value proposition will ensure a negotiated price that accurately reflects the benefit to each patient, without compromising access.

Finally, CCPA welcomes CMS seeking to improve the data collection process from patients through a forthcoming Information Collection Request (ICR) on Negotiation Data Elements and Drug Price Negotiation Process ICR for initial price applicability year 2027. We look forward to providing comments when that document is released. In the meantime, as mentioned in the multi-organization letter to CMS (attached), last year's process for submitting stakeholder organization and patient information was difficult to navigate, with comments shoe-horned into prescriptive frameworks. We urge CMS to allow for broad comments that allows patients and their advocates to share their unique experience – by granting them the ability to give the kind of broad comments CMS regularly collects through Notice and Comment rulemaking.

3. Protecting Patient Access to All Medications

In addition to emphasizing greater patient input and valuing all patients, **we urge CMS to proactively establish clear and concrete policies to protect patient access to treatments, especially in light of formulary changes that prioritize negotiated or non-negotiated treatments over other products**. CCPA appreciates the discussion in Section 110 on Part D formularies and the reiteration of current policies meant to protect patient access and medical decision-making. CCPA strongly believes that health care policies should not prioritize financial savings over patients; in reducing the price for certain medications, patients risk having access to more expensive products deprioritized (even if the other product is potentially a better treatment for them); likewise, patients may face new barriers, such as new prior authorization requirements, step therapy, or other utilization management hurdles, to accessing non-negotiated products. CMS must ensure that patients retain the same level of access to all products as was available before the MDPNP and the selection of specific treatments for negotiation. **In implementing Section 110 and protecting patient access to prescription products, CCPA urges CMS to proactively implement policies that would protect patients from increased barriers to care, create specific opportunities for patient feedback, and ensure robust monitoring and complaint resolution process to address issues as they arise.**

4. Conclusion

We thank you for receiving comments on this matter and we hope to continue an ongoing dialogue with the agency throughout this second cycle of the MDPNP.

Sincerely,

Liz Helms
Founder/Director
Chronic Care Policy Alliance
1001 K St., 6th Floor
Sacramento, CA 95814
www.chroniccarealliance.org

Kristin Julason Damato
Senior Vice President
Global Public Policy & Government Affairs
The Cigna Group
701 Pennsylvania Avenue, NW
Suite 720
Washington, DC 20004
Telephone (202) 719-5557
Facsimile (202) 719-6755
Kristin.JulasonDamato@TheCignaGroup.com

July 2, 2024

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Medicare Drug Price Negotiation Program Guidance
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Drug Price Negotiation Program Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

To Whom It May Concern:

The Cigna Group welcomes the opportunity to respond to the draft guidance on the Medicare Drug Price Negotiation for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) for 2026 and 2027.

The Cigna Group is a global health services organization committed to improving health and vitality. Our Cigna Healthcare and Evernorth Health Services divisions are major providers of medical, pharmacy, dental, and related products and services, with over 190 million customer relationships in the more than 30 countries and jurisdictions in which we operate. Within the United States, Cigna provides medical coverage to approximately 14.9 million Americans in the commercial group health plan market, predominantly in the self-insured segment. For 2023, we will be providing coverage in the individual Affordable Care Act insurance segment in sixteen states, both on- and off-Exchange, to more than 770,000 people. Additionally, we serve approximately 4.4 million people through our Medicare Advantage (MA), Medicare Prescription Drug Program and Medicare Supplemental products. In all of the segments we serve, Cigna is focused on working to deliver quality health care that is affordable, predictable, and simple – so people can live healthier, more vibrant lives.

Cigna companies strive every day to improve prescription drug affordability for Medicare beneficiaries and our customers. As the Centers for Medicare & Medicaid Services (CMS) works to implement the Inflation Reduction Act's (IRA's) Medicare Drug Price Negotiation Program, Cigna offers three key recommendations regarding the processes involved in manufacturer effectuation of the MFP:

- First, CMS should maintain the 30-day window for plans to submit prescription drug event (PDE) records because a shortened window would lead to inaccurate information being sent to Primary Manufacturers and heighten administrative burden on all parties.
- Second, CMS should clarify the definition of what constitutes "reasonable belief" that a claim is 340B-eligible. Moreover, if a Primary Manufacturer asserts that a claim is 340B-eligible and declines to pay a retrospective refund based on data it possesses outside of the Medicare Transaction Facilitator's (MTF's) possession, the Primary Manufacturer should be required to share thorough documentation of 340B eligibility with the reporting of payment elements to the MTF, rather than only sharing such documentation upon request from CMS (as described in Section 90.2). To allow Primary Manufacturers to decline payment of refunds without sharing documentation up front will expose dispensing entities to indiscriminate non-payment of retrospective refunds.
- Third, the MTF should be owned or operated by an independent entity not owned, directly or indirectly, by Primary Manufacturers to ensure over time that the Medicare drug price negotiation process is not based on the data gathered by the MTF, but rather the factors and variables described under the IRA and CMS's guidance.

We provide more detailed section-by-section comments below.

* * *

Section 40 – Requirements for Manufacturers of Selected Drugs

40.2.2. Data and Information Use Provisions and Limitations

CMS details that it will not publicly discuss ongoing negotiations with a Primary Manufacturer, but will make public a narrative explanation of the negotiation process and share redacted information regarding the data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable. The agency further explains that a Primary Manufacturer may choose to publicly disclose information regarding ongoing negotiations with CMS at its discretion, but reminds manufacturers that statements to or discussions with other Primary Manufacturers also engaged in the MFP negotiation process with CMS could negatively impact the competitive process for each independent MFP negotiation.

Cigna Comments:

Cigna is concerned that manufacturer disclosure of information regarding MFP negotiations could negatively impact the negotiations process for other non-selected Part D drugs, and we strongly recommend that CMS recognize this impact in the final guidance. We believe that such disclosure could inadvertently result in increasing beneficiary, employer, and taxpayer costs, and CMS should highlight the antitrust implications for the other markets. CMS could consider adopting policies that limit disclosure of negotiation information that could limit competitive impacts.

40.4.1 Medicare Transaction Facilitator Data Facilitator

CMS intends to engage with the MTF to facilitate the exchange of certain claim-level data elements and payment elements for selected drugs, including the transmission of certain claim-level data elements to the Primary Manufacturer and receipt of payment-related data elements from the manufacturer. Under the Negotiation Program, Primary Manufacturer participation in the MTF data exchange is mandatory and Primary Manufacturers must report to the MTF whether and how (e.g., via retroactive reimbursement) the Primary Manufacturer has made the MFP available for each claim, or why no refund payment has been made on a claim. CMS intends to leverage existing Part D claims data in this data exchange and does not envision dispensing entities separately transmitting claims data to Primary Manufacturers. Regarding the claims-level data elements, CMS believes that the selected data elements provide the minimum necessary information to the Primary Manufacturer that verifies the selected drug was dispensed to an MFP-eligible individual and for the transmission of such data to start the 14-day prompt MFP payment window.

CMS states that the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispense based on the quantity dispensed. Regardless of whether the Primary Manufacturer uses the potential MTF payment facilitation functionality, the Primary Manufacturer bears responsibility for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP

After the Primary Manufacturer makes payment to the dispensing entity and sends the report with payment-related data to the MTF, CMS is considering having the MTF generate an electronic remittance advice to the dispensing entity for purposes of reconciling manufacturer retrospective MFP refunds. CMS welcomes comment from interested parties on the concept of the MTF creating and sending an electronic remittance advice to dispensing entities to reconcile the payment provided by the Primary Manufacturer's retrospective refund payment. Additionally, CMS welcomes feedback on other methods for electronic remittance advice, including Primary Manufacturer electronic remittance advices, and specific data elements for such electronic remittance advices to ensure that accounts receivables can be closed for dispensing entities.

CMS notes that it is currently evaluating whether the 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely

payment of MTF refunds. CMS is also considering how to address claim adjustments and reversals and recognizes that adjustments and reversals could occur after the 14-day prompt MFP payment window has concluded. CMS envisions claim adjustments or reversals would entail transmission of additional data elements and reports with payment-related data when a change to original payment is warranted, based on an adjustment claim.

Cigna Comments:

Cigna is concerned that a seven-day window for PDE record submissions is too short and could potentially lead to manufacturers receiving information on prescriptions that may need to be reversed due to various factors. For example, patients typically have 7 to 14 days, depending on the pharmacy, to pick up a prescription and sometimes do not do so. In these cases, the pharmacy has to reverse the claim, but the reversal would have to occur outside of a seven-day window. Thus, manufacturers would be at risk of receiving inaccurate information. Furthermore, a seven-day PDE submission window would necessitate submission of PDEs at least twice per week for all PDEs, not just those associated with the Medicare drug negotiation program. We are concerned that the extremely high volume of PDE record transmissions will be administratively overwhelming.

Cigna recommends that CMS maintain the current 30-day window for PDE submission. However, if CMS were to consider a change, we recommend only modifying the initial PDE submission window and giving plans at least 21 days to submit PDE records. This would allow adequate time to address any claim reversals and reprocessing, which would ensure data accuracy and prevent pharmacy reimbursement issues. In addition, the window for claim adjustments or corrections should be a minimum of 30 days. Notwithstanding, if a shortened PDE submission timeframe is adopted, we would urge CMS to exercise enforcement discretion for a minimum of a year while the new PDE submission timeframe is evaluated for operational effectiveness.

In addition, we are concerned that reliance on the PDE may delay payments to pharmacies. CMS has taken as long as 6 days to accept PDEs, though these are noted to be outliers, and sometimes CMS's responses to PDEs require either corrections or new files. There are also situations where PDEs are reversed. Payment reconciliation may not be completely resolved until 6 months after plan year closing. Although this may occur infrequently, pharmacies will be at financial risk for retroactive repayment requests by manufacturers. Manufacturers may use the absence of a PDE to delay payment within the statutory prompt pay framework.

Finally, CMS should ensure that the MTF not be owned or operated, directly or indirectly, by Primary Manufacturers, as such an entity could enable manufacturers access to information that could skew the Medicare drug price negotiation process. We are concerned that this could undermine the goal of achieving fair prices and affordability for beneficiaries under the Medicare drug price negotiation program.

40.4.2 Nonduplication with 340B Ceiling Price

CMS states that the Primary Manufacturer is required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug. CMS further clarifies that a Primary Manufacturer that provides access to the MFP for a selected drug is not required to provide a 340B ceiling price on that same selected drug claim if the MFP is lower than the 340B ceiling price, and these price concessions are not cumulative, but manufacturers must ensure that the appropriate price concession is honored.

CMS notes that received requests from numerous interested parties for CMS to assume responsibility for "deduplicating" the 340B ceiling price and the MFP, but asserts that CMS will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP.

CMS will provide primary manufacturers a process to identify 340B-eligible claims through: 1) claims-level data from dispensing entities (voluntary for 340B data element; and 2) reporting of payment elements to the MTF by the primary manufacturer

Cigna Comments:

Cigna is concerned that the approach to 340B-eligible claims will result in potential retrospective refund nonpayment issues. In the absence of the MTF's possession of complete data on 340B-eligible claims, Primary Manufacturers may unilaterally identify a given claim as 340B-eligible based on limited information and refuse to pay a retrospective refund based on data that it possesses outside of the MTF's data that is exchanged or otherwise possessed. If the MTF is not able to identify a given claim as 340B eligible, Primary Manufacturers should be required to share with reporting of payment elements to the MTF thorough documentation that the claim is 340B eligible to support non-payment of a refund. We comment further on this below in the context of Section 90.2.1.

Additionally, we are concerned that the 14-day prompt payment period for primary manufacturers may not provide adequate time to allow for the deduplication of 340B-eligible claims, which may cause delays for MFP effectuations. Delay in MFP effectuation would cause dispensing entities financial strain and risk. Furthermore, the lack of a standardized deduplication methodology could lead to disputes on the methodologies employed by manufacturers, which could also result in MFP payment delays to dispensing entities. Finally, we recommend that CMS clearly define what manufacturer "reasonable belief" is that a claim is a 340B-eligible so that disagreements between covered entities and manufacturers do not arise.

Section 60 – Negotiations Process

60.6 Publication of MFP

Pursuant to law, CMS will publish by November 30, 2025, the MFP for each selected drug for initial price applicability year 2027. CMS will publish the following on the CMS website: the selected drug, the initial price applicability year, the MFP file, and the explanation for the MFP.

Cigna Comments:

Cigna would like to underscore the importance of CMS publishing MFPs by the November 30, 2025, deadline to ensure that Part D plans have adequate time to operationalize the formulary inclusion requirement and MFP requirements and incorporate them into dispensing entity negotiations and bid development for 2027.

Section 90. Manufacturer Compliance and Oversight

90.2.1 Manufacturer Plans for Effectuating MFP

CMS mandates that Primary Manufacturers submit their plan for MFP availability, including deduplication of 340B covered units for the selected drug, to CMS in writing at least seven months before the initial price applicability year starts. (by June 1, 2025, for selected drugs with 2026 as the initial price applicability year). Primary Manufacturers' plans must also include description(s) of the types of documentation and data they would collect, maintain, and deliver to CMS, if requested, for the purposes of auditing and compliance with the requirement to make the MFP available. Although this deadline is earlier than previously stated, CMS believes it allows for thorough evaluation and potential outreach to Primary Manufacturers for missing information. Upon receiving these plans, CMS will conduct a risk assessment for each submission.

Cigna Comments:

As mentioned above regarding Section 40.4.2 (nonduplication with 340B ceiling price), we urge CMS to ensure that Primary Manufacturers share thorough documentation to support nonpayment of refund amounts based on deduplication of 340B covered units. In the absence of claim-level documentation and identification, we are concerned that Primary Manufacturers may indiscriminately decide not to pay retrospective refunds on selected drugs.

Cigna supports CMS's guidance that such documentation should also be maintained by Primary Manufacturers and be made available to CMS for auditing and compliance enforcement purposes.

Conclusion

Thank you for your consideration of these comments as we work together to improve prescription drug affordability for Medicare beneficiaries. Cigna would welcome the opportunity to discuss these issues with you in more detail at your convenience.

Respectfully,

Kristin Julason Damato

COMMUNITY ONCOLOGY ALLIANCE

Dedicated to Advocating for Community Oncology Patients and Practices

1225 New York Avenue, NW, Suite 600, Washington, D.C. 20005
(202) 729-8147 | communityoncology.org

July 2, 2024

Submitted Via Email (IRARebateandNegotiation@cms.hhs.gov)

Re: Medicare Drug Price Negotiation Program Draft Guidance

Comments Submitted by the Community Oncology Alliance

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this comment letter regarding the Medicare Drug Price Negotiation Program Draft Guidance for Initial Price Applicability Year ("IPAY") 2027.

COA is an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding more than 20 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

Integral to COA is the Community Oncology Pharmacy Association ("COPA"), a peer-to-peer network of independent community oncology and urology practices with medically integrated oncology dispensing services that provide patient-centered and multidisciplinary care. COPA breaks down regulatory and operational barriers to ensure patients have timely and unrestricted access to pharmacy services as an integral part of their care.

Medically integrated dispensing benefits patients through timely access to drugs, copay assistance, monitoring compliance, and management of side effects. Practices with medically integrated dispensing are already under financial pressures due to existing market trends and policies (e.g., Direct and Indirect Remuneration ("DIR fees")) and now face looming additional financial pressures associated with Maximum Fair Price ("MFP") effectuation that has been considered for pharmacies, but not specifically for community oncology practices with medically integrated dispensing.

To that end, COA appreciates the Medicare drug price negotiation program's goal of lowering drug costs for beneficiaries. **However, COA is very concerned with how the Centers for Medicare and Medicaid Services' ("CMS'") implementation of the program's Maximum Fair Price throughout the drug supply chain will impact the ability of community practices with medically integrated dispensing to provide quality, affordable care to their patients.**

COA is concerned that given the way CMS is choosing to operationalize the MFP, there could be variable approaches and different processes associated with negotiated drugs. Manufacturers may choose between a retrospective and prospective payment model. Both of these approaches create operational challenges for community practices and they may need to manage multiple processes across manufacturers of selected drugs.

COA has identified several factors related to how the CMS draft guidance proposes to effectuate the MFP in 2026 and 2027 that may detrimentally impact independent practices with medically integrated dispensing, including:

- Administrative Burdens Associated with Prospective Effectuation
- Financial Risk Associated with Retrospective MFP Effectuation
- MFP and IRA Impact on Community Oncology Practices Beyond Cancer

Administrative Burdens Associated with Prospective Effectuation

Under a prospective model, practices would be able to acquire negotiated drugs at or below MFP and then receive MFP-based reimbursement from Part D plans. But the lower acquisition price is only applicable for Medicare beneficiaries. From a prospective model standpoint, practices are very concerned about managing separate product inventories for MFP and non-MFP eligible patients. Where large pharmacies and specialty pharmacies have sophisticated inventory management systems, small community practices do not have the same resources or staffing to track and maintain separate inventories. This will be particularly challenging as cancer drugs often require complex storage and handling.

Financial Risk Associated with Retrospective MFP Effectuation

Under the proposed retrospective effectuation model, manufacturers need to provide a reconciliation to the dispensing entity to close the gap between acquisition cost and MFP-based reimbursement. As COA has previously expressed, we are very concerned and frustrated with the decision to put providers (and, in this case, pharmacies) in the middle of the operationalization of a negotiation process that takes place between manufacturers and the government.

As proposed by CMS, under the retrospective model, it may take up to 30 days for a plan to submit the necessary Prescription Drug Event ("PDE") records to the Medicare Transaction Facilitator ("MTF"), which in turn needs to transfer relevant data to the manufacturer. It may then take another 14 days for the manufacturer to issue a refund. Under this timeframe, practices could be floating the difference between acquisition costs and reimbursement for up to two months longer than they do currently. The challenge will be significant for all dispensing entities, but especially true for community practices that dispense high-cost cancer medications. The extended timeline would create more significant cash flows for COA members than for chain pharmacies or PBM-owned specialty pharmacies amid unprecedented reimbursement pressures. Where CMS is evaluating the length of the timeline to submit PDE records, COA urges the agency to shorten the data submission timeline to the shortest period possible operationally.

Another concern by community practices of retrospective MFP effectuation is the proposal for manufacturer refunds to be based off a standardized amount (i.e., the difference between a negotiated drug's Wholesale Acquisition Cost and the MFP). Community practices acquire treatments for their patients at various prices, and it is unclear based on the draft guidance how manufacturers will be able to determine each practice's acquisition costs and whether the standardized amount will be sufficient relative to these various prices. This dynamic may increase operational pressures on practices to guarantee that manufacturers have the necessary information to ensure dispensing entities, like community practices, receive adequate payment.

Additionally, the voluntary nature of the payment model that could facilitate the MFP-associated transactions could create operational challenges for practices. The decision to allow manufacturers to choose which model to utilize means that practices must track different approaches drug by drug and work with multiple vendors to process payments as opposed to having them flow through a single entity (e.g., the MTF) or existing stakeholders (e.g., Group Purchasing Organizations).

Finally, and just as importantly, the new payment model leaves practices without clear insight into true operating margins during lengthy refund periods. If there are instances of medications being dispensed at a loss during these periods it will leave practices without a timely and accurate insight of income or losses. The inability to accurately project or track dispensing losses – a very real issue in today's dispensing environment, as CMS knows well from our ongoing concern with post-DIR fee reimbursement – this could be economically devastating for a community practice.

MFP and IRA Impact on Community Oncology Practices Beyond Cancer

Oncologists approach patient care in a holistic manner, including treatment of prevalent comorbidities that patients with cancer experience (e.g., cardiovascular disease, diabetes). Many of these treatments are commonly dispensed by oncologists in addition to cancer medications. COA is very concerned that the financial risk that our medically integrated dispensing oncology practices would be exposed to extends far beyond oncolytics and implicates a number of other products subject to Medicare price negotiation. Community practice exposure to several negotiated products will increase the financial burden relative to the amount they must float under the retrospective payment model or the challenge of managing multiple inventories under a prospective model. As a result, community oncologists may opt out of dispensing oral medications to Medicare patients, at a time when the benefits of in-office dispensing are becoming very evident.

In addition to the immediate concerns for implementation of the IRA in Part D MFP, COA remains incredibly concerned about the impact of the IRA on Medicare Part B reimbursement. A previous independent analysis estimates that the Part B add-on reimbursement for oncology providers would fall by at least 49.4 percent once the IRA was implemented.[1] This is because the add-on payment that providers receive will be based on the negotiated MFP price of the drug, which will be significantly lower than current ASP. Community oncology practices are currently facing unprecedented pressures from severe inflation, sequester cuts, and reduced Medicare reimbursement. They simply cannot shoulder what would be a massive and untenable decrease in Medicare drug reimbursement. COA calls upon CMS and Congress to address the unintended negative consequences of the IRA MFP in Medicare Part B reimbursement through a technical fix as soon as possible. This would help the government avoid major unintended negative consequences that would damage the stability of our nation's independent cancer care system.

Conclusion

COA appreciates the opportunity to comment on the draft guidance for MPF effectuation. We look forward to working with CMS to further patient-centered policies and improve both the quality and cost of oncology care while continuing to ensure access.

We are available to discuss any of our concerns or recommendations regarding the comments provided in this letter and thank you for your consideration.

Sincerely,

Ted Okon
Executive Director

Judith Alberto, MHA, RPh, BCOP
Director of Clinical Initiatives and COPA Liaison

[1] Avalere Health. "IRA Medicare Part B Negotiation Shifts Financial Risk to Physicians." November 2022. Available here.

COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Centers for
Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

Thank you for the opportunity to provide comments on the May 3, 2024, memorandum entitled "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027."

The Council for Affordable Health Coverage (CAHC) has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease. CAHC (www.cahc.net) is a broad-based alliance with a primary focus: ensuring all Americans have access to affordable coverage. Our members include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, pharmaceutical manufacturers, and pharmacy benefit managers.

We are submitting comments on three aspects of the Draft Guidance:

1. 30.1 Identification of Qualifying Since Source Drugs for Initial Price Applicability Year 2027
2. 40.4 Providing Access to the MFP in 2026 and 2027
3. 60.4 Negotiation Process

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

CAHC is concerned that CMS has adopted an overly broad definition for drugs subject to the Inflation Reduction Act's (IRA) Maximum Fair Price (MFP), grouping together multiple drug products that should be considered separately. CMS' policy will negatively impact patients with chronic and rare diseases by disincentivizing post-approval research and likely violates Section 1192(d)(3)(B) of the law. That Section envisions CMS using data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. CMS has interpreted the section to add another requirement that aggregates data for all products with the same active moiety or ingredient across products with different NDAs or

BLAs. While CMS treats these products the same for pricing, these are different products entirely used to treat different conditions or populations, and with different approvals by FDA. The IRA approach for the drug selection process did not envision this, and its absence does not mean CMS has authority to add this requirement.

In terms of impact, this decision will negatively impact patients with serious chronic or life-threatening conditions. CMS' policy to combine all indications, dosage forms and strengths together as one drug will result in CMS negotiating one MFP for multiple products that share an active ingredient immediately upon launch even if such treatments have not been on the market for 7 years, as required by the law. This means a new drug could face a price set by CMS on the first day of market approval, even if that drug treats an entirely different disease via meaningful clinical advancements, addresses an unmet need, or treats additional patient populations. As a result, manufacturers will have significantly reduced incentives to continue clinical programs after FDA approval of the initial use.

This flawed policy is anti-patient, anti-innovation, and violates the letter and intent of the law, and should be revised to apply separately to each NDA or BLA.

40.4 Providing Access to the MFP in 2026 and 2027

This guidance states that "any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities…[thereby ensuring] that Part D MFP-eligible individuals will have access to the MFP at the point-of-sale."[1] CMS defines a 14-day prompt MFP payment window for manufacturers to ensure the dispensing entity receives the correct amount of reimbursement based on the MFP. CMS also details options for how a Medicare Transaction Facilitator (MTF) should facilitate the exchange of data and payment between manufacturers and other pharmaceutical supply chain entities but questions remain as to the entire role of the MTF.

CAHC has significant concerns related to the manufacturer effectuation of the MFP, notably the 14-day prompt MFP payment window and how to operationalize the MFP discounts in a system where there are daily payments on thousands of claims to thousands of pharmacies. The pharmaceutical industry and supply chain are not currently set-up in a way that ensures this data and money exchange could be seamlessly implemented within the defined time frames. CMS is not prepared for this and needs to take a strong role in building and implementing the Medicare Transaction Facilitator (MTF).

In order to avoid failure in effectuating the MFP, CMS should direct- with precision- a facilitator built off workable transaction standards currently adopted in the market with adequate data to adjudicate claims within a reasonable time frame.

CMS recognizes that the market does not currently include a direct relationship between manufacturers and pharmacies/dispensing entities. As such, CMS outlines two payment facilitation options for the MFP: (1) Transmittal of banking information only; or (2) pass-through of MFP refunds. CAHC supports option 2, the "pass-through of MFP refunds", as the only viable solution for a functional marketplace. CAHC also

[1] Medicare Drug Price Negotiation Program: Draft Guidance.

suggests CMS consider providing some degree of a government-funded float by bearing the costs of operationalization of this MTF function so pharmacies are not financially overburdened.

Recommendation: CMS needs to provide stability by leveraging systems that already exist, such as the coverage gap discount. Providing a government float to dispensing entities to allow them the flexibility to ensure MFP payments are being made appropriately and promptly in the 14-day window is essential for the operation of the system.

60.4 Negotiation Process

While we appreciate CMS making revisions in this draft guidance based on the lessons learned from implementing the program thus far, including extending the comment period from 30- to 60 days, there is still much room for improvement, especially in the area of stakeholder engagement and public feedback.

CMS states they will "host patient-focused events to seek verbal input from patients and other interested parties" and "intends to improve upon the design [from the previous guidance]."

The patient-focused events need to be more accessible than those in the past, allow those participating enough time to share their feedback, and demonstrate how CMS will use what they learn from those sessions in practice. Listen-only discussion formats are not the best option as they limit the opportunities for engagement and further clarifying questions. CAHC agrees with CMS' suggestion that these events should promote discussion as opposed to being listen-only. A law of this magnitude and complexity should have robust stakeholder feedback, including diverse views from every party impacted.

Additionally, in our comments from last year, we highlighted how the inclusion of language that bars manufacturers from being transparent about government activities during the negotiation process is an egregious overreach of government censorship. The need to shield the CMS decision-making process from scrutiny will erode public confidence in the price-setting process and should be removed. Now a year later, we know more about the negotiation process, however, there is still little public information of how drugs were selected and why, zero public release of regulatory impact or Office of the Assistant Secretary for Planning and Evaluation (ASPE) analysis of CMS' decisions, or even what was done with the information CMS collected during last Fall's stakeholder listening sessions, including who was asked to speak and why. This darkness shrouding the program hides behind Section 1198's requirement that HHS implement the program through guidance and ignore long-established practices to deal transparently with the public and release pertinent information on what government is doing and why. While Congress required CMS to protect proprietary information, it did not require CMS to operate in secret about its processes and analysis. CMS should release all materials to the public that will help the public understand the operations and thinking of the agency while creating meaningful venues for input that mirror the long-established practices ensconced in the Administrative Procedure Act.

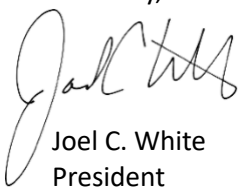
There is nothing in law that precludes CMS from having a more transparent, accountable process. We encourage you to open up the process and commit to the responsible implementation of the law.

Conclusion

While we share your goal of lowering the cost of healthcare, achieving this goal must be approached systemically and not in a way that creates a slew of unintended consequences, namely harming our most vulnerable patients. We encourage you to revisit the policy and procedures outlined in the draft guidance.

If you have questions about these comments, please do not hesitate to contact me.

Sincerely,



Joel C. White
President
Council for Affordable Health Coverage

the campaign for
SUSTAINABLE Rx PRICING

July 1, 2024

Dr. Meena Seshamani
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Deputy Administrator Seshamani:

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based nonpartisan coalition of leaders committed to fostering an informed discussion on sustainable drug pricing. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, public payors, pharmacy benefit companies, and health plans. We are committed to the goal of lowering the cost of prescription drugs for patients. We support bipartisan, market-based solutions that promote competition, improve affordability, and enhance list price transparency while maintaining patient access to innovative medications that improve health outcomes and save lives.

Prescription drug pricing trends are simply not sustainable for U.S. patients, families, taxpayers, businesses, and our economy as whole. Twenty-two cents of every health care dollar go toward prescription drugs – with prescription drugs contributing more to health care costs than any other type of health care service.[1] The median annual list price among drugs newly approved by the Food and Drug Administration (FDA) in 2023 was more than $300,000 – a significant increase from 2022 when the median launch price was $220,000.[2] For one-time gene therapy treatments, list prices were even higher in 2023 ranging from $2.2 million to $3.2 million.[3]

Drug makers increased prices on 775 drugs to start 2024 even though many Americans already cannot afford the medications they need to get well and remain healthy.[4] [5] The price increases implemented at the outset of the year follow years of unsustainable price increases imposed by Big Pharma on consumers and taxpayers. During the period of July 2021 to July 2022, for example, drug makers raised prices in excess of inflation for 1,216 drugs, with an average price

[1] AHIP. Where Does Your Health Care Dollar Go? September 6, 2022.
[2] Beasley, D. "Prices for new US drugs rose 35% in 2023, more than previous year." Reuters. February 23, 2024.
[3] *Ibid*.
[4] Calfas, J. Drug Makers Raise Prices of Ozempic, Mounjaro, and Hundreds of Other Drugs. *The Wall Street Journal.* January 18, 2024.
[5] Kirzinger A et al. Public Opinion on Prescription Drugs and Their Prices . Kaiser Family Foundation. August 21, 2023.

increase of 31.6 percent.[6] The average price increase was nearly $150 per drug (10.0 percent) in January 2022 and was $250 (7.8 percent) in July 2022.[7]

Despite efforts from the branded pharmaceutical industry to suggest otherwise, drug makers – and drug makers alone – are the drivers of the unsustainable growth in drug prices and excessive spending on prescription drugs today. Drug companies set excessively high list prices at launch for new drugs and raise those prices every year oftentimes at rates that far exceed inflation.

Spending on high-priced drugs places significant strain on patients, federal health programs, and taxpayers. For example, spending on drugs and pharmacy services now comprise approximately 19 percent of all Medicare expenditures, according to the Medicare Payment Advisory Commission (MedPAC).[8] High-priced drugs also substantially burden the many small businesses and large employers who seek to offer affordable health insurance and their employees because, as prescription drug expenditures increase, cost-sharing and premium costs also rise.[9] Far too often consumers experience the unfortunate and unfair choice of purchasing medications and paying their bills for food and housing. Patients and their families simply should never be presented with such a choice.

CSRxP thus believes it is imperative to rein in out-of-control drug prices and strongly supports efforts from the Centers for Medicare and Medicaid Services (CMS) to make prescription drugs more affordable for Medicare beneficiaries. To that end, we welcome the opportunity to comment on the Medicare Drug Price Negotiation Program Draft Guidance. In particular, CSRxP wishes to express support for the following policies described in the draft guidance:

1. **Definition of a "qualifying single source drug" (30.1):** CSRxP supports maintaining the existing definition of a "qualifying single source drug" for initial price applicability year 2027 as covering all strengths, dosage forms, and formulations of a drug selected for negotiation.

2. **Evidence about therapeutic alternatives for a selected drug (50.2)**: CSRxP supports continuing CMS' current policy of considering data submitted by a range of interested parties, including drug value assessments that do not assign a lower value to the elderly, disabled, or terminally ill, when considering evidence about alternative treatments to the selected drug.

[6] U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation Office of Health Policy. "Price Increases for Prescription Drugs, 2016 – 2022." September 30, 2022.
[7] *Ibid*.
[8] MedPAC. Overview: Medicare drug spending. June 16, 2016.
[9] American Academy of Actuaries. "Prescription Drug Spending in the U.S. Health Care System." March 2018.

3. **Methodology for the development of the initial offer (60.3):** CSRxP supports the agency's approach to utilize the lower of the following pricing methodologies as a starting point for developing an initial offer for 2027 selected drugs: (1) the Net Part D Plan Payment and Beneficiary Liability and/or the Part B Average Sales Price (ASP) of the identified therapeutic alternative(s); or (2) the Maximum Fair Price (MFP) for the initial price applicability year 2026 selected drug(s) of the identified therapeutic alternative(s).

4. **Identifying indication(s) for the selected drug and therapeutic alternative(s) for each indication (60.3.1):** CSRxP supports continuing CMS' current policy of considering both FDA-approved indication(s) and off-label indication(s) included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia when identifying indication(s) for the selected drug and the therapeutic alternative(s) for each indication.

5. **Part D formulary inclusion of selected drugs (111)**: CSRxP supports maintaining the current approach of giving plans flexibility in formulary management of 2027 drugs selected for negotiation so long as they adhere to existing nondiscrimination formulary requirements.

CSRxP's comments on the Medicare Drug Price Negotiation Program Draft Guidance reflect our strong commitment to working with CMS to improve prescription drug affordability while at the same time preserving access to innovative therapies that enable patients to get well and stay healthy. Without major actions, Medicare beneficiaries and taxpayers will continue to face unsustainable growth in prescription drug prices and spending.

1. **Definition of a "Qualifying Single Source Drug" (30.1)**

CSRxP supports maintaining the current definition of a "qualifying single source drug" under the Negotiation Program for initial price applicability year 2027, which specifies that the "qualifying single source drug" include: (1) all dosage forms and strengths of the same active moiety and the same holder of a New Drug Application (NDA), inclusive of products that are marketed pursuant to different NDAs; and (2) all dosage forms and strengths of a biological product with the same active ingredient and the same holder of the Biologics License Application (BLA), inclusive of products that are marketed pursuant to different BLAs.

This definition of a "qualifying single source drug" meaningfully helps to mitigate opportunities for drug manufacturers to game the process and find inappropriate ways to exclude drugs that might otherwise be eligible from the Negotiation Program. As a result, Medicare beneficiaries can benefit fully from access to the negotiated MFP of the selected drug regardless of strength, dosage form, branding, or indications.

Furthermore, CSRxP does not anticipate that this approach will discourage innovation. Given the size of the Medicare patient population, as well as the Medicare program's relatively small role in the context of a global pharmaceutical market, we expect that manufacturers have more than sufficient incentives to continue to engage in research and development of new therapies and new indications of existing therapies, leading to future innovations in treatment.

2. **Evidence About Therapeutic Alternatives for a Selected Drug (50.2)**

CSRxP supports maintaining CMS' current policy to consider evidence submitted from a range of interested parties about therapeutic alternatives to a 2027 selected drug, including drug value assessments. Use of drug value assessments that incorporate both clinical evidence and cost analyses will best ensure that Medicare pays more for drugs that offer high value to Medicare beneficiaries and less for drugs that do not offer that same level of value to beneficiaries.

Consistent with statutory requirements, CSRxP continues to believe and agree that any drug value assessments CMS considers in the Negotiation Program should reflect the rights and needs of all Medicare beneficiaries and must not discriminate against the disabled, elderly, or terminally ill. As part of this overall approach, we support the agency's consideration in the negotiations process of drug value assessments that clearly separate prohibited discriminatory evidence from other relevant evidence.

3. **Methodology for the Development of the Initial Offer (60.3)**

CSRxP supports the agency's approach to utilize the lower of the following pricing methodologies as a starting point for developing an initial offer for 2027 selected drugs: (1) the Net Part D Plan Payment and Beneficiary Liability amount and/or the Part B Average Sales Price

(ASP) of the identified therapeutic alternative(s); or (2) the Maximum Fair Price (MFP) for the initial price applicability year 2026 selected drug(s) of the identified therapeutic alternative(s). This approach importantly reflects the competitive net prices generated in the marketplace in Part B and Part D, as well as MFPs previously determined for 2026 selected drugs, as applicable. Consequently, this approach will ensure that Medicare beneficiaries can access 2027 selected drugs at the lowest possible MFP the agency can justify.

4. **Identifying indication(s) for the selected drug and therapeutic alternative(s) for each indication (60.3.1)**

CSRxP supports continuing CMS' current policy of considering both FDA-approved indication(s) and off-label indication(s) included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia when identifying indication(s) for the selected drug and the therapeutic alternative(s) for each indication. Incorporating on-label and off-label indications will give the agency a greater number of therapeutic comparators to reference and consider as it works to obtain the lowest possible MFP CMS can justify.

5. **Part D formulary inclusion of selected drugs (110)**

CSRxP supports the agency's approach to maintain current policy and give plans flexibility in how they incorporate selected drugs into their Part D formularies – so long as they adhere to existing nondiscrimination requirements. Keeping the ability to utilize formulary management tools will best ensure that plans can negotiate effectively with biopharmaceutical companies to lower overall prescription drug costs and spending for Medicare beneficiaries and taxpayers, while at the same time ensuring that meaningful, appropriate beneficiary protections are in place.

Conclusion

In conclusion, CSRxP again wishes to thank CMS for the opportunity to comment on Medicare Drug Price Negotiation Program Draft Guidance. Prescription drug prices are out-of-control and are only getting higher. Medicare beneficiaries and taxpayers simply cannot continue to pay for needlessly high-priced drugs that increase the profitability of Big Pharma at the expense of patients and taxpayers. CSRxP looks forward to our continued work with CMS to make prescription drugs more affordable for Medicare beneficiaries while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

Sincerely,

Lauren Aronson
Executive Director
Campaign for Sustainable Rx Pricing

Submitted via email to: IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

The Honorable Xavier Becerra
Secretary, Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services

Meena Seshamani, MD, Ph.D.
Director, Center for Medicare
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Draft Guidance on the Medicare Drug Price Negotiation Program

Dear Secretary Becerra, Administrator Brooks-LaSure, and Director Seshamani:

Thank you for the opportunity to respond to the Draft Guidance on the Medicare Drug Price Negotiation Program (Program) released on May 3, 2024.

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. CVS Health offers Medicare Advantage Prescription Drug (MAPD) plans in 46 states and D.C. Aetna also offers robust standalone prescription drug plans (PDPs) to individuals in all 50 states and D.C. Our unique healthcare model gives us an unparalleled insight into how health systems may be improved to help consumers navigate the healthcare system–as well as their personal healthcare–by eliminating disparities, improving access, lowering costs, and being a trusted partner for every meaningful moment of health. And we do it all with heart, each and every day.

CVS Health recognizes the complexity of the Program requirements and appreciates CMS's proposal to engage the Medicare Transactions Facilitator (MTF) to facilitate the process to ensure the maximum fair price (MFP) is made available to Part D enrollees and dispensing entities. It is critical that dispensing entities are provided sufficient information to perform the MFP reconciliation process. This includes information on PDE rejects and sufficient key data elements on each claim as outlined in greater detail below. Given the multiple system and process changes that will be required of dispensing entities, it is important that CMS make the process as streamlined and simple for these entities as possible, beginning with streamlining the enrollment process and allowing dispensing entities to have a meaningful avenue to pursue shortfalls in reimbursement.

While we understand the importance of PDE data to the process, we have significant operational concerns with reducing the PDE window to 7 days and believe that this will cause more issues than it solves. We are also particularly concerned about the handling of PDE rejects within the Program and ask that CMS clearly address in guidance how dispensing entities will be kept whole when a PDE is rejected for a valid Part D drug for which the pharmacy should be entitled to the MFP.

Finally, formularies are an essential tool to contain drug costs and help encourage clinically appropriate and cost-effective drug choices. Congress was mindful of this in establishing the Program, requiring that only selected drugs be included on the formulary and specifically not dictating formulary placement, understanding that this would undermine the goals of the Program to control drug costs. We ask that CMS implement this requirement in accordance with the intent of Congress and the language of the Inflation Reduction Act of 2022, and not add restrictions on the formulary placement of selected drugs.

We have included a more detailed discussion of our recommendations in the attached, Appendix I.

Thank you for considering our comments and recommendations. CVS Health is committed to collaborating with CMS as it implements the Negotiation Program and other policies to promote affordable, comprehensive care and provides beneficiaries with innovative coverage choices to meet their needs. We welcome any follow-up questions you may have and stand ready to support CMS as it works to refine the Program to ensure it achieves its intended goals as smoothly and efficiently as possible.

Sincerely,

Melissa Schulman
Senior Vice President, Government & Public Affairs
CVS Health

Appendix 1

Contents

Section 30. Identification of Selected Drugs for Initial Price Applicability Year 2027

CMS states that its approach to identifying a potential qualifying single source drug aligns with the requirement in the statute to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug, and that this is also appropriate because CMS is aware that existing NDA / BLA holders have obtained approval for new dosage forms or different routes of administration of the same active moiety / active ingredient under different NDAs or BLAs.

We are concerned this approach creates risks and confusion with existing pharmacy industry processes. Pharmacy claims processing and pricing rules are based on the specific NDC-11 product, accounting for variations in cost in the production of different dosage forms. As an example, the cost to produce a sterile injectable form of a drug product is significantly different than the oral dosage form. While this may not directly impact Medicare Part D claims due to the requirement to pass the MFP onto the patient and the dispensing pharmacy, it creates anomalies, conflict and reimbursement risks as seen with similar Medicare Part B HCPCS code generalization (as referenced by CMS in Section 30 of the draft guidance) and payment price comparisons across payers.

CMS states that it will look to PDE data as one source to determine whether a generic or biosimilar is marketed on a bona fide basis. We encourage CMS to consider other sources, since Part D plan formularies may treat the brand or reference product as

preferred, where the PDE data may not reflect the availability of the generic or biosimilar product in the marketplace.

Recommendations:

- MFP price should align to the distinct dosage form of the drug, as manufacturing costs will vary based on product form where these costs are passed down to the purchasing provider.
- CMS should consider sources of data other than the PDE to determine whether a generic or biosimilar is marketed on a bona fide basis. If available within the PDE data, the NCPDP Dispense as Written Code (DAW), can provide additional insight, where DAW <> 0 indicates the multi-source status of the drug.

Section 40.2 Submission of Manufacturer Data to Inform Negotiation

Throughout the draft guidance document, CMS references the NDC-11 format, which identifies the specific strength and package size of the product. We appreciate this level of specificity, as the pharmacy claim adjudication process is based on the NDC-11 product ID. As CMS is aware, a final FDA rule is pending that may change the manufacturer label code from the current 5-digit format to 6-digits, resulting in a 12-digit NDC. We recommend this potential change be considered as new systems and processes are developed to support the program reconciliation process.

Recommendation:

- CMS should consider the potential NDC format change from 11 to 12-digits as program system capabilities are designed.

Section 40.4.1 Medicare Transaction Facilitator Data Facilitation

Overall, the MFP reconciliation process described in the draft guidance will require significant system enhancements and new financial processes for pharmacies, including management of pharmacy enrollment with new entities. This is further complicated by the fact the only data available to the pharmacy is the Medicare Part D claim response that will contain the NCPDP Approved Message Code value of MFP. While this Approved Message Code (if returned by the payer) can be used to trigger pharmacy financial systems to book another expected payment, the estimated payment amount will also be required. Pharmacies will require enhancements to calculate the estimated WAC-MFP amount and integrate the information into their existing claim and financial systems. Accuracy, and alignment on timing of changes to WAC prices will be a critical component in preventing financial errors and reducing the time and resource needs to resolve discrepancies. Below we address specific aspects of the proposed process.

<u>PDE Rejects</u>

A major area of concern for pharmacies is the lack of information available to pharmacies when a PDE record is rejected. There are over 200 PDE error codes that could result in a PDE reject. Today, PDE rejects do not impact the pharmacy. However,

this will change beginning January 1, 2026, as a PDE reject could delay or prevent the MFP reconciliation process from occurring unless PDE rejects are addressed in final guidance. If not addressed, pharmacies will have no visibility to these rejects or ability to control or resolve them.

For example, a PDE may reject indicating the submitting Part D plan is not the plan of record. The rejected PDE is returned to the submitting Part D plan, where per CMS guidance that plan initiates payer-to-payer claim reconciliation with the Part D plan of record for the claim date of service. The pharmacy's claim information remains under the original Part D plan, and payment is received from this plan. The pharmacy would expect the MFP payment reconciliation process to occur based on the pharmacy claim information. MFP payment should not be delayed or altered due to the PDE reject process.

With over 200 PDE reject situations, CMS may need to consider establishing PDE reject types to ensure the expected MFP payment and reconciliation process occurs. If the PDE reject type indicates the claim for an MFP NDC is not a covered Part D claim, CMS guidance will be necessary to ensure the pharmacy is kept whole.

Transaction Volume/Reversal Rates

In addition to system enhancements that will be required to support the MFP reconciliation process, pharmacies will need additional dedicated resources to identify, research and resolve potential over and under payments. The draft guidance proposes to use the PDEs submitted to and accepted by CMS's Drug Data Processing System (DDPS) to identify claims eligible for the MFP. However, as mentioned above, pharmacies have no visibility to which PDEs are submitted, rejected, or accepted. This lack of relevant information will tax the pharmacy payment reconciliation process further, requiring additional research to identify and reconcile payments. Pharmacy systems will also be burdened by the influx of reconciliation records reflecting the transaction-based process as a claim is submitted on one day, potentially reversed on the next and then potentially edited on a subsequent day. From a CVS retail pharmacy perspective, on average 10% of all Medicare Part D claims are reversed on a subsequent date. We are concerned the MTF and manufacturer may have difficulty tracking and accurately accounting for these reversed claims. We ask the final guidance to clearly address how pharmacies will be provided sufficient information to perform the payment reconciliation processes and prevent unintended financial risks, including but not limited to information on PDE rejects.

MTF Claims Level Data Elements

CMS states that under Option 1, the MTF would provide manufacturers with all minimum necessary information to provide refunds to participating dispensing entities and could foster a wide variety of market-driven payment solutions. We appreciate CMS limiting the information shared with the manufacturer to the minimum necessary and, specifically, protecting both member and prescriber identifiers. However, there are other data elements not listed in Table 2 that may be critical for the MTF, manufacturers and

pharmacies to reconcile the MFP transaction data. At a minimum, the date the Part D plan received and processed the claim (i.e., the claim adjudication date) will be necessary to determine the last status of a previously paid claim. This could be a claim reversal, or a subsequent paid claim, with the same date of service, and the same or different dispensed quantity, or potentially NDC. The date of service and the MTF process dates alone are insufficient to manage transaction reversals and edits. The NCPDP Approved Message Code value for MTF should also be included to ensure all parties involved are using the same list of MFP NDCs.

Additionally, CMS may need to consider potential conflicts between the processes described in this draft guidance and the Medicare Prescription Payment Plan (MPPP) processes, particularly with respect to their impact on the claim date of service and MFP transaction matching processes. For example:

- 01/01/2026: Claim paid with 01/01/2026 date of service as MFP, with MPPP Likely to Benefit notice issued
- 01/07/2026: PDE record is created, MFP data sent to MTF
- 01/08/2026: Member contacts their plan to enroll in MPPP
- 01/09/2026: Member picks up their prescription, expecting $0 MPPP point of service charge
    - Pharmacy must reverse the claim with the 01/01/2026 date of service
    - Pharmacy resubmits the Medicare Part D claim with a 01/09/2026 date of service, and the MPPP COB transaction
- 01/16/2026: Part D plan
    - Submits PDE reversal for the 01/01/2026 date of service
    - Submits PDE for the 01/09/2026 MFP claim
- MTF will need to reconcile the claims with the 01/01/2026 and 01/09/2026 dates of service
    - This may require use of the following attributes to determine the last status of an MFP claim:
        - Transaction Type/Code (Claim/Reversal)
        - Pharmacy NPI
        - Prescription Number
        - Prescription Fill Number (Refill Number)
        - Date of Service
        - NDC
        - MTF ICN – (Based on how/when an ICN is assigned)

<u>Pharmacy Enrollment</u>

Pharmacies need to reduce the number of entities involved in the MTF process to facilitate MTF payment/reconciliation and reduce barriers in addressing missing, under or overpayments. To support this, pharmacy enrollment should be with the MTF where, as outlined under Option 2, the MTF would coordinate the payment and remittance process with the pharmacy. The pharmacy enrollment process should require only minimum necessary data elements and support a single enrollment form from a chain

pharmacy for all its locations, rather than requiring each location to complete and sign an enrollment form. Pharmacies should not be required to provide immediate notification of closed locations, as MFP claims data may still be pending processing post the pharmacy closed date. Similarly, new locations under an existing chain pharmacy should not have to be enrolled immediately for MTF payment processing to occur. Rather this could be supported with the use of the NCPDP Pharmacy Data file and chain code affiliations. The sooner the MTF vendor is identified, the sooner these critical processes can be defined, developed, and tested.

PDE Submission Window

CMS states that it is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. From a pharmacy perspective, we appreciate CMS' recognition of MFP cash flow delays to pharmacies under the current 30-day PDE reporting window. While shortening the window to 7 days is intended to reduce impact, pharmacies will still incur a minimum of a 25-day lag as a result of the complete MTF process flow. In addition, a 7-day window creates other issues and concerns, which we outline in greater detail below.

- Claim reversals. When dispensed medications are not picked-up by the patient, pharmacies reverse the claim when their protocols indicate to do so, usually between 7 and 14 days after the original claim submission. If CMS implements a 7-day window for PDE submissions, it will see a large volume of PDE reversals, far beyond anything experienced today. This is because many claim reversals today occur before the PDE is submitted, and so these claim transactions are not in the CMS' Drug Data Processing System (DDPS). If the proposed 7-day PDE window is implemented, this will result in an inordinate number of manufacturer payments to dispensers that will later need to be recouped by the manufacturer.
- PDE File Cycles. CVS Caremark currently submits PDE data every 7 days on behalf of its Part D plans. While the file created includes 7 days of data, it represents claims from 8 days prior through 2 days prior to the date the file is generated. This process includes:
    - one day to extract the claims data,
    - a second day to format the data into the required file format,
    - a third day to generate and send the PDE data file.

  This process meets the current CMS 30-day PDE reporting requirement. If a 7-day reporting cycle were required to support MFP processes, two days of data would be missing from each week's file. PBMs would have to support creating multiple files per week, which would add significant risk, burden, and cost to the process. A file would have to be created immediately after receiving and processing the PDE response files from DDPS. This means the timing of the next file could not be set to be submitted on specific days, it would have to be sent upon completion of the processing of the DDPS PDE responses. This would be necessary due to:
    - DDPS system requirements for DDPS to send the response to the current file before receiving the next file,

    - DDPS rejected PDEs are recycled and resent on the very next submission.
- Response Delays. If all Part D sponsors are required to submit PDEs weekly, we are concerned that DDPS would not be able to send response files as promptly as they do today. New submission files cannot be sent until the DDPS response file has been received, as this is a limitation in the DDPS system.
- DDPS errors. A 7-day window is likely to result in increased DDPS errors in handling rejects, adjustments leading to PDE resubmissions, or glitches in LICS or enrollment information causing mismatched CMS data, as well as other scenarios, cause a delay in an accepted PDE if accepted at all. These events do not make the claim invalid but can lead to delay in MFP reconciliation payment to the pharmacy or an outright loss.
- Retrospective PDE deletions. There may be scenarios where it is determined much later that a PDE should not have been submitted at all (e.g., a hospice or ESRD claim or claim determined to be fraudulent on audit). It is not clear from the draft guidance how these situations would be handled to ensure accuracy of payment.

Remittance Data

Since the MFP payment process starts at the Part D claim adjudication process, pharmacies will need to book expected MFP payments/recoupments at the claim level. As a result, the remittance data from the manufacturer to the MTF, then to the pharmacy must also be at the claim level and not a mass reporting of dollars and claim counts within an invoice format. The data shared between DDPS, MTF and the manufacturer will need to include transaction dates and transaction reference numbers to clearly identify Part D claim adjustments and the resulting MFP payment or recoupment. As pharmacy systems currently support the X12 835 file format for remittance data, this would be the most feasible format for the manufacturers and MTF to support. The remittance file sent to the pharmacy must include minimum necessary claim detail to support matching the MFP payment record to the associated Medicare Part D prescription claim. Manufacturers can refer to EFT and ERA: Payment Remittance Reassociation Basics (cms.gov) for basic information.

Additionally, the Payment Elements and Method for Determining MFP Discount/Refund Amount codes (as listed under Table 3 and 4 of the guidance) to be shared between the manufacturer and MTF will need to be mapped to existing or request new X12 835 CARC and RARC codes. A Claim Adjustment Reason Code (CARC) is a denied or an adjusted claim from a payer & Remittance Advice Remark Codes (RARCs) are used to provide additional explanation for an adjustment already described by a Claim Adjustment Reason Code. At a minimum, a new MFP Discount/Refund Amount Code may need to be established to clearly identify Medicare Secondary Payer (MSP) claims where the No MFP payment is made due to the MSP payment amount being $0 (See comments in Section 80 below). It may be beneficial to establish a dedicated Task Force to step through the MFP reconciliation process, inclusive of retrospective

adjustments to establish the necessary standardized code sets for system implementation and compliance to the X12 835 standard.

Recommendations

- To streamline the MTF and MFP reconciliation process and mitigate unintended risks, CMS guidance should:
    - Instruct Part D plans to always return the NCPDP Approved Message Code of “MFP” for paid claims where the submitted NDC-11 is on the selected drug list.
    - Include the Approved Message Code of “MFP” and the claim adjudication date as required data elements within the PDE, MTF and manufacturer data transactions to ensure consistency in identification of MFP claims and support subsequent transaction adjustments.
    - Establish service level requirements for the MTF and manufacturers to ensure necessary system performance and data processing measures are maintained to support transaction volume, variability in data timing and identification of adjusted transactions where changes to key elements (e.g., NDC, dispensed quantity, date of service, etc.) may have occurred.
    - Shorten the PDE submission window to no less than a 10-day submission window to mitigate file creation, loading and processing burdens and delays. Any shorter PDE window considered should apply to claims for selected MFP drugs only.
    - Identify PDE rejects that should not prevent the MFP reconciliation process from occurring to keep the pharmacy whole. Also establish guidance for any PDE rejects that must prevent MFP reconciliation (e.g.; not an MFP drug), to ensure the Part D plan completes the necessary reconciliation process with the pharmacy.
    - Address use cases where other Medicare programs may impact the MFP payment and reconciliation process, e.g., MPPP, Medicare Secondary Payer (MSP) claims.
    - Establish a streamlined, expedited pharmacy enrollment process with the MTF and leverage the NCPDP Pharmacy Data file and chain code attributes to facilitate MFP payment where pharmacy status may have recently changed.
    - Require all manufacturers to support both Option 1 and Option 2 at the election of the pharmacy.
    - Require all manufacturers and the MTF to support the X12 835 remittance file format, reporting MFP payments at the claim level, leveraging the applicable X12 CARC and RARC code sets.
        - At a minimum, the MFP remittance file sent to the pharmacy needs to include the following claim level attributes:
            - Prescription Number
            - Prescription Fill Number

        - Pharmacy ID
        - Claim Date of Service (Fill Date)
        - Cardholder ID
        - MTF's claim reference number
        - NDC
        - Charged Amount
        - Payment Amount
    - MTF should support existing Electronic Funds Transfer (EFT) set-up processing, where the below payee registration information is used:
        - Bank Name
        - Routing Number
        - Account Number
        - Bank Phone Number
        - Provider Name (i.e., Pharmacy Corporate Chain Name)
        - Pharmacy Chain Code
        - Corporate Address, State, & Zip
        - Primary Phone Number & Email Address of enroller

- CMS should publicly identify the selected MTF vendor no later than Q4 2024, to allow stakeholders to coordinate necessary terms of agreement, EFT/ERA registration, pharmacy enrollment and end to end testing.
- CMS should establish a task force, inclusive of representatives from all stakeholder groups, to collaborate, assist in MTF system design, define and solve for distinct use cases and coordinate end to end testing.

Section 40.4.2 Nonduplication with 340B Ceiling Price

The mechanism to address 340B reconciliation is not specifically addressed in this draft guidance. Any approach should preserve existing 340B relationships to ensure patient access to care, coordination of system enhancements, contractual agreements and standardization of costs basis. There is a need for a process to oversee 340B duplicates and financial calculations. Due to the many different scenarios and stakeholders involved, we recommend that CMS develop a standardized approach with stakeholder input that provides the necessary level of transparency on critical process issues.

Recommendations:

- CVS Health encourages CMS to establish a process with stakeholder input to eliminate duplication of MFP and 340B discounts and ensure that the MFP is provided as required by the statute. This is an immediate need as new processes may need to be established and agreements entered to support inventory management, financial tracking and ensure continuity of patient care at the 340B covered entities.

Section 40.4.3 Retrospective Refund Amount to Effectuate the MFP
CMS states that it will provide primary manufacturers with a Standard Default Refund Amount that reflects the difference between the selected drug's WAC and MFP, and that this difference generally best approximates the acquisition costs of dispensing entities. CMS notes, however, that this standardized pricing metric may not apply universally, and that the primary manufacturer is ultimately responsible for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP.

We strongly support establishment of a Standard Default Refund Amount that can be used to pay dispensing entities. This is a critical step to allow pharmacies to manage their financial systems and to mitigate the financial risks that could impact patient access to care. While the draft guidance references WAC to calculate the Standard Default Refund Amount, it does not explicitly state that manufacturers may not use an amount less than WAC. Additionally, the draft guidance does not specify how updated WAC or MFP prices, that may be available to different stakeholders at different times, will be managed within the MFP reconciliation process.

Recommendations:

- The final guidance should state explicitly that the Standard Default Refund Amount used to effectuate MFP cannot be less than WAC.
- CMS should clarify that the WAC and/or MFP price applied to a transaction is based on the Part D claim date of service and the WAC/MFP effective and term dates.
- CMS should require appropriate notification to dispensing pharmacies, inclusive of the necessary remittance file adjustment codes, when retrospective mass adjustments are applied due to timing gaps in integrating updated WAC and MFP pricing.
- CMS should specify the pricing source for WAC and MFP prices to ensure standardization in application.

Section 40.4.4 Options for Medicare Transaction Facilitator Payment Facilitation
CMS solicits comments on two distinct payment facilitation options. While Option 1 offers some benefits in that it would ensure that the necessary MFP claims data is provided to each manufacturer, it also comes with greater risks. In particular, there is the risk of variability in manufacturer implementation, and there will be more systems that will require enhancements and ongoing maintenance. In contrast, Option 2 appears to present a more streamlined and standardized solution. Option 2 would reduce overall implementation risks, making it more likely that the expedited timeline for implementation will be met. While the draft guidance outlines the two options, critically, it does not state which entity decides which option applies. If Option 2 is truly intended to be an option for pharmacies, the final guidance should state explicitly that manufacturers must support Option 2 if this is the preferred approach by a particular pharmacy.

We appreciate and thank CMS for stating explicitly that neither manufacturers nor their contracted entities may charge dispensing entities any transaction or other fees for the data exchanges facilitated through the MTF.

Recommendation:

- The final guidance should adopt Option 2 or otherwise make clear that manufacturers must support Option 2 for any pharmacies that elect this option.

Section 40.4.5 Medicare Transaction Facilitator Dispensing Entity Participation Requirements

As noted above in our comments to section 40.4.1, we ask that only the minimum necessary information be required for pharmacy enrollment to facilitate the MFP effectuation remittance process. We appreciate CMS' recognition that additional pharmacy information may be necessary for the remittance process to occur. This should be no different than existing pharmacy electronic fund transfer (EFT) and electronic remittance advice (ERA) registration processes. The sooner the MTF vendor is identified, the sooner these critical processes can be defined, developed and tested.

Recommendations:

- Publicly identify the selected MTF vendor no later than Q4 2024, to allow stakeholders to coordinate necessary terms of agreement, EFT/ERA registration, pharmacy enrollment and end to end testing.
- Establish a streamlined, expedited pharmacy enrollment process with the MTF, leverage the NCPDP Pharmacy Data file and chain code attributes to facilitate MFP payment where pharmacy status may have recently changed.
- Leverage existing EFT/ERA provider, payer and banking system registration processes to support the MFP reconciliation and adjustment process.

Section 80 MFP-Eligible Individuals in 2026 and 2027

While there are relatively few beneficiaries with Medicare Secondary coverage, specific guidance may be necessary to ensure consistency in the application of the MFP when the claim is processed as a Medicare secondary payer claim. Guidance is necessary to clarify that the MFP calculation should proceed in the same way as when Medicare is primary, and that it should not be necessary for pharmacies to disclose proprietary financial information.

Recommendation:

- The final guidance should specify that the retrospective Standard Default Payment amount applies to Medicare Secondary Payer (MSP) claims.

Section 90.2.2 Negotiation Program Complaints and Disputes
The dispute resolution process should also address disputes that arise as a result of the failure of a claim to reach the MTF for any number of reasons. To do so, the dispute process will require the provision of certain minimum necessary information from the originating Medicare Part D claim (e.g., pharmacy NPI, date of service, transaction date, NDC, quantity, RX #) to allow CMS and each entity in the process to locate the specific transactions and associated data sources that applied.

The draft guidance is unclear as to whether an issue with the dispensing entity not receiving the expected MTF payment is a dispute, a compliant, or an issue to be initiated with the MTF Help Desk. There is significant uncertainty and financial risk with the new multi-step MFP retrospective payment process. Gaps in expected processes could lead to further financial constraints on pharmacy sustainability. Therefore, the 2026 negotiated MFP process should aim to minimize risk to all stakeholders, ensuring necessary new systems, processes and resources are available and working as expected.

The 2026 MFP negotiated prices will not be published until September 2024, and the MTF vendor has not yet been identified. This leaves a minimal 15-month period to establish all necessary systems, processes, secure additional resources and complete end to end testing to support MFP payment, reconciliation and dispute processes. This also requires pharmacies to address financial gaps due to the 25-day delay for the MFP Standard Default Payment. This is in addition to many other regulatory impacts to the pharmacy industry that could impact the financial stability of pharmacy stakeholders.

Recommendation:

- CVS Health encourages CMS to evaluate the potential impact to patients and stakeholders due to expedited timeline and inevitable gaps with 2026 MFP implementation. We ask CMS to consider these concerns and consider the risk to all stakeholders when determining 2026 MFP negotiated prices.

Section 90.4 Monitoring for Bona Fide Marketing of Generic or Biosimilar
Section 70 of the draft guidance specifically states authorized generics would not qualify as meeting the statutory requirement that a generic drug or a biosimilar is being marketed. Section 110 (Part D Formulary Inclusion of Selected Drugs) does not reference authorized generics as it relates to the MFP selected drugs within plan formularies. It is important to note, there are current gaps within some drug data files, where authorized generics may be mistakenly interpreted as generic alternatives. This results in misapplication of brand/generic pricing rules and will be further compromised with MFP pricing and plan formulary restrictions. Authorized generics using the reference products NDA should be clearly identified as an NDA brand product. This will be critical to ensure the retrospective Default Standard Payment of the authorized generics WAC price minus MFP.

Recommendation:

- CMS should consider what appropriate steps can be taken to ensure manufacturers use appropriate FDA New Drug Application (NDA) product identifiers when reporting marketed authorized generic products within industry and CMS drug information data files so that authorized generics of selected drugs are appropriately treated as selected drugs throughout the process.

Section 110 Part D Formulary Inclusion of Selected Drugs

CMS states that it is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. CMS then states that will use its formulary review process to, among other things, assess instances where Part D sponsors place selected drugs on non-preferred tiers or higher tiers than non-selected drugs or impose more restrictive utilization management for a selected drug compared to a non-selected drug in the same class, and will require additional justification for these formulary designs.

We are concerned that through this process, CMS is effectively adding new restrictions on the formulary placement of selected drugs. This will further limit the leverage of Part D plans and their PBMs in negotiations with manufacturer, resulting in higher drug costs and undermining the Program. Similarly, while all utilization management (UM) edits should be medically appropriate and subject to CMS review on this basis, there is no basis to call out UM edits on selected drugs for special scrutiny. The IRA explicitly requires only selected drugs to be included on a Part D plan's formulary, and any CMS formulary review that focuses exclusively on the placement of selected drugs should be exclusively for this purpose. Any further limitation on the tier placement of selected drugs on the UM edits that may be applied to these drugs would be contrary to the IRA and the intent of Congress, and counter to the goals of the Program.

At a minimum, we ask that CMS clarify that if a plan currently has a selected drug on a non-preferred tier or higher tier than a selected drug or has more restrictive utilization management for a selected drug, that such a formulary will be deemed acceptable without requiring further justification. For example:

- If the MFP selected drugs were non-preferred before the MFP effectuation date, as of the MFP effectuation date these drugs can remain non-preferred.
- If the MFP selected drug is on a higher tier than other non-selected drugs (in the same class) before the MFP effectuation date, as of the MFP effectuation date these selected drugs can remain on the higher tier.
- If the MFP selected drug has stricter utilization management coverage rules than other non-selected drugs (in the same class), as of the MFP effectuation date these drugs can retain the same UM criteria.

Recommendation:

- Consistent with the statutory requirements for the Program in the IRA, CMS should not place additional tier placement or UM edit restrictions or justification requirements on selected drugs.
- At a minimum, CMS should consider the formulary status of a selected drug before the MFP effectuation date and allow the same or less restrictive formulary status to apply as of the MFP effectuation date without further justification.

July 2, 2024

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director,
Center for Medicare & Medicaid Services
7500 Security Boulevard Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Secretary Becerra and Deputy Administrator Seshamani,

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies, advocate for access to care for people with CF, and fund and accredit a nationwide network of more than 130 specialized CF care centers. We thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments on the Draft Guidance on the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2027.

Cystic fibrosis is a life-threatening genetic disease that affects close to 40,000 children and adults in the United States. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening complications. If left untreated, infections and pulmonary exacerbations caused by CF can result in irreversible lung damage and the associated symptoms of CF lead to early death, usually by respiratory failure. Through thorough, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. With recent advancements in treatment options, more people with CF are aging onto Medicare than ever before.

As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high quality, specialized CF care, we provide the following comments and recommendations on the draft guidance.

Evidence About Therapeutic Alternatives for the Selected Drug
The CF Foundation understands that identifying therapeutic alternatives are an important factor in determining the maximum fair price (MFP). As CMS identifies in the draft guidance, we highly recommend consulting with clinicians, patients, and patient organization in this stage to ensure that the

appropriate therapeutic alternatives are identified.

As mentioned above, cystic fibrosis is a multi-organ system disease that requires a wide range of therapies. For example, over 80 percent of people with CF take pancreatic enzyme replacement therapy (PERT).[1] CF can cause the ducts in the pancreas to become clogged with thick, sticky mucus which leads to destruction of the pancreas. Decreased pancreatic function leads to malabsorption of calories and nutrients, and therefore, difficulty with growth and weight gain. Patients with pancreatic insufficiency require lifelong PERT with each meal and snack to maintain adequate nutrition and prevent abdominal discomfort after eating.

While pancreatic enzyme therapies can have nearly identical FDA labels and may be interchangeable in some populations, people with CF experience variable responses to these therapies in terms of symptom relief and fat absorption. Although the drug substance is the same, the dissolution properties of PERTs are not identical. The degree of acidification of the GI tract in each CF patient also varies, causing some patients to have a better clinical response to one product over another. The variable clinical benefit of one PERT versus another is unique to the CF population and underscores the need to include therapy-specific patient and clinical input when defining therapeutic alternatives or this purpose. We ask CMS to incorporate this type of feedback as part of the analysis in the therapeutic alternatives.

Patient-Focused Events

We appreciate CMS's commitment to improving engagement with patients throughout the negotiation process. Providing health information in a public forum like this can be intimidating, confusing, and burdensome for patients. It can also be emotionally taxing to contemplate potential coverage changes of preferred medications and to discuss personal health challenges. In order for patients to feel as though this process is transparent and accessible and understand how the agency is incorporating their feedback into the negotiation process, they first need to understand the purpose of the negotiations and the role the patient. We recommend CMS provide more plain language resources about the negotiation process, explaining why this will ultimately lower patient out of pocket costs.

As suggested in the draft guidance, we strongly support CMS shifting to a format that provides the opportunity for agency officials to ask questions and engage with speakers. Patients and caregivers appreciate the opportunity to have a back-and-forth exchange and see that there is an active audience listening to them.

In addition, CMS must educate patients and caregivers prior to these events about the negotiation process and how their information will be used. This is critical to ensure adequate patient participation and patient advocacy groups and clinician organizations can be partners in reaching these communities. Moreover, we recommend CMS provide diverse opportunities for patient engagement, which may include online surveys, written comments, oral testimony, and focus groups, to accommodate a variety of preferences and accessibility limitations. CMS should also involve people living with a disease and caregivers when developing questions to ensure they make sense to the affected populations. Events should offer an audio only option and be held at variety of times to accommodate adults living with a disease and adult caregivers that are working and unable to join a meeting during business hours.

[1] Cystic Fibrosis Foundation Patient Registry 2022, Accessed June 25, 2024. Available: https://www.cff.org/medical-professionals/patient-registry

We also recommend CMS have different events for different stakeholder types, such as separate events for clinicians and patients/caregivers. Clinicians who specialize in the treatment of certain diseases and conditions bring a critical perspective about the benefit of therapies and availability of alternative treatments, and CMS should solicit their input in dedicated event forum to better understand how therapies are used in clinical practice.

Data Collection on Impact

In order to evaluate the long-term impacts of the drug price negotiations on patient access and cost, we recommend CMS implement a data collection and analysis system looking at impacts both across a manufacturer's drug portfolio, Part D plans, and in other insurance markets (marketplace, Medicare Advantage, and commercial plans). This should include drug expenditures to identify cost-shifting from a MFP product to a non-negotiated product, as well as trends in utilization and health outcomes.

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Thank you for the opportunity to provide comments on the 2027 Draft Guidance. The Cystic Fibrosis Foundation looks forward to working with CMS on these critical issues to ensure access and affordability to treatment for people with CF. Should you have any questions, please contact Theresa Alban, Federal Policy Senior Manager, at talban@cff.org.

Sincerely,

Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation

ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

On behalf of the patient populations we represent, the undersigned organizations applaud CMS for continuing to seek input on how best to engage and protect patients through the negotiation process.

While we were pleased that patient listening sessions were added as a component of the negotiations, there is much room for improvement to ensure that substantive feedback from patients is obtained. We appreciate CMS is willing to listen to our suggestions and make adjustments as the program evolves.Therefore, we respectfully encourage CMS to incorporate the enclosed recommendations to ensure patients are heard by policymakers, the data collected is meaningful to the process, and access to medications is not compromised due to increased utilization management.

Listening Session Feedback

Patients and patient organizations who participated in the listening sessions are appreciative for the opportunity to ensure our voices were counted. However, it is still unclear, even after the fact, what CMS sought to accomplish through the initial round of listening sessions and what, if any, information they gleaned or acted upon from the events.

While we understand CMS did not provide clear instructions or parameters for public comments as a way to encourage broad, unscripted participation, the lack of guidance and clear data points left participants feeling unsure if their testimony was useful for the agency. Further, patients were provided last-minute guidance and rules on their comments during some, but not all, of the pre-session conferences, creating discrepancies across sessions and leading to confusion among participants.

Due to the testimonial format imposed by CMS, many of the patients we represent who participated in the listening sessions were left feeling confused as to whether they were heard, as their comments were not acknowledged by regulators and no feedback was provided. Also, inadequate accommodations were available for speakers who might have health hardships or disabilities. Additionally, the sessions themselves necessitated patients share personal stories and information in a very public and national forum. Sessions were held exclusively online and during traditional business hours, prohibiting anyone without a flexible schedule or work situation from participating.

Furthermore, the process to apply and submit requested forms was complicated. The application itself was quite lengthy and not seemingly tailored to a patient or layman audience.

For example, one form was sent as a PDF file and another as a Word document. Patients who did not have these applications on their computer relied on patient organization staff or family members to assist them. The Word document had formatting issues, so if the person could not figure out how to add information in a different way, it's possible they did not return it. One patient electronically signed the PDF, but was told she was unable to sign in that manner.

Listening Session Guidance

To address these concerns, we suggest that CMS adopt a roundtable format for future listening sessions. This would encourage more patient participation and enable participants to provide substantive input, rather than short statements. Roundtables could also be organized by stakeholder type, to allow for patients to participate only with other patients, to facilitate sharing and discussion.

Additionally, we encourage CMS to vary the times, locations, and formats for the sessions - including the opportunity to submit pre-recorded, virtual comments. This would allow a broader population of citizens to participate, including those with alternative schedules and those who do not have access or comfort with conference technology. CMS should hold in-person sessions in multiple regions of the country to ensure that all communities can be heard. These smaller and less formal formats will likely also increase patient comfort in sharing the personal health experiences that are so important for CMS to hear.

Further, we recommend that CMS issue clear guidance in advance of the roundtables, including topics for discussion and the information being sought by regulators, so that participants can share relevant and focused information. Additionally, we encourage CMS to simplify the application process and provide multiple options for submission, including online forms, to broaden the opportunity for individuals with less technological expertise. This includes providing the opportunity for applicants to disclose any special needs and request any necessary accommodations in advance.

Implement Patient Protections Against Increased Utilization Management

As noted in the guidance, many of the changes to Medicare that are currently being implemented, including but not limited to negotiation, could lead to plans to implement more utilization management provisions that could limit patient access to medications. We encourage CMS to proactively implement patient protections against harmful and abusive practices, rather than wait for plans to act against patient interests before stepping in.

In the interest of patients, we also encourage CMS to create a dedicated portal and/or methodology for patients to provide immediate and direct feedback to CMS on any detrimental policies they experience. CMS should publicize the existence and importance of feedback directly to Medicare beneficiaries, as well as senior advocates, including area agencies on aging and other servicers. Finally, we encourage CMS to incorporate this topic into future listening sessions to ensure the issue is being monitored and patients have opportunity to provide direct feedback to regulators.

ENSURING ACCESS THROUGH
COLLABORATIVE HEALTH

We greatly appreciate efforts by CMS to ensure patients and their advocates are heard and look forward to engaging on these and other issues as the negotiation program progresses. If you have any questions, please reach out to Tiffany Westrich-Robertson at tiffany@aiarthritis.org.

Sincerely,

Ensuring Access through Collaborative Health (EACH) Coalition
Advocates for Compassionate Therapy Now
AiArthritis
Aimed Alliance
Alliance for Aging Research
Alliance for Patient Access
Arthritis Foundation
Autoimmune Association
Biomarker Collaborative
California Hepatitis C Task Force
Caring Ambassadors Program
Chronic Care Policy Alliance
Exon 20 Group
HealthHIV
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Association of Hepatitis Task Forces
MET Crusaders
Multiple Sclerosis Foundation
National Eczema Association
Neuropathy Action Foundation
Partnership to Improve Patient Care
PD-L1 Amplifieds
Rare Access Action Project
Spondylitis Association of America

Electronically Submitted via
IRARebateandNegotiation@cms.hhs.gov

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1851 Harbor Bay Parkway
Alameda, CA 94502

650.837.7000 MAIN
650.837.8205 FAX
www.exelixis.com

June 28, 2024

BY ELECTRONIC FILING (IRARebateandNegotiation@cms.hhs.gov)

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

Exelixis appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) draft guidance on the Medicare Drug Price Negotiation Program (Negotiation Program), including draft guidance on manufacturer effectuation of the maximum fair price (MFP) for initial price applicability years (IPAYs) 2026 and 2027 (the Draft Guidance).[1]

Our comments reflect the distinct perspective of a midsize, innovative, research-based biotechnology company that is driven by a singular focus – accelerating the discovery, development, and commercialization of new medicines for difficult-to-treat cancers. Put simply, Exelixis is on a mission to help cancer patients recover stronger and live longer. At the core of our mission is a long-standing commitment to research and development (R&D). Exelixis was founded in 1994, focused initially on early-stage scientific research before shifting exclusively to cancer. Throughout our history – including during rollercoaster years of successes and failures that are characteristic of biopharmaceutical innovation – we have maintained industry-leading R&D investments towards delivering the next generation of medicines to raise the standard of care for patients with cancer. For example, before we had a commercialized product, we spent between 73 percent and 87 percent of operating expenses on R&D (nearly $2.3 billion). In 2023,

[1] CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

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we invested approximately 57 percent of our revenue for the year in R&D, and we anticipate investing approximately 51 percent of our revenues in R&D in 2024.[2]

As an oncology-focused biotech, when investigating therapeutic possibilities of our candidate products we often initially focus on a "proof of concept" for a rare form of cancer that serves a smaller patient population before expanding to additional indications. This approach is common in oncology drug development and is the approach that Exelixis took with our flagship molecule, cabozantinib. Two years after FDA first approved cabozantinib for patients with rare thyroid cancer (COMETRIQ®), Exelixis suffered a catastrophic event when two of our phase 3 registrational cabozantinib clinical trials failed in prostate cancer. These events forced us to restrict spending immediately, reduce our workforce by more than 70 percent, and focus our limited financial resources on two important and difficult-to-treat indications – kidney and liver cancer. After COMETRIQ® was approved, Exelixis invested an additional *$2 billion* in the cabozantinib molecule to develop CABOMETYX®, which was first approved in 2016 and is a leading therapy for three different types of cancer and the standard of care for renal cell carcinoma. We continue to invest in the development of cabozantinib to serve additional patient populations where there is an unmet need, including metastatic castration-resistant prostate cancer.[3]

We are not "Big Pharma;" our resources are finite. Today, we are almost exclusively fueled by revenues from the clinical success of our flagship targeted therapy, CABOMETYX®. This makes us highly sensitive to shifts in the legal and policy environment, such as the Negotiation Program and how it is implemented. The structure of the Negotiation Program, as CMS apparently intends to implement it, would begin the march towards "negotiations" (price controls) at the time of the first approval, threatening to put this proven clinical development model at risk.

Recognizing the potential adverse impact of drug pricing reforms on companies like ours, Congress made clear its intent to protect "small biotechnology companies that take on a disproportionate share of the risk of R&D."[4] For example, the Small Biotech Exception[5] and the phase-ins of the Part D discounts[6] are critical protections that reflect Congress' intent to shield the most innovative companies. We urge CMS to embody Congress' intent and implement the

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[2] Exelixis, *Exelixis Announces Preliminary Fiscal Year 2023 Financial Results, Provides 2024 Financial Guidance, and Outlines Key Priorities and Milestones for 2024* (Jan. 7, 2024), https://ir.exelixis.com/news-releases/news-release-details/exelixis-announces-preliminary-fiscal-year-2023-financial.
[3] Exelixis, *Exelixis Announces First Quarter 2024 Financial Results and Provides Corporate Update* (Apr. 30, 2024), https://ir.exelixis.com/news-releases/news-release-details/exelixis-announces-first-quarter-2024-financial-results-and.
[4] Senate Finance Committee, Principles on Drug Pricing Reform, at 3 (June 2021), https://www.finance.senate.gov/imo/media/doc/062221%20SFC%20Drug%20Pricing%20Principles.pdf?mkt_tok=ODUwLVRBQS01MTEAAAF97KYIIu1pYXn0sb-9R4Bmtmf7z6MatzpyrNBkUmvXcZtYCDK6T2Wn8o3zlGmYdajTQhBZOj8FuawPXmVP5lDqMOAoH99yfPhYDj9pUjkuwgyq.
[5] Social Security Act (SSA) §§ 1192(d)(2)(A); 1194(d).
[6] SSA § 1860D-14C(g)(4)(B)-(C).

Inflation Reduction Act (IRA) in a manner that safeguards incentives for vulnerable biotech companies – like Exelixis and its peers – to continue high-risk investments in groundbreaking medicines that give patients hope. Foundational decisions that CMS makes at this early stage, such as how to effectuate the MFP and the establishment of effective controls that actually prevent duplicate 340B and MFP discounts, will have profound impacts on the operations and pipeline investments of companies like ours. We therefore strongly encourage CMS to take a forward-looking approach to IRA implementation. While the Agency certainly should support patient access to the medicines of today, it is equally important that it encourage the development of treatments and cures for the next generation of patients.

Our comments are summarized as follows:[7]

- CMS cannot abdicate to manufacturers its statutory obligation to deduplicate 340B and MFP discounts. Under CMS's proposed approach, it would be impossible for manufacturers to deduplicate claims in many cases, given covered entities' strong financial incentives not to use 340B indicators or provide claim-level data to manufacturers. Thus, CMS should establish a central mechanism for determining whether a claim for a selected drug also is subject to a 340B discount, as well as mandate and enforce the use of 340B and non-340B claim indicators. Alternatively, CMS should clarify that manufacturers have the right to request and receive information necessary for deduplication from covered entities.

- Exelixis supports the establishment of a Medicare Transaction Facilitator (MTF) to help verify the MFP-eligibility of claims and facilitate MFP discount payments from manufacturers to dispensers of selected drugs. However, we also believe that CMS should establish additional safeguards to ensure that the MFP is provided to eligible beneficiaries and that the MFP discount amount is calculated in accordance with the statute. Specifically, we recommend that CMS:
    - provide manufacturers with sufficient information to independently verify whether a claim is MFP-eligible, including but not limited to, a mandatory 340B claim indicator.
    - extend the 14-day prompt MFP payment window to at least 37 days.
    - clarify that manufacturers are *not* required to provide the Standard Default Refund Amount if a dispenser acquires a selected drug at an amount less than the wholesale acquisition cost (WAC).
    - define "acquisition cost" to exclude wholesaler or other service fees that could artificially inflate the MFP discount amount.

[7] We incorporate by reference the comments of our trade association, the Biotechnology Innovation Organization (BIO).

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1851 Harbor Bay Parkway
Alameda, CA 94502
650.837.7000 MAIN
650.837.8205 FAX
www.exelixis.com

I. The Statute Requires CMS to Take a More Active Role in 340B Nonduplication

The IRA includes a 340B nonduplication provision, which explicitly *requires* CMS to take an active role in preventing MFP/340B duplicate discounts.[8] CMS, however, takes the position that it is not responsible for nonduplication and is proposing to entirely abdicate nonduplication to manufacturers.

Exelixis has serious concerns that under CMS's proposal, there will be a significant risk of duplicate 340B/MFP discounts. Our concerns are well-founded. Even though there is a statutory 340B/Medicaid duplicate discount prohibition,[9] duplicate discounting is pervasive because of the lack of federal oversight and adequate safeguards.[10] These risks have compounded, as the 340B Program has morphed from a program originally specifically intended to expand access to medicines and care to low-income and underserved patients,[11] into a massive mechanism for the transfer of resources from the pharmaceutical industry to large hospital systems, corporate pharmacy chains, and pharmacy benefit managers (PBMs). This has created perverse financial incentives in the 340B Program that have shifted the focus from vulnerable patients to the bottom lines of corporate entities.

For small and midsize biotechs, like Exelixis, it is critical that CMS take its obligation to deduplicate 340B/MFP discounts seriously. From 2019 to 2023, the number of units that Exelixis provided at 340B pricing increased approximately *three-fold*. The ever-increasing volume of 340B discounts depletes resources that we and our peer companies could otherwise invest in R&D to develop the next generation of innovative, critical medicines that serve the American public health.[12] Therefore, as explained in further detail below, Exelixis strongly encourages CMS to establish a central process for identifying claims subject to the IRA's 340B nonduplication provision (e.g., expanding the role of the MTF or establishing a separate third-party administrator (TPA)). As an alternative, if CMS does not take on deduplication itself, it must provide manufacturers with the necessary information to do so. Specifically, CMS should (1) require dispensers to use a 340B indicator, enforce instances of non-compliance, and prohibit Part D plans from processing claims that do not include the required indicator, and/or (2) affirmatively give manufacturers the right to request and receive claim-level data from covered entities.

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[8] SSA § 1193(d).
[9] SSA § 1927(a)(5)(C); Public Health Service Act § 340B(a)(5)(A).
[10] *See* GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf.
[11] *See* H.R. Rep. 102-384(II), at 12 (1992) (stating that the purpose of the 340B Program is to "provide[] protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans"); *see also id.* at 10 ("Testimony presented by [a hospital official] describes the adverse impact of drug price increases on public hospitals which serve large numbers of low-income and uninsured patients.").
[12] *See* IQVIA, *Emerging Biopharma's Contribution to Innovation* (June 13, 2022), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation.

A. The Explosion of the 340B Program Coupled With Inadequate Safeguards Has Led to Extensive 340B/Medicaid Duplicate Discounting

Since Congress established the 340B Program in 1992, it has exploded in size, becoming the second largest federal healthcare program, behind only Medicare Part D.[13] In 2023, the 340B Program reached $124.1 billion in WAC dollars, representing a year-over-year increase of 16.5 percent.[14] This growth has been driven, in large part, by policies that have permitted more entities to participate in the 340B Program,[15] creating a profit stream for corporate hospital systems, pharmacies, and PBMs with no direct or even measurable indirect benefit for vulnerable patients.[16] Rather, these corporate entities have a strong financial incentive to increase 340B-priced purchases, in order to pad their profits.[17]

Corporate hospital entities grow ever more creative in the methodologies they deploy to increase their ability to purchase 340B-priced drugs. For example, covered entities are expanding their reach into more affluent areas (through contract pharmacies, child sites, and consolidation) with higher rates of health insurance, "maximiz[ing] hospitals' ability to generate profits from the 340B drug discounts."[18] In particular, Congress has expressed concern about covered entities "stripping . . . vital services" from parent hospitals that serve as the basis for 340B Program

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[13] BRG, *Measuring the Relative Size of the 340B Program,* at 5 (June 2022), https://media.thinkbrg.com/wp-content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf.

[14] Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, IQVIA, at 2 (May 2024), https://www.iqvia.com/locations/united-states/library/white-papers/the-340b-drug-discount-program-grew-to-$124b-in-2023#:~:text=In%20the%20last%20five%20years,should%20prepare%20for%20what's%20next.

[15] *See* IQVIA, *340B Drug Discount Program Growth Drivers* (Apr. 16, 2021), https://www.iqvia.com/locations/united-states/blogs/2021/04/340b-drug-discount-program-growth-drivers (discussing the growth of hospital covered entities, child sites, and contract pharmacies); s*ee also* Adam J. Fein, *EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels (July 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html.

[16] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480, at 30 (June 2018), https://www.gao.gov/assets/gao-18-480.pdf ("Of the 55 covered entities responding to our questionnaire, 30 reported providing low-income, uninsured patients discounts on 340B drugs dispensed at some or all of their contract pharmacies, and 25 said they did not offer discounts at their contract pharmacies. All 30 covered entities providing patients with discounts reported providing discounts on the drug price for some or all 340B drugs dispensed at contract pharmacies. Federal grantees were more likely than hospitals to provide such discounts and to provide them at all contract pharmacies."); OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 14 (Feb. 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf ("Eight of thirty covered entities reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements.").

[17] For example, PBMs and PBM-owned contract pharmacies are siphoning 340B discounts, including charging fees to covered entities that are not charged to non-340B covered entities or limiting their participation in plan networks. Nat'l Ass'n of Cmty. Health Ctrs., *Prevent Discriminatory Contracting with the 340B Drug Pricing Program*, https://www.nachc.org/wp-content/uploads/2024/01/340B_Discriminatory-Contracting.pdf.

[18] Rena M. Conti and Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2014.0540?journalCode=hlthaff&journalCode=hlthaff.

eligibility and reopening formerly-independent physician practices as "child sites" in far-off, wealthier neighborhoods.[19]

Combined with lax federal oversight, there is no question that the 340B Program is replete with abuse, including Medicaid/340B duplicate discounts that are not being effectively detected or prevented.[20] For example, in a 2020 report, the Government Accountability Office (GAO) concluded that "[l]imitations in federal oversight impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts" and stressed that HRSA's failure to "ensure that covered entities are complying with 340B Program requirements, including the prohibition on duplicate discounts in managed care . . . not only puts drug manufacturers at risk of providing duplicate discounts, but also compromises the integrity of the 340B Program."[21] The U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) has expressed similar concerns, stating that "[e]ffective methods for identifying 340B claims are needed to ensure compliance with the statutory prohibition on duplicate discounts."[22]

Thus, Exelixis' concern that duplicate 340B/MFP discounts will be significant without adequate federal oversight and safeguards is justified. The risk is particularly pronounced for manufacturers of oncology medicines, with the Congressional Budget Office recently reporting that as of 2021, 47 percent of 340B spending at hospital-based facilities was on cancer drugs. [23] Additionally, our internal data suggests that, for Exelixis, the risk of 340B duplicate discounts may be even greater under the IRA than Medicaid or commercial channels. The data shows that Medicare patient site of care for our medicines tends to be in a hospital or hospital outpatient department, many of which may qualify as 340B covered entities (or child sites).

B. CMS Abdicates 340B Deduplication to Manufacturers

Given the pervasive duplicate discounting in the 340B and Medicaid programs, it is astounding that in the Draft Guidance, CMS states that it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[24] CMS takes the position that the Agency "is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim."[25] Instead, CMS "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other

[19] *See* Senate HELP Letter to Bon Secours Mercy Health (Sep. 28, 2023), https://www.help.senate.gov/imo/media/doc/bon_secours_340b_letter.pdf.
[20] *See* GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf; *see also* OIG, State Efforts to Exclude 340B Drugs from Managed Care Rebates, at 16 (June 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[21] *See* GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf.
[22] *See* OIG, State Efforts to Exclude 340B Drugs from Managed Care Rebates, at 16 (June 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[23] CBO, Spending in the 340B Drug Pricing Program, 2010 to 2021, at 5 (June 17, 2024), https://www.cbo.gov/system/files/2024-06/60339-340B-Drug-Pricing-Program.pdf.
[24] Draft Guidance § 40.4.2.
[25] *Id.*

prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price."[26] CMS "anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders to ensure the process is not unduly burdensome for dispensing entities, 340B covered entities, and patients."[27]

As explained further below, Exelixis strongly disagrees with CMS. Unless CMS takes seriously its statutory obligation to implement and oversee the IRA's 340B nonduplication requirement, we have significant concerns about compliance with this critical statutory provision, due to the strong incentive for covered entities to look the other way rather than work with manufacturers to guard against duplicate discounts. Absent CMS taking a more active role in deduplication, at a minimum, CMS should provide manufacturers with sufficient information to determine whether a claim is 340B-eligible (e.g., mandatory 340B claim modifier, claim-level data from covered entities).

C. The Statute Requires CMS to Take an Active Role in Deduplicating 340B and MFP Discounts

The IRA unambiguously requires CMS to implement the 340B/MFP nonduplication provision:

- First, the 340B nonduplication requirement is placed under section 1193 of the Social Security Act (SSA), which is the section that governs ***CMS's*** agreement with Primary Manufacturers.[28] By placing the nonduplication requirement in this section, Congress clearly envisioned that CMS would have a role in preventing 340B and MFP duplicate discounts through the terms of its agreements with manufacturers.

- Second, under section 1196 of the SSA, CMS has an affirmative obligation to administer the Negotiation Program, including effectuation of the MFP. Specifically, CMS is required to "establish[] procedures to carry out the provisions of this part . . . with respect to . . . [MFP]-eligible individuals."[29] Given that an MFP discount is not owed if the 340B ceiling price is lower, the 340B nonduplication requirement is a core component of MFP effectuation. Thus, consistent with its obligation to establish a process to effectuate the MFP, CMS has an express obligation to implement the 340B nonduplication requirement.

Given this statutory directive, CMS's abdication of its responsibility for working against MFP/340B duplication is perplexing. Although CMS expects manufacturers will "utiliz[e] data available from covered entities and their 340B TPAs, and other prescription drug supply chain

[26] *Id.*
[27] *Id.*
[28] SSA § 1193(d).
[29] SSA § 1196(a)(3).

stakeholders" to identify claims subject to the 340B/MFP nonduplication requirement,[30] the Draft Guidance does not require stakeholders to provide such data. Moreover, it does not explain a manufacturer's recourse if such supply chain stakeholders refuse to cooperate by providing sufficient data (and in a timely manner) in order for a manufacturer to identify whether a MFP or a 340B discount is owed on a particular claim. Coupled with CMS's decision not to require a mandatory 340B claim modifier (discussed further in section I.E), it is unclear how CMS expects that manufacturers will be able to identify claims subject to the statutory nonduplication requirement, without sufficient information and within the 14-day prompt MFP payment window (discussed further in section II.A.3).

This hands-off approach does *not* work. The financial incentives for covered entities to construct obstacles and not cooperate with manufacturers to prevent duplicate discounts are simply too great. As discussed above, government watchdogs have attributed the prolific duplicate discounting in the Medicaid program, in part, to HRSA's and CMS's lax oversight.[31] Without a centralized method, detecting duplicate discounts "requires extensive coordination" between parties that have opposing incentives.[32] While manufacturers are purportedly protected by the statute's prohibition on duplicate discounts, the corporate entities that have infiltrated the 340B Program have a financial incentive to maximize the number of 340B-priced purchases. This has led to disputes between manufacturers and covered entities that cannot be resolved through good faith inquiries. There is ongoing, protracted litigation regarding the legality of conditions on 340B pricing, including manufacturers' requests for limited claim-level data to identify duplicate discounts.[33] Although covered entities and contract pharmacies assert that claim-level data requirements are burdensome, courts have found that "the only record evidence . . . indicates that the burden of providing claims data is 'minimal.'"[34] Given covered entities' and contract pharmacies' resistance to providing data to identify 340B claims in the Medicaid program, it is boggling that CMS expects such entities will voluntarily provide the necessary information to manufacturers within the limited time period before manufacturers must pay the MFP discount. If CMS leaves 340B nonduplication unchecked, the same program integrity concerns that plague the Medicaid and 340B programs will carry over to the Negotiation Program.

D. CMS Should Establish a Process to Identify Claims Subject to the 340B Nonduplication Requirement

It is critically important that CMS establish a process to identify claims subject to the 340B nonduplication requirement. For example, CMS could expand the role of the current MTF or establish an independent, centralized TPA to help determine whether a claim for a selected

[30] Draft Guidance § 40.4.2.
[31] *See* section I.A.
[32] *See* GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf.
[33] *See, e.g., Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health and Human Servs.*, No. 21-3167 (3d Cir. Jan. 30, 2023).
[34] *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, at 19 (D.C. Cir. May 21, 2024).

drug is 340B-eligible. Such a process would minimize the burden on all involved stakeholders, as it would streamline reporting from dispensers to a single entity (i.e., the MTF or TPA), rather than to multiple separate manufacturers with potentially disparate reporting requests and processes. Additionally, it likely would reduce the number of disputes about whether a given unit is subject to an MFP or 340B discount, if the determination is facilitated by a neutral third-party. Moreover, CMS could leverage this centralized process to comply with other 340B nonduplication requirements – including the exclusion of 340B units from the Part D inflation rebate calculation, which CMS also must implement before January 1, 2026.[35]

E. CMS Should Mandate 340B and Non-340B Indicators

The Draft Guidance proposes that "indicators may be *voluntarily* applied to a Part D claim by the dispensing entity to indicate a Part D claim is being billed for a Section 340B drug."[36] Exelixis believes that a voluntary 340B indicator requirement is meaningless and will result in little to no improvement. We strongly encourage CMS to *require* dispensers to utilize 340B indicators.

According to a recent IQVIA study, 340B indicators are rarely used when they are voluntary. The study found that "[m]odifier usage reached 90% in some segments when reporting was mandatory [and] fell below 20% when it was optional . . . ."[37] Limited use of 340B indicators is not surprising given, as the D.C. Circuit recently explained, the "financial incentive" of the "covered entity, the pharmacy, and the third-party administrator . . . to catalog as many prescriptions as possible as eligible for the [340B] discount."[38]

A mandatory 340B indicator would be consistent with HHS OIG's and CMS's own recommendations to reduce the risk of duplicate discounts. For example, HHS OIG has recommended that CMS "require States to use claim-level methods to identify 340B claims," which could include a 340B indicator, stating that such requirement would "improve accuracy in identifying 340B claims and thereby reduce the risk of duplicate discounts."[39] Additionally, a claim-level modifier is one of *your* recommended "best practices" for States to prevent 340B and Medicaid duplicate discounts.[40] We encourage CMS to follow its own advice and coordinate with HRSA to expand the 340B indicator requirement to all 340B claims, regardless of the payor. In addition to ensuring compliance with the IRA's nonduplication requirements related to

[35] SSA § 1860D-14B(b)(1)(B).
[36] Draft Guidance § 40.4.1 (emphasis added).
[37] IQVIA, *Can 340B Modifiers Avoid Duplicate Discounts in the IRA?* (Feb. 21, 2023), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.
[38] *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, at 8-9 (D.C. Cir. May 21, 2024).
[39] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430, at 16, 18 (June 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[40] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid, at 4-5 (Jan. 8, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_110.pdf.

the MFP and inflation rebates, the 340B claim modifier could help prevent duplicate discounts prohibited under Medicaid, TRICARE,[41] and commercial and Part D agreements.

Moreover, the fact that the IQVIA study (discussed above) demonstrates that 340B modifier use falls short of 100 percent even when it is mandatory underscores the need for additional safeguards and robust enforcement to ensure that duplicate discounts are actually prevented. Specifically, in addition to an affirmative 340B indicator, CMS also should require indicators for *non-340B* claims and require Part D plans to reject claims without either indicator. This would be consistent with CMS's approach for the Medicare Part B discarded drug refund, where providers and suppliers submitting claims for single-dose container or single-use package drugs that are payable under Part B must include the "JW" modifier to note the amount of drug that was discarded or the "JZ" modifier to attest that no amount of drug was discarded.[42] CMS established the JZ modifier after "observ[ing] low compliance with JW modifier use."[43] Exelixis believes that this approach would ultimately reduce the burden on covered entities by mitigating potential disagreements about whether a claim is 340B-eligible.

II. Exelixis Supports the MTF, But Strongly Encourages CMS to Adopt Additional Safeguards Consistent With Other Federal Healthcare Programs

Exelixis supports CMS's proposal to contract with an MTF, which would provide claim-level data to Primary Manufacturers[44] and may also facilitate MFP discount payments from Primary Manufacturers to dispensers of selected drugs.[45] We are concerned, however, that CMS is not providing manufacturers with sufficient information or time to independently verify whether a claim is MFP-eligible before the manufacturer would be required to pay the MFP discount. Given the complexity of determining whether a claim is MFP-eligible – particularly, as discussed above, deduplicating 340B claims that may be associated with the MFP claim – Exelixis strongly recommends that CMS provide manufacturers with additional data elements and time to independently verify whether a claim is MFP-eligible. Separately, we have concerns that CMS's proposed approach to defining the "Standard Default Refund Amount" could artificially inflate the discount amount, requiring a manufacturer to sell its drugs at a price even lower than the "agreed" upon MFP. To address this concern, we recommend that CMS define

[41] *See* 10 U.S.C. § 1074g(f) ("[T]he TRICARE retail pharmacy program shall be treated as an element of the Department of Defense for purposes of the procurement of drugs by Federal agencies under section 8126 of title 38 [Veterans Health Care Act of 1992, under which DoD drug purchase prices are capped at the Federal Ceiling Price] to the extent necessary to ensure that pharmaceuticals paid for by the Department of Defense that are provided by pharmacies under the program to eligible covered beneficiaries under this section are subject to the pricing standards in such section 8126."); 32 C.F.R. § 199.21(q)(2)(iii)(E) (excluding from the definition of a "covered drug" subject to TRRx rebates "[a] drug provided under a prescription and dispensed by a pharmacy under section 340B of the Public Health Service Act").

[42] Medicare Program, Discarded Drugs and Biologicals — JW Modifier and JZ Modifier Policy, Frequently Asked Questions, https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf.

[43] *Id.*

[44] Draft Guidance § 40.4.1.

[45] Draft Guidance § 40.4.4.

"acquisition cost" and clarify that manufacturers are not required to provide the Standard Default Refund Amount if an entity acquires a selected drug at a price lower than WAC.

A. CMS Should Provide Manufacturers with Sufficient Information and Time to Independently Verify Whether a Claim is MFP-Eligible

1. CMS Should Provide Manufacturers with an Opportunity to Independently Verify MFP-Eligibility

Exelixis appreciates that the proposed MTF would provide Primary Manufacturers with "certain claims-level data elements confirming that a selected drug was dispensed to an MFP-eligible individual and identifying which dispensing entity dispensed the selected drug to the MFP-eligible individual."[46] However, we vehemently disagree that the "dual verification" of MFP-eligibility by the Part D plan sponsor and CMS's Drug Data Processing System (DDPS) "obviate[s] the need for additional verification by the manufacturer."[47] Exelixis strongly believes that CMS should provide Primary Manufacturers with an opportunity to *independently* verify whether a given claim is MFP-eligible before requiring a manufacturer to provide the MFP discount to a dispenser.

Manufacturer verification is necessary to ensure nonduplication of the MFP and 340B discounts, particularly if (as proposed) CMS abdicates responsibility for 340B deduplication, but does not provide a means for manufacturers to access the information they would need to determine if a claim is 340B-eligible (i.e., mandatory 340B claim modifier or claim-level data from covered entities). Under CMS's current proposal, it is entirely unclear how manufacturers would be able to detect claims subject to the IRA's nonduplication provision. Providing manufacturers with information that would allow them to verify whether a given claim is MFP-eligible would improve the integrity of the MFP effectuation process, reduce the risk and frequency of disputes, and help ensure confidence in the MFP effectuation process for all stakeholders.

2. The MTF Should Provide Manufacturers with Sufficient Claim-Level Data to Verify Whether a Claim is MFP-Eligible

Exelixis also recommends that CMS expand the list of claim-level data elements that the MTF would provide Primary Manufacturers. The data elements that CMS proposes to provide Primary Manufacturers do not include information that a manufacturer would need to verify an individual's MFP-eligibility and the amount of any required discount.

[46] *Id.*
[47] Draft Guidance § 40.4.1.

At a minimum, in addition to the currently proposed data elements, Exelixis believes that manufacturers would need access to the following claim-level data elements:

- National drug code
- Drug description
- Rx ID
- Billing code
- 340B indicator (mandatory)
- Dispensing pharmacy/provider name
- Prescribing national provider identifier (NPI)
- Billed units
- Billed amount
- Reimbursement amount
- Submission date
- Claim date (dispense date)
- Medicare plan ID

We emphasize the importance of making the 340B indicator mandatory for dispensing entities. As discussed in section I.E of this letter, given the competing financial incentives inherent in the 340B Program, we believe that a 340B indicator will have no benefit unless its use is required and enforced. Furthermore, given CMS's hands-off approach to 340B nonduplication, if 340B claims are not consistently identified, manufacturers will have no way to detect 340B-eligible claims, rendering the IRA's nonduplication requirement meaningless.

These additional elements that Exelixis is requesting are ones that states generally provide manufacturers before a manufacturer is required to pay a rebate under the Medicaid Drug Rebate Program. Thus, providing such elements to support a manufacturer's verification of the MFP-eligibility of a claim would be consistent with other federal healthcare programs.

3. CMS Should Extend the Time Period Before the MFP Discount Must be Paid, Consistent with Industry Standards

Finally, Exelixis recommends that CMS extend the period before a manufacturer is required to provide the MFP discount to a dispenser of a selected drug. Under the Draft Guidance, the "Primary Manufacturer's receipt of the claim-level data elements starts the 14-day prompt MFP payment window in which the Primary Manufacturer must provide access to the MFP . . . ."[48]

Requiring a manufacturer to pay the MFP discount within 14 days of receiving the data elements from the MTF would not provide manufacturers with sufficient time to verify MFP-eligibility. Verifying the eligibility of a claim involves several complex determinations,

[48] *Id.*

including whether an individual is MFP-eligible, whether a unit was subject to a 340B discount, and the amount of the MFP discount (if required). As a midsize biotech with limited resources, a 14-day timeline would be extremely burdensome and would require significant changes to our current operations. As stated in our IPAY 2026 Initial Guidance comments, Exelixis continues to believe that manufacturers should have time comparable to existing industry standards before they are required to pay the MFP discount.[49] For example, manufacturers have 38 days after receiving an invoice to pay a discount under the Part D Coverage Gap Discount Program[50] and the new Part D Manufacturer Discount Program.[51] Additionally, manufacturers have 37 days to pay a rebate after receiving a rebate invoice under the Medicaid Drug Rebate Program.[52] A period of *at least* this long is necessary for verifying whether a particular claim is eligible for an MFP discount, especially if CMS maintains that it will not deduplicate 340B claims.

B. CMS Should Define "Acquisition Cost" and Should Not Require Manufacturers to Provide the Standard Default Refund Amount if the Acquisition Cost Differs from WAC

Exelixis supports CMS's decision to establish a Standard Default Refund Amount, given the variability in dispensing entities' actual acquisition costs. The actual acquisition cost can be highly variable – both from pharmacy-to-pharmacy, as well as within a pharmacy if more than one wholesaler supplies a product to a pharmacy. As we stated in our IPAY 2026 Initial Guidance comments, we believe that the annual non-Federal average manufacturer price (ANFAMP) is a better approximation for pharmacies' actual acquisition costs than WAC, because it includes chargeback-based discounts that are processed through wholesalers to end customers, including pharmacies.[53] Additionally, as explained below, we encourage CMS to further clarify when the Standard Default Refund Amount is (or is not) required to guard against potential incentives to inflate the MFP discount amount.

1. The Standard Default Refund Amount Should Not be Required if the Acquisition Cost was Lower than WAC

First, Exelixis encourages CMS to make clear in the final guidance that Primary Manufacturers are *not* required to pay the Standard Default Refund Amount if a selected drug's acquisition cost is lower than WAC. The statute requires manufacturers to provide access to the MFP – not more.[54] While the Draft Guidance includes assurances that dispensing entities that

[49] Exelixis IPAY 2026 Initial Guidance Comments at 5.
[50] 42 C.F.R. § 423.2315(b)(3).
[51] CMS, Medicare Part D Manufacturer Discount Program Final Guidance § 80.1.1 (Nov. 17, 2023), https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.
[52] CMS, Interest Calculation for Late Rebate Payments, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/interest-calculation-for-late-rebate-payments/index.html#:~:text=In%20accordance%20with%20section%201927,before%20interest%20begins%20to%20accrue.
[53] Exelixis IPAY 2026 Initial Guidance Comments at 5.
[54] SSA § 1193(a)(1).

acquire a selected drug at an amount *greater* than WAC would receive the full MFP discount,[55] it does not adequately assure manufacturers that they are not required to provide the Standard Default Refund Amount if the dispensing entity's acquisition cost is *less* than WAC. This may occur, for example, if a manufacturer offers price concessions, such as a prompt pay discount, that lower the dispensing entity's acquisition cost for a selected drug to an amount lower than WAC.

In the final guidance, Exelixis encourages CMS to provide additional specificity on the process for manufacturers and dispensing entities to agree on a refund amount that differs from the Standard Default Refund Amount. CMS should make clear that dispensing entities are not entitled to the Standard Default Refund Amount if their acquisition cost (as defined below) is less than WAC. Manufacturers should have the option to pay either the Standard Default Refund Amount or a refund amount equal to the difference between the MFP and an appropriate proxy of acquisition cost (e.g., the current contract price between the manufacturer and the wholesaler), which as explained above, is not always WAC. If manufacturers are required to pay the Standard Default Refund Amount even if the dispensing entity's acquisition cost is less than WAC, this could foster problematic incentives to artificially inflate discount payments from manufacturers. On the flip side, it also could disincentivize manufacturers from offering discounts to supply chain stakeholders, if a manufacturer were effectively required to double-pay such discounts. Thus, not only does our proposed approach align with the statute, but it also would promote fairness and integrity in the MFP effectuation process.

2. CMS Should Define "Acquisition Cost" to Exclude Service Fees and Finance Charges

Finally, Exelixis requests that CMS define the "acquisition cost" of a selected drug. Exelixis believes that a dispensing entity's acquisition cost should reflect the price at which the dispenser purchases a selected drug from a manufacturer or wholesaler, excluding any service fees or finance charges. In order to prevent potential gaming of the MFP discount amount, CMS should define a dispensing entity's "acquisition cost" such that it does *not* include wholesaler or other service fees that could artificially inflate the MFP discount amount.

III. Conclusion

Although the IRA's Small Biotech Exception currently shields small and midsize biotechnology companies from selection, absent further Congressional action, these protections will soon end. As CMS makes foundational decisions about the Negotiation Program, such as 340B nonduplication and MFP effectuation, we strongly encourage the Agency to consider the long-term impact of its policies on all interested stakeholders, including patients, providers, and manufacturers of all sizes. In particular, we urge CMS to actively guard against 340B/MFP duplicate discounts. Given the strong financial incentives for covered entities to construct obstacles and not cooperate with manufacturers on deduplication, it is critical that CMS establish

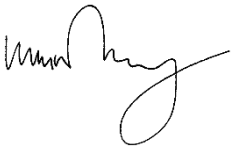
[55] Draft Guidance § 40.4.3.

EXELIXIS®
1851 Harbor Bay Parkway
Alameda, CA 94502
650.837.7000 MAIN
650.837.8205 FAX
www.exelixis.com

mechanisms to prevent the program integrity violations that afflict the Medicaid and 340B programs from carrying over to the Negotiation Program. For small and midsize biotechs with finite resources, the decisions that CMS is making *now* could make or break our ability to continue industry-leading R&D investments that we believe will deliver the next generation of life-saving medicines to patients with currently unmet needs.

Thank you for considering Exelixis' comments on the Draft Guidance. If you have any questions, please feel free to contact Jim Fenton at jfenton@exelixis.com. We look forward to continuing to engage with you on IRA implementation.

Sincerely,



Michael M. Morrissey, Ph.D.
President and Chief Executive Officer
Exelixis, Inc.

FAMILIESUSA
THE VOICE FOR HEALTH CARE CONSUMERS

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare and Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

Re: CMS_FRDOC_0001-3836 Guidance: Inflation Reduction Act Medicare Drug Price Negotiation Program

Dear Administrator Brooks-LaSure,

On behalf of Families USA, I want to thank you for the opportunity to comment on the Medicare Drug Price Negotiation Program Draft Guidance for the Initial Price Applicability Year 2027 and the Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereafter referred to as "draft guidance"). Families USA is a leading national, non-partisan voice for health care consumers, dedicated to the achievement of high quality, affordable health care and improved health for all. Central to realizing that vision is reducing the burden of prescription drug costs on America's families.

The high and rising cost of prescription drugs in the United States is a profound health problem and a significant economic burden on our nation's families, including for people who rely on Medicare for their health coverage. Large drug corporations often seek to maximize their profits by raising the prices of both existing and new prescription drugs to obscene, price gouging levels. As a result, U.S. drug prices are nearly twice as high as prices in other comparable countries, even after rebates.[i] And millions of Medicare beneficiaries, particularly lower-income and Black and Latino beneficiaries, struggle to obtain the prescription medications that they need due to cost.[ii]

Families USA applauds the Biden Administration and the Centers for Medicare and Medicaid Services (CMS) for their continued work in implementing the historic prescription drug pricing reforms authorized by the *Inflation Reduction Act (IRA)*. Consumers across America are eagerly anticipating the announcement of the negotiated prices for the first ten drugs included in the Drug Negotiation Program and the implementation of those prices in 2026. This will undoubtedly lower drug costs for millions of older adults and people with disabilities.

Families USA also commends CMS for continuing to proactively engage with the public, and particularly consumers and those who directly represent their interests, to improve the negotiation process and incorporate early lessons learned before announcing the next 15 drugs for negotiation. We thank CMS for voluntarily providing the public with opportunities to submit feedback regarding implementation of the Medicare Drug Negotiation Program, and are particularly grateful for the opportunity to comment on this draft guidance.

We believe the experiences of the millions of people who rely on Medicare to access affordable prescription drugs must remain the focus of implementation efforts. To that end, this comment letter will provide recommendations across the following areas:

1. Section 60.4: The negotiation process;
2. Section 60.3.2: Developing a starting point for the initial offer; and
3. Section 40.4: Providing access to the MFP for 2026 and 2027.

Section 60.4: The Negotiation Process

The draft guidance describes the proposed negotiation process for the initial price applicability year 2027. Consistent with the year 2026 process, the proposed year 2027 process includes what CMS describes as "patient-focused events to seek verbal input from patients and other interested parties."[iii] CMS further states that it intends to include "patients, beneficiaries, caregivers, and consumer and patient organizations" to share their experiences related to selected drugs.[iv]

Families USA supports CMS in its goal of incorporating consumer experiences into the negotiation process. Incorporating the experiences of patients, their families, and caregivers is vitally important for CMS's understanding of the real-world implications of the prices set by drug companies. In the year 2026 process, CMS conducted listening sessions with various stakeholders for each of the ten drugs chosen. Those listening sessions were designed for participants to speak directly to CMS about how certain conditions impact patient lives and the lives of their caregivers or families, including the accessibility and affordability of the drugs under negotiation and any therapeutic alternatives.[v] However, the listening sessions for the year 2026 negotiation process included many participants who work at or are otherwise affiliated with organizations that receive funding from drug manufacturers.[vi] Many of these speakers failed to disclose their conflict-of-interest at the sessions, as disclosure was *voluntary*.[vii]

In order for CMS to accurately assess the needs and interests of consumers, and for that information to inform the negotiation process in a meaningful way, it is essential that any and all potential conflicts of interest held by those speaking at patient-focused events are clearly disclosed. Without this safeguard, drug manufacturers are incentivized to leverage their patient networks to obscure the true experience of consumers. In many cases, drug manufacturers may actually co-opt consumers' and patients' voices to advocate for the ability to continue abusing the drug supply chain and increasing prices, including through nefarious practices such as false threats of patients losing access to certain medications.[viii]

Ensuring the integrity of the process to collect input on the true consumer experience is paramount. Throughout the negotiation process, drug manufacturers have numerous opportunities to represent the importance of their drug, their financial interests, and their company's goals.[ix] In addition, drug manufacturers have the opportunity to submit data on the costs associated with the research, development, and manufacture of each drug up for negotiation and several opportunities to engage in dialogue with CMS as they participate in negotiations to establish the maximum fair price (MFP).[x] In contrast, patients do not have an additional forum to speak directly to CMS during the negotiation period.[xi] Without knowing whether participants in the listening sessions have conflicts of interest that might impact their feedback, CMS lacks critical information needed to weigh the information shared. Proper evaluation of potential speaker bias is critical for CMS to reach an MFP that is fair for the people who rely on the lifesaving and life sustaining medications being negotiated.

CMS should therefore *require* the disclosure of conflicts of interest for all participants in the patient listening sessions so that they can discern which participants have specific ties to drug manufacturers, and better understand the influences behind the experiences and interests presented in those sessions.

Section 60.3.2: Developing a Starting Point for the Initial Offer

The IRA requires CMS to develop and apply a consistent methodology and process for negotiating with drug manufacturers to arrive at an MFP. It clearly states that CMS must develop a negotiation process that "aims to achieve the lowest maximum fair price for each selected drug."[xii] A vital step in the negotiation process is how CMS arrives at the initial price that it offers to drug manufacturers. The law lists nine factors that CMS is required to "consider" when calculating an initial and final MFP offer. However, the IRA provides no direction for how CMS should prioritize, weight, or define these factors when arriving at a pricing decision.

The proposed guidance outlines the plan to reach the initial MFP offer for the price applicability year 2027. Aside from making small adjustments to consider Coverage Gap Discount Payments (CGDP) and 2026 MFP for therapeutic alternatives, the proposed guidance states CMS will "[use] the same approach that the agency used for initial price applicability year 2026."[xiii]

This means: First, CMS will identify therapeutic alternatives for the selected drug subject to negotiation. As laid out in the guidance, to determine the starting point for the initial MFP offer, CMS will use the lower of either:[xiv]

a. Net Part D Plan Payment and Beneficiary Liability, which reflects the total gross covered drug cost (TGCDC), net of direct and indirect renumeration (DIR), and coverage gap discount program payments, or
b. MFP for initial price applicability year 2026 selected drugs, if applicable.

In other words, CMS will use the Part D Net price or the previously negotiated MFP for a therapeutic alternative in creating a starting point for the initial MFP offer.

Second, based on the prices of those therapeutic alternatives, CMS will adjust the initial price offer based on statutorily defined factors, including but not limited to: therapeutic advance represented by the drug and costs of existing therapeutic alternatives; prescribing info for the drug and therapeutic alternatives; comparative effectiveness of the drug and therapeutic alternative; and unmet medical needs that the drug and therapeutic alternatives address.[xv] These factor adjustments will help CMS to arrive at a "preliminary price."

Third, CMS will adjust the preliminary price based on a number of manufacturer-specific data.

We strongly support CMS adjusting the MFP offer based on comparative effectiveness research, such as patient-reported outcomes and patient experience data as well as manufacturer-specific data (e.g., research and development costs, unit costs of production). However, as noted in our April 2023 comment letter pertaining to the first round of drug negotiation guidance, we continue to be deeply concerned with CMS's approach that anchors the initial price point to Part D net prices of therapeutic alternatives.[xvi] Substantial evidence shows that the drug prices paid by Medicare Part D are significantly inflated compared to the prices paid by other public payers within the U.S., as well as prices paid by other comparable countries.[xvii] For instance, according to the Government Accountability Office (GAO), Part D net prices were at least two to four times higher than publicly available prices in comparable countries in 2020.[xviii] CMS even acknowledges these concerns in their proposed guidance, stating "the therapeutic alternative(s) for a selected drug may not be priced to reflect its clinical benefit."[xix]

We are deeply concerned that Part D net prices do not reflect the true value of these medications and relying on them as a fundamental starting point for drug negotiation will undermine the Medicare Drug Negotiation Program and its ability to achieve meaningful cost savings for consumers and families. Additionally, we are deeply concerned that the continued use of Part D net prices to establish CMS's initial price offer to drug companies sets a dangerous precedent for the future of Medicare drug negotiations by preserving the use of inflated drug prices in establishing prices. And that this will ultimately lead to CMS adopting these status quo higher prices as the standard for initiating drug price negotiations. In the long term, this could serve to drive up the cost of prescription drugs, threatening the very intent of the IRA to establish fair and rational prices for prescription drugs for our nation's families.

Based on these concerns, **Families USA strongly encourages CMS to avoid the use of Part D net prices as a starting point for developing an MFP initial offer. Instead, we encourage CMS to employ a cost-effectiveness approach to develop a preliminary price range, which could then be adjusted to arrive at an MFP. Specifically, we recommend CMS establish non-biased cost-effectiveness targets or thresholds that serve as an initial price range for each selected drug, and which could then be adjusted based on comparative effectiveness research, the prices of therapeutic alternatives, and other manufacturer-specific data to arrive at an MFP.**

To calculate these targets, CMS should, in consultation with the HHS Office of the Assistant Secretary for Planning and Evaluation, determine an upper and lower bound cost or price per unit of health gained (as well as cost per condition-specific measure of clinical benefit) that it deems

appropriate.[xx] This should also reflect the opportunity cost of the treatment in relation to the treatment's added net benefits for Medicare patients over time.[xxi] We believe the cost effectiveness approach outlined above guarantees that the MFP calculated by CMS truly reflects the therapeutic value of the drug subject to negotiation and, importantly, avoids relying on prices that are all too often the result of widespread market failures and pharmaceutical industry gaming.[xxii] Further, this approach has the added benefit of providing the strongest financial incentives for drug manufacturers to focus on true therapeutic innovations.

Section 40.4: Providing Access to the MFP for 2026 and 2027

To ensure the IRA and the Medicare Drug Negotiation Program truly result in lower drug prices for people who rely on Medicare for their health care, eligible beneficiaries must have access to the lower negotiated price at point of sale. In the proposed guidance, CMS reiterated it plans to require that the negotiated price of a Part D drug is the basis for determining beneficiary cost-sharing and for benefit administration at the point of sale.[xxiii] **Families USA applauds CMS for maintaining this policy to ensure every consumer and family that relies on Medicare for their health care has access to and benefits from the lower negotiated price for drugs selected for Medicare negotiation.**

CMS is also clear that drug companies themselves are responsible for ensuring that the MFP reaches all those consumers who are eligible for it. **Families USA supports CMS in this position and its work to hold drug companies accountable to the prices that are negotiated and to seniors' and people with disabilities' access to those medications.** At the core of the issue of access is the issue of affordability. Medication is not truly accessible if the people who need it cannot afford to buy it. It is, and should always be, the responsibility of the drug companies to provide their products — people's lifesaving and sustaining prescription medications — at the price that is fairly negotiated.

Conclusion

Families USA greatly appreciates CMS taking this important step in continuing implementation of the Medicare Drug Negotiation Program authorized by the IRA by releasing this proposed negotiation guidance for the price applicability year 2027. This historic health care reform promises to radically reduce the high cost of prescription drugs and help ensure that consumers and families that rely on Medicare for health coverage have access to affordable, live-saving medications. Families USA thanks CMS for the work it has done since the IRA's passage to start lowering drug costs for our nation's seniors and people with disabilities, and we look forward to continuing to work in partnership with CMS on the implementation of this program, as well as other efforts to lower the high cost of prescription drugs

Thank you for taking time to review this comment. Please contact Ben Anderson at banderson@familiesusa.org or Hazel Law at hlaw@familiesusa.org with any questions.

Sincerely,

Sophia Tripoli

Senior Director of Health Policy

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[xviii] Government Accountability Office. "Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France," GAO-21-282, 28 April, 2021.

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IRARebateandNegotiation@cms.hhs.gov
Subject line: Comment on Draft Guidance on the Medicare Drug Price Negotiation Program

Meena Seshamani, M.D., Ph.D
Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Deputy Administrator, Seshamani,

First Databank (FDB), appreciates the opportunity to comment on the CMS draft guidance regarding Inflation Reduction Act (IRA).

Publication of the Selected Drug list for year 2027

CMS intends to publish the selected drug list for the initial price applicability year 2027 by February 1, 2025. Will CMS publish a separate csv file be published for 2027 and each subsequent year?

Proposed Maximum Fair Price File Layout and Definition Document (May 3, 2024)

The following questions and comments are related to the proposed file layout.

1. Could you please clarify the meaning of xref NDC-11 means? Is this used when the manufacturer changes the NDC of an existing product?
2. The proposed unit price is specific to two digits to the right of the decimal while other published CMS unit price types have 5-6 digits. Will the proposed unit price remain as two digits to the right of the decimal?
3. Will the MFP unit, package and 30-day price be set once a year? How often will CMS update the MFP list?

FDB appreciates when CMS provides content in files where the layout and format are consistent. Maintaining consistency in the layout and format helps ensure that there are no delays in the receipt of content to our customers.

Genentech
A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

July 2, 2024

Meena Seshamani, MD, PhD
Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Sent via electronic mail

Re: Comments on *Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*

Dear Dr. Seshamani:

Genentech appreciates the opportunity to provide comments on the *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (the "Guidance"). We believe we have aligned goals in seeing the Inflation Reduction Act (IRA) implemented to reduce patient costs, prudently spend taxpayer funds on needed medicines, and maintain or improve the innovation ecosystem in the United States.

Genentech pioneered the biotech industry and revolutionized how we treat some of the world's most complex health problems. Today, as a member of the Roche Group, we remain dedicated to pursuing breakthrough research, developing life-changing medicines, unlocking advances in data and technology, and partnering across society to take on systemic issues that stand in the way of better health care for all. In 2023, Roche and Genentech collectively invested nearly $15 billion globally in research and development. Our efforts have resulted in the delivery of 25 new medicines over the last thirteen years, providing hope to patients facing life-threatening and difficult-to-treat conditions including cancer, multiple sclerosis, and hemophilia. We market more than 40 approved medicines in the United States and are actively pursuing 85 investigational medicines. Furthermore, we have been granted 40 FDA Breakthrough Therapy Designations for medicines with the potential to provide a substantial improvement over currently available treatments.

Access to clinically appropriate treatment is essential to improving health and health equity for Americans. To this end, we provide the following comments and recommendations to help us achieve our shared goals of reducing Medicare spending and patient out-of-pocket costs, while still delivering needed innovations to patients today and in the future. Below, we provide recommendations on how, through this guidance, CMS can better:

- improve the process for soliciting public input to ensure the patient voice is heard;
- protect patients by establishing a transparent, predictable, and patient-centric process to evaluate the therapeutic alternative factors;
- preserve incentives for innovation through CMS's processes for drug selection and establishing the maximum fair price;
- remove barriers for successful generic and biosimilar competition; and
- ensure program integrity by facilitating data exchange and validation.

We welcome the opportunity to discuss these ideas with you further and address any questions you may have. Please reach out to me anytime.

Sincerely,

Dan Neves
Director, Federal Policy
U.S. Policy and Evidence

* * * * *

I. CMS should improve the process for soliciting public input to ensure the patient voice is heard.

A. CMS should improve the process for soliciting patient input and improve transparency as to how the patient perspective is used in price setting.

Genentech appreciates CMS's recognition of the need for improvements to the stakeholder engagement process established under the Initial Price Applicability Year (IPAY) 2026 guidance, and thanks the agency for seeking ways to improve upon the process for IPAY 2027.

Patient advocacy organizations and others have driven efforts to expand the conceptualization of unmet medical need and other patient-centric considerations, making the solicitation of their input of paramount importance. For instance, we support the work and considerations of other thought leaders in this space including the National Health Council,[1] the National Pharmaceutical Council,[2] pValue[3] (University of Colorado), and the PACE Center[4] (University of Maryland). Their combined work is showing that patient-elicited value sets are unique to patients, and these groups are pioneering how to use deliberative processes to get prioritized insights from stakeholders, and collecting data on what patients are about when choosing their medicines. As such, we urge CMS to transparently incorporate these findings into its decision-making frameworks.

The consideration of various event formats, including roundtable sessions and focus groups, is a positive step towards ensuring that the voices of patients, caregivers, providers, and health data experts are heard. Such inclusive and interactive settings are instrumental in shaping healthcare policies that reflect the real-world experiences and needs of patients and caregivers. We recommend that CMS establish a number of options for public input, to include each of the options proposed, as this may increase engagement among diverse stakeholders who may be more comfortable engaging with CMS in certain formats.

However, as we stated in our comments to the IPAY 2026 Draft Guidance, we urge CMS to provide more transparency into how it is utilizing and prioritizing the data collected from stakeholders. Specifically, CMS should provide transparency into how it is utilizing stakeholder perspectives on unmet need, therapeutic advances, and therapeutic alternatives to inform the initial price offering. As part of our recommendations regarding the therapeutic alternative factors, below, we offer our recommendations as to how CMS should improve transparency in this regard.

B. CMS should improve the data collection process to reduce the burden of reporting information on patients, caregivers, providers, and other stakeholders.

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[1]https://nationalhealthcouncil.org/blog/the-nhcs-new-value-classroom-tools-to-help-patient-group-staff-engage-on-a-value-assessment/

[2]https://www.npcnow.org/sites/default/files/2021-04/npc-guiding-practices-for-patient-centered-value-assessment.pdf

[3] https://pubmed.ncbi.nlm.nih.gov/36316575/
https://www.jmcp.org/doi/full/10.18553/jmcp.2021.27.7.936
https://www.ispor.org/docs/default-source/intl2023/ispor23zemplenyiposter-pdf.pdf?sfvrsn=8d2f17ef_0
https://www.valueinhealthjournal.com/article/S1098-3015(23)06041-2/fulltext

[4] https://pubmed.ncbi.nlm.nih.gov/32676998/
https://pubmed.ncbi.nlm.nih.gov/33554310/

As part of the IPAY 2027 process, CMS intends to improve upon the information collection process, question format, and content received relative to IPAY 2026 with the forthcoming Negotiation Data Elements and Drug Price Negotiation Process Information Collection Request (ICR). CMS proposes to group questions related to the therapeutic alternative factors within the following categories: manufacturer input, patient or caregiver experience, clinical experience, and health research (e.g., economic and health equity data). CMS is also considering revising questions within these categories to - for example, obtain information pertaining to patients' conditions by requesting a description about what it is like to live with a medical condition treated by the selected drug or its therapeutic alternative(s) and the factors a patient cares about most when assessing the value of a drug.

Genentech supports these efforts and urges CMS to ease the ICR process for patients, caregivers, and other stakeholders by enhancing understandability and format. We support and urge CMS to request specific information on both the non-clinical as well as clinical benefits of a selected drug. As described below, broader evidence collection and consideration for factors like unmet medical need that accounts for multiple domains—including non-clinical benefits, disease severity or burden, and impact on health inequities—are more appropriate and would more accurately capture a medicine's value to patients, their caregivers, and society.

C. CMS should implement safeguards to preserve access (formulary placement and cost-sharing) to both selected and non-selected drugs.

We support the agency's goal of ensuring that selected drugs are covered under Part D; however we have concerns about *how* these products may be covered, and the consequences for patients. When it comes to access to needed treatment, no patient should be worse off under the Negotiation Program than they are today, regardless of whether a patient is taking a selected or non-selected drug. Under the current system, manufacturers often provide rebates and, in some therapeutic classes, such rebates are very common and serve as a considerable source of revenue for plans. In these classes, we can expect a plan may nominally include a (lower-price, lower-rebate) selected drug on its formulary—thereby technically complying with the statutory requirement—while implementing utilization management techniques (e.g., step therapy or tiering) that adversely affect patient access to the selected drug. At the same time, we are also concerned that patients taking non-selected drugs could be worse off than today as plans face increased liability under the Part D benefit beginning in 2025. Under this scenario, plans may restrict access (via increased utilization management, higher patient out-of-pocket costs, or non-coverage) for non-selected drugs, for which coverage is not required.

We appreciate CMS's commitment to closely monitor Part D plan formulary requirements, but we urge CMS to provide additional specificity around the requirements for coverage of both selected and non-selected drugs, and in doing so, implement safeguards to ensure that plans cannot disrupt care for patients or otherwise make them worse off than under current formulary guidelines.

II. CMS should establish a transparent, predictable, and patient-centric process to evaluate the therapeutic alternative factors that more accurately reflects a selected drug's ability to address unmet need.

We reiterate here our comments to the IPAY 2026 Draft Guidance that stress the necessity for CMS to clearly define evidence standards that reflect therapeutic advances and unmet needs from the patient's perspective. **It is crucial to create a transparent and predictable system that incorporates feedback from stakeholders—including patients, caregivers, and providers—to ensure that pricing mechanisms are meaningful to Medicare beneficiaries.** Otherwise, there is a risk of deterring investments in vital research and development, particularly for therapies more likely to be selected under the Negotiation Program, or that face a shorter pre-negotiation period. We believe that a balanced approach is achievable and propose that CMS incorporate the following considerations into its IPAY 2027 guidance to achieve this goal. These considerations are critical to the implementation of the Negotiation Program and they should be central to determining the value of a medicine and, as we discuss below, how an initial MFP is determined.

A. CMS should adopt methods to measure and compare value that more broadly consider benefits to patients, caregivers, their families, and society.

Genentech believes that better understanding the holistic impact of treatments on patients is essential when measuring value and when comparing value across therapeutic alternatives. Innovative medicines bring both clinical and non-clinical value to patients, their caregivers and their families—improving both health outcomes and quality of life. These impacts also bring value to the patient's employers, their insurers, and society at large. Unfortunately, many factors that patients value most are not currently discussed or considered when assessing a product's value. Indeed, many of the methods and data commonly used to measure and compare value—and by extension therapeutic advancement determinations—today fail to capture the majority of what matters most to patients and their caregivers. However, methods and frameworks do exist to collect and evaluate the value of medicines to patients and their caregivers. For instance, we believe that PCORI's Principles for the Consideration of the Full Range of Outcomes Data in PCORI-Funded Research provides a useful starting point for how to operationalize outcomes important to patients (e.g., measurement of disease burden can reflect time spent in the hospital, time away from usual activities, out-of-pocket costs, and time spent on transportation to treatment).

B. CMS should broaden its standard for "unmet medical need" to include considerations of unmet medical need throughout a drug's lifecycle.

CMS's current considerations of unmet medical need are limited to "where no other treatment options exist or existing treatments do not adequately address the disease or condition" *at the time of negotiation.* This limited view of unmet medical need discounts the advancements a medicine brings and the benefits it has afforded to patients throughout its lifecycle. **We therefore urge CMS to consider the landscape of unmet medical need *when the product was approved and over its life cycle*.** This approach would reward products that are first-in-class, and clear the path for successive products that further improve patient outcomes. It would also create additional predictability for innovators as it is impossible, when making critical investment decisions for investigational therapies, to predict what the overall treatment landscape will look like some two decades later (which would influence the return on investment and thus the investment decision itself).

For these reasons, **it is essential that a selected drug be recognized for its attributes over the course of its lifecycle to encourage continued innovation**. If CMS continues to examine the benefits a product provides only at the time CMS establishes the initial MFP offer—which will occur at least 7 or 11 years

after the product's initial approval and potentially decades after the initial research investment—manufacturers could not reliably invest in addressing unmet needs and potential therapeutic advances. Such a methodology would consider the availability of products that were approved well after the manufacturer decided to invest in the development of the selected drug, and fail to recognize the particular value of groundbreaking products in a therapeutic area. A predictable and meaningful pricing system is key to incentivizing investment in the types of therapies that are valued most highly. Without a system that clearly defines and predictably recognizes therapeutic advances and products addressing unmet medical needs, we anticipate that investment[5] will move away from the riskiest and most needed research and development efforts.

C. CMS should expand its definition for unmet medical need to include non-clinical as well as clinical benefits.

A broader unmet medical need definition that accounts for multiple domains—including non-clinical benefits, disease severity or burden, and impact on health disparities—is more appropriate and would better capture a medicine's value to patients, their caregivers, and society.

We appreciate CMS's assertion that it will consider "outcomes such as changes to productivity, independence, and quality of life…" when considering the impact of a selected drug on specific populations. **However, we urge CMS to also consider the following value elements when evaluating whether a selected drug addresses unmet need:**

- Patient and family/caregiver mental and social well-being
- Improvement or maintenance of quality of life, including returning to, or maintaining, independent functional status
- Improvement in clinical/disease outcomes
- A sustainable cost to the patient, including cost of the treatment, cost of ancillary services, and avoided medical costs due to the therapy
- Preference for characteristics of a treatment (convenience, patient satisfaction, route of administration)
- Providing hope for better quality of life or hope to survive until newer therapies are available
- Reduction in caregiver and family burden
- Patient (and family) quality of life, including flexibility to pursue education and advance career
- Equitable access for all patients
- Access to new innovations

D. CMS should continue to avoid discriminatory metrics in setting prices under the Negotiation Program.

Consistent with the need to ensure the Negotiation Program maintains a patient-centric focus, we thank CMS for its acknowledgment of the potential discriminatory nature of cost-effectiveness measures that treat extending the life of individuals who are elderly, disabled, or terminally ill as of lower value. Such metrics fail to capture the societal value placed on health outcomes, particularly the added value of

[5] Investment includes capital from manufacturers but is also much broader, including capital from venture capital funds and the limited partners typically funding them, public investors, and personal investors.

life-extending treatments. We commend the agency's recent efforts to strengthen non-discrimination protections generally through its Accessibility & Nondiscrimination Notice, finalization of the Section 1557 rule, and solicitation of comments of Section 504 of the Rehabilitation Act of 1973 (Sec. 504).

We refer to and reiterate our Sec. 504 comments here, as they are relevant when evaluating the evidence used when determining therapeutic advancements as required under the Negotiation Program. Specifically, we recommend that CMS explicitly prohibit the use of certain value assessment methods that rely on "cost per generic health metric" analyses or thresholds, given their inherently high risk of discriminatory impact on vulnerable and marginalized patient populations, particularly patients with disabilities. Value assessment tools that use cost-effectiveness analyses relying on generic health metrics that compare *across* diseases and patient populations carry a significant risk for discrimination against persons with disabilities who are systematically undervalued by these metrics and comparisons. Use of cost per generic health metric analyses (common examples include but are not limited to quality adjusted life years (QALYs), equal value life years (evLYs), and healthy years in total (HYT)) in the context of the Negotiation Program can similarly lead to discriminatory barriers that undervalue innovative medicines for disease states affecting persons with higher disability status, as well as patients with more advanced age, terminal illness, and patients of racial/ethnic groups with lower life expectancy. It is imperative that healthcare evaluation and policy reflect a comprehensive understanding of value that aligns with societal preferences and ensures equity for all patient populations.

III. CMS should revise the Draft Guidance to better preserve incentives for innovation.

A. CMS should adopt a narrower QSSD definition for consistency with the statute and to preserve incentives for innovation.

Despite a clear directive from Congress, CMS proposes to maintain a broad interpretation of the statutory term "qualifying single source drug" (QSSD) that inappropriately groups drug and biological products based on their active moiety or active ingredient. Specifically, CMS states that a QSSD includes all dosage forms and strengths of a drug with the same active moiety or active ingredient, even if they are marketed under different NDAs or BLAs. We strongly disagree with CMS's interpretation. The statute makes no reference to either active moiety or active ingredient, and instead clearly lays out a different QSSD definition that requires:

- **Unique dosage forms, strengths, and routes of administration of a given drug or biologic can only be considered as a QSSD (i.e., "aggregated") if they are approved under a single NDA or BLA.** In reference to the approval of a QSSD under an NDA or BLA, the statute specifically refers to "such approval" or "such licensure" in the singular form. Additionally, the terms "drug product" and "biological product" refer to the finished product, not active moiety or active ingredient.

  AND

- **Each drug, defined as a single NDA/BLA, must independently have been approved for a set period to be a QSSD.** In order for a drug to be considered a QSSD, it must be approved by the

FDA for a set period before the relevant selected drug publication date. The statute explicitly states that a drug or biological must: (i) be approved or licensed under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act (as applicable) and marketed pursuant to such approval, and (ii) the 7 or 11 years must "have elapsed since the date of such approval [licensure]". This clear articulation demonstrates that Congress had not intended the age requirement to be based on the date of the *first* approval of an active ingredient or active moiety, even if it was under a different NDA/BLA.

Improperly accelerating the selection of drugs for the Negotiation Program by aggregating products and looking back at the earliest date of approval and total spend is not only contrary to statutory intent but will have the effect of discouraging investment in further development of active ingredients/active moieties.

If CMS nonetheless proceeds with its QSSD definition for IPAY 2027, it should continue with the policy of excluding all dosage forms and strengths of a drug with the same active moiety or active ingredient as soon as there is a biosimilar or generic on the market. This is the only way to read the statute because the generic/biosimilar exclusion applies at the level of the "drug". If CMS is defining the "drug" to refer to all products with the same active ingredient, the existence of a generic for one of those products means that the entire drug (i.e., all products with the same active ingredient) is a reference product for the generic. That is, CMS cannot have it both ways—group everything together for the timeframe part of the QSSD definition, but view things separately for the generic/biosimilar part.

Additionally, as CMS is evaluating whether a biosimilar is marketed, we urge CMS to clarify that a biosimilar must not carry all of the indications of the reference product to be considered marketed for purposes of the negotiation program. This interpretation is in line with long-standing FDA practice in which generic and biosimilar products are not required to carry every indication of their brand or reference product in order to gain FDA approval and subsequently enter the market. We are concerned that if CMS does not harmonize its determination of "marketed" with FDA practice, it would result in harm to the competitive marketplace due to false determinations that a biosimilar was not marketed, and the erroneous imposition of an MFP on a reference product with biosimilar or generic competition.

B. CMS should toll the pre-negotiation period while a given orphan drug qualifies for the orphan drug exclusion.

As we shared in our comments to the IPAY 2026 Draft Guidance, Genentech has a long history of transforming the lives of those with rare diseases, and we were encouraged by Congress' continued support of rare disease drug development by excluding certain orphan drugs from the QSSD definition (hereafter the Orphan Drug Exclusion, or ODE). However, we are concerned that an overly narrow interpretation of the statutory exclusion could discourage investment in bringing additional indications of orphan drugs to market, particularly ones that treat a small number of patients or take significant additional time to develop. The Draft Guidance states that "[i]n order to qualify for the Orphan Drug Exclusion, all dosage forms and strengths of the qualifying single source drug described in section 30.1 of this Revised Guidance must meet the criteria for exclusion." Under this interpretation of the statute, loss of ODE for any single drug product or biological product with shared active ingredient or active moiety (across multiple NDAs/BLAs and irrespective of the time post-approval) would result in the loss of such exclusivity for all products with that active ingredient/active moiety, undercutting the incentives for further drug development in orphan disease areas—incentives that have led to significant scientific

breakthroughs and benefitted countless patients over the last several decades.

To address this issue, CMS should clarify that, for a product that initially qualifies for the orphan drug exclusion, the 7- or 11-year period prior to negotiation eligibility starts only upon loss of the orphan drug exclusion.

We continue to believe that the statute strongly supports tolling the pre-negotiation period for eligible orphan drugs. For purposes of the Negotiation Program, a drug can only be classified as a QSSD once "at least 7 years…since the date of such approval [under section 505(c)]" or "at least 11 years…since the date of such licensure [under section 351(a)]" have elapsed. However, the term QSSD is defined to expressly exclude drugs that qualify for the ODE.[6] The best read of the statute is thus that, for so long as a drug qualifies for the orphan drug exclusion, the product is entirely exempt from the QSSD definition and all of its sub-elements. Thus, the 7- or 11-year pre-negotiation period that would otherwise apply to a QSSD is tolled until the first day after the orphan drug no longer qualifies for the orphan drug exclusion. Any other approach would defeat the intent of excluding eligible orphan drugs from the QSSD definition in its entirety, and have a significant impact on drug development decisions for rare disease treatments.

C. CMS should take steps to ensure its process for establishing the MFP does not undercut incentives for biopharmaceutical innovation.

We remain concerned that CMS's proposed methodology to develop an initial offer, as outlined in the Draft Guidance (Section 60.3) would undercut incentives to undertake the most difficult and riskiest research and development efforts. At a principle level, we believe that CMS should implement the Negotiation Program to achieve both of the following overarching and equally important goals: (1) delivering cost savings to Medicare and its beneficiaries to promote access to therapies today, and (2) maintaining incentives to invest in the innovations that can deliver meaningful benefits to patients in the future.

We urge CMS not to overlook the crucial nature of the latter, as the majority of survival gains in cancer have come from biopharmaceutical advances[7], and yet at least 95% of rare diseases lack a treatment[8], requiring continued investment in these and other disease areas. To achieve this important aim, it is critical that CMS create a process that predictably recognizes therapeutic advances and treatment options that address unmet medical needs by weighting benefits to patients and society most heavily, and only considering manufacturer-specific data in cases where there is no evidence of such benefits.

We therefore urge CMS to amend its proposed MFP methodology to:

- Establish an MFP at the ceiling price for products that, over the course of the product's lifecycle, have: (1) provided therapeutic advancements and/or (2) treated previously unmet medical needs.
- For selected drugs that do not meet one or both of the above criteria, CMS would establish the MFP by considering evidence regarding the comparative effectiveness of the drug to determine

[6] *See* SSA § 1192(e)(3)(A) ("Exclusions.—In this part, the term [QSSD] does not include any of the following…(A) Certain Orphan Drugs.")

[7] "Has Medical Innovation Reduced Cancer Mortality?," CESifo Economic Studies, published online 14 November 2013.

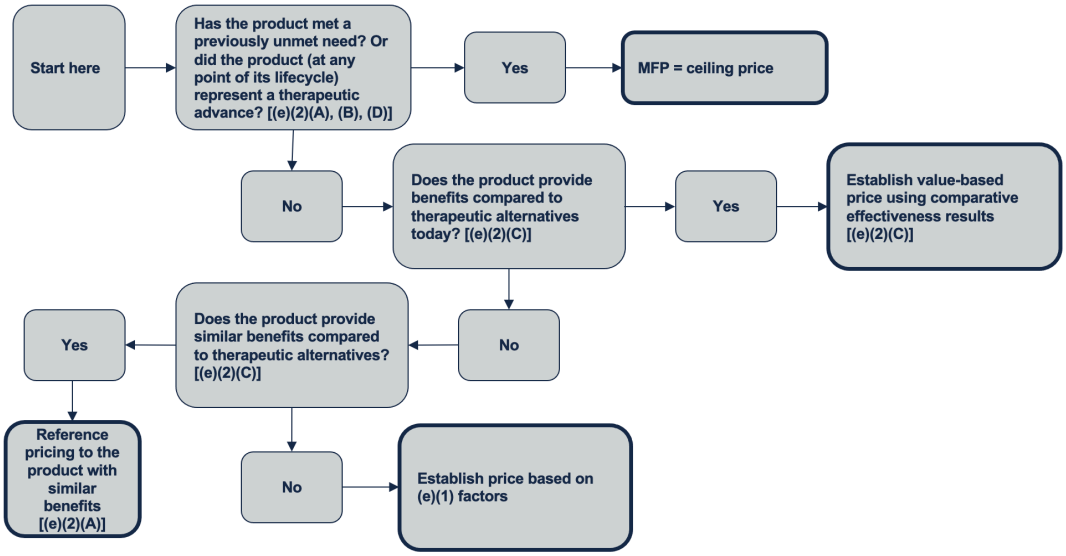
[8] https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf

whether the selected drug provides benefits compared to therapeutic alternatives.

- To avoid unintended consequences of setting MFPs too low, CMS should only use the manufacturer specific factors, enumerated in Section 1194(e)(1) of the Social Security Act, when a product provides fewer benefits than its therapeutic alternatives.

Figure 1, below, illustrates how CMS would apply these standards in practice. For more detail on each of these points, we refer CMS to our comments to the IPAY 2026 Draft Guidance.

Figure 1. Decision Tree to Represent Recommended Methodology for Developing an Initial Offer



Off-label Indications

CMS has indicated that when identifying a potential therapeutic alternative to a selected drug, it may consider off-label uses for the potential therapeutic alternative if such use is included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. We disagree with this approach for several reasons. First, head-to-head comparative effectiveness data between FDA-approved drugs and off-label uses of other drugs is often challenging or impossible to obtain, making it difficult to assess their relative efficacy and safety. Second, drugs with labeled indications have undergone a rigorous process of establishing safety and efficacy through FDA approval, whereas off-label uses have not been subject to the same level of scrutiny. This raises concerns about patient safety and the reliability of the data supporting their use. Furthermore, including off-label use for therapeutic alternatives may disincentivize pharmaceutical companies from investing in the costly and time-consuming process of seeking FDA approval for new indications, potentially limiting the development of evidence-based therapies.

Rather than considering off-label uses, CMS should focus on comparing a selected drug with its FDA-approved therapeutic alternatives to ensure a fair and transparent process that prioritizes patient

safety and evidence-based medicine.

IV. CMS should remove barriers for successful generic and biosimilar market/competition.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) established the biosimilars market in the United States, which has been important to delivering increased access to biologic medicines for patients while producing savings to the healthcare system. The current market incentivizes biosimilar development—including the changes to biosimilar reimbursement made by the IRA—drive competition, lower prices, and reduce spending, while increasing access and choice for patients and providers. Competition is strong, and gaining momentum as waves of new biosimilar entrants are introduced in a short period of time, leading to swift price erosion. An analysis from 2023 projected biosimilars savings over a five year period to exceed $180B — a more than four-fold increase from the previous five years — driven by significant biosimilar launches in immunology, including for Humira.[9] Notably, this is over seven-fold higher than CBO estimates of the first decade of the pathway (2009-2018).[10]

Current biosimilar adoption rates have already translated into major savings for the US healthcare system. In 2022 alone, biosimilars saved $9.4 billion[11], which follows a dramatic upward trend from the launch of the first biosimilar in 2015. Experience with biosimilar use is growing, which will lead to even further competition and lower prices; biosimilar uptake is tracking toward 60% for newer biosimilar launches. Importantly, the US is keeping pace with the EU who pioneered biosimilars approvals a decade earlier.[12] In the first five years, 11 biosimilars were approved in the EU. In the US, 26 biosimilars were approved in the five years after the first US approval in 2015, and today there are 49 approved biosimilars.[13] The EU has seen widespread adoption of biosimilars in the last 13 years which has led to consistent price reduction and we are seeing the same trends in the US.

At Genentech, we have seen direct impacts from biosimilar competition. Recent biosimilar launches of bevacizumab, trastuzumab, and rituximab reached nearly 60% volume share by the end of their second year on the market, significantly higher and faster than prior biosimilars, and prices have fallen as the products compete.[14] That increased choice means not only increased competition but also increased supply, which goes a long way to help prevent drug shortages. All together, the biosimilars market is strong and is working as intended.

In recognition of the need to protect biosimilar competition, the Negotiation Program provides a "pause" if CMS determines there is a "high likelihood" that a biosimilar will be "licensed and marketed" before the date that is two years after the selected drug publication date with respect to the IPAY. It also exempts a branded drug from inclusion in the Negotiation Program to the extent it has a marketed biosimilar, further evidencing Congressional intent to preserve the biosimilar market. But certain choices by CMS to

[9]Biosimilars in the United States 2023–2027: Competition, Savings, and Sustainability, IQVIA; https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/biosimilars-in-the-united-states-2023-2027
[10] The Congressional Budget Offices projected the BPCIA to reduce total expenditures on biologics in the United States by $25B between 2009 and 2018. https://www.cbo.gov/publication/41712
[11] https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[12] http://gabi-journal.net/a-white-paper-us-biosimilars-market-on-pace-with-europe.html
[13] https://www.centerforbiosimilars.com/biosimilar-approvals
[14]https://www.amgen.com/science/biosimilars/-/media/Themes/CorporateAffairs/amgen-com/amgen-com/downloads/science/biosimilars/2022-Amgen-Biosimilars-Trend-Report-USACBU81422.aspx

institute opaque and burdensome standards and procedures that do not align to the statute threaten to upend the competitive marketplace established by the BPCIA, as well as Congress' express intent to preserve the incentives for biosimilar innovation.

A. CMS should establish a clearer and less burdensome interpretation of the "high likelihood" standard.

Genentech supports and incorporates by reference herein the legal, policy, and other arguments in opposition to CMS's interpretation of the "high likelihood" requirement detailed in the comments on the IPAY 2027 Guidance filed by the Pharmaceutical Research and Manufacturers of America ("PhRMA"). **Namely that CMS's interpretation of the "high likelihood" requirement is untethered from the statute, unworkably vague, and overly rigid.** Instead, when establishing the criteria necessary to qualify for the "pause", CMS should prioritize clear criteria and reduce burden on biosimilar manufacturers. As such, CMS's "high likelihood" determination should focus on the absence of definitive evidence of an inability to come to market in any agreements the biosimilar manufacturer files with the FTC, the manufacturing schedule submitted to the FDA, or certain disclosures by the biosimilar manufacturer made to the SEC that pertain to the marketing of the biosimilar product. Furthermore, CMS should rely on documents already submitted to other agencies during the biosimilar manufacturer's pre-launch process. These documents align to statute and would indicate to CMS those instances where the biosimilar manufacturer does not plan to or is unable to market the biosimilar product during the pause time frame. CMS's request for additional documentation would be overly burdensome and counterproductive to prioritizing a functional biosimilar market (discussed more below).

As part of the Negotiation Program, statute establishes a 1+1 framework for the pause, whereby a biosimilar manufacturer must apply for an initial pause period of one year, and subsequently apply again for a second year of the pause. As part of the application for the second year pause, CMS proposes to seek "clear and convincing evidence" of a "significant amount of progress" toward biosimilar marketing. As part of this proposal, CMS requests comment regarding the types of documentation and information necessary to make such a determination. Understanding that the statute established a 1+1 framework for the "pause" instead of an automatic 2-year pause, CMS should take any and all steps to remain flexible and reduce biosimilar manufacturer burden. As such, CMS should again focus on the absence of (new) definitive evidence of an inability to come to market—namely, manufacturing schedule changes outside of the second year timeframe or negative FDA action with respect to the application without correction or resubmission of the application by the biosimilar manufacturer. In addition, CMS should accept biosimilar manufacturer attestation as sufficient evidence of progress made. This would ensure that CMS is implementing the pause in the least burdensome manner that provides the best chance to maintain the biosimilar competitive marketplace.

Importantly, should a biosimilar not launch by the end of the second year of the pause, the reference product would be selected for the Negotiation Program during the next cycle and the manufacturer would be required to pay a rebate to CMS equal to the amount that CMS would have realized absent the two-year pause. When making determinations for granting the "pause," CMS should weigh the risks of granting a pause where a biosimilar is not launched within the two-year window versus not granting a pause where a biosimilar would have launched within the two-year window. For the former, the reference product is selected and, if an agreement is reached on a MFP, CMS is made whole through the rebate

provision should a biosimilar not launch as expected. However, with the latter, CMS risks distorting the biosimilar market while also using a valuable selected drug slot on a reference product that would have seen a reduction in price regardless.

Therefore, it is imperative that CMS prioritize implementation of the "pause" in a clear and flexible manner that protects the competitive biosimilar marketplace by granting the biosimilar "pause" when there is an absence of evidence that the biosimilar manufacturer will *not* meet its manufacturing and launch schedule..

B. CMS should adopt a standard for biosimilar marketing that tracks the statutory QSSD definition.

We reiterate our comments from the IPAY 2026 Draft Guidance here regarding the "robust and meaningful competition standard" when investigating whether a drug has generic or biosimilar competition. The statute defines a QSSD as a product without a marketed generic or biosimilar, among other requirements. In determining whether a product has a marketed generic or biosimilar, we appreciate that CMS would want to investigate whether the generic or biosimilar is truly offered for sale. However, CMS has exceeded the bounds of the statute by proposing to establish a "robust and meaningful competition" standard and to impose requirements that the product be "widely available" or show up in the Prescription Drug Event (PDE) data. We strongly urge CMS to focus on the statutory standard of whether the generic or biosimilar is merely marketed—that is, made available for sale—and not to adopt these standards that exceed CMS's authority under the statute.

Specifically, Genentech supports and incorporates by reference herein the legal, policy, and other arguments in opposition to CMS's extra-statutory concept of "bona fide marketing" detailed in the comments on the IPAY 2027 Guidance filed by the Pharmaceutical Research and Manufacturers of America ("PhRMA"). **Specifically, the statute does not allow for imposition of CMS's "bona fide" qualifier.** The statute defines a QSSD as a drug product "that is not the listed drug for any [generic] drug that is approved and marketed under section 505(j) of the FDCA and a biological product "that is not the reference product for any [biosimilar] biological product that is licensed and marketed under section 351(k)" of the PHSA. Additionally, when determining when a drug is no longer considered a selected drug, the statute uses the term "marketed" without the "bona fide" qualifier. CMS's utilization of the "bona fide" qualifier is vague and implies a higher standard for marketing than Congress intended.

V. CMS should ensure program integrity by facilitating data exchange and validation.

We appreciate the Agency's recognition of the importance of a mechanism and process by which data are collected and validated through a neutral entity. We also appreciate CMS's attempt to establish a workable system to effectuate the MFP in time for IPAY 2026. However, we continue to believe the ideal solution would be a clearinghouse that would serve a greater role in validating—or facilitation of manufacturer validation of—discount claims, beyond the limited scope described in the Draft Guidance and that would be mandatory for all participants.

And while we understand there may be barriers to establishing a truly comprehensive solution for MFP effectuation, particularly in advance of January 1, 2026, we note that the solution proposed by CMS in

this Draft Guidance is flawed in several ways, most notably:

- The proposed 14-day payment window is not long enough for manufacturers to validate claims, and is much shorter than the 38-day period to effectuate reimbursement under the CGDP.
- The proposed Medicare Transaction Facilitator (MTF) payment facilitation process is voluntary for dispensers, which could make the entire process unworkable, as manufacturers could be left to manage thousands of disparate processes across thousands of pharmacies.
- The proposed MTF solution does not adequately address 340B de-duplication, notwithstanding the long-standing issues related to duplicate discounts due to the lack of oversight over the 340B program.

Below, we provide more detail on each of these concerns.

14-day Payment Window

We support prompt payment of dispensers but stress the foremost importance of valid and accurate payments. We appreciate CMS's solicitation around reducing the time for Part D plans to submit PDE records to the DDPS from 30 days to 7 days. However, we question whether this is truly feasible and whether there are any tradeoffs in reducing that time, such as sacrificing the rigor of the validation. Moreover, the 14-day payment window is insufficient for manufacturers to independently validate the accuracy of the discount claim and ensure adherence to statutory obligations. CMS should adopt the 38-day payment window from the CGDP, as it is a well-established and more workable timeframe. CMS should also include de-identified patient ID to facilitate manufacturer validation of duplicate discount claims.

Participation in the MTF-Facilitated Payment Process

With only limited time before implementation and without assurances of a flawless MTF, we believe the payment process should be mandatory for all dispensers to avoid a situation where manufacturers who opt to use the MTF-facilitated payment process are forced to operate outside that process with potentially thousands of dispensers. If it remains voluntary for dispensers for IPAY 2026, CMS should require dispensers to commit to their choice (opt-in or opt-out) for a full year, and CMS should continue to commit to a system that is mandatory for dispensers in future years.

Regarding the payment facilitation options CMS proposes, we support a modified version of Option 2, whereby dispensers submit banking information as is proposed in Option 1. In this way, if the manufacturer and dispenser exercise their ability to opt out of the MTF-facilitated payment process, the manufacturer has the information necessary to remit payment through an alternative process. Additionally, to the extent CMS retains the 14-day payment window, this window should only apply to payments made under the MTF-facilitated payment process. That is, if a manufacturer chooses to opt-out of the MTF payment facilitation process, the manufacturer and the dispenser with whom it enters into an agreement should be able to determine the appropriate time window for payment.

340B

Compliance with the duplicate discount prohibition is a condition of covered entities' eligibility for the

340B Program.[15] However, in its fiscal year 2023 covered entity audits, HRSA uncovered duplicate discount errors in nearly 25 percent of cases examined.[16] Duplicate discounts are the direct result of a lack of uniform requirements in place for covered entities and MCOs, a lack of data transparency, and a lack of oversight and effective enforcement mechanisms to ensure compliance. To improve program compliance and integrity with regard to the duplicate discount prohibition, CMS itself has—for several years—acknowledged the value of greater claims transparency to improve program integrity[17]

We reiterate that an ideal solution would be an independent entity that serves as a clearinghouse for *all* claims data, facilitating the exchange of necessary information to identify 340B claims, prevent duplicate discounts, and resolve other issues or disputes. Such a mechanism would be a much-needed improvement to the patchwork of data systems that are inconsistent and opaque, and would bring a level of transparency needed to address the inefficiencies of our healthcare system while still protecting patient and other confidential information.

At the same time, we acknowledge the difficulty for some dispensing entities to quickly identify 340B eligibility, and we note the discriminatory practices of payers/PBMs based on 340B identifiers. We also note the still-low compliance with JG and TB modifiers, despite the fact they are mandatory for certain categories of covered entities. We encourage CMS to continue to explore ways to improve identification of 340B claims at the point of sale. Until then, we appreciate CMS's acknowledgement that all parties—manufacturers, TPAs, and other stakeholders—must work together to address any duplication of MFP and 340B discounts.

In addition to the points above, we strongly encourage CMS to make the following changes or clarifications in the final guidance.

- Manufacturer effectuation plans should be made available only to dispensing entities, and should be held confidentially by those parties (i.e., not made available to the public).
- CMS should clarify that manufacturers are held harmless for any MFP discount that does not reach the dispenser in the defined period due to incorrect bank information provided by the dispensing entity or any technical issue outside the control of the manufacturer. CMS should clarify that errors in payment due to incorrect data submitted to, or transmitted by, the MTF should not be attributed to the manufacturer or, at a minimum, that the manufacturer has an opportunity to correct once the error comes to light.
- CMS should adopt a dispute and complaints process akin to the MDP, and require good faith efforts recognizing the complexity of, and short time to implement, this process.

[15] See 42 U.S.C. § 256b(a)(4) ("In this section, the term 'covered entity' means an entity that meets the requirements described in paragraph (5)" of section 340B(a), which includes both the duplicate discount and diversion prohibitions described in subsections (a)(5)(A) and (a)(5)(B), respectively.).
[16] HRSA. *Program integrity: FY 2023 Audit Results.* https://www.hrsa.gov/opa/program-integrity/fy-23-audit-results
[17] CMS. Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. January 2020. https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_142.pdf.

June 28, 2024

Via email (IRARebateandNegotiation@cms.hhs.gov)

Dr. Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

Gilead Sciences, Inc. (Gilead) appreciates this opportunity to comment on the above-captioned memorandum providing draft guidance (Draft Guidance) regarding the "Medicare Drug Price Negotiation Program" (MFP Program) under sections 11001 and 11002 of the Inflation Reduction Act (IRA) for Initial Price Applicability Year (IPAY) 2027 and the effectuation of the Maximum Fair Price (MFP) in IPAYs 2026 and 2027.[1]

Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines in areas of unmet medical need. We endeavor to transform and simplify care for people with life-threatening illnesses around the world. Our portfolio of products and pipeline of investigational drugs includes treatments for human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), liver diseases, cancer, inflammatory and respiratory diseases, and cardiovascular conditions. Our portfolio of marketed products includes a number of category firsts, including complete treatment regimens for HIV infection available in a once-daily single pill, the first oral antiretroviral pill available to reduce the risk of acquiring HIV infection in certain high-risk adults, and the first Hepatitis C virus (HCV) treatment to provide a complete regimen in a single tablet. Gilead is committed to ensuring that people have access to our medicines.

We appreciate the efforts of the Centers for Medicare & Medicaid Services (CMS) to provide Draft Guidance to pharmaceutical manufacturers and to solicit stakeholder comments. The comments herein are intended to further build on suggestions included in the comments of the

[1] Memorandum from Dr. Meena Seshamani, M.D. Ph.D., CMS Deputy Administrator and Director of the Center for Medicare to Interested Parties (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

Pharmaceutical Research and Manufacturers of America (PhRMA), the Biotechnology Innovation Organization (BIO), and the National Pharmaceutical Council.

Consistent with our prior comment letters filed in response to CMS' IPAY 2026 initial guidance regarding the implementation of the MFP Program[2] and the Negotiation Data Elements Information Collection Request (ICR),[3] we remain concerned that the MFP Program could hinder continued biopharmaceutical innovation, particularly with respect to HIV treatments, as well as the discovery of an eventual cure and an end to the HIV epidemic. We also continue to urge CMS to implement the MFP Program in accordance with the statute, including enforcing the statutory 340B nonduplication requirement. Failing to enforce such limitations will exacerbate the impact of the IRA on the incentives and resources of manufacturers to invest in the development of innovative drugs and therefore, further limit the scope of therapies patients will be able to access in the future. Together, we believe that our suggestions will help promote efficiency, accuracy, and reliability in the MFP Program (including MFP effectuation), consistent with Congress' intent.

Gilead's specific comments can be summarized as follows:

- **CMS Should Treat Fixed Combination Drugs as Distinct Qualifying Single Source Drugs (QSSDs).** Gilead supports CMS' continued treatment of fixed combination drugs as distinct QSSDs. Not only is such treatment consistent with the statutory language, but it is also supported by the clinical benefits these medicines bring to patients. This is particularly true when treating infectious diseases like HIV, which require multiple drugs that attack different parts of the viral lifecycle to suppress viral replication and slow the progression of disease. In many cases, fixed combination drugs also allow for simplification of dosing frequencies, reduce pill burden, and lower the risk of selective non-adherence. Treating fixed combination drugs as distinct QSSDs improves incentives for developing critical lifesaving medications and spurs new scientific discoveries, improving patient access to combination products that lead to better outcomes and fewer hospitalizations, potentially saving overall healthcare costs.

- **CMS Should Abandon Its Non-Statutory Bona Fide Marketing Standard.** CMS' proposal to apply a bona fide marketing standard deviates from the statute, which requires only that a generic drug be "approved and marketed." CMS should follow the statutory language and consider only whether a generic has been introduced or delivered for introduction into interstate commerce. Gilead also urges that CMS not overly rely on Prescription Drug Event (PDE) data, which reflects only Part D claims and does not capture the full scope of generic drugs covered by the statutory language.

- **Gilead Supports a Larger Role for the Medicare Transaction Facilitator (MTF), but Additional Safeguards, Guidance, and Controls are Necessary to Improve Effectuation of the MFP.**

[2] April 14, 2023 Letter from Gilead to Dr. Meena Seshamani, re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Applicability Year 2026, and Solicitation of Comments.

[3] May 22, 2023 Letter from Gilead to William Parham, re: Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB, 0938-NEW).

- CMS should implement additional safeguards and processes to ensure that manufacturers have access to necessary data in a timely, efficient, and consistent manner to verify whether an MFP or a 340B discount is owed with respect to a particular claim. For example, Gilead urges CMS to adopt a claims clearinghouse model to validate claims, prevent duplicate discounts, and leverage efficiencies to prevent duplication of efforts and disputes. Gilead appreciates CMS' recognition that manufacturers need claims data to validate 340B status and proposal for addressing claims identified as 340B after an MFP discount has been paid, but the process laid out in the guidance needs further development before manufacturers can rely on it.
- CMS could also consider mandatory reporting of the 340B Claim Indicator and limiting the timeframe during which 340B discounts can be claimed as an alternative approach for ensuring compliance with the IRA's 340B nonduplication requirement.
- In light of the substantial time and efforts required for a manufacturer to verify the MFP-eligibility of a claim, and to reduce the potential for duplicate discounts and fraud, CMS should extend the period before a manufacturer is required to pay the MFP discount from 14 days to 38 days.
- CMS should mandate use of the Standard Default Refund Amount in all cases. If, however, CMS expects manufacturers to adjust the rebate amount if a dispensing entity demonstrates that it paid more than the wholesale acquisition cost (WAC) to acquire a selected drug, CMS should permit manufacturers to: (1) only adjust the rebate amount if the dispensing entity notified the manufacturer that it paid a price exceeding WAC; (2) cap payment to eligible dispensers based on the price at which their distributor sold the drug to the dispenser; (3) adjust the rebate amount downward if the manufacturer has documentation to support that the entity paid less than the WAC; and (4) utilize the standard rebate amount if the manufacturer and dispenser reasonably cannot agree on an alternative rebate amount.
- With respect to MTF payment facilitation, Gilead supports Option 2 in which manufacturers provide the MTF with aggregate refund amounts that the MTF passes to the dispensing entities.

- **CMS Should Appropriately Value Selected Drugs and their Therapeutic Alternatives, Giving Substantial Weight to Patient Outcomes and Clinical Appropriateness.**
  - Gilead agrees with CMS' proposal to consider the patient experience in the MFP determination process and strongly encourages CMS to ensure patients have continued access to the specific therapies they need. CMS should give substantial weight to the factors that are most important to patients when assessing the value of a drug. In particular, CMS should ensure that the MFP determinations do not increase reliance on formulary exclusions or utilization management that in turn make drugs inaccessible to patients.
  - Gilead urges CMS to identify therapeutic alternatives *only* based on clinical appropriateness and clarify that cost should not be taken into consideration of such therapeutic alternatives.
  - Consistent with the revised guidance for IPAY 2026, CMS should not include Part D discounts from the definitions of "Manufacturer Net Medicare Part D Price" and "Net Part D Plan Payment and Beneficiary Liability." Congress specifically provided that Medicare Part D discounts are not owed on selected drugs and subtracting these discounts when determining MFP undermines that intent.

- CMS should clarify its definition of Federal Supply Schedule (FSS) price, in order to avoid disincentivizing manufacturers from offering discounts to FSS and Big Four customers. In general, CMS should not require manufacturers to report any metrics that include voluntary prices to Federal agencies.

- **CMS Should Confirm that Part D Plans May Not Restrict Access to Selected Drugs Through Utilization Management, Especially for Protected Classes Drugs.**
  - To help ensure the MFP Program does not reduce patient access, CMS should strengthen its guidance on formulary placement of selected drugs to make clear that Part D plans may not impose utilization management requirements, such as prior authorization and step therapy, on selected drugs.
  - At a minimum, CMS should emphasize that antiretrovirals remain a protected class and confirm that the formulary protections for drugs in the protected classes continue to apply regardless of whether they are selected drugs.

Our more detailed comments on the Draft Guidance are set forth below. We hope that CMS will consider these comments when developing further guidance.

I. CMS' Continued Treatment of Fixed Combination Drugs as Distinct QSSDs is Supported by the Statute and Will Encourage Development of these Critical Medications for Patients

The statute limits a QSSD to a drug approved under a new drug application (NDA) or biologics license application (BLA) and uses the terms "drug product" or "biological product" — which refer to the finished product, not an active ingredient or active moiety — in the QSSD definition. The QSSD definition also requires "at least 7 years" to have elapsed from the date of "such approval" to the selected drug publication date for a drug product and "at least 11 years" from the date of "such licensure" to the selected drug publication date for a biological product, further supporting that a QSSD encompasses a single drug product approved under a single NDA (including all sNDAs) or a single biological product approved under a single BLA (including all sBLAs) .

Had Congress intended to define a QSSD based on an active moiety or active ingredient, it would have stated so explicitly, given that it is familiar with these terms and concepts and has used them in other statutory provisions. Accordingly, as set forth in greater detail in PhRMA's comments, CMS may not treat products with different FDA approvals as the same QSSD. For the reasons described below, this is particularly true for fixed combination products.

A. <u>The IRA Makes Clear that Fixed Combination Products are Unique QSSDs.</u>

Gilead strongly supports CMS' continued treatment of fixed combination drugs with distinct combinations of active moieties or active ingredients as distinct QSSDs. Specifically, as under the IPAY 2026 Guidance, the IPAY 2027 Draft Guidance proposes that if a selected drug is "a fixed combination drug with two or more active moieties / active ingredients," then "the distinct combination of active moieties / active ingredients will be considered as one active moiety / active

ingredient for the purpose of identifying potential qualifying single source drugs."[4] This approach is consistent with the QSSD statutory definition, which limits a QSSD to a drug approved under a new drug application (NDA) or biologics license application (BLA) and uses the terms "drug product" or "biological product." FDA treats fixed-dose combination drugs as new drug products requiring robust review and approval to ensure patient safety and efficacy. FDA requires the submission and review of original NDAs or BLAs, as opposed to a supplemental application, even when a combination drug consists only of previously approved active moieties.[5] FDA's requirement for an original NDA or BLA ensures that the agency can assess the complete and extensive evidence developed for fixed combination drugs.[6] Such applications are subject to user fee requirements and a lengthy review period in recognition of the significant FDA resources necessary for review of NDAs or BLAs for combination drugs.[7]

Moreover, treating fixed combination drugs as distinct QSSDs is consistent with Section 1192(d)(3)(B) of the Act, which describes the data CMS will use to determine whether a QSSD satisfies the criteria for a negotiation-eligible drug. That provision states that in determining whether a QSSD is a "negotiation-eligible drug," CMS "shall use data that is aggregated across dosage forms and strengths of *the drug*" — *i.e.*, a single drug — "including new formulations of *the drug*, such as an extended release formulation."[8] Because different fixed combination products comprise multiple active moieties or active ingredients that may be included in other drugs, they cannot be new formulations of a *single* drug, as required by the statutory language referencing "new formulations of ***the*** drug."

Combination products also are not merely changes in the "dosage form" or "strength" of an existing drug. Because the statute uses the word "including" as a bridge between "dosage forms and strengths" and "new formulations," it makes clear that "new formulations" are a *subcategory* of "dosage forms and strength" changes.[9] Further reinforcing this reading, the only listed example of a new formulation in the statute — "extended release formulations" — involves precisely that kind of change: Extended release formulations "typically involve changes to the dosage form or

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[4] Section 30.1, Draft Guidance (citing 21 C.F.R. § 300.50).

[5] FDA, *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*, at 3 (Dec. 2004) ("Every . . . combination of two or more different active ingredients should be submitted in a separate original application.").

[6] For example, as the FDA notes, "[a]n NDA or ANDA is generally the appropriate marketing authorization pathway for a drug-led combination product," and an "NDA for a drug-led combination product must contain, among other things, a demonstration of the safety and effectiveness of the product for the conditions prescribed, recommended, or suggested in the proposed labeling." FDA, *Guidance for Industry and FDA Staff: Principles of Premarket Pathways for Combination Products*, at 12 (Jan. 2022). FDA goes on to note that "[t]o appropriately ensure the safety and effectiveness of a combination product in a single application, such application should enable a substantially similar evaluation to that which would be applied to each constituent part if they were reviewed under separate applications . . . including consideration of data and information that would be reviewed under the separate applications." *Id.* at 6.

[7] FDA, PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022, https://www.fda.gov/media/99140/download.

[8] 42 U.S.C. § 1320f-1(d)(3)(B) (emphasis added).

[9] *See, e.g.*, *Hincapie-Zapata v. U.S. Att'y Gen.*, 977 F.3d 1197, 1202 (11th Cir. 2020) ("Sometimes the listed examples are broader than the general category and need to be limited in the light of that category. For example, the phrase 'any American automobile, including any truck or minivan,' would not naturally be construed to encompass a foreign-manufactured truck or minivan." (citation, quotation marks, and brackets omitted)).

strength of a drug."[10] Fixed combination drugs, by contrast, are *not* merely changes in the "dosage form" or "dosage strength" of an existing drug. Rather, they include the addition of an entirely different molecular entity and constitute distinct drugs that involve significant alterations from existing products.

If Congress intended "new formulations" to include significant changes such as combinations, it would not have chosen, as the sole example of a "new formulation," an extended release formulation that merely constitutes a slight alteration in dosage form. Combination products treat conditions in novel ways and are expensive and timely to research and develop. Unlike, for example, extended-release formulations, combination therapies require complex chemistry and years of development. Formulating novel combination products requires multiple approaches and becomes increasingly sophisticated as more components are incorporated into an STR. Physical compatibility, dosage strength, pill size, solubility, permeability, and stability differences among the components necessitate many attempts to develop one single combination product. To ensure that all of the medicines in a pill are delivered to a patient and made bio-available, Gilead typically develops and tests between five and ten formulations of our medicines before identifying a combination that works for patients.

B. Combination Products Represent Important Scientific Advancements in Patient Care.

Not only is treating fixed combination drugs as distinct QSSDs consistent with the IRA, but it is also supported by the clinical benefits these medicines bring to patients. The standard of care for treating infectious diseases like HIV and HCV utilizes multiple drugs that attack different parts of the viral lifecycle to suppress viral replication and slow the progression of disease.[11] Fixed-dose Singe-Table Treatment Regimens (STRs) require complex clinical development to combine these multiple drugs into a single pill, thus simplifying dosing frequencies, reducing pill burden, and lowering the risk of selective non-adherence, where a patient takes part of a regimen but not the full regimen.[12]

Adherence concerns are particularly important for HIV treatments. In order to fully benefit from HIV treatment, patients must take their medicines every day, exactly as prescribed. This was particularly challenging in the past as early treatment regimens required patients to take as many as 25 pills, as often as three times a day.[13] Starting with the approval of ATRIPLA® in 2006, Gilead has prioritized the development of novel combination products, such as STRs, to avoid these complex dosing regimens which can decrease patient adherence, negatively impact patient health outcomes, potentially lead to transmission of HIV, and development of resistant forms of the HIV

[10] *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 16-CV-2372 (DLF), 2020 WL 3402344, at *11 (D.D.C. June 19, 2020).
[11] HHS states that "Monotherapy for the treatment of HIV is not recommended outside of a clinical trial. The optimal regimen for initial treatment of HIV includes multiple antiretroviral (ARV) drugs from at least two different HIV drug classes." U.S. Department of Health and Human Services, AIDSinfo, *HIV/AIDS Glossary: Monotherapy*, https://clinicalinfo.hiv.gov/en/glossary/monotherapy.
[12] Jenna Yager, et al., *Relationship Between Single Tablet Antiretroviral Regimen and Adherence to Antiretroviral and Non-Antiretroviral Medications Among Veterans' Affairs Patients with Human Immunodeficiency Virus*, 31 AIDS PATIENT CARE AND STDS 370-76 (2017).
[13] Noemi Astuti & Franco Maggiolo, *Single-Tablet Regimens in HIV Therapy*, 3 INFECTIOUS DISEASES AND THERAPY 1-17 (2014); Jamielynn C. Sebaaly & Denise Kelley, *Single-Tablet Regimens for the Treatment of HIV-1 Infection*, 4 ANNALS OF PHARMACOTHERAPY 332-344 (2016).

virus which can limit future treatment options.[14] A review of records from the Veterans Health Administration (VHA) indicated that "STR is associated with higher adherence rates, decreased hospitalizations, and more patients with an undetectable viral load in VHA patients with HIV/AIDS."[15] Studies have shown that compared to patients on STRs, patients on multi-tablet regimens ((MTRs), which are regimens of two or more pills per day) have poorer persistence, with a 60% higher rate of discontinuation.[16] Other studies show that approximately 25.3% of patients receiving an STR achieved 95% adherence or greater, compared with 17.4% of patients receiving two or more pills per day.[17] Patients on STRs also achieved greater viral suppression compared to MTRs.[18,19] Extensive research shows that improved viral suppression leads to better control of HIV, significantly decreased rates of hospitalization and lower healthcare costs,[20] reduced risk of treatment discontinuation, and avoidance of adverse consequences, such as drug resistance.[21]

Treating combination products with the same active moiety or the same active ingredient as the same QSSD would also equate treatments that are not recommended by guidelines with other treatments that are recommended by guidelines. For example, the Department of Health and Human Services (HHS) HIV treatment guidelines include two tables: one for initial treatments recommended for most people with HIV, and one for treatments *not* recommended as initial treatment.[22] The regimens listed in these tables include some overlapping components (in different combinations), such as lamivudine, TDF, or abacavir. How specific drugs/agents are used and what they are combined with result in clinically different options for patients living with HIV.

Further, the same components used in different regimens and combinations may present different uses, be indicated for different patient populations, and/or have different clinical profiles. As an example, TRUVADA® is comprised of FTC and TDF and has been approved for both prevention of HIV in HIV negative patients as well as part of treatment for HIV positive patients. When used for treatment, it must be used in combination with other antiretrovirals because it is not a complete HIV treatment by itself. Using an incomplete HIV treatment regimen raises significant clinical risks for patients in increasing the potential for developing drug resistance, as

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[14] Charlotte Charpentier, et al., Conference on Retroviruses and Opportunistic Infections, Abstract #726 (2012).
[15] Scott S. Sutton, et al., *Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks*. Am J Manag Care. 2016 Apr;22(4):242-8. PMID: 27143289., pubmed.ncbi.nlm.nih.gov/27143289/.
[16] Dionne M. Hines, et al., *Persistence Among Treatment-Native HIV-1 Patients: Single Versus Multiple Table Regimen Comparison*, Academy of Managed Care Pharmacy NEXUS 2017 (Oct. 2017).
[17] C. Cohen, et al., Association of Partial Adherence (PA) To Antiretroviral Therapy With Hospitalizations and Healthcare Costs in an HIV Population, 15 *Journal of the International AIDS Society* 18060 (2012).
[18] David B. Hanna, et al., *Increase in STR Use and Associated Improvements in Adherence-Related Outcomes in HIV-Infected Women*, 65 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 587-96 (2014) (noting that MTRs are not less effective if they are also taken daily as prescribed).
[19] *See e.g.*, Scott S. Sutton, et al., *Odds of Viral Suppression by Single-Tablet Regimens, Multiple-Tablet Regimens, and Adherence Level in HIV/AIDS Patients Receiving Antiretroviral Therapy*, 37 PHARMACOTHERAPY 2014-13 (2017); Jenna Yager, et al., *supra* note 1212.
[20] Sutton S, Magagnoli J, Hardin J., *Impact of Pill Burden on Adherence, Risk of Hospitalization, and Viral Suppression in Patients with HIV Infection and AIDS Receiving Antiretroviral Therapy*, 36 PHARMACOTHERAPY 385-401 (2016); Sutton S, Hardin JW, Bramley TJ, D'Souza AO, Bennett CL, *Single- versus multiple-tablet HIV regimens: adherence and hospitalization risks*, 22 AMERICAN JOURNAL OF MANAGED CARE 242-48 (2016).
[21] Jenna Yager, et al., *supra* note 1212, C. Cohen, et al., *supra* note 1717, David R. Bangsberg, et al., *Adherence-Resistance Relationships For Protease And Non-Nucleoside Reverse Transcriptase Inhibitors Explained By Virological Fitness*, 20 AIDS 223-32 (2006).
[22] AIDSinfo, *supra* note 11, at Tables 6 and 10.

noted above. However, STRIBILD, which includes the components of TRUVADA (FTC/TDF) is effective at treating HIV and can be used as a complete treatment. Treating these products as the same "drug" would ignore the tremendous clinical differences between them for patients.

C. Treating Combination Products as New Formulations Would Stifle Innovation and Harm Patients.

Given the important clinical benefits of combination products, public health agencies have recognized the importance of incentivizing their development. For example, FDA has adopted policies for the express purpose of supporting combination drug development and approval.[23] FDA's efforts to support combination drug development have extended to combinations containing a new active moiety and to combinations containing previously approved active moieties. In 2014, for example, FDA issued guidance revising the agency's interpretation of the 5-year new chemical (NCE) exclusivity provisions to allow for broader application in the context of combination drugs.[24] Whereas FDA historically had deemed combination drugs ineligible for NCE exclusivity if they contained any previously approved active moiety, FDA's revised policy provided for NCE exclusivity so long as the combination drug contains "a single, new active moiety."[25]

But treating combination products as part of the same QSSD would undermine these policies and discourage the development and approval of new treatment options for patients, particularly with respect to combination drugs. Doing so also would create a financial incentive to bring any new molecule to market separately—while disincentivizing development and use of combination products like STRs that lead to better outcomes and fewer hospitalizations. Because combination therapies are critically important to the successful treatment of infectious diseases, this could result in worse outcomes for patients, increase costs to the healthcare system, and frustrate efforts to end the HIV epidemic.

II. CMS Should Abandon Its Non-Statutory Bona Fide Marketing Standard.

CMS's proposal to apply a "bona fide marketing" standard to determine whether a generic or biosimilar has been marketed conflicts with the statute and is unduly restrictive. The statute provides that a drug does not qualify as a QSSD if an FDA-approved generic drug is "approved and marketed" or a biologic is "licensed and marketed."[26] As explained by PhRMA and by other commentors, the "bona fide marketing" standard proposed by CMS deviates from the plain meaning of "marketed" and imposes requirements not found in the statute, replacing a clear statutory rule with an amorphous totality of the circumstances analysis that creates considerable uncertainty and delay in determining the effect of a generic or biosimilar on whether the listed drug or reference product qualifies as a QSSD. CMS should instead follow the statutory language

[23] FDA, *Guidance for Industry: New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products*, at 2 (Oct. 2014) (noting also that combination drugs "have been shown to improve treatment response, lower the risk of developing resistance, and lower the rates of adverse events").
[24] *Id.* at 7-8.
[25] *Id.* at 8.
[26] SSA § 1192(e)(1)(A)(iii) & (B)(iii).

and ask only whether the generic or biosimilar has been "marketed"—i.e., introduced or delivered for introduction into interstate commerce.

To the extent CMS retains the bona fide marketing standard, which it should not, Gilead urges CMS not to overly rely on PDE data. Congress provided that a drug does not qualify as a QSSD if it is "the listed drug for *any* drug that approved and marketed under section 355(j)."[27] Congress did not limit the relevant universe of generic drugs solely or instruct CMS to rely on those included in PDE data, which reflects only Part D claims. CMS should begin its analysis with a broader range of data and allow manufacturers to submit additional data as needed to demonstrate that a generic or biosimilar has entered the market.

III. Gilead Appreciates that CMS is Considering a Larger Role for the MTF, but Additional Safeguards, Guidance, and Controls are Needed to Improve Effectuation of the MFP in Accordance with the Statute

Gilead supports the use of a single, neutral MTF to perform the following dual roles: (1) to provide claims-level data elements to manufacturers, facilitating the validation of MFP-eligible claims and preventing diversion; and (2) to administer retrospective MFP discounts from manufacturers to dispensing entities. Below, we provide several specific recommendations to enhance the role of the MTF and improve MFP effectuation and compliance with the 340B nonduplication requirement.

A. Additional Guidance, Safeguards, and Processes, such as a 340B Claims Clearinghouse, are Needed.

Gilead supports the 340B Program as one way to ensure broader access to medicines for uninsured, low-income patients. We are concerned, however, based in part on our experience with the 340B Program, that unless further guidance is provided and sufficient guardrails are put in place, it will be difficult, if not impossible, to identify and prevent duplicate discounts consistent with the IRA's 340B nonduplication requirement. In particular, additional guidance should be issued by Health Resources and Services Administration (HRSA) sanctioning the non-duplication process finalized by CMS.

The 340B Program has experienced unprecedented growth in recent years; by one estimate, purchases under the 340B Program totaled nearly $44 billion in 2021, an increase of 15.6% over 2020.[28] The following year, in 2022, 340B purchases increased by 22.3%, reaching a record $53.7 billion.[29] Today, the 340B Program is the second largest federal healthcare program in terms of prescription drug sales, behind only Medicare Part D.[30]

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[27] SSA § 1192(e)(1)(A)(iii) (emphasis added).
[28] Drug Channels, *The 340B Program Climbed to $44 Billion in 2021—With Hospitals Grabbing Most of the Money* (Aug. 15, 2022), https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html.
[29] Drug Channels, *EXCLUSIVE: The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021* (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.
[30] BRG, Measuring the Relative Size of the 340B Program (June 2022), https://www.thinkbrg.com/insights/publications/measuring-relative-size-340b-program-2020-update/.

Gilead is disappointed that CMS proposes that it "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[31] CMS is *required* under the statute to "establish[] procedures to carry out the provisions of [the MFP Program] . . . with respect to . . . [MFP]-eligible individuals,"[32] and the 340B nonduplication requirement is a core component of MFP effectuation because it determines whether 340B covered entities are owed the MFP for drugs dispensed to MFP-eligible individuals. Therefore, CMS cannot simply refuse to facilitate the implementation of this requirement. Given the importance of a robust process to validate claims, as we have previously commented, we thus urge CMS to adopt a claims clearinghouse model to validate 340B claims and prevent duplicate discounts.[33]

CMS could refer to the Oregon Medicaid program's model as an example of a claims clearinghouse, while building in additional components to ensure data accuracy.[34] Under this model, 340B claims must be identified and sent to the state rebate vendor for each calendar quarter within thirty days after the end of that quarter, and the state rebate vendor uses the 340B claims files to match up the original paid encounter and exclude the claim from the quarterly drug rebate process.[35] If there is an error and a validation fails, the claim is sent back to the trading partner for correction.[36]

CMS could consider using the MTF or a Third-Party Administrator (TPA) to manage the clearinghouse, similar to the agency's use of a TPA for the Part D Coverage Gap Discount Program and the new Manufacturer Discount Program. The TPA could collect 340B claims information from providers and provide it to manufacturers for validation. If a manufacturer reviews the claims data and as a result, disputes the 340B status of a particular prescription, and the covered entity agrees that the claim was inappropriately billed (either as a 340B claim or non-340B claim), that manufacturer should have the ability to submit data to the clearinghouse to update the claim information.

If CMS implements a clearinghouse model, Gilead encourages CMS to set forth clear, applicable requirements for all 340B stakeholders. CMS also should establish penalties for covered entities that do not submit claims data to the clearinghouse in the specified time frame or underreporting 340B claims over a specified time period. For example, CMS, in consultation with HRSA, could provide that a covered entity's repeated failure to comply could result in losing eligibility for participating in either Medicare or the 340B program. Additionally, if CMS establishes a clearinghouse, Gilead encourages HHS to employ the same clearinghouse to comply with other statutory requirements that involve identifying 340B claims, such as the prohibition against Medicaid duplicate discounts and the non-duplication prohibitions applicable to Medicare inflation rebates. To ensure accuracy of data reporting, covered entities should report all 340B

[31] Section 40.4.2, Draft Guidance.
[32] SSA § 1196(a)(3).
[33] March 10, 2023 Letter from Gilead to Dr. Meena Seshamani, re: Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments; April 14, 2023 Letter from Gilead to Dr. Meena Seshamani, re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191-1198 of the Social Security Act for Initial Applicability Year 2026, and Solicitation of Comments.
[34] Oregon Health Authority, Retroactive 340B Claims File Instructions, https://www.oregon.gov/oha/HSD/OHP/Tools/340B%20Claims%20File%20Instructions%20and%20Design.docx.
[35] *Id.*
[36] *Id.*

sales, not just Medicare sales. Additionally, manufacturers should be able to receive 340B claims data from the clearinghouse. This would allow verification that the 340B claims reported match the 340B discounts provided to each covered entity on each drug.

Using the same TPA to administer both the MFP discount program and a 340B clearinghouse would provide valuable efficiencies. The TPA could obtain Medicare Part D PDE data from CMS in addition to 340B claims information from covered entities, and use this information to remove 340B claims identified in time from the MFP invoices provided to manufacturers (unless the MFP is lower than the 340B ceiling price, in which case the amount invoiced to the manufacturer would be reduced to equal the difference between the MFP and the 340B ceiling price).

While Gilead is optimistic about the role that a 340B claims clearinghouse could play in preventing prohibited 340B duplicate discounts broadly, we recognize that significant work must be done for such a clearinghouse to be implemented effectively. In this context, it is critical that a clearinghouse receive accurate and timely data to identify MFP-eligible claims and prevent diversion of product subject to the MFP discount to individuals that are not MFP-eligible individuals. Until and unless CMS and HRSA require and enforce timely identification of 340B claims before an MFP discount is paid, another process will be necessary to ensure non-duplication of 340B and MFP payments.

To this end, Gilead appreciates that CMS acknowledges that manufacturers will require data from covered entities to validate 340B claims.[37] Gilead also appreciates that CMS is proposing that, if a drug is identified as 340B after a MFP discount has been paid, the manufacturer can pay the covered entity the difference between the MFP and the ceiling price and not also be required to replenish at the 340B ceiling price.[38] However, there is not yet an established process for all covered entities to provide this data to manufacturers in a timely, efficient, and consistent manner. Nor has HRSA clarified how it would treat manufacturers' efforts to verify 340B eligibility by manufacturers. Therefore, obtaining such data from covered entities is likely to be decentralized and burdensome for manufacturers, particularly given that there are more than 50,000 covered entities (and the number of covered entities is continually growing).[39] Therefore, Gilead urges CMS to continue to explore the claims clearinghouse model, which we believe could ultimately efficiently and effectively identify and prevent 340B/MFP duplicate discounts and support compliance with other statutory requirements that involve identifying 340B claims, such as the prohibition against Medicaid duplicate discounts and the exclusion of 340B units from the Part D

B. CMS Could also Mandate Timely Use of a 340B Claim Indicator for Dispensing Entities to Help Identify Duplicate Discounts.

Prior to the IRA, Gilead developed robust processes and procedures to identify rebate claims by state Medicaid programs for drugs purchased by covered entities through the 340B

[37] Specifically, CMS "anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders." Section 40.4.2, Draft Guidance.
[38] Section 40.4.2, Draft Guidance.
[39] 340B Drug Pricing Program, National Pharmaceutical Council, https://www.npcnow.org/topics/health-spending/340b-drug-pricing-program.

Program.[40] Yet, despite our efforts, these processes have inherent limitations, due, in large part, to limited quality and availability of Medicaid claims-level data and lack of agency guidance that establishes clear and consistent process for preventing duplicate discounts.

Mandatory timely use of a 340B Claim Indicator by dispensing entities could be another approach that helps prevent duplicate discounts between the 340B and MFP Programs. As currently contemplated in the list of MTF Claim-Level Data Elements contained in Table 2 of the Draft Guidance, the 340B Claim Indicator will be "[u]sed to verify MFP eligibility," but will only be available "as *voluntarily* reported by dispensing entity."[41] If CMS does not establish a claims clearinghouse or work with HRSA to develop another clear process for manufacturers to access 340B claims data, we strongly urge CMS to make reporting of the 340B Claim Indicator **mandatory** for dispensing entities and limit the timeframe for claiming 340B discounts to ensure accuracy of those claims indicators. As CMS has acknowledged, the IRA includes an express 340B nonduplication requirement: manufacturers of selected drugs only are required to provide the lower of the MFP *or* the 340B ceiling price—but not both—when a covered entity dispenses a selected drug to a Medicare beneficiary that is a "patient" of the covered entity.[42] None of the other Claim-Level Data Elements in Table 2 are sufficient to identify whether a unit was purchased at the 340B price, making the 340B Claim Indicator a critical data element to identify and prevent duplicate discounts.

Research has shown that covered entities do not consistently include 340B modifiers on insurance claims where use of such modifiers is not mandatory. For example, a 2023 study found that "[m]odifier usage reached 90% in some segments when reporting was mandatory, fell below 20% when it was optional, and dropped below 1% when it was impractical."[43] It is therefore critically important that CMS establish a uniform, mandatory standard for reporting 340B units to facilitate compliance with the 340B nonduplication requirement. Unless CMS mandates use of a 340B Claim Indicator, identification of 340B units in MTF Claim-Level Data from the PDE Record will be incomplete as 340B modifiers will not be used consistently, undermining the intent of the statutory prohibition against duplicate MFP and 340B discounts.

Gilead further recommends that – if the agency chooses to rely on a claims modifier – CMS work with the Health Resources and Services Administration (HRSA) to require that all covered entities and contract pharmacies identify a patient as 340B-eligible at the point of sale and dispense product purchased under the 340B Program to that patient.

This identification requirement would help ensure that a pharmacy knows the 340B status of a particular unit of drug at the time the product is dispensed and thus can include a 340B indicator as appropriate on the claim. This would facilitate accurate claims information submitted in real-time and prior to adjudication. If point of sale identification is not possible, CMS could establish a system for pharmacies to determine 340B status before the MTF determines if a MFP discount is owed and resubmit the 340B identification field without rebilling the claim. This would

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[40] *See* 42 U.S.C. § 256b(a)(5)(A).
[41] MTF Claim-Level Data Elements, Table 2, Draft Guidance (emphasis added).
[42] SSA § 1193(d).
[43] Rory Martin, *et al.*, Can 340B Modifiers Avoid Duplicate Discounts in the IRA?, IQVIA White Paper (Feb. 2023), https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.

allow the pharmacy to correct claims while avoiding updated billing changes after dispense, such as when the applicable payer changes or a payer's coverage rules change.

Research shows that 340B claims modifier usage was higher when the 340B status of the claim was known prior to or at the point of sale.[44] The requirement to identify a patient as 340B-eligible at the point of sale should also apply regardless of the insurance that the patient presents at the time of dispense, to encourage pharmacies to adopt and employ consistent processes that will improve the accuracy of 340B identification. Additionally, with respect to Medicare Part D claims, CMS also should require pharmacies to populate the 340B identifier on the claim at the point of sale to identify the claim as either 340B or not 340B and require Part D plan sponsors to deny claims that do not have the field populated with one of these values.

C. CMS Should Give Manufacturers More than 14 Days to Pay MFP Discounts and Confirm Payment to the MTF.

In section 40.4.1 of the Draft Guidance, CMS proposes that the MFP must be passed through to the dispensing entity within 14 days of the MTF sending claim-level data elements to the manufacturer that verify that the selected drug was dispensed to an MFP-eligible individual. This time limit is far too short. Identifying claims subject to the 340B nonduplication requirement is a resource- and cost-intensive process, and 14 days is wholly insufficient for manufacturers to perform even basic due diligence on the claims, particularly given the limited data that manufacturers would receive from the MTF. CMS should give manufacturers at least 38 days to provide the MFP discount to the dispensing entity (and sufficient data) to adequately validate the MFP-eligibility of claims. This would be consistent with the time that manufacturers have to pay coverage gap discounts and Medicaid rebates.

For drugs in certain therapeutic classes, including HIV, verification by manufacturers also is important to help avoid fraud stemming from the availability of significant statutory discounts. Gilead, for example, has been subject to fraudulent schemes by providers to exploit the 340B program. In 2020, Gilead brought an action in United States District Court for the Southern District of Florida against two networks of healthcare providers in Florida engaged in schemes to defraud Gilead's charitable free-drug medication assistance program (MAP) for critical pre-exposure prophylaxis (PrEP) HIV medications. The scheme allowed the providers to secure substantial profits for each bottle of PrEP medication purchased at 340B prices and purportedly dispensed to enrollees in Gilead's MAP; defendants obtained even greater fraudulent profits when they sought reimbursement from Gilead for dispensing PrEP medication that they illicitly repurchased from recruits for as little as $10, when they did not actually dispense the prescribed medication, or when they illegally resold the already-dispensed PrEP medication on the black market.[45] A subsequent consent decree, default judgment, and permanent injunction in 2022 and 2023 resolved these (and other) allegations and permanently enjoined the providers involved. While Gilead's legal action

[44] *Id.* (The "340B status of a drug must be known at the point of sale to the patient in order to apply the modifier to the claim prior to adjudication. While this is possible for pharmacies that identify 340B transactions at the point of sale, which may occur in entity-owned pharmacies and often in those that use physical inventory, the drug's 340B status is unknown for pharmacies using the 340B replenishment model and virtual inventory which is used by almost all contract pharmacies.").

[45] First Amended Complaint, *Gilead Sciences, Inc.; Gilead Sciences Ireland UC*, v. *AJC Medical Group, Inc. et al.*, Case No. 20-cv-24523-AMC (S.D. Fla.) (March 14, 2022).

against these fraudulent schemes helps protect Gilead's ability to provide free life-saving HIV medications to eligible individuals, the action demonstrates the time-consuming difficulty manufacturers face in identifying, investigating, and taking action with respect to fraud committed in connection with the 340B program. This action alone took over 18 months--and 899 filings on the docket--to resolve once filed (not including the time to investigate and prepare). Timeframes that essentially prohibit any eligibility verification by the manufacturer will only encourage such fraud and drain resources that could better be spent on developing innovations for this nation's seniors.

In the absence of sufficient time to validate claims and adequate claim-level data (including the 340B Claim Indicator), the availability of the proposed dispute resolution process as contemplated in Section 90.2.2 of the Draft Guidance also will be of limited value to manufacturers. The Draft Guidance states that "[t]he disputing party will need to submit evidence supporting its position when making the report."[46] Manufacturers, however, may not be able to feasibly provide such evidence, given the limited time frame for manufacturers within which the MFP must be passed through to the dispensing entity and limited data available to manufacturers. Thus, CMS should provide sufficient claim-level data to manufacturers and extend the timeframe within which the MFP must be passed through to the dispensing entity.

D. CMS Should Permit Use of the "Standard Default Rebate Amount" in All Circumstances. If CMS Does Not, We Urge the Agency to Cap the Rebate Amount and Clarify the Limited Situations when an Alternative Rebate Amount is Appropriate.

Gilead appreciates that the Draft Guidance would establish a "standard default rebate amount" that "offers a reliable refund amount for both manufacturers and dispensing entities."[47] The Draft Guidance also states, however, that "the Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug."[48] This language introduces ambiguity that undermines the clarity and efficiency of a "standard" rebate amount for both manufacturers and dispensers. We also are concerned that administration of a non-standard rebate amount is operationally infeasible, as manufacturers in many cases will not have information regarding the price at which the end customer purchases a drug from a distributor. Instead, CMS should mandate use of the "standard default rebate amount" in all cases.

If CMS nevertheless expects manufacturers to adjust the rebate amount, Gilead recommends that CMS: (1) clarify that an adjustment to the rebate amount would only be required if the dispensing entity notifies the manufacturer that it paid a price that exceeded WAC; (2) allow manufacturers to cap payment to eligible dispensers based on the price at which their distributor sold the drug to the dispenser (exclusive of fees or other terms independently negotiated between the distributor and the dispenser); (3) allow manufacturers to adjust the rebate amount downward if the manufacturer has documentation to support that the entity paid less than the WAC, to avoid the dispenser receiving a price lower than the MFP (which is not required by the statute); and (4)

[46] Section 90.2.2, Draft Guidance.
[47] Section 40.4.3, Draft Guidance
[48] *Id*.

clarify that if the manufacturer and dispenser reasonably cannot agree on an alternative rebate amount, the standard rebate amount will apply.

E. Gilead Supports Payment Facilitation Option 2, Under Which Manufacturers Provide the MTF with Aggregated Refund Amounts and Require Dispensers to Participate in MTF if Manufacturers Choose to Do So.

Finally, Gilead strongly recommends that CMS implement MTF payment facilitation Option 2, through which the MTF receives aggregate refund amounts from manufacturers and passes the refunds to dispensing entities. This will provide efficiency for both manufacturers and dispensers by allowing them to interact directly (and resolve any payment issues) with a single entity rather than with multiple manufacturers and thousands of dispensers. In contrast, Option 1, which would involve the MTF collecting banking information from participating dispensing entities and providing that information to Primary Manufacturers, would duplicate efforts, increase risk of inadvertent errors, and burden both manufacturers and dispensers. Generally, Gilead (and likely many other manufacturers) sells to end customers through distributors and does not maintain independent relationships with dispensing entities. Therefore, we are not privy to the banking information (which may change from time-to-time) for the potentially thousands of dispensers across the United States. Gilead thus supports having the MTF serve as a centralized entity to efficiently facilitate MFP discount payments from manufacturers to all dispensing entities.

Gilead is also concerned that CMS proposes to require manufacturers to agree on payment arrangements with every dispenser in the country. If a manufacturer chooses to use the MTF to pass through funds, CMS should recognize manufacturers' participation in the MTF as sufficient to make the MFP available. This approach would simplify the process for both manufacturers and dispensers. Without this assurance there is a risk that dispensers will demand unreasonable payment approaches from manufacturers, which we cannot meet or which greatly increase the cost and complexity of providing the MFP.

IV. CMS Should Appropriately Value Selected Drugs and their Therapeutic Alternatives, Giving Substantial Weight to Patient Outcomes and Clinical Appropriateness.

A. It is Important that CMS Meaningfully Consider Patient Views when Assessing the Negotiation Data Elements.

Gilead is encouraged to see CMS' interest in patient views on disease conditions and areas of value in the "Negotiation Data Elements," as discussed in Section 50.2 and the Appendix of the Draft Guidance. Gilead strongly encourages CMS to ensure that this patient input is meaningfully considered during the MFP determination process. Gilead agrees with CMS' proposal to solicit information about the patient experience and encourages CMS to give substantial weight to the factors that patients care most about when assessing the value of a drug. Patients can best express the value that HIV medications bring to them, and CMS should consider this patient perspective in its review of the Negotiation Data Elements. This approach is consistent with Gilead's pricing principles, which prioritize the value of our medicines along with patient access and health system sustainability.

B. Gilead Urges CMS to Identify Therapeutic Alternatives Based Solely on Clinical Appropriateness; for HIV Medicines, this Should be Based on HHS Guidelines A1 Recommendations for STRs.

The Draft Guidance states that CMS will "*prioritize* clinical appropriateness" in its consideration of therapeutic alternatives, including in developing an initial offer.[49] However, Gilead urges CMS to identify therapeutic alternatives *solely* based on clinical appropriateness, consistent with CMS' approach in the IPAY 2026 Revised Guidance.[50] Specifically, CMS should clarify that the selection of therapeutic alternatives should be based exclusively on clinical appropriateness, and should not take the cost of therapy into consideration. In general, we are concerned that many of the proposed manufacturer data submission requirements relate to factors such as pricing, costs of production and distribution, and other cost-related factors of the selected drug. As noted above, Gilead prices our drugs based on such drugs' value to patients and society, with the understanding that the value medicines bring will be recognized by the healthcare system and will provide an opportunity to support the discovery of future treatments. If CMS were to prioritize the cost of a therapy over clinical appropriateness in its consideration of therapeutic alternatives, selection of therapeutic alternatives may not ultimately reflect the benefits that medicines bring to patients and society. Clinical appropriateness should be determined through review of clinical guidelines, and input from clinical experts, manufacturers, providers, and other stakeholders. The statute's reference to "therapeutic" alternatives makes clear that such alternatives should be selected based on their therapeutic use and not cost.[51]

The Draft Guidance also provides that "CMS will begin by identifying therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action, and then also consider therapeutic alternatives in different pharmacologic classes…"[52] Gilead believes that identifying therapeutic alternatives based on pharmacologic class is not practical for HIV medicines and other combination products with active ingredients from multiple pharmacological classes. As described above in Section I, STRs with multiple active ingredients predominate in the HIV class, given their significant clinical benefits to patients. Certain HIV products thus are in three pharmacological classes, for example. In these cases, the most clinically appropriate approach for identifying comparators is to follow HHS Guidelines A1 recommendations[53] for STRs only.

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[49] Section 60.3.1, Draft Guidance (emphasis added).

[50] Memorandum from Dr. Meena Seshamani, M.D. Ph.D., CMS Deputy Administrator and Director of the Center for Medicare to Interested Parties, Section 60.3.1 (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf (hereinafter, "IPAY 2026 Revised Guidance") ("In all cases, CMS *will* select therapeutic alternatives based on clinical appropriateness") (emphasis added). See also IPAY 2026 Revised Guidance at 53 ("CMS will identify the therapeutic alternative(s) based on clinical appropriateness and consideration of various sources of evidence including clinical guidelines, peer-reviewed literature, drug compendia, and data submitted by manufacturers and the public, *and not based on the cost of therapeutic alternative(s)*.") (emphasis added).

[51] Only then, *after* the therapeutic alternatives are identified, can CMS consider their cost as a factor in determining the MFP. SSA § 1194(e)(2).

[52] Section 60.3.1, Draft Guidance.

[53] *See* Federally Approved Clinical Practice Guidelines for HIV/AIDS, https://clinicalinfo.hiv.gov/en/guidelines.

C. CMS Should Clarify How Designation as a "Therapeutic Advance" Will Impact the MFP Determination.

CMS states in Section 60.3 of the Draft Guidance that, for purposes of determining an initial offer, CMS will consider, among other information, the extent to which a selected drug represents a therapeutic advance compared to its therapeutic alternatives. Gilead appreciates CMS' consideration of innovation in drug development. In the HIV treatment space, as manufacturers develop novel HIV therapies, these discoveries over time help build toward a cure for the disease, while offering new options to improve patient adherence and protect against disease resistance. Gilead requests additional detail from CMS on how the therapeutic advance assessment will impact the MFP determination process. Specifically, CMS provides in Section 60.3.3.1 of the Guidance that, for drugs with therapeutic alternatives, it "may consider a selected drug to represent a therapeutic advance if evidence indicates that the selected drug represents a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s) for an indication(s)." Gilead welcomes CMS' willingness to designate a product as a "therapeutic advance," as discussed in Section 60.3.3.1, but would appreciate more clarity about what the designation of the therapeutic advance will mean for CMS' pricing considerations and how it will impact the initial offer calculation CMS describes in Section 60.3 of the Guidance.

Gilead also requests that CMS clarify the variety of types of "outcomes" it will consider in comparing effectiveness between a selected drug and its therapeutic alternative(s). Gilead encourages CMS to strongly consider outcomes that are meaningful to patients, such as changes in quality of life, productivity, and independence, as well as outcomes that can advance public health and equity. In addition, Gilead urges CMS to consider outcomes that are meaningful to physicians, such as whether a therapy allows a patient to maintain effective control of their disease with minimal safety risk or risk of resistance formation. CMS provides that it will determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by examining improvements in outcomes in its therapeutic alternative(s), and then gives the example of a drug that is curative versus one that delays disease progression.[54] While curative drugs and those that delay disease progression are undoubtedly meaningful to patients, Gilead urges CMS to consider that therapeutic advances in HIV are critical for achievement of public health and equity goals.

D. CMS Should Not Include Coverage Gap Discounts When Considering Sales Data for a Selected Drug or When Valuing its Therapeutic Alternatives.

In addition, we have concerns regarding the way CMS proposes to include coverage gap discounts in its consideration of a selected drug's sales data and determination of the value of its therapeutic alternative(s). Under the Market Data and Revenue and Sales Volume Data reporting requirements, CMS establishes a new Manufacturer Net Medicare Part D Price metric, reported at the NDC-11 level, that includes "coverage gap discounts and other supply chain concessions (*e.g.*, wholesale discounts) not reflected in the sum of the plan-specific enrollment weighted amounts calculation, and utilization that may differ from the PDE data."[55] Further, CMS proposes to use the Net Part D Plan Payment and Beneficiary Liability, which it defines as "the lower of Part D

[54] Section 60.3.3.1, Draft Guidance.
[55] Appendix: Market Data and Revenue and Sales Volume Data, at 134, Draft Guidance.

total gross covered drug cost (TGCDC) net of DIR and [coverage gap discount program] payments," to value therapeutic alternative(s) of the selected drug.[56]

Gilead strongly opposes inclusion of the coverage gap discount as part of either of these metrics. The coverage gap discount is part of the Medicare Part D benefit structure, like the deductible or the government contribution. It is not part of the price of the drug from the manufacturer to the Medicare Part D plan or any other customer. Moreover, Congress specifically provided that Medicare Part D statutory discounts (*i.e.*, discounts under the new Manufacturer Discount Program) are *not* owed on selected drugs.[57] Including Medicare Part D prices net of coverage gap discounts as part of the MFP determination process — either when considering prices of the selected drug in the U.S. market or when valuating its therapeutic alternatives — would undermine Congress' intent in creating a clear separation between MFP discounts and Part D statutory discounts, because it would effectively incorporate the Part D statutory discounts into the MFP determination.

E. CMS Should Clarify that the FSS Price Excludes Temporary Price Reductions and Blanket Purchase Agreements.

Manufacturers may offer voluntary discounts to FSS purchasers that are below the Big Four or Dual FSS price that is negotiated with the Department of Veterans Affairs (VA). Congress and CMS have excluded these FSS voluntary discounts from the Medicaid Best Price determination.[58] Gilead appreciates that CMS has defined the "Big Four price" as the price "described in 38 U.S.C. § 8126."[59] We encourage CMS also to clarify the definition of FSS price in the required Market Data and Revenue and Sales Volume Data reporting to exclude voluntary discounts to these purchasers, to avoid disincentivizing manufacturers from offering such discounts. In general, CMS should not require reporting by manufacturers of any metrics that include voluntary prices to Federal agencies.

Therefore, Gilead encourages CMS to clarify that the "Federal supply schedule (FSS) price" is the FSS price negotiated with the VA for other government agencies, exclusive of any temporary price reductions (TPRs) or blanket purchase agreements (BPAs). This clarification will encourage the parties to continue to negotiate voluntary discounts, benefitting VA and other federal government agency patients.

III. CMS Should Confirm that Part D Plans May Not Restrict Access to Selected Drugs Through Utilization Management, Especially for Protected Classes Drugs

Gilead encourages CMS to strengthen its guidance on formulary placement of selected drugs to make clear that Part D plans may not impose utilization management requirements, such as prior authorization and step therapy, on selected drugs. In a section titled "Coverage of Selected Drugs," the IRA requires that Part D plans include selected drugs on their formularies.[60] But as CMS acknowledges in the Draft Guidance, "Part D sponsors may be incentivized in certain

[56] Section 60.3, Draft Guidance.
[57] SSA § 1860D-14C(g)(2)(B).
[58] SSA § 1927(c)(1)(C)(i)(I).
[59] Appendix: Market Data and Revenue and Sales Volume Data, at 133, Draft Guidance.
[60] IRA § 11001(b)(1)(E).

circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."[61]

CMS has recognized that utilization management can have the same effect on patients as non-coverage, and thus such restrictions would be contrary to the purpose of the relevant IRA section: "Coverage of Selected Drugs." [62] By reducing patient access, such restrictions also could adversely affect the progression of a patient's disease and their overall health.[63] Such a result also would increase costs for seniors and the government, which is the opposite of what Congress intended to achieve through the IRA.[64] It could also discourage enrollment by beneficiaries who rely on treatment with a selected drug, in violation of the statutory non-discrimination provision.[65]

We therefore appreciate CMS' commitment in the Draft Guidance to maintaining a robust clinical formulary review process to identify instances where Part D sponsors place selected drugs on non-preferred tiers, place a selected drug on a higher tier than non-selected drugs in the same class, require utilization management of an alternative brand drug prior to a selected drug with an MFP, or impose more restrictive utilization management for a selected drug compared to a non-selected drug in the same class.[66] These are helpful steps, but we remain concerned that that Part D plans will disadvantage selected drugs to steer Part D beneficiaries in favor of non-selected drugs. We urge CMS to implement additional safeguards to protect patient access and prevent discriminatory behavior.

In particular, we recommend that, for selected drugs, CMS make clear that Part D sponsor formularies should not be allowed to implement utilization management requirements for selected drugs, such as prior authorization or step therapy requirements, that are intended to steer beneficiaries to other alternatives. This policy is consistent with the intent of the IRA provision requiring coverage of selected drugs and CMS' statement in the Draft Guidance that it will assess, among other things, instances where Part D sponsors impose more restrictive utilization management for a selected drug compared to a non-selected drug in the same class.

At a minimum, we urge CMS to reinforce that antiretrovirals remain a protected class and confirm that the formulary protections for drugs in the protected classes continue to apply regardless of whether they are selected drugs.[67] Nothing in the IRA or its legislative history

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[61] Section 110, Draft Guidance.
[62] Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.41 ("a formulary drug whose access is restricted via UM requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant UM requirements are not met for a particular enrollee").
[63] 83 Fed. Reg. 62152, 62187 (Nov. 30, 2018) ("[s]everal studies show that enrollees become discouraged when step therapy is used" and that the delay caused by step therapy "may cause a worsening of conditions leading to increased medical costs.").
[64] H.R. Rep. No. 117-130, at 5 (2021) (describing the purpose of the program as "lowering costs for seniors and the Federal Government").
[65] SSA § 1860D-11(e)(2)(D)(1).
[66] Section 110, Draft Guidance.
[67] CMS, Medicare Prescription Drug Benefit Manual, Ch. 6, § 30.2.5 Protected Classes, https://cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.

indicates any intent by Congress to disrupt the longstanding protected classes protections. To the contrary, the "Coverage of Selected Drugs" provision demonstrates Congress' concern about ensuring access to selected drugs, and the protected classes policy is in full harmony with that intent.

* * * *

Gilead hopes CMS will incorporate these suggestions into its revised final guidance and implement the MFP Program with a goal of ensuring that it does not disincentivize biopharmaceutical innovation, which could hinder finding a cure for HIV and ending the HIV epidemic. If you have any questions, please do not hesitate to contact Michelle Drozd at Michelle.Drozd2@gilead.com or James Class at james.class@gilead.com.

Sincerely,

Rekha Ramesh
Vice President, U.S. Policy,
Government Affairs and Policy
Gilead Sciences, Inc.

GREATER NEW YORK HOSPITAL ASSOCIATION
PRESIDENT, KENNETH E. RASKE • 555 WEST 57TH STREET, NEW YORK, NY 10019 • T (212) 246-7100 • F (212) 262-6350 • WWW.GNYHA.ORG

July 2, 2024

Meena Seshamani, MD, PhD
Deputy Administrator and Director, Center for Medicare, Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

On behalf of the more than 206 public and private not-for-profit hospitals and health systems in five states that make up the membership of the Greater New York Hospital Association (GNYHA), we appreciate this opportunity to comment on the Draft Guidance on the Medicare Drug Price Negotiation Program (the "Draft Guidance") issued by the Centers for Medicare & Medicaid Services (CMS) on May 3, 2024. **Our comments focus on one specific element of the Draft Guidance: the implications for, and adverse consequences to, 340B Program operations and savings that will inadvertently occur if the Draft Guidance for implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) is not revised.**

As we more fully discuss below, GNYHA urges CMS to solicit stakeholder input on the interplay between the MFP for Medicare Part D claims and the 340B ceiling price, and workable solutions to the CMS-acknowledged need to "deduplify" MFP and 340B claims. CMS must then develop specific processes to preserve access to 340B discounts based on such feedback. The current proposal creates too much risk of lost 340B savings and relies too heavily on the goodwill of drug manufacturers to maintain access to 340B discounts in an already adversarial environment in which manufacturers are trying to shrink the 340B program.

GNYHA members strongly support MFP implementation overall and are not advocating for a delay in implementing the Medicare Drug Price Negotiation Program. We do, however, believe it is necessary to proceed deliberately and with caution regarding Part D prescriptions that are eligible for 340B discounts.

The 340B Program

The 340B program is an essential tool for safety net hospitals that are challenged to develop sustainable financial strategies that support the provision of health care to the underserved. These hospitals experience significant shortfalls in Medicare and Medicaid reimbursement relative to their operating costs. In New York, we estimate that Medicare covers about 85% of hospital costs, while Medicaid only covers 70%.[1] On average, 70% of New York hospital discharges and 60% of outpatient visits are covered by these government payers. Only some institutions can offset these shortfalls by negotiating favorable rates with

[1] GNYHA analysis of New York State Institutional Cost Reports, 2022.

commercial payers. This situation is exacerbated by the financial impact of the COVID-19 emergency and the extraordinary, unremitting increases in labor costs, among other stressors. As a result, the median operating margin for New York hospitals in 2022 was -2.5%, and 63% experienced negative operating margins.[2]

Yet the 340B program—and by extension the hospitals and patients it supports—is under attack. The list of manufacturers imposing limits on covered entities' contract pharmacy arrangements is long and growing. Manufacturers and other entities in the distribution and access chain, including commercial payers and pharmacy benefit managers (PBMs), impose onerous administrative and data reporting requirements. Not surprisingly, the Heath Resources and Services Administration's attempts to regulate this behavior have been challenged in court by manufacturers. Distressed 340B providers are currently seeking legislative redress in the states, resulting in more legal challenges. **Implementation of the important and welcomed Medicare Drug Price Negotiation Program should not subject 340B covered entities to further erosion of 340B program savings and the concomitant ability to stretch scarce resources to serve their communities.**

The Draft Guidance re. Nonduplication with 340B Ceiling Price

The Proposed Model

The IRA requires drug manufacturers to provide 340B covered entities access to the lower of MFP or the 340B ceiling price[3]. It is critical that any MFP implementation process allows for the identification of 340B-eligible dispenses and ensures covered entities do not lose access to 340B discounts.

CMS proposes a retrospective model for determining MFP eligibility of Part D claims and ensuring that dispensing entities have access to MFP pricing. CMS would contract with a Medicare transaction facilitator (MTF) to, among other functions, provide manufacturers with claim-level data that has been verified for MFP eligibility, and receive data from manufacturers about their payments to dispensing entities to effectuate access to the MFP pricing within a 14-day prompt pay window.

Under the proposed model, to ensure that 340B covered entities benefit from the statutory guarantee of access to the lower of 340B or MFP pricing, manufacturers would need to know that a claim is 340B eligible and the 340B ceiling price is lower than the MFP. According to the Draft Guidance, unless the manufacturer indicates to the MTF that a claim is 340B eligible and the 340B ceiling price is lower than the MFP, the manufacturer must provide access to the MFP within the 14-day prompt pay window. CMS allows that manufacturers may subsequently determine that a drug that received MFP pricing is, in fact, 340B eligible, and reimburse the covered entity for the difference between the MFP and 340B ceiling price. But this would delay the length of time a 340B covered entity must wait to realize its 340B discounts, and create potential cash flow issues. It also puts covered entities in the position of having to pursue reimbursement to which they are entitled.

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[2] *Ibid*.
[3] 1193(d)

Moreover, according to the Draft Guidance, even when it is subsequently determined that a drug that has received MFP pricing is 340B eligible and the covered entity is entitled to the difference in pricing, the manufacturer is not required to also replenish the covered entity's (or contract pharmacy's) 340B stock at the 340B ceiling price. If implemented, this impact on replenishment could significantly undermine a covered entity's 340B program.

Deduplication Needs

CMS notes that it received multiple requests for it to assume responsibility for deduplicating the 340B ceiling price and MFP, and that it is declining to do so at this time. Instead, CMS will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their 340B third-party administrators (340B TPAs) into a future MTF process. CMS also allows that dispensing entities can voluntarily include a 340B eligibility indicator on Part D claims. This indicator would get passed from the MFT to the manufacturer, which could then determine if the claim is entitled to the 340B ceiling price. Additionally, CMS intends to provide manufacturers with a process to identify applicable 340B claims when reporting payment elements to the MTF. Further, CMS strongly encourages manufacturers to work with dispensing entities, covered entities, and 340B TPAs to facilitate access to the lower of MFP or 340B ceiling pricing.

Essentially, covered entities are left with two options under the Draft Guidance to ensure access to 340B discounts: 1) rely on the voluntary point of sale claim indicator that a given dispense is 340B eligible or 2) rely on manufacturers to develop a workable process for maintaining access to 340B pricing, including replenishment.

- Regarding the 340B claims indicator, because many hospitals use a replenishment model for their 340B program—where dispenses are determined 340B eligible after the fact and virtual 340B drug inventories are accrued—the dispensing pharmacy is often not aware at the point of sale whether a given prescription is 340B eligible. A deduplication model that depends on claim indicators attached at the point of sale by dispensing pharmacies is therefore unworkable.

- As for a manufacturer-developed identification process, GNYHA member hospitals strongly object to a model that allows manufacturers to determine what information to require from covered entities to maintain access to 340B pricing. Covered entities are already struggling with demands for claims data from manufacturers, often required as a condition for purchasing drugs at 340B discounts. These overbroad demands exceed what is needed to audit Medicaid duplicate discounts and seemingly serve competitive business purposes rather than legitimate policy or regulatory needs. A deduplication process that exacerbates this existing dynamic is very concerning. We also note that, in light of the recent Change Healthcare cyberattack, all stakeholders should be cautious about exchanging more than minimum necessary data. CMS itself explains that it selected MTF claim-level data elements that provide the minimum necessary information to the manufacturer.

Stakeholder-Informed Revisions are Essential

Covered entities have implemented their 340B programs with great diligence. To ensure compliance with a heavily regulated program, they contract with 340B TPAs that verify claims eligibility and carefully monitor utilization and purchasing. Layering an additional process on top of the finely tuned 340B

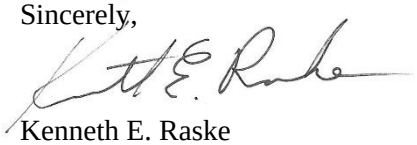
operations, including requiring new data sharing and third-party administrators for overlapping purposes, overcomplicates an already nuanced process and creates too much opportunity for misalignment and error. The MFP and 340B programs must be carefully coordinated.

The issue flagged above—that the Draft Guidance would limit replenishment of certain 340B-eligible dispenses—is a particularly concerning example of creating multiple processes at cross-purposes. We strongly object to an MFP implementation that interferes with a 340B covered entity's replenishment model and creates additional impediments to accessing 340B pricing.

We urge CMS to develop a deduplication process that is informed by stakeholder feedback and does not further erode 340B program savings, and/or place covered entities in the untenable position of having to choose between access to 340B savings and complying with unchecked data requests from manufacturers. CMS should prioritize its planned exploration of the feasibility of incorporating 340B-related transactional data from 340B covered entities or their 340B TPAs into a future MTF process. CMS could, for example, explore a model where covered entities retrospectively submit 340B claims data to the MTF, which would then remove the 340B identified claims from the claims-level data submitted to manufacturers. We are also aware of additional proposals being developed by stakeholders that warrant consideration.

Thank you for the opportunity to comment on the Draft Guidance. Please contact Emily Leish with any questions. We are available to help facilitate stakeholder feedback and assist with implementation. We look forward to working together on this important initiative.

Sincerely,



Kenneth E. Raske
President

July 2, 2024

VIA ELECTRONIC SUBMISSION —

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

GSK is writing in response to the Centers for Medicare and Medicaid Services (CMS or the Agency) recent IPAY 2027 Proposed Guidance (hereinafter, Proposed Guidance), which, once finalized, will take effect on January 1, 2027. GSK reasonably believes that one or more GSK product(s) may be directly impacted and subject to price setting under the Inflation Reduction Act (IRA) statute and applicable Proposed Guidance. Given those potential implications, GSK has a vested interest in the development, interpretation, and application of the final IPAY 2027 Proposed Guidance that will be issued by CMS. As CMS finalizes this Proposed Guidance, GSK appreciates CMS's willingness to solicit comments and offer listening sessions to understand stakeholder impacts and concerns related to implementation. While GSK is a member of both BIO and PhRMA and supports each organization's respective comments on this issue, we respectfully submit these more targeted comments in response to CMS's Proposed Guidance. [1]

GSK is a global biopharma leader with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. With a clear and defined focus on leading the way in disease prevention, GSK's aim is to positively impact the health of more than 2.5 billion people over the next ten years. GSK supports policy solutions that transform our healthcare system to one that rewards innovation, prevents the onset and progression of disease, improves patient outcomes, and achieves higher-value care.

With a vested interest in ensuring the IPAY 2027 Proposed Guidance is implemented effectively, once finalized, GSK encourages CMS to take clear actions to reduce the negative effects on

[1] GSK recognizes CMS will receive many comments on this Proposed Guidance, The reason GSK lays out the letter in this framework is to ensure CMS knows where to consider our recommendations per each section of the proposal.

innovation and access that could result if the Proposed Guidance is finalized as proposed. Specifically, GSK offers suggestions in the following six key areas:

1) Revise the definition of Qualified Single Source Drugs (QSSD) to only aggregate products for price setting on a case-by-case basis for each individual product.

2) Ensure that the Medicare Transaction Facilitator (MTF) is operational for manufacturers to effectively provide Manufacturer Fair Price (MFP) to entities. To successfully operationalize the MTF, CMS must:

- Ensure 340B claims are appropriately flagged by the MTF and visible to manufacturers to mitigate the risk of statutorily prohibited 340B duplicate discounts;
- Revise the current enforcement approach so that civil monetary penalties (CMPs) apply to all non-compliant entities across the supply chain (i.e., covered entities intentionally seeking duplicate discounts); and
- Provide the necessary provisions so that the 14-day claims verification timeline is extended to match the current Coverage Gap Discount Program (CGDP) review process.

3) Ensure manufacturers do not experience excessive operational burden, including increased operational cost, and can demonstrate compliance to effectively effectuate MFP. Specifically:

- CMS should ensure manufacturer protections are in place without putting more overbearing controls in the price setting process.
    - This concern could be resolved if CMS requires program participation, enforcing CMPs for all entities involved in the process.
- Manufacturers should have the ability to rely on the MTF and pharmacies' participation. Manufacturers cannot sustain building and maintaining countless different payment processes with all U.S. pharmacies. In the Proposed Guidance, CMS has required manufacturer compliance requirements; however, CMS lacks requiring controls to ensure manufacturers have the structure to demonstrate compliance.
    - GSK believes CMS has the authority to require entities to use this payment processing pathway through Part D contractual agreements.
- CMS should allow manufacturers the ability to communicate with MTF and pharmacies.

4) Select therapeutic alternatives used for price comparisons should be based on recommendations from clinical experts and patients. Additionally, those alternatives should be limited to the drug's in-class products, omitting therapies prescribed via off-label use or generic equivalents, and only comparing products with similar dosing requirements.

5) Refrain from using Part D net price of the purported therapeutic alternative as a metric to develop manufacturers' initial MFP offers. This approach, as suggested by CMS, is not how manufacturers operationally reflect the use of net price - as this is not a "price" any customer pays for a product. Additionally, as part of this process, it is critical that manufacturers have a

clear understanding of how CMS is describing information from clinicians and patients when setting MFP.

6) As a core component of the price setting process employed by CMS, the Agency should provide manufacturers with clear visibility into how the MFP offer is developed through the use of both verbal and written communications, including a description of how patient and clinician's feedback is used to establish MFP. To effectively ensure manufacturers have the appropriate context to meaningfully engage in the offer-counteroffer process, GSK recommends that the Agency:

- Hold face-to-face meetings with manufacturers and provide the requisite amount of time for those meetings,
- Ensure it maintains communications with manufacturers during the offer and counteroffer process; and
- Provide manufacturers participating in the negotiation process with the detailed methodology and weighting of factors that are used to develop CMS's offer.

In the sections below, we expand on these points and provide additional recommendations:

I. Section 30.1 - Identification of Qualifying Single Source Drugs (QSSD) for Initial Price Applicability Year 2027

<u>Recommendation</u>: CMS should not aggregate products for price setting based simply on the product's active ingredient or moiety, rather a case-by-case analysis regarding aggregation is more aligned with the statutory purpose and the actual scope of CMS's regulatory authority.

Redefining QSSD eligibility will support manufacturers' ability to invest in novel therapy options in the future. In particular, the aggregation of products seems intended to prevent gamesmanship on the part of sponsors seeking to preserve exclusivity in the market without innovation. However, aggregation goes beyond regulatory authority, is overboard, and could have devastating consequences for innovation.

When defining QSSD, CMS should consider the complexities pertaining to different New Drug Applications (NDAs), Biologics License Applications (BLAs), and certain supplements, which can have widely divergent clinical profiles, as well as research & development costs, regardless of whether they share the same active moiety or active ingredient. Specifically, there may be significant clinical meaningful differences between products (e.g., significant contribution to patient care, extending a product to treat/prevent another disease, etc.) that utilize the same active ingredient or active moiety and these clinically meaningful differences should be part of the consideration regarding whether a NDA, BLA, or supplement should be considered as its own standalone QSSD.

CMS should understand that not all changes after approval of an active moiety or ingredient are minor. Certain changes may in fact require substantial new studies as support. Meaningful product approval data, when available, should be considered when evaluating the appropriateness of aggregating products under the same QSSD. Examples of such studies may include expansion of indications or, as in the case of HIV medications, a meaningful change in the application. These

changes should be differentiated from minor changes like minor formulation changes or minor labeling updates, which can potentially be aggregated under the same QSSD.

Additionally, a case-by-case analysis may also be necessary in instances where an application may contain a different active moiety or ingredient during the lifecycle of the product. For example, certain biological supplements within the same application may introduce a new "active ingredient" and those should be treated as a separate QSSD per the statute (e.g., influenza vaccines, COVID-19 vaccines, pneumococcal vaccines, etc.). As a specific recommendation, **GSK requests CMS to treat each formulation of a vaccine as a distinct fixed combination biologic product, precluding aggregation with earlier versions of the vaccine and resetting the 11 year-post licensure eligibility timeframe.**

CMS's current treatment of products containing the same active ingredient or moiety as one drug under the price setting program is problematic and discourages the development of novel dosage forms and formulations. As a finer point, CMS's current interpretation of QSSD for the purposes of price setting under the IRA has the potential to stifle the development of innovative and lifesaving treatments.

II. Section 40.4 - Providing Access to the MFP in 2026 and 2027

<u>Recommendation</u>: GSK does not support providing dispensing entities with prospective pricing as this framework would result in high diversion risk to manufacturers.

CMS proposes manufacturers must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Both proposed payment options to dispensing entities are not viable because at the point-of-sale, the payer type is unknown. Therefore, manufacturers would be at risk for high diversion and duplicate discount occurrences. This would not just apply to 340B transactions, but would also significantly increase the risk of diversion and duplicate discounts across the commercial supply chain.

III. Section 40.4.1 – Medicare Transaction Facilitator (MTF) Data Facilitation

<u>Recommendation</u>: **CMS should grant an extended prompt-pay timeline, like the operational timelines of the current Coverage Gap Discount Program (CGDP) and require claims to be batched monthly or quarterly**.

GSK believes the 14-day prompt-pay window does not provide enough time for manufacturers to process claims accurately and thoroughly to ensure compliance with the price setting program.

GSK believes it is critical that the prompt-pay window be expanded so that manufacturers can effectively make the determination as to whether the 340B price or the MFP applies, scrub for duplicate and errant claims, and invoice in a way that is compliant under statute. As manufacturers scrub data to process a claim, they not only verify patient eligibility, but also must verify that the quantity is correct, and that each claim is unique to ensure its validity. The proposed 14-day window

grossly underestimates the operational process manufacturers must undertake to verify and pay a claim. It does not provide enough time to support necessary claims verification by manufacturers. Further, CMS should ensure any revisions to previously submitted claims should re-start the clock for additional processing.

As context, listed below are some specific examples of what manufacturers validate in Part D claims submissions: 1) item quantity that falls outside of the minimum or maximum quantities defined for the product; 2) duplicates that are identified in Medicare Part D utilization; and 3) whether the pharmacy is valid. To support proper verification of claims, CMS should extend the prompt pay timeline to be consistent with the current CGDP rules (38 days).

GSK believes the 14-day cycle CMS proposes will result in undue operational burden and costs to manufacturers to process daily unbatched claims with limited validation. Payers typically submit monthly or quarterly batched (all claims for a given month or quarter) within a set number of days after the end of the applicable period. The framework used by plans today is predictable and manageable. Trying to manage an unknown number of claims arriving daily with a short turnaround time to validate and pay those claims on a timely basis will be unmanageable and cost prohibitive for manufacturers. In addition, the limited validation upfront due to the 14-day cycle time requirement could result in an increase in disputes later in the process.

IV. Section 40.4.2 - 340B Non-Duplication

Recommendation: **GSK recommends CMS implement and enforce mandatory claims modifiers on 340B claims, require covered entities to share 340B claims data with manufacturers (via the MTF/clearinghouse) and permit the establishment and use of a private sector solution credit model allowing manufacturers to identify claims on which a 340B discount is owed, fulfilling the statutory obligations required of manufacturers.[2]**

GSK recommends CMS require covered entities to provide 340B detailed claims data, including but not limited to, the Prescriber ID (i.e., NPI) along with Provider and Pharmacy NPI ID (with the file location) as part of the MTF data requirements. Further, require covered entities to share 340B claims data with manufacturers (via the MTF/clearinghouse) and permit the establishment and use of a private sector solution to shift 340B discounts to a rebate model. These data metrics and sharing practices will allow manufacturers to determine the appropriate payment due (based on 340B status) and prevent duplicate discounts.

Specifically related to the 340B program, GSK is concerned that CMS has failed to adequately take the necessary steps to safeguard against duplicate discounting, as is required by statute. The statute clearly requires that the 340B status of a claim be known before a manufacturer is required to provide any MFP discount. Often, 340B claims from contract pharmacies are not identified until weeks after dispensing. Not having claims identification could result in manufacturer dispensing duplicate payments, particularly without an extended MFP processing cycle time. CMS should prioritize efforts on the 340B non-duplication requirement, such that a manufacturer is not required to provide both a 340B discount and the MFP on a selected drug in a single transaction.

[2] CMS will also have to apply modifiers to in the IRA Inflation Rebate Program. Therefore, CMS should consider how to apply modifiers in this section of the law, as well.

Currently, the lack of a mechanism to prevent both MFP and 340B discounts on the same drug unit is concerning and will present significant operational challenges for GSK (and all manufacturers) as the 340B patient eligibility is unclear at time of dispensing. Given the HHS Secretary's statutory obligation to operationalize the MFP process, deduplication is not a responsibility CMS can push onto manufacturers, particularly when manufacturers don't have access to the resources and data necessary to identify 340B transactions. HHS must, at a minimum, ensure that its relevant subagencies are working closely together to appropriately implement provisions of the IRA. Specifically, the Secretary must ensure CMS and the Health Resources and Services Administration (HRSA) are closely collaborating to ensure that manufacturers are not subject to duplicate discounts. Accordingly, CMS and HRSA must take action within their authority to facilitate and enforce deduplication, such as through a provider requirement, to identify 340B claims or a condition requiring covered entities to submit claims data at a later date to receive 340B discounted pricing for a 340B drug.

While GSK recognizes that CMS's authority over the 340B program is limited, there are steps the agency can take to mitigate some 340B-related IRA challenges. Specifically, CMS could contractually require Part D plans to obtain information about 340B claims from in-network pharmacies that are also affiliated with 340B hospitals and grantees and require participating providers to identify 340B claims.

CMS lays out options in the Proposed Guidance to identify 340B claims, but those identification mechanisms are voluntary for 340B covered entities and grantees. This approach will not work and does not serve as a realistic solution since covered entities have no compelling reason, absent a mandate with CMPs as the enforcement mechanism, to report their 340B claims. Should the agency decide to move forward with its proposed voluntary 340B reporting approach, the agency must recognize the vastly inequitable position it places on manufacturers and the significant challenges it will create in effectively implementing core components of the statute.

In order to effectively operationalize the removal of 340B units from MFP, CMS should require the MTF to promptly identify 340B claims to determine whether an MFP discount is due. The MTF or clearinghouse should calculate the discount amount by accounting for the value of the 340B ceiling price relative to the MFP. The MTF then would rely on the HRSA OPAIS 340B ceiling price to determine whether the 340B price was lower than the MFP and, if so, calculate the adjustment applicable to the claim.

Should CMS not make meaningful changes to resolve the 340B-MFP complications present in the Proposed Guidance, GSK anticipates there will be significant implementation and financial challenges with 340B and MFP effectuation. For example, manufacturers do not have the financial means to carry millions of dollars in excessive payments and should not be financially responsible to pay both 340B and MFP. In that scenario, under the disputes process, GSK recommends CMS use enforcement discretion in instances where a manufacturer is acting in a timely manner or taking steps to rectify any errors made due to the 340B operational challenges associated with the Proposed Guidance. CMS should consider holding manufacturers harmless that demonstrate a good faith effort to provide covered entities with the lesser of the MFP or the 340B ceiling price.

V. Section 40.4.3 - Retrospective MFP Refund Amount

<u>Recommendation</u>: GSK supports CMS implementing a refund amount that is the difference between the lesser of the Standard Discount Refund Amount (SDRA), or WAC, and MFP.

CMS should provide clarity regarding the facilitation process for non-standard MFP refund amounts**.** Specifically, GSK recommends CMS use the SDRA (or WAC) minus the MFP of the selected drug. CMS should use this standard to issue refunds as it is important such refunds rely on the quantity of the product dispensed. Across the supply chain, WAC is the standardized public pricing metric available to all entities. Further, this suggested (quantity) dispensing practice is standard and consistent among relevant stakeholders seeking payment for prescription drugs. Lastly, **CMS should ensure manufacturers do not pay higher than WAC for any payment or refund of MFP. Also, the MTF must be required to provide to the manufacturer the cost bases amount used for the calculation of the MFP -** bolstering efforts for manufacturers to comply with statutory requirements.

GSK believes these metrics and processes reflect the current reimbursement structure that allows manufacturers a consistent framework to base payments, making implementation smoother across the supply chain. This level of transparency will allow manufacturers the ability to understand the metrics used to calculate MFP.

VI. Section 40.4.4 – Options for MTF Payment Facilitation

<u>Recommendation:</u> CMS should require mandatory participation and work with HRSA to implement CMPs for noncompliance with the IRA's price setting program[3], on all entities, including pharmacies and dispensing entities. Additionally, CMS should implement Option 2 (provide banking information) and allow manufacturers to agree with dispensers on payment timelines.

GSK recommends CMS require mandatory participation in the MTF payment processor and implement CMPs for noncompliance with the IRA's price setting program[4] on all entities, including pharmacies and dispensing entities. Requiring payment participation with flexible dispenser timelines will ensure the program has functional operation measures, encompassing all covered entities. Without these metrics, manufacturers do not have relationships with every pharmacy in the U.S. – and cannot operationally, nor feasibly, establish multiple payment processes for all pharmacies across the supply chain.

Most importantly, GSK believes that without requiring mandatory MTF payment participation of all program entities, manufacturers will not be able to comply with providing MFP to every pharmacy – specifically those not utilizing CMS's payment facilitation model accurately and within a short time frame. Further, lack of mandatory participation allows pharmacies to come back to manufacturers to request additional payments of WAC + MFP, which without clarity, results in manufacturer disputes.

GSK supports CMS's Option 2, *MTF Pass Through of Primary Manufacturer Funds to Dispensing Entities*. However, GSK encourages CMS to develop a hybrid-model for MTF payment facilitation.

[3] Specific to the IRA's Price Setting Program, implemented through this Proposed (once final) Guidance.
[4] *ibid*

Specifically, the model should include banking information provided by the MFP recipient. Lastly, manufacturers electing to provide MFP refunds outside the MTF payment facilitation process should be able to agree with dispensers on a payment timeline.

Like most manufacturers, GSK does not have established relationships with every pharmacy in the country and developing case-by-case pharmacy arrangements at the single-entity level is not operationally feasible. By not implementing these specific practices and requiring program participation of all entities involved in effectuating MFP, the lack of consistency could create supply chain disruptions for manufacturers, pharmacies, and patients.

VII. Section 40.4.5 – MTF Dispensing Entity Participation Requirements

Recommendation: **GSK recommends CMS revise its current position, which allows dispensers the ability to opt-out of participating in the MTF. Instead, CMS should make MTF participation mandatory to participate in the Medicare program, similar to the requirement for CGDP and the new IRA Medicare Part D Redesign Program.**

GSK believes CMS should revise its current position, which allows dispensers to opt out of the MTF. Instead, CMS should require mandatory participation of dispensers so that manufacturers have a way to ensure they are receiving transactions from all pharmacies in the U.S. A manufacturer's ability to anticipate the timelines that dispensers are required to participate in the MTF provides the transparency that arrangements will be fulfilled. This clarity and enforcement strengthen the ability of manufacturers to fulfill statutory requirements to offer MFP to all eligible beneficiaries.

Unlike dispensers, manufacturers have statutory obligations to provide entities with MFP, otherwise manufacturers can be assessed CMPs. CMS should require and provide oversight that dispensers remain contractually obligated to remain part of the MTF if there is an agreement to participate. This requirement will ensure manufacturers are compliant with price setting program requirements.

VIII. Section 50 - Negotiation Factors

Recommendation: **GSK recommends CMS clarify the weight of factors to develop MFP; GSK recommends CMS product value factors should be weighted heavier than the manufacturer specific data.**

The negotiation factors focused on comparative product value ("Evidence About Alternative Treatments", e.g., comparative effectiveness) should be weighted much more highly than the factors focused on cost recovery ("Manufacturer-Submitted Data", e.g., R&D costs). The "Manufacturer-Submitted Data" factors have no connection to the value that a product brings to patients and society. Consideration of these factors in developing an MFP will further negatively impact innovation and create misaligned incentives for the development of drugs that address diseases with highest unmet need.

IX. Section 50.1 – Manufacturer Specific Data

Recommendation: GSK recommends CMS provide clarity that manufacturers are only obligated to report restatements to government price (GP) calculations during the price setting period.

GSK recommends CMS provide clarity to manufacturers for how they should report restatements to data submissions required of Primary Manufacturers under sections 1193(a)(4)(A) and 1194(e)(1) of the Act and previously submitted to CMS through the initial response to the Negotiation Data Elements ICR Form. GSK supports submission during the active price setting period, opposing requiring manufacturers to report GP restatement updates once the MFP is set. Without clarity in a final guidance, manufacturers could face the obligation to provide ongoing restatements to GP reporting, creating unnecessary operational burdens for manufacturers.

X. Section 50.2 – Evidence About Therapeutic Alternatives (TA) for the Selected Drug, Section 60.3.1 - Identifying Indications for the Selected Drug and Therapeutic, & Section 60.3.3.1 - Analysis for Selected Drugs with Therapeutic Alternative(s)

Recommendation: GSK recommends CMS limit therapeutic alternative comparisons to only in-class therapy indications, only price compare products with equivalent dosing administration, and rely on clinical expertise and patient feedback when conducting product comparisons and provide transparency into the review process.

GSK recommends CMS limit therapeutic alternative comparisons to only in-class therapies. Additionally, therapeutic alternatives used as price comparators should only include products with the same dosing requirements (e.g., once daily). Further, GSK recommends CMS refrain from considering products' off-label use as a price comparator when establishing MFP. Using a product's off-label use, as opposed to a product's indication, is too broad a framework for CMS to establish a comparative pricing alternative. CMS should consider the ramifications of comparing products that are not fully equivalent – including generic products – and how that practice could stifle future therapy innovation.

Selection of therapeutic alternatives should be based solely on clinical appropriateness; cost of alternatives should not be considered – this includes generic products. In previous IPAY guidance, CMS considers a comparable drug class when looking at therapeutic alternatives to benchmark the price of a newly selected MFP product. In this new 2027 Proposed Guidance, CMS suggests they may take a more expansive view of therapeutic alternatives, including greater consideration of therapies outside of a drug's class. Compared to the original 2026 guidance, this suggests CMS is downgrading reliance on clinical appropriateness by considering the price of products outside of a drug's class.

Clinical guidelines are the most appropriate and useful source of information in therapeutic alternative selection. Existing evidence, including clinical trials and pre-/post-approval real-world evidence, should also be considered in decisions on therapeutic alternatives, with the recognition that registration of clinical trials may have used comparators that were appropriate at the time but are no longer relevant due to advances in treatment and new standards of care. CMS should also directly engage clinical experts to inform therapeutic alternative selection. These are existing

practices used by clinicians and provide a consistent framework for patients to obtain the medicines they require.

Additionally, GSK recommends CMS rely on clinical expertise and patient experiences when seeking to determine therapeutic alternatives. To ensure the Agency is using viable metrics, CMS should provide manufacturers' transparency into the review process to ensure proper comparisons are being used as therapeutic alternatives.

Finally, in the appendix CMS offers a new definition of "therapeutic advance." This definition states that "a selected drug may be considered a therapeutic advance when … (it) represents a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s)." It is unclear why an improvement would need to be "substantial" to be considered a therapeutic advance, and further CMS offers no criteria for what is considered "substantial." This seems like an unreasonably high standard and could result in arbitrary, inconsistent, and non-transparent determinations. GSK recommends that CMS reconsider "substantial" as the standard, and that criteria be provided to help ensure consistency in applying the standard.

XI. Section 60.3 – Methodology for Developing an Initial Offer

Recommendation: **GSK recommends CMS define the methodology for calculating therapeutic alternative pricing and ensure manufacturer transparency exists during the price setting process to confirm proper price comparisons are made between the therapeutic alternative and the selected product.**

CMS should ensure that price comparisons for selected products and therapeutic alternatives are properly calculated to ensure they are comparable and should consider making this information available during the negotiation process. Transparency is a key element and attribute to this process.

It is important that CMS ensure manufacturers' ceiling price is calculated correctly and proper therapeutic alternative comparisons are used to effectively ensure appropriate pricing to manufacturers. CMS states that they may use an alternative methodology to calculate the price per 30-day equivalent supply for the therapeutic alternative(s) covered under Part B, but CMS provides no clarity as to how this will be done.

Specifically, CMS should consider the proper dosing of selected products and their therapeutic alternatives (e.g., factors including, but not limited to, weight-based dosing, loading doses, different dosing schedules comparing manufacturer product & alternatives). GSK understands CMS is providing a calculation of the manufacturer ceiling price, but the proposal does not state how CMS will calculate pricing across doses and forms for therapeutic alternative products. Also, it is not clear whether CMS will provide visibility to therapeutic alternative price calculations during the negotiation process. GSK believes CMS should provide manufacturers with the methodology used to develop offers, especially for complex biologics. Not only does GSK believe it is important that CMS use proper price comparisons, but also that CMS should base such pricing and rely upon clinical expertise when reviewing weight-based dosing.

XII. Section 60.4 – Negotiation Process

<u>Recommendation:</u> CMS should allow manufacturers visibility to third-party input received for the initial offer.

CMS should implement a patient and provider engagement framework for incorporating clinical and patient-centric metrics when evaluating MFP-selected products and their therapeutic alternatives. Specifically, CMS should adopt the following to appropriately assess clinical value and unmet need:

- Provide targeted questions to patient and/or provider groups;
- Solicit clear, specific outcomes of interest;
- Conduct focus group-like sessions with patients and/or providers;
- Leverage existing beneficiary communication tools (e.g., call centers, beneficiary surveys) to conduct patient surveys;
- Incorporate methodology for using patient and/or provider input into MFP justification; and
- Establish standards on qualitative and quantitative data to understand what defines "good."

The engagement recommendations should apply to other sections including adjustment of starting point (Section 60.3.3), selection of therapeutic alternatives (Section 60.3.3.1), and the price setting process (Section 60.4). Further, manufacturers need to have visibility to the meeting minutes, third-party meetings, and written commentary when developing the MFP offer. In order to have an effective and transparent price setting process, CMS needs to provide manufacturers with a summary of feedback received by third parties that helped inform the price setting process.

XIII. Section 60.4.3 – Negotiation Process After Manufacturer Counteroffer

<u>Recommendation</u>: GSK recommends CMS provide manufacturers comprehensive, written materials for counteroffers in addition to face-to-face meetings in price setting meetings to discuss the offers and counteroffers.

GSK recommends CMS allow manufacturers the opportunity to meet with the Agency, virtually or in-person, during the price setting process regarding offers and counteroffers. Negotiation cannot occur without proper dialogue to ensure CMS and manufacturers understand the offers and counteroffers made.

XIV. Section 60.6 – Publication of the MFP

<u>Recommendation</u>: GSK recommends CMS refrain from implementing retroactive MFP application given this could create duplicative 340B payments.

In Proposed Guidance, CMS solicits feedback on the potential revisions to files that should be handled to address situations where MFP would need to be retroactively applied to reprocess selected drug claims. GSK recommends CMS consider how 340B payments would work with this type of retroactive process. Without 340B claims verification provided to the manufacturer or MTF, manufacturers could be subject to duplicate discounting – resulting in manufacturers cash flow issues. Unless CMS requires covered entities to provide manufacturers and/or the MTF with claims data to identify 340B units, retroactive MFP would result in federally prohibited duplicate discounts.

XV. Section 90.2.1 – Manufacturers Plans for Effectuating MFP

<u>Recommendation</u>: GSK recommends CMS batch claims - consistent with the current CGDP process, refrain from posting manufacturer plans in a public format, and clarify dispenser participation in the MTF payment process aligns with manufacturer agreements.

Specifically, GSK believes the 14-day cycle CMS proposes results in manufacturers receiving daily claims, creating undue burden and costs to manufacturers to process daily unbatched claims. In addition to batching claims, CMS should extend the claims approval timeline to reflect the current CGDP timelines (no less than 38 days) to process claims. GSK recommends CMS refrain from posting manufacturers' plans in a public format (e.g., online), even if proprietary information is redacted. The distribution of this information should be limited to Part D stakeholders (e.g., dispensers) like the current CGDP process works today.

Further, to ensure manufacturers can effectuate MFP, CMS should clarify how the voluntary nature of dispenser participation in the MTF payment process aligns with the detailed requirements expected from manufacturers in the (dispenser) plans submitted to the agency. Lastly, to ensure CMS receives communication from stakeholders providing more detailed feedback on effectively implementing this process, CMS should issue the relevant ICR associated with this Proposed Guidance as soon as possible.

XVI. Section 90.2.2 – Negotiation Program Complaints and Disputes Process

<u>Recommendation</u>: **GSK recommends CMS refrain from mirroring the CGDP dispute process and apply CMPs to pharmacies to ensure program compliance.**

Should CMS seek to mirror the CGDP process, GSK recommends CMS first consider providing clarity within the final guidance to ensure the MTF/CMS review(s) 340B claims on behalf of the manufacturer as opposed to the covered entity. Specifically, CMS should establish an appeals process for disputes and provide clarity on dispute parties (e.g., if a dispenser claim hinges on an error in data provided to the MTF, dispute should be between dispenser and Part D plan, not the Primary Manufacturer). CMS should also require dispensers, members of the public, and others to engage in good faith efforts with manufacturers to resolve disputes prior to submitting complaints through the CMS process.

As previously stated, MFP claims should be subject to the same level of validation as other Medicare Part D claims. A few examples include identification of transaction items where quantity falls outside of the defined minimum or maximum quantities defined for the product, duplicates identified in Medicare Part D utilization, 340B discounts, and instances where the pharmacy is not valid. Claims scrubbed as part of these validations should not be subject to the MFP and disputed. GSK also recommends CMS provide clarity on timelines associated with the dispute resolution process. Lastly, CMS should clarify that manufacturers utilizing private contracts to effectuate the MFP can require parties to abide by dispute decisions.

Additionally, while GSK understands that CMS may lack certain enforcement authority over providers, CMS could include certain terms and conditions to help facilitate the MFP process through Medicare program agreements.

To ensure manufacturers can provide MFP and meet statutory requirements of the law, GSK recommends CMS apply CMPs to pharmacies (similar to manufacturers) to ensure program compliance and that the chargeback model works effectively. As the proposal exists now, manufacturers do not have safeguards to ensure other program entities will participate and comply with the program. For example, manufacturers cannot sell at the MFP amount via the chargeback model because of pharmacy diversion issues related to 340B.

XVII. Section 100.1 - Failure of Manufacturer to Ensure Access to a Price Less than or Equal to the MFP

Recommendation: GSK recommends CMS ensure the MFP-selected products are not disadvantaged on drug formularies.

CMS should ensure that products selected for MFP are not disadvantaged on plans' drug formularies. It is foreseeable for PBMs to prefer non-MFP products with high manufacturer rebates over MFP products, potentially subjecting the MFP product to utilization management. Currently, there is no requirement for plans to cover or prefer MFP-selected products on Part D formularies. GSK is concerned that the broad flexibility CMS provides plans to bypass MFP-selected products places manufacturers in an unfair position when negotiating pricing agreements with health plans as plans are guaranteed a manufacturer's MFP regardless of whether the MFP product has utilization management in place relative to a competitor product.

XVIII. Appendix

Primary Manufacturer agreements with Secondary Manufacturer

Recommendation: GSK recommends CMS refrain from holding Primary Manufacturers responsible for Secondary Manufacturers.

GSK believes CMS should remove that requirement that Primary Manufacturers are responsible for Secondary Manufacturer's operational effectuation of MFP. Secondary Manufacturers are legal actors with distinct corporate identities and have their own agreements with CMS for Medicare participation. CMS's policy is likely to result in unforeseen, unworkable scenarios, including situations where a Primary Manufacturer may need to provide or receive proprietary data from the Secondary Manufacturer (such as potentially 340B or sales data) in order to comply with CMS policy, conflicting with fundamental corporate law principles.

XIX. ICR Comments

Recommendation: GSK recommends CMS's new required manufacturer net Medicare Part D price definition in the ICR, use the same calculation as defined in Section 60.3.2.

CMS should remove reference to other supply chain concessions that do not apply to the calculation defined in Section 60.3.2. Manufacturers cannot "follow-the-pill" through all of the possible entities in the supply chain. GSK generally sells its products indirectly through wholesalers and specialty

distributors. Even if GSK had chargeback or other data from the wholesaler's sale to a pharmacy or a provider/supplier, GSK has no visibility to the patient to which a unit of product is dispensed or administered. Consequently, there would be no connecting that unit of product to a subsequent payer rebate. In most cases, GSK would lose the ability to track a product after the sale to the wholesaler or specialty distributor. GSK is unaware of any system that currently permits a drug unit to be tracked through all possible supply chain purchasers. A new standard and information collection process would need to be implemented to enable the type of "track and trace" system necessary to operationalize this misguided proposal. Manufacturers would be unnecessarily penalized by a policy that is fundamentally counter to a plain reading of statute and operationally infeasible.

In conclusion, GSK believes that while the IRA includes provisions intended to reduce federal government spending and lower prescription drug costs for Medicare beneficiaries, it also will have unintended consequences, well beyond those products selected for direct price setting. As stated in our concerns, the IRA includes provisions that could harm future biopharmaceutical innovation and inadvertently negatively impact patient access to medicines and vaccines. Moreover, GSK is concerned that without the appropriate consideration and meaningful balancing of stakeholder input, those meant to benefit from this program – Medicare patients – could, instead, be detrimentally affected. GSK is deeply committed to our patients and believes it is very important that CMS seek feedback to incorporate patient advocates' recommendations throughout the implementation of the IRA.

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GSK appreciates the opportunity to comment on the IPAY 2027 Proposed Guidance. Please contact Harmeet Dhillon harmeet.s.dhillon@gsk.com if you have any questions about the topics discussed in our comments or if GSK can provide any further information.

Sincerely,

Harmeet Dhillon

www.HaystackProject.org

VIA ELECTRONIC DELIVERY to: IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Brooks-LaSure:

Last year, Haystack Project submitted comments to the Centers for Medicare & Medicaid Services' (CMS') initial guidance for initial payment applicability year (IPAY) 2026, cautioning that "(a) the IRA has the potential to exact unintended, but catastrophic, consequences for patients with extremely rare conditions; and (b) CMS may not have a sufficient understanding of our communities' unique challenges to steer its policies in a "do no harm" direction." Once again, we have significant concerns that CMS' implementation of the Medicare Drug Price Negotiation Program (MDPNP) continues to stray from the patient-centered approach this Administration has committed to take as steward of the Medicare program. CMS' proposals to expand opportunities for patient engagement are welcome procedural refinements that are, unfortunately, unlikely to resolve the potential for unintended consequences on patient access to existing treatments and development of new rare and ultra-rare disease treatments.

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare (20,000 or fewer US patients) disease patient advocacy organizations to coordinate and focus efforts that highlight and address systemic reimbursement obstacles to patient access. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for

all Americans. We strive to amplify the patient and caregiver voice in these disease states where unmet need is high and treatment delays and inadequacies can be catastrophic.

Our comments to the Initial Guidance for IPAY 2026 emphasized that there are inherent differences in commercial realities between the treatments our patients and caregivers rely upon and those that address more common diseases and conditions. We briefly reiterate those contextual factors that increase the likelihood that the MDPNP will exact unintended consequences on our patient communities. Our primary concern with last year's guidance was that CMS' statutory interpretations and implementation policies created very real financial disincentives to investment in ultra-rare indications for new and existing treatments. Rare and ultra-rare disease patients similarly fear that CMS' pursuit of aggressively low negotiated prices in the initial years of the MDPNP could further disrupt incentive frameworks for development of new rare and ultra-rare treatment options. We ask that CMS take a cautious approach when considering initial offers significantly below the ceiling price in the initial years of the MDPNP and do so only when there is a compelling, patient-centered justification.

Haystack is also concerned that the Draft Guidance for IPAY 2027, taken as a whole, adds a new threat. Specifically, the combination of an expansive view of "qualified single source drug," the potentially unworkable Primary/Secondary Manufacturer framework, and CMS' failure to account for supply chain transactions impacting acquisition costs for dispensing entities make the negotiation program a riskier prospect than the statute requires. CMS has faced several lawsuits that challenge the Agency's implementation policies and statutory interpretations and assert that the penalties for not participating in the MDPNP are coercive. We expect that CMS' refinement of the processes for manufacturers declining to enter into a negotiation agreement, including mechanisms that would enable manufacturers to avoid imposition of excise tax penalties, were newly incorporated to mitigate the chance that any of the lawsuits challenging the MDPNP would succeed. Haystack Project recognizes that fundamental concepts of "agreement" and "negotiation" assume an element of choice for all parties.

We also doubt that Congress intended to create a Medicare cost-savings program that could ultimately deprive patients covered by the Medicare and Medicaid programs of necessary medications. The lack of legal challenges to the MDPNP from the patient community to date likely reflects both the lack of financial means groups like Haystack have to mount such a challenge and the widely held belief that declining to participate in the negotiation process was not a real option. We may not see a manufacturer decline to participate in negotiation this year, but the possibility is real. Once a manufacturer

withdraws their products from the Medicare and Medicaid programs, it will be too late to prevent the resulting harms to patients.

Background

Despite existing incentives for orphan drug development, significant unmet need predominates in extremely rare conditions and rare cancers:

- Of the approximately 7,000 rare diseases identified to date, 95% have no FDA-approved treatment option.
- 80% of rare diseases are genetic in origin, and present throughout a person's life, even if symptoms are not immediately apparent.
- Patients often progress to more serious and more costly disease states by the time they receive a diagnosis.
- If a diagnosed condition has no FDA-approved option, treatment often involves off-label use of existing products.
- lack of disease-specific natural history severely complicates research toward new, targeted treatments.

The economic calculation of unmet patient need balanced against research and development costs, projected risk, and population-based revenue estimates is complex and often fragile. As affected populations dwindle below 20,000 or even into and below the hundreds, the balance can be far more tenuous, and risks or uncertainties can discourage the investor interest required to take promising therapeutic candidates from bench to market.

Haystack and its member organizations appreciate that the IRA Part D benefit redesign provisions offer significant financial relief to our patient communities. We expect that the Part D out-of-pocket cap will reduce financial stress on patients and their families so that more patients can base their treatment decisions on medical need rather than financial resources. Since most ultra-rare disease patients will routinely reach the $2000 out-of-pocket cap within the initial months of the plan year, it is unlikely that they will receive the financial benefits from the MDPNP that individuals with more common conditions treated by less costly drugs receive. Our communities of patients and caregivers fear that unless CMS recognizes the potential impacts the MDPNP might have on rare disease treatment access and innovation, its implementation of the negotiation program will likely disrupt the

balance of incentives and risks inherent to developing new treatments and new uses of existing treatments for ultra-rare conditions.

CMS' definition of qualified single source drug is a broad interpretation of the IRA that frustrates Congress' intent to consider therapeutic alternatives.

CMS' MDPNP guidance for IPAY 2026 was drafted as "final" with respect to the decision to broadly define "qualified single source drug" (QSSD) for negotiation eligibility and selection purposes. Haystack appreciates CMS' stated intent to consider comments on this portion of the Draft Guidance for IPAY 2027. We had previously noted that the definition of QSSD will shape the MDPNP and could negate existing incentives for manufacturers to secure new approvals in small population conditions. In reiterating its intent to maintain its policy of defining QSSD through active moiety or active ingredient, CMS stated that:

> This approach to identifying a potential qualifying single source drug aligns with the requirement in section 1192(d)(3)(B) of the Act to use data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. Consistent with this statutory instruction, this approach is also appropriate because CMS is aware that existing NDA / BLA holders have obtained approval for new dosage forms or different routes of administration of the same active moiety/active ingredient under different NDAs or BLAs.

Haystack once again urges CMS to reconsider this approach. The IRA's timeline for negotiation eligibility begins at FDA approval of an NDA or BLA, not the manufacturer's first NDA or BLA approval for an active moiety/active ingredient. Longstanding public policy has, however, favored pursuit of new NDAs/BLAs that enable on-label use of treatments in multiple diseases and conditions, including multiple orphan and/or non-orphan conditions and mixes of orphan NDAs/BLAs with approvals in more common conditions. There are also instances where FDA finds that a manufacturer's new formulation is sufficiently distinct from the original NDA/BLA that it is, in essence, a new product. By wrapping all treatments with the same active moiety/active ingredient into a single QSSD, CMS fails to distinguish between reducing incentives that deter generic competition and neutralizing incentives that further public policy goals and/or align with FDA processes and determinations.

We remain concerned that defining QSSD by active moiety/active ingredient will have a significant detrimental effect on new approvals of existing drugs, particularly in ultra-rare

diseases for which statutory exclusivity has helped drive research and development. It is unlikely, if not impossible, that a manufacturer could recoup the costs of achieving FDA approval in an ultra-rare follow-on indication for a drug subject to a negotiated price, particularly given the relatively short timeline to renegotiation to a lower price based on a change in status to long monopoly drug.

Moreover, the statute directs CMS to consider the cost of therapeutic alternatives to a selected drug in reaching an initial offer. This makes far less sense within the context of multiple indications in divergent disease states with diverse sets of recommended dosages and alternative therapies. Any calculation based on aggregated and/or weighted costs of therapies that are appropriate for some, but not all, indications would likely fail to reflect the cost of other treatments for **any** indication.

The examples below illustrate the operational complexities associated with CMS' QSSD definition and the impact that definition could have on new approvals in ultra-rare conditions:

- Imbruvica provides an example of divergent uses and therapeutic alternatives. Imbruvica's highest volume of use in Medicare is for Chronic Lymphocytic Leukemia (CLL) but a year before its selection for negotiation, it was approved for pediatric chronic graft versus host disease (cGVHD). This is a very rare indication for which many of the underlying conditions leading to a need for transplant are extremely rare. Imbruvica has lost market share year over year due to competing products within its therapeutic class and is scheduled for renegotiation as a "long monopoly" drug for IPAY 2030. The in-class competition has led to improved alternatives within the BTK inhibitor class for CLL patients. Haystack is concerned that the MDPNP will discourage manufacturers of newer BTK inhibitors from pursuing new approvals in cGVHD given that the high proportion of Medicare patients will drive a short timeline to selection for negotiation followed by relatively rapid selection for renegotiation.

- Gavorestat is an investigational aldose reductase inhibitor that is being studied in two orphan indications, Galactosemia and sorbitol dehydrogenase deficiency (SORD), a recently discovered type of Charcot-Marie-Tooth disease. Future studies are also being considered in PMM2 congenital disorder of glycosylation (*PMM2*-CDG). These conditions do not fall into a single orphan designation and the product would be ineligible for the MDPNP orphan drug exclusion. A manufacturer could mitigate the risk that the MDPNP might hamper its ability to generate sufficient

revenue to cover research and development and recognize an acceptable return on investment by seeking approval in a single orphan indication, adjusting launch pricing to account for IRA impacts, or both.

- Although introduction of a biosimilar may prevent CMS' selection of the biologic denosumab, this treatment illustrates the unintended consequences of CMS' active moiety/active ingredient definition of QSSD. Prolia is administered as 60 mg subcutaneous injection every 6 months for its FDA-approved indication in treating osteoporosis. Denosumab is also approved under the brand name Xgeva for bone metastasis, multiple myeloma (approximately 37,000 cases per year) and in giant cell tumors of the bone (an extremely rare (1 in 1,000,000) predominantly noncancerous condition that destroys the bone). The recommended dose of XGEVA is 120 mg administered as a single subcutaneous injection once every 4 weeks additional 120 mg doses on days 8 and 15 of the first month of therapy. CMS' definition of QSSD creates problems that make it all but impossible to utilize the statutory process and arrive at any initial offer that reflects the cost of treatment based on therapeutic alternatives for any indication. Differential dosing and extremely divergent therapeutic alternatives are relatively common for products with multiple approvals and especially so when one or more approval is in an ultra-rare condition.

As we stated in comments to the guidance for IPAY 2026, FDA approval is extremely important within the context of ultra-rare conditions. Individuals with relatively common conditions have access to off-label use of promising therapies developed for other conditions based on compendia listings. Off-label treatments for extremely small population conditions are rarely included in the various compendia relied upon for Part D coverage. This means that even if an off-label use is within the standard of care, lack of compendia inclusion places that medically necessary treatment outside the definition of Part D covered drug and patient access is completely foreclosed. Over the years, Haystack has heard from several patient groups that treatments within the standard of care for their ultra-rare condition are simply not covered.

We are also concerned that CMS' definition leads to complicated Primary/Secondary Manufacturer relationships. It is not uncommon for smaller manufacturers to fund research and development efforts by licensing arrangements providing for exclusive commercialization rights for one or more indications to another manufacturer. These arrangements may, but do not always, provide for the licensing manufacturer to hold the NDA/BLA. Under CMS' QSSD definition, whether these separate NDAs/BLAs for distinct indications are considered one drug for which negotiation eligibility turns on the date of the

first NDA/BLA will depend solely on whether pre-IRA contract terms provided for the manufacturer with commercialization rights also holds the NDA/BLA. Although it appears that the Draft Guidance would permit the Primary Manufacturer to transfer the NDA/BLA to the Secondary Manufacturer, we believe that CMS' QSSD definition and delegation of all MDPNP responsibilities and liabilities to the Primary Manufacturer significantly impacts both the value of the NDA/BLA and the relative negotiation positions between the parties.

As noted above, Haystack is concerned that CMS' approach will not only eviscerate existing incentives for manufacturers to study new, ultra-rare uses of existing drugs, but increase the likelihood that a manufacturer might look at the MDPNP as a whole and determine that withdrawal from Medicare and Medicaid agreements is the better business decision. That possibility is particularly dangerous for our patient communities given the limited set of available therapies to manage ultra-rare disease symptoms or slow disease progression. We firmly believe that CMS can achieve the MDPNP's goals of lowering prices of high-cost prescription drugs without deterring innovation in rare and ultra-rare diseases or creating unworkable scenarios for manufacturers that have transferred commercialization rights for specific indications to one or more other, unrelated entities.

The Orphan Drug Exclusion should be implemented (or amended) to maintain incentives for developing new treatments in rare conditions and expanding labeled indications of existing therapies.

Haystack recognizes that CMS has limited discretion in implementing the orphan drug exception, and its implementation policy likely reflect its view that the statute requires CMS confirmation of a single orphan designation into which all approved indications fit.

Our member organizations have voiced significant concerns that the IRA's narrow exception for orphan drugs would introduce a new set of considerations to deter pursuit of FDA approval for multiple uses of promising new therapies. The smaller the population, the less likely it is that a manufacturer could justify investing in the research needed for FDA approval, particularly when such approval would lead to loss of eligibility for the exception. Our patient communities are particularly concerned that:

- Manufacturers will tend to focus on an orphan designation with the largest patient population, even if studying the product in that population might delay a first approval.

- Research and development programs confirming clinical benefit for accelerated approval treatments may be halted and indications/designations withdrawn if they fall outside a single orphan drug designation.

- Investors and shareholders will pressure manufacturers to ensure that initial price points for newly approved drugs are sufficient to recoup research and development costs and achieve a profit margin from successful innovations.

Once again, we appreciate that CMS has limited discretion in implementing the orphan drug exception. We believe, however, that CMS could significantly alleviate the concerns expressed by Haystack and other patient advocacy organizations by revising its QSSD definition from the active moiety/active ingredient framework to the NDA/BLA approach outlined above. CMS could comply with the statutory requirement that it aggregate dosage forms, strengths, and formulations for each NDA/BLA.

Finally, we reiterate our request from last year's comments that CMS engage in meaningful dialogue with Haystack Project and other patient-centered organizations to preserve the balance in incentives and risks that has spurred innovation in rare and ultra-rare disease treatments, including through CMMI and CMS' general demonstration authority.

CMS' criteria for identifying off-label uses and therapeutic alternatives does not fully account for uses in ultra-rare conditions.

Haystack remains concerned that CMS' implementation of the MDPNP fails to consider ultra-rare patients for whom unmet need is a near-universal reality. The Draft Guidance retains the criteria applied in IPAY 2026 with respect to identifying off-label indications. Specifically, CMS will look first to the FDA-approved indications that are not subject to a Part D coverage exclusion and then consider off-label uses that are included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. Since ultra-rare off-label tend not to receive attention from CMS' set of recognized compendia, CMS will not consider the experience of these patients, the set of therapeutic alternatives available, or any unmet need the selected drug addresses. Although these ultra-rare uses are often rendered non-covered based on the statutory definition of a Part D covered drug, there are instances for which patients receive coverage based on the disease symptoms for which the drug is prescribed. For example, a hypothetical anti-hypertensive product might be the standard of care in a hypothetical ultra-rare condition that leads to severe hypertension. CMS' set of evidence sources for identifying off-label uses would not reveal the ultra-rare use or that the specific drug is the **only** product that can manage

hypertension without exacerbating underlying disease symptoms or introducing significant side effects.

CMS' process for identifying potential therapeutic alternatives introduces a different set of complexities. CMS states that it will look beyond the sources used to identify off-label uses and include clinical guidelines and peer-reviewed studies. To the extent that the drug is not used for a cancer indication, this expansive set of therapeutic alternatives could include treatments that are outside the definition of a Part D covered drug and ineligible for coverage. Haystack and its member organizations are acutely aware that their prescribed medications may be noncovered by Part D due to lack of inclusion in compendia because it impacts their access to treatment. We expect that many stakeholders are unaware of the impact of CMS' broad interpretation of therapeutic alternatives.

If CMS intends to include noncovered treatments within the set of therapeutic alternatives considered in calculating an initial offer, it should state that intention clearly so that stakeholders have an opportunity to comment. An alternative approach might be to broaden the set of uses of the selected drug CMS considers and, if an ultra-rare use is not included in compendia but is supported by guidelines and/or peer-reviewed studies, the evidence for therapeutic alternatives should similarly not be limited to compendia-listed uses.

CMS should reconsider its decision to engage in complex, subjective inquiries to confirm that a generic drug or biosimilar is marketed on a bona fide basis.

Haystack understands that one of the goals of the MDPNP is to shift manufacturer incentives away from behaviors that deter generic competition. We support that goal and believe that robust competition through multiple branded in-class treatments can lead to improved treatment options and introduction of generic competition can reduce drug costs. The IRA seeks to rebalance incentives by exempting products with generic competition from the MDPNP. We urge CMS to apply the exemption in a manner that aligns with the statutory goals of changing manufacturer behaviors. An inquiry into the behavior of unrelated entities that have secured approval to market generic alternatives reduces the extent to which any manufacturer can avoid price negotiation by removing obstacles to generic product development.

CMS has acknowledged that there is no objective measure of bona fide marketing and suggested that it will engage in a holistic inquiry based on the totality of the circumstances. This ambiguous bona fide marketing requirement will inevitably lead to inconsistencies in

any determination on whether introduction of a generic or biosimilar exempts a particular drug from selection. CMS' stated intent to continue monitoring marketing activities of a generic or biosimilar manufacturer to ensure that those activities continue to constitute bona fide marketing creates an additional layer of unpredictability. We believe that these activities will require significant time and expertise within the Agency and ultimately complicate successful MDPNP implementation. We do, however, support CMS' inquiry into whether a manufacturer enters into an agreement with a generic competitor to limit the number of generic or biosimilar units marketed or influence the pricing of a generic or biosimilar.

Haystack appreciates CMS' proposal to expand its stakeholder engagement beyond the listening sessions conducted for IPAY 2026.

Haystack has met with CMS to express its concerns with the listening session format for patient engagement, and we appreciate CMS efforts to enhance opportunities for patients to contribute to CMS' decision processes through patient-focused events. In particular, we support CMS events that are patient-focused and facilitate discussion among speakers and dialogue between speakers/attendees and CMS staff.

We urge CMS to:

- Leverage relationships with patient advocacy organizations, including Haystack, by enabling CMS participation in events organized by these organizations. We expect that patient participation and willingness to engage in candid dialogue would be more robust when conducted within the familiar context of an advocacy organization event.
- Provide clear information on the types of information CMS seeks and how it intends to use that information in arriving at an initial offer for a selected drug.
- Permit questions from patients and clinicians on the MDPNP generally as well as the impact negotiation might have on the patient's access to and cost of the selected drug.
- Ensure that patients and clinicians are informed on applicable formulary requirements, including limitations on adverse tier placement, step therapy protocols, and burdensome prior authorization requirements so they can advocate for their access to the selected drug and/or alternative therapies.

Conclusion

Haystack appreciates the opportunity to submit feedback on the Draft Guidance for IPAY 2027. Our member organizations remain concerned that CMS decisions on the initial years of the MDPNP could determine the set of new treatment options in ultra-rare conditions for the foreseeable future.

We would appreciate the opportunity to meet with IRA implementation staff and leadership to further discuss the concerns within our communities so that the MDPNP improves the experience of Medicare beneficiaries with ultra-rare conditions. We thank you for your consideration of our comments and look forward to a substantive discussion to ensure that all Medicare beneficiaries have access to the treatments they need.

Alliance to Cure Cavernous Malformation
Alstrom Syndrome International
Association for Creatine Deficiencies (ACD)
Biomarker Collaborative
CancerCare
Casey's Cure Foundation
CDG CARE
Chondrosarcoma Foundation
Choroideremia Research Foundation
CLL Society
CSNK2A1 Foundation
Cutaneous Lymphoma Foundation
Desmoid Tumor Research Foundation
Dup15q Alliance
Exon 20 Group
Galactosemia Foundation
HealthTree Foundation
Hope for Stomach Cancer
ICAN, International Cancer Advocacy Network
International Foundation for CDKL5 Research
International Pemphigus & Pemphigoid Foundation
International Waldenstrom's Macroglobulinemia Foundation (IWMF
MET Crusaders
MitoAction
MLD Foundation

NTM Info & Research
Organic Acidemia Association
PD-L1 Amplifieds
SYNGAP1 Foundation
The Global Foundation for Peroxisomal Disorders
The Sturge-Weber Foundation
TSC Alliance
United Porphyrias Association
Usher 1F Collaborative
Usher Syndrome Coalition

Healthcare Distribution Alliance

HEALTH DELIVERED

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IRARebateandNegotiation@cms.hhs.gov

Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program **Draft Guidance**

Deputy Administrator Seshamani,

Thank you for the opportunity to respond to the Draft Guidance on the Medicare Drug Price Negotiation Program issued on May 3, 2024. Our comments address the sections of the guidance pertaining to the Manufacturer Effectuation of the Maximum Fair Price (MFP).

As you know, the Healthcare Distribution Alliance (HDA) is the national trade organization representing primary pharmaceutical distributors. HDA's members ensure the safe and efficient distribution of prescription medications to healthcare providers and the patients they serve. Our members are the vital link between the nation's pharmaceutical manufacturers and more than 300,000 pharmacies, hospitals, physicians, clinics, long-term care facilities, durable medical equipment providers, and other licensed sites of care nationwide.

1. Cash Flow Impact on Pharmacies

By its nature, a retrospective discount model strains the operating cash requirements of pharmacies because they must purchase inventory at the wholesale acquisition cost (WAC) and then endure a waiting period following dispensing to receive the retrospective discount.

We believe the projected length of the waiting period, as outlined in the guidance, will exacerbate the financial stress pharmacies are currently facing. Assuming it takes seven days for the claim to arrive at CMS' Drug Data Processing System (DDPS), one to two additional days for the claim to be delivered to the Medicare Transaction Facilitator (MTF), and another one to two days for the MTF to process and deliver the claim to the manufacturer, this results in a total of 9 to 11 days before the 14-day prompt pay clock begins, culminating in a potential waiting period of up to 25 days. Importantly, this best-case scenario assumes that the DDPS, the MTF, and the manufacturer efficiently process claims and that the current 30-day deadline for plans to submit data to DDPS is reduced to 7 days.

Most pharmacies pay their distributors on 15-day terms, so a 25-day waiting period will put extra pressure on even the best-operating pharmacies. It could worsen if the 30-day lag in submission of prescription drug event (PDE) data to DDPS is not reduced and the MTF reporting cadence is biweekly, potentially resulting in a 45-day waiting period before the 14-day prompt pay clock begins, even if the MTF is able to perform process claims and deliver them to manufacturers in a single day. Any measures that CMS can implement to shorten the duration of the best-case scenario would be beneficial to all dispensers. For example, if Part D plans could submit claims the day following adjudication, and if the DDPS and MTF processes could be optimized to ensure a one-day turnaround, the claims could reach manufacturers in three to four days, reducing the pressure on pharmacies.

2. Standard Default Refund Amount

We agree that requiring the standard default refund amount to be the difference between WAC and the negotiated MFP for Part D claims is both practical and equitable. We believe that if alternative refund methodologies are negotiated between manufacturers and pharmacies, there could be both operational and financial risks to pharmacies.

3. Electronic Remittance Advices

CMS is soliciting comments on electronic remittance advices. Many of our member companies operate Pharmacy Services Administrative Organizations (PSAOs) that provide central payment and central reconciliation services to independent pharmacies, routinely processing electronic data interchange (EDI) 835 remittance advices in their normal course of business.

In our collective experience, it is a best practice for the entity making the payment to produce the EDI 835, and it is essential that the grand total of the detail lines in the EDI 835 match the amount of the ACH deposit. While the EDI 835 is a healthcare remittance advice standard, it supports various implementation options. We recommend that CMS continue to engage with interested parties at the National Council for Prescription Drug Programs (NCPDP) to specify a formal implementation of the EDI 835 standard to support MFP payments. From a feature standpoint, a standardized implementation should allow for reporting one or more fields that can link details of a prospective payment to the retrospective process.

Since participation in any MTF payment facilitation will be voluntary for dispensing entities and manufacturers, we anticipate that manufacturers will require their contracted vendors to develop payment and remittance advice capabilities emphasizing the need for consistency. A standardized implementation with a single payment facilitator across all manufacturers would enable our members' central payment and reconciliation services to operate accurately and reliably for our pharmacy customers.

4. 340B Duplicate Discounts

CMS has encouraged wholesalers, along with other drug supply chain stakeholders, to collaborate with manufacturers and covered entities to address the 340B duplicate discount issue with potential industry solutions. We are concerned, however, that the lack of CMS guidance at this time may cause confusion and delay or limit industry from advancing the necessary solutions. We urge CMS to reconsider the MTF as a single entity handling data, payments, and 340B deduplication to ensure a seamless experience for the supply chain and patients on day one of the program.

It's important to note that duplicate discounts will occur at contract pharmacies if the covered entity (or its contracted administrator) follows the current practice of shipping replacement products to the contract pharmacy after retrospectively designating a Medicare claim as 340B eligible. We believe all affected parties are motivated to prevent duplicate discounts up front to eliminate the need for retrospective de-duplication and complex audits. This might be accomplished by patterning the processes in place today to ensure Medicaid claims are not dispensed using products purchased at the 340B price.

In addition, implementing a process that claws back MFP refunds as part of the 340B deduplication process would be confusing for dispensers and pose challenges for PSAOs and other entities managing reconciliation systems on behalf of pharmacies to align with 340B records, given the disparate and unconnected systems managing each function. Any 340B de-duplication process or system designed should take into account all stakeholders' operational and financial reporting requirements in the 340B process (manufacturers, distributors, dispensers, and covered entities).

5. Claim Adjustments and Reversals

With regard to whether CMS should recognize a specific timeframe for addressing claim adjustments, we believe that imposing such timeframes on the backend is unnecessary to ensure all parties are made whole. The Part D plans control the business rules governing these transactions, and they are best positioned to manage the timing of claim adjustments, which typically take the form of a reversal followed by a new claim. The backend process should mirror that of third-party payors when paying claims, where it is common for a claim to be paid in one payment cycle only to be reversed in the next payment cycle. It is critical that individual transactions flow through the entire backend system to ensure integrity, accountability, and accuracy at each step without the need for back-end imposed timeframes. In the case where a pharmacy submits and later reverses a claim within the same manufacturer payment batch, both transactions should be included as separate line items in the 835, reflecting a positive amount as payment for the claim and a corresponding negative amount for the reversal. This allows the reconciliation service receiving the remittance advice, such as the PSAOs operated by our member companies, to efficiently reconcile all transactions and address any discrepancies.

6. Function of CMS' DDPS System

In the revised guidance, CMS specifies that the MTF will furnish manufacturers with data verified independently by both the Part D plan sponsor and CMS' DDPS. This ensures dual verification for each claim, confirming both an individual's eligibility for Part D and coverage of the selected drug. However, this process introduces the risk of a claim being initially paid as an MFP claim by the plan but subsequently failing verification at the DDPS. Addressing this scenario requires thorough examination, as the dispenser will have already created a receivable record expecting payment for the claim. We would respectfully request that CMS provide guidance on what would be the remedy if this were to occur.

7. Collection of Pharmacy Payment Information.

CMS is soliciting comments on what information would be required by interested parties for either of its two options to efficiently facilitate payments. One critical element missing in the revised guidance is for CMS to also collect the delivery address for the EDI 835 remittance advice.

PSAOs that operate central pay and reconciliation services can play a valuable role by populating the pharmacy's financial information on behalf of the pharmacy, including the PSAOs central bank account information and the PSAOs delivery address for remittance advices.

Maintaining the financial information of dispensing entities will require more robust capabilities than might be apparent at first glance and warrants planning sessions with industry experts. Given that payors have been forced to implement over time, there must be protocols in place to control changes. Examples include pharmacy ownership changes and pharmacies switching from one PSAO to another. These changes typically require dual controls with future effective dates.

8. CMS Payment Facilitation Options

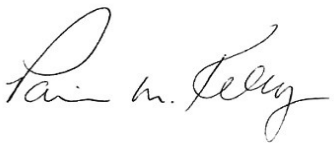
CMS is soliciting comments on the two MTF payment facilitation functionality options it is considering. Additionally, CMS is seeking input on any other functionalities interested parties believe would help facilitate timely refunds between manufacturers and dispensing entities to effectuate the MFP. As wholesalers, we are not directly affected and do not express a preference. However, we understand that our pharmacy customers favor "Option 2" as described in the draft guidance, with the MTF facilitating payments and remittance advices. Conversely, we have heard manufacturers express reluctance to comingle funds in the payment process. If this reluctance continues to be expressed in the comments CMS receives on this draft guidance, there is a middle ground that CMS might consider.

A hybrid option, akin to Option 2, would involve the MTF facilitating all payments. Instead of sending a single payment from a single MTF bank account, the MTF would issue a single payment and remittance advice for each manufacturer. To fund the payments, the ACH payment file would be compiled by the MTF and drawn directly from the manufacturers' designated bank accounts. For pharmacies, similar to Option 2, the MTF could play a central role and drive standardized processes and predictability. For manufacturers, it would eliminate the commingling of funds. In today's digital environment, the systems that ingest and process bank deposits and remittance advices would easily handle segregated payments, and the industry would still gain many of the same benefits from the efficiency, standardization, and predictability envisioned in Option 2.

Conclusion

Thank you for the opportunity to provide feedback on the MFP effectuation process. We appreciate serving as a resource for the MDPNP implementation team and stand ready to work with CMS to consider additional processes and solutions as needed. If you have any questions or require additional information, please contact Patrick Kelly (pkelly@hda.org).

Sincerely,



Patrick Kelly
Executive Vice President, Government Affairs

Humana Inc.
500 W. Main St.
Louisville, KY 40202-2946
www.humana.com

Humana

July 2, 2024

Meena Seshamani, M.D., Ph. D.
Deputy Administrator and Director of the Center for Medicare
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Comments on Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

Humana appreciates the opportunity to offer feedback and recommendations to CMS on the Medicare Drug Price Negotiation Program established by the Inflation Reduction Act (IRA). We provide these comments in response to the CMS proposed guidance dated May 3, 2024, titled "*Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.*" Humana currently services approximately 5.9 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 2.9 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As a long-time sponsor of Part D plans, we hope you find our feedback and recommendations constructive in facilitating pharmacy and patient access to maximum fair price (MFP) for drugs selected under the Medicare Drug Price Negotiation Program.

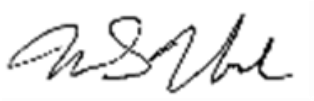
Humana supports the policy goal of establishing the Medicare Drug Price Negotiation Program as a mechanism to constrain the costs of medications frequently used by Medicare enrollees. Our comments, however, are limited to the new concept of a Medicare Transaction Facilitator (MTF). CMS seeks to establish a new entity that will facilitate reimbursements to participating pharmacies to ensure that those pharmacies have timely access to the MFP negotiated by CMS. As CMS works to finalize the parameters of the MTF services, the agency should:

- **Investigate ways to limit the delay in MFP refunds and the undue burden this may place on pharmacies.** One industry practice CMS might look to is existing contract language between supply chain participants in the Part D space, which could be used as model for establishing estimated *prospective* payments from manufacturers to pharmacies.
- **Consider alternatives to using Part D prescription drug event (PDE) data for the MTF to facilitate the MFP refund process.** At a minimum, we urge CMS to not move forward with the Agency's suggestion to shorten the PDE submission window from 30 days to 7 days.
- **Finalize the proposal for the MTF to provide optional payment facilitation services.** If CMS can only proceed with one option, we believe Option 2, which would provide for bulk payments via

the MTF, would be preferable and could result in administrative efficiencies for dispensing entities compared to Option 1.

We value this opportunity to provide recommendations related to the MTF and are pleased to answer any questions you may have with respect to the comments below. As always, our feedback is aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to Medicare beneficiaries, and improving their total health care experience. We hope you find this feedback helpful.

Sincerely,



Michael Hoak
Vice President, Public Policy

Section 40.4 Providing Access to the MFP in 2026 and 2027

CMS describes how manufacturers of selected drugs are obligated to ensure that the maximum fair price (MFP) is made available to pharmacies and other dispensing entities that dispense the selected drug to MFP-eligible individuals. CMS proposes to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between manufacturers of drugs with an MFP and dispensing entities to support the verification that the selected drug was dispensed to an MFP-eligible individual.

> **Humana Comment:** We recognize that CMS' interpretation of the Inflation Reduction Act requires that the manufacturer is responsible for making the MFP available, including by refunding the pharmacy directly, as opposed to passing payments through the Part D plan or PBM. However, due to existing data limitations that will likely continue into 2026, it is possible that pharmacies will be waiting for MFP refunds for several weeks after a drug is dispensed.
>
> We encourage CMS to investigate ways to limit the delay in MFP refunds and the undue burden this may place on pharmacies. One industry practice CMS might look to is contract language between supply chain participants in the Part D space. Under these contract terms, participants pay a portion of payments due to the contracted supply chain participant (e.g., 80-90 percent) *up front* on a monthly basis based on estimated utilization, with a "true-up" or reconciliation occurring on a quarterly basis. CMS could use this model to facilitate estimated prospective payments from manufacturers to pharmacies to mitigate delays in MFP refunds that would occur under the protocols CMS proposes in the draft guidance. In the initial months of 2026, pharmacies that elect to receive advance payments could provide data on past utilization among Medicare beneficiaries as the basis for an advance payment calculation.

Section 40.4.1 Medicare Transaction Facilitator Data Facilitation

CMS describes the parameters associated with MTF data exchange services. CMS intends for the MTF to provide drug manufacturers with data that has been verified by both the Part D plan sponsor and CMS' Drug Data Processing System (DDPS), resulting in dual verification for each claim being transmitted of both an individual's eligibility for Part D and Part D coverage of the selected drug. CMS details data elements that would need to be transmitted from the MTF to the relevant manufacturer in order to facilitate prompt payment to pharmacies.

CMS solicits comments on whether the current 30-day window for submission of all Part D prescription drug event (PDE) data could be shortened to facilitate timely transfer of relevant data elements to manufacturers. CMS is considering shortening the window to seven calendar days with transmission of these files occurring on either a daily or bi-weekly frequency. CMS also invites comments on whether CMS should recognize a certain timeframe for paying or collecting claim adjustments, whether these should be considered as offsets to future claims to a dispensing entity that was overpaid, and any additional approaches commenters may wish to see from the MTF data functionality for addressing claim adjustments.

Lastly, CMS proposes that the MTF will generate electronic remittance advice to the dispensing pharmacy for purposes of reconciling retrospective refunds provided by manufacturers in support of the

MFP thresholds. CMS solicits comments on this issue, including whether other methods for electronic remittance advice and data transfer would be more appropriate.

Humana Comment: We recognize CMS' interest in using Prescription Drug Event (PDE) for purposes of the MTF data functionality. However, we disagree with the use of the PDE to validate claims for a number of reasons. First, some PDEs are never accepted, such as when there is a retroactive eligibility change. In these cases, the pharmacy may not receive a refund from the manufacturer for a drug dispensed to an individual who the pharmacy and plan believed was MFP-eligible at the time. It is unclear how these situations will be addressed under the CMS proposal.

Additionally, as CMS recognizes in the draft guidance, there is currently a 30-day window for submission of PDE data. Although we appreciate CMS' desire to ensure that pharmacies are refunded for the difference between their acquisition costs and the MFP in a timely manner, we are concerned that shortening that window to 7 days following adjudication is too restrictive and will result in the use of inaccurate data for purposes of MFP refunds. It often takes pharmacies up to 14 days to reverse a claim when a member doesn't pick up their prescription. With a shortened PDE submission window, CMS will need to ensure that manufacturers are notified of any changes in the status or amount of claims that affect their MFP obligations. In the draft guidance, CMS does not provide detail on how it will track and communicate claim adjustments and reversals to manufacturers and pharmacies, and how it will resolve any disputes or discrepancies that may arise. Additionally, CMS notes that the PDE data is validated by the Part D sponsor and therefore is appropriate for use by the MTF; shortening the data submission window introduces more errors into this data and therefore runs counter to CMS' intent.

If CMS decides to proceed with the use of PDE data for the MTF, we suggest not shortening the submission window to less than 14 days following claim adjudication. Otherwise, the manufacturer may be refunding pharmacies for a large number of claims that will be reversed. If CMS changes the current 30-day submission window, we would also suggest <u>not</u> using different PDE data submission windows for selected drugs versus non-selected drugs. Ultimately, we encourage CMS to consider developing a new data source for purposes of the MTF, such as a mechanism for pharmacies to submit claims directly to the MTF.

Lastly, we support the proposal for the MTF to produce and transmit an electronic remittance advice back to the pharmacy for purposes of reconciling MFP refunds. Provision of an electronic remittance advice to pharmacies will be necessary to provide for appropriate internal reconciliation and tracking purposes.

<u>Section 40.4.3 Retrospective Refund Amount to Effectuate the MFP</u>

CMS proposes to establish a standard default refund amount for selected drugs that reflects the difference between the selected drug's wholesale acquisition cost (WAC) and the MFP. CMS suggests this standard generally best approximates the actual acquisition costs of pharmacies and offers a

reliable refund amount reflective of both manufacturer and pharmacy needs. This would not change the fundamental responsibility of a manufacturer to calculate and pay an appropriate amount to a pharmacy in order to effectuate the MFP. CMS solicits comments on which dispensing entities may have acquisition costs greater than the WAC of a selected drug, when this situation may occur, and evidence a manufacturer and dispensing entity might review to determine acquisition costs higher than WAC.

> **Humana Comment:** We support CMS' proposal to use WAC for the standard default refund amount. As CMS notes, WAC is a widely available and reliable pricing metric for brand drugs, published and regularly updated in large pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process.

Section 40.4.4 Options for Medicare Transaction Facilitator Payment Facilitation

CMS is considering how the MTF could offer additional functionality to facilitate the retrospective reimbursement by the manufacturer to the dispensing entity for the difference between the pharmacy's acquisition cost and the MFP. CMS is soliciting comment on two distinct payment facilitation options that would be optional: The first option would involve the MTF collecting banking information from participating dispensing entities and providing that information to manufacturers in order to facilitate private transactions. The second option would involve the MTF receiving aggregated refund amounts from participating Manufacturers and passing through the refunds to participating pharmacies. CMS is seeking input on which of these options would be most appropriate and what information would be required under either option in order to efficiently facilitate payments to dispensing entities.

> **Humana Comment:** We appreciate CMS' proposal for the MTF to provide additional functionality to facilitate reimbursement by the manufacturer to the pharmacy for the difference between the acquisition costs and the MFP. However, we are concerned that under Option 1, pharmacies would be required to receive and reconcile payments from each manufacturer of selected drugs, which would become increasingly difficult as the number of selected drugs grows each year. Therefore, if only one option were available, Option 2, which would provide for bulk payments via the MTF, would be preferable and could result in administrative efficiencies for pharmacies compared to Option 1. However, we have questions and concerns about the security, privacy, and accountability of such a system, as well as the potential for fraud or abuse. We request that CMS provide more information on how it will ensure the integrity and reliability of the voluntary payment facilitation functionality, and how it will protect the interests and rights of all parties involved.

Section 40.4.5 Medicare Transaction Facilitator Dispensing Entity Participation Requirements

CMS proposes conditions related to participation in MTF services by dispensing entities. If a dispensing entity chooses to utilize the MTF for payment facilitation, the dispensing entity would be required to register with the MTF and provide information to enable accurate payment facilitation. Dispensing entities, whether choosing to utilize any potential MTF payment facilitation functionality or not, are encouraged to use the MTF complaint and dispute process, as described in section 90.2.2 of the draft guidance, so that CMS is alerted to situations where MFP may not have been made available. CMS is

also soliciting comments on other potential considerations for facilitation services that may be provided through the MTF for dispensing entities, such as circumstances that might constitute a breach of the dispensing entity's participation agreement or timing requirements to initiate a dispute.

> **Humana Comment:** As mentioned above, effectuation of the MFP will result in new processes and requirements that pharmacies will be required to take on. Therefore, we appreciate CMS' clarification that pharmacies should not be charged for MTF services. However, pharmacies will also vary in their sophistication and ability to work directly with manufacturers to arrange for MFP refunds. The MTF payment facilitation process will help minimize the need for pharmacies to enter into agreements with individual manufacturers. Provision of an electronic remittance advice will also be necessary to provide for appropriate internal reconciliation. We encourage CMS to continue to solicit feedback from pharmacies as the MTF process is implemented in 2026 and into 2027.

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

14 Beacon Street
Suite 800
Boston, MA 02108
617-528-4013
www.icer.org

June 28, 2024

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

Thank you for the opportunity to comment on the draft guidance published May 3, 2024 on the proposed approach to conducting drug price negotiations for initial price applicability year 2027. The Institute for Clinical and Economic Review (ICER) is a private, independent, non-profit organization that conducts rigorous research to inform the balance of fairness in the pricing of, access to, and incentives for innovation for new and established drugs and other therapies. Our organization also has a long track record of engaging with patients, caregivers, clinicians, manufacturers, payers, and other stakeholders as informants to and participants in our research. It is with these foci that we provide comments on selected sections of the draft guidance, organized by section below.

50.2--Evidence About Therapeutic Alternatives for the Selected Drug (pp.68-69)

As mentioned in the previous guidance for the first negotiation year, CMS is appropriately soliciting information from manufacturers and other stakeholders on comparative effectiveness and level of benefit relative to therapeutic alternatives, details of prescribing information, data in specific patient populations of interest, patient experience data, and information on unmet need. CMS is also appropriately requesting information on productivity, independence, and quality of life with the requirement that there is measurable and quantifiable impact of the drug(s) in question. We also applaud CMS for changing its data request process to codify and group the information received (e.g., patient experience, clinical experience, equity and economic data, etc.), but remain concerned that separate collection and reporting of such data may prevent the agency from clearly communicating how each element affects CMS' overall assessment of

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Suite 800
Boston, MA 02108
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product value. A clearly articulated value framework, such as the one that ICER employs (https://icer.org/our-approach/methods-process/value-assessment-framework/), can combine such disparate data elements into a unified analysis that also illustrates which elements are driving the findings. We urge CMS to consider such a framework as a platform for negotiation.

60.3.3.1--Analysis for Selected Drugs with Therapeutic Alternative(s) (pp.84-85)

As before, CMS describes the generation of an initial offer as "…based on the totality of the relevant information and evidence submitted and gathered through CMS' analysis based on the clinical benefit the selected drug provides." While, as described above, we feel strongly that a primarily quantitative approach to value assessment provides the necessary rigor and transparency, transparency should guide CMS' activities regardless of the methodologic approach taken. All stakeholders, irrespective of their level of comfort with the analysis that CMS conducts, should understand how the offer was arrived at, the key considerations that informed the offer amount, and any uncertainties that may remain based on the data available.

60.3.4--Adjusting the Preliminary Price Based on Consideration of Manufacturer-Specific Data (pp. 87-88)

We agree that manufacturer-specific negotiation factors, such as research and development costs, costs of production and distribution, the level of Federal financial support for drug development, and the like should only be used to fine-tune an initial offer that is based primarily on the evidence for the level of therapeutic advance the drug represents, its comparative effectiveness relative to therapeutic alternatives, and the level of unmet need the drug may address. We recommend that CMS consider providing context around unmet need and using quantitative inputs when possible. For example, ICER's most recent value framework update (https://icer.org/wp-content/uploads/2023/09/ICER_Processes_For-Publication_092523.pdf) includes the calculation of "shortfalls" that represent the amount of future health (expressed in proportional and/or absolute terms) that patients would be expected to lose without access to a given treatment. Shortfalls can be calculated using life expectancy estimates (for treatments that primarily extend life only) or with measures that value quality of life during life extension equally, such as the equal value life year (evLY).

For individuals with rare diseases and other special populations, CMS may also wish to seek input from patients, caregivers, and other stakeholders on specific aspects of unmet need, such as "spillover" effects on families and communities as well as infrastructure needs for screening and treatment, as ICER does when our process is adapted for ultra-rare conditions (https://icer.org/wp-content/uploads/2020/10/ICER_URD_Framework_Adapt_013120.pdf).

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14 Beacon Street
Suite 800
Boston, MA 02108
617-528-4013
www.icer.org

60.4—Negotiation Process (p. 89)

We are pleased to see CMS' commitment to improving the process by which patients, patient organizations, beneficiaries, caregivers, and consumers can share their experiences and perspectives on the selected drugs for negotiation. As CMS considers the tradeoffs between different formats for such engagement, ICER's stakeholder engagement process may offer a model for incorporating patient perspectives that prioritizes transparency, accessibility, and equality of participation. ICER's value framework update (see link above) outlines our approach to engaging the patient community through effective onboarding, small-group interviews, and participation as patient experts during ICER's livestreamed public meeting.

As stated above, transparency should guide CMS' activities, including how CMS invites and incorporates patient testimony into decisions around drug price negotiations. Patient representatives should first be provided with a clear and lay-friendly explanation of the goals of the CMS process, why patient input is being requested, and ultimately how this input will be incorporated into the final offer. This may be conveyed during an introductory public webinar or in written form with convenient access on the CMS website. Providing these introductory materials can more effectively engage a wider audience and promote trust and participation in the process.

For each ICER assessment, we conduct small-group interviews (not technically fulfilling the requirements to be considered focus groups) with a diverse set of patients and caregivers that enhance ICER's understanding of the priorities and challenges of a specific patient community. These interviews have allowed ICER's research team to ask specific questions and clarify responses via interactive discussion. Although the interviews themselves are confidential, the overarching insights gained are summarized in ICER's evidence report to provide appropriate background on living with the specific condition and contextualize the findings regarding treatment alternatives.

During ICER's livestreamed public meeting, patient organization representatives as well as individual patients and caregivers are invited to participate as panelists or oral commenters. These patient perspectives are critical to informing the independent appraisal committee that deliberates and votes on the clinical effectiveness and value of the treatment under review. Patient representatives also participate as panelists alongside clinicians, insurers, and manufacturers during a policy roundtable session. As an equal stakeholder at the table, the contributions from these patient participants help shape ICER's key policy recommendations for fair pricing and fair access to the treatment under review.

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14 Beacon Street
Suite 800
Boston, MA 02108
617-528-4013
www.icer.org

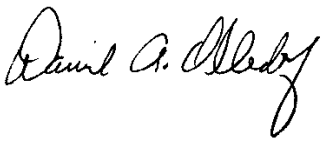
Both discussion formats proposed by CMS present important benefits and challenges:

- The small-group private interviews with only patient and caregiver participants allow for a more focused and candid discussion about the experience with current treatments or the impacts of living with a certain condition. However, given the closed nature of these discussions, we recommend that a summary report of patient perspectives be published and made available following the discussion.
- A public livestreamed roundtable discussion allows patients to participate as equal contributors and directly impact the perspectives of other participating stakeholders. Given the mix of participants, this format may limit the number of patients invited and thereby minimize the depth of patient contributions during the discussion.

Despite these challenges, we feel strongly that CMS should consider employing both formats, given the benefits of detailed understanding from small-group interviews and full deliberative participation in roundtable discussions. Regardless of the format(s) used, CMS should clearly communicate how patient perspectives will be incorporated into its negotiations, and prioritize transparency and accessibility in its approach to patient and other stakeholder participation.

Dr. Seshamani, we hope you find these comments useful as you seek to refine CMS' processes for the next round of drug price negotiations. Please feel free to contact us with any questions or requests for clarification on our comments as well as our approaches to stakeholder engagement and analysis.

With best regards,



Daniel A. Ollendorf, PhD, MPH
Chief Scientific Officer and Director of Health Technology Assessment Methods and Engagement

Cc: Catherine Koola Fischer, MPH, Director of Patient Engagement

incubate
INVEST + INNOVATE = CURE

June 28, 2024

Meena Seshamani, M.D., Ph.D.
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

Dear Dr. Seshamani,

I write on behalf of Incubate to offer feedback regarding the Draft Guidance on the Medicare Drug Price Negotiation Program. Incubate is a coalition of life-science venture capitalists that seeks to educate policymakers on the role of venture capital in bringing promising, innovative treatments to patients in need.

The drug negotiation process, as laid out in the draft guidance, could inhibit life sciences investment into novel drug development in three key ways.

First, the definition of a "qualifying single source drug" (QSSD) is overly broad and threatens to discourage biotech companies from researching new formulations and follow-on indications.

The guidance lumps together all medicines that share the same core molecule or active ingredient -- irrespective of their dosage, delivery mechanism, indication, and date of FDA approval -- as a single QSSD.[1] That means that revenue from all those different permutations would be aggregated when determining which medicines qualify for the price negotiation program. And the negotiated price would apply to all these various permutations.

This will discourage investors from funding follow-on research.

Consider a real world example -- edaravone, an antioxidant used to treat strokes and amyotrophic lateral sclerosis, better known as Lou Gehrig's Disease.[2] In 2017, the FDA approved an intravenous form for ALS patients.[3] Five years later, after the manufacturer ran additional clinical trials, the FDA approved an oral version of the drug, also to treat ALS, providing an important option for patients with ALS because it is self-administered and can be taken at home.[4]

In the future, investors and biotech companies will be less likely to fund research for any alternative forms or formulations that could provide important treatment options or even treat entirely different diseases or patient populations if the additional revenue from this new

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf pg 7

[2] https://medlineplus.gov/druginfo/meds/a617027.html#:~:text=Edaravone%20injection%20is%20used%20to,muscles%20to%20shrink%20and%20weaken).

[3] https://www.fda.gov/news-events/press-announcements/fda-approves-drug-treat-als

[4] https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-oral-form-treatment-adults-amyotrophic-lateral-sclerosis-als

formulation or indication would make the drugs more likely to be selected for the price negotiation program. Similarly, they'll be less likely to invest in the lengthy and expensive clinical trials to explore these new formulations and new indications for existing medicines.

Second, the guidelines lack transparency concerning the process.

The price negotiations themselves take place behind closed doors. There's no transparency on how officials arrive at the prices they select, and there's little room for actual negotiation, since if companies refuse the government's offer, they face either punitive taxes or must withdraw all of their medicines -- not just the ones selected for price controls -- from Medicare and Medicaid.

This lack of transparency and predictability creates additional uncertainty for investors, substantially increasing risk while reducing expected returns on investment which is, of course, central to venture capitalists' calculus when deciding which projects to fund.

Third, the guidance states that officials will consider the "research and development (R&D) costs of the Primary Manufacturer for the selected drug and the extent to which the Primary Manufacturer has recouped those costs."[5] Focusing on whether a manufacturer has merely recouped R&D costs, however, overlooks the true cost of bringing a drug to market.

Drug development is lengthy, risky, and expensive. It routinely takes over a decade to shepherd a drug from the lab to pre-clinical studies to clinical trials to FDA approval.[6][7] Andor every one drug that enters clinical trials and makes it to patients, nine fail in clinical trials.[8] The result is that R&D costs average over two billion dollars per approved medicine, when the costs of failures are included.

Venture investors are willing to take on enormous risk because of the potential for a single blockbuster drug to provide a return on investment that not only covers its own development costs, but also the costs of those numerous failures. Even more importantly, the few successes provide the resources for investors to continue funding research into new treatments and cures. When setting a "maximum fair price" of a drug, CMS must account for this reality and not merely compare R&D costs of a blockbuster medicine that has revenues that are, by definition, highly atypical.

We are thankful for the opportunity to provide input on this draft guidance. We hope CMS seriously weighs the concerns of life sciences venture capitalists and considers revising the guidelines to protect funding for medical advancements.

---

[5] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf pg 66

[6] https://www.ncbi.nlm.nih.gov/books/NBK22930/

[7] https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub

[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9293739/

Sincerely,

John Stanford
Executive Director of Incubate
Incubate is a 501c(4) organization with the mission to ensure patients continue to reap the benefits of the unrelenting innovation spurred by venture capital investment in the life sciences industry and protected by the American system of intellectual property. Incubate submits these comments in support to the January 4, 2021 Proposed Rule Docket Number 201207-0327.

1550 Columbus Street
Sun Prairie, WI 53590
800.755-1531 phone
800.274-5525 fax

Submitted electronically to: IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244

Re: Draft Guidance Medicare Drug Price Negotiation Program: Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Deputy Administrator Seshamani,

The Independent Pharmacy Cooperative (IPC) appreciates the opportunity to provide comments to CMS on its *Draft Guidance Medicare Drug Price Negotiation Program, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*.

The IPC is the nation's largest group purchasing organization and trade group representing the interests of pharmacist owners, managers, and employees of more than 2000 independent community pharmacies in all 50 states, the District of Columbia and the Commonwealth of Puerto Rico. IPC also owns and operates a drug distribution warehouse that services a total of 7000 independent pharmacies across the country. We are submitting these comments on behalf of our stores that serve Medicare patients, many of whom are the most vulnerable patients in the medically underserved areas.

Most fundamentally, by enacting this program as a major change to the Medicare Modernization Act (MMA) Congress created an express and clear exemption from the MMA's statutory prohibition on the HHS Secretary from interfering with drug pricing provisions in the Part D program. Indeed, Congress has given HHS the express statutory authority to establish a negotiated price for the number of drugs allowed in each Medicare Part D year covered by the IRA. CMS must approach implementing this law with a program to fully embrace this Congressional delegated power to set drug prices and payments at levels that pay pharmacies in full for the cost to dispense these high-cost drugs, including the true cost to professionally dispense a Part D prescription.

IPC believes that for this Medicare Drug Price Negotiation Program (MDPNP) to work as intended, CMS must implement the program in a way that does not harm independent pharmacies and patient access. IPC hopes to avoid a similar disruption to independent pharmacy that occurred in January 2006 with the launch of the Medicare Part D program, which had significant negative effects on independent retail and LTC pharmacies, who had to financially float the program, and where states had to intervene with assistance.

To place the impact of the new MDPNP in perspective, the average community pharmacy dispenses 58 prescriptions for MFP drugs each month for Medicare recipients, which represents 30 percent of the brand name medicines that they fill for Part D recipients. These 58 medications represent $44,000 each month in drug acquisition cost. If the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This vast number is only for year one of the MFP program and will grow larger and larger as more drugs are added each year to the program.

In order to preserve patient access to MFP drugs under this program, and to ensure that pharmacies are paid timely, IPC joins other pharmacy industry organizations in urging CMS to ensure and verify the following, among other asks in these comments:

1. That the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price;
2. That the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP;
3. That under the IRA, pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions;
4. That PBMs and plans should not be able to impose any pharmacy price concessions that would ultimately reduce patient access to MFP drugs;
5. That pharmacy reimbursement will incorporate a negotiated price that is: 1) no lower than the maximum fair price, and; 2) cover acquisition cost plus commensurate professional dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements;
6. That pharmacies will be paid timely within Medicare prompt pay requirements, within 14 days of adjudicating the claim;
7. That CMS will shorten the current 30-day window of the time that Part D plan sponsors have to submit complete Part D Prescription Drug Event (PDE) records to CMS' Drug Data Processing System (DDPS), to 7 days;
    a. To expedite payment to pharmacies, IPC suggests that CMS prefund the Medicare Transaction Facilitator (MTF) through a pre-funded revolving fund assessed on the manufacturers for the selected MFP chosen drugs based on the previous year's Medicare volume.
8. To ensure the prompt payment requirements are met, CMS direct manufacturers and 340B covered entities to determine all 340B claim eligibility for MFP drugs within a time period to align with payment of the claims within 14 days of adjudicating the claim.
9. That the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds; and

10. That neither plans, PBMs, manufacturers, wholesalers, CMS nor any other entity assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program and that any EFT fees should be borne by the manufacturer and not the pharmacy or a wholesaler.

CMS Must Address Part D Plan Sponsor/PBM Payments to Pharmacies for MFP Drugs to Ensure Beneficiary Access to MFP Drugs

IPC believes the final Guidance must address Part D plan sponsor/PBM payment for MFP drugs. IPC joins other pharmacy industry organizations in requesting confirmation from CMS that the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price.

Under the Inflation Reduction Act, there is a process by which the Secretary selects MFP drugs. Once a drug is selected, the Secretary is required to enter into agreements with manufacturers to set the MFP for particular drugs. The manufacturer is then required to "provide access to such price . . . to maximum fair price eligible individuals who . . . are dispensed such drug (and to pharmacies, mail order serves, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs)."[1] In addition, the basic definition of "maximum fair price" means the amount negotiated between the Secretary and a manufacturer for a selected drug—that is, for the ingredient cost of that drug.[2] Given the above, IPC believes the Congress made it clear in the IRA that the selected drug ingredient cost equates to the MFP, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP.

Consequently, IPC contends, as does other pharmacy industry groups, that it also follows that the Inflation Reduction Act requires that pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions. There are a few reasons that CMS should arrive at this conclusion. First, as discussed above, the IRA is constructed around treating MFP as the ingredient cost, and it uses a single definition for MFP throughout. Second, the amended definition of "negotiated prices" supports this conclusion. For non-MFP drugs, the total amount of the negotiated price for a non-MFP drug includes (1) the ingredient cost, (2) any "price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs," and (3) "any dispensing fees for such drug[ ]."[3] These MMA negotiated price after concessions statutory requirement do not exist under the IRA for MFP selected drugs. *In contrast, for MFP drugs* [emphasis added], the "negotiated price" is simply a payment (1) "no greater than the maximum fair price" for the drug and (2) "any dispending fees."[4] Thus, unlike non-MFP drugs, where Congress acknowledged the existence of "concessions" in addition to ingredient costs, Congress did not provide PDP sponsors explicit authorization to extract "concessions" for MFP drugs. That is because the IRA provides HHS the express legal mandate to gain these concessions upfront through the negotiated prices process. Therefore, PDP sponsors must reimburse pharmacies at ingredient cost plus a dispensing fee.

[1] 42 U.S.C. § 1320f-2(a)(1) (NCPA emphasis added); *accord id.* § 1320f-2(a)(2), (a)(3).
[2] *Id.* § 1320f(c)(3); *see also id.* § 1320f-3 (describing the negotiating process for the "maximum fair price").
[3] *Id.* § 1320w-102(d)(1)(B).
[4] *Id.* § 1320w-102(d)(1)(D).

For CMS to allow the PDPs to set a reimbursement floor for any MFP covered drug at less than the Federal Government's negotiated price ceiling would allow PDP sponsors to financially benefit from an illegal price concession (i.e., DIR). And that would come at great harm to the dispensing PDP network pharmacy while denying any financial benefit to the Federal Government, State Governments[5] and, most importantly, for the Part D senior beneficiary for whom the IRA MDPNP is designed to deliver to lower net prescription drug prices for these high-priced drugs.

340B claims identification. IPC notes that in the draft guidance, the 340B Claim Indicator in Table 2 of the MTF claim-level data elements is labelled "as voluntarily reported by [the] dispensing entity." IPC joins other industry groups in supporting CMS not requiring pharmacies to identify 340B claims and re-emphasizes the infeasibility of pharmacies identifying those claims either proactively or retroactively. The consensus in the pharmacy industry is that the N1 transaction is not feasible as it is not adopted by pharmacy information systems.[6]

Manufacturer calculating and paying dispensing entity. According to the draft guidance, "regardless of whether the Primary Manufacturer uses the potential MTF payment facilitation functionality, the Primary Manufacturer bears responsibility for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP." CMS should require that the manufacturer pay the difference between Wholesale Acquisition Cost (WAC) and MFP.

14-day prompt payment. IPC is in full agreement with all in the pharmacy industry that pharmacies need to be fully paid timely, within 14 days of adjudicating any Part D MFP eligible claim. As CMS acknowledges, under 42 C.F.R. § 423.520 (Prompt Payment by Part D Sponsors), Part D sponsors are required to pay pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.[7] At the outset of the Part D program and before this provision was put in place, independent pharmacies were closing rapidly due to delays in payment that caused significant detrimental impacts on cashflow. Independent pharmacies operate on small margins and are presently closing at the rate of over 1 per day, decreasing beneficiary access to care in their local communities. While IPC recognizes CMS's effort to incorporate a 14-day prompt payment requirement for Primary Manufacturers, the proposed trigger for that window can vary widely depending on when data is transmitted from the MTF to the Primary Manufacturer. **IPC stresses that independent pharmacies - to be able to afford to carry these high-priced drugs - need to be paid all amounts owed for the MFP by both the PDP and the manufacturer within 14 days of adjudicating the claim.**

Counter to this requirement for 14-day prompt pay to pharmacies that was enacted to preserve Part D adequate networks, CMS is proposing in this draft guidance that Part D plan sponsors have 30 days to submit complete PDE records to DDPS. Once those records are sent, the MTF would then need to send the data to the Primary Manufacturers. Depending on the frequency of the transmission, this could result in pharmacies waiting more than several days to receive the amounts owed to them. CMS states that it is evaluating

[5] Since these Part D MFP high-cost selected drugs are most likely to be dispensed disproportionally to Medicare-Medicaid dually eligible patients, allowing Medicare PDPs to reimburse pharmacies less than the MFP negotiated price will inflate every State Medicaid program's Part D dual eligible "claw back" payment financial liability to CMS under MMA.

[6] See the full comments of National Community Pharmacy Association (NCPA) in its March 2023 feedback on CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*

[7] See 42 C.F.R. § 423.520, available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.520.

whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. **CMS must shorten the current 30-day window to 7 days, to ensure pharmacies receive prompt payment.**

Even if the 7-day window for submitting PDE records is implemented, pharmacies will still be waiting longer than 14-days to receive MFP related payments. In the draft guidance, CMS stated that the MFP must be passed through to the dispensing entity within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. Given the 7-day window that IPC recommends that CMS should implement to submit PDE records, plus the 14-day manufacturer prompt pay window, this means pharmacies will be waiting at a minimum of 21 days for payment. This is unsustainable for independent pharmacies. Pharmacies need to be made whole within 14 days of adjudicating the claim at the pharmacy, period. Pharmacies must pay their wholesalers on an approximate two-week payment cycle and cannot float the MFP program. **Full payment for any MFP designated Part D drug to pharmacies should in no circumstances exceed the 14-day prompt pay requirement under Medicare Part D including 340B claims.**

Manufacturer prefunding MTF.

IPC proposes that to ensure Part D patients receive MFP designated drugs from their pharmacy of choice that CMS develop a mandate for all affected drug manufacturers of MFP designated drugs to prefund the MFP program with a revolving fund that CMS' MTF will utilize to pay the pharmacies the difference between the MFP price and WAC. CMS should calculate each manufacturer's portion of the revolving fund based on the price differential between the MTF and the previous Part D plan year's total spend for each drug that CMS paid to plans, post-price concessions. The MTF will then make these claim payments within the 14-day Part D prompt pay legal requirement. This program operation will be necessary to ensure that independent pharmacies will have the necessary cash flow to continue to dispense these Part D MFP drugs so that these senior patients to not experience drug therapy disruptions or have to resort to polypharmacy or mail order as their only means to access their drug benefit for these higher cost prescription drugs.

Electronic remittance advice. **IPC strongly supports CMS's proposal to require electronic remittance advices be provided to dispensing entities showing MTF reconciliation and joins other pharmacy industry organizations in suggesting that CMS mandate a provision of requiring that the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds.** Additionally, IPC joins other commenters in asking that CMS mandate standardization of 835s. While the 835 is a standard, there are multiple variations in use today by PBMs which complicates the work of reconciliation vendors. Manufacturers could use a standard implementation of the 835 for MFP payments that could be fleshed out in an NCPDP task group. Further, CMS must collect the delivery address for the 835s. Additionally, CMS should ensure that the MTF should be responsible for generating the EDI 820 document that relates to banking financial standards. This information should be made available in the MTF portal for each pharmacy.

Retrospective Refund Amount to Effectuate the MFP

WAC as benchmark. In this draft guidance, while CMS stated that it "intends" for the MTF to use WAC as the standardized pricing metric to calculate the Standard Default Refund Amount, it does not expressly

require the Primary Manufacturer to use WAC for reconciliation purposes. The MTF will provide the Primary Manufacturer with the Standard Default Refund Amount (i.e., WAC minus MFP) as part of the transmitted data elements. The Primary Manufacturer may elect to use the Standard Default Refund Amount, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including any non-guaranteed purchasing incentives, such as prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. WAC is a widely available pricing metric, published and regularly updated in large pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process, and that does not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties. **IPC agrees with other pharmacy industry commenters that pharmacies need protection from manufacturers arbitrarily imposing refund amounts other than the Standard Default Refund Amount (WAC minus MFP) that do not appropriately effectuate the MFP. IPC joins other pharmacy industry groups in thanking CMS for stipulating in the guidance that the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispensing based on the quantity dispensed. And IPC joins NCPA in endorsing the use of WAC as the standardized metric.**

We have concerns that it is voluntary for manufacturers to adopt WAC, given that manufacturers and dispensing entities can "agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost," and therefore agree to a different benchmark. In other words, the MTF sends the amount as part of the minimum data elements to the manufacturer, which is WAC-MFP. If the pharmacy and the manufacturer have agreed on a different amount other than WAC, then when the manufacturer sends the data elements back to the MTF, the MTF would send a different amount because that is the indicator that the standardized refund was paid. **IPC agrees with other pharmacy industry groups in strongly urging CMS to require the use of WAC as the standardized metric and that any difference between WAC and MFP is the Standard Default Refund Amount.**

Reimbursement from Part D Plan Sponsors/PBMs for MFP drugs must be reasonable to ensure beneficiary access. Part D plans are required to provide "reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy."

Agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all the following:

Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year. (ii) Providing a copy

of a standard contract to a requesting pharmacy within 7 business days after receiving such a request from the pharmacy.[8]

CMS must ensure that for MFP drugs, Part D plan sponsor/PBM pharmacy reimbursement should be no lower than the maximum fair price and include a commensurate professional dispensing fee in line with Medicaid fee-for-service.

CMS must ensure that plans, PBMs, manufacturers, wholesalers, CMS nor any other entity be allowed to assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program. Any EFT fees should be borne by the manufacturer and not the pharmacy. These EFT fees also should not be imposed on wholesalers that cannot be captured in the MFP.

IPC and other pharmacy organizations believes that CMS should create a streamline pharmacy enrollment process, eliminating the need for individual enrollment forms/portal access for every pharmacy location.

Conclusion

IPC appreciates the opportunity to share with you our organization's comments and suggestions for ways for CMS to implement a Medicare Drug Price Negotiation Program, consistent with the statutory requirements in the Inflation Reduction Act. We hope CMS sees IPC's submission as constructive input to create a successful program that does provide these high-cost drugs in a more affordable way to Part D seniors and dual eligible beneficiaries by creating a workable system for dispensing pharmacies to fully participate in this program.

If you have any questions or need any additional information, please feel free to contact me by either email: mark.kinney@ipcrx.com or by phone (608-628-7311).

Respectfully submitted,

Mark Kinney

Mark Kinney, R.Ph.
Executive Vice President of Government Relations

[8] 42 CFR §423.505(b)(18). Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.505.

Comment on Guidance: Inflation Reduction Act Medicare Drug Price Negotiation Program

CMS hosting patient-focused events to get input and experiences on conditions treated by selected drugs and alternatives from important stakeholders, such as patients, beneficiaries, will be very beneficial. Regarding events that promote discussion, in addition to round table sessions and focus groups, it may be worthwhile to consider hosting a panel discussion. While a panel discussion does have structured conversations, it also facilitates discussion. The panel can be conducted in-person, virtually, or through a hybrid format to allow for more participants. The panel will allow for an exchange of viewpoints on the drug(s) in question. The panel discussion could be a suitable potential option when considering combining events for selected drugs that treat like condition(s)/disease(s). Furthermore, it is vital to mitigate patients' and other interested parties' barriers to participation. It is important that CMS can reach a large group of patients and those that are affected by the chosen drug list. This is to get the most amount of input in the effects of drug pricing on the overall financial wellbeing of the intended user. To reach such an audience, CMS must make the participation dates for public input more available and visible. CMS can reach out to patient organizations that has a disease outreach program, whether it is community-based or hospital-based, that may be impacted by the drug in question. Since the target audience would be spread across the United States, allowing those who would like to participate an opportunity to view a livestream, even if it is audio only, would allow them to hear the comments and viewpoints. Also, for those who are participating through the audio only livestream, if they were permitted to submit comments during the live stream, it would garner more interest and input. Another way to mitigate any barriers to participation is to target senior outreach community programs across the nation asking for participants. This is necessary as older adults can be highly affected by price variations in the marketplace. For instance, many of the price increases for existing drugs have outpaced inflation. Between January 2022 and January 2023, over 4,200 drug products saw an increase in price, of which 46% were larger than the rate of inflation (Bosworth et al., 2023). This has serious implications for older adults, especially those with incomes below the poverty line or have fixed incomes (Olson et al., 2022). Then post event, having a summary that is easily found on the CMS website for parties interested on the feedback would help with transparency. The CMS website can be difficult at times to navigate for the intended user, which can hinder participation. As such, mail outreach with a request for participation as well as simple navigation on the website would increase participation in the discussions on the selected drugs. Overall, this would allow for patients and other key stakeholders to have a role in the negotiation process for achieving the lowest maximum fair price for each selected drug.

In regard to the process, timing, and frequency of the claim-level data file transmissions, verification of a recipient's eligibility of getting medication from a dispensary claim is done both by the Part D plan sponsor and CMS' Drug Data Processing System to ensure the recipient is eligible for the drug. As such, transmission of this information through the Medicare Transaction Facilitator to the Primary Manufacture may not require a third verification by the Primary Manufacture of the Maximum Fair Price drug. Since the verification process has been vetted out by both the plan sponsor and CMS, any further verification may extend the start of the 14-day payment process. It may also increase the cost of making sure that the Primary Manufacture keeps the Medicare eligible recipient's personal data secure. This is because the Primary Manufacture will obtain more patient information than what CMS would send to them upon verification, and as such will need a secure database. This is vital as the average cost of a

healthcare data breach costs almost $11 million (Alder, 2023). This may also require a revisit to the time frame by which the Part D plans have to submit their claims to CMS. To secure a timely refund payment, reducing the time from 30 days to 15 days from the time the claim is submitted and verified, would allow for a timelier transfer of data to the Primary Manufacture. From the perspective of an insurance plan who contracts with pharmacy benefit managers, the rebate would help offset the cost of premiums for drugs on the list, that are negotiated at lower rates (Romanzo, 2021).

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June 4, 2024

[redacted]

Re: Comments on Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Sir or Madam:

I offer the comments listed below on the Medicare Drug Medicare Price Negotiation draft guidance to contribute to a comprehensive review of evidence-based regulation solutions to inform the Centers for Medicare & Medicaid Services (CMS) on their actions going forward. I am an independent, nonpartisan researcher with policy experience at a local, state, and federal level, and a background in public health and health policy.

I appreciate the opportunity to offer a public comment on the CMS's review of information and input pertaining to the implementation of the Negotiation Program for initial price applicability year 2027 and manufacturer effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. This Negotiation Program holds great potential for lowering prescription drug costs and decreasing barriers to health for both Medicare enrollees and insured American residents, if implemented effectively. With several states implementing similar negotiation programs in their state Medicaid programs, I urge the CMS to consider which of these mechanisms may be successfully implemented at a federal level based on existing reports and research. Since the process of selecting drugs for federal negotiation is already solidified, this comment only reviews negotiation tactics. In the comment below, the current enhanced negotiation tactics used in Massachusetts and New York to reduce prescription drug costs will be summarized and accompanied by potential guideposts for federal implementation.[1]

Massachusetts

In the state of Massachusetts, a law (HB 4000) focused on reviewing the costs of specific prescription drugs to ensure their affordability was passed in 2019.[2] This law allowed the Executive Office of Health and Human Services to negotiate supplemental rebate agreements directly with manufacturers for drugs covered by MassHealth based on a drug's value, efficacy, or outcomes.[3] Based on this law, if the Executive Office is unable to negotiate a supplemental rebate, the office can identify a proposed value of a drug informed by public hearings and manufacturer testimonies, and further negotiate with the manufacturer.[4] The US Centers for Medicare & Medicaid Services could apply these strategies on a federal level by having the

[1] "State Laws Passed to Lower Prescription Drug Costs: 2017–2024," National Academy for State Health Policy, last modified May 16, 2024, https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/
[2] Ibid.
[3] Ibid.
[4] Ibid.

Administrator of CMS act in the role of the Massachusetts Executive Office and focus on negotiating a Maximum Fair Price rather than a supplemental rebate. On a state level, if these additional negotiations are unsuccessful, the manufacturer is typically referred to a Health Policy Commission which can require the manufacturer to disclose the drug's pricing information and wholesale acquisition cost from the past five years.[5] The Commission then recommends its own supplemental rebate value and if the manufacturer's pricing is above the recommended value, the Commission can request additional information and price justification from the manufacturer. However, the Commission's analysis and research must originate from an independent third party. On a federal level, instead of creating a Health Policy Commission, the CMS could recruit the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) for the role or create a sub-committee of the MEDCAC to advise them.[6] It has been estimated that between 2019 and 2023, Massachusetts' reform laws have resulted in over $300 million in savings for the state's Medicaid program.[7]

New York

In New York, the state passed the 2018 Health and Mental Hygiene budget (S 2007)[8] in 2017 which allowed the state to institute a global spending cap for Medicaid with a separate spending cap for Part D and prescription drugs. If this cap is exceeded, the Medicaid program can negotiate with drug companies for supplemental rebates.[9] The process used to negotiate supplemental rebates in New York could be replicated at a federal level.[10] After specific drugs have been selected for negotiation, the Commissioner of Health identifies preliminary target supplemental rebate amounts and the state Department of Health informs drug manufacturers that its products will be under the review of the state's Drug Utilization Review Board.[11] At a federal level, this could translate to the office of the Administrator of CMS identifying preliminary target Maximum Fair Prices and negotiating accordingly. CMS could also create a federal Medicare Drug Utilization Review Board which the Administrator and CMS can refer manufacturers to in the case of being unable to reach an agreement. The board could conduct a value assessment of the drug which considers existing rebates, affordability, value, therapeutic benefits, and any significant or unjustified[12] rises in price culminating in the recommendation of

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[5] Ibid.
[6] "Medicare Evidence Development & Coverage Advisory Committee," Centers for Medicare & Medicaid Services, last modified April 17, 2024, https://www.cms.gov/medicare/regulations-guidance/advisory-committees/evidence-development-coverage#:~:text=The%20Medicare%20Evidence%20Development%20%26%20Coverage,CMS%20on%20specific%20clinical%20topics.
[7] "Press Statement: MA Prescription Drug Affordability Coalition Commends Senate Passage of Rx Cost Reform; Urges Swift Legislative Action," MA Prescription Drug Affordability Coalition, November 16, 2023, https://hcfama.org/press-statement-ma-prescription-drug-affordability-coalition-commends-senate-passage-of-rx-cost-reform-urges-swift-legislative-action-november-16-2023/
[8] "SECTION 280 Medicaid drug cap," The New York State Senate, accessed May 21, 2024, https://www.nysenate.gov/legislation/laws/PBH/280
[9] Alisa Chester, "New York's Medicaid Drug Cap," *Pew*, April 2, 2018, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap
[10] Ibid.
[11] Ibid.
[12] "SECTION 280 Medicaid drug cap," The New York State Senate, accessed May 21, 2024, https://www.nysenate.gov/legislation/laws/PBH/280

a final recommended Maximum Fair Price.[13] If necessary, the Administrator could require additional information about the drug, such as costs associated with its research and development, manufacturing, administrative, and advertising as well as average rebates, discounts, and profit margins. If an agreement is still not reached, similar to the New York model, the CMS could remove the drug from its managed care program formulary.[14] It is important to note that this strategy resulted in the successful negotiation of supplemental rebates for at least six drugs in New York without requiring the involvement of the Drug Utilization Review Board and was projected to save $119 million for the state in 2018 alone, saving approximately 11.1 percent of the state's projected pharmacy expenditure.[15]

Conclusion

Based on existing state mechanisms for negotiating supplemental rebates for specific prescription drugs on Medicaid formularies, it can be deduced that successful programs involve a sequential negotiation process which incorporates additional stakeholders and information if an initial negotiation is unsuccessful. Within these negotiation models, manufacturers are incentivized to reach an agreement quickly as the longer it takes for manufacturers to come to an agreement, the more drug research, data, and pricing information are disclosed. Speed is an important factor in this process as prolonged negotiations may limit patient access to the drug. Thus, these state negotiation strategies should be incorporated at a federal level to reward companies which quickly agree to negotiation terms and to place the onus of further negotiation on companies which reject proposed Maximum Fair Prices.

I appreciate the opportunity to comment on the CMS's efforts to engage stakeholders on the issue of the Medicare Drug Price Negotiation Program as they are responsible for the single largest payer for health care services in the country. Therefore, I wish to thank the Center for its consideration of my comments.

Sincerely,

[redacted]

[13] Alisa Chester, "New York's Medicaid Drug Cap," *Pew*, April 2, 2018, https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2018/04/new-yorks-medicaid-drug-cap
[14] Ibid.
[15] Ibid.

To whom it may concern:

When a patient has tried several generics even at a higher dose, as well as other medications that could possibly help them and they all fail, it is not fair to deny medicare part D recipients the drug manufacturer coupons. This can make the difference in a person on medicare being able to get their prescriptions.

With ample doctor notes and pharmacy records a person can prove that the other medications and the generic medications do not work.

The laws that are in place are actually preventing people on medicare from being able to get the medications they NEED because they cannot afford them.

I understand the need for the law however, it is so strict that it's only protecting the pharmacies and it is actually "harming people on medicare" to protect pharmacies.

*****This needs changed as soon as possible and "should have been written with provisions and more thought put into it when it was passed into law way back in the 80's". *****

This is truly a disgrace, and I hope you will really look at this law and change it.

Thank you for your consideration,

[redacted]

Federal Register :: Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program Draft Guidance; Comment Request

When considering the proper negotiated Maximum Fair Prices for drugs, the Centers for Medicare & Medicaid Services should put more emphasis on the needs of the patients, over the profits of the manufacturers. Groups like NORD have concerns that the Centers for Medicare & Medicaid Services "fails to meaningfully track the impact of the price negotiation on patients and rare disease drug development (National Organization for Rare Disorders, 2024)." However, several studies "have found that drugs approved for rare diseases earn similar revenues to drugs that treat more common conditions, raising questions about whether such incentives are necessary (Vogel et al., 2024)."

This raises the question: why would innovation be hindered for drugs that treat the rarest of conditions, but not for others? The answer is, it won't. In fact, according to a study in JAMA Internal Medicine, "by virtue of the $200 million per year in Medicare spending requirement, it is likely that any drug eligible for the sole orphan exemption is among the most financially successful of all drugs treating a single rare disease (Vogel et al., 2024)." Furthermore, a recent report published by the Congressional Budget Office "found that reducing profits of top drugs by 15 to 25 percent would be associated with a negligible drop in the number of new drugs introduced over the next decade (Santoro, 2024)."

There is also potential for drugs currently excluded from negotiations due to the sole orphan exemption to "conduct clinical trials for additional patient populations while foregoing FDA approval and thereby retaining the sole orphan exemption (Vogel et al., 2024)." While this is currently a hypothetical, it is not outside of the realm of possibilities. Drug manufacturers have been known to stack new patents on drugs to keep generics off the market, known as patent thicketing. The only difference here is that manufactures may choose to forego new disease indications to continue their large profits. While these drug developers and manufacturers have done amazing work in creating these advanced therapies, that does not mean they should be the only ones to benefit. Ensuring that the people who actually need them can afford them is paramount.

A similar concern of mine is the sole orphan drug exemption. While I know this is not currently allowed due to the provisions of the Inflation Reduction Act (National Organization for Rare Disorders, 2024), as you know, there is a process for the Centers for Medicare & Medicaid Services to support changing that statute. Through the A-19 legislative proposal, CMS can present a legislative proposal which can be "considered by HHS and may be submitted as recommendations to the Office of Management and Budget (OMB) for introduction to the Congress (National Institute of Health, 2005)." Through this process, the Centers for Medicare & Medicaid Services could propose

changing the language in the Inflation Reduction Act to include drugs with the sole orphan drug classification for negotiation. According to the Jama Internal Medicine study, if the Inflation Reduction Act had been in effect from 2012 to 2021 and covered 25 drugs meeting the definition of a sole orphan drug under the legislation, “the sole orphan exemption would have prevented Medicare from negotiating prices on otherwise-eligible drugs with a total $1.1 to $3.0 billion in Medicare spending each year (Vogel et al., 2024).” This represents significant savings for the Medicare program that the program is currently missing out on due to the existing legislative text.

While I am extremely excited about the prospect of a second round of drugs up for negotiation thanks to the Inflation Reduction Act, there is more work that needs to be done. The program could save significantly more money, while providing needed medicines to those who need them most. I agree that we must ensure sustained research and development by drug manufacturers, however, shielding companies with the most profitable drugs from negotiations is not the right approach. Thank you to everyone who worked on this important proposed rule, and I hope that my comments will be considered!

Sincerely,

[redacted]

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Document: CMS_FRDOC_0001-DRAFT-13548
Comment on CMS_FRDOC_0001-3836

Submitter Information

Name: [redacted]
Address:
[redacted]
Email: [redacted]

General Comment

I am writing as a healthcare professional (pharmacist) and as a patient myself. The ability to negotiate price for Medicare is profoundly important and has the potential to save millions of lives and millions of dollars. It is impossible to overstate the importance. I have watched in my professional practice as the price of brand name drugs turned people away from getting their prescriptions so many times. When generic medications came along, the prices were high initially, and then came down for most people to afford. Then, in 2014, the price of a well known antibiotic used for all manner of skin and soft tissue infection and also Lyme disease, skyrocketed. The price soared over 1000% for reasons never clearly explained. This is unacceptable. It appeared to be a scheme to fix generic prices at the expense of patients. This happened once again with another company that raised prices 5000% on a drug that had been around for decades. The promise of generics to be affordable alternatives has been hijacked by greed. Our system of creating, manufacturing, and delivering life saving medications to patients must not be subject to ordinary or extraordinary market forces. Kaiser Health News and Stanford Law School both wrote about the astronomical pricing increases during that time period and things have not improved. [redacted]

[redacted] Though I am not on Medicare yet, these negotiations have the potential to change medicine and pharmacy in the most profound ways - for current and future Medicare recipients. Thank you for the opportunity to comment on these essential proceedings.

ISPO
The professional society for health economics and outcomes research

Improving healthcare decisions

505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648

P +1-609-586-4981
info@ispor.org
www.ispor.org

July 2, 2024

Dear The Centers for Medicare & Medicaid Services (CMS):

ISPOR – The Professional Society for Health Economics and Outcomes Research - is pleased to respond on behalf of its membership to your consultation entitled "**Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.**"

ISPOR is a scientific and educational society with many of our members engaged in evaluating health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in over 100 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government, and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the ISPOR Institutional Council. We solicited comments from the entire ISPOR membership. The attached document provides a summary based on their comments. We hope they prove useful.

ISPOR would be happy to answer any questions about our response, to serve as a partner, or to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Robert Abbott
CEO & Executive Director
ISPOR

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505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648

P +1-609-586-4981
info@ispor.org
www.ispor.org

Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Clear and transparent communication. Maintaining transparency throughout the negotiation process is critically important. Transparent negotiations that incorporate considerations of alternative treatments and comprehensive manufacturer data have the potential to reduce costs for Medicare beneficiaries and create secondary effects for commercial markets. However, it is essential to strike a balance between transparency and confidentiality; without proper safeguards, there is a risk of compromising proprietary information, which could stifle innovation in drug development. All stakeholders want to make progress against diseases with high unmet need for patients.

Evidence about alternative treatments. Clarification is needed regarding the process of analyzing drugs with multiple indications (and potentially different treatment alternatives for said indications). Products with multiple indications will almost certainly be selected for drug price negotiations. The need for clarification will increase as more products with multiple indications are selected leading to major analytical challenges to define a negotiated price. For example, a weighting method could be applied to address the challenge of assessing multiple indications. If indication weighting is pursued for high-volume indications, we request that CMS also consider selecting smaller indications that address high unmet need when considering the selection of alternative treatment comparators. For example, incentives to invest in research and development for pediatric oncology indications should be maintained. For all indications, we encourage CMS to consider comparator treatments that are currently considered the best standard of care.

When selecting a set of alternative therapies, it is also important to consider the stage of the product's lifecycle. At launch, products are often compared to placebo or the current standard of care. For example, comparing apixaban to warfarin reflects the previous standard of care. In health economics and outcomes research (HEOR), apixaban would be compared with other Factor Xa Inhibitors. When the approved therapy represents a major advance or new standard of care, the appropriate alternative can be determined by evaluating clinical guidelines (if available) or by asking manufacturers to provide indirect comparison data against appropriate comparators. These approaches are prevalent in health technology assessment (HTA) bodies globally.

ISPOR's membership would be pleased to help CMS with identifying methods to determine appropriate treatment alternatives.

Unmet medical need. It remains unclear how CMS is applying the definition of unmet medical need. Unmet medical need is a subjective term that lacks consensus.

Unmet medical need is dynamic and may change based on the stage of the product's lifecycle. Unmet need will decrease as the approved therapy is adopted and becomes the new standard of care.

In some cases, unmet medical need is addressed by providers through the use of drugs off-label. We request clarification as to how CMS will consider off-label indications. Questions related to off-label indications will increase as CMS approaches the 2028 implementation of Part B drug Negotiations.

The degree and context of unmet medical need may also differ based on a person's socioeconomic background and disease status. We propose the development of a "whole health" approach to quantifying unmet medical need. ISPOR defines whole health as "the collective impact of physical, behavioral, spiritual, and socioeconomic factors on one's health. It prioritizes enhancing health outcomes and the coordination of health and social service systems through a personalized and team-based approach, while promoting overall

505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648
P +1-609-586-4981
info@ispor.org
www.ispor.org

well-being, disease prevention, and equitable and accessible care."[1] Individuals diagnosed with conditions for which there are no approved medications can experience negative whole health effects. HEOR uses data from a variety of sources, such as electronic medical records, claims data, patient surveys, and economic models to develop a comprehensive value assessment.

Furthermore, ISPOR seeks clarification regarding a potential premium for products with new indications addressing unmet medical need. For example, Japan provides about an 8% premium on pricing for drugs that meet unmet medical needs.[2] We ask that CMS consider a similar approach when assessing the current and future value of a product as there is a risk of disincentivizing new indication development.

Assessment of value. ISPOR recommends that a comprehensive value assessment should be the main focus of setting prices, as opposed to drug development and manufacturing costs. Data that manufacturers are currently required to submit includes information on financial costs (eg, research and development, production costs) and revenue. The CMS guidance should reflect broader aspects of value, such as clinical benefit, improvements in patient reported outcomes, reduction in toxicity, systemic cost offsets, functional status, and caregiver spillover effects. We recommend investigating elements of value in the ISPOR Value Flower. [3] It will be important to consider the value proposition of a drug relative to the three different patient groups that Medicare serves: Adults aged 65 and older; individuals diagnosed with end-stage renal disease (ESRD); and dual eligible (Medicare and Medicaid). ISPOR members have the methods and experience to build comprehensive value assessments based on these different patient populations.

Use of real-world data in decision making. CMS has mentioned that the gold standard of evidence is randomized controlled trials (RCTs) and that real-world evidence (RWE) will be used as secondary evidence. RCTs may not provide the most relevant evidence for today's decisions. For example, RCTs that support older indications and products that have been on the market for 7+ years often have RCTs that no longer reflect the current state of medicine and clinical care management. As we noted in our 2023 response to CMS's guidance document, we recommend the use of both comparative effectiveness and RWE to inform decisions. RWE has been shown to appropriately complement RCT data.[4-5] ISPOR has issued several good practice guidance reports on the use and grading of RWE and comparative effectiveness.[6-14] We also strongly encourage using Hypotheses-Evaluating Treatment Effect (HETE) RWE studies, whose study protocols are provided as a part of the Real-World Evidence Registry, and standardized matrix has been used for its reporting.[15-17]

Patient engagement. We are encouraged by CMS' request for assistance to establish best practices for engaging patients in the drug price negotiation process. We ask CMS to consider using studies that genuinely engage patients in research. An ISPOR working group defined patient engagement in research as, "the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise."[18]

We encourage CMS to consider two recent publications by experts in the field (and active ISPOR members) about frameworks for patient-centered research.[19-20] We also encourage CMS to refer to the US Food and Drug Administration (US FDA), especially their experiences with the patient-focused drug development (PFDD) program, for examples of best practices in engaging patients in decision making.[21] ISPOR has also partnered with Health Technology Assessment international (HTAi) to publish good practices in stakeholder engagement in deliberative processes.[22] The National Health Council (NHC) and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) also have recommended resources and expertise with engaging patients in discussions in the United States. [23-24]

ISPOR would be happy to help collaborate with CMS as a neutral third party to facilitate engagement with

505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648
P +1-609-586-4981
info@ispor.org
www.ispor.org

patient representatives for a systematic and scalable discussion framework.

PICOs. We recommend the development of a clear scoping framework so manufacturers can estimate the resources required to generate and submit relevant information. We then propose that the scope for PICOs (**P**opulation, **I**ntervention, **C**omparator, **O**utcomes) for each relevant indication for each product under consideration should reflect a mutual consensus between the manufacturer and CMS. The finalization of the PICOs ideally would incorporate robust input from patient and provider organizations.

Ensuring safeguards for patient access. A review of the CMS Prescription Drug Plan Formulary and Pharmacy Network information files analysis found that access to protected class drugs placed on specialty tiers of prescription drug plans and Medicare Advantage prescription drug plans, was heavily restricted due to utilization management tools (eg, prior authorization, step edits). These restrictions may impede patient access and affordability.[25-26] If evidence-based safeguards are not established for drugs selected under the program, patients might experience similar hurdles for drugs under price applicability year 2026, 2027 and beyond.

Current Part D policy requires sponsors to include all drugs within 1 of the 6 protected classes (ie, antiretrovirals) without prior authorization and step therapy. This approach ensures that patients have unimpeded access to necessary medications without lengthy delays and affordability concerns. Therefore, we urge CMS to incorporate similar safeguards across selected drugs within the program to prevent potential barriers that could hinder patient access.

Medicare Transaction Facilitator. With respect to CMS plans to develop a Medicare Transaction Facilitator (MTF) to assist with data facilitation in a retrospective rebate model, ISPOR anticipates a great deal of planning and dialogue will be required to facilitate an efficient exchange of data between pharmaceutical supply chain entities and Medicare. ISPOR can organize and manage meetings of this size and complexity and as well as develop specialized training programs to support MTF implementation. ISPOR would look forward to further dialogue with CMS on this topic.

In conclusion, ISPOR welcomes further conversations with CMS about best practices in using evidence to make decisions. Evidence-based value assessments conducted using rigorous HEOR scientific practices are critical to make sound decisions. As the leading global Society, we have many experts and years of experience that we can provide CMS to help make these decisions. We welcome the opportunity to continue the policy dialogue for many years to come.

We acknowledge the ISPOR Institutional Council and ISPOR members (Inma Hernandez, Peter Neumann, Elisabeth Oehrlein, Eberechukwu Onukwugha, Eleanor Perfetto, Sean Sullivan, Joseph Washington) for their assistance in assembling these comments, as well as ISPOR staff (Laura Pizzi, Mitch Higashi, and Kelly Lenahan).

505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648
P +1-609-586-4981
info@ispor.org
www.ispor.org

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505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648
P +1-609-586-4981
info@ispor.org
www.ispor.org

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505 LAWRENCE SQUARE BLVD SOUTH
LAWRENCEVILLE, NJ 08648
P +1-609-586-4981
info@ispor.org
www.ispor.org

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IVI INNOVATION AND VALUE INITIATIVE

June 28, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Seshamani,

The Innovation and Value Initiative (IVI) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the revised draft guidance for implementation of the Medicare Drug Price Negotiation Program (DPNP) for initial price applicability year 2027 and manufacturer effectuation of the maximum fair price (MFP) in 2026 and 2027.

IVI is a 501(c)3, non-profit research organization committed to advancing the science, practice, and use of health technology assessment (HTA) in healthcare. Founded in 2017, the organization includes members from the research, patient, payer/purchaser, clinician, and innovator stakeholder communities. IVI's work emphasizes collaboration and exploration of new solutions to pursue a U.S. learning healthcare system supported by patient-centered HTA and focused on high-quality, efficient, innovative, and equitable care for all people and communities. We believe this is only possible with a fundamental shift to resource allocation, coverage, and access-related decision-making that aims to maximize value for all stakeholders—particularly patients and other covered individuals.

As described in our April 14, 2023, comments on the initial Medicare DPNP draft guidance,[1] our work is guided by our Principles for Value Assessment.[2] These principles apply not only to the narrow context of HTA but are the foundation of a patient-centered and equitable health system based on value to all stakeholders. We continue to believe the implementation by CMS of the Medicare DPNP should be grounded in these principles, the foremost among them being patient-centricity, transparency, equity, and vigorous methods enhancement.

[1] Available at: https://thevalueinitiative.org/wp-content/uploads/2024/06/IVI-Comments-to-CMS-regarding-IRA-implementation_FINAL.pdf

[2] Full description of our Principles for Value Assessment in the U.S. available at: https://thevalueinitiative.org/who-we-are/value-principles/

These principles guide all our work, especially in our engagement around DPNP, health equity, and patient engagement issues. With these principles as our framework, we offer the following comments with the summary recommendation that CMS communicate publicly how input from patients, families, and caregivers was used to implement the process and drive decision-making.

IVI commends CMS for its openness to dialogue and its implementation efforts to date

We recognize that in addition to the challenge of building and implementing a complex new program under significant time constraints, CMS must balance the competing needs, concerns, and requests of diverse stakeholder groups while ensuring the program adheres to the statutory requirements laid out in sections 1191 through 1198 of the Social Security Act, as added by sections 11001 and 11002 of the Inflation Reduction Act (IRA).

As in our past comments, IVI recognizes that the legislation includes specific guidelines and places limitations on the implementation of the DPNP. We commend CMS for its ongoing efforts to develop thoughtful, thorough guidance under considerable time constraints. The current draft guidance, revised for 2027 negotiations, reflects important learnings from the past year's negotiation process, CMS's commitment to continuous improvement of the negotiation process, and CMS's active efforts to incorporate the feedback provided by stakeholders, especially patients and caregivers.

IVI acknowledges and appreciates the openness of CMS and the IRA implementation staff to engage in discussions around challenging topics such as the equity implications of IRA implementation choices.

The Draft Guidance reflects important improvements over initial guidance

Changes and additions included in the draft guidance have addressed several concerns about the guidance for price applicability year 2026 and incorporate some learnings and feedback received in the first year of Medicare DPNP implementation. In particular, we commend CMS for the following revisions and additions to improve the Medicare DPNP:

Incorporation of equity as a principle and component of the DPNP

A principal concern included in IVI's comments on the initial guidance for the Medicare DPNP was a lack of consideration of health equity. This omission from the initial

guidance belied the interest expressed by CMS during interactions with IVI both prior to the initial guidance and in subsequent months. We applaud CMS for making some key changes in the draft guidance that represent significant steps toward implementing an equity-centered Medicare DPNP, especially:

- Committing (in Section 60.3.3.1) to "evaluate health outcomes for specific populations, including **through an access and equity lens;**"
- Expansion of the definition of "specific populations" to include those that may experience disparities in access to care, health outcomes, or other factors that impact health equity (in Appendix A); and
- Addition to Appendix A of a definition of "health equity."

Further comments and recommendations on this topic are described below.

Commitment to more effective and robust engagement opportunities for patients, caregivers, and other stakeholders

The draft guidance (specifically section 60.4) and supporting materials, such as the specific areas for comment in the accompanying Fact Sheet[3], demonstrate CMS's commitment to continuing to improve engagement with patients, caregivers, and other non-manufacturer stakeholders. IVI applauds CMS for recognizing the need for improvement, humility in inviting suggestions and feedback, and openness to expanding opportunities for engagement. We recognize that engagement activities represent a resource- and time-intensive addition to Medicare DPNP implementation. A robust engagement program is essential to a patient- and equity-centered DPNP.

Further comments and recommendations on this topic are described below.

Improved clarity around definitions, outcomes, and analyses

The draft guidance improves upon the previous guidance for price applicability year 2026 by providing clarification on several points, including:

- Addition of clearly stated definitions of unmet need and therapeutic advance;
- Additional information in Section 60.3.3.1 on the types of outcomes that CMS may consider; and
- Clarification in section 50.2 of the criteria by which submitted evidence will be weighed and adjudicated (e.g., study limitations, generalizability, etc.) and statement that, "in considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus

[3] Available at: https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf

> on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus."

Engagement is key to ensuring patient- and equity-centered implementation

In our interactions with CMS, past comments on Medicare DPNP guidance, and published recommendations for DPNP implementation, IVI has repeatedly stressed the importance of adopting an inclusive and patient-driven approach. Such an approach is essential to ensuring CMS's negotiation process and its resulting impacts on access and outcomes advance patient well-being and principles of equity.

IVI commends CMS for recognizing the shortcomings of the patient listening sessions and stakeholder engagement opportunities in the first round of negotiations. By openly inviting input on how to better engage with patients and other stakeholders, CMS is taking an important step toward improving processes in the upcoming round of 2027 negotiations. In response, IVI offers the following recommendations:

Format and frequency

The draft guidance notes a variety of potential meeting formats (listening sessions, focus groups, and others). IVI recommends that CMS not limit engagement to a single type or subset of formats, but rather outline a set of potential formats from which CMS may select the most appropriate based on topic and intended use of the information. CMS should engage with subject matter experts in academia and patient communities to develop this set of optional formats and decision guidance to assist in selecting a format for a given event.

In addition, IVI strongly recommends that CMS establish a mechanism for external stakeholders to request meetings on specific topics. IVI recognizes that CMS has a finite capacity to organize such meetings, and a well-articulated process for determining which meetings to host should be developed, including provisions for CMS-approved meetings held by external parties.

Role of engagement activities in negotiation process

Listening sessions, focus groups, and other engagement activities provide a medium for collection of patient experience information, as the draft guidance notes. These sessions should also be incorporated as a tool in the analysis and negotiation process itself.

For example, the draft guidance states at the beginning of section 60.3.3.1 that "CMS will identify outcomes to evaluate for each indication of the selected drug." Patients, caregivers, and other non-manufacturer stakeholders should be formally engaged in identifying and prioritizing both existing health disparities and the outcomes evaluated. Similarly, CMS should use stakeholder sessions, such as roundtables, to discuss prioritization of these disparities and outcomes based on patient-identified importance.

In addition, engagement activities should encompass broader questions intended to inform negotiation processes generally (not specific to a given drug or therapeutic area). For example, CMS should incorporate engagement activities to better articulate an equity approach within the DPNP. Ideally, these activities would begin before CMS receives data from manufacturers. Engagement activities themselves in addition to an advisory group, such as a standing stakeholder review committee, could also provide a mechanism for review, evaluation, and accountability currently lacking in the program.

Further steps to center equity are needed

As stated above, CMS has demonstrated interest in addressing equity-related concerns since beginning the implementation of the IRA, and IVI commends CMS for improving the draft guidance.

On December 5, 2023, IVI partnered with the Alliance for Aging Research, National Pharmaceutical Council, and Leavitt Partners, LLC, to host a half-day symposium to examine issues related to equity and engagement in implementation of the IRA by the CMS, to identify concrete, realistic, and actionable recommendations. The symposium brought together lived experience, policy and scientific expertise from various perspectives including patients and patient advocacy, quality measurement, government agencies, the biopharmaceutical industry, academia, and elsewhere.

The proceedings from this symposium[4], as previously shared with CMS, generated multiple important insights and recommendations. Above all, the discussion underscored that, while the work needed to advance equity and inclusion is complex and challenging, it is also critical that CMS demonstrate leadership in committing both philosophically and materially to a collaborative equity-centered approach to implementation, particularly in the Drug Price Negotiation Program (DPNP), with agency support for development and implementation of this process by the CMS DPNP staff. An overarching theme of the discussion with critical implications for Medicare DPNP implementation was that equity is not a "solvable problem" but rather an "ongoing goal"

[4] Available at: https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf

that CMS should continuously strive towards in all decisions made in the implementation of IRA and conduct of the DPNP.

IVI commends CMS for indicating its intention to evaluate health outcomes "through an access and equity lens." However, equity-centered implementation requires that CMS apply such a lens to the evaluation of health outcomes and the entire DPNP process itself. Furthermore, an access and equity lens should consider implications for equity across all dimensions of the Medicare DPNP, including:

- Process, especially regarding partnership-based and community engagement opportunities, inclusion of specific populations, and self-evaluation;
- Identification of disparities and equity analysis of how the process impacts existing disparities:
- Representativeness, bias, and outcomes included in evidence and analysis; and
- Impacts on access, health outcomes, financial burden, and other potential outcomes for Medicare enrollees and the broader U.S. population.

While recognizing the failure of IRA legislation to include equity as a goal or consideration, IVI strongly recommends that CMS incorporate the following as central components of the Medicare DPNP:

- Robust patient and health equity stakeholder and community engagement program that actively goes to where patients are and brings stakeholders into an ongoing dialogue with a meaningful role in DPNP operations;
- Compensation for patients and caregivers to acknowledge their time and expertise through participation in engagement activities (e.g., focus groups, interviews, and other patient-focused events);
- Transparent, accessible, and explicit communication of goals, intentions, needs, practices, and uncertainties, both forward-looking and past reporting, in multiple formats—plain language, threshold languages, infographics, video vignettes, etc.; and
- Continuous quality measurement and improvement based on process and outcomes measures, regular reflection and evaluation, incorporation of learnings into program changes, and external reporting of these efforts.

In the draft guidance, CMS has taken important initial steps toward such an approach. IVI commends CMS for taking these initial steps and recognizes that the equity-centered approach described above will require time, resources, and potential clarification to the governing legislation. In the meantime, CMS should indicate its intentions through external communications and engagements that clarify long-term goals and equity objectives. Similarly, CMS should incorporate plans for regular qualitative and, if possible, quantitative self-evaluation that includes an assessment of

Medicare DPNP implementation within the recently revised CMS Health Equity Framework[5].

In addition, IVI offers the following specific recommendations regarding the content of the draft guidance:

- Clarification of "access and equity lens"
    - Provide a provisional definition that reflects the considerations outlined in the comments above.
    - As part of discussion of potential engagement opportunities in Section 60.4, include equity-focused engagement activities (e.g., focus groups or town halls) intended to contribute to defining this term.
- Include a discussion of if/how unmet medical needs will be treated differently for specific populations in Section 60.3.

Further information on past and planned approaches is needed

While IVI appreciates the steps CMS has taken to address previous comments and provide more specificity and transparency around its "qualitative approach," a high degree of uncertainty and lack of clarity persists. Areas of concern include:

- Adjudication of evidence – especially regarding relative weighting of evidence types and sources, steps to ensure patient experience data and patient preference data are included, and measures to ensure representation and consideration of specific populations;
- Role of engagement and patient voices in DPNP implementation and operation decisions, evaluation and analysis, negotiations, and determination of Maximum Fair Price;
- Steps to specify outcomes for inclusion in analyses or other aspects of negotiations, especially concerning consideration of patient preferences, equity, and potential for bias by omission; and
- Methods to address nuance and complexity when evaluating therapies across multiple indications, particularly when affected populations or equity implications may vary across indications.

As stated in our comments on the guidance for Price Applicability Year 2026, IVI understands the need for flexibility in CMS's approach. As CMS refines this approach over the initial years of program implementation, we strongly encourage CMS to

[5] Available at: https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf

develop a detailed and well-articulated framework for this approach for inclusion in program guidance. In the meantime, however, visibility into CMS's approach is limited to observation of CMS's actions and justifications for determination of MFP in prior years' negotiations.

Publication of CMS's approach to determining MFP for the year 2026 is not expected until Spring 2025. We fully recognize that the statute clearly specifies timelines for DPNP implementation. Nonetheless, without insight into decisions made as part of this qualitative approach to date, it is important to emphasize that the ability of the public to provide constructive comments and recommendations on the draft guidance is limited. In the interim, we strongly encourage CMS to explore options for sharing information about its approach to date to bolster transparency, improve the quality and relevance of public comment, and reduce the risk of perpetuating issues with or unintended consequences of CMS's approach.

CMS has noted that the implementation of the Medicare DPNP will be iterative, with continual improvements. It is impossible to provide constructive, or even relevant, comments and suggestions without an articulated strategy or set of objectives. CMS should communicate a roadmap for DPNP implementation over the coming years, with clearly stated objectives and areas of need for insight.

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact me or Mark Linthicum, Director of Policy, at mark.linthicum@thevalueinitiative.org for further discussion.

Sincerely,

Jason Spangler, MD, MPH, FACPM
Chief Executive Officer
Innovation and Value Initiative

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

July 2, 2024

VIA Electronic Filing – IRARebateandNegotiation@cms.hhs.gov

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Seshamani:

On behalf of Johnson & Johnson (J&J) we submit the following comments in response to the Centers for Medicare & Medicaid Services' (CMS, the Agency) Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the ("MFP") in 2026 and 2027 (Draft Guidance). At Johnson & Johnson, we are driven by a passion to achieve the best version of health for everyone, everywhere, for as long as possible. In the next decade, we will see more transformation in health than in the past century – and we are ready to lead the way. For nearly 130 years, we have led the way in innovation and are continuing this heritage today by bringing important new pharmaceutical products to market in a range of therapeutic areas on behalf of all our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries. Focusing exclusively on transformational healthcare innovation allows us to move with purpose and speed to tackle the world's toughest health challenges.

J&J is committed to a workable effectuation of the "MFP" for IPAY 2026. We appreciate the strength of our partnership with CMS in collectively working toward our shared implementation goals; however, we are concerned about the significant work ahead to achieve a successful implementation model that is workable for the critical Inflation Reduction Act (IRA) stakeholders, namely CMS and the Medicare beneficiaries, the pharmacies and the manufacturers of selected drugs in 2026.[1]

[1] Although we are challenging the constitutionality of the IRA in federal court, J&J is committed to compliance with the law and working toward a workable implementation so long as the law is in place.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

J&J will continue our active CMS engagement as we prepare for IPAY 2026. Within this response we outline our "MFP" Effectuation Principles and the Critical Requirements for Program implementation and success.

J&J Recommends that CMS:

I. Effectuation of the "Maximum Fair Price"

1. Partner with J&J and other manufacturers to address the critical factors to ensure program success.
2. Prospectively fund the Medicare Transaction Facilitator (MTF) with "MFP" discounts to ensure a successful effectuation model.
    i. Cash flow magnitude requires a CMS pre-fund to mitigate untenable financial risk to pharmacies and other stakeholders.
    ii. A CMS pre-fund enables timely payment to the dispensing entities, as envisioned by the Agency.
    iii. CMS has the legal authority to advance funding to effectuate the "MFP".
    iv. A CMS pre-fund model underpins the feasibility of the rest of the model and scalability of the program requirements under the IRA(the Program).
3. Implement a standardized end-to-end "MFP" effectuation process operationalized by a single, neutral MTF for operational feasibility.
4. Require dispensing entities to participate in the MTF payment functionality in order to access the "MFP" made available by manufacturers through the MTF payment functionality.
5. Provide a civil monetary penalty (CMP) safe harbor for manufacturers participating in the MTF payment functionality.
6. Avoid adopting the infeasible 14-day timeline for IPAY 2026 and 2027.
7. Upon receipt of the critical claims level data from the MTF, manufacturers must be provided with 45 days to comply with their fiduciary and compliance obligations.
8. Align the frequency of MTF-provided claims level data to a quarterly billing cycle under the CMS pre-fund model.
9. Establish a transparent dispute resolution and appeals process with clear timelines and an appeals process.
10. Establish additional payment justification codes to account for future payment scenarios.
11. Set the standard default refund amount (SDRA) for Part D as the lesser of Wholesale Acquisition Cost (WAC) minus the "MFP" of the selected drug based upon the quantity dispensed at the time of dispensing or the manufacturer-contracted price minus the "MFP."
12. Clarify that sales and units to 340B covered entities should continue to be excluded from government price calculations for selected products even when the "MFP" is below the 340B ceiling price.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

13. Require a 340B claim indicator on all pharmacy claims to enable manufacturers and CMS to accurately identify 340B claims to avoid duplicate discounts, as required by statute.
14. Expand the claims level data provided to manufacturers to also include National Provider Identifier (NPI) and encrypted patient ID, in addition to mandatory 340B modifiers.

II. Align the Definition of "Manufacturer" with the Statute
1. Rescind all policies that would hold Primary Manufacturers accountable for submitting data and pricing actions of unaffiliated Secondary Manufacturers.

III. Recommendations on CMS Product Selection Policies
1. Abandon CMS' definition of a qualifying single source drug (QSSD) which departs from well-established statutory definitions and will disincentivize important research.
2. Remove the extra-statutory bona fide marketing standard.
3. Align to the statute in implementing the plasma-derived product exclusion from QSSDs.
4. Provide greater transparency in pricing and therapeutic alternative selection methodologies.

IV. Recommendations for the "Negotiation" Process
1. Allow for substantive, scientifically rigorous dialogue on the clinical evidence in IRA discussions.
2. Provide manufacturers with an explanation of "MFP" in advance of publication.
3. Improve and streamline the registration process for patient listening sessions and provide greater transparency on how the Agency uses stakeholder input to inform the "negotiation" process and determination of "MFP".
4. Publish the updated Medicare drug spending data during 2024 with minimal data lag to allow companies to prepare effectively for IPAY 2027 drug selection cycle.
5. Limit manufacturer-specific data required for submission.
6. Revise definitions included in Appendix A.

I. Effectuation of the "Maximum Fair Price" ("MFP")

J&J "MFP" Effectuation Principles

Motivated by Our Credo[2] and long-time commitments to the Medicare program and those beneficiaries served by it, J&J is committed to delivering the highest standards for our patients and stakeholder partners. Compliance is foundational to our business, and we strive for accurate, efficient, timely, compliant financial transactions within all our partnerships. This legacy has led the J&J team to be considered a 'gold standard' in government contracting. We take this heritage very seriously, and our goal is to partner with the Agency to achieve an "MFP" effectuation

[2] https://www.jnj.com/our-credo

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

process that both maintains our gold standard framework of compliance and fiduciary responsibilities within government programs, and is workable for the pharmaceutical supply chain, most critically the pharmacies and impacted manufacturers.

Given J&J's foundational tenets of delivering the highest standards and compliance adherence within government contracts and price reporting, we are deeply concerned about our ability to comply with our statutory obligations to make the "MFP" available to "MFP" eligible beneficiaries as envisioned within the law and subsequent Draft Guidance. We urge CMS to continue to partner with J&J and other manufacturers to address the following critical factors within the final guidance and through other program instruction to ensure program success. We believe strongly that establishing an effectuation model based on our principles advanced here will best ensure that beneficiaries have continued access to selected drugs.

Fortunately, there is a viable path forward in implementation, provided the critical success factors J&J is advancing are directly addressed.

Critical Factors to Program Success

1. Financial risk mitigation: Ensure a payment infrastructure enables timely payment to pharmacies and protects stakeholders from cash flow risk.
2. Limit channel partner business model disruption: Establish a workable model that, wherever possible, is fit-for-purpose within the current pharmaceutical distribution flow and minimizes disruption to pharmacies, provider practices and most importantly beneficiaries.
3. Alignment with statutory compliance: Enable data transparency to support manufacturers in meeting statutory requirements.
4. Manufacturer operating model alignment: Incorporate current operational norms, including the practices of existing government programs into the program's operating model.
5. Scalability: Establish an operating model which will enable program growth, including additional cycles of drug selection and inclusion of Part B in future years.

CMS Pre-Funding the "MFP" Discount is Required

An effectuation model in which CMS prospectively funds the MTF with the "MFP" discounts ("CMS pre-fund model") is the way to ensure a successful day one effectuation model in IPAY 2026. A CMS pre-fund model will achieve 1) manufacturer compliance with their statutory obligation to provide access to the "MFP" to eligible individuals, without duplication with 340B, 2) beneficiaries to benefit at the point of sale, and 3) timely payment to pharmacies for "MFP" eligible drugs. Given the cashflow magnitude, only CMS can pre-fund the MTF with these discount amounts.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

1. *Cash Flow Magnitude Requires a CMS Pre-Fund*

   Given the magnitude of the cash flow necessary to administer the program and CMS' authority and significant discretion under the statute (as discussed in more detail in Section 3 below), CMS should pre-fund the "MFP" discount. Under a CMS pre-fund model, CMS would provide the upfront cash flow required to administer the program and provide a payment infrastructure that enables timely payment to pharmacies and protects stakeholders from cash flow risk. On a quarterly cycle, manufacturers will make payments based on invoices from the MTF to effectuate the "MFP" accurately and compliantly in a manner consistent with current commercial and government programs, replenishing the CMS pre-fund pool. The ten selected drugs for IPAY 2026 represent $50B in annual sales. Given the products' significant reach and sales, "MFP" discounts across these drugs could equate to billions in monthly cash flow. Cash flow of this magnitude must be supported via the government. Under the effectuation model outlined in the Draft Guidance, pharmacies are bearing this financial risk. We are concerned that an infeasible model will make it impossible for pharmacies to be made whole in the timeline envisioned by CMS, resulting in untenable financial risk for pharmacies and significant risks for beneficiaries' access.

   There is also significant financial risk associated with the large number of claw backs from duplicate, reversed and 340B claims. Published data shows that for five of the ten selected drugs, between 47 and 74 percent of Part D claims are 340B claims.[3] Without the critical data transparency to verify 340B claims prior to payment of the "MFP" discount on claims, the number of overpayments will be significant, and many manufacturers cannot bear the substantial financial risk given the large volume, especially as the program scales.

2. *Enables Timely "MFP" Discount Payments to Dispensing Entities and Pharmacies*

   A CMS pre-fund enables timely payment to the dispensing entities, as envisioned by the Agency. Under a CMS pre-fund model, CMS will prospectively fund the MTF to assure funds are available for timely pharmacy re-payment. This approach reduces financial risk for dispensing entities, reduces supply chain disruption and fits into existing pharmacy flows. To provide more clarity on our recommended approach, Image 1 below illustrates a J&J recommended example timeline with process steps for a CMS pre-fund model for effectuation.

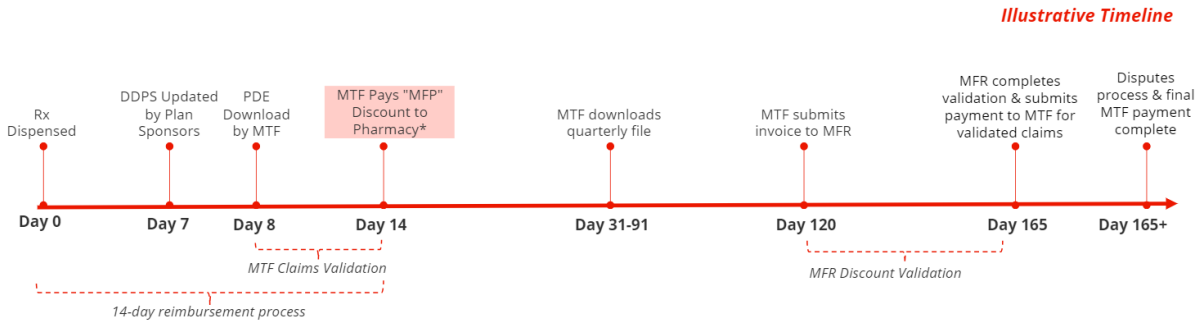
[3] Dickson S, Gabriel N, Hernandez I. Trends in Proportion of Medicare Part D Claims Subject to 340B Discounts, 2013-2020. *JAMA Health Forum.* 2023;4(11):e234091. doi:10.1001/jamahealthforum.2023.4091

Johnson & Johnson

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

Image 1. Illustrative "MFP" Pre-fund Effectuation Model Example



Under a CMS pre-fund model, the plans would reimburse dispensing entities with the “MFP” for selected products on eligible claims. In a timely manner, the MTF would pay the "MFP" discount amount (for example, WAC-MFP) for an eligible claim to the dispensing entity. This could enable CMS to achieve the 14-day reimbursement to pharmacies in a workable process. On a quarterly basis, the MTF will submit an invoice to manufacturers of selected drugs with the required claims level data. This approach aligns with existing processes under other CMS programs. Manufacturers would have a 45-day processing period to perform required compliance and data validation steps, calculate and confirm payment amounts, and issue payment. These steps are described in more detail below in the Data Validation and Calculation section of our comments.

3. *CMS has the Legal Authority to Advance Funding to Effectuate the “MFP”*

CMS is authorized to advance funding to effectuate the “MFP” pursuant to its legal authority as demonstrated in the analysis provided in Exhibit 1. In support of the existence of legal authority for effectuation under the IRA, there is precedent for CMS advancing payment in order to implement and administer the Medicare Coverage Gap Discount Program (CGDP), established under the Affordable Care Act (ACA). Effectuation of the “MFP” can be implemented in the same way as the CGDP because the CGDP is functionally indistinguishable to the IRA. Under both the CGDP and IRA, discounts must be made available at the point of sale, and neither the ACA nor IRA specify how this is to be done. Under the CGDP, CMS advances funds to effectuate the manufacturer discounts. The statutory authority for effectuation under ACA and IRA is substantially similar and supports a CMS pre-fund model in the IRA. Furthermore, under both the ACA and IRA, the Secretary is given broad authority to establish procedures to implement the IRA.

4. *A CMS Pre-Fund Model Underpins the Feasibility of the Rest of the Model and Scalability of the Program*

A CMS-prefund model minimizes disruption across the supply chain by incorporating existing operational norms from other CMS programs. A CMS pre-fund model achieves our

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

shared goals for effectuation by enabling much needed stability for all stakeholders, especially because it leverages some existing procedures in place under the CGDP. Similar to CGDP, under a CMS pre-fund model, the MTF would provide the "MFP" discount amount on eligible claims to dispensing entities in a timely manner, while enabling an MTF-facilitated reconciliation process with manufacturers for those amounts on a regular quarterly billing cycle.

A CMS pre-fund model improves operational workability by providing more predictability and supports program integrity by allowing sufficient time for manufacturers to validate claims prior to payment of "MFP" discount amounts. In addition to improved workability, a CMS pre-fund model reduces financial risk for manufacturers and pharmacies, thereby minimizing risk of negative consequences on beneficiary access. It also supports program sustainability as the number of manufacturers and selected products grows.

The MTF Must Serve as the Centralized Facilitator in the "MFP" Effectuation Model

J&J appreciates the steps CMS has taken to recognize the need for an MTF in the "MFP" effectuation process. We appreciate and agree with CMS' clarification in the Draft Guidance that manufacturers and dispensing entities would not have to pay any fees to participate in the MTF, as CMS would bear the cost of operationalizing the MTF. A standardized "MFP" effectuation process operationalized by a single neutral MTF is necessary for operational feasibility.

The MTF as the End-to-End Solution:

- Provides process standardization across industry, limiting process variability across pharmacies through mandatory MTF participation (as mandated by manufacturer contracts or otherwise);
- Aligns to existing industry norms including current tried and tested rebate payment processes across other government programs (CGDP, Medicaid Drug Rebate Program (MDRP), etc.);
- Enhances operational efficiency, allowing for a central hub to manage manufacturer and pharmacy transactions and ensuring transparency & consistency in decision making.
- Promotes program integrity by ensuring CMS is able to manage the program end-to-end; and
- Enables the ability for all parties, including CMS and manufactures, to meet statutory obligations under IRA and Sarbanes Oxley (SOX).

As described in more detail below, core functionalities of an end-to-end solution for the MTF must include the following:

1. Payment processing and tracking;
2. Data collection and sharing;

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

3. Data validation and calculations; and
4. Dispute facilitation.

1. *Payment Processing and Tracking: MTF-Enabled Payment Facilitation Is Critical to a Successful "MFP" Effectuation Model*

In the Draft Guidance, CMS outlines two MTF payment facilitation options for stakeholder feedback. Under Option 1, the MTF would collect and share dispensing entities' banking information with manufacturers to facilitate private transactions. Under Option 2, the MTF would pass through Primary Manufacturer funds to dispensing entities. We strongly believe the MTF should provide a single platform for manufacturers to transmit "MFP" discount payments. We are concerned that Option 1 is too limited, providing the MTF with no role in distributing payment, and creates significant variability because it would require manufacturers to establish separate processes for every dispensing entity. We do not support this option because it introduces significant compliance and fraud risk concerns for manufacturers.

J&J strongly supports Option 2, with further improvements. Option 2 improves operational flows and reduces compliance risk by providing a single platform for transmitting payments. It may reduce the need for manufacturers to establish agreements with and separate payment processes for dispensing entities.

However, J&J has concerns with Option 2 and urges CMS to adopt changes to improve operational feasibility. As described above, we recommend a CMS pre-fund model in which the MTF would issue "MFP" discount payments to dispensing entities from the CMS pre-funded account and reconcile these payments on a quarterly basis with manufacturers. This approach eliminates the need for manufacturers to issue payment directly to dispensing entities. J&J recommends the following additional changes to Option 2:

- *Options Exist for CMS to Compel Dispensing Entity Participation in Option 2*

  CMS states in the Draft Guidance that the MTF payment functionality is voluntary, and dispensing entities would need to opt-in by agreeing to the terms of an MTF payment facilitation participation agreement. J&J is concerned that optional participation – and therefore lack of standardization – in the MTF payment functionality for dispensing entities will make manufacturer compliance infeasible by creating an unwieldy amount of variability in payment processes. It is not feasible for manufacturers to establish different payment approaches to satisfy the requests of different dispensing entities, especially because it could result in a system in which manufacturers must operationalize thousands of unique payment solutions. The lack of standardization will also create significant challenges for pharmacies that would need to manage differing payment solutions depending on a manufacturer's decision to participate in the MTF payment functionality.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

With the goal of achieving a uniform payment process to promote program integrity and operational feasibility, J&J urges CMS to require dispensing entities to participate in the MTF payment functionality in order to access the "MFP" made available by manufacturers. Under the IRA (Section 1196(a)), the Secretary has broad authority to establish procedures to provide "access" to the "MFP", and CMS is not prohibited from compelling dispensing entity participation in the MTF payment functionality. Just as CMS exercised its discretion to require providers to utilize their NPI numbers to facilitate payment under Medicare, CMS can require a process for dispensing entities to facilitate payment of the "MFP". CMS is mandating participation in the MTF's data exchange functionality, demonstrating its ability to mandate participation in the MTF processes. Therefore, we urge CMS to leverage this same authority and mandate dispensing entity participation in the MTF payment process.

- *Provide a CMP Safe Harbor for Manufacturers Participating in the MTF Payment Functionality*

  Manufacturer participation in the CMS MTF payment functionality Option 2 is a clear indicator of a manufacturer's good faith efforts to comply with its statutory obligations to provide access to the "MFP" without duplication with 340B discounts. We ask CMS to leverage its broad statutory authority and significant discretion in implementing the IRA to determine that such good faith efforts are deemed "access" under the law, and that manufacturers using Option 2 should therefore be deemed as having provided access to the "MFP" and granted a safe harbor from CMPs. This safe harbor would protect manufacturers from CMPs, including in scenarios, for example, in which a dispensing entity declines to participate in the MTF payment facilitation option, or in cases where the MTF has technical issues outside of the control of the manufacturer which may delay payment. J&J urges CMS to establish this safe harbor especially in the first years of the program to recognize good faith efforts of manufacturers to participate in the MTF payment facilitation option in order to comply with their statutory obligations.

- *Recommend CMS Establish Additional Payment Justification Codes*

  CMS outlines in the Draft Guidance its intent to require Primary Manufacturers to transmit claim-level payment elements in their reports with payment-related data to the MTF within the 14-day prompt "MFP" payment window. CMS clarifies that manufacturers must populate one of the required payment elements, "Method for Determining "MFP" Discount/Refund Amount," with one of several pre-identified justification codes to indicate if the "MFP" refund payment was at the "Standard Default Refund Amount", a different amount, or to provide the reason an "MFP" refund payment was not provided. J&J recommends CMS adopt additional

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

justification codes to account for other scenarios which are likely to occur.

J&J asks CMS to include a code for claims that are under dispute by a manufacturer. This is common in other drug payment programs, including under MDRP and Tricare which have a a partial payment mechanism on a disputed claim until resolution. Therefore, we encourage CMS to adopt a similar approach for "MFP" effectuation and add this important additional payment justification code.

In addition, we recommend CMS include a justification code to account for scenarios in which manufacturers do not issue the "MFP" discount payment in order to offset a prior claim. In the Draft Guidance, CMS states it is considering how to handle claim adjustments and resubmissions. J&J proposes CMS add an additional justification code to account for adjustments, thereby allowing manufacturers to offset past claims.

Lastly, while we agree with CMS' inclusion of a justification code to account for the 1193(d)(1) exception for 340B claims to avoid duplicate discounts with 340B, we ask CMS to expand the examples provided in Table 4 for that justification code. Because manufacturers may not receive the information required to accurately identify and verify 340B claims, they will need to develop and establish processes and reasonable assumptions to support avoidance of statutorily prohibited duplicate discounts. Therefore, we recommend that CMS expand on the examples described in Table 4 to include "Suspected 340B Claim."

- *Recommendations for the Rebate Amount Calculation and Implications for Other Government Price Reporting Programs*

  J&J appreciates CMS establishing and providing to manufacturers the "Standard Default Refund Amount", based on WAC minus "MFP" of the selected drug based upon the quantity dispensed at the time of dispensing. We also appreciate CMS providing manufacturers with the flexibility to determine the appropriate discount based on acquisition cost. We are aligned to BIO's recommendations that CMS set the Standard Default Refund Amount for Part D as the lesser of WAC minus the "MFP" of the selected drug based upon the quantity dispensed at the time of dispensing, or the manufacturer-contracted price minus the "MFP", and that CMS grant a CMP safe harbor to manufacturers providing the standard default amount when the manufacturer provides a good faith effort to make the "MFP" available based on the WAC.

  J&J asks CMS to clarify that the "MFP" discount amount calculation should be based off WAC and 340B price at time of dispense. As part of the MDRP, standard government price refiles can occur up to twelve quarters or three years after date of dispense which may have a minimal impact on 340B price as a result of rounding or

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

to reconcile estimates. Manufacturers should not be liable for recalculating the discount amounts (using the lower of "MFP" or 340B price) based off of these government pricing refiles that could change the 340B price. We ask CMS to utilize WAC and 340B price at time of dispense for purposes of determining the lower of the "MFP" or 340B price.

Moreover, we note that if the 340B price changes retroactively on a unit where "MFP" is also applicable, the change to the 340B price would neutralize the change to the "MFP discount. Thus, for example, where a 340B ceiling price is retroactively reduced by $0.02 per unit, the manufacturer owes the 340B covered entity $0.02 per unit to bring the covered entity's final price down by the $0.02. If the manufacturer also paid the covered entity an "MFP" discount on those units (i.e., the difference between the 340B ceiling price and the "MFP"), then the manufacturer would have overpaid the "MFP" discount by $0.02 per unit and the covered entity would owe the manufacturer $0.02 per unit. The $0.02 owed to the covered entity on the 340B price and the $0.02 owed to the manufacturer on the "MFP" discount wash out. This effectively means there would be no need for manufacturers to process any retroactive 340B ceiling price restatements on units where an "MFP" discount was also applicable and no need to recalculate the "MFP" discount. We ask CMS to confirm that the 340B price at time of dispense is used for purposes of determining the lower of the "MFP" or 340B price and that the "MFP" discount amount recalculation is not required when there is a change in 340B price.

Additionally, J&J notes that 340B sales and units are excluded from calculations for Average Sales Price (ASP) under Part B and MDRP government price calculations. To reduce implications of the IRA on these longstanding government price calculations and regulated exclusions, we ask CMS to clarify that 340B sales and units should continue to be excluded from these government price calculations for selected products when the manufacturer identifies the unit is a 340B unit, including in cases when the "MFP" is lower than the 340B price. As required under Medicaid regulations, any prices charged to a 340B covered entity shall be excluded from Best Price, including prices below 340B ceiling (subceiling prices) .[4,5]

2. *Data Collection and Sharing: Critical 340B Data Transparency and Importance of Claims Transparency*

Under a CMS pre-fund model for "MFP" effectuation, data transparency remains critical for manufacturers to comply with their statutory requirements to make "MFP" available to "MFP" eligible individuals without duplication with 340B discounts. J&J appreciates and supports CMS emphasizing the importance of claims level data for manufacturers outlined by

[4] 81 Fed. Reg. at 5257
[5] 1927(c)(1)(C)(i)

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

CMS in Table 2 of the Draft Guidance. The claims level data included in Table 2 is critical to enabling program transparency and integrity.

However, additional data transparency is required to enable manufacturers to comply with the statutory requirement to avoid duplicate discounts with 340B. In the Draft Guidance, CMS clarifies that the "340B Claim Indicator" is voluntarily for reporting by dispensing entities and will only be shared by the MTF with manufacturers in instances in which it has been reported. J&J underscores that because there is significant lag time for data from the 340B third party administrator, with no regulation on timing and frequency of 340B third party administrator data, and no mandated use of 340B claim indicators, significant challenges exist in accurately avoiding duplicate discounts on 340B claims.

In the Draft Guidance, CMS declines to "assume responsibility for deduplicating discounts between the 340B ceiling price and "MFP" and indicates instead that covered entity may "voluntarily and proactively" disclose 340B and "MFP" eligibility. This would effectively mean 340B covered entities could choose not to identify 340B/"MFP" claims which, in turn, means they would be able to hinder manufacturers from identifying 340B/"MFP" claims and force manufacturers to pay both a 340B discount and the full "MFP" discount in clear violation of the IRA's prohibition of duplicate 340B and "MFP" discounts. Allowing covered entities to submit this information at a later date would only add inordinate complexity and prolong this violation of federal law. In our experience, a very limited number of CEs voluntarily provide the 340B identifier on claims. We are concerned that a lack of sufficient 340B data transparency will impede program integrity and result in a high volume of future disputes and claw backs. Mandatory use of 340B claim indicators or modifiers is critical in enabling manufacturers and CMS to accurately identify 340B claims to avoid duplicate discounts, as required by statute. J&J supports a mandatory requirement for a 340B claim indicator on all pharmacy claims.

J&J recommends addition of the following mandated data elements to Table 2, which are required under any successful "MFP" effectuation model, including with or without a CMS pre-fund of the MTF:

- 340B modifiers: As stated above, J&J urges mandatory 340B modifiers that are required consistently across all channels to help to verify 340B claims. Voluntary use is not sufficient.
- Provider NPI: This field exists today in the National Council for Prescription Drug Programs (NCPDP) Medical standards and is included under the CGDP. It is a standard field needed to ensure each utilization of claims is unique, and it supports manufacturer identification of 340B claims.
- Encrypted patient ID: This field is included today in the NCPDP Rx and Medical standards. It is a standard field to ensure each utilization of claims is unique when applied consistently across all claims for all eligible programs.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

3. *Data Validation and Calculations: 45 Day Manufacturing Processing Period Required for Data Validation and Payment*

J&J shares CMS' goal of timely payment to eligible dispensing entities. We recognize that timely payment is critical to reduce financial risk to pharmacies and could have ramifications for patient access to selected products and to cost sharing based on "MFP". However, no statutory mandate requires payment from manufacturers within 14 days and a perpetual 14-day manufacturer payment timeline – that is triggered by each individual claim and re-starts on a daily basis – is not feasible for manufacturers or sustainable for the Program as it grows.

A payment system in which manufacturers, rather than payers, pay daily on thousands of claims to over 60,000+ pharmacies across the country with only 14 days to validate data, calculate discount amounts and issue payment is a significant departure from the way any drug payment program is operated today. It is impossible under today's pharmaceutical distribution system and would take years to implement. This is even more complicated when considering the statutory mandate to avoid duplicate discounts with 340B, especially given the magnitude of Part D claims that are 340B (for example, 47% to 74% for five of the ten selected drugs for IPAY 2026), for which data ordinarily is not available within 14 days.[6] An overhaul of this magnitude would take years and significant stakeholder collaboration to achieve successfully.

We urge CMS to abandon the proposal for an infeasible 14-day timeline for IPAY 2026 and 2027.

- *14-Day Manufacturer Prompt Payment Timeline Does Not Align with Existing Programs*

  In the Draft Guidance, CMS states that the 14-day prompt "MFP" payment window "aligns with the timing requirement in the longstanding prompt pay rules in Part D." However, J&J strongly disagrees. The 14-day prompt pay timeline under Part D referred to in the Draft Guidance is specific to the payment window for plans rather than manufacturers. In fact, as noted above, manufacturer payment terms under existing CMS programs provide significantly more time than 14 days to manufacturers. For example, manufacturer payment due terms post invoice under the MDRP is 37 days, under the CGDP is 38 days, and under Medicare Part D is up to 90 days. 14 days is significantly shorter than existing programs, with a significant larger scale given the large volume of dispensing entities under Part D. "MFP" effectuation is far more complicated than the basic payment transaction covered under Part D prompt pay rules, and therefore, we ask CMS to abandon this infeasible timeline

[6] Dickson S, Gabriel N, Hernandez I. Trends in Proportion of Medicare Part D Claims Subject to 340B Discounts, 2013-2020. *JAMA Health Forum.* 2023;4(11):e234091. doi:10.1001/jamahealthforum.2023.4091

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

because of manufacturers' inability to comply, especially as the program grows.

- *Sufficient Time Required for Manufacturer Data Validation to Enable Program Integrity and Manufacturer Compliance*

  Once manufacturers receive the critical claims level data from the MTF, manufacturers must be provided with 45 days to comply with their fiduciary and compliance obligations to scrub data to determine claims eligibility. Claim eligibility validation is separate than the patient eligibility verification that will be performed by plans and CMS.

  Manufacturer claim eligibility validation steps must be completed *before* manufacturers begin "MFP" discount calculations and facilitate payment to dispensing entities. This validation is required to enable manufacturer compliance, including with IRA and SOX, ensure program integrity, incentivize data quality, and reduce risk of a high volume of future disputes and claw backs that could overwhelm the system. It includes necessary scrubbing of data for inaccuracies, errors, contract non-compliance or fraud, and 340B verification. Given the expected high number of 340B Part D claims, it is critical that manufacturers have sufficient time to validate these claims to avoid a high volume of disputes and claw backs. The required process involves multiple levels of validation across different teams, systems and data sets to perform high level data standardization and integrity checks, verify manufacturer and provider contract compliance, and validate claim eligibility.

  To provide additional detail, some of these required manufacturer validation steps are outlined below:

High Level Data Standardization & Data Integrity	• Standardize data for further analysis • Identify any missing national drug codes (NDCs), Prescription number (Rx #), Fill Dates, etc.
Manufacturer and Provider Contract Compliance	• Identify formularies utilized • Pull relevant formulary files • Assess formulary specific items (step edit, prior authorization, quantity limits, etc.) • Establish formulary compliance
Claim Validation	• 340B duplicates utilizing the data procured from 340B third party administrators (TPAs) • Unit of measurement accuracy, aberrant quantity review • Prescription fulfillment

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

	• Double submissions • Plan eligibility • Determine acquisition cost • Data integrity reviews to assess compliance to NCPDP standards

We are also concerned that some of the data required to complete manufacturers' required validation is not typically available to manufacturers within 14 days, including the following:

- 340B Data: in limited circumstances where 340B covered entity currently submit data identifying claims as 340B, that data is typically not available for 3-4 weeks post prescription fulfilment;
- Reversals: Drug reversal data regarding prescription abandonment is not available within the proposed 7-day window for plans to submit prescription drug event (PDE) records to the Drug Data Processing System (DDPS);
- Duplicates: PDE data alone is insufficient to identify duplicate claims submitted across programs; and
- Units of Measurement: DDPS is unable to highlight the errors in units of measurement for a given product.

- *Frequency of MTF-Provided Claims Level Data Should Align to Recommended Quarterly Billing Cycle Under the CMS Pre-Fund Model*

In the Draft Guidance, CMS seeks feedback on the frequency in which the MTF should provide claims level data to manufacturers, suggesting daily or biweekly. There are significant challenges with the frequency of both of these suggested timelines, primarily because CMS intends to start the manufacturer 14-day prompt pay window upon manufacturer receipt of this data. Under this approach, manufacturers would be restarting a new "MFP" payment cycle across 60,000+ dispensing entities every single day or bi-weekly. J&J opposes this model because it does not enable manufacturer compliance or support program scalability. This model is infeasible for manufacturers. Unlike payers, manufacturers are not subject to such frequent billing cycles and short payment terms under existing programs, which, as noted above, typically provide manufacturers with 37-70 days to validate data and issue payment.

As demonstrated in the J&J recommended process flow provided above, we ask CMS to adopt a quarterly manufacturer billing cycle facilitated by the MTF in which claims level data would be provided to manufacturers as part of the quarterly reconciliation process under the CMS pre-fund model for eligible "MFP" discount payments made

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

by the MTF to dispensers. This process must provide at least 45 days for manufacturer processing, which includes the data validation steps outlined above, steps required to calculate the "MFP" discount amount accurately, and an enhanced ability to facilitate payment compliance with CMS guidance. A CMS pre-fund model enables this approach, which aligns to other programs, while ensuring timely payment to dispensing entities.

4. *Dispute Facilitation: CMS Must Establish a Transparent Dispute Resolution and Appeals Process*

J&J thanks CMS for outlining in the Draft Guidance a process to address complaints and disputes related to "MFP" availability and MTF functionality. A robust dispute resolution process is a critical component of the Program. While we strongly support the inclusion of a dispute resolution process, we urge CMS to provide additional details for the process in final guidance. J&J suggests that CMS provide clarity in timelines, transparency in responses, multiple levels of resolution, and a process for appeals. J&J is aligned to PhRMA's recommendations on the dispute resolution process.

J&J recommends the MTF-facilitated dispute resolution and appeals process include:

- Defined timelines and decision matrix: clearly defined timelines, transparent decisions, including detailed rationale on claim rejection. For example, rationale should go beyond favorable / unfavorable.
- Clearly defined appeal process: a process for appeal or request secondary reviews for rejected disputes.
- Detailed dispute reporting capability: ability for manufacturers to provide detailed reports on disputed claims including a dispute code, amount disputed and detailed rationale beyond 'reason not paid' to be shared with involved parties.
- Ability to attach evidence: ability for manufacturers to attach the relevant evidence/files tied to the disputed claim and share with MTF via email.
- Ability to raise recurring issues: ability for manufacturers to share the recurrent issues specific to a pharmacy or dispensing entity with MTF to identify opportunities for process streamlining and corrective actions.
- Partial payment mechanism for manufacturers: Aligned to existing norms across other government programs, manufacturers should not be required to pay on disputed claims until resolution.

Critical Partnership Needed Leading Up to Start of IPAY 2026

J&J recognizes CMS' interest in advancing the submission deadline for a Primary Manufacturer of a selected drug to send its plan for ensuring "MFP" availability to CMS in writing for IPAY 2026 from December 2, 2025 to June 1, 2025. However, by June 1, 2025, manufacturers of

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

selected drugs for IPAY 2026 will have already made critical decisions and started to implement the infrastructure and processes to make the "MFP" available to "MFP" eligible individuals at the start of the program on January 1, 2026. While we understand CMS' obligation to review these plans for consistency and compliance with the law, reversal of or amendments to critical decisions made by manufacturers as of June 1, 2025, may not be possible in time for IPAY 2026.

J&J stresses the importance of the ongoing partnership between CMS, the pharmacies and manufacturers to ensure a viable "MFP" effectuation model at the start of the program. Leading up to January 1, 2026, we ask CMS to provide a meaningful forum for manufacturers of selected drugs for IPAY 2026 to partner and collaborate with CMS to identify the best solutions in implementing the "MFP" effectuation process, align on critical decisions for the process flow, and develop an integrated governance model to build and manage aligned timelines.

II. Align Manufacturer Definition with Statute

Primary Manufacturers Cannot Be Held Responsible for Secondary Manufacturers or Third Party Manufacturers with Whom They Have No Contracts

J&J continues to have significant concern with CMS' intent to enter into Medicare Price Negotiation Agreements only with "Primary Manufacturers," and to hold Primary Manufacturers that enter into Agreements with CMS accountable for collecting and reporting necessary information applicable to any Secondary Manufacturer; and ensuring that any Secondary Manufacturer make the "MFP" available to "MFP" eligible individuals, pharmacies, mail order services and other dispensers. Despite the clear definition for "manufacturer" in the IRA, CMS has adopted different definitions. This approach improperly ignores and overrides the statutorily adopted manufacturer definition in a manner that exceeds CMS authority. The terms "primary" and "secondary" manufacturer are not referenced in the IRA. Under the IRA, the statutory definition adopted for "manufacturer" includes "... any entity which is engaged in production...OR the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products."[7] We urge CMS to follow the statute in defining manufacturer to align with the term defined in section 1847A(c)(6)(A) of the Act. In our experience, the IPAY 2026 "negotiation" cycle illuminated many challenges in operationalizing "MFP" effectuation as detailed below.

CMS' use of the Primary/Secondary Manufacturer construct in the IRA is inoperable and disregards the reality that different participants in the pharmaceutical supply chain are free to create new NDCs without express consent or authorization from the NDA/BLA holder. In this Draft Guidance, CMS states that Primary Manufacturers have an ongoing obligation to timely report any changes to the list of NDC-11s of a selected drug so that the lists remain complete and accurate. CMS further clarifies that failure of the Primary Manufacturer to provide timely information material to the accuracy of the list of NDC-11s of the selected drug may cause the

[7] 42 U.S.C. 1396r-8(k)(5)

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

Primary Manufacturer to be subject to CMPs per section 1197(c) of the Act. We are concerned that this is not feasible for Primary Manufacturers in scenarios when there are NDC additions or deletions from unaffiliated Secondary Manufacturers or third party manufacturers, given that Primary Manufacturers have no control over or timely visibility into their NDC updates. While there are often Secondary Manufacturers that meet the definition of "manufacturer" under the Act, there also are other parties that would fall under CMS' broad definition of Secondary Manufacturer that are simply repackers that are not selling a product or trade unit.

Distinctly, these entities solely provide repacking services for which they create new NDCs for different package sizes. The Secondary Manufacturer definition overreaches to encompass repackers for which Primary Manufacturers neither have a contract with nor have authorized the provision of repacking services or creation of NDCs. Actions to update NDCs may be taken by third parties with which manufacturers may have no relationship and no visibility into independent arrangements where they create new NDCs for repacking purposes. Additionally, there could be no utilization for NDCs created for repacking services provided in certain settings, such as hospitals, or for delivery purposes only.

In addition, CMS clarifies in the Draft Guidance that a Primary Manufacturer is responsible for the MTF transactions associated with any Secondary Manufacturer. Given that Primary Manufacturers may have no affiliation or contract with a Secondary Manufacturer, Primary Manufacturers will have to make reasonable assumptions to implement CMS' guidance, including, for example, limiting responsibility for any unaffiliated Secondary Manufacturer that a Primary Manufacturer is not contracted with.

We underscore that in many instances, Primary Manufacturers and Secondary Manufacturers are distinct and unaffiliated entities. Primary and Secondary Manufacturers can be direct competitors in a market, and there is no incentive to exchange or provide commercial practices. We are concerned that sharing the required data across Primary and Secondary Manufacturers could heighten exposure to federal and state antitrust laws due to the sharing of proprietary information as CMS noted in its February 2016 Medicaid Program Final Rule, in which the Agency agreed not to finalize its proposal regarding the sharing of pricing data between competing manufacturers and recognized the challenges of obtaining pricing information from non- related manufacturers. Even if a Primary Manufacturer were willing to try to compel a Secondary Manufacturer to share the required information for submission, it would require restructuring of contracts and business terms, as well as the establishment of a process to obtain the information, and it would be infeasible to do so in the period provided in the law and the process outlined by CMS. In fact. J&J has attempted to do so in connection with the IPAY 2026 "negotiation" cycle and has confirmed the timing and process make it infeasible.

J&J continues to urge CMS to rescind all policies which would hold Primary Manufacturers accountable for the submission of data and pricing actions of unaffiliated Secondary Manufacturers, as Primary Manufacturers do not have access to the required data elements for Secondary Manufacturers and do not have the needed control or authority to ensure their

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

compliance. We continue to urge CMS to use the unique product labeler ID assigned to each establishment by the FDA to better identify Primary Manufacturer instead of reviewing only the holder of NDA/BLA.

III. Recommendations on CMS Product Selection Policies

The Agency's Definition of a Qualified Single Source Drug Departs from Well-Established Statutory Definitions and Will Disincentivize Important Research

We reiterate the comments we made on the draft IPAY 2026 guidance relative to CMS' definition of QSSD. The current definition is inconsistent with the plain language of the IRA, and CMS erroneously relies on language that applies only to the determination of eligibility for the small biotech exemption to aggregate products approved under separate New Drug Applications (NDAs) or Biologics License Applications (BLAs) into a single QSSD. In addition, CMS' decision to aggregate products in this way creates a significant disincentive to continued product development, which will have a negative impact on important innovation for patients. CMS should conform the QSSD definition to the statutory requirements such that to be included in a QSSD, each individual drug product or biological product must be approved or licensed under the same NDA or BLA, either as part of the original application or under a supplement to such application, and at least seven years or 11 years (as applicable) before the selected drug publication date.

Remove the Extra-Statutory "Bona Fide" Marketing Standard

We also reiterate the objection we made on the draft IPAY 2026 guidance on the issue of CMS' "bona fide" marketing standard. § 1192(e) states that the presence of an "approved and marketed" generic drug under FDCA § 505(j) or biosimilar under PHS § 351(k) results in the exclusion of the reference product from the definition of a QSSD. This is a critically important protection provided to manufacturers that face generic competition and, therefore, already are subject to substantial pricing pressure. In articulating this protection, the plain language of the statute refers to a generic drug or biosimilar that is "marketed." IRA § 1192(e).

However, CMS creates a new standard to determine whether a reference drug or biological is excluded from the definition of a QSSD and, therefore, protected from the compulsory discounting mechanism. That new standard – not found in the statute – requires "bona fide marketing" of the generic drug or biosimilar.

This change in substantive legal standard is troubling for several reasons. First CMS has effectively added the phrase "bona fide" to the statute. Second, the standard is undefined. Regulated parties are provided no notice as to what CMS believes is "bona fide" marketing and what is not. Indeed, the criteria to be applied are not disclosed, creating substantial uncertainty for manufacturers and others seeking to understand which products are eligible for selection.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

An extra-statutory "bona fide" marketing standard, applied to generic drugs and biosimilars, undermines the statutory purpose to protect otherwise qualifying single source drugs from the compulsory discounting mechanism. The risk that the application of that standard would render that protection a nullity appears significant. We therefore urge CMS to remove the "bona fide" marketing requirement and apply the statute as written.

Plasma-Derived Product Exclusion from Qualifying Single Source Drugs

CMS proposes to refer to "approved product labeling" to determine if products fall within the plasma-derived product exclusion outlined in section 1192(e)(3)(C) of the Act. We urge CMS to strictly adopt the language in accordance with section 1192(e)(3)(C) of the Act. CMS should look to other FDA resources like the Approved Cellular and Gene Therapy Products website to clarify that other plasma-derived products are aligned to section 1192(e)(3)(C).

CMS Should Provide Greater Transparency in Pricing and Therapeutic Alternative Selection Methodologies

CMS has stated that if the price of the therapeutic alternative is above the "MFP" ceiling or if there is no therapeutic alternative, then CMS will use lower of the Federal Supply Schedule (FSS) or the "Big Four" price as the starting point. This approach is inconsistent with CMS' stated intent to "start developing the initial offer within the context of the cost and clinical benefit of one or more drugs that treat the same disease or condition".[8] Instead of arbitrarily selecting the lowest federal price for the selected drug, it would be more appropriate for CMS to use the closest possible price to the price of the therapeutic alternative—the ceiling price—as the starting point for developing the initial offer. Selection of the ceiling price as the starting point would better reflect the cost and clinical benefit associated with the alternative.

IV. Recommendations for the "Negotiation" Process

IRA Discussions on Selected Products Must Allow for Substantive Scientifically Rigorous Dialogue on the Clinical Evidence

We strongly urge the Agency to enhance (or ramp-up) the dialogue and discussion on the clinical evidence for selected products. Transparency into the process is important, and while we appreciate the opportunity to have multiple, in-person engagements with Agency, we prefer CMS focus on the quality of these engagements over the number of meetings held.

We respectively offer the following recommendations. CMS should:

[8] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA
T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

1. Include a panel of experts comprised of clinicians and epidemiologists with relevant disease area expertise to engage in meaningful dialogue on the facts and evidence in discussion pertinent to evaluation.
2. Strive for transparent, interactive, and scientifically rigorous discussions on how CMS has evaluated disease area guidelines, consulted expert clinical opinion, and how CMS reviewed, interpreted and analyzed randomized clinical trials, real-world evidence, and other literature in their methodology. Transparency is needed regarding CMS' clinical advisors, including names and credentials of subject matter experts.
3. Facilitate an evidence-based engagement, and transparency on rationale, regarding how evidence is driving toward an "MFP". Transparency is required for all parties to engage in meaningful dialogue. CMS should provide a response detailing agreement/disagreement with the manufacturer's clinical and scientific arguments and where adjustments in price were made based on clinical and scientific evaluation. For example, as a party to the "negotiation", manufacturers should be able to understand how evidence reviewed by CMS influences the ongoing discussions in establishing an "MFP".
4. Use a consistent evaluation methodology across all products. CMS should clearly delineate, in updated guidance, its approach to reviewing evidence and engage in a transparent, scientifically rigorous process with consideration of study limitations and biases, consistent, replicable, and open process. CMS should share with manufacturers their evaluation of the data robustness.

In summary, we urge CMS to clarify how the statutorily defined factors will be used to determine the "MFP" before the "negotiation" process starts. This explanation should be offered across all the factors and be transparent to all stakeholders, particularly those party to the Agreement. CMS should use a consistent evaluation methodology across all products, clearly delineate in updated guidance its approach to reviewing evidence, and engage in a transparent, scientifically rigorous, consistent, replicable, and open process.

Manufacturers Should Receive an Explanation of "MFP" in Advance of Publication

Aligned to our previous comments on IPAY 2026 Guidance, J&J underscores our strong recommendation that CMS provide manufacturers the opportunity to review, respond to, and approve the public explanation of the "MFP" to:

1. Ensure "MFP" explanations are succinct and simple. The establishment of "MFP" selection process was not intended to give drug sequencing medical guidance, and prescribing decisions should be left to physicians to avoid impacts to beneficiary treatment which may be in contrast with standards of care. Therefore, it is important that the "MFP" explanation be simple and succinct to avoid any potential appearance as a medical communication which would create risk for beneficiaries by signaling medical advice.

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA
T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

2. To confirm that no confidential or proprietary information would be improperly disclosed. The ramifications of an inappropriate disclosure of proprietary information in a publicly posted explanation are so significant for manufacturers that an additional level of review is warranted.
3. Reflect a process akin to other manufacturer reviews provided by other agencies (i.e. FDA, CDC).

Recommended Improvements to Stakeholder Feedback Sessions

J&J appreciates CMS' consideration of changes to make the patient listening sessions more valuable. We note that the lottery registration process used for the listening sessions in IPAY 2026 made it difficult for patients to sign up, and we also understand from feedback from advocacy groups that the registration system required too much personal health information. Therefore, we encourage CMS to improve and streamline the registration process and limit personal health information to only what is necessary so the right advocacy voices can be heard. J&J supports live, interactive targeted sessions in which CMS would have the ability to ask questions, and we also support round table discussions that should include representation from the full ecosystem of care, including patients, caregivers, and healthcare professionals. Moreover, we ask CMS to provide greater transparency on how the Agency uses stakeholder's input to inform the "negotiation" process and determination of "MFP".

Provide Timely Access to Expenditure Data

Given the substantial amount of data and evidence that manufacturers of selected products must provide within one month of product selection, it is essential for manufacturers to accurately forecast whether their products are likely to be selected. Our experience of the IPAY 2026 selection process is that the data available from CMS is generally too old to reliably predict the list of selected products. We urge CMS to take steps to publish updated Medicare drug spending data during 2024 with minimal data lag to allow companies to prepare effectively for the IPAY 2027 cycle.

CMS Should Limit Manufacturer Specific Data Required for Submission

J&J continues to have significant concern with the extensive amounts of data required for submission. We ask the Agency to limit required data to those critical for price setting methodology, as described in the statue, to minimize unnecessary burden on manufacturers for data that does not add value to CMS' evaluation. We urge CMS to provide more transparency and specificity on how each of these data points are used in the price setting process.

Recommendations on Revisions to Definitions in Appendix A

In Appendix A of the Draft Guidance, CMS outlines the definitions and standards to be collected for use in the Program. CMS describes its intent to publish the "negotiation" Data Elements

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

Information Collection Request (ICR) for IPAY 2027 on how Primary Manufacturers and members of the public may submit relevant data, and solicits comments on potential revisions to definitions in Appendix A. J&J recommends CMS make the following changes to the definitions outlined in Appendix A:

- *Research and Development (R&D) Costs*
  J&J recommends that CMS simplify the R&D reporting requirements to allow the Primary Manufacturer to offer an attestation in instances where the manufacturer believes to have fully recouped the R&D costs. While collection of R&D data for the purposes of determining Primary Manufacturer cost recoupment is required by statute, we continue to have concern that the approach currently outlined by CMS is unnecessarily burdensome. The calculation of R&D spending may not be compatible with existing financial accounting practices and neglects the multi-faceted and interlinked elements that comprise the research ecosystem, which may result in an incomplete and inaccurate calculation of R&D investment and ignore indirect costs. CMS' approach on R&D costs does not accurately reflect the true costs of innovation or the associated risk. We urge CMS to simplify R&D cost reporting as one reported number that meets the requirements of the statute.

- *Prior Federal Financial Support*
  J&J recommends CMS remove these data from manufacturer submission requirements. We continue to have concerns, as described in our comments last year, that CMS employs an overly broad definition for novel therapeutic discovery and development of a selected drug to set the "MFP". We are concerned with the unintended consequences of creating the perception that prior financial support could be used as factor for CMS to justify a reduction in the "MFP". We are particularly concerned about the inclusion of tax credits for orphan disease drugs as a form of prior Federal financial support, as adjustments to the "MFP" based on this could be antithetical to the incentives of drug development for the treatment of individuals, and Medicare beneficiaries, with rare disease. Many of these data elements are not known to manufacturers, or the level of granularity requested is not captured. Therefore, we recommend CMS remove these data from manufacturer submission requirements or limit this information solely to funding that resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a US government agency.

- *Patents, Exclusivities, and Approvals*
  As part of the "negotiation" process, CMS requires the Primary and/or Secondary Manufacturer to submit data on patents and regulatory exclusivities.[9]

  Patents and regulatory exclusivities are key incentives for innovator manufacturers to make the investments necessary to develop transformative treatments for patients. A

[9] Section 50.1, page 66, Appendix A, page 132

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

patent is a constitutionally protected property right granted by the US Patent and Trademark Office that protects new and innovative inventions. Patents are an essential incentive that allow innovative pharmaceutical companies to take on the considerable risk, and make the substantial investments, required to develop new medicines that benefit patients. The patent system also promotes knowledge sharing, options for patients and doctors, and is a key driver of economic growth. Regulatory exclusivities, like patent rights, are also a critical incentive for innovator companies to invest in R&D. These exclusivities attach upon approval of a drug and are only awarded when an innovator meets the statutory requirements of the FD&C Act. Regulatory exclusivities are part of a balanced legal framework that grants innovative pharmaceutical companies a defined and limited period of exclusivity. Upon expiry of this period, generic companies are permitted to reference innovator clinical data which facilitates generic entry. Together, patent and regulatory exclusivities provide the predictable incentive framework necessary for the development of innovative medicines, which in turn yield significant benefits for patients.

Here, we encourage the Agency to revise its guidance so that: (A) expired and non-public patents and (B) expired regulatory exclusivities are not required for submission. Instead, this information should be disclosed at the discretion of the Primary and/or Secondary Manufacturer.

In regard to patents, Section 50.1 and Appendix A of the Draft Guidance requires a Primary Manufacturer to submit to CMS "relevant patents," both *expired* and unexpired, that are related to the selected drug. (Appendix A, page 132) We urge the Agency not to require the submission of expired patents. This requirement creates an undue burden for Primary and/or Secondary Manufacturer(s) because: (i) CMS has embraced an expansive definition of QSSD that encompasses multiple strengths and formulations of an active moiety, and (ii) the request for patents "related to the selected drug" is vague and overly broad. The Agency, moreover, has not indicated how expired patent information will be used to determine the "MFP". To this end, expired patents should not be relevant to determining an "MFP" since they describe innovation that may be freely practiced by anyone.

Additionally, we urge the Agency not to require the submission of non-public patent applications as this forced disclosure of confidential information may hinder industry collaboration. For example, a Primary Manufacturer and Secondary Manufacturer may be collaborators advancing a particular drug with one mechanism of action to treat a particular disease in a certain therapeutic area. However, the Primary Manufacturer and Secondary Manufacturer may also be developing competing products with a different mechanism of action in the same disease and therapeutic area. In this scenario, if the collaboration drug is selected for "negotiation", the Secondary Manufacturer could be forced to disclose confidential patent information to the Primary Manufacturer relating to their competitor product since the strategies for protecting both products may be

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA
T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

scientifically intertwined (e.g., patent protection for assays, methods of treatment, combination therapies, etc.). Accordingly, this forced disclosure will disincentivize companies from collaborating, which will hinder the discovery and development of new innovations and ultimately reduce patient choice. As such, we strongly encourage CMS to update its guidance to clarify that the submission of any non-public patent information by a Primary or Secondary Manufacturer should be discretionary.

CMS is also seeking to collect information regarding the selected drug's regulatory exclusivities. We encourage the Agency to clarify that expired regulatory exclusivities are not required for submission. Instead, this information should be disclosed at the discretion of the Primary and/or Secondary Manufacturer. In view of CMS' expansive definition of QSSD, requiring the submission of expired regulatory exclusivities is labor-intensive. This onerous requirement is further complicated by the fact that expired regulatory exclusivities are not maintained in the course of regular business activities. Expired regulatory exclusivities, moreover, should not be relevant to determining an "MFP" as they do not delay or prohibit competition. Accordingly, any limited value that expired regulatory exclusivities may have in determining an "MFP" is far outweighed by the heavy burden of the request.

Lastly, requiring a Primary and/or Secondary Manufacturer to submit expired regulatory exclusivities disproportionally and negatively impacts small molecule drugs. Unlike biologics, small molecule drugs may be rewarded one or more New Clinical Investigation ("NCI") Exclusivities for developing different innovations relating to new indications to help patients. However, these NCI Exclusivities often run concurrently with a later expiring exclusivity, such as a drug's New Chemical Entity ("NCE") Exclusivity. As a result, many expired NCI exclusivities may never have been material to a product's market share as they expire before, or shortly after, the expiry of the NCE exclusivity. In sum, for all of the above reasons, we strongly encourage CMS to update its guidance to clarify that the submission of any expired regulatory exclusivities by a Primary or Secondary Manufacturer should be discretionary.

- *Market data and Revenue and Sales Volume Data*
  As outlined in our previous comments, J&J is concerned with the requirements for Primary Manufacturers to submit to CMS market data and revenue and sales volume data for the selected drug to inform the "negotiation" process. We are concerned that these definitions are very broad and often considered confidential, proprietary information. We ask CMS to remove these data from submission requirements.

- *Manufacturer Net Medicare Part D Price*
  J&J opposes the inclusion of this price in manufacturer submitted data, which was not included in manufacturer requirements for IPAY 2026. CMS calculated this information in IPAY 2026 for selected drugs and therapeutic alternatives, and therefore asking for manufacturer submission when the Agency has demonstrated its ability to provide this

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

price point creates unnecessary burden. Moreover, we are concerned that manufacturer submission of this price could create flawed comparisons with therapeutic alternatives because manufacturers are unable to validate or understand how this information is being used, especially because rebates for therapeutic alternatives are proprietary. We also ask CMS to share with manufacturers of selected drugs the net Medicare Part D price for therapeutic alternatives.

- *Therapeutic Advance*
  For this optional evidence, CMS describes in the definition that it represents a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s) for an indication(s) or in outcomes when there is no therapeutic alternative. However, the definition of substantial is arbitrary, and we ask CMS to provide additional clarity, including on if substantial improvements encompasses both safety and efficacy.

- *Outcomes*
  For this optional evidence, CMS defines it to include clinical outcomes or outcomes related to the functioning, symptoms, quality of life, or other aspects of a patient's life. J&J asks CMS to further clarify if it also includes cost of care outcomes.

- *Specific Populations*
  CMS defines specific populations that could be submitted as optional additional evidence about therapeutic treatments. J&J recommends that CMS also include in its definition 'patients with multiple comorbidities.'

- *Unmet Medical Need*
  J&J recommends that CMS broaden the definition of unmet need beyond the availability of therapies to also include the drug's therapeutic profile correlated to the needs of patients and subpopulations, especially those with historically disparate access or outcomes. CMS should take an approach that harmonizes the definition in Appendix A with FDA's definition for unmet medical need, and orphan and pediatric regulatory exclusivities codified in other federal statutes.[10]

- *Off Label Use*
  CMS defines off label use as use of drug that is not approved by the FDA but is included in nationally recognized, evidence-based guidelines. However, we ask CMS to clarify how manufacturers can provide evidence related to off label use that may not be included in evidence-based guidelines.

Conclusion

J&J appreciates this opportunity to provide our feedback to CMS on this Draft Guidance. Recognizing the limited amount of time before IPAY 2026, we urge CMS to work closely with

[10] https://www.fda.gov/media/86377/download

Johnson & Johnson Services, Inc
1350 I (Eye) Street, NW, Suite 1210
Washington, DC 20005 USA

T +1 202 589-1000
jroche8@its.jnj.com
jnj.com

manufacturers of selected products and other key stakeholders to ensure operational readiness for IPAY 2026. We look forward to continued dialogue with the Agency.

Sincerely,

Jacqueline Roche, DrPH
Head, Payment and Delivery Policy & Global Policy Institute
Johnson & Johnson Worldwide Government Affairs & Policy

Akin

Exhibit 1

M E M O R A N D U M

June 27, 2024

To: Johnson & Johnson

From: Kelly M. Cleary

Re: Effectuation of Maximum Fair Price

You have asked us to consider whether the Centers for Medicare & Medicare Services (CMS) can facilitate access to the maximum fair price (MFP) of selected drugs by advancing funding to cover the spread between a dispensing entity's acquisition cost and the MFP, and thereafter recouping such funds from the manufacturer. As explained below, we believe that CMS has the authority to advance funding to effectuate the MFP at the point of sale and has already set a precedent for doing so in its implementation of the Medicare Coverage Gap Discount Program.

I. Background

Section 11001 of the Inflation Reduction Act (IRA) (Pub. L. 117-169) directs the Secretary to establish a Drug Price Negotiation Program ("Negotiation Program") and to enter into agreements with manufacturers of selected drugs that set a "maximum fair price" for those drugs. Under these agreements, manufacturers must provide eligible Medicare beneficiaries with "access" to the MFP at the point of sale. Manufacturers must also provide access to the MFP to the pharmacy, mail order service, or other dispensing entity ("dispensing entities"). The statute is silent as to what it means to "provide access" to the MFP and does not prescribe the means by which the manufacturer provides access.

The IRA incorporates the MFP into the Part D prescription drug benefit program by adopting the MFP as a cap on the negotiated prices used for payment of the selected covered Part D drugs.[11] Under Medicare Part D, the Part D plan sponsors (or MA organizations offering MAPD plans) are obligated to administer the benefit, and must provide their enrollees with access to the negotiated prices (or, in the case of selected drugs, the MFP).[12] CMS is responsible

[11] Social Security Act § 1860D-2(d)(1)(D).

[12] *Id.* §§ 1860D-2(d)(1)(A), (D). CMS has stated that while the IRA requires manufacturers to provide access to the MFP to MFP-eligible individuals, Part D plan sponsors will "facilitate" access "in the normal course of

for the administration of the Drug Price Negotiation Program[3] and the Part D Program.[4] To effectively administer the Part D Program, and to discharge its duties under the IRA, CMS must establish processes to ensure that beneficiaries have access to covered drugs at negotiated prices that reflect the negotiated MFP.[5]

CMS has explained in draft guidance that it expects manufacturers to "provide access" to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (a "retrospective refund").[6] With respect to the retrospective refunds, CMS has stated it intends to contract with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between manufacturers and dispensing entities in order to support the verification that the selected drug was dispensed to an MFP-eligible individual, to facilitate prompt payment of the MFP refund, and to collect confirmation from manufacturers that the MFP refund was paid. [7] CMS will require manufacturers to participate in this data exchange.

CMS is also considering using the MTF to administer retrospective refunds. Under one option described by CMS, the MTF would receive aggregated refund amounts from participating manufacturers and pass through the refunds to participating dispensing entities.[8] CMS has indicated that participation with the MTF for payment of retrospective refunds would be

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https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturereffectuation-mfp-2026-2027.pdf [hereinafter "March 2023 Draft MFP Guidance"].

[3] The IRA assigns CMS specific functions related to the administration of the Drug Price Negotiation Program, including establishment of procedures "to carry out the provisions of this part" with respect to Medicare beneficiaries eligible to receive the MFP. Social Security Act § 1196(a)(3). The IRA also calls on CMS to establish procedures related to the computation and application of the MFP. *Id.* at § 1196(a)(1)-(2).

[4] *Id.* at § 1808(a).

[5] *Id.* at § 1196(a)(1)-(3) (directing CMS to establish procedures to ensure the MFP is correctly computed and applied, and to "carry out the provisions of this part" with respect to beneficiaries enrolled in Part D and Part B).

[6] March 2023 Draft MFP Guidance, at 32.

[7] CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*, at 37 (May 3, 2024),

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operations." CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*, at 36 (Mar. 15, 2023),

https://www.cms.gov/files/document/medicaredrug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf [hereinafter "May 2023 Draft MFP Guidance"].

[8] *Id.* at 52-60.

voluntary for manufacturers and dispensing entities.[13] CMS has said it would cover the cost of the MTF refund functionality, but would not use federal funds "to resolve or make payment related to disputes that may arise between parties participating in the MTF, including with respect to nonpayment or insufficient payment by a particular party."[14]

II. Analysis

Under its existing authorities, CMS can receive and distribute funds from manufacturers, either directly or through a third party administrator (like the MTF).[15] Further, CMS can make advance distributions, subject to reconciliation or recoupment, as necessary to ensure the MFP is provided at the point of sale.

A. CMS already advances funds to effectuate manufacturer discounts under the Coverage Gap Discount Program

There is precedent for CMS making such advanced payments to effectuate benefits under the Part D program.[16] Specifically, CMS makes advance payments to Part D sponsors to effectuate manufacturer discounts under the Medicare Coverage Gap Discount Program ("Discount Program").[17] Created by the Affordable Care Act, the Discount Program makes drug manufacturer discounts available to eligible Medicare beneficiaries at the point of sale when receiving applicable covered Part D drugs while in the coverage gap phase.

The Discount Program's authorizing legislation sets up a structure whereby manufacturers must agree to provide eligible Medicare beneficiaries access to discounted prices

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[13] *Id.* at 53.

[14] *Id.* at 58-59.

[15] Unlike the authorities governing the ACA's Coverage Gap Discount Program and the IRA's Manufacturer Discount Program (*see* Social Security Act §§ 1860D-14A(d)(2)(A), 1860D-14C(d)(2)), the statutory provisions establishing the Drug Price Negotiation Program do not prohibit CMS from receiving or distributing any funds of a manufacturer under the Program.

[16] CMS also uses advance payments in other Medicare payment systems. For instance, CMS has on occasion made advanced payments to Part B physicians and other suppliers. In 1989, in response to a backlog of pending claims, CMS authorized its contractors to make conditional partial payments to suppliers on claims that the contractors were unable to process within the prescribed time limits. These partial payments were subject to later recoupment once the claims were actually processed. This was designed to avoid untimely payments to the suppliers. CMS later codified this practice in regulation, *see* 42 C.F.R. § 421.214, and has since used advanced payments to address cash flow challenges related to the COVID-19 pandemic and, most recently, the Change Healthcare breach.

[17] *See* 42 C.F.R. § 423.2320. CMS is taking a similar approach in implementing the new Manufacturer Discount Program established by the IRA and codified at section 1860D-14C of the Social Security Act.

at the point of sale. It also charges the Secretary with establishing procedures to ensure the discounts are properly applied at the point of sale, and that the dispensing pharmacies are reimbursed for the difference between the negotiated price (inclusive of any discounts) and the acquisition cost of the drug within a set timeframe (14 days for claims submitted electronically).[18] The statute prohibits CMS from receiving or distributing manufacturer funds, and instead requires that CMS contract with a third party to facilitate the transfers.[19]

In implementing the Discount Program, CMS recognized that "[w]hile manufacturer discounts under the Discount Program must be made available at point-of-sale, the Affordable Care Act does not specify how this should be done."[20] Exercising the considerable discretion afforded to it under the statute, CMS ultimately determined that the best and most accurate way to effectuate manufacturer discounts at the point of sale was to require Part D sponsors to provide the discounts on the manufacturer's behalf.[21] In justifying this approach, CMS noted that the only entity that could effectively provide the discount at the point of sale was the Part D sponsor, because no other entity would have access to the information necessary to effectuate the discount.[22] The manufacturers, in turn, could discharge their obligation by reimbursing Part D sponsors in accordance with quarterly invoices.[23]

Under the structure established by CMS, Part D sponsors are obligated to reimburse pharmacies on discounted drugs within 14 days, per statutory requirements, but do not receive payments from manufacturers until later in the process (38 calendar days after distribution of quarterly invoices).[24] Thus, Part D sponsors have to make a sizable cash outlay to meet the statutory prompt pay requirement. CMS determined it necessary to provide "interim coverage gap payments" to Part D sponsors, which were designed to "ensure that Part D sponsors will have the funds available to advance the manufacturer discounts to applicable beneficiaries at the point of sale."[25] CMS established the process now codified at 42 C.F.R. § 423.2320, whereby CMS makes monthly interim payments to allow Part D sponsors to advance discounts to

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[18] Social Security Act §§ 1860D-14A(c)(1)(A)(iv), (g)(3)(A).

[19] *Id.* § 1860D-14A(d)(2), (3).

[20] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, 77 Fed. Reg. 22,072, 22,079 (April 12, 2012).

[21] *Id*. at 22,086.

[22] *See* CMS, *Medicare Coverage Gap Discount Program Memorandum*, at 3 (April 30, 2010), https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/2011CoverageGapDiscount_043010v2.pdf [hereinafter "2010 Draft Coverage Gap Guidance"]. At the time, CMS also considered using a third party administrator to directly adjudicate the discount payment to pharmacies, but determined that then-existing HIPAA billing standards could not support the transfer of information necessary to implement the discount.

[23] *Id* at 4.

[24] 42 C.F.R. § 423.2315(b)(3).

[25] 77 Fed. Reg. at 22,086.

beneficiaries, and reconciles interim payments with amounts invoiced to manufacturers. These advance payments appear to be funded through the Part D Account in the Supplemental Medical Insurance (SMI) Trust Fund.[26]

B. The statutory authority underlying the Negotiation Program is materially similar to that of the Coverage Gap Discount Program, and would support CMS effectuating the MFP using a process that resembles the payment process for coverage gap discounts

As far as statutory authority, there are no material differences between how discounts are made available under the Discount Program and how the MFP is made available through the Negotiation Program:

1. *In both programs, the manufacturer is responsible for providing access to the discount/MFP to eligible beneficiaries*.[27]

Even though the authorizing statute for the Discount Program made the manufacturer responsible for providing the discount, CMS required the Part D sponsor to make applicable discounts available at the pharmacy, by mail order service, or at any other point of sale for applicable drugs.[28] The manufacturer, in turn, is bound by an agreement with CMS to promptly pay back the Part D sponsors within 38 days of receiving a quarterly invoice.[29] CMS reasoned that the Part D sponsor, rather than the manufacturer, had the information necessary to provide

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[26] *See, e.g.*, BDS. TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2023 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, at 108-09 (Mar. 31, 2023), https://www.cms.gov/oact/tr/2023. Social Security Act section 1860D-16 governs the use of the Part D Account. This section authorizes funds for "such amounts as the Secretary certifies are necessary to make payments to operate the program under [Part D], *including*—" various statutory subsidies and administrative expenses. 1860D-16(b)(1). The use of the word "including" is presumed to mean that the list is not an exhaustive list, *see generally,* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS, at 132 (2012), and the Secretary therefore has considerable authority to determine which amounts are necessary to administer the Part D program.

[27] Social Security Act §§ 1860D-14A(b)(1)(A) (Medicare Coverage Gap Discount Program) ("An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices…"), 1860D-14C(b)(1)(A) (Manufacturer Discount Program) ("An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices…"), 1193(a)(3) (Manufacturer Agreements under the Drug Price Negotiation Program) (providing that "access to the maximum fair price . . . shall be provided by the manufacturer to" eligible beneficiaries).

[28] CMS, MEDICARE COVERAGE GAP DISCOUNT PROGRAM AGREEMENT, at 8, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/ManuAgreement.pdf (last accessed Jun. 21, 2024).

[29] *Id.* at 6. 42 C.F.R. §§ 423.2315(b)(3).

the discount at the point of sale, and it was therefore appropriate to require Part D sponsors to provide the discount on the manufacturer's behalf.[30]

CMS could similarly require Part D sponsors to provide the MFP at the point of sale. While section 1193(a) requires manufacturers to "provide access" to the MFP to both beneficiaries and dispensing entities, CMS could effectuate this statutory mandate by requiring the Part D sponsor to provide the MFP on behalf of manufacturers and require manufacturers to provide refunds to the Part D sponsor. As with the coverage gap discount, Part D sponsors have the information necessary to provide the MFP to the beneficiary at the point of sale and have an independent obligation to account for the MFP in determining the negotiated price in order to determine beneficiary cost sharing and administer the benefit at the point of sale.[31]

2. *In both programs, access to the discount/MFP must be provided at the point-of-sale*.[32]

Section 1193(a) extends the manufacturer's obligation to "provide access" to the MFP to the dispensing entity at the point of sale. The Discount Program statute does not contain a similar obligation with respect to discounts, and expressly allows for the pharmacy to be made whole *after* the point of sale.[33] Just as CMS has allowed manufacturers to discharge their obligations to discount-eligible beneficiaries through repayment to Part D sponsors, CMS could allow manufacturers to discharge their MFP-related obligations to dispensing entities through repayment to Part D sponsors who pay retrospective refunds on manufacturers' behalf.

3. *Under both programs, the Secretary is given broad authority to establish procedures necessary to carry out the statutory directives, including establishing procedures for providing "access" to the discount/MFP.*[34]

The statutes authorizing the Discount Program and the Negotiation Program both create obligations for manufacturers to "provide access" to discounts/MFP, but neither define what it

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[30] Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities, 76 Fed. Reg. 63,018, 63,021–22 (Oct. 11, 2011).

[31] Social Security Act § 1860D-2(d)(1)(D).

[32] *Id.* at §§ 1193(a)(3)(A) (Manufacturer Agreements under the Drug Price Negotiation Program), 1860D14A(b)(1)(B) (Medicare Coverage Gap Discount Program).

[33] *Id.* at § 1860D-14A (c)(1)(A)(iv) (providing for procedures to ensure that the dispensing entity is reimbursed for the difference between the negotiated price and the discounted price *after* the product is dispensed). This nuance could be interpreted to mean that Congress wanted the pharmacy to receive the benefit of the MFP at the point of sale, not at some later point in time. However, CMS has already interpreted the statute to allow manufacturers to satisfy their obligations to dispensing entities through payment of retrospective refunds.

[34] *Id.* at §§ 1196(a), 1860D-14A(c), 1860D-14A(c).

means to provide access or prescribe how access is provided. Instead, both statutes give CMS broad authority to establish procedures necessary to administer the programs. Further, CMS also has statutory authority to implement both programs through program instruction,[35] and has the authority to makes such rules "as may be necessary to the efficient administration of the functions with which [it] is charged under this Act."[36] CMS therefore has significant discretion in determining the most effective and efficient means of ensuring that beneficiaries and dispensing entities are able to access the MFP at the point of sale.

Given the similarities outlined above, there is no reason why CMS could not effectuate the MFP in the same manner as the discounts under the Discount Program, including making advance monthly MFP payments to Part D sponsors in order to ensure that Part D sponsors will have the funds available to advance the manufacturer's MFP to applicable beneficiaries (and dispensing entities). CMS could adopt the same framework as currently laid out in 42 C.F.R. § 423.2320(a), and, just as CMS has done for the advance coverage gap discount payments, it could draw from the Part D Account in the SMI Trust Fund. CMS has the authority to establish requirements in the manufacturer agreements that it deems "necessary for purposes of administering the program and monitoring compliance with the program."[37]

C. CMS could also effectuate the MFP by contracting with the MTF to administer transfers of retrospective refunds and by structuring payments under the contract such that the MTF is able to promptly pay dispensing entities in advance of collecting on manufacturer obligations.

Alternatively, CMS could implement retrospective refunds through a contract with the MTF, which would adjudicate the retrospective rebates directly between dispensing entities and manufacturers (i.e., without advancement of funds by the Part D sponsor).[38] Indeed, there is nothing in the law that would prohibit CMS (or its contractor) from receiving or distributing manufacturer funds to effectuate the MFP,[39] and CMS has already expressed an interest in using the MTF to administer retrospective refunds.[40] Further, while CMS has taken the position that

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[35] *Id.* at § 1860D-14A(d)(5); IRA § 11001(c).

[36] Social Security Act §1102(a).

[37] *Id.* at § 1193(a)(5).

[38] CMS considered this model in 2010 for the Coverage Gap Discount Program, but declined to use that model because at the time there was no approved billing standard that could support the transfer of information from the Part D sponsor that would be necessary to accurately determine payment. *See*, CMS, *Medicare Coverage Gap Discount Program beginning in 2011*, at 3 (Apr. 30, 2010), https://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovContra/downloads/2011CoverageGapDiscount_043010v2.pdf.

[39] Unlike the authorities governing the Discount Program (*see* Social Security Act §§ 1860D-14A(d)(2)(A), the statutory provisions establishing the Negotiation Program do not prohibit CMS from receiving or distributing any funds of a manufacturer under the Program.

[40] May 2023 Draft MFP Guidance at 37.

it cannot fund the manufacturers' obligations,[41] CMS does not appear to have foreclosed the possibility of advancing MFP refunds that the manufacturers are obligated to repay.[42]

To ensure that dispensing pharmacies are timely reimbursed for the difference between the MFP and acquisition costs, CMS could require that the MTF contractor pay invoices from the dispensing entity within 14 days (or some other period). Further, CMS could establish a payment schedule under the MTF contract that provides a funding stream adequate to cover invoice payments. Costs the MTF incurs in collecting refund payments from manufacturers (including any costs associated with the need to advance refund payments to dispensing entities) would be administrative costs that CMS could reimburse under the contract.

[41] *Id* at 58–59.

[42] Social Security Act section 1874(a) contemplates the use of advance payments where necessary to administer the Medicare program, providing that CMS "may perform any of [its] functions under this title [XVIII] directly, or by contract *providing for payment in advance* or by way of reimbursement, and in such installments, as the Secretary may deem necessary."

III. Conclusion

CMS has the authority to establish procedures it deems necessary to effectively and efficiently manage how the MFP is provided under the Part D benefit. If CMS determines that it must advance manufacturer payments in order to ensure that dispensing pharmacies are timely repaid for providing the MFP, it can establish procedures for making such advance payments and recovering funds from manufacturers. These advance funds could be paid through the Part D Account or through programmatic appropriations as contract costs.

From: Olivia Little <Olivia.Little@jchosp.com>
Sent: Friday, June 28, 2024 9:23 AM
To: CMS IRA Rebate and Negotiation
Subject: Medicare Drug Price Negotiation Program Draft Guidance

Categories: Comments

On May 3, 2024, the Centers for Medicare & Medicaid Services (CMS) issued draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. Johnson County Hospital is very concerned that the guidance, if implemented as proposed, would impermissibly interfere with hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on 340B hospitals, would recommend that 340B hospitals share their claims data directly with manufacturers, and would force hospitals to float greater drugs costs until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price. We call on CMS to abandon its current proposal and develop a workable plan that allows hospitals to continue using 340B regardless of which price is lowest.

Sincerely,

Olivia Little, MHA, MLS (ASCP)^{CM}, CPhT, 340B ACE
340B Director
Johnson County Hospital
202 High St
Tecumseh, NE 68450
402-335-6391

JOHNSON COUNTY HOSPITAL

Out of Office July 4th-21st.

KAISER PERMANENTE®

June 26, 2024

Dr. Meena Seshamani, M.D., Ph.D.
Deputy Administrator, Director of the Center for Medicare
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Re: ***Medicare Drug Price Negotiation Program Draft Guidance***

Dear Dr. Seshamani:

Kaiser Permanente appreciates the opportunity to comment on the *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (hereinafter "Draft Guidance").

Kaiser Permanente is the largest private integrated health care delivery system in the U.S., delivering health care to 12.6 million members in eight states and the District of Columbia.[1] Kaiser Foundation Health Plan, Inc. and our health plan subsidiaries are Medicare Advantage Organizations (MAOs) and provide more than 1.9 million Medicare beneficiaries with prescription drug coverage through Medicare Advantage-Part D plans. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

Within our footprint, we maintain a primarily internalized pharmacy system, including over 537 outpatient, hospital, infusion, specialty and mail order pharmacy sites staffed by over 14,800 pharmacy personnel. Kaiser Permanente spends approximately $11.7 billion annually on pharmaceuticals. Our Permanente Medical Group (PMG) physicians and other authorized practitioners prescribe, and our pharmacies dispense, over 100 million outpatient prescriptions, 60 million inpatient prescriptions and 60 million clinic infusions annually.

We appreciate CMS' continued efforts to provide timely implementation guidance for the Medicare Drug Price Negotiation Program (hereinafter the "Negotiation Program"). As the first cycle of Medicare negotiations is underway, we view this program as a critical mechanism toward addressing a dysfunctional prescription drug market and curbing unsustainably high drug prices for Medicare beneficiaries. The Negotiation Program and the negotiated maximum fair prices (MFPs) must continue to improve drug affordability and be careful to not functionally create a

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 40 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

One Kaiser Plaza
Oakland, CA 94612

price floor for selected drugs that would prevent health systems from negotiating deeper discounts for patients.

As an integrated delivery system, Kaiser Permanente is uniquely impacted by various aspects of the Negotiation Program since we are a prescription drug purchaser that negotiates directly with pharmaceutical manufacturers, a dispensing entity, as well as a Medicare Advantage Prescription Drug plan. We offer the following recommendations to ensure the Draft Guidance accounts for integrated systems that perform multiple functions impacted by the Negotiation Program:

- Primary Manufacturers should only be required to transmit data that confirms the MFP has been provided to the dispensing entity without disclosing additional payment terms that would divulge additional discount amounts greater than what is required to effectuate the MFP;

- CMS should clarify that if dispensing entities opt into the Medicare Transaction Facilitator (MTF) payment facilitation process they are not required to utilize the process for all selected drugs; and

- For the duration of the Negotiation Program, CMS should continue its formulary inclusion policies to not implement explicit tier placement or utilization management requirements and refrain from applying any special formulary treatment toward selected drugs.

Section 40.4 – Providing Access to the MFP in 2026 and 2027

The Draft Guidance reiterates CMS' commitment to engage with a Medicare Transaction Facilitator (MTF) to facilitate the exchange of data between pharmaceutical supply chain entities, a process which will support the verification that the selected drug was dispensed to an MFP-eligible individual. While Primary Manufacturer participation in the MTF data exchange is mandatory, CMS intends to leverage existing Part D claims data in this data exchange and does not envision dispensing entities separately transmitting claims data to Primary Manufacturers. Kaiser Permanente supports CMS' plan to leverage existing Part D claims data for this data exchange process.

Additionally, CMS is requiring Primary Manufacturers to transmit reports to the MTF with payment-related data so that CMS can verify access to the MFP has been timely provided to the dispensing entity. The payment-related data elements include the "Amount of Payment Sent as the MFP Refund" (if any) and the "Method for Determining MFP Discount/Refund Amount." We urge CMS to clarify that Primary Manufacturers need only transmit data for these elements that confirm the MFP has been provided without disclosing additional payment terms that would divulge additional discount amounts greater than what is required to effectuate the MFP, if applicable.

For example, when the Primary Manufacturer transmits information for the data element "Amount of Payment Sent as the MFP Refund," the value listed should only be required to reflect an amount that confirms the MFP was made available, even if the Primary Manufacturer is providing a greater

discount to the dispensing entity. We are concerned that if a Primary Manufacturer is required to disclose the value of any additional discounts beyond what is needed to effectuate the MFP, such disclosure could create a chilling effect for manufacturers that might be willing to offer deeper discounts on selected drugs to health systems with a demonstrated superior capacity to effectively drive market share of preferred drugs, whether measured by formulary-consistent prescribing, dispensing or otherwise. Given that the intent of the Inflation Reduction Act (IRA) is to lower drug costs, and not have the MFP effectively serve as a price floor, it is important that the MTF data transmission process protect competition and the ability of purchasers to negotiate greater discounts to lower both individual and overall drug costs for patients.

CMS is also soliciting comments on two voluntary options for the MTF to facilitate payments between Primary Manufacturers and dispensing entities. The Draft Guidance notes that to participate in the MTF's payment facilitation functionality, dispensing entities and Primary Manufacturers would need to opt-in by agreeing to the terms of an MTF payment facilitation participation agreement, but nothing would preclude a Primary Manufacturer and a dispensing entity from reaching agreements outside of the MTF on the effectuation of the MFP. We recommend CMS clarify that this means if dispensing entities opt into the MTF payment facilitation process they are not required to utilize the process for all selected drugs.

We anticipate situations where a dispensing entity may have existing relationships with some Primary Manufacturers and choose to effectuate the MFP outside of the MTF process, while also availing themselves of the MTF payment facilitation in other cases where they do not have an existing relationship with a Primary Manufacturer. CMS should ensure such arrangements are allowed to continue.

Section 110 – Part D Formulary Inclusion of Selected Drugs

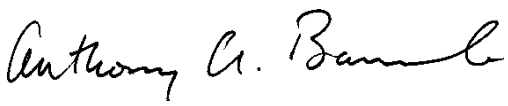
CMS intends to continue its formulary inclusion policies as described in previous guidance, including that CMS will not apply explicit tier placement or utilization management requirements. We strongly support this policy as it remains consistent with the statutory approach of the IRA, which does not specify how selected drugs are required to be included on Part D formularies. Part D plans must continue to have flexibility in designing evidence-based formularies that support appropriate, safe and cost-effective access to covered drugs.

We strongly urge CMS to continue this policy moving forward and refrain from applying any special formulary treatment toward selected drugs, such as establishing selected drugs as a protected class or requiring preferred placement within Part D formularies. We anticipate instances where Kaiser Permanente may have negotiated significant discounts on a therapeutic alternative to a selected drug, perhaps lower than the negotiated MFP, and requiring us to place the higher-priced selected drug in a preferred position on our formulary would lead to increased costs for members and the Part D program while jeopardizing our ability to secure continued discounts on the alternative product. The Negotiation Program should not serve as a mechanism to reduce competition and create winners in certain drug classes.

* * *

We appreciate CMS' consideration of our comments, and we look forward to working together to ensure the successful continued implementation of the IRA and the Negotiation Program. Please feel free to contact me at (510) 271-6835 or anthony.barrueta@kp.org or Simon Vismantas at (425) 677-1267 or simon.p.vismantas@kp.org with any questions or concerns.

Sincerely,



Anthony A. Barrueta
Senior Vice President
Government Relations

kalderos

Submitted by email to IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Meena Seshamani
CMS Deputy Administrator, Director of the Center for Medicare
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

Kalderos appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' ("CMS") Medicare Drug Price Negotiation Program Draft Guidance regarding the Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter, "Draft Guidance").

Kalderos is building unifying technologies that bring transparency, trust, and efficiency to drug discount and rebate programs, including the 340B Drug Discount Program (the "340B Program"), in compliance with applicable laws and regulations. We are on a mission to solve systemic problems within the healthcare system, redefining how the business of healthcare performs. Kalderos seeks to solve the problems in drug discount and rebate programs by connecting the stakeholders; enabling simple, streamlined communication; and applying machine learning to create smart data science tools. We are genuinely committed to being an honest broker administering a fair, balanced process assisting providers (including 340B covered entities), payors, and manufacturers to ensure the right drug price is applied to the right transaction through a proactive compliance mindset, consistent with laws and contract terms.

I. Kalderos's Role in and Experience with Discounts and Rebates Spans Years and Hundreds of Millions in Identified Non-compliance.

Kalderos builds solutions to ensure that stakeholders comply with all statutory and regulatory requirements of discount and rebate programs, including those imposed by the Inflation Reduction Act of 2022 ("IRA") and other federal and state laws concerning drug pricing and reimbursement. Kalderos supports the goals outlined by CMS in the Draft Guidance, particularly those goals related to transparency, program integrity, and compliance.

The essence of Kalderos's honest-broker approach is to be fair to payers, providers, and manufacturers in a manner that is consistent with all applicable laws and regulations. To that end, Kalderos has evaluated and developed solutions to facilitate coordination between providers and manufacturers, while simultaneously ensuring that there are systems in place to identify, dispute, and resolve noncompliance within drug discount and rebate programs.

However, despite years of attempts to educate providers and payers about how to prevent noncompliant discounts and rebates from happening, we continue to identify hundreds of millions of dollars each year in noncompliance. This is further evidence that traditional chargeback-based or similar solutions are unsuccessful at preventing drug discount and rebate noncompliance. Indeed, drug discount programs are only expanding and becoming more complex. As an alternative to the traditional, ineffective chargeback model, Kalderos has developed the Direct Discount Platform, a technology-driven model for effectuating the 340B price directly to covered entities as a rebate.

The Direct Discount Platform offers a number of significant benefits that impact all stakeholders in the 340B Program. Using a rebate model, complete claims-level data is exchanged between all parties to effectuate a discount, preventing nearly 100% of noncompliant discounts. Additionally, all stakeholders will be able to access a central ledger of claim and rebate information, ensuring complete transparency to all parties. This transparent approach fosters trust and creates positive working relationships with all stakeholders, instead of adversarial ones. Further, since 340B rebate funds flow directly to covered entities, they experience greater control over program savings. In many cases, covered entities will access rebates faster without the need to wait for accumulation and replenishment of the discounted drug.

Finally, the Direct Discount Platform is configurable and can be used for compliance with other discount programs, including the effectuation of the MFP. Indeed, CMS has recognized in the Draft Guidance that a rebate model is important for the effectuation of the MFP at the point of sale while complying with the duplicate discount prohibitions built into the statute. The Direct Discount Platform will work seamlessly with drugs subject to an MFP. We believe it is crucial that a technology-based rebate system enter the market now to transition the system to rebates in advance of MFPs going live in 2026. Kalderos would welcome an opportunity to conduct a functional demonstration of the Direct Discount Platform to CMS.

Importantly, we are concerned that the Draft Guidance fails to provide a process for ensuring that compliance with the MFP duplicate discount provision is followed. It is of vital importance that the final guidance regarding the Medicare Drug Price Negotiation Program ("Price Negotiation Program" or the "Program") adequately addresses the manner by which noncompliant MFP transactions can be prevented from occurring, and in cases where noncompliance is unable to be prevented, provide a manner to identify and resolve disputes. Failure to do so would significantly weaken the purpose and intent of the Price Negotiation Program, as without effective safeguards against these issues, CMS will be unable to ensure that eligible individuals receive access to products at the MFP without triggering a duplicate discount, consistent with the statute. Such failure could also open the Price Negotiation Program to challenge based on an arbitrary and capricious implementation of the Program.

It is with this background in mind that we offer the following comments on the Draft Guidance.

* * *

II. Executive Summary of Comments

1. **CMS must establish a process that permits manufacturers to obtain data to prevent duplicate discounts**. By declining to take ownership over preventing duplicate discounts, CMS has shifted this burden to manufacturers. In doing so, CMS must establish a process that permits manufacturers to obtain data to be able to effectively prevent duplicates.

2. **Kalderos does not support the use of a single Medicare Transaction Facilitator ("MTF").** There should be multiple entities in the marketplace tasked with facilitating the exchange of data and payment between pharmaceutical supply chain entities. ***However*, if only one MTF is selected, Kalderos is best positioned to carry out the responsibilities of the MTF.**

3. **Kalderos believes that a rebate model is necessary to effectuate the MFP, and this position is consistent with the Draft Guidance.** It is necessary to effectuate the MFP through a rebate model, as opposed to the traditional chargeback-based model or similar credit-based model, because a rebate model permits unit-based payments, while chargeback- and credit-based models are limited to effectuating the MFP at the package level, even when the drug is dispensed at the unit level. Kalderos has developed a technology-driven rebate model, the Direct Discount Platform, that is configurable and can be used for compliance with other discount programs, including the effectuation of the MFP. We believe it is crucial that a technology-based rebate system enter the market now to transition the system to rebates in advance of MFPs going live in 2026.

4. **CMS must permit manufacturers to audit the data submitted when requesting an MFP rebate to reduce the risk of the submission of inaccurate data.** It is standard commercial practice to permit drug manufacturers to audit the data provided by parties who request a rebate or chargeback. CMS must permit manufacturers and other stakeholders, like Kalderos, to enter into agreements with dispensing entities to audit the data submitted by dispensing entities requesting a MFP rebate.

5. **Additional guidance is needed to ensure that complaints and disputes related to the MFP are handled appropriately.** Kalderos supports CMS' proposal to establish a centralized intake system for receiving reports related to access to the MFP. However, we urge CMS to issue guidance establishing a process for manufacturers and other stakeholders to report duplicate discounts or other MFP dispensing issues to CMS so that they have an opportunity to formally engage in the program integrity process.

III. CMS Must Establish A Process that Permits Manufacturers To Obtain Data To Prevent Duplicate Discounts.

We appreciate that the statutory language found in § 1193(d) of the IRA makes clear that the Primary Manufacturer of a selected drug is not required to provide access to the MFP for a selected drug to MFP-eligible individuals who are also eligible to receive the drug at the 340B discounted price if the 340B discounted price is lower than the MFP for such selected drug.

However, we are concerned that the Draft Guidance does not expressly prohibit covered entities or their contract pharmacies from "accumulating" a transaction where a 340B-eligible beneficiary receives a product at MFP, potentially leading to a covered entity or contract pharmacy receiving both a MFP rebate and a 340B chargeback on the same unit dispensed. Instead, the Draft Guidance places the burden on the manufacturer for preventing a MFP and 340B discount applying to the same dispense.

In the Draft Guidance, CMS states that it will not, at this time, "assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[1] Instead, CMS "will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities" and "intends to provide Primary Manufacturers a process to identify applicable 340B-eligible claims through the reporting of payment elements to the MTF."[2] By declining to make any reasonable plan to address duplicates or to take ownership over preventing duplicate discounts, CMS has shifted this burden to manufacturers. In doing so, CMS must establish a process that permits manufacturers to obtain data to be able to effectively prevent these duplicates.

Identifying when the right discount applies to the right dispense, without triggering duplicate discount provisions, is a challenging task and costs significant time, money, and resources. Over the years, stakeholders have implemented several different approaches to prevent duplicate discounts, including modifiers, all of which have failed to be effective. Our experience with the use of modifiers finds them to be inadequate to consistently identify duplicate claims. For example, in some states, 340B covered entities must submit a code when seeking reimbursement from a state to identify when the entity dispensed a 340B drug. If a code were used on a claim, the state would exclude that claim when seeking rebates from the manufacturer. Despite the apparent benefits of using claims-level code data rather than dispensing entity claim data, modifiers have been largely ineffective in preventing duplicate discounts. For example, even if a 340B covered entity correctly identifies a claim as a 340B claim as opposed to a MFP claim, which does not occur consistently, that modifier may be removed at some point given the many handoffs between a pharmacy, third-party administrator, or pharmacy benefit manager ("PBM"), among others. We understand that thirty-eight (38) states require claims modifiers from covered entities when submitting claims to Medicaid for reimbursement. For these states, Kalderos has identified approximately $150,000,000 in 340B duplicate discounts over the last six years. In light of these challenges, we urge CMS to not rely exclusively on modifiers and to encourage the sharing of claims level data to allow clear review of claims among stakeholders.

[1] CMS, "Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027" at 49.
[2] *Id.*

In the context of the Medicaid Drug Rebate Program ("MDRP"), stakeholders have repeatedly discussed the need for the transparent provision of robust claims data to improve dispute resolution processes. In fact, CMS itself has repeatedly emphasized the importance of claims data in disputes.[3] Specifically, CMS has noted that providing claims level data may reduce the state's administrative burden and expense of researching manufacturer dispute issues.[4]

Namely, rebate or chargeback requests for the MFP should include a minimum level of claims data. For example, claims covered by Part D should include, at minimum, the data points included in the chart below. Without manufacturers receiving claims data and using the claims data to validate and identify duplicate claims to CMS, accurately providing the MFP will be impossible.

Minimum Required Claims Data Fields	
Field Number	**Field**
1	Unique Transaction ID
2	Rx ID
3	Fill Number
4	NDC-11
5	Quantity Dispensed / Administered / Wasted
6	Days Supply
7	Patient First Name
8	Patient Last Name
9	Patient Date of Birth
10	Patient Sex
11	Patient Zip Code
12	Ordering Physician NPI
13	CE Submitter (340B ID)

[3] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020), available at https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf (stating ""when states provide claims level data to manufacturers, we would expect there to be a reduction in number of disputes due to more accurate information being provided" and that "manufacturers likely need claims level data for true invoice validation purposes.").

[4] *Id.*

14	CE Submitter (NPI)
15	Dispense Location - Retail (NPI)
16	DEA of Pharmacy
17	HIN of Pharmacy
18	Written Date / Prescribed Date
19	Date of Service
20	Paid Date
21	BIN
22	PCN
23	GRP

Further, under the Draft Guidance, manufacturers are expected to determine whether the drug is 340B-eligible within the 14-day MFP payment window.[5] It is critical that manufacturers have access to the minimum necessary claims data in order to determine 340B eligibility within this timeframe.

Under Kalderos' Direct Discount Platform, manufacturers will have access to a ledger of claims data information that will allow them to prevent Medicaid, Medicare, and, if applicable, commercial duplicate discounts with 340B discounts going forward. Further, all stakeholders can access a central ledger of claim and rebate information, ensuring complete transparency to all parties. Kalderos would be glad to conduct a demonstration to CMS to show how the Direct Discount Platform works in practice.

IV. Multiple Medicare Transaction Facilitators ("MTFs") Are Needed To Ensure Integrity and Efficiency.

Kalderos does not support the use of a single MTF. There should be multiple entities in the marketplace tasked with facilitating the exchange of data and payment between pharmaceutical supply chain entities. There is significant risk in relying on a single MTF, both from a data integrity and functionality perspective. CMS should allow manufacturers to identify a data facilitator of their choice to promote innovation and efficiency.

However, if a single MTF is selected, the selected MTF should be an entity currently on the market that has extensive experience with data exchange and facilitation and is accustomed

[5] Draft Guidance at 48.

to interacting with both manufacturers and dispensing entities. Further, it is critical that the MTF have experience facilitating discount solutions.

If only one MTF is selected, Kalderos is best positioned to be selected as the MTF. As discussed above, we create technology solutions to discount program compliance challenges and are ready to expand our current offerings to MFP compliance. We have ample experience with data ingestion, claims analysis, and data sharing for the efficient and prompt processing of discount and rebate requests for payment. Our platform is already configured to carry out the exact processes that a MTF would need to perform to effectively exchange data and permit payment between pharmaceutical supply chain entities. Kalderos can conduct these processes at scale in an efficient manner. No other company is better suited or more prepared to take on this role.

While other players in the marketplace may appear well-positioned to take on this role, they are not suitable candidates to serve as the MTF as they stand to benefit from facilitating the exchange of data and payment; have failed to act to prevent duplicate discounts in their current roles; have a vested interest in 340B volumes and are dependent on the chargeback model; and are biased in the marketplace.

Further, Kalderos generally agrees with the anticipated MTF Data Flow illustrated in Section 40.4.1 of the Draft Guidance. This process is aligned with the flow of data through Kalderos' current systems and platforms. Additionally, Kalderos agrees that the selected MTF claim level data elements described in Section 40.4.1 of the Draft Guidance represent the minimum necessary information needed for the manufacturer to verify that the selected drug was dispensed to an MFP-eligible individual.

Additionally, Kalderos supports CMS' proposal to permit the MTF to voluntarily collect banking information from participating dispensing entities and provide that information to manufacturers electing to receive such information in order for the manufacturer to provide payment to those accounts. In fact, Kalderos already provides data services that, through a third-party money transmitter, efficiently provide for payment from manufacturers to providers and from providers to manufacturers, in the event of errors in requests or payment. Processing payments is a significant regulatory hurdle as the operation must comply with complex regulatory requirements. Kalderos has already put in the resources to ensure compliant payment processing.

V. A Rebate Model is Necessary to Effectuate the MFP.

Kalderos believes that a rebate model is necessary to effectuate the MFP, and this position is consistent with the Draft Guidance.

Specifically, the Draft Guidance addresses manufacturers' obligation to make the MFP available to covered entities and their contract pharmacies by: "(1) using retrospective reimbursement to issue refunds to dispensing entities as required to ensure the MFP is made available to dispensing entities, (2) providing access to the MFP through prospective sale of selected drugs at prices no greater than the MFP, or (3) using some combination of these two

approaches."[6] Further, manufacturers must submit their plan for making the MFP available, including their process for deduplicating 340B covered units for the selected drug, to CMS at least seven months before the start of the initial price applicability year for the selected drug (*i.e.*, by May 2025).[7]

Importantly, it is necessary to effectuate the MFP through a rebate model, as opposed to the traditional chargeback-based model or credit-based model, because a rebate model permits unit-based payments, while chargeback-based and credit-based models are limited to effectuating the MFP at the package level, even when the drug is dispensed at the unit level. Accordingly, utilizing a chargeback or credit model to effectuate the MFP would cause the same challenges that occur with MDRP duplicates, because such models would only permit the MFP to be realized through package-based purchases.

Further, in the case of a prospective model, the MFP would have already been applied upon realization that the claim was a 340B claim, unless the manufacturer owned or managed the accumulator on behalf of each dispensing entity. In that case, the manufacturer would need to correct the payment through a refund or similar mechanism. Accordingly, a prospective model would still require retrospective actions, including refunds, in order to correct errors.

We appreciate CMS' recognition that identifying when the MFP should apply at the point-of-sale, and ensuring that 340B pricing is not provided on the same dispense, will be a challenge. Manufacturers must have the ability to review claims data after a dispense, confirm the applicable price, and provide a retrospective rebate to the end customer. We further appreciate that manufacturers may take different approaches and agree that manufacturers should share their process with CMS to ensure transparency for all stakeholders.

As previewed above, Kalderos has developed a technology-driven rebate model, the Direct Discount Platform, that is configurable and can be used for compliance with other discount programs, including the effectuation of the MFP. In developing and testing this Platform, we built the proper architecture to protect data while being easily scalable and interoperable with other systems. The Direct Discount Platform will work seamlessly with drugs subject to an MFP. We believe it is crucial that a technology-based rebate system enter the market now to transition the system to rebates in advance of MFPs going live in 2026. Kalderos is prepared to conduct an operational demonstration of the Direct Discount Platform to CMS at your convenience.

Additionally, manufacturers should be permitted to establish a process whereby manufacturers can decline a request to pay a claim at MFP pricing if they can show it was dispensed as a 340B drug and the 340B ceiling price was less than MFP. This approach will not be effective in practice because manufacturers will not have the necessary data in the 14-day window to dispute the MFP.

Further, the Draft Guidance states that if a 340B claim comes in after an MFP rebate is paid, manufacturers are not on the hook for full replenishment, but are only required to pay the

[6] Draft Guidance at 110.
[7] *Id.*

difference between the MFP and the 340B ceiling price. This would not be possible under the current replenishment model.

In contrast, under a rebate model, complete claims-level data is exchanged between all parties to effectuate a discount, preventing nearly 100% of noncompliant discounts. Additionally, all stakeholders will be able to access a central ledger of claim and rebate information, ensuring complete transparency to all parties.

VI. CMS Must Permit Manufacturers to Audit the Data Submitted When Requesting an MFP Rebate.

Data inaccuracies related to the Medicare and Medicaid programs remain a significant challenge, with some estimating that such errors cost the Medicare and Medicaid programs up to $100 billion per year.[8] CMS must permit drug manufacturers to audit the data submitted by dispensing entities when requesting a MFP rebate to reduce the risk of the submission of inaccurate data.

We note that it is standard commercial practice to permit drug manufacturers to audit the data provided by parties who request a rebate or chargeback. For example, contracts between manufacturers and wholesalers typically permit the manufacturer to audit supporting evidence relating to chargebacks. Similarly, rebate agreements between manufacturers and PBMs typically permit the manufacturer to audit supporting evidence related to commercial rebates. These audits reduce the risk of inaccurate data being submitted by allowing the manufacturer the ability to verify the accuracy and legitimacy of discount or rebate requests.

In addition to the commercially standard practice allowing manufacturers to audit wholesalers and PBMs, similar audit language is typically included in contracts between wholesalers and pharmacies, as well as audit language found in contracts between PBMs and pharmacies. Should a manufacturer choose to contract with wholesalers or PBMs to effectuate MFPs between the manufacturer and beneficiaries/dispensing entities, the manufacturer's standard audit language, combined with the audit language contained in wholesaler and PBM agreements with dispensing entities, will allow the manufacturer the ability to audit data submitted by dispensing entities.

Accordingly, we ask that CMS explicitly permit manufacturers and other stakeholders, like Kalderos who are not wholesalers or PBMs, to enter into agreements with dispensing entities to audit the data submitted by dispensing entities requesting a MFP rebate.

We note that, under a claims-based rebate model (such as Kalderos' Direct Discount Platform), auditing is less critical, as all parties have access to a central ledger of claim and discount information, ensuring complete transparency to all parties. This approach fosters trust and creates positive working relationships between key stakeholders.

[8] *See* CloudMed, 340B Recovery, available at https://www.cloudmed.com/government-navigation-suite/340b-recovery/ for an example of 340B Recovery Services.

VII. Additional Guidance Is Needed To Ensure That Complaints And Disputes Related To The MFP Are Handled Appropriately.

Kalderos supports CMS' proposal to establish a centralized intake system for receiving reports related to access to the MFP. Section 90.2.2 of the Draft Guidance states that this system is "intended to address complaints and disputes related to MFP availability and MTF functionality, and is not intended to receive general comments or feedback related to the implementation of the Negotiation Program as a whole."[9]

However, we note that the Draft Guidance does not establish a formal process or mechanism to enable the appropriate handling and referral of disputes and complaints that present evidence of potential non-compliance.

While we support CMS' intent to monitor the Price Negotiation Program, we are concerned that the Draft Guidance does not provide manufacturers with an adequate opportunity to participate in program integrity. Specifically, we are concerned that the lack of a formalized process for manufacturers to report duplicate discounts or other MFP dispensing issues to CMS will limit manufacturers' ability to implement effective safeguards against such risks. Effective program integrity requires the participation of all parties with obligations under the IRA. We urge CMS to issue guidance establishing a process for manufacturers and other stakeholders to formally engage in the program integrity process.

* * *

Thank you for the opportunity to submit these comments to the Draft Guidance. If you have any questions about these comments, please do not hesitate to contact me at angie.franks@kalderos.com.

Sincerely,

DocuSigned by:
Angie Franks
C01E098E1C33473...

Angie Franks
Chief Executive officer
Kalderos

[9] Draft Guidance at 113.

Dear CMS Team,
On behalf of the King County Medical Society (KCMS), one of the largest medical societies in the US, I am sharing our comments on the draft guidance for the second cycle of the Medicare Drug Price "Negotiation" Program, released on May 3, 2024.
We commend CMS's ongoing efforts to refine and improve this critical program.
Specific comments:
I. Incorporating Patient Input: We support CMS's initiative to enhance patient-focused events to gather input on selected drugs. We recommend:

- Expanding the Format: Including diverse methods such as virtual town halls and online surveys to reach a broader patient base.
- Detailed Feedback: Collecting more specific data on patient experiences with selected drugs and therapeutic alternatives will provide valuable insights for initial offer development.

II. Revising the Negotiation Process: The proposed updates are positive to the Negotiation Data Elements and the process. We suggest:

- Categorized Data Requests: Grouping questions by topic (e.g., manufacturer input, patient experience, clinical evidence) to streamline the information collection process.
- Enhanced Facilitation: Increasing the number of manufacturer-CMS meetings and allowing for additional written offers will improve the negotiation process's transparency and efficiency.

III. Ensuring Patient Access to Part D Drugs: We are concerned about patient access disruptions due to the Part D redesign and MFP implementation. To mitigate these issues, we propose:

- Regular Reviews: Conduct annual reviews of Part D sponsor formularies to ensure selected drugs are not disadvantaged compared to non-selected medications in the same class.
- Addressing Utilization Management: Ensuring selected drugs are not subjected to more restrictive utilization management practices.

IV. Streamlining Prior Authorization Processes:

- Reducing Administrative Burden: Simplifying the prior authorization process for Medicare Part D drugs to reduce the administrative burden on healthcare professionals.
- Faster Approvals: Implementing speedier approval times for prior authorizations ensures patients have timely access to necessary medications.

V. Ensuring Healthcare Equity:

- Addressing Disparities: Implementing specific measures to address disparities in drug access and affordability, particularly for underserved and marginalized communities.
- Inclusive Data Collection: Collecting and analyzing data on how drug pricing and access policies affect diverse patient populations, including racial and ethnic minorities, low-income patients, and those in rural areas.

VI. Enhancing Patient Education and Support:

- Clear Communication: Ensuring patients are informed about changes to their drug coverage and what it means for their out-of-pocket costs.
- Support Programs: Creating or expanding programs that help patients navigate the Medicare Part D system, including assistance with understanding benefits, coverage options, and any new processes introduced by the negotiation program.

Conclusion: The King County Medical Society believes these enhancements to the Medicare Drug Price "Negotiation" Program will benefit patients, healthcare professionals, and the healthcare system. We appreciate CMS's commitment to public engagement and look forward to continued collaboration.

Thank you for considering our comments. Please feel free to contact us for further information or clarification.

Nancy

Nancy L. Belcher, Ph.D., MPA
CEO, King County Medical Society & KCMS Community Foundation

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Comments by:	Fred Ledley, M.D., Edward Zhou, PharmD., Paula Chaves da Silva, Ph.D. Center for Integration of Science and Industry, Bentley University[1]
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This comment focuses on Section 50.1, provisions 1 & 3 of the draft guidance regarding the negotiation of a "maximum fair price" under the Inflation Reduction Act (IRA), research and development (R&D) costs of the primary manufacturer, and prior federal financial support for novel therapeutic discovery and development. Specifically, we argue that **a negotiated, "maximum fair price" must consider both public sector (federal) and private sector (manufacturer) investments and provide returns to both commensurate with the scale and risk of their investments.** This comment addresses three issues and makes specific recommendations regarding each:

1. **In negotiating a "maximum fair price," both parties may be expected to consider their investment and returns.**
2. **Prior federal financial support for R&D may be estimated from the NIH investment in basic and applied research related to each product.**
3. **The return on federal investment in discovery and development should be estimated as a social return on investment (SROI) based on elements of social value created by new drugs.**

These comments are based on research conducted at the Center for Integration of Science and Industry characterizing the federal investment in the discovery and development of the ten drugs selected for price negotiation in the first year of the IRA as well as the health benefit accruing to the public from the Medicare Part D spending on these drugs (Zhou et al. 2024; Ledley 2024). Those studies followed a series of papers describing (i) methods for characterizing the NIH contribution to the drugs approved 2010-2019 including funding for basic and applied research, clinical development, and patents related to each drug, (ii) the total NIH investment cost accounting for estimated costs of clinical failures and discount rates for public sector investment, (iii) the cost savings to industry from this NIH investment, and (iv) an accounting-based approach for estimating social and private value creation from selected products.[2]

Contact information: Fred D. Ledley, Center for Integration of Science and Industry, Jennison 143, Bentley University, 175 Forest Street, Waltham, MA; email: fledley@bentley.edu; tel: +1.781.891.2046; website: www.bentley.edu/sciindustry

1. A "fair price" negotiation should consider the investment and returns of both parties.

The IRA identifies specific elements that CMS may consider in negotiating a "maximum fair price" as well as a process of cost analysis. The elements identified by CMS resemble those considered in other federal policies or legal precedents relating to "fair" or "reasonable" prices. While not directly applicable to the IRA, these precedents share the common principle that a "fair" or "reasonable" price cannot be determined purely by cost analysis, but require considerations of markets, competition, investment, risk, and return.

In a free market, a product may be considered to have a "fair market value" that is determined by negotiation between informed and unpressured parties. Legal precedent defines the fair market value as *"price that a prudent businessperson would pay for an item or service under competitive market conditions, given a reasonable knowledge of the marketplace."*[3] The "fair market value" is often considered a reflection of the inherent value of a product.

The concept of a product having a "fair price" is different in that it recognizes that the parties in a "fair price" negotiation may consider not only the intrinsic value of a product, but costs related to the product, market competition, or expectations for return on investments in the product. For example, government procurement requires that contracting officers determine a "fair and reasonable" price. Like the IRA, federal policies regarding "fair and reasonable" price begin with a cost analysis to identify cost elements such as material, labor, and manufacture or acquisition costs as well as competitive market factors, investments, profit, and the cost of capital (i.e., expected return on investment) among other factors.[4] A separate legal precedent for determining a "reasonable price" holds that a reasonable price "*…involves balancing of the investor and consumer interests…*" and should allow companies to achieve returns "*…commensurate with returns on investments in other enterprises having corresponding risks…*"[5] In each of these precedents for "fair" or "reasonable" price, it is expected that both parties will consider their respective investments and returns.

Consistent with these precedents, the IRA explicitly authorizes CMS to consider both "research and development costs of the manufacturer for the drug" and "prior federal financial support for novel therapeutic discovery and development with respect to the drug" in price negotiations. By analogy to models of fair or reasonable pricing, the **"maximum fair price" of a drug under the IRA cannot be solely determined by analysis of the value provided by a pharmaceutical product (i.e., cost-effectiveness thresholds), but must also consider the investments made by both the public and private sectors, the scale and risks of these investments, and the returns** among other factors including market competition.

The draft guidance explicitly recognizes that monetary costs are typically estimated with the cost of capital. For industry costs, the guidance recognizes that (in calculating industry costs) research and development (R&D) costs apply a cost-of-capital adjustment to each company's R&D spending to reflect the "time-value" of the investment. Specifically, the guidance recommends using an 8.1% cost of capital in estimating industry investment costs.[6] Theoretically, public sector spending is not associated with a cost of capital, but the Office of

Management and Budget recommends estimating the cost of federal (public) spending with either a 3% discount rate reflecting the historical cost of borrowing or a 7% discount rate (OMB 1992, 2017). In this context, both manufacturer and federal investments should be estimated with appropriate adjustments to assure that both the public and private sector receive at least the minimal expected returns.

Building on these precents and policies, we offer several specific recommendations concerning the draft guidance and how CMS should consider both manufacturer R&D costs and prior federal financial support for discovery and development.

> **Recommendation #1. The draft guidance should explicitly state that the negotiation of the "maximum fair price" shall consider the investment cost of both the manufacturer's R&D and federal financial support as well as the returns on both manufacturer and federal investments.**
>
> **Recommendation #2. The draft guidance should explicitly state that both manufacturer costs and federal funding should be estimated with appropriate adjustments for the time-value of this investment.**

2. Federal funding for new drug discovery and development can be estimated from the NIH investments in basic or applied research related to each product.

It is widely recognized that basic and applied biomedical research funded by the federal government makes a substantive contribution to the discovery or development of most, or all, new drugs, with the government contribution focused primarily on basic or applied research and industry responsible for clinical development and commercialization.[7] While most research on the federal contribution to new drug approvals focuses on studies contributing to clinical trials or patents, our work has demonstrated that a mature body of basic research on the drug target is requisite for drug approval. Specifically, our analysis on >500 drugs shows that few targeted therapeutics are approved before basic research matures beyond an analytically described "established" threshold and that clinical development timelines average three years longer when clinical trials are initiated before the "established" threshold is reached (McNamee, Walsh, and Ledley 2017; Cleary, Jackson, and Ledley 2020; Beierlein et al. 2017; McNamee and Ledley 2017). Therefore, we believe that federal funding for both applied research on drugs in development and basic research on their targets constitute "federal financial support for novel therapeutic discovery and development" and elements that CMS needs to consider in negotiating a fair market price.

Much of the research describing federal spending on drug discovery or development, however, is unable to delineate drug-specific costs.[8] We have described a method for estimating NIH funding for basic or applied research contributing to approval of specific drugs. The method identifies NIH-funded projects that supported published research related to the drug target (basic research) prior to approval of a first-in-class product associated with that target or the

approved drug (applied research) prior to first FDA approval[9] (Cleary, Jackson, and Ledley 2020; Cleary et al. 2023b; Cleary et al. 2018; Zhou et al. 2024; Zhou, Jackson, and Ledley 2023). Our studies have identified $187 billion in NIH funding leading to drug approvals from 2010-2019, with 83% of this total representing basic research and 17% representing applied research (Cleary, Jackson, and Ledley 2020; Cleary et al. 2023a). Follow-on studies demonstrated that only 3.3% of total NIH funding involved phased clinical trials leading to first FDA approval (Zhou, Jackson, and Ledley 2023).[10]

We have identified NIH funding totaling $11.7 billion for basic or applied research leading to approval of the drugs selected for price negotiation in year 1 of the IRA (Zhou et al. 2024).[11] Drug specific NIH spending is shown in Table 1. Table 1 also shows drug specific NIH investment costs calculated with estimated cost of failed clinical trials and a 3% discount rate appropriate for public investments (OMB 1992, 2017).

This analysis also estimated the NIH investment cost with spillovers resulting from the application of basic research on each drug target to an average of 2.85 new molecular entities (NMEs) (Santos et al. 2017; Cleary et al. 2023b). This reflects the average NIH investment cost across a broad portfolio of first-in-class and follow-on products (Table 1).

Table 1. Estimated federal (NIH) spending and investment costs leading to first approval of drugs selected for price negotiation in year one of the IRA

Generic Name (Brand Name)	Total NIH Funding[a]	NIH Investment Cost (3%)[b]	Investment Cost with Spillovers (3%)[c]
etanercept (Enbrel)	$2,606.3	$2,799.5	$1,036.2
insulin aspart (Novolog)	N/A	N/A	N/A
sitagliptin (Januvia)	$227.5	$317.5	$163.8
ustekinumab (Stelara)	$6,482.1	$6,951.5	$2,501.8
rivaroxaban (Xarelto)	$763.6	$895.4	$379.0
apixaban (Eliquis)	$790.6	$910.9	$404.8
ibrutinib (Imbruvica)	$566.0	$683.8	$382.5
empagliflozin (Jardiance)	$434.2	$539.6	$249.0
dapagliflozin (Farxiga)	$437.3	$547.9	$257.3
sacubitril[d]/valsartan (Entresto)	$901.1	$1,078.6	$435.4

All values are in millions and inflation-adjusted to 2018. Rows are not additive as NIH funding may contribute to more than one drug. a. NIH funding for basic research and applied research. b. NIH costs with estimated cost of failure and 3% discount rate. c. Spillovers based on allocating basic research costs to 2.85 drug approvals per biological target. d Sacubitril is the NME in this combination product. Table adapted from Zhou et al. 2024.

NIH funding for basic and applied research provides substantial cost-savings to industry. The cost savings to industry may be estimated as the additional industry spending that would have been necessary to establish a body of basic research requisite for successful drug development. Cost savings are estimated from total NIH spending on basic and applied research calculated with an 8.1%, and 10.5% cost of capital expected by industry.[12] The estimated drug-specific cost savings are shown in Table 2.

Table 2. Estimated federal (NIH) investment costs leading to first approval of drugs selected for price negotiation in year one of the IRA with estimated cost savings to industry after cost of capital adjustments used by industry or by CMS price negotiations.

Generic Name (Brand Name)	Total NIH Funding[a]	Savings to Industry (8.1%)[b]	Savings to Industry (10.5%)[c]
etanercept (Enbrel)	$2,606.3	$3,652.7	$4,176.2
insulin aspart (Novolog)[d]	N/A	N/A	N/A
sitagliptin (Januvia)	$227.5	$393.7	$455.8
ustekinumab (Stelara)	$6,482.1	$9,348.5	$10,815.4
rivaroxaban (Xarelto)	$763.6	$1,248.9	$1,485.8
apixaban (Eliquis)	$790.6	$1,260.2	$1,494.1
ibrutinib (Imbruvica)	$566.0	$871.1	$1,001.7
empagliflozin (Jardiance)	$434.2	$704.7	$821.3
dapagliflozin (Farxiga)	$437.3	$714.5	$832.0
sacubitril[e]/valsartan (Entresto)	$901.1	$1,491.6	$1,763.8

Values are in millions and inflation-adjusted to 2018. Rows are not additive as NIH funding may contribute to more than one drug. a. NIH funding for basic and applied research. b. NIH costs (including estimated costs of clinical failures) calculated with 8.1% discount rate.[13] c. NIH costs (including estimated costs of clinical failures) calculated with a 10.5% discount equivalent to the cost of capital used by DiMasi et al. 2016. d. The first-in-class recombinant insulin was approved in 1982. No data on NIH funding is available before this date. e. Sacubitril is the NME in this combination product. Table adapted from Zhou et al. 2024.

We offer several specific recommendations concerning CMS consideration of "federal financial support for novel therapeutic discovery and development."

Recommendation #3. Since the NIH provides >80% of all federal financial support for life science research (Boroush and Guci 2022), we consider estimates of the NIH investment cost with estimated clinical failures to be an appropriate proxy for federal financial support for discovery and development.[14] We further recommend that federal financial support be estimated with the 3% discount rate suggested by OMB.

Recommendation #4. Consideration of the "federal financial support" should not be limited to the "*extent to which the Primary Manufacturer benefited from federal financial support…*" nor should it be limited to "*…funding for the discovery and development…*" nor should it be limited to any specific time period related to the initiation of research, any action on the part of the primary manufacturer, or to the development or regulatory process. The Act places no limits on the beneficiary of federal funding, explicitly includes "prior" federal financial support, and does not limit the timeframe of this support. **The language in the guidelines should state explicitly that "*CMS shall consider all federal financial support with respect to the selected drug prior to directly contributing to discovery or development through drug approval.*"**

Recommendation #5. There should be no limits on the form of federal financial support considered by CMS. The definition of "federal financial support for novel therapeutic discovery and development" should be restated to explicitly include the

"appropriation or licensing of discoveries, research, or development (i.e., regulatory approvals) or utilization of research resources, capabilities, consortia, centers, facilities, or personnel receiving federal financial support and related to the selected drug." We would further recommend that the draft guidance explicitly address federal financial support provided through public private partnerships with government, academia, or non-profit organizations as well as support provided through cancer centers, clinical consortia, Clinical and Translational Science Awards, Program Project Grants, or Collaborative Agreements.[15]

3. The return on federal investment in discovery and development can be estimated as a social return on investment (SROI) based on elements of social value created by new drugs.

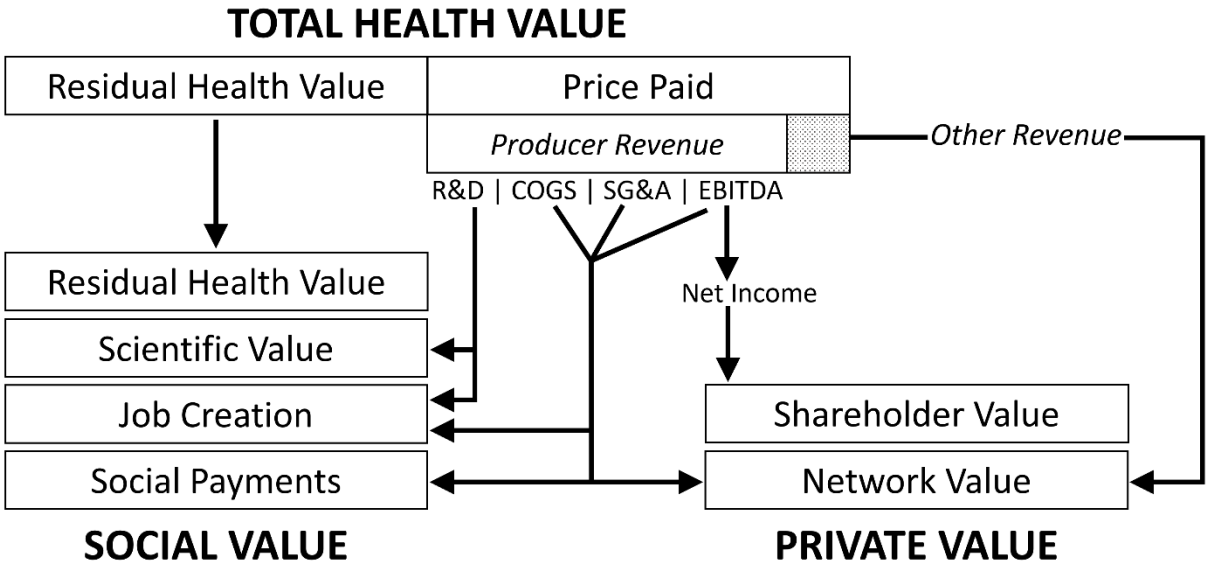
Our comments are predicated on the concept that there should be an equitable return on investments made by both the public and private sector.[16] For industry, the return is measured in terms of the value provided to shareholders and contributions to the GDP. For government, we believe return should be measured in terms of the social value created through commercialization of new drugs. Social value has been defined as the "*…benefits or reductions of costs for society … that go beyond the private gains and general benefits of market activity*" (Phills, Deiglmeier, and Miller 2008) or the value accruing to "*…non-investor stakeholders affected by business: individuals, employees, communities, and society*" (Lingane and Olsen 2004).

There is evidence from broad econometric studies that the value provided to society from innovative drugs (i.e., consumer surplus) is often greater than the value provided to producers (i.e., producer surplus) (Lakdawalla et al. 2010; Camejo et al. 2014; Philipson and Jena 2006).These methodologies are unable to distinguish the impacts of individual drugs on society and are not applicable to assessing the social value or returns provided by specific products.

We have described an accounting-based approach, which recognizes that there are multiple elements to the value created by new medicines (Neumann, Garrison, and Willke 2022; Lakdawalla et al. 2018; Stiglitz 2019) ranging from health benefits and pharmaceutical revenues to job creation, scientific advances, increased economic activity, an expanded tax base, and support for public institutions. This approach is based on the concept of estimating "total stakeholder value" as the sum of value accruing to different stakeholders (Mitchell et al. 2015; Lingane and Olsen 2004).

This model posits that the total value created through commercialization of a new pharmaceutical product is the "total health value" accruing to those who use the products.[17] A portion of this value is then distributed among different stakeholders from the price paid for the drug and how this revenue is expensed or invested by the pharmaceutical manufacturer (Chaves da Silva, Conti, and Ledley submitted; Zhou et al. 2024). **In this analysis, the "residual health value," or total health value minus the price paid, represents the most appropriate measure of the value retained by the patient or social sector.**[18] A schematic of this method is shown in Figure 1.

Figure 1. Schematic of method for estimating social and private value creation from commercialization of individual drugs or classes of drugs.[19]



Our 2024 working paper (Zhou et al. 2024) describes a preliminary analysis of the total and residual health value created by Medicare Part D spending on the ten drugs selected for price negotiation in the first year of the IRA 2017-2021. Table 3 shows the total Medicare Part D spending on each drug and the number of beneficiaries.

Table 3. Medicare Part D spending and number of beneficiaries treated with drugs selected for price negotiation in first year of the IRA 2017-2021.

Brand name (Generic Name)	Initial indication	Part D spending[a] (millions)	Number of beneficiaries[b]
Enbrel (etanercept)	Rheumatoid arthritis	$9,985	239,511
NovoLog[c] (insulin aspart)	Diabetes mellitus (Type 1, 2)	$11,965	4,292,206
Januvia (sitagliptin)	Diabetes mellitus (Type 2)	$17,066	4,619,191
Stelara (ustekinumab)	plaque psoriasis	$4,306	58,569
Xarelto (rivaroxaban)	prophylaxis of deep vein thrombosis and pulmonary embolism	$19,442	5,579,404
Eliquis (apixaban)	nonvalvular atrial fibrillation	$36,614	10,724,482
Imbruvica (ibrutinib)	mantle cell lymphoma	$11,459	119,019
Jardiance (empagliflozin)	Diabetes mellitus (Type 2)	$8,187	2,252,196
Farxiga (dapagliflozin)	Diabetes mellitus (Type 2)	$3,085	908,804
Entresto (sacubitril/valsartan)	chronic heart failure	$4,271	1,141,574
TOTAL		**$126,381**	**29,934,956**

Part D spending values are inflation-adjusted to 2018. a. Part D spending includes amounts paid by Medicare Part D plan sponsors and beneficiaries but not manufacturers' discounts or rebates. b. Number of beneficiaries = number of Part D beneficiaries utilizing the drug. c. Includes multiple forms/types of the drug. NovoLog includes Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill. Enbrel includes Enbrel Mini and Enbrel Sureclick. Source: CMS (https://data.cms.gov). Table adapted from Zhou et al. 2024.

Table 4 shows the total and residual health value created for beneficiaries by Medicare Part D spending on these drugs. **Excluding Januvia and NovoLog, total Medicare Part D spending was $97.3 billion and the total health value created by these sales is estimated to have been $67.7 billion from 2017-2021. This results in a negative residual health value of -$29.7 billion, analogous to a negative consumer surplus.**[20]

Table 4. Total health value created 2017-2021 by Medicare Part D spending on drugs subject to price negotiation in the first year of the IRA.

Brand Name (Generic Name)	QALYs/year per Beneficiary	Total Health Value		Residual Health Value[b]
		QALYs	$[a]	
Enbrel (etanercept)	0.08	19,161	$1,993	-$7,993
NovoLog (insulin aspart)[c]	N/A	N/A	N/A	NA
Januvia (sitagliptin)[c]	N/A	N/A	N/A	NA
Stelara (ustekinumab)	0.14	8,200	$853	-$3,453
Xarelto (rivaroxaban)	0.03	167,382	$17,408	-$2,034
Eliquis (apixaban)	0.02	214,490	$22,307	-$14,307
Imbruvica (ibrutinib)	0.13	15,472	$1,609	-$9,850
Jardiance (empagliflozin)	0.06	135,132	$14,054	$5,867
Farxiga (dapagliflozin)	0.05	45,440	$4,726	$1,640
Entresto (sacubitril[d]/valsartan)	0.04	45,663	$4,749	$478
TOTAL	**0.55**	**650,940**	**$67,698**	**-$29,652**

Dollar values are in millions and inflation-adjusted to 2018. a. Calculated with WTP/QALY of $104K. b. Total health value minus Medicare Part D spending including amounts paid by Medicare Part D plan sponsors and beneficiaries but not manufacturers' discounts or rebates. c. NovoLog and Januvia are not included in this analysis. d. Sacubitril is the NME in this combination product. Table adapted from Zhou et al. 2024.

This preliminary analysis was based on publicly available data on Medicare Part D spending. A complete analysis of the total and residual health value created through commercialization of these products and the balance between social and private value creation requires data on the number of people utilizing the drug and the price paid in US and global populations. While those data were not available for our research, they will be provided to CMS under the provisions of the IRA. As such CMS will be uniquely positioned to make a complete assessment of the health value, social value, and private value created by these products and the balance between social and private value creation. **We believe that such an assessment should serve as the basis for estimating the total social return on investment as well as more traditional return on investment metrics related to the value created for shareholders or the economy.**

We would emphasize that benchmarking the Medicare Part D price to the health value provided by the product as anticipated in value-based pricing results in zero residual health value. This pricing strategy does not provide a consumer surplus or margin contributing to the social return on federal investments in these product (Tremblay, Poirier, and Monfort 2024; Shafrin et al. 2023). This approach could allow manufacturers to realize most of the return from product sales (Basu et al. 2023). **We argue that the maximum fair price should be a price at which the social value (i.e., residual (net) health value + job creation + science + payments to**

the public sector) is comparable to the private returns to industry (Laplane and Mazzucato 2020; Lazonick and Mazzucato 2013; Ledley 2024; Zhou et al. 2024).

We offer the following recommendations:

> **Recommendation #6. CMS should utilize data provided by industry concerning the number of individuals treated with each product and the price paid to estimate the total health value created and the distribution of this value between social value and private value.**
>
> **Recommendation #7. The maximum fair price should be established that provides for both social and private value creation as well as an equitable balance between the social returns on public sector investments and financial returns on producer investment. These returns should be commensurate with the scale and risk of their respective contributions.**

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Endnotes

[1] Dr. Ledley is Director of the Center for Integration of Science and Industry and Professor in the Departments of Natural & Applied Sciences and Management. Dr. Zhou is a Research Fellow in the Center for Integration of Science and Industry and Adjunct Professor, Department of Natural & Applied Sciences. Dr. Chaves da Silva is a Research Fellow at the Center for Integration of Science and Industry.

[2] This research is described in a series of papers including Cleary et al. (2018); Cleary et al. (2020); Cleary et al. (2023); Ledley and Cleary, (2023); Zhou et al. (2023); Chaves da Silva et al. (submitted).

[3] From *United States v. Cartwright, 411 US 546* quoted by Legal Information Institute, Cornell Law School fair market value | Wex | US Law | LII / Legal Information Institute (cornell.edu)

[4] For example, Title 48—Federal Acquisition Regulations System CHAPTER 1—FEDERAL ACQUISITION REGULATION SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES PART 15—CONTRACTING BY NEGOTIATION Subpart 15.4—Contract Pricing 15.404-1 Proposal analysis techniques. “(a) General. The objective of proposal analysis is to ensure that the final agreed-to price is fair and reasonable.“; “4) “Cost analysis may also be used to evaluate data other than certified cost or pricing data to determine cost reasonableness or cost realism when a fair and reasonable price cannot be determined through price analysis alone.“; “ (c) Cost analysis is the review and evaluation of any separate cost elements and profit or fee in an offeror’s or contractor’s proposal, as needed to determine a fair and reasonable price or to determine cost realism, and the application of judgment to determine how well the proposed costs represent what the cost of the contract should be, assuming reasonable economy and efficiency.” https://www.law.cornell.edu/cfr/text/48/15.404-1

[5] “…involves a balancing of the investor and consumer interests,” which does not, however, ‘ensure that the business shall produce net revenues.’ ... From the investor or company point of view it is important that there be enough revenue not only for operating expenses but also for the capital costs of the business. These include service on the debt and dividends on the stock... By that standard the return to the equity owner should be commensurate with returns on investments in other enterprises having corresponding risks.” Quoted in Congressional research Service op cit and referencing: FPC v. Hope Natural Gas Co., 320 U.S. 591, 603 (1944) (citing Chicago & Grand Trunk Ry. v. Wellman, 143 U.S. 339, 345–46 (1892); and Missouri ex rel. Southwestern Bell Tel. Co. v. Public Serv. Comm’n, 262 U.S. 276, 291 (1923).

[6] We would note that various values for cost of capital have been used in the literature describing industry investment costs, with 10.5% being the most commonly used value (DiMasi, Grabowski, and Hansen 2016;

Wouters, McKee, and Luyten 2020; Rennane, Baker, and Mulcahy 2021) and the one used in our comparisons of federal and industry spending on new drug approvals (Cleary et al. 2023b; Zhou et al. 2024).

[7] There is an extensive research on the public sector contribution to new drug approvals (Comroe Jr and Dripps 1976; Toole 2012; Sampat and Lichtenberg 2011; Chakravarthy et al. 2016; Stevens et al. 2011; Nayak, Avorn, and Kesselheim 2019; Cleary, Jackson, and Ledley 2020; Zhou, Jackson, and Ledley 2023; Cleary et al. 2023a)

[8] Many studies of the NIH contribution to pharmaceutical innovation consider total NIH budget allocations (Sekar 2020; Lazonick and Tulum 2011; Moses et al. 2015) or categories of funding included in the Research, Condition, and Disease Categories (RCDC) and Research Portfolio Online Reporting Tools (RePORT) (Torrey et al. 2020; Sampat, Buterbaugh, and Perl 2013; Ballreich et al. 2021)

[9] Briefly, the method involves identifying publications (PMIDs) in the PubMed database related to the drug or the drug target using validated search parameters. Drug searches included 12 years before first drug approval and resulting PMID are designated applied research. Target searches included 12 years before approval of a first-in-class drug associated with that target and resulting PMID are designated basic research. NIH-funded projects (grants) associated with these PMID are then identified in the NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER) database. NIH costs are estimated from one year of project funding corresponding to the publication year, eliminating PMIDs with publication dates before the first year of project funding and accounting for lags of 1-4 years after the end year of project funding. Duplicate project year and NIH funding arising from are eliminated separately for each data point shown. Clinical development costs are estimated from PMID describing phase 1, phase 2, or phase 3 trials or NCT numbers. The method is described in the eMethod section of Cleary et al. (2023) with modifications described by Zhou et al. (2023); Zhou et al. (2024).

[10] This research estimated the average NIH spending for each first-in-class drug approved 2010-2019 to be $1.4 billion/drug, comparable to the $1.5 billion average industry spending reported by DiMasi et al. (2016). The average NIH investment cost was estimated to be $1.7 billion/drug (calculated with estimated costs of failed clinical trials and a 3% annual discount rate on public investments reflecting the cost of government borrowing (OMB 1992, 2017)). This amount is not less than industry spending on drugs reported by (Wouters, McKee, and Luyten 2020) with estimated costs of pre-human research, failed clinical trials, and a 10.5% cost of capital. The estimated cost savings to industry study also estimated the cost savings to industry was $2.9 billion/drug, comparable to average industry costs estimated by Dimasi et al. (2016) and greater than those reported by Wouters et al. (2020).

[11] The analysis did not estimate NIH costs related to insulin aspart, which was considered a follow-on product to recombinant insulin approved in 1982. No NIH funding data is available before 1985.

[12] This calculation is based on the NIH investment cost for basic research without spillovers, assuming that corporate basic research would be treated as intellectual property and would need to be replicated by other companies developing other products associated with the same target.

[13] This value is explicitly cited in the draft guidance "*The use of 8.1 percent is consistent with assumptions used by the Congressional Budget Office (CBO), see "Research and Development in the Pharmaceutical Industry," CBO (April 2021), available at https://www.cbo.gov/publication/57126."*

[14] It is critical that the methods used to identify federal financial support identify support for both basic and applied research. Case study methods are frequently used to characterize the NIH contributions related to specific patents (Azoulay et al. 2019; Sampat and Lichtenberg 2011) or clinical trials of approved products (Nayak, Avorn, and Kesselheim 2019; Chakravarthy et al. 2016; Zycher, DiMasi, and Milne 2010). These methods, however, implicitly focus on federal contributions to development and do not capture contributions to basic research, which are, by definition, undertaken "without specific applications towards processes or products in mind."(NSF 2018). Broader, analytical methods are required to capture both basic and applied science as well as the broad body of research necessary to replicate, refute, or refine scientific advances, without which applications of federally funded research may not be successfully adopted by industry (Bretz, Maurer, and Xi 2019; NAS 2019).

[15] The Clinical Translational Science Award programs represent the centerpiece of the NIH's efforts to accelerate innovation by "reengineering the clinical research enterprise"(Zerhouni 2005; Zerhouni 2003) but typically provide patient populations, centers for data or laboratory analysis, and training or salaries for clinical investigators rather than direct funding for investigator-initiated clinical or translational research. The initial Broad Agency Announcement (BAA) of funding available from ARPA-H (March 15, 2023) extends this focus, describing strategies for achieving "Health Science Futures" through investments in molecular platforms, biological engineering approaches, foundational advances in degenerative diseases and personalized medicine, AI-enabled models, and "clinical trial readiness" (ARPA-H 2023). Zhou et al. (2023) characterized the NIH project type utilized to support clinical development of drugs approved 2010-2019. The analysis showed that >90% of NIH costs for phased clinical development were provided by "Program Projects and Centers", which typically support core research capabilities, or "Collaborative Agreements", which typically fund government-initiated research programs and includes the Clinical Translational Science Awards (CTSA) program (Liverman et al. 2013).

[16] There is longstanding concern that industry practices fail to balance the value accruing to society with the value accruing to corporations and their shareholders (Mazzucato 2016; Leopold, Chambers, and Wagner 2016; Angelis et al. 2023; Mattingly et al. 2021; GAO 2022). Lazonick and Mazzucato have described a disconnect between those who contribute labor and capital to innovation and those who realize financial rewards (Lazonick and Mazzucato 2013).

[17] Total health value is estimated from the health benefit (in QALYs) to individual taking a specific product (ICER 2020; Neumann, Cohen, and Weinstein 2014; Weinstein, Torrance, and McGuire 2009; Cohen, Neumann, and Ollendorf 2023) and the number of people to use the product. Health value can then be described in dollars based on individuals' willingness to pay per QALY (WTP/QALY), specifically their WTP/QALY (Martín-Fernández et al. 2014). This use of the QALY metric is distinct from its application in Health Technology Assessment (HTA) or cost-effectiveness studies (ICER 2020; Neumann, Cohen, and Weinstein 2014; Weinstein, Torrance, and McGuire 2009).

[18] Residual Health Value is the health-related, consumer surplus as a measure of the social benefits of drugs relative to the producer surplus as a measure of the value retained by industry (Camejo et al. 2014; Philipson and Jena 2006)). More importantly, this reflects clinical evidence that high drug prices are associated with economic insecurity, poor adherence to treatment regimens, food insecurity, and poor housing, all of which represent social determinants of health that impact health outcomes and can lower the net benefit of being prescribed expensive products (XCENDA 2020; Herman et al. 2015; IQVIA 2020; Berkowitz et al. 2015; Berkowitz, Seligman, and Choudhry 2014; Berkowitz et al. 2018; Blanchard et al. 2013; Afulani et al. 2015; Caouette, Boss, and Lynn 2020). For example, with respect to Medicare Part D. a 2020 report from IQVIA notes: "the cost exposure of Medicare Part D patients represents a potentially significant cost barrier to adherence" (IQVIA 2020). The negative residual health values described in this report are similar to those described by (Woods et al. 2021) which the authors ascribe to the "health opportunity cost" of high drug prices for branded drugs.

[19] Schematic of method for estimating social and private value creation from commercialization of individual drugs or classes of drugs. The method is described in detail: Chaves da Silva and Ledley, A Novel Framework to Estimate Social and Private Value Created Through Commercialization of a Pharmaceutical Product (Tech Note 2024-1), https://scholars.bentley.edu/cisi_pubs/4/. Figure adapted from Chaves da Silva et al., submitted.

[20] This estimate of the residual health value includes the amounts paid by the Medicare Part D plan sponsors and beneficiaries but does not take into account manufacturer's discounts or rebates. There is no publicly available data on the rebates associated with individual drug products (Feldman et al. 2021; Anderson-Cook, Maeda, and Nelson 2019; Dicken 2023). Using estimated average rebate increasing from 17.5% in 2014 to 25% in 2021, there would be a negative residual health value of -$6.9 billion. (Zhou et al. 2024). A complete analysis would require data on the price paid net discounts and rebates.

LEUKEMIA & LYMPHOMA SOCIETY®

July 2, 2024

Meena Seshamani, MD, PhD
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

The Leukemia & Lymphoma Society (LLS) appreciates the opportunity to provide comment on this initial guidance implementing the Inflation Reduction Act (IRA)'s drug price negotiation program. LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and to improve the quality of life of patients and their families. We advance that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated health care, regardless of the source of their coverage.

Patient Engagement

Patient engagement is an important step to better understanding the burden of their condition, desired treatment outcomes, and views on benefits and risks. Driven by the work of the Food and Drug Administration on patient-focused drug development (PFDD), many companies in the biopharmaceutical community have devoted significant resources to better understand patient populations and are working to bring to market products that best suit their needs. While patients will benefit from lower-priced medicines, it is important for CMS to consider the positive impact it can have on PFDD if companies are rewarded for demonstrating that their products represent therapeutic advancements over other products and meet unmet needs that are identified as the most important to patients.

We appreciate CMS's continuing commitment to hosting patient-focused events to seek patient, caregiver, and advocate input. However, based on the previous round of negotiations, it is not clear to patient advocates what information CMS would find most useful and from which sub-categories of patients. We offer the following recommendations to improve on the clarity and usefulness of these listening sessions:

- Provide advanced notice where practicable regarding the date and time of patient-focused feedback sessions.
- Once the previous round of negotiations has concluded, provide public written feedback regarding the results and how CMS arrived at them.

    - Specifically, for each drug, what factors did CMS find most compelling from the information the agency gathered that led to their decisions? Should patient feedback be focused on comparative effectiveness? Pricing? Access? Alternatives?
    - This will help guide patients and stakeholders in round 2 when asked to submit information.
- Provide guidance on what kind of patients or providers CMS wants to hear from during patient-focused feedback sessions?
    - In addition to patients taking the drug being negotiated, does CMS also wish to hear from patients on comparator drugs?
    - Is CMS interested in hearing about provider attitudes towards prescribing both the target of negotiations and comparator drugs?
- As the number of drugs chosen for negotiation grows, we recommend that CMS hold stakeholder feedback meetings by therapeutic area.
- Listening sessions should be broadly accessible, including through hybrid virtual and in-person meetings. This will facilitate broader testimony from patients who cannot attend in-person events.

Input Regarding Clinical Benefit

We ask CMS to provide more clarity on how the agency intends to leverage negotiation data elements to ensure that the agency is evaluating these elements with the patients' experiences, preferred outcomes, and needs in mind. For instance, we ask that CMS transparently outline a consistent methodology for how data related to therapeutic alternatives will result in changes to an initial or final offer. As part of this methodology, we ask CMS to ensure that data explicitly related to patient value is prioritized. We also ask that CMS emphasize patient experience and value in the evaluation of data. CMS should prioritize patient experience and patient experience data among the many factors CMS identifies in the guidance as sources that will inform an initial/final offer. Specifically, CMS should ensure that, among the data sets that inform any initial or final offer, patient experience of the selected drug and/or therapeutic alternative(s) has an outsized impact. CMS should also articulate how patient experience data influenced initial and final offers.

Maintaining Beneficiary Protections

We appreciate the IRA's provision requiring all Part D plans to cover each drug with negotiated prices for all years for which the price is in effect during the price-applicability period. This provision helps ensure that beneficiaries will benefit from the negotiation process and have access to the lowest-price drugs. LLS encourages CMS to monitor Part D plans to ensure beneficiaries have access to all negotiated drugs and provide opportunities to comment on beneficiary protections in the future.

We applaud CMS for reminding plans that their use of utilization management (UM) techniques (e.g., step therapy, prior authorization, etc.) or cost-sharing requirements employed by Part D

plans with respect to negotiated drugs must not be targeted to create barriers for patients that need access to negotiated drugs and their equivalents considered during negotiation. We support CMS stringently applying its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

Orphan Drug Exemption

We appreciate that the IRA includes a limited exemption for orphan drugs that only treat one rare disease from drug price negotiation. However, we are concerned about CMS's current interpretation of this rare disease exemption, which makes products eligible for negotiation if they have been designated for two or more orphan diseases even if the drug is not actually FDA-approved to treat the second orphan disease. This will likely disincentivize drug companies from conducting even the basic research necessary to develop a drug for additional rare diseases. Designating a drug for a rare disease is done very early on in the drug development process and does not allow the company to market the drug because it has not been proven to be safe and effective in treating that specific condition. We urge CMS to clarify that obtaining additional designations for a small molecule or biologic will not make a drug negotiation eligible until the drug has been approved by FDA to treat a second disease or condition.

Conclusion

LLS thanks CMS again for its leadership in this important area and this opportunity to provide comment on this proposed guidance. If you have any questions or would like to discuss our comments further, please contact Phil Waters, Director of Federal Public Policy at The Leukemia & Lymphoma Society at phil.waters@lls.org.

Sincerely,

Bethany Lilly
Executive Director of Public Policy

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

June 28, 2024

VIA E-MAIL (IRARebateandNegotiation@cms.hhs.gov)

Meena Seshamani, M.D., Ph.D
CMS Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Medicare Drug Price Negotiation Program Draft Guidance for IPAY 2027

Dear Dr. Seshamani,

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to the IPAY 2027 Draft Guidance (Guidance) on the "Medicare Drug Price Negotiation Program" (Program).[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

As a member of both the Pharmaceutical Researchers and Manufacturers Association of America (PhRMA) and the Biotechnology Industry Organization (BIO), Lilly largely joins those groups in their comments on the Guidance and encourages CMS to carefully consider the input of those organizations. That said, Lilly would like to offer the following comments to highlight matters of concern and Lilly-specific positions.

Lilly remains troubled by the language of the statute and this Guidance continuing to classify the process by which CMS sets a "maximum fair price" (MFP) as a "negotiation." It is not. We continue to object to being coerced to agree that the price, which is dictated by the government via this process, constitutes a "maximum fair price." This characterization of the price as fair, aside from working a reputational harm, poses a non-trivial legal risk that plaintiffs' attorneys, or others, will seek to use this "admission" to advance legal claims that other prices charged by manufacturers result in an "unfair" price or a deceptive trade practice. Because these terms are legally defined and prescribed by the Inflation Reduction Act of 2022 (IRA), we will occasionally adopt them for purposes of this letter; however, we do not agree that their use is appropriate or compatible with their plain meaning.

We appreciate that CMS is obligated to implement the IRA, but we urge the Agency to appreciate that this law was rushed through Congress, outside of regular order, and approved along the narrowest of party-line votes. The lack of regular order meant that legislators could not fully explore the policy implications of all the concepts and statutory language created by the IRA and the legislative rush meant that many concepts may not have been fully thought through.

We have identified several unintended consequences that warrant both cautious implementation and, to the extent CMS may do so, corrective or ameliorative implementation. In many respects, the IRA is a solution in search of a problem: Today, **two-thirds of Medicare beneficiaries believe that their Medicare coverage fully meets their expectations and 93-96% reported their coverage generally meets their expectations.**[2] With respect to Medicare Part D, **85 percent are satisfied with their Medicare**

[1] Centers for Medicare and Medicaid Services (CMS). *Draft Guidance on the Medicare Drug Price Negotiation Program.* May 3, 2024. Available: https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[2] The Commonwealth Fund. *What Do Medicare Beneficiaries Value About Their Coverage.* February 22, 2024. Available: https://www.commonwealthfund.org/publications/surveys/2024/feb/what-do-medicare-beneficiaries-value-about-their-coverage.

Part D prescription drug coverage with over eight out of 10 also saying that their Part D plans provide good value.[3] The drug pricing provisions of the IRA introduce substantial new controls for Medicare, marking a significant departure from the current market-based systems likely disrupting the coverage valued by its beneficiaries. Below we highlight such potential unintended consequences due to the IRA in the following areas:

1. The IRA Has Increased Part D Premiums Significantly, With More Increases on the Way

The implementation of IRA has already led to a noticeable increase in premiums. A new report indicates that **premiums for Medicare Part D drug plans have surged by an overwhelming 21% on average from 2023 to 2024** and 45% of standalone Part D Plan (PDP) enrollees may face premium increases of more than 25%.[4] To compare, only 13% of enrollees had at least a 25% increase in 2023 and given additional IRA changes some commentators expect next year's premiums to increase by 50%.[5] While the IRA's premium stabilization program limits the growth of base beneficiary premiums to 6%, individual plan premiums vary and many saw increases.

2. The IRA Will Increase the Cost of Prescription Drugs to the Federal Government

CMS's own analysts have concluded that "**In 2026, Medicare prescription drug spending is projected to increase 12.0 percent, mostly due to the expected reductions in rebates on drugs with negotiated prices.**"[6] This must not have been what Congress intended, as the Congressional Budget Office, itself, estimated that the prescription drug provisions of the law would reduce the federal budget deficit by $237 billion from 2022 to 2031.[7]

CMS was aware when it announced the initial list of drugs subject to price setting that many of the medicines selected for the Program already have significant rebates and discounts because of private market negotiation.[8] Because of those negotiations, the **medicines selected on the IPAY 2026 list had, in aggregate, out-of-pocket expenses of $378 per member or $31 per month.**[9] Considering the majority of the medicines selected benefit from substantial rebates, patients will see minimal out-of-pocket savings as a consequence of the Program's structure, and may see increases (see below).

3. The IRA Will Lead to Higher Patient Out of Pocket (OOP) Costs for Selected Medicines

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[3] Healthcare Leadership Council. 85 Percent of U.S. Seniors are Satisfied with Their Medicare Part D Prescription Drug Coverage, According to Nationwide Survey. Available: https://www.hlc.org/news/85-percent-of-u-s-seniors-are-satisfied-with-their-medicare-part-d-prescription-drug-coverage-according-to-nationwide-survey/.

[4] Avalere. *Part D Premium Increases, Market Disruption Expected in 2024*. October 11, 2023. Available: https://avalere.com/insights/part-d-premium-increases-market-disruption-expected-in-2024.

[5] White, Joel. "Inflation Reduction Act's Dirty Little Secret: Largest Premium Increase Ever for Medicare Drug Benefit Op-Ed. May 3, 2024. Available: https://townhall.com/columnists/joelwhite/2024/05/03/inflation-reduction-acts-dirty-little-secret-largest-premium-increase-ever-for-medicare-drug-benefit-n2638574.

[6] Health Affairs. *National Health Expenditure Projections, 2023-32: Payer Trends Diverge As Pandemic-Related Policies Fade.* June 12, 2024. Available: https://doi.org/10.1377/hlthaff.2024.00469.

[7] Congressional Budget Office (CBO). How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. February 17, 2023. Available: https://www.cbo.gov/publication/58850.

[8] Pink Sheet. *Big Rebates Already a Factor For Drugs On Medicare Negotiation List.* August 23, 2023. Available: https://pink.citeline.com/PS148774/Big-Rebates-Already-A-Big-Factor-For-Drugs-On-Medicare-Negotiation-List.

[9] Assistant Secretary for Planning and Evalulation (ASPE) Office of Health Policy. *Inflation Reduction Act Research Series – Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program.* December 14, 2023. Available: https://aspe.hhs.gov/sites/default/files/documents/23148a5897ea92a142aab21e2ec29ca2/ASPE-IRA-Drug-Negotiation-Fact-Sheet.pdf.

For millions of beneficiaries, the IRA's price setting provision could actually increase out of pocket costs. While selected medicines must be covered, plans can place them on non-preferred tiers, which often results in higher out-of-pocket costs for patients due to increased copays or coinsurance rates. Based on recent Milliman analysis, the Program will cause **an average annual beneficiary OOP increase of $70 or 12% for utilizers of selected medicines** in 2026 due to the provisions in the IRA.[10] Additionally, the use of prior authorization and step therapy can further limit accessibility. The changes to reinsurance and fiscal responsibility with the MFP's introduction could incentivize plans to favor medicines with higher list prices and rebates, potentially impacting the preference for selected medicines. This complex interplay of formulary placement and financial incentives can significantly affect which medicines are more accessible to patients.

4. The IRA Will Continue to Incentivize High List Priced Drugs with High Rebates

The IRA creates a preference for high-list price products due to the way rebates are applied to plan obligations. Beginning in 2025, the changes to the Part D benefit structure will be significantly altered and the amount contributed during the catastrophic phase is tied to how a manufacturer's direct and indirect remuneration (DIR) rebate is allocated. It is anticipated that a larger portion of the DIR rebate will go towards the plans' total drug costs, with the remainder going to the government's costs. Currently, plans receive about 65% of the DIR, but it is projected that this will increase to 85% in 2025.[11] As a result, plans are inclined to favor products with higher list prices and rebates over those with lower list prices and rebates, due to a greater portion of manufacturer rebates is allocated towards the plan's obligations.

5. The IRA Will Reduce, If Not Eradicate, Stand Alone Part D Plans (PDPs)

In addition to growing PDP premiums, the number of PDPs available to Medicare enrollees is decreasing. The total number of PDPs decreased by 11% in 2024, while Medicare Advantage (MA-PD) plan offerings remained relatively stable.[12] Notably, MA-PD plans are also more expensive to the government, a gap that amounted to $7 billion in additional spending in 2019.[13] This trend raises concerns about the sustainability of such plans and the potential impact on future Medicare funding. As the government projects to pay between $500 and $600 billion in Medicare Advantage payments to private health plans in 2025, the financial implications of these trends underscore the need to ensure the accessibility of prescription drug coverage for Medicare enrollees.[14]

6. The IRA Could Financially Harm Pharmacies

While the Program requires a 14-day prompt payment from manufacturer to dispensing providers on valid claims, the fact that manufacturers must collect and validate these claims, itself, takes time. Moreover, manufacturers have only one chance to get this right and it must be on the front-end, because manufacturers lack audit rights on the back end and there are no administrative or judicial options (these are, in fact, banned by the statute) through which manufactures could obtain repayment. The challenges in managing the complexities of receiving and processing claim-level data elements, conducting secure data exchanges, calculating

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[10] Milliman. Expected Impact of Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program on Medicare Part D Beneficiary Out-of-Pocket Costs. June 24, 2024. Available: https://www.milliman.com/-/media/milliman/pdfs/2024-articles/6-25-24_expected-oop-cost-impact-drug-price-negotiation.ashx.

[11] Drug Channels. Surprise! Thanks to the IRA, Part D Plans Will Prefer High-List, High-Rebate Drugs. February 21, 2024. Available: https://www.drugchannels.net/2024/02/surprise-thanks-to-ira-part-d-plans.html.

[12] Kaiser Family Foundation. *Medicare Part D in 2024: A First Look at Prescription Drug Plan Availability, Premiums, and Cost Sharing*. November 8, 2023. Available: https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2024-a-first-look-at-prescription-drug-plan-availability-premiums-and-cost-sharing/.

[13] Kaiser Family Foundation. *Payments to Medicare Advantage Plans Boosted Medicare Spending by $7 Billion in 2019*. August 17, 2021. Available: https://www.kff.org/medicare/press-release/payments-to-medicare-advantage-plans-boosted-medicare-spending-by-7-billion-in-2019/.

[14] Centers for Medicare and Medicaid Services (CMS). CMS Finalizes Payment Updates for 2025 Medicare Advantage and Part D Programs. April 1, 2024. Available: https://www.cms.gov/newsroom/press-releases/cms-finalizes-payment-updates-2025-medicare-advantage-and-medicare-part-d-programs.

accurate refunds, and maintaining compliance with statutory obligations all take time. And while manufacturers will seek to expedite this validation process and make prompt payments (it is in our interest to have robust dispensing networks for our medicines) we are also concerned that some of these providers will have to incur the upfront costs of "floating" the MFP to the beneficiary. This was likely not contemplated by Congress or intended under the IRA.

7. The IRA Is Going to Disrupt 340B Program Operations

Manufacturers are required to ensure that the MFP is accessible to 340B covered entities when it is lower than the 340B ceiling price for a given medicines. However, CMS has clarified that it will not be responsible for "deduplicating" these discounts, creating a functional vacuum.[15] Moreover, CMS will not require covered entities to identify 340B/MFP prescriptions; the agency will only commit to sharing 340B data with manufacturers to the extent dispensing entity "proactively and voluntarily" identifies the drug as 340B.[16] Because there are no systems – let alone incentives – for covered entities to proactively and voluntarily identify these dispenses, manufacturers risk extending double discounts on drugs that are both MFP and 340B. Other provisions in the IRA, notably the Part B and Part D inflation rebates, also prohibit duplicate discounts and CMS has similarly disclaimed responsibility for ensuring compliance by the dispensing entities. Unless CMS and its sister agency, HRSA, work promptly and in close cooperation to address these IRA provisions holistically, the 340B system will likely be disrupted.

8. The IRA Will Stifle Innovation, Discourage Valuable Research on Additional Uses for Drugs, and Result in Fewer Drugs Coming to Market

One of the largest areas of concern is the potential unintended consequences of the IRA on pharmaceutical innovation. Below we provide several examples of the how the IRA will result in decreased research and development (R&D) investment and reduced innovation:

- Impact on small molecule medicines: One of the most important and controversial IRA provisions was permitting the federal government to impose price controls on small molecule medicines four years earlier than biologics. There is no scientific or policy rationale for this "9/13" disparity and it will disincentivize research and development for medicines that are approved under a New Drug Application (NDA) – including certain RNA-based medicines – and favor medicines approved under a Biologics License Application (BLA). The University of Chicago estimates a $232 billion reduction in research and development for small molecule medicines over the next 20 years due to the IRA.[17] According to the paper, the **IRA's "pill penalty" is projected to result in 188 fewer small molecule medicines, including 79 fewer over the next 20 years.** The IRA is estimated to reduce the net present value of small molecules by 40%, significantly reducing the return-on-investment, and there is considerable evidence to suggest that venture funds and biopharmaceutical companies will pull back from small molecule research.[18]

- Impact on RNA based therapies: RNA-based therapies are a new class of treatments that use RNA to alter disease pathways, offering potential for conditions unresponsive to traditional treatments. One of the greatest advantages of RNA-based medicines is their ability to target almost any genetic component within the cell, many of which may be considered "undruggable" using conventional small molecule or protein-based therapeutics. Further, unlike other genetic medicines, RNA therapies have the potential to offer durability of treatment effect without making permanent changes to a patient's

[15] *See* Guidance at 49.
[16] *Id.*
[17] The University of Chicago. The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. October 5, 2023. Available: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.
[18] No Patient Left Behind. The Impact of the Inflation Reduction Act on Early-Stage Biomedical Investment Decisions. May 7, 2024. Available: https://www.nopatientleftbehind.org/resource-materials/j9yk2v9mfzftn8528fan30fdwy2xiw.

genetic code. This means these therapies may be dosed only once or twice a year, offering unique benefits for patients. As of early 2024, over 130 such therapies are in clinical trials, targeting a variety of diseases with a focus on rare conditions lacking alternative treatments.[19] RNA-based therapies such as small interfering RNAs (siRNAs) and antisense oligonucleotides (ASOs) have been regulated by FDA as small molecule medicines, despite complexities associated with product development and resource investment comparable to other gene therapies that FDA regulates as biologics. This classification, along with the disparities introduced by the IRA, poses a risk to the advancement of innovative technologies within this critical field.

- Impact on opioid alternative development: The Society of Actuaries estimates the total economic burden caused by the opioid epidemic from 2015 to 2018 was $631 billion, with other estimates that included the statistical value of life ranging up to $2.5 trillion during this time frame.[20] To help combat the opioid epidemic, research into pain relief alternative therapies is underway and there is a high probability that the resulting approved solutions are small molecule medications.[21] The IRA significantly reduces the return-on-investment for small molecule medicines, and there is considerable evidence to suggest that venture funds and biopharmaceutical companies will pull back from small molecule research, given the reduced future profitability of these products.[22] In contrast to the massive $631 billion in four-year costs arising from the opioid epidemic, the Congressional Budget Office (CBO) estimates that savings from the price control provisions of the IRA will generate savings of only $129 billion during the ten-year period of 2022–2031.[23] Discouraging research on potential small molecule opioid alternatives, which could result in greater savings than the Program, is a mistake. Non-opioid pain research projects are markedly more complicated than most other drug therapies. The **IRA will make those discoveries nearly impossible because the number of R&D projects that need funding will shrink considerably.**

- Impact on subsequent indications: The disparity in negotiation timelines outlined above also could negatively impact research for additional indications for medicines. **A recent study found that among the 50 medicines with the highest Part D spending in 2020, subsequent indications through post-approval clinical trials for small molecule medicines were approved between 7.5 years to 9 years after the medicine was first approved.**[24] The researchers assert that because of FDA approval timelines and IRA eligibility beginning 9 years after launch for small molecule medicines, firms may be less likely to conduct post-approval research towards additional indications, which may result in patients having access to fewer on-label treatment options.[25] Similarly, the USC Schaffer Center for Health Policy states that because the IRA shortens the timeframe in which firms can earn returns on R&D on new indications, firms may be less likely to invest in studies that quantify efficacy, safety, and value of applications of existing products to new disease areas.[26]

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[19] Avalere. Overview and Outlook for RNA-Based Therapies. May 2024. Available: https://avalere.com/wp-content/uploads/2024/06/20240522-Lilly-RNA-Based-Therapies-White-Paper-vFINAL.pdf.
[20] Pioneer Institute. The Left-Hand Doesn't Know What the Right-Hand is Doing: The Federal Government and Opioids. April 2024. Available: https://pioneerinstitute.org/wp-content/uploads/PNR-554-Opiod-WP-v02.pdf.
[21] Ibid.
[22] Ibid.
[23] Congressional Budget Office (CBO). How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act. February 17, 2023. Available: https://www.cbo.gov/system/files/2023-02/58850-IRA-Drug-Provs.pdf.
[24] American Journal of Managed Care. Unintended Consequences of Inflation Reduction Act: Clinical Development Toward Subsequent Indications. February 2, 2024. Available at: https://www.ajmc.com/view/unintended-consequences-of-the-inflation-reduction-act-clinical-development-toward-subsequent-indications.
[25] Ibid.
[26] USC Schaffer Center for Health Policy. Mitigating the Inflation Reductions Act's Adverse Impacts on the Prescription Drug Market. April 13. 2023. Available: https://healthpolicy.usc.edu/research/mitigating-the-inflation-reduction-acts-potential-adverse-impacts-on-the-prescription-drug-market/.

- Impact on orphan drugs and rare diseases: While orphan drugs with multiple indications for the same rare disease are exempt from the negotiations program, an orphan drug will become eligible as soon as it is designated for a second rare disease. The National Organization for Rare Disorder details that **more than 75 percent of orphan drugs are only approved for a single rare disease and the IRA potentially discourages research into additional uses for these drugs**, which would be a step back for the rare disease community.[27] In examining follow-on indications for orphan drugs, a recent study found that **61 percent of follow-on indications between 2003 and 2022 were also for orphan drug conditions**, and 58 percent of follow-on indications were approved through Food and Drug Administration (FDA) expedited review programs for unmet need or serious illness.[28] The researchers assert that the orphan drug exclusion in the IRA may lead manufacturers to develop more single-indication orphan drugs and could have nontrivial impact on follow-on indications for orphan drugs.

- Impact on generic and biosimilar development: The IRA further disincentivizes the development of generic and biosimilar medicines that lower costs for patients and generate savings for the broader health care system. Today's robust U.S. generic and biosimilar markets increase competition and yield substantial savings for patients and the government. However, the Program could set a price so low that biosimilar and generic manufacturers may not see any benefit to bringing their products to market in the first place.

We expect this list of unintended consequences of the IRA to grow further, especially if CMS is not careful in implementing the law's commands. Other substantiative comments can be summarized as follows:

I. In effectuating the MFP, we recommend the following:

   A. CMS should reconsider mandating only manufacturers to participate in data collection and instead distribute this responsibility among all stakeholders in the pharmaceutical supply chain.

   B. We urge CMS to revise the Guidance to define the Standard Default Rebate Amount (SDRA) as the lesser of WAC minus MFP to prevent Gaming.

   C. CMS should preserve the voluntary nature of MTF payment facilitation and allow flexibility in choosing between the two payment facilitation options.

II. We strongly urge CMS to rescind its policy on identifying 'Qualified Single Source Drugs' (QSSDs) and instead distinguish between different QSSDs by reference to distinct New Drug Applications (NDAs) or Biologics License Applications (BLAs). Accordingly, CMS should aggregate Medicare expenditures and apply the MFP across only those dosage forms and strengths that are marketed under a single distinct NDA or BLA for each QSSD.

III. We strongly urge CMS to rescind its unlawful bona fide marketing standard. CMS should instead use the definition of "marketed" in the NDRA, which manufacturers already report under the Medicaid Drug Rebate Program (MDRP).

IV. With respect to the MFP process, we recommend the following:

   A. CMS should enhance the proposed "consistent methodology and process" for "negotiation" and "renegotiation." Specifically, we ask that this process include fully bespoke negotiations, consideration of all information

[27] NORD. The Needs of Rare Disease Patients and the Value of Orphan Drugs Will Take Center Stage at this Week's Rare Disease Congressional Hearing. Available: https://rarediseases.org/rare-disease-congressional-hearing/.
[28] Center for the Evaluation of Value and Risk in Health, Tufts Medical Center. Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act. August 15, 2023. Available: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808362..

submitted, a thorough justification of the initial offer and the response to any counteroffer, and full opportunity to supplement submitted information where there are material changes or otherwise for good cause shown.

B. CMS should permit manufacturers to rely on reasonable assumptions in connection with data submissions and provide voluntary explanations of data submissions, as appropriate.

C. CMS should modify its proposed MFP setting process to allow for greater dialogue between the parties throughout the process and to specify that additional meetings (beyond the current maximum of three) may be held if agreed to by both parties.

D. CMS should establish more detailed safeguards to ensure that confidential commercial information is adequately protected from disclosure. Additionally, CMS's proposed policies regarding use and destruction of information by manufacturers are unlawful, and therefore CMS must abandon them.

V. In setting the MFP, we urge CMS account for special considerations by adopting the following recommendations:

A. CMS should allow manufacturers to submit evidence demonstrating that a price will imperil patient access, and CMS should specify that the MFP will not be set below the lower of either that price or the MFP ceiling price.

B. CMS should clarify that it will not set the MFP below the MFP ceiling for any initial price applicability year (IPAY) during which the medicine is under patent protection.

C. For a small molecule medicine, CMS should specify that it will not set the MFP below the MFP ceiling until at least 13 years have lapsed since the medicine's approval.

D. CMS should specify that the MFP will not be set below the MFP ceiling price where a state uses the MFP as a reference point in setting a price or payment limit outside of the Medicare market. And we ask that CMS specify that such use of the MFP will constitute a "material change" triggering selection for "renegotiation."

E. CMS should specify that the MFP will not be set below the MFP ceiling if the selected medicine is subject to a value-based purchasing arrangement (VBP) and the multiple Best Prices (BPs) reporting option (MBPRO).

VI. We urge CMS to clarify that selected medicines are not subject to an inflation rebate.

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I. Effectuating the MFP

A. CMS should reconsider mandating only manufacturers to participate in data collection and instead distribute this responsibility among all stakeholders in the pharmaceutical supply chain.

At Section 40, CMS outlines the role of the MTF in facilitating the exchange of claim-level and payment-related data for selected medicines. It is important to consider the implications of mandating manufacturers' participation in this data collection process but not mandating input from other entities. Effectuating the MFP is inherently a multi-party process and any "requirement" as to one party should be a requirement as to all parties. Consider a made-up pharmacy, call it the "Alaskan Libertarian Pharmacy," that does not want to sign up with the MTF. This provider would need to find a different way to receive an MFP refund payment from a manufacturer, but CMS's Guidance does not change the rules applicable to manufacturers when interacting with this pharmacy,

even though the pharmacy may not be willing to share all of the information required to accurately effectuate an MFP. Requiring only the Primary Manufacturer to transmit and receive specific data elements places a disproportionate burden on these entities and decreases the likelihood that any data sharing efforts will meet the requirements to accurately effectuate MFP.

Of course, if the private market builds a better MTF mousetrap, manufacturers should be permitted to satisfy their "make available" obligations outside the MTF. Similarly, for providers that opt to effectuate the MFP outside of the MTF framework, the manufactures and the provider should be allowed to reach their own, independent, terms and conditions – not be governed by those set forth in the Guidance.

B. We urge CMS to revise the Guidance to define the Standard Default Rebate Amount (SDRA) as the lesser of WAC minus MFP to prevent Gaming.

Lilly appreciates CMS' proposal to define an SDRA and believes it will streamline effectuation of the MFP, however we have concerns regarding the CMS Guidance's stance that the "SDRA may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug". The notion that manufacturers have to cover the mark ups charged by others in the supply chain creates serious concerns. First, this concept creates incentives for gaming by encouraging middlemen, dispensers and other entities within the pharmaceutical supply chain to "jack up" prices because they know the manufacturer will come along an pay for all of these inflated costs. The argument might be that this would not occur because someone would have to "float" the inflated acquisition price, but as we have seen in other programs, there is no end to creativity intermediaries will deploy to derive profits from drug companies. Second, such a requirement could present an "as applied" challenge under the Fifth Amendment's prohibition against a taking without just compensation.

Consider as an example a selected medicine with a WAC of $100 and an MFP of $60. The wholesaler purchases the selected medicine from the manufacturer at a price of $94, and the dispenser purchases the selected medicine from the wholesaler at a price of $97. Utilizing the SDRA, the manufacturer would owe an MFP refund of $40, giving both wholesaler and dispenser a margin of $3 on the transaction. However, to use an extreme example, the dispenser and wholesaler could enter into an arrangement to acquire the selected medicine at a cost of $10,0000. The manufacturer would then owe the difference between $10,000 and $60 (or $9,940) on a drug it sold for $100. If the wholesaler agrees to retrospectively refund a portion of the acquisition price to the dispenser or gives the customer a discount or benefit on some other product or service, both will receive margins substantially higher than before.

This problem is exacerbated by the fact that manufacturers lack influence over the prices dispensers pay to supply chain intermediaries, such as wholesalers. If CMS was the party at risk to such gamesmanship, we have no doubt the agency would take steps to prevent the misallocation of taxpayer dollars. But as the Department of Justice recently recognized in a similar situation, "it is arguably worse for the government to play fast and loose with others' (drugmakers') money on the line."[29] To prevent the possibility of artificially increased MFP reimbursements, Lilly urges CMS to implement a policy where the SDRA is determined by the lesser amount between WAC minus MFP and Acquisition Cost minus MFP.

C. CMS should preserve the voluntary nature of MTF payment facilitation and allow flexibility in choosing between the two payment facilitation options.

CMS outlines their consideration in utilizing an MTF to facilitate transactions between manufacturers and dispensing entities.[30] This exploration includes the potential implementation of a voluntary payment facilitation functionality to streamline the process of providing retrospective refunds to dispensing entities.[31] The voluntary nature of this proposal is particularly beneficial, as it allows

[29] Reply Mem. (Doc. 24) at p. 17, *Albany Med. Health Sys. v. HRSA*, No. 23-3252 (D.D.C. Apr. 19, 2024).
[30] *See* Guidance at 53.
[31] *Id.*

manufacturers and dispensing entities to choose the facilitation method that best suits their operational needs. This flexibility is crucial given that the complete onus is on manufacturers to comply with the statutory requirements, with significant CMPs for non-compliance. By offering these options on a voluntary basis, CMS ensures that manufacturers can tailor their approach to compliance, mitigating the risk of penalties while fostering cooperation and efficiency within the industry. This approach respects the autonomy of the involved parties, encouraging broader participation without imposing rigid mandates, ultimately supporting a more efficient and compliant payment facilitation process.

CMS is soliciting feedback on two options for MTF payment facilitation: Option 1, where the MTF collects and shares banking information with manufacturers to enable direct refunds to dispensing entities, and Option 2, where the MTF directly receives aggregated refund amounts from manufacturers and passes these payments through to the dispensing entities.[32] Both options offer unique benefits tailored to address the varying needs of manufacturers and dispensing entities, particularly given the diversity of medicines selected for the Program. The flexibility to use either option can accommodate different operational models and foster innovative, market-driven solutions. The ability to use either option helps ensure that manufacturers can fulfill their statutory obligations while offering voluntary participation, allowing stakeholders to choose the method that best suits operational needs.

II. Identifying QSSDs

Lilly reiterates concerns raised in our comment letter to the 2026 IPAY Initial Guidance.

A. CMS Must Rescind Its Policy on Identifying Distinct Qualified Single Source Drugs (QSSDs) and Instead Distinguish Between Different QSSDs by Reference to Distinct NDAs or BLAs (Section 30).

Under the Program, CMS selects a QSSD for the MFP process based on the agency's calculation of "total expenditures" under Part B or Part D for dosage forms and strengths of the drug, and then applies the drug's MFP to all such dosage forms and strengths.[33] Importantly, the statute does not specify how to make a number of threshold determinations necessary for the fulfillment of these directives, namely:

- How to identify a QSSD and distinguish it from another when selecting a QSSD for the MFP process;
- How to identify "the drug" when aggregating Part B or Part D expenditures across dosage forms and strengths of "the drug;" and

[32] *See* Guidance 55-58.

[33] SSA §§ 1192(e)(1), (d)(3)(B), 1196(a)(2). The statute employs different articulations when referring to the versions of the drug that must be taken into account in aggregating Medicare expenditures and applying the MFP. Specifically, section 1192(d)(3)(B) of the SSA refers to aggregation of Medicare expenditures "across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." And section 1196(a)(2) refers to application of the MFP to "different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug." Regardless, the statutory text makes clear that, whether aggregating Medicare expenditures or applying the MFP, CMS may consider only formulations within dosage forms and strengths of the drug, and not any other formulations. This is so because the statute directs such aggregation and application at dosage forms and strengths of the drug, with all references to formulations appearing only in language qualifying such directives. *See BST Holdings, LLC. v. OSHA,* 17 F.4th 604, 613 (5th Cir. 2021) ("To avoid 'giving unintended breadth to the Acts of Congress,' [a basic rule of interpretation is to] 'rely on the principle of noscitur a sociis—a word is known by the company it keeps.'"); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("It is a 'fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.'").

- How to identify "[the] drug" when applying the MFP across dosage forms and strengths of "[the] drug."

In the Guidance, CMS sets forth an approach to identifying a distinct QSSD by reference to active moiety (drugs) or active ingredient (biologics). Specifically, CMS defines QSSD to include all dosage forms and strengths of drugs or biologics that share the same active moiety or ingredient of the same NDA or BLA holder, respectively, regardless of whether the drugs or biologics are marketed pursuant to distinct NDAs or BLAs. As such, for the first IPAY, CMS will aggregate Part D expenditures across all dosage forms and strengths of drugs or biologics sharing an active moiety or an active ingredient of the same NDA or BLA holder and will apply the MFP across all such dosage forms andstrengths.

As explained below, CMS's approach contradicts the plain language of the statute. By law, CMS is required to identify each QSSD by reference to its NDA or BLA, such that:

- A QSSD is defined by reference to whether the product has a distinct NDA orBLA;
- Expenditures are aggregated across dosage forms and strengths marketed pursuant to a common NDA or BLA; and
- The MFP is applied across the dosage forms and strengths specific to each such NDA orBLA.

CMS's contrary approach is not merely inconsistent with the statute, but it is also fundamentally unsound as a matter of policy, and risks constraining pharmaceutical and biotechnology innovation through a sweepingly overinclusive interpretation of what constitutes a distinct QSSD. Under the QSSD definition as interpreted by CMS, any innovation related to formulation made post the initial NDA/BLA, which could be meaningfully beneficial to patients, has no significance.

1. Distinct QSSDs Must Be Defined by Reference to Distinct NDAs or BLAs

Under section 1192 of the SSA, only "qualifying single source drugs" are subject to the MFP process. Subject to certain exclusions, "qualifying single source drugs" are defined as:

- Drugs approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), "for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval," and that are not a listed drug for a drug approved and marketed under an abbreviated new drug application (ANDA) pursuant to section 505(j) of the FDCA (i.e., for a generic); and
- Biologics licensed under section 351(a) of the Public Health Service Act (PHSA), "for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure," and that are not the reference product for any biological product licensed and marketed under 351(k) of the PHSA (i.e., for a biosimilar).[34]

The statutory text plainly specifies that a "qualifying single source drug" is defined by reference to each "such approval" or "such licensure," which starts each seven- or eleven-year clock. As such, the statute requires that a distinct QSSD be defined by reference to a distinct approval or licensure, i.e., a distinct NDA or BLA.

CMS's Guidance takes a contrary approach. The agency says that it intends to treat all dosage forms and strengths of products with the same active moiety (drug) or active ingredient (biologic) under applications held by the same primary manufacturer as the same QSSD, regardless of whether such products are approved or licensed under distinct applications.[35]

[34] *Id.* § 1192(e)(1). Selected drug publication date is a term of art meaning that, with respect to each IPAY, February 1 of the year that begins 2 years prior to such year. *Id.* § 1191(b)(3).
[35] *See* Guidance at 8.

CMS's approach cannot be reconciled with the statutory definition of QSSD.[36] Congress explicitly defined a QSSD by reference to "such approval" and "such license" to denote that QSSDs must be distinguished by their distinct approvals or licensures. As such, CMS's policy is fundamentally at odds with the language of the statute, which evidences Congress's clear intent to distinguish QSSDs by reference to distinct "approvals" or "licensures" – that is, whether they have a distinct NDA/BLA.

The statute reinforces Congressional intent to distinguish QSSDs based on their NDAs or BLAs by specifying in the QSSD definition that a QSSD that is a Part D drug must meet the "covered Part D drug" definition in the Medicare statute.[37] The Medicare statute, in turn, defines a "covered Part D drug" by reference to the "covered outpatient drug" definition in the MDRP statute.[38] And, under the MDRP statute, a "covered outpatient drug" is defined by reference to a Food and Drug Administration (FDA) approval or licensure under an NDA or BLA.[39] Indeed, the government itself recognizes as much.[40]

The MDRP statute provides for only one exception to the rule that a drug or biologic is defined by reference to its NDA or BLA, and Congress specifically amended the statute to provide for such exception. Congress affirmatively amended the MDRP statute to treat a line extension as the same drug as its predecessor version(s), even when approved under a distinct NDA or BLA, when calculating the line extension's Medicaid rebate amount.25 Under the Program, no similar statutory exception exists, reinforcing the conclusion that Congress intended that a QSSD be identified by its NDA or BLA.26 Congress clearly would have said otherwise had it intended any other result. Indeed, elsewhere in the IRA, Congress did do so. In the provisions governing the IRA's Part D inflation rebate program, Congress expressly referenced the MDRP statute's line extension provision to enable the grouping of products across NDAs or BLAs.[41] By contrast, Congress pointedly declined to do likewise in defining a QSSD.

Although the interpretive "inquiry begins with the statutory text, and ends there as [well because] the text is unambiguous,"[42] Lilly notes that there are a host of additional factors that lend further support for the conclusion that Congress intended QSSDs to be distinguished on the basis of distinct NDAs/BLAs.

First, FDA's framework for approving products via distinct applications strongly supports the use of distinct NDAs/BLAs as the standard for distinguishing between QSSDs. As a general matter, prescription drugs and biologics may be marketed only if approved or licensed by FDA.[43] Manufacturers seeking approval of a new drug must submit data to FDA sufficient to satisfy the safety and effectiveness standard for approval of an NDA[44] And manufacturers of a new biologic likewise must demonstrate to FDA the safety, purity, and potency of the product in order to be licensed under a BLA.[45]

FDA has spoken directly to the circumstances under which a change to an approved product can be approved by submitting a supplement to an already-approved NDA/BLA, and that for which a separate NDA/BLA should be submitted instead.[46] It is reasonable and appropriate to rely on these FDA standards, such that a product approved/licensed via a separate NDA/BLA (as

[36] *Love v. Tippy*, 133 F.3d 1066, 1069 (8th Cir. 1998) (it is well-settled that "if a statute is unambiguous the statute governs").
[37] SSA § 1192(e).
[38] *Id.* § 1860D-2(e)(1).
[39] *Id.* § 1127(k)(2).
[40] *See, e.g.*, Reply Brief in Support of Def.'s Cross-Mot. for Summ. J., *Ipsen Biopharms., Inc. v. Price*, at 19 (D.D.C. Oct. 30, 2017) ("CMS has long interpreted the Medicaid Drug Rebate provisions of the [SSA] such that each covered outpatient drug is identified by its [NDA] number").
[41] SSA § 1860D–14B(b)(5)(B).
[42] *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 177 (2004).
[43] 21 U.S.C. § 355(a); 42 U.S.C. § 262(a)(1)(A).
[44] 21 U.S.C. § 355(c),(d); 21 C.F.R. §§ 314.105, 314.125.
[45] 42 U.S.C. § 262(a)(2)(C); 21 C.F.R. §§ 601.2(a), 601.4(a).
[46] Food and Drug Administration (FDA). *Guidance for Industry: Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*. December 2004. Available: https://www.fda.gov/media/72397/download.

opposed to by a supplement to an already-approved NDA/BLA) is considered a distinct QSSD. For example, FDA directs manufacturers of a new active ingredient, e.g., a different salt, ester, or complex of an approved moiety, to submit a separate application.[47] On the other hand, a proposed different strength should be approved via a supplement.[48] And different container sizes and package types of a drug with the same indication and route of administration are all approved under a common application.[49] Certain changes in dosage form or route of administration may be approved via a supplement, but others should be approved via a separate application.[50]

Second, a distinct NDA/BLA standard is consistent with the balance the statute strikes between the often-competing interests in encouraging pharmaceutical and biotechnology innovation and reducing prescription drug costs. The statute seeks to address this tension by, among other things, establishing a period of time after approval or licensure during which a product is not eligible for selection for the MFP process, thus preserving an incentive for the manufacturer to research and develop next-generation products. Similarly, distinguishing between products by the NDA/BLA under which they are approved reflects a balance between more significant changes (i.e., those requiring a new NDA/BLA), yielding distinct products for MFP setting purposes, and less significant ones (i.e., those approved under a supplement to an already-approved application), which are appropriately considered modifications of the same product. Any standard that does not reflect this distinction contravenes the balance Congress crafted by putting next-generation products at risk of being subject to MFP setting on an unduly short (and potentially immediate) time frame.[51] Accordingly, the sweeping, extra-statutory approach set forth in the Guidance risks dramatically discouraging development of next-generation products.

Lastly, CMS's approach is also unnecessarily complicated. Defining each QSSD by reference to its NDA or BLA makes practical sense. It establishes a readily administrable bright line test for all parties under the Program. CMS will be able to easily identify the relevant dosage forms and strengths of a selected drug for purposes of aggregating Medicare expenditures and applying the MFP, and manufacturers will be able to confidently track the 7- or 11-year timeline from the NDA/BLA approval/licensure date for selection eligibility and make research and development decisions accordingly. By contrast, the approach in the Guidance adds unnecessary complexity to what Congress intended to be an easily administrable statutory standard.

For the foregoing reasons, Lilly vigorously disagrees with CMS's stated approach to identifying a QSSD for legal and policy reasons. We urge CMS instead to define each "qualifying single source drug" by reference to its NDA or BLA, as required by the statute and the dictates of sound public policy.[52]

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[47] *Id.* at 3.
[48] *Id.* at 4.
[49] *Id.*
[50] *Id.* at 3.
[51] This is the same balance between encouraging innovation and reducing drug costs that the Hatch-Waxman Amendments to the FDCA reflect by granting 5-year and 3-year exclusivity to innovative products, but then allowing easy market entry for generics after exclusivity expires. *See Amarin Pharm. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 198 (D.D.C. 2015) ("[T]he [Hatch-Waxman] Act sought to balance two competing policy goals: (1) encouraging the development of generic drugs to increase competition and lower prices in the pharmaceutical industry, while (2) maintaining incentives for pharmaceutical companies to invest in innovation and the creation of new drugs."); *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers.").
[52] As CMS itself acknowledges, the agency must apply its definition of "qualifying single source drug" across all uses of such term in the statute. *See* Guidance at 10. Accordingly, if (contrary to the plain language of the statute) CMS maintains that products that share the same active moiety (drugs) or the same active ingredient (biologics) are the same QSSD, Lilly agrees with CMS that the market entry of a generic or biosimilar for any of such product must necessarily disqualify *all* such products from treatment as a QSSD. *See id.* Any other approach would be irreconcilable with CMS's stated approach to identifying a "qualifying single source drug." *See, e.g., Nat'l Credit Union Admin. v. First Nat. Bank & Tr. Co.*, 522 U.S. 479, 501–02 (1998) (a basic canon of interpretation is that similar or identical language must "be accorded a consistent meaning"). Importantly, CMS cannot bootstrap itself out of this outcome through its unlawful bona fide marketing standard for determining when a generic or biosimilar is marketed. *See* Section II.

2. CMS Must Aggregate Part B or Part D Expenditures on a QSSD Across Only Those Dosage Forms and Strengths That Are Marketed Under the Distinct NDA or BLA of Such Drug.

A necessary corollary to the requirement that each QSSD be defined by reference to its distinct NDA or BLA is that CMS must aggregate Medicare expenditures across only those dosage forms and strengths of the QSSD that are marketed under the applicable NDA or BLA. This follows from the statutory definition of "negotiation-eligible drug," which is defined as a QSSD that is among the 50 QSSDs with the highest total expenditures under Part B or Part D during a specified period.[53] To calculate total expenditures on a QSSD, the statute instructs that CMS must "use all data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug."[54]

Because the statute requires QSSDs to be distinguished by reference to their distinct NDAs/BLAs, it necessarily follows that total Part B or Part D expenditures must similarly be aggregated by distinct NDA/BLA. The statute could not be clearer on this point. It requires expenditure data to be "aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or pack size or package type of the drug" to determine whether a QSSD is among the highest Medicare expenditure QSSDs during a specified period and thus an MFP-eligible drug.[55] "The drug" can only refer to the QSSD, which, for the reasons stated above, must be defined by its NDA/BLA. It follows, then, that references to the "dosage forms and strengths of the drug" are to the various dosage forms and strengths that are approved under the given NDA or BLA. Further, the succeeding phrase – starting with "including" – necessarily presents "new formulations" as examples of the broader category of products that the phrase qualifies (i.e., "dosage forms and strengths of the drug"). Put differently, the word "including" limits the new formulations of the QSSD (as identified by its NDA or BLA) for which CMS may aggregate Medicare expenditures to a subset of formulations – those related to a change in dosage form or strength. And, as noted above, this interpretation is entirely in keeping with the distinct NDA/BLA standard, as distinct dosage forms and strengths, including new formulations thereof, may indeed be approved under a single application.[56]

Thus, CMS must aggregate Medicare expenditures across only those dosage forms and strengths (including any new formulations thereof) marketed under the applicable NDA or BLA in determining whether a product is MFP-eligible. This approach is mandated by the language of the statute, reflects a logical and coherent approach to its implementation, and gives effect to the Congressional intent underlying the MFP regime overall.

3. CMS Must Apply the MFP Across Those Dosage Forms and Strengths Approved Under the NDA or BLA of the Selected QSSD.

The statute also directs CMS to adopt "procedures to compute and apply the maximum fair prices across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug."[57] In the Guidance, CMS says that it will apply the MFP across all dosage forms and strengths of a given active moiety or active ingredient whose approvals or licensures, respectively, are held by the same primary manufacturer.[58] However, just as CMS musts define distinct QSSDs by distinct NDAs or BLAs, and must aggregate Medicare expenditures for purposes of identifying MFP-eligible drugs

[53] SSA § 1192(d). In some cases, a drug may be reimbursed under both Part B and Part D depending on where it is administered or dispensed. Because the statute distinguishes between drugs reimbursed under Part D and those reimbursed under Part B, expenditures under each part are aggregated separately for purposes of determining MFP eligibility.
[54] *Id.* § 1192(d)(3)(B).
[55] *Id.* § 1192(d) (emphasis added).
[56] We note that some changes in dosage form may be approved via a supplement to an already-approved NDA or BLA, while others require submission of a new application. Submitting Separate Marketing Applications.
[57] SSA § 1196(a)(2).
[58] *See* Guidance at 8.

across dosage forms and strengths within a given NDA or BLA, so, too, must CMS compute and apply the MFP across the dosage forms and strengths within the NDA or BLA of the selected QSSD. This necessarily follows from the statutory text, which plainly directs that the MFP be applied across dosage forms and strengths of such drug. The admonition that follows – to ignore specific formulations in doing so – can be logically understood to mean only that, in applying the MFP across dosage forms and strengths, the fact that there may be multiple specific formulations of those dosage forms and strengths does not alter such directive.

CMS should also recognize that manufacturers might be forced discontinue to making certain product presentations if the MFP, which is set for a molecule regardless of product presentation, renders specific product presentations no longer economically viable. This is most likely to undermine patient convenience and potentially patient adherence, further arguing for CMS to take a more granular approach to its definition of QSSD.

4. CMS Cannot Compel Manufacturers to Offer Every "Package Size" or Product Presentation of a Dosage Form and Strength for a QSSD.

In Section 60 of the Draft Guidance, CMS purports to require manufacturers to offer every package size or product presentation to patients. This is not what the statute commands. The statute requires only that the manufacturer offer the MFP "across different strengths and dosage forms" of a QSSD. 42 U.S.C. § 1320f-5(a)(2). Some product presentations – say a fully connected digital product delivery system for insulins – have a much higher price than a simple, multi-use vial. Both might have the same dosage form (injectable) and the same strength (say 100 units per mL) so they are a single "dosage form and strength." However, they might have very different unit costs and shipping considerations, such that a manufacturer would not offer one or the other to Medicare beneficiaries. CMS cannot add words to the statute that are not there, in this case "and package size or type." *See Landstar Express Am., Inc. v. Fed. Mar. Comm'n*, 569 F.3d 493, 500 (D.C. Cir. 2009) ("[A]n agency cannot rewrite a statute just to serve a perceived statutory 'spirit.'").

III. CMS Must Rescind Its Bona Fide Marketing Standard; CMS Should Instead Use the "Market Date" Reported Under the MDRP (Section 90)

Lilly continues to be troubled by CMS's "heads I win, tails you use" potential application of the "bona fide marketing" standard. The statute uses the date on which a generic or biosimilar was "marketed" as a key reference point across multiple aspects of the Program's implementation:

- **A drug or biologic is not MFP-eligible if a generic or biosimilar is marketed by what would otherwise be the drug or biologic's selection date.** The statute specifically excludes from the definition of a "qualifying single source drug" any product that is "the listed drug for any drug that is approved and marketed under [the FDCA]" or "the reference product for any biological product that is licensed and marketed under [the PHSA]."[59]

- **If a biosimilar manufacturer requests and is granted a delay in the selection of a biologic for negotiation and the biosimilar is marketed within two years of the date on which the biologic would otherwise have been selected for the MFP process, the biologic will never be subject to selection for the MFP process.** Under specified circumstances, a biosimilar manufacturer will be granted a delay in selection of a biologic for negotiation "if [CMS] determines that there is a high likelihood . . . that a biosimilar biological product . . . will be licensed and marketed . . . before the date that is 2 years after [what would otherwise have been the biologic's selection date]."[60]

[59] SSA § 1192(e)(1)(A)(iii); (B)(iii). Note that these and other provisions of the SSA refer to when a drug or biologic is **both** approved or licensed **and** marketed. The discussion herein presumes that a drug or biologic will be marketed only if it has been approved or licensed, so focuses only on the later of the two relevant dates, i.e., the date on which the drug or biologic is marketed.
[60] *Id.* § 1192(f)(1)(A).

- **A biologic is not eligible for delay in selection for the MFP process if it is not marketed within one year of licensure of the biosimilar.** Specifically, the statute states that "[i]n no case shall the Secretary delay the inclusion of a biological product on the [selected drug list] if more than 1 year has elapsed since the biosimilar biological product has been licensed" and "marketing has not commenced for such biosimilar biological product."[61]

The date on which **CMS determines** that a generic or biosimilar has been marketed also has critical implications for whether a drug or biologic will be subject to an MFP and for how long, as well as for how long a manufacturer will be assessed an excise tax if found to be non-compliant with program requirements:

- **If CMS determines after a drug or biologic is selected for the MFP process, but before the end of the "negotiation" period, that a generic or biosimilar has been marketed, the process for setting an MFP terminates.** Under the statute, a drug or biologic that has been selected for the MFP process and for which CMS has made a determination by the end of the "negotiation" period that a generic or biosimilar drug has been marketed shall not be subject to the MFP process for such period.[62]

- **If CMS determines after the end of the "negotiation" period that a generic or biosimilar has been marketed, the drug or biologic generally will cease to be subject to the MFP starting with the first year that begins at least nine months after the date of such determination.** By statute, a selected drug generally will be subject to the MFP until the year that is "at least 9 months after the date on which [CMS] determines" that at least one generic or biosimilar has been marketed.[63]

- **For a manufacturer that is subject to an excise tax as a result of noncompliance with program requirements, the excise tax ceases on the date on which CMS determines that a generic or biosimilar has launched.** Manufacturers may be subject an excise tax for failure to enter into an agreement to negotiate, failure to agree to an MFP, or failure to submit certain data to CMS.[64] The excise tax will cease to apply at any of certain points in time specified by statute, one of which is the date on which CMS determines that a generic or biosimilar has been marketed.[65]

In the Guidance, CMS defines "marketed" in a manner that contorts this entirely straightforward statutory standard into a standard that is utterly untethered from the statute and that blatantly purports to expand agency authority far beyond the limits that Congress clearly imposed. CMS states, without any claim of statutory support, that a finding that a generic or biosimilar is "marketed" requires a finding that the generic or biosimilar presents "bona fide" competition based on the evaluation of prescription drug event (PDE) and Average Manufacturer Price (AMP) data over a 12-month period.[66] At least in the context of evaluating whether the application of the MFP should terminate, CMS states that such standard is met by reference to whether the generic or biosimilar presents "meaningful competition," as determined based on the agency's subjective judgment.[67]

For the reasons stated below, Lilly urges CMS to rescind its bona fide marketing standard as extra- statutory and therefore unlawful. CMS should instead uniformly define (1) the date on which a generic or biosimilar is marketed and (2) the date on which CMS determines that a generic or biosimilar has been marketed by reference to the MDRP market date.

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[61] *Id.* § 1192(f)(2)(D)(iii).
[62] *Id.*§ 1192(c)(2).
[63] *Id.* § 1192(c)(1).
[64] IRC § 5000D(b)(1)-(3).
[65] *Id.* § 5000D(b)(1)(B).
[66] *See* Guidance at104.
[67] *Id.* at 115. Note that the Guidance does not make clear if the agency intends to apply its bona fide marketing standard in all situations under the statute where the marketing of a generic or biosimilar is consequential, e.g., the biosimilar delay provision. If CMS intends to use an alternative standard in any given situation, it should clearly articulate such alternative and subject it to public comment.

A. CMS' Bona Fide Marketing Standard is Unlawful

Lilly is deeply troubled by CMS's bona fide marketing standard for multiple reasons. First and foremost, the standard is incompatible with the clear statutory language. As a matter of plain language definitions, "marketing" refers to the "work of advertising and offering goods or services for sale,"[68] or the action of "buying or selling" in a commercial marketplace.[69] This means that, once the act of selling or buying has occurred, a product necessarily has been marketed. CMS has no discretion to interpret the statute otherwise.

CMS has recognized as much in its very own proposed policy implementing a different provision of the IRA, which looks to how CMS has already defined the term "marketed" in analogous contexts. Specifically, as recently as February of this year, CMS proposed to determine when a medicine is "marketed" for purposes of the IRA's Part D inflation rebate provision by reference to the "market date" that the manufacturer is required to report under the MDRP program.[70] This fully accords with the fact that CMS has long defined "marketed" under the NDRA to mean that a "drug is available for sale by a manufacturer in the states."[71] And, notably, under the Part D program, CMS has long recognized that the date on which a product is "release[d] onto the market" triggers Part D coverage decision-making.[72] Therefore, the PDE data on which CMS's bona fide marketing standard relies to determine whether a product is "marketed" show utilization of the product after the point in time when the product has been recognized as having come to market – under CMS's own policy.

Simply put, CMS has already defined when a drug is "marketed," under the IRA as well as under other drug pricing programs, and none of those definitions reflects the "bona fide marketing" standard CMS has invented. Here, CMS seeks to wholly replace the statutory reference point – the date of marketing – with an extra-statutory standard tied to the degree of utilization. Doing so patently lacks any legal basis. For purposes of evaluating whether a product is marketed, it is completely irrelevant whether the product is being utilized sufficiently, particularly where sufficiency is based on the agency's subjective judgment of whether adequate competition exists. The only consideration bearing on the statutory standard of marketing is whether the product is sold in the commercial marketplace.[73]

Second, the agency's "bona fide marketing" standard remains vaguely defined to provide notice to stakeholders of its parameters. It is unclear whether CMS expects the generic or biosimilar manufacturer to have captured a percentage of the market or what factors (e.g., size of market, clinical advantage offered by the reference product) CMS will consider. Even after CMS determines that the

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[68] Cambridge English Dictionary, Definition of Marketing, https://dictionary.cambridge.org/us/dictionary/english/marketing.
[69] Oxford English Dictionary, Definition of Marketing, https://www.oed.com/view/Entry/114186?rskey=iyHQfr&result=2#eid.
[70] CMS, Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of SSA, and Solicitation of Comments, § 40.3 (Feb. 9, 2023). The CMS proposed guidance for the Part B inflation rebate uses the "date of first sale" reported for ASP purposes, which likewise has no qualitative component in its determination. CMS, Medicare Part B Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1847A(i) of the Social Security Act, and Solicitation of Comments, § 50.3 (Feb. 9, 2023).
[71] NDRA § I(I); 83 Fed. Reg. 12,770 (Mar. 23, 2018) (emphasis added).
[72] CMS requires that Part D plan sponsor P&T committees "make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and … make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met." Prescription Drug Benefit Manual, ch. 6 § 30.1.5.
[73] Congress knows full well how to impose a "bona fide" qualitative standard when evaluating a given activity in relation to drug pricing. In the context of the MDRP, Congress specifically amended the statute to clarify that only "bona fide" service fees are exempt from the calculation of Average Manufacturer Price. SSA § 1927(k)(1)(B)(i)(II) as amended by Pub. L. 111–148, § 2503(a) (2010). And, in implementing that standard, CMS has engaged in extensive rulemaking to define the parameters of the "bona fide" determination. *See* 81 Fed. Reg. 5170 (Feb. 1, 2016). Such statutory basis for a "bona fide" standard is notably absent here, yet CMS is impermissibly purporting to substitute this standard for the one clearly prescribed by Congress.

generic or biosimilar manufacturers has engaged in bona fide marketing, CMS intends to monitor PDE data for continued "meaningful competition."[74] Again, CMS fails to offer concrete explanations of what it will look for, e.g., does the agency expect the level of competition to stay the same? To increase? The Guidance remains too ambiguous to put either listed drug or reference product manufacturers or generic/biosimilar manufacturers on notice of how the agency intends to operationalize the standard.

Third, this very subjectivity provides CMS with boundless authority that Congress clearly did not delegate. The MFP termination date is a notable example. That date is defined by reference to the date on which CMS determines that a generic or biosimilar has been marketed.[75] There is a simple and straightforward means for making this determination: the MDRP market date. CMS recognizes that such date triggers the start of MDRP rebate liability as well as the IRA's Part D inflation rebate liability, but, on no justifiable basis, does not recognize that such date triggers the termination of MFP liability. CMS's bona fide marketing standard purports to vests the agency with limitless discretion to delay the MFP termination date, even indefinitely, based on the agency's subjective judgment as to the extra-statutory consideration of utilization sufficiency.

In addition, CMS is implicitly asserting the authority to re-institute an MFP after one has been terminated, if the agency concludes based on PDE data that utilization of the generic or biosimilar ceases to be "meaningful."[76] Nothing in the text or structure of the statute purports to give CMS such sweeping authorities. Through its bona fide marketing standard, CMS is "effectively [seeking to] introduce[e] a whole new regime of regulation," which "is not the one that Congress established."[77] This is patently unlawful. "It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress Thus, if there is no statute conferring authority, a federal agency has none."[78]

Fourth, CMS's approach guarantees a significant delay between the date on which CMS determines that a generic or biosimilar has been marketed and the date on which the generic or biosimilar was in fact marketed. This is because it takes time for sales to be reflected in the PDE data. Under CMS's long-standing policy, Part D plan sponsors must determine within 180 days from the date on which a newly approved drug is released onto the market whether to add the drug to their formulary. Many Part D plan sponsors will not add a newly approved drug to their formulary until the 180-day mark, and, thus, the first six months of PDE data following the market entry of the drug will necessarily reflect only very limited uptake. The absence of PDE data, then, by no means substantiates the absence of marketing. CMS's bona fide marketing standard (exacerbated by the agency's intent to evaluate PDE data only once per month)[79] clearly contradicts the statute as it ensures that CMS's determination of when a generic or biosimilar has been marketed will not accurately reflect when the generic or biosimilar was in fact marketed. Further, PDE data are not publicly available or otherwise transparent and thus, further aggravate credibility and verification concerns with the MFP process.

Compounding this concern is that, even where plan sponsors add a newly approved generic or biosimilar to their formulary, widespread utilization of the generic or biosimilar cannot be expected to occur overnight. Even after a product is made available for sale, providers and patients must become comfortable with switching to the new product.[80] Under any rational interpretation of the word, the product is marketed during this transition period. And the fact that there may be a period of transition before claims data reflect a higher-level utilization does not mean that the market is failing to work as intended.

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[74] *See* Guidance at 115.
[75] SSA § 1192(c)(2).
[76] *See* Guidance at 115.
[77] *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 114 (1994).
[78] *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001).
[79] *See* Guidance at 104.
[80] Uptake of a biosimilar, in particular, can be slow for myriad reasons. *See, e.g.,* Zachary Brennan, *Biopharma CEOs Explain Problems with Biosimilars to Congress*, Regulatory Aff. Profs. Soc'y (Apr. 12, 2019), *available at* https://www.raps.org/news-and-articles/news-articles/2019/4/biopharma-ceos-explain-problems-with- biosimilars-t (for example, uptake may by limited "due to physician confusion regarding interchangeability and extrapolation, and a lack of physician, patient, and payer incentives").

From a policy perspective, generic and biosimilar competition is a bedrock for affordability in the pharmaceutical industry. Approximately 90% of the drugs used in the US are generic[81,82] and come at significantly reduced prices (i.e., approximately 20% of the brand drug price for oral generics within the early years of generic availability)[83,84] Generic drug prices are so low that the environment has been described as a "race to the bottom" in terms of pricing, a situation that many have argued is unsustainable and leads to shortages, generic manufacturers leaving the market. By not being clear and setting the "marketed" bar arbitrarily and unnecessarily high for generic competition to be sufficient to remove a selected drug and allow for normal market-based competition, CMS increases the likelihood that generic drugs will be competing in the market with their reference branded drugs being subject to the MFP. In this situation, the generic drug, in order to be competitive, would necessarily have to price their drug at roughly 20-40% of the MFP of the reference product, which is already deeply discounted. Given fixed costs of development and the already "race to the bottom" environment for generic manufacturers, this policy would put the sustainability of the generic industry as a whole in jeopardy and could result in monumental impacts to patient affordability in commercial (and public) markets. Combining this issue with the untenable burden on the biosimilar manufacturers to submit a delay request without knowing if the reference product of relevance is being selected, (argued elsewhere in the letter), in total, represents a lack of alignment by CMS with the IRA's intent to safeguard the biosimilar and generic industry.

CMS should make every effort to avoid any delay in its determination that a generic or biosimilar has been marketed, as such a delay may be of enormous consequence to reference biologic manufacturers and biosimilar manufacturers alike. In particular, Lilly is remains concerned that the prospect of an unnecessarily extended MFP will create dramatic disincentives against generic and biosimilar market entry, thereby defeating Congress's objective of encouraging such market-based competitors.[85]

B. CMS Should Instead Set the Program Date of Marketing and the Date of CMS's Determination of Marketing by Reference to the Definition of "Marketed" in the NDRA

A lawful and infinitely more reasonable approach would be for CMS to define the date of marketing and the date of CMS's determination of marketing in a uniform fashion by reference to the familiar market date already reported by manufacturers for purposes of the MDRP.

Specifically, CMS defines "market date" in MDRP guidance as "the earliest date the drug was first marketed under the application number by any labeler."[86] The NDRA in turn provides that a drug is first "marketed" on the date on which it was first "available for sale by a manufacturer in the states."[87]

Manufacturers routinely report this date when reporting pricing data under the MDRP, and such date is ascertainable for generics and biosimilars regardless of whether they are subject to ASP reporting.[88] Thus, there exists a long-standing construct with which

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[81] Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report*. October 14, 2021. Available: https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines- Savings-Report-web.pdf.
[82] USC Schaeffer Center. *U.S. Consumers Overpay for Generic Drugs*. USC Schaeffer Center White Paper Series. May 21, 2022. Available: https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-generic-drugs/.
[83] US Food and Drug Administration (FDA). *Generic Drug Facts*. November 1, 2022. Available: https://www.fda.gov/drugs/generic-drugs/generic-drug-facts.
[84] IMS Institute for Health Informatics. *Price Declines after Branded Medicines Lose Exclusivity in the U.S.* January 1, 2016. Available: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf.
[85] In addition, a lag of a single day between the date of marketing and the date of CMS's determination of such marketing can result in the MFP being extended for a full additional year.
[86] CMS, MDRP Data Guide § 5.15 (Apr. 2022).
[87] NDRA § I(l); 83 Fed. Reg. 12,770 (Mar. 23, 2018) (emphasis added).
[88] The "first sale date" reported for ASP purposes is not a reliable method for determining the date of marketing here. The date of first sale is reported only for products subject to ASP reporting, and thus may not be available for all generics and biosimilars whose marketing is implicated by the Program, whereas the market date reported under the MDRP is more broadly reported and therefore a better metric to use.

CMS and manufacturers are well familiar, and to which they have ready access, on which the agency can and should rely to determine the date on which a generic or biosimilar launched for purposes of the Program. This approach has the added benefit of ensuring consistency across the MDRP and the Program for both the agency and manufacturers.

Adoption of the NDRA definition of "marketed" for purposes of the Program would eliminate any legal concerns, as CMS would be adopting a standard that comports with the plain language definition of marketing. Lilly emphasizes that it is especially critical that this standard be adopted in the context of the date of **CMS's determination** of the date of marketing: As noted above, if there is a lag of even one day between the date of marketing the date of CMS's determination of such marketing, a selected drug can be subject to the MFP for **an additional 12 months**.

IV. The MFP "Negotiation" Process

A. CMS Should Enhance the Proposed "Consistent Methodology and Process" for Initially Setting the MFP ("Negotiation") and Resetting the MFP ("Renegotiation")

The statute provides that CMS must "develop and use a consistent methodology and process" to negotiate the MFP.[89] Additionally, the statute provides that, beginning in 2028, CMS may enter into renegotiations for a selected medicine in certain circumstances specified by statute, and that CMS must "specify the process for renegotiation," which "shall, to the extent practicable, be consistent with the methodology and process" for initial negotiations.[90] Thus, Congress intended the methodology and process governing both negotiation and renegotiation to be transparent and predictable for all entities involved.

Under the Guidance, CMS lays out its proposed framework for how the MFP process will proceed, including the process governing CMS offers, manufacturer counteroffers, and CMS responses to counteroffers – including justifications supporting such offers, counteroffers, and responses. CMS also proposes a framework for meetings between the manufacturer of the selected medicine and the agency. Under the Guidance, such meetings will occur only where CMS rejects a manufacturer counteroffer, in which case CMS will extend a meeting invitation.[91] The initial meeting is to take place within 30 days of receipt of the counteroffer or within 60 days of sharing the initial offer, whichever is later. Thereafter, CMS proposes to allow each party the opportunity to request one additional meeting – such that a maximum of three meetings is possible for each selected drug.[92] At such meetings, the parties may discuss new information bearing on the negotiation of the MFP, however discussion of disputes and program policies are out of scope.[93]

Lilly asks that CMS modify its proposed MFP process to include the recommendations set forth below.

1. CMS Should Commit to Engaging in Bespoke Negotiations with Each Manufacturer of a Selected Medicine

CMS's proposal allows for potential dialogue between the parties, which represents an important step toward implementing a meaningful process "for negotiations" as part of the Program.[94] Nevertheless, we are concerned by the arbitrary limitations on engagement in the Guidance. As noted above, under the Guidance, real dialogue is limited to (1) instances where CMS rejects a counteroffer and (2) a maximum of three meetings. Importantly, the benefit of meaningful dialogue is not limited to when a counteroffer has been rejected. Engagement between the parties is equally beneficial in informing an initial offer. In fact, such early discussions can negate the need for a counteroffer, thereby generating efficiencies for both the agency and manufacturers.

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[89] SSA § 1194(b)(1).
[90] *Id.* §§ 1194(f)(2), (4)(A)-(B).
[91] *See* Guidance at 95.
[92] *Id.* at 94.
[93] *Id.* at 94-95.
[94] SSA § 1194(b)(1).

Even more concerning is the arbitrary cap on the number of allowable meetings. Lilly does not see any benefit to decreasing the number of available meetings or in establishing a categorical limit on the number of meetings between the parties. If both CMS and the manufacturer of the selected medicine believe that one or more additional meetings would be productive to setting a more appropriate MFP, then CMS should allow such additional meetings to proceed rather than cutting off helpful discussions prematurely based on an arbitrary limit on the total number of meetings permitted.

Lilly recommends that CMS modify its proposed MFP setting process to allow for greater dialogue between the parties throughout the process and to specify that additional meetings (beyond the current maximum of three) may be held if agreed to by both parties. Further, to ensure productive dialogue, we urge CMS to commit to engaging substantively with the manufacturer in each meeting.

Given the limited number of medicines subject to negotiation in a given year, the recommended changes are manageable for the agency to implement and will facilitate a more productive and tailored process – which will be critical to any success under the program. There is also ample time to effectuate any additional meetings. The statute requires CMS to make the initial offer by June 1 of the year of the selection year and also provides that the manufacturer must accept the offer or make a counteroffer within 30 days.[95] Even if CMS were to wait until June 1 to make the initial offer, and even if the manufacturer were to wait until the 30th day to make a counteroffer, there would still be four remaining months in the negotiation period. Therefore, more than adequate time exists in the negotiation timeline for the contemplated additional process. CMS's failure to modify this process would further underscore our belief that the MFP regime is not a "negotiation."

2. CMS Should Commit to Considering All Information Submitted by a Manufacturer in Setting the MFP

CMS should specify that it will consider **all** information submitted by manufacturers throughout the process. Although the justifications for the initial offer and the manufacturer's counteroffer are moored to the negotiation factors enumerated in the statute, the statute by no means precludes CMS from considering additional information that a manufacturer determines relevant to the MFP process.[96] Further, CMS's counteroffer responses are not statutorily required to be justified by reference to the statutorily enumerated negotiation factors.[97] The statute clearly permits the agency to set the MFP by reference to any and all information submitted by manufacturers, and CMS should commit to considering all such information.

In the Guidance, CMS does not specify that a manufacturer may submit, and that the agency will consider, any information that the manufacturer determines relevant to the MFP process. The accompanying proposed information collection request (ICR) suggests that this is intentional, as the proposed ICR solicits information **only** with respect to the statutorily enumerated negotiation factors (and, even then, does so in an unduly cramped manner by imposing a severe word limit) and does **not** provide for any supplementary submission.[98] CMS should not narrow the universe of relevant evidence that it will consider during the MFP setting process.

3. CMS Should Fulsomely Justify the Initial Offer and Any Response to a Counteroffer in Writing and Afford Manufacturers an Opportunity to Comment on Any Response Before an MFP is Set

It is important that CMS provide a meaningful justification in support of its offers and responses to any counteroffers. Negotiations involving offers and counteroffers are commonplace in the commercial sector. And they commonly entail robust, open, and bilateral dialogue between the parties to facilitate mutually agreeable terms. By establishing a "negotiation" process, Congress intended the Program to be premised on such familiar concept.

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[95] SSA § 1191(d)(5)(B), 1194(b)(2)(B).
[96] *See id.* § 1194(b)(2)(B), (C)(ii)(II).
[97] *Id.* § 1194(b)(2)(D).
[98] CMS, Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB 0938-NEW) (ICR Form for Negotiation Data Elements).

Congress also established requirements to facilitate transparency in the process, which is a necessary predicate to good faith dialogue during negotiations. By statute, CMS must provide an initial offer, in writing, to the manufacturer of the selected medicine and include with it a justification based on the factors described in section 1194(e) of the SSA.[99] The manufacturer of the selected medicine may make a counteroffer to the initial offer, and, where the manufacturer does so, CMS must respond in writing.[100]

These statutory requirements limit the scope of the agency's discretion under the statute, and such limitation can be meaningfully effectuated only if CMS is fully transparent as to the information under section 1194(e)(2) on which the agency relied. Additionally, to abide by the patient-centered intent of this statutory program, CMS must describe what threshold and measurement will be used to "determine the effects of the selected medicine and its therapeutic alternative(s) on specific populations"[101] and whether the selected medicine fills an "unmet medical need."[102] It is well known that patient centricity has revealed a misalignment between what patients report as important to them about their disease and/or treatment, and the data and measurements typically utilized in research and public policy decision-making.[103] If CMS relies more heavily on "Manufacturer-Specific Data" (section 1194(e)(1)) than "Evidence About Alternative Treatments" (section 1194(e)(2)), including data supporting "unmet medical need," CMS may be disregarding what is most meaningful to patients.

When determining therapeutic alternatives for a selected medicine, CMS should rely on external organizations for purposes of evidence synthesis or technology assessment only if such organizations meet specified standards. Such standards should ensure organizational independence, patient- centered procedures and methods, methodological rigor, and transparency. CMS should apply these same rigor and transparency standards to its internal "claims analysis" and review when adjusting the MFP starting point based on clinical evidence.[104] Furthermore, we recommend that the MFP for a selected medicine be set at the ceiling if such medicine demonstrates significant patient benefit.

To give meaning to the agency's stated goal of promoting transparency, we urge CMS to commit to including meaningful explanations as to how the agency arrived at the offer and the response to any counteroffer, including how the offer or response is supported by statutorily enumerated negotiation factors, how such factors (and any other information) were weighed and considered, and any non- manufacturer sources of information relied upon.[105]

Additionally, we ask that CMS agree to respond to any counteroffer within 30 days of receipt. We also ask that CMS agree to give manufacturers at least 30 days to comment on the response. For any such comment process to facility a more effective MFP process, CMS must actually consider the comments before setting the MFP. We ask CMS to commit to this. Not only will this further transparency and fairness in the MFP process, but it will also help to ensure that the agency is not inadvertently setting the MFP based on any misunderstanding or gap in information.

4. CMS Should Clarify That a Manufacturer May Broadly Supplement Its Timely Submission After the Submission Deadline Where Subsequent Developments Arise or Otherwise for Good Cause

[99] *Id.* §§ 1191(d)(5)(B), 1194(b)(2)(B).
[100] *Id.* § 1194(b)(2)(C)–(D).
[101] *Id.* § 1194(e)(2)(C).
[102] *See* Guidance at 60.3.3.1.
[103] Perfetto, E.M., Oehrlein, E.M., Love, T.R., Bright, J., & A. Kennedy. *Patient-Centered Core Impact Sets: What They Are and Why We Need Them.* The Patient – Patient-Centered Outcomes Research (2022).
[104] *See* Guidance at 60.3.3.
[105] *See* CMS, Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026 (Jan. 11, 2023).

As part of the MFP process, a manufacturer of a selected medicine will be required to submit certain information regarding the drug's non-FAMP, as well as other specified information relevant to the MFP process.[106] For example, the statute contemplates the manufacturer submitting data regarding research and development costs, production and distribution costs, market data, and revenue and sales volumes.[107] Further, CMS has signaled that the manufacturer will be permitted to submit evidence about alternative treatments.[108]

Such manufacturer-provided information must be submitted by March 1 of the year of the selection date, just one month after a medicine is selected for negotiation.[109] Given this tight deadline, there is a very real possibility that unforeseeable changes will occur after the submission deadline, such as new data regarding comparative effectiveness becoming available, a new therapeutic alternative coming to market, production costs unexpectedly increasing, or restatement of pricing data.

Manufacturers have every incentive to diligently comply with CMS's submission requirements, but there is a legitimate need for flexibility in allowing manufacturers to supplement their timely submissions to ensure CMS has the most accurate understanding of the dynamics surrounding the selected drug. This is especially so both because of the novelty of the program and in light of the fact that manufacturers have only a month to compile and submit voluminous amounts of complex information. In some cases, the required information may not even be available in the format that CMS requests at the time of an initial submission.

The agency's current proposal does acknowledge that there may be a need to provide supplemental information to the agency after the submission deadline, but inexplicably limits presentation of such new information to **the negotiation meetings and counteroffer justifications**. This is inadequate. As CMS knows, new information can take many forms, including detailed new empirical evidence, records of governmental action, and other materials not amenable to being provided or meaningfully digested in the context of a meeting discussion. And limiting the presentation of such information to the negotiation meetings necessarily means that CMS will be unable to review and consider that information ahead of such meetings, making those meetings less efficient than they otherwise could be. Moreover, such circumstances will occur only where there is a rejection of a manufacturer offer, such that there is no vehicle for consideration of new information at the initial offer stage, rending the MFP process unnecessarily inefficient.

Given the very short period afforded for preparation of an initial submission and the real possibility that new information of relevance to the MFP setting process will become available after the submission deadline, we ask that CMS to establish a more meaningful process to share additional information with the agency after the submission deadline has passed. Specifically, **in addition to being able to share new information at negotiation meetings**, CMS should broadly permit a manufacturer to supplement a timely submission if new information of relevance to the MFP process becomes available after the submission deadline or otherwise for good cause shown.

B. CMS Should Permit Manufacturers to Rely on Reasonable Assumptions in Connection with Information Submissions and Provide Voluntary Explanations of Information Submissions as Appropriate

Under the Program, manufacturers must submit vast quantities of information to CMS, and the agency must then consider such information, along with certain other statutorily enumerated negotiation factors. Required manufacturer-submitted information includes research and development costs of the selected drug, current unit costs of production and distribution of the drug; prior

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[106] *Id.* §§ 1194(b)(2)(A), 1193(a)(4). Presumably, CMS will designate information submitted by manufacturers under section 1194(e)(1) as information that is due by March 1 of a given year (or October 2, 2023, for IPAY 2026) under section 1193(a)(4).
[107] *Id.* § 1194(e)(1).
[108] CMS. *Medicare Drug Price Negotiation Program: Next Steps in Implementation for Initial Price Applicability Year 2026*, at 2. January 11, 2023. Available: https://www.cms.gov/files/document/medicare-drug-price- negotiation-program-next-steps-implementation-2026.pdf; *see also* SSA § 1194(e)(2).
[109] SSA § 1194(e)(1).

federal financial support for certain discovery and development of the drug; data on certain pending and approved patent applications, FDA exclusivities, and FDA applications or approvals regarding the drug; and market, revenue, and sales volume data in the United States for the drug.[110] CMS appears to intend such information to be submitted only through its proposed ICR.[111]

1. CMS Should Revise Its Proposed ICR to Allow Manufacturers Greater Ability to Provide Voluntary Explanations of Information Submissions

Consistent with the agency's own recognition of the importance of assumptions with respect to research and development costs and current unit costs of production and distribution,[112] CMS should apply such reasoning to all other data elements. The proposed ICR includes fields for manufacturers to provide voluntary explanations of the data submitted.[113] However, the fields are limited to explanations of how a manufacturer made a particular calculation and are subject to word limits.[114]

Lilly is concerned that the proposed ICR provides manufacturers no meaningful way to justify or provide additional background and context with respect to their data submissions, beyond that which is specifically requested by CMS in the accompanying instructions. It is vital that CMS provide manufacturers the opportunity to do so, as it will provide CMS with meaningful insight into how manufacturers developed their submissions and any assumptions the manufacturer was required to make in seeking to fulfill its data submission obligations. Our recommendation is consistent with the agency's framing of such fields in the Guidance as space for "narrative text."[115]

This recommendation is especially critical with respect to products approved long ago as the information required to complete a data field may be unavailable due to common data retention policies or otherwise in the course of business. Under these circumstances, CMS must afford manufacturers flexibility to comply with information requests – for example, with respect to research and development expenses, by allowing manufacturers to stipulate to the fact that direct costs were recouped in the explanation section.

For these reasons, we recommend that CMS specify that manufacturers may include voluntary explanations as part of their data submissions, and that the agency commit to considering such explanations. To allow for submission of any such explanations as appropriate, CMS should remove the arbitrary word limit. The ability to justify data submissions is of the utmost consequence when potentially hundreds of millions of dollars in CMPs are on the line should CMS believe that a submission of required information is false or incomplete.

We further urge CMS to permit manufacturers to stipulate to the fact that they have "recouped" their direct research and development (R&D) costs on a particular product should they so choose. As noted above, several drugs that CMS may consider for inclusion on the list of drugs subject to price setting were approved decades ago. Routine document retention, retirement, and destruction policies will likely render collecting the data necessary to precisely report direct R&D expenditures for such products impossible. Moreover, it does not matter – for innovative biopharmaceutical manufacturers - whether R&D costs have been "recouped." Discovering new chemical or biological entities is not like "discovering" the next generation of the iPhone or building a utility, for example. Where there is relative certainty that a new product will "work," a recoupment calculation might make sense. For biopharmaceuticals, discovery is high risk, and successfully launching a product is far from assured. Revenue from currently marketed products fund the exploration, research, and discovery of future medicines. Characterization of the goal as "recoupment"

[110] SSA § 1194(e)(1).
[111] *See* ICR for Negotiation Data Elements.
[112] *See* Guidance at 87.
[113] ICR Form for Negotiation Data Elements.
[114] *Id.*
[115] *See* Guidance at 87.

is wrong – finding the next cure, or the next dozen cures, is what we do. Consequently, whether CMS determines that a product has "recouped" its own R&D costs is, frankly, not the reference point.

2. CMS Should Permit Manufacturers to Rely on Reasonable Assumptions

In addition, CMS should specify that manufacturers may make reasonable assumptions when interpreting statutory (or any future regulatory) requirements regarding such information submissions.[116] As CMS well knows, reasonable assumptions serve an important role to bridge gaps in statutory, regulatory, and sub-regulatory instructions. There are often unresolved ambiguities in how complex information submission requirements interact with equally multi-faceted business practices and products. Reasonable assumptions allow manufacturers to set forth their understanding of how legal requirements apply to their singular circumstances, and thereby help to ensure that regulatory regimes can be operationalized even where significant ambiguities cannot reasonably be expected to be clarified or resolved, particularly on a regulated entity-by-regulated entity basis.

CMS also already has well-established frameworks governing reasonable assumptions. For example, in the ASP and MDRP reporting contexts, CMS has long permitted manufacturers to make reasonable assumptions where there is no agency guidance addressing a given issue.[117] CMS can and should readily adopt a similar approach here. In doing so, manufacturers will be permitted to make reasonable assumptions in furnishing required information consistent with the general requirements and intent of the Program, applicable regulations, and customary business practices. As noted above, such reasonable assumptions can be documented and described in the proposed ICR, such that the agency is apprised of manufacturers' thinking and assumptions.

Neither the Guidance nor the proposed ICR addresses reasonable assumptions. Rather, the Guidance sets forth an appendix of proposed definitions related to manufacturer-specific data,[118] and the proposed ICR restates the proposed definitions.[119] This approach is problematic – because the agency proposes a standardized and rigid data submission framework applicable to all manufacturers and products.

Such a framework will inevitably lack the flexibility needed to accommodate the unique attributes that necessarily characterize the multitude of therapies eligible for selection for the MFP process. For context, there are over 20,000 prescription drug products currently approved for marketing in the United States, each with its own unique attributes.[120] Among other things, there are myriad differences in products' development histories, FDA regulatory histories, chains of ownership, and pricing and sales arrangements across the multi-layered drug distribution chain. Accordingly, it is impossible to develop a coherent "one-size-fits-all" approach to data submissions (and ill-advised for CMS to seek to do so). Attempting to shoehorn countless varying technologies, business practices, and circumstances into a single framework will inevitably result in less useful, relevant, and complete information being provided to CMS. It will also be a recipe for arbitrary decision-making.[121] CMS will effectively be blinding itself to the full complement of data that a manufacturer deems most relevant to its product's development and pricing and that it reasonably views as falling within the categories of information required by statute to be considered.[122]

As such, Lilly recommends that CMS rescind its appendix of proposed definitions (also included in the proposed ICR). CMS should instead adopt the aforementioned approach grounded in CMS's long- standing reasonable assumptions framework, and not attempt

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[116] *See* SSA § 1194(e)(1); *see also id.* §§ 1193(a)(4), 1194(b)(2)(A) (manufacturer information submission obligations).
[117] *See, e.g.*, 71 Fed. Reg. 69,624, 69,667 (Dec. 1, 2006) (reasonable assumptions regarding ASP reporting); 83 Fed. Reg. 12,770, 12,785 (Mar. 23, 2018) (MDRP agreement provision governing reasonable assumptions).
[118] *See* Guidance, app. A.
[119] *See* ICR Form for Negotiation Data Elements.
[120] *See* FDA, Fact Sheet: FDA at a Glance, https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance#:~:text=There%20are%20over%2020%2C000%20prescription,FDA%2Dapproved%20animal%20drug%20products (Aug. 17, 2022).
[121] *See* 5 U.S.C. § 706 (2)(A).
[122] *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency decision-making must be based on **relevant** data and cannot fail to consider important aspects of the problem at hand).

to shoehorn a broad universe of unique circumstances into highly regimented and inflexible data definitions. To the extent CMS disregards Lilly's request, please see **Appendix A** to this letter setting forth some of our preliminary concerns with CMS's data requests.

C. Confidential Commercial Information

1. CMS Should Establish More Robust Safeguards to Ensure That Confidential Commercial Information Submitted by Manufacturers is Protected from Disclosure.

The Program requires manufacturers to submit a host of information to CMS, including highly confidential manufacturer-specific data regarding research and development costs, revenue information, and sales volumes data.[123] Congress recognized the havoc that would be wreaked if sensitive information were publicly disclosed. As such, the statute imposes a stringent duty on CMS to maintain the confidentiality of such information: "Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part."[124]

Consistent with this broad statutory mandate of confidentiality, CMS states in its Guidance that it will "implement a confidentiality policy that is consistent with existing requirements for protecting proprietary information, including Exemptions 3 and/or 4 of [the Freedom of Information Act (FOIA)]."[125] However, the Guidance is devoid of any meaningful detail as to **how** CMS specifically intends to protect the confidential and proprietary information of manufacturers.

Lilly strongly urges CMS to specify the specific safeguards that the agency will put into place to protect the confidentiality of manufacturer information, including by adopting the safeguards described below. Lilly also urges CMS to implement all such safeguards in a manner that maximizes protection of confidential commercial information. Further, Lilly emphasizes that requirements of confidentiality are meaningful only if there are consequences in the event of a breach. As such, failure by CMS to protect confidential commercial information should result in a "renegotiation" if the manufacturer requests it.

i. Scope of Protection for Confidential Commercial Information

CMS's Guidance confirms that, at minimum, the familiar safeguards under FOIA will apply to information submitted under the Program.[126] Lilly appreciates this confirmation, including with respect to FOIA Exemption 4's prohibition on disclosure of information designated as confidential without providing a pre-disclosure notification and an opportunity to raise objections to disclosure.[127] Lilly also requests that CMS explicitly confirm that that, under the Program, manufacturer information will also be protected from disclosure to the same extent as such information is so protected under all other applicable federal laws and policies. For example, the Medicare statute provides that information submitted by manufacturers that relates to ASP "is confidential and shall not be disclosed by [CMS] in a form which discloses the identity of a specific manufacturer . . . or prices charged for drugs or biologicals by such manufacturer," except in limited circumstances that are not relevant here.[128] Similarly, the Medicaid statute provides that "information disclosed by manufacturers . . . under [the MDRP] . . . is confidential and shall not be disclosed by [CMS] . . . in a form which discloses the identity of a specific manufacturer . . . [or] prices charged for drugs by such manufacturer," except under limited circumstances that are not relevant here. Furthermore, the 340B Program generally protects the disclosure of information

[123] SSA § 1194(e)(1).
[124] *Id.* § 1193(c).
[125] *See* Guidance at 33.
[126] *See* Guidance at 29; *see also* 45 C.F.R. §§ 5.41, 5.42.
[127] *See* 45 C.F.R. §§ 5.41, 5.42.
[128] SSA § 1847A(f)(2)(D) (subject to certain limited exceptions).

submitted by manufacturers participating in the program.[129] CMS should implement safeguards that ensure that information submitted under the Program is protected from disclosure to the same extent that such information is so protected under these federal laws and policies.

ii. Confidentiality Safeguards with Respect to the Public Explanation of the MFP

Lilly strongly urges CMS to adopt additional safeguards around the agency's public explanation of the MFP. The statute requires CMS to publish such explanation of the MFP for each selected drug.[130] This public explanation poses an inherent risk of exposure of confidential commercial information given that the MFP likely will be based at least in part on drug pricing and other confidential commercial information. We recognize and appreciate CMS's stated intention to protect data elements containing non-public commercial or financial information from disclosure and to make only high-level comments about such information in the agency's public explanation of the MFP.[131]

However, Lilly believes that additional safeguards are needed to protect against **inadvertent** disclosure of proprietary information. Lilly recommends that CMS give manufacturers a reasonable opportunity to review the draft explanation in advance of public disclosure, including an opportunity to identify to CMS any way in which the draft explanation would directly or indirectly disclose manufacturers' confidential information. Doing so is well warranted given that Congress emphasized the need for confidentiality in the specific context of the public explanation of the MFP by explicitly cross-referencing the statute's confidentiality requirements in the provision requiring such explanation.[132]

iii. Robust Storage and Access Controls

Lilly asks CMS to confirm that all trade secret, proprietary, and otherwise confidential commercial information of manufacturers will be stored in a secure manner with appropriate data privacy and security protections, as is necessary to protect sensitive information from inadvertent or malicious improper disclosure. Among other things, CMS should ensure that all confidential commercial information is stored appropriately in the Health Plan Management System (HPMS). We also ask that CMS specify how it intends to maintain similar confidentiality protections for information submitted to CMS via e-mail or Box. Among other things, we are concerned about the use of a third-party commercial platform like Box to collect voluminous amounts of proprietary information, and urge CMS to set forth the means by which the agency will ensure submitted information is kept confidential, including as against intentional or inadvertent misuse by Box personnel.

In evaluating other safeguards to better protect confidential records held by the agency, Lilly notes that CMS already implements many protections with respect to product and pricing data submitted by manufacturers participating in the MDRP. Under the MDRP, data are uploaded to an online interface that both state and manufacturer users access. Functionality of the interface, however, is limited by the user's role: State users do not have the ability to view quarterly or monthly pricing records or any product information because "some of this information is confidential (e.g., Baseline AMP data)."[133] To the extent not already accounted for, CMS should implement similar safeguards with respect to HPMS, and limit access by CMS staff to confidential information in HMPS only to situations where there is a programmatic need. CMS should also consider whether CMS's MDRP online interface includes other privacy and security protections that can be incorporated into the systems used to store confidential information under the Program to make such systems more robust in protecting the confidential information of manufacturers.

2. CMS Must Abandon Its Proposed Policies Regarding Data Use and Destruction

[129] *Id.* § 1927(b)(3)(D) (subject to certain limited exceptions).
[130] SSA § 1195(a)(2).
[131] *See* Guidance at 33.
[132] SSA § 1195(a)(2).
[133] CMS, *Medicaid Drug Programs (MDP) User Manual* 1 (Nov. 3, 2021).

i. The Records Destruction Requirement is Unenforceable Under the Terms of the Program Agreement, and, if CMS Were to Seek to Enforce it, Such Enforcement Would be Violative of Manufacturers' Due Process Rights

As an initial matter, CMS's proposed requirement that a manufacturer destroy specified records, after the Program agreement terminates, is unenforceable. It is well-established that, when an agreement terminates, the obligations it imposes on parties terminate as well.[134] Thus, if a manufacturer declines to destroy such records after termination of the Program agreement, it violates no requirement of any such agreement. Accordingly, no CMP may be imposed.[135] This is true because, as CMS acknowledges,[136] such information is protected from disclosure under FOIA, independent of whether a Program agreement is in force. Thus, as a requirement of the Program agreement established under section 1193(a)(5) of the SSA, the record destruction obligation ends with termination of the agreement, and therefore cannot be enforced after the agreement ceases to be in effect.

CMS must accede to this limitation against enforcement. If CMS were to treat the record destruction proposal as an enforceable requirement, it would raise serious questions of due process. As CMS knows, the statute imposes vast CMPs, including a CMP equal to $100 million per piece of false information submitted by a small biotech drug or biosimilar manufacturer under section 1192(d)(2) or 1192(f)(1)(B) and $1 million per day for a failure to submit required information.[137] The magnitude of these sanctions means that record-keeping is of paramount importance: Manufacturers must maintain complete records for evidentiary reasons to protect against mistaken penalties that could otherwise cost them hundreds of millions of dollars. By proposing to require that manufacturers destroy such records, the Guidance raises fundamental concerns under the Due Process Clause of the Fifth Amendment that would become ripe if the data destruction policy were treated as enforceable. "[T]he essence of due process is fundamental fairness," and little could be more fundamentally unfair than mandating destruction of the very records needed to verify an entity's innocence against erroneous penalty.[138] As the Supreme Court has long held, due process mandates a meaningful "opportunity to be heard."[139] Just as this includes the "opportunity to present reasons . . . why proposed action should not be taken," it must also include the right to maintain the evidence necessary to support such reasons.[140]

Enforcement of the record destruction proposal would also be patently arbitrary and capricious. Agency action is arbitrary and capricious if it "frustrate[s] the policy that Congress sought to implement."[141] This describes exactly CMS's proposal. Mandated record destruction is irreconcilable with Congress's clear intent to establish a meaningful appeal process to challenge the imposition of a CMP. Specifically, section 1197(d) requires the Program to incorporate procedural requirements imposed under section 1128A. In turn, section 1128A(e) expressly provides that a party may "apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material."[142] CMS may not impose a record destruction requirement that subverts the clear intent of this provision, which is to enable a party to present any material evidence to a court when a case is heard on appeal, without violating the prohibition against arbitrary and capricious agency action.[143]

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[134] It is a "traditional principle that contractual obligations will cease, in the ordinary course, upon termination of the . . . agreement." *M&G Polymers USA, LLC v. Tackett*, 574 U.S. 427, 441–42 (2015) (citing *Litton Fin. Printing Div., Litton Bus. Sys., Inc. v. NLRB*, 501 U.S. 190, 207 (1991)).

[135] *See* SSA § 1198(c) (authorizing the imposition of a CMP of $1 million per day only for a violation of a requirement of a Program agreement established under section 1193(a)(5)); *see also id.* § 1193(a)(5).

[136] *Id.* at 32–33.

[137] *Id.* At 118-119.

[138] *Evans v. Wilkerson*, 605 F.2d 369, 371 (7th Cir. 1979).

[139] *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) (internal quotation marks omitted).

[140] *See Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985) (citing Friendly, "Some Kind of Hearing." 123 U. Pa. L. Rev. 1267, 1281 (1975)).

[141] *Mylan Labs. Ltd. v. FDA*, 910 F. Supp. 2d 299, 306 (D.D.C. 2012).

[142] SSA § 1128A(e).

[143] *See* 5 U.S.C. § 706(2)(A).

V. Setting the MFP: Special Considerations

A. CMS Should Allow Manufacturers to Submit Evidence Demonstrating That Pricing Below a Specified Level Would Imperil Patient Access, and CMS Should Specify That the MFP Will Not Be Set Below That Price (or the MFP Ceiling Price If Lower)

Government price-setting has been shown by research to have profoundly negative impacts on innovation and thus impede patient access to critical therapies. For example, one study in Europe found that a "10% drop in the price of medicines in price-controlled [European Union] markets was associated with . . . an 8% increase in the delay of access to medicines."[144] Other studies have shown that reductions in pharmaceutical revenues caused by pricing regulation reduce the annual number of marketed therapies.[145] Research has also demonstrated that government price-setting is associated with drastic declines in early stage research, which is the precursor to robust future transformational therapeutic innovation.[146] The adverse consequences of discouraging innovation are ultimately borne by patients, who are prevented from accessing the most effective treatments.[147]

There may be instances where a manufacturer demonstrates that setting the MFP below a particular price would imperil patient access to the selected drug. In other words, such a mandated price would be so far below the market price that a mismatch between supply and demand would result. To protect patient access to medicines, we urge CMS to specify that, in such cases, it will not set the MFP below the lower of such price or the MFP ceiling price. Patient access should be a paramount consideration in interactions with manufacturers to set the MFP, and CMS should develop policies to specifically account for this concern to mitigate the negative impact on patients that could follow from the imposition of an unreasonably low MFP.

B. CMS Should Clarify That It Will Not Set the MFP Below the MFP Ceiling Price During Any Year of the Price Applicability Period During Which the Medicine Is Under Patent Protection

As part of the MFP setting process, the statute requires CMS to consider a number of factors in setting the MFP for a selected drug, including "[d]ata on pending and approved patent applications [and] exclusivities recognized by [FDA]."[148] In the Guidance, CMS indicates that, if a selected drug has patents and exclusivities that will last a number of years, CMS may adjust the "preliminary price" downward.[149] Lilly strongly urges CMS to change course, and instead afford pricing relief based on whether, based on information submitted by the manufacturer, a selected drug will have any remaining patent protection at the start of the price applicability period that cannot be designed around (the basic drug substance patent) or that cannot be avoided via a "skinny label" (collectively, the "primary patents"). If it will, CMS should set the MFP at the MFP ceiling price during any year of the price applicability period during which the drug is under such patent protection.

The statute permits CMS to subject a drug to MFP setting at least seven years post-approval and a biologic at least eleven years post-approval.[150] In many cases, by the time the price applicability period for a selected drug begins, the product's regulatory exclusivity period will have expired—but this is not necessarily the case for its patent protection period.[151] Patents afford longer

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[144] D. Schulthess and H. Bowen, *The Historical Impact of Price Controls on the Biopharma Industry*, Vital Transformations (Nov. 22, 2021).
[145] *See, e.g.*, D. Acemoglu & J. Linn, Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry, Q. J. of Econ., Vol. 119 (2004).
[146] *See* T. Abbott & J. Vernon, The Cost of US Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions, 28 Managerial & Decision Econ. 293 (2007).
[147] *See* N. Sood, et al., *The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen Countries*, 28 Health Affairs 11 (2009).
[148] SSA § 1194(e)(1)(D).
[149] *See* Guidance at 88.
[150] SSA § 1192(e)(1)(A)-(B).
[151] *See* FDA, Frequently Asked Questions on Patents and Exclusivity, *Available at* https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#howlongexclusivity. (last accessed May 2024).

exclusivity periods, meaning that it may very well be the case that there will be remaining patent protection for a selected drug that extends into the price applicability period.

It is vital that selected drugs still under patent protection be given special protection. The process of bringing pharmaceutical or biotechnology product from research and development to market is exorbitantly long and expensive.[152] Many candidates fail despite significant investment. In a 2021 study of research and development costs, the Congressional Budget Office (CBO) found that "[t]he amount of money that drug companies devote to [research and development] is determined by the amount of revenue they expect to earn from a new drug, the expected cost of developing that drug, and policies that influence the supply of and demand for drugs."[153] The CBO also found that estimates of the average research and development costs for new drugs range from less than $1 billion to more than $2 billion, while only about 12% of all drugs that enter clinical trials are ultimately approved by FDA.[154]

The patent system, like regulatory exclusivities, is designed to recognize the risks and costs inherent in innovation and reward such investment in research and development. Indeed, courts have expressly recognized that "the encouragement of investment-based risk is the fundamental purpose of the patent grant."[155] It is the patent protection period that affords a manufacturer the opportunity to recover its research and development costs – not only for the drug for which the patent was awarded but also for other research and development investments that the manufacturer may have made. Simply put, the risk associated with bringing, and the investment required to bring, a new drug to market dwarfs the corresponding risk and investment for a copy product. From a technical perspective, the entry barrier for a new drug is sky high relative to that of the corresponding copy product.

CMS should take special care not to upset the long-standing policy designs of the U.S. patent system. It can do so by honoring any remaining patent period for selected drugs by specifying that the MFP will not be set below the MFP ceiling price for during any year during the price applicability period into which the drug's patent protection period extends.

C. For a Small Molecule Medicines, CMS Should Specify That It Will Not Set the MFP Below the MFP Ceiling Until at Least the First Year of the Price Applicability Period That Starts After the Date on Which Thirteen Years Have Lapsed Since Its Approval

To be MFP-eligible, biologics (large molecules) must be at least eleven years post-licensure, while drugs (small molecules) must be at least seven years post-approval.[156] The approximately two-year time lag between selection for the MFP process and application of the MFP means that an MFP cannot apply to a biologic until at least approximately **thirteen** years after licensure, whereas an MFP cannot apply to a drug until at least approximately nine years post-approval. CMS should set the MFP at the MFP ceiling until at least the first year during the price applicability period that starts at least **thirteen years after** the approval of a drug. This approach is necessary to help preserve small molecule innovation in parity with large molecule innovation.

In particular, Lilly is concerned that the nine- and thirteen-year distinction arbitrarily promotes large molecule biologic innovation to the detriment of small molecule drug innovation. Studies show that, in the first five years on the market, most products (whether small or large molecules) achieve modest levels of annual sales.[157] Accordingly, manufacturers may seek the economic benefit of an additional four-year shelter from selection for the MFP process by focusing research and development on biologics instead of drugs.

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[152] *See also, e.g.*, Henry Grabowski, et al., Continuing trends in U.S. brand-name and generic drug competition, 24 J. Med. Econ. 908, 914 (2021) (finding that the average 2017-19 MEP of 13.0 years for new molecular entities (NMEs) of more than $250 million has changed relatively little over the past decade and remains lower than for all NMEs (14.1 years). Paragraph IV challenges are more frequent and occur earlier for NMEs>$250 million. Generic share erosion remains high for both NME types.

[153] CBO. *Research and Development in the Pharmaceutical Industry*. Apr. 8, 2021. *Available:* https://www.cbo.gov/publication/57126.

[154] *Id.*

[155] *BIO v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007).

[156] SSA § 1192(e)(1).

[157] Quintiles IMS Inst., *Lifetime Trends in Biopharmaceutical Innovation: Recent Evidence and Implications*, at 2 (Jan. 2017).

Disincentivizing manufacturers from investing in small molecule drugs presents serious risk to patient access to effective treatments. Studies have shown that biologics account for 37% of net drug spending in the United States and are estimated to cost 22 times more than small molecule drugs.[158] Such costs are prohibitive for many patients. Small molecule drugs, on the other hand, are generally less expensive to develop and produce than biologics. Lower production costs translate into lower drug prices, increasing accessibility for patients. Nevertheless, small molecule drugs do not enjoy the same additional four years of freedom from selection for the MFP process that biologics enjoy.

Moreover, while patients benefit from access to both types of products, small molecule drugs figure more prominently in the treatment plans of most Americans. Many biologics must be stored and administered in specialized clinics under the supervision of medical professionals.[159] One reason for this restriction is that biologics (which are produced from living organisms) require strict control over storage and handling that is often unnecessary for more stable chemically-derived small molecule drugs.[160] Also, with respect to a biologic, medical professional supervision may be necessary to administer care if the patient suffers from a serious, life-threatening side effect, such as an unintended immune response to the product. As a result, patient access to biologic treatments may be limited by geographic and/or time constraints. Small molecule drugs, by contrast, are more easily administrated and more readily mobile.

Accordingly, CMS should promote small molecule drug development to the greatest extent possible by setting the MFP for a small molecule drug at the MFP ceiling until at least the first year of the price applicability period that starts after the date on which the drug is thirteen years post-approval thereby helping to counterbalance the incentives that place a disproportionate emphasis on biologic development at the expense of small molecule drug development.

D. CMS Should Ensure Continued Manufacturer Participation in the Program – and Access for Patients to the MFP – by Including Meaningful Protections for Manufacturers Against "Spillover" Risks

Since the enactment of the IRA, several states have proposed legislation that would authorize or require the state to rely on a selected drug's MFP as a reference point in setting a price or payment limit outside of the Medicare market.[161] And at least one state agency has promulgated regulations authorizing the state's Prescription Drug Affordability Board to consider a selected drug's MFP in setting an upper payment limit for the drug, as subject to an affordability review.[162] It is also possible that commercial entities will seek to invoke the MFP as a reference price in commercial negotiations. However, MFPs are not reference prices or objective external benchmarks; they are prices that manufacturers, based on forced disclosure of highly sensitive data, are compelled to make available with respect to Medicare beneficiaries because failure to do so will result in a penalty (styled as an excise tax) of up to 1900% of daily sales and/or effective exclusion from doing business with Medicare and Medicaid.

The MFP is not designed to serve as a reference price or external benchmark across non-Medicare markets. Indeed, broad spillover of this compelled price could engender risks to all federal healthcare program beneficiaries because widespread and unintended reliance on the MFP (by states or commercial entities) will make it impossible for manufacturers to continue to participate in federal programs at all. This is why Congress explicitly restricted the obligation to provide access to the MFP to units furnished or dispensed to **Medicare** beneficiaries.

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[158] Forbes. *Biologic Medicines: The Biggest Driver of Rising Drug Prices*. March 8, 2019, Available: https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising- drug-prices/?sh=520ce94118b0; F. D. Makurvet, *Biologics vs. Small Molecules: Drug Costs and Patient Access*, 9 Medicine in Drug Discovery 1,4 (2021).

[159] T. Morrow & L. H. Felcone, *Defining the difference: What Makes Biologics Unique*, 1 Biotechnology Healthcare 24 (2004).

[160] *Id.*

[161] *See, e.g.*, S.B. 967, Va. Gen. Assembly (2023) (providing that the prescription drug affordability board "may adopt the Medicare maximum fair price . . . for a prescription drug product as the upper payment limit amount"); H.F. 17, Minn. Leg., 93rd Sess. (2023) ("When setting an upper payment limit for a drug subject to the Medicare maximum fair price under United States Code, title 42, section 1191(c), the board shall set the upper payment limit at the Medicare maximum fair price.").

[162] 3 Colo. Code Regs. § 702-9:4.1(C)(2)(a)(ix).

The MFP is also not a rational metric for statewide drug pricing or payment restrictions—because it is not set by reference to any objective metric tied to the appropriate price or payment that should be applied to a drug across any given state market. Further, expanding the application of the MFP outside of the Medicare market risks fundamentally disrupting the careful balance that Congress struck in establishing the Program thereby jeopardizing patient access and impeding innovation.[163] It would, for example, greatly skew the projected revenue and sales volume for a selected drug as well as the return on investment in research and development costs, factors that CMS must consider in setting an MFP.

More fundamentally, if the MFP is used as a reference point for non-Medicare markets, manufacturers will be unable to invest in ongoing innovation because they will face undue limitations on their ability to recoup the potentially billions of dollars in research and development costs associated with developing a single drug, much less the countless additional billions of dollars spent on research and development that never culminate in an approved product.[164] Congress did not intend for the Program to grind the wheels of innovation to a halt, and unambiguously limited the scope of the MFP accordingly.

It is imperative that CMS address need to protect incentives for innovation by limiting the expansion of the MFP beyond the Medicare market and, thus, outside of the scope intended by Congress. To mitigate these serious concerns, Lilly asks CMS to address this in the Program agreement. We think there are at least two options. First, CMS could specify in the agreement that the MFP will not be set below the MFP ceiling price where the manufacturer shows that the MFP will be or has been used as a reference point in setting a pricing or payment limit outside of the Medicare market. Alternatively, CMS could specify that, where there is a non-trivial amount of spillover of MFP pricing outside the Medicare market (say 5% of unit sales), that constitutes a "material change" to the agreement that triggers a "renegotiation."

E. CMS Should Specify That the MFP Will Not Be Set Below Ceiling Price if the Selected Medicine Is Subject to a VBP Subject to the MBPRO

CMS has repeatedly expressed a strong interest in promoting value-based pricing of and payment for drugs and biologics to promote access to the highest quality of care available while also achieving cost savings within its programs and across the health care system more generally.[165]

In 2020, CMS promulgated a rule to better promote VBPs in the commercial and Medicaid marketplaces in light of historical obstacles under the MDRP by establishing the MBPRO.[166] The MBPRO is a new option for reporting BP where a manufacturer offers a VBP in the commercial market. Manufacturers that elect to report via the MBPRO are required to submit two distinct sets of BP data: (1) the set of potential BPs available under the VBP (VBP BP), which reflect the multiple value-based prices available under the arrangement; and (2) a single non-value-based BP (non-VBP BP), which reflects the lowest price available from the manufacturer outside of the VBP.[167] MBPRO ensures that state Medicaid programs have a choice between (1) participating in the VBP, in which case the Medicaid rebate amount is calculated based on the VBP BP, and (2) not participating in the VBP, in which case the Medicaid rebate amount is calculated based on the non-VBP BP.

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[163] D. Schulthess and H. Bowen, The Historical Impact of Price Controls on the Biopharma Industry, Vital Transformations (Nov. 22, 2021).
[164] M. Schlander, et al., How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment, PharmacoEconomics 1243–1269 (2021).
[165] *See, e.g.*, 85 Fed. Reg. 87,000, 87,032 (Dec. 31, 2020); 83 Fed. Reg. 22,692 (May 16, 2018) (explaining that "[v]alue-based transformation of our entire healthcare system is a top [Department of Health and Human Services (HHS)] priority"); CMS, *What are the value-based programs?* February 2023. Available: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.
[166] 85 Fed. Reg. at 87,032
[167] 85 Fed. Reg. at 87,025.

In establishing the MBPRO, CMS recognized the "interest among patient and consumer groups, states, and manufacturers in the new multiple best price policy" in light of the shift to value-based pricing and payment that it represents.[168] CMS also stated that the policy "is meant to help improve patient access to new medications, particularly new high cost therapies such as gene or cell therapies, by facilitating the use of VBP arrangements when purchasing such medications."[169]

More recently, the Center for Medicare and Medicaid Innovation (CMMI) proposed a set of innovative models to further value-based pricing and payment, including a Cell and Gene Therapy Access Model that will enable CMS to coordinate and administer outcomes-based agreements with manufacturers of certain cell and gene therapies on behalf of state Medicaid programs.[170] This VBP-oriented model is consistent with the stated policy priorities of the Biden Administration. In fact, the model was in direct response to an Executive Order issued by President Biden on October 14, 2022, requiring HHS to consider models that "would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs," including through the use of "value-based payment that promotes high quality care."[171]

VI. Other Considerations

A. CMS Should Clarify That Selected Medicines Are Not Subject to an Inflation Rebate

As part of soliciting comment on the interaction between inflation rebates and selected medicines,[172] CMS contends that "[t]he Part B and Part D inflation rebate programs apply to selected drugs, regardless of the status of the medicine as a selected medicine. Alternatively said, whether a drug is a selected drug will have no bearing as to whether the drug is also subject to the Part B and Part D inflation rebate programs."[173]

CMS's contention is troubling because it is untrue. Selected drugs are not subject to inflation rebates, and Lilly urges CMS to clarify that this is the case. Under the statute, the Part B inflation rebate calculation is based on the amount by which "106 percent of the amount **determined under paragraph (4)** of [section 1847A(b) of the SSA] for [a Part B rebatable drug] during the calendar quarter . . . . exceeds . . . the inflation-adjusted payment amount . . . for such Part B rebatable drug during the calendar quarter."[174]

Importantly, the circumstances under which an amount is "determined" under paragraph (4) of section 1847A(b) is dictated by section 1847A(b)(1).[175] Section 1847A(b)(1) dictates a payment amount of, "in the case of a single source drug or biological . . . , 106 percent of the amount **determined under paragraph (4) of section 1847A(b)** ***or*** in the case of such a drug or biological product that is a selected drug . . . , with respect to a price applicability period . . . , 106 percent of the maximum fair price . . . applicable for such drug and a year during such period."[176]

In other words, a selected drug's payment **must** be determined under section 1847A(b)(1), and such payment amount must be determined **without regard to paragraph (4)** of section 1847A(b). Taken together, this means paragraph (4) defines the payment amount **only** for a **non-selected** drug. Accordingly, by statute, the Part B inflation rebate **cannot** be applicable to a selected drug – because there is no amount "determined under paragraph (4)," and therefore Part B inflation rebates cannot be applicable.

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[168] 86 Fed. Reg. 28,742, 28,744 (May 28, 2021).
[169] 85 Fed. Reg. at 87,032.
[170] HHS. *HHS Secretary Responds to the President's Executive Order on Drug Prices.* February 14, 2023. *Available:* https://www.hhs.gov/about/news/2023/02/14/hhs-secretary-responds-to-the-presidents-executive-order-on-drug-prices.html.
[171] Executive Order No. 14087, 87 Fed. Reg. 63,399, 63,399–400 (Oct. 14, 2022).
[172] *See* Guidance at 123.
[173] *See* Guidance at 124.
[174] SSA § 1847A(i)(3) (emphasis added).
[175] *See Id.* § 1847A(b)(1).
[176] *Id.* § 1847A(b)(1)(B) (emphasis added).

There is also every reason to believe such outcome was intended by Congress. There is no policy reason for application of inflation rebates to selected drugs. The MFP already constrains Medicare expenditures for selected drugs, and thus it would be illogical Congress to apply inflation rebates in addition to the MFP.[177] This is especially true because the MFP already shields Medicare from price increases outpacing inflation, which is the very situation that inflation rebates were designed to address. Accordingly, we ask that CMS clarify that a selected drug is not subject to an inflation rebate, consistent with both the language of the statute and sound public policy.

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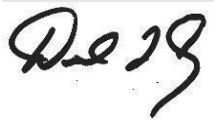
Lilly is grateful for the opportunity to comment on certain sections of the Draft Guidance. We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you in the future to help ensure that patients have meaningful access to affordable health care benefits and prescription drug coverage. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,



Derek L. Asay
Senior Vice President,
Government Strategy and Federal Accounts

Shawn O'Neail
Senior Vice President,
Global Government Affairs

[177] *Id.* §§ 1847A(b)(1)(B); 1860D-2(d)(1)(D).

Comments Related to Guidance Appendix A:

Definitions for Purposes of Collecting Manufacturer-Specific Data

In this Appendix, we provide our comments to CMS's proposed definitions for the purposes of collecting manufacturer-specific data found in Appendix A to the Draft Guidance.

As a threshold matter, we highlight that the U.S. Securities and Exchange Commission (SEC) and other governmental bodies do not require external reporting of costs (including research and development costs) or profits at a product-specific level, and therefore Lilly does not prepare standard financial statements with this data at a product-specific level. Further, Lilly is not required to allocate all actual costs to individual Lilly products in the regular course of business, and estimated cost data for individual products would reflect informal and unaudited financial analysis. Instead, Lilly produces audited financial reports on an enterprise level pursuant to governing regulatory standards and accounting principles. These audited annual reports are submitted to the SEC pursuant to federal laws and regulations.

We note that in some circumstances, CMS's guidance diverges from SEC and/or generally accepted accounting principles (U.S. GAAP). As a result, Lilly believes manufacturers will need to make many reasonable assumptions for the purposes of calculating much of the data manufacturers will be required to submit to CMS. For manufacturers like Lilly, this data will be prepared solely for purposes of complying with the requirements of the IRA.

Research and Development (R&D) Costs – General Comments

1. **CMS Should Allow Manufacturers to Stipulate to R&D Recoupment. Alternatively, CMS Should Streamline R&D Reporting to Ensure its Approach is the Least Burdensome Necessary to Achieve the Statutory and Program Objectives.**

In the Draft Guidance, CMS continues to require that manufacturers identify R&D expenses for a selected drug, determine whether such expenses should be reported in one of five categories of R&D spend defined by CMS, determine whether such expenses are "direct" or "indirect" or are "incurred for an FDA approved indication," and perform various ad hoc calculations to include, exclude, or allocate such expenses in the manufacturer's report. As we've previously described, however, neither U.S. GAAP nor SEC require external reporting of R&D costs at a product-specific level, nor are manufacturers required to capture and categorize R&D data in the manner CMS proposes.

We continue to be concerned that CMS requires R&D data to be reported at a level of prescribed detail and categorization that is inconsistent with the manufacturer's audited financial statements, U.S. GAAP, and/or U.S. SEC reporting standards. The proposal will require manufacturers to mine their financial systems and other books and records to attempt to identify transactions (some of which could be decades-old and captured in since-retired systems) for "reconstruction" purposes and to develop new and manual methodologies to allocate or calculate the requested data, solely for the purposes of the Program.

We reiterate that for the purposes of the Program (e.g., for adjustments to the Preliminary Price), CMS does not need for manufacturers to mine all R&D transactions, determine whether such transactions are "direct" or "indirect" costs based on a CMS-specific paradigm, determine whether such transactions are "for FDA-approved indications" of the selected drug, divide R&D data into five categories, and perform various other adjustments (e.g., removing federal funding) or allocations inconsistent with U.S. GAAP. Simply, CMS does not need all of the information it is requesting, and it is requesting an unprecedented amount of information.

For the purposes of drastically reducing the reporting burden on manufacturers and improving consistency of manufacturer data submissions, we recommend that CMS amend its reporting requirement to allow a single global response in which a manufacturer

can attest whether it has recouped its R&D costs. If a manufacturer certifies that it has recouped its R&D costs, then CMS need not gather any additional information. If a manufacturer does not or cannot certify that it has recouped its R&D costs, then the manufacturer can provide additional information.

Alternatively, CMS should significantly streamline the R&D reporting requirement to better align with how manufacturers capture and report R&D data in their financial systems today. Specifically, CMS should collect R&D data in two categories: (1) costs of R&D before initial FDA approval (an aggregate way to gather all basic/preclinical and clinical development), and (2) costs of R&D after FDA approval, which would include Phase IV costs. Such approach would both reduce reporting burden on manufacturers and improving consistency of manufacturer data submissions.

2. **CMS Should Not Limit the Definition of R&D Costs to Costs Associated with "All FDA-Approved Indications of a Drug."**

CMS proposes to limit the definitions of R&D costs to only costs incurred "for all FDA-approved indications of a drug." First, this definition *excludes* costs that are otherwise included in the manufacturer's audited and publicly disclosed financial statements and ignores material costs incurred by manufacturers (e.g., to conduct trials that further the understanding of approved molecules, to invest in R&D for indications approved in non-U.S. markets – indications that may be approved by the U.S. FDA at a later time).

Moreover, manufacturer systems generally are not configured to assign costs to a specific indication, particularly in early research where research is indication-agnostic and focused on the molecule safety, toxicity and general efficacy. Additionally, late phase research efforts may support a portion of or the entirety of a manufacturer's portfolio and would not be assigned to a specific molecule or indication. As a result, manufacturers will likely develop assumptions to determine whether and to what extent expenses (particularly those not associated with a specific clinical trial) are reasonably associated with an FDA-approved indication.

To further standardize and improve consistency of submitted information, aid in CMS' interpretation of the submitted information, and significantly reduce the reporting burden on Primary Manufacturers, we recommend that CMS define R&D costs without limiting those costs to those incurred for FDA-approved indications. Alternatively, we recommend below that CMS specify that certain categories of research, e.g., basic pre-clinical research, is assumed to be for FDA approved indications.

3. **CMS Should Not Exclude "Costs Associated with Ongoing Basic Pre-Clinical Research, Clinical Trials, and Pending Approvals" from the Definition of R&D Costs.**

CMS proposes to exclude "costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals" from the definition of R&D costs. As we previously noted, this definition *excludes* costs that are otherwise included in the manufacturer's audited and publicly disclosed financial statements and ignores meaningful expenses incurred by manufacturers to advance and seek approval of innovative therapies (e.g., manufacturers may continue to conduct trials to gain approval for additional indications of a drug). Importantly, once a selected drug is subject to an MFP, such MFP applies to all *future* indications of the drug unless a new MFP is established through the renegotiation process at some future point. This means material R&D costs for these future indications (e.g., costs that may have been *ongoing* at the time of the drug's selection) may never be reported by a manufacturer, and the drug's MFP will be determined without consideration of such costs.

Moreover, manufacturers may need to manually identify and exclude these costs from the data they report to CMS, in a manner inconsistent with their reporting under U.S. GAAP and to the SEC. To further standardize and improve consistency of submitted information, aid in CMS' interpretation of the submitted information, and significantly reduce the reporting burden on Primary Manufacturers, we recommend that CMS define R&D costs to *include* ongoing costs. Such approach better reflects the treatment of these expenses under U.S. GAAP and results in a more appropriate R&D cost recoupment calculation (i.e., the comparison of lifetime revenue to lifetime costs, which include ongoing costs).

4. CMS Should Specifically Identify Milestone Payments As R&D Costs.

CMS is silent as to the treatment of milestone payments made to third parties related to R&D (e.g., a payment paid based on achieving a Phase 1 or Phase 2 milestone). We recommend that CMS specifically state that milestone payments may be reported as R&D costs, consistent with recent SEC statements and consistent with the definition of direct research expenses, as such expenses can be specifically attributed to the discovery and preclinical or clinical development of the selected drug.

Research and Development (R&D) Costs – Comments on Specific Definitions

1. Definitions for 1. R&D: Acquisition Costs

CMS defines "acquisition costs" as "costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug." Such rights can be acquired via a number of different deal structures, and we assume this definition includes costs associated with licensing arrangements, co-development or clinical product supply agreements, and/or milestone payments. We recommend CMS acknowledge these diverse payment classifications in the final definition.

We also highlight that a manufacturer may acquire another company and that the acquisition cost may entitle the manufacturer to the rights to several potential drugs of the acquired company. In such circumstances, we recommend CMS acknowledge the manufacturers will need to make certain assumptions in order to apportion the costs associated with acquiring a company to the selected drug.

2. Definitions for 2. R&D: Basic Pre-Clinical Research Costs

CMS defines basic pre-clinical research costs as "all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses." CMS provides examples of direct and indirect expenses in the Draft Guidance. We note three specific concerns with these definitions that create meaningful data collection burden and may result in inconsistency in manufacturer submissions.

First, we assume that the overwhelming majority of – if not all – pre-clinical research costs are reasonably associated with or are "for" an FDA approved indication, as these early costs provide an understanding of toxicity and safety of a potential medicine. Ultimately, many of the pre-clinical expenses result in information that is submitted to FDA when seeking drug approval. Also, in most cases, a manufacturer will not know the expected FDA label until the end of the R&D cycle, well after pre-clinical costs were incurred, and there is no "flag" in manufacturer financial systems that links pre-clinical R&D costs to an FDA approved indication.

Accordingly, to help drive consistency in manufacturer submissions and reduce manufacturer reporting burden, we recommend that CMS allow all relevant pre-clinical expenses be reported, regardless of whether those expenses are explicitly tied to an FDA-approved indication. Alternatively, we recommend CMS explicitly acknowledge that pre-clinical research costs are presumed to be for an FDA-approved indication.

Second, in this R&D cost category only, CMS proposes to allow manufacturers to capture a portion of "indirect" research costs. As we previously highlighted, manufacturer financial systems are not configured to classify all expenses as direct v. indirect nor assign all direct expenses to a particular potential drug, as neither U.S. GAAP nor SEC regulations require delineation of R&D expenses in this way. Even if manufacturers have otherwise assigned "direct" and "indirect" labels to costs in their financial systems, such labels would be for internal management reporting purposes only, and – because not required for any other purpose – the methodologies for such assignment will likely have evolved over the decades in which the manufacturer incurred expenses.

Accordingly, to help drive consistency in manufacturer submissions and reduce manufacturer reporting burden, we recommend that CMS allow manufacturers to stipulate recoupment, as described above. Alternatively, we propose that CMS provide additional examples of direct and indirect expenses as well as explicitly recognize that manufacturers will need to make reasonable assumptions for the purposes of calculating the values required to be submitted, which may be prepared solely for purposes of complying with Program requirements.

Third, in this R&D category of R&D costs in particular, much of the responsive data may not be available. The R&D costs associated with many of the products that may be subject to the Program may have been incurred more than 20 years ago, and this data was never required to be captured or retained in perpetuity. As a result, CMS may receive inconsistent depictions of manufacturers' R&D expenses – those without access to historical data will be unable to fully reflect the R&D costs associated with a selected drug, whereas those with new products may be able to – ultimately jeopardizing the usefulness of the data to the Program. As a result, we recommend that CMS allow manufacturers to stipulate recoupment, as described above, or explicitly allow manufacturers to estimate the amount of relevant expenses in this category.

3. Definitions for 3. R&D: Post-Investigational New Drug (IND) Application Costs

The definitions in this R&D cost category are also limited to only those expenses "for each FDA-approved indication." In addition, CMS does not allow reporting of indirect expenses or any "ongoing" research. These limitations meaningful limit the data that can be reported to CMS by excluding transactions that are otherwise included in manufacturers' financial statements. As a result, if CMS does not accept our recommendation to allow reporting of "ongoing" research in all R&D cost categories, we recommend that CMS allow the reporting of "ongoing" research in this category specifically, as it represents a meaningful amount of expense and would facilitate a better understanding and interpretation by CMS of the research and development costs of a selected drug that will be subject to MFP for all future indications (unless the selected drug is renegotiated).

4. Definitions for 4. R&D: Abandoned and Failed Drug Costs

The definitions in this R&D cost category are also limited to only direct expenses. We recommend that CMS allow reporting of indirect expenses to better depict the expenses incurred.

Also, as we described in our previous written comments, we appreciate CMS's acknowledgement that manufacturers incur R&D costs associated with failed or abandoned products. However, CMS continues to propose limiting the reporting of *basic pre-clinical research* costs for failed or abandoned products to those costs associated with products that have "the same active moiety / active ingredient or mechanism of action as the selected drug."

We disagree with this limitation and believe it is overly narrow, as a large portion of basic pre-clinical research expense would not be assignable to any marketed product. For example, Lilly has made significant investment in researching Alzheimer Tau Tangle targeting molecules, some of which has failed, but all of which has contributed to the overall advancement of Alzheimer's research. As a result, we recommend that CMS specially allow manufacturers to allocate the basic pre-clinical research costs associated with abandoned or failed products to selected dugs in the same disease state or therapeutic class. This recommendation is consistent with CMS's proposal to include in "failed or abandoned drug costs" an allocation of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.

5. Definitions for 5. R&D: All Other R&D Direct Costs

We appreciate that CMS has provided additional clarity in this definition by providing other examples of costs including Phase IV studies that were not required and post-IND costs for indications that did not receive FDA approval. To help further standardize and

improve the consistency of information submitted by manufacturers, and to ensure better alignment with the universe of expenses included in manufacturers' financial statements, we recommend CMS include additional examples such as:

- Basic pre-clinical expenses for a selected product that occur after the date on which the first IND went into effect, i.e., pre-clinical expenses that may take place outside of the reporting timeframe for "Basic Pre-Clinical Research Costs."
- Real world evidence generation and/or observational research.
- Investigator-initiated studies, safety monitoring, and ongoing regulatory fees.
- Legal Costs (e.g., patent filing costs).
- Other post-approval research and development expenses, e.g., those related to providing additional insights to inform the use of approved drugs, new indications or line extensions, food-effect studies, etc., to the extent not reportable in another category.

We also again encourage CMS to allow reporting of ongoing direct and indirect costs, if not in the categories above, then here in category 5.

Current Unit Costs of Production and Distribution – Comments on Specific Definitions

As a threshold matter, we reiterate that the SEC does not require external reporting of costs at a product-specific level, nor is such reporting required under U.S. GAAP. Therefore, Lilly does not prepare standard financial statements with this data at a product-specific or package-specific level. As a result, manufacturers will need to make reasonable assumptions for the purposes of calculating the values required to be submitted, which may be prepared solely for purposes of complying with Program requirements.

1. Definition of Relevant Production and Distribution 12-month Period

The Draft Guidance indicates that manufacturers must provide "[a]verage unit costs during the 12-month period ending October 31, 2024 (for selected drugs for initial price applicability year)." This date range that is inconsistent with SEC reporting periods. Most manufacturers, particularly those who are also publicly traded companies, have systems, processes, and controls that are performed on a quarterly or annual basis to help ensure accurate external financial reporting. Under the Draft Guidance, manufacturers will need to implement additional controls to assess the completeness and accuracy of production and distribution cost data on an off-cycle basis. To alleviate this burden, and assuming CMS continues to want a 12-month average cost, we recommend that CMS request production and distribution data as of the close of the company's most recent fiscal year to align with the company's external financial reporting. Alternatively, we propose CMS align its request date to a quarter close, e.g., September 30, 2024 or December 31, 2024.

2. Definition of Distribution: CMS Should Define Distribution Costs to Include Additional Channel Fees and Expenses.

CMS proposes to define costs of distribution as all direct, and an allocation of indirect, costs related to "packaging and packaging materials; labeling (e.g., the mechanical aspects of printing and affixing the approved label); shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer." We note that manufacturers incur channel fees, including prompt pay discounts, administrative fees for inventory management and other wholesalers services, etc. These not explicitly called out in the Draft Guidance, and they may be treated by manufacturers as a reduction in revenue, or as a distribution cost. Thus, to further standardize and improve the consistency of information submitted by manufacturers, we recommend that CMS explicitly include these expenses in the definition of distribution costs.

3. CMS Should Allow Allocation of Various Other Costs Associated with Producing and Distributing Product.

We agree with CMS's recognition that manufacturers will need to allocate various direct and indirect costs. We recommend that CMS preserve flexibility in manufacturers' ability to identify and allocate various product manufacturing costs in a manner consistent with U.S. GAAP and/or SEC reporting. Such costs may include expenses associated with royalties or other margin sharing arrangements, amortization of intangible assets, use/yield variances, purchase price variances, idle plant expenses, the impact of foreign exchange rate changes on inventories sold, etc. These expenses are part of standard U.S. GAAP accounting.

CMS should also factor in capital outlays required to build, improve, and/or maintain manufacturing facilities. While some of these costs may be reflected in the unit costs of production through depreciation expense, depreciation will not be representative of the significant capital investments required for entry and ongoing operations. CMS should carefully consider these investments when evaluating the total cost picture. In some product classes, there may not be alternative manufacturers with sufficient capacity given the significant barriers to entry.

Finally, CMS should consider the costs a new entrant would bear if they had to bring such a product to market and manufacturer the product at the same capacity as an incumbent manufacturer. This "replacement cost" is a better representation of the current benefit to society than costs in the past might have been.

4. **CMS Should Specify that the Exclusion of "Transfer Prices" from the Definition of "Current Unit Costs of Production and Distribution" Does Not Apply to Actual Costs to Produce and Distribute a Selected Drug Incurred by Different "Members of the Same Controlled Group of the Primary Manufacturer."**

CMS has revised the definition of "current unit costs of production and distribution . . . not to include . . . [t]ransfer prices." CMS defines Transfer Prices as "prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, "controlled group" of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of Treasury regulations thereunder."

We note that several entities, all of which may be considered a single employer under the Internal Revenue Code (i.e., the Primary Manufacturer), may incur costs to produce and distribute the product. For example, one entity may incur costs to manufacture the active pharmaceutical ingredient, which could include "purchase of raw ingredients [or] excipients."[178] A second entity may incur costs to finish the medicine (e.g., "formulation and preparation of the finished drug product").[179] These expenses are not traditionally considered "transfer prices," and expenses associated with these activities otherwise meet the definition of production and distribution costs. Thus, we assume a Primary Manufacturer may include these costs from different entities when calculating production and distribution expenses for the selected drug. We recommend that CMS explicitly indicate as such in the Final Guidance.

<u>Prior Federal Financial Support</u>

1. **CMS Should Define "Federal Funding" to Exclude "Indirect Federal Funding" and Should Allow Direct Federal Funding to be Allocated.**

CMS is proposing to exclude "Federal funding" from the determination of R&D costs. CMS defines "Federal financial support" as including "tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of

[178] Draft Guidance.
[179] Draft Guidance.

office/laboratory space or equipment), and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug."

As we previously noted, this requirement creates another new and material data capture and reporting burden inconsistent with U.S. GAAP. Manufacturers are not required to carve out – proportionally – federal funding from their financial statements or disclosures. And federal funding of preclinical research (like most preclinical research) may not be product specific. As a result, such funding would need to be allocated.

Further, while manufacturer accounting systems may be able to identify direct federal funding (e.g., grants or contracts), they are highly unlikely to capture indirect funding, and CMS leaves open the question of whether and to what extent indirect funding must be considered. For example, the federal government may provide funding to a third-party entity or foundation that provides funding to manufacturers for R&D purposes. Because this indirect government funding may be unknown to manufacturers, and because this third-party engagement may have occurred several years ago, we recommend that CMS explicitly exclude *indirect* Federal funding from the definition of "Federal funding."

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

I write today in regard to the proposed draft guidance dated May 3, 2024, which pertains to the implementation of the Inflation Reduction Act's Maximum Fair Price (MFP) provisions. As an organization, these regulations raise serios concerns about their impact on our operations and financial viability, especially in relation to our participation in the 340B drug discount program. We urge you to take seriously the potential unintended consequences of the proposed regulation and alter future proposals to protect care delivery providers.

The Marshfield Clinic Health System is an integrated health system serving Wisconsin and northern Michigan. Our 1,400 providers deliver care for 3.5 million patient encounters each year across our eleven hospitals (including 3 critical access hospitals) and over sixty ambulatory clinical sites in over 40 communities. Half of the ambulatory facilities are in communities of less than 4,000 people. Marshfield Clinic Health System is one of the largest fully integrated health systems serving rural residents from locations in rural communities. The system's primary service area encompasses over 80 percent of the rural population of the state of Wisconsin. We are the largest provider of primary and specialty care in our region including services provided to children through our very own Marshfield Children's Hospital. Marshfield Clinic Health System is also a teaching health system, providing over 1,300 students with over 2,300 educational experiences annually throughout our system. The Marshfield Clinic Research Institute is the largest privately-funded research entity in the state of Wisconsin.

Our integrated health systems relies heavily on the 340B program and the proposed changes could bring into jeopardy continued operations in some facets of our work because of a decrease in 340B revenues. Critical Issues Raised by the Proposed Guidance:

1. **Operational and Financial Burdens:** The requirement for 340B hospitals to share claims data directly with manufacturers, as well as the necessity for hospitals to advance higher drug costs pending manufacturer refunds, introduces substantial operational complexities and financial strain.
2. **Compliance and Process Concerns:** CMS's guidance fails to meet its statutory obligations to ensure that 340B covered entities (CEs) can procure drugs at the lower of the 340B ceiling price or the MFP. The guidance suggests a problematic claims process that would not permit effective use of 340B-priced drugs when their cost is below the MFP. Moreover, the recommended practice of CEs submitting their 340B claims data directly to each of potentially hundreds of manufacturers is unfeasible and burdensome.

Recommendations for CMS:

- **Develop Alternative Methodologies:** We suggest that CMS consider developing methodologies that allow CEs to submit 340B claims data retrospectively to CMS's Medicare Transaction

Facilitator (MTF). This system should be designed to identify 340B claims and withhold them from being submitted to manufacturers, akin to successful models used in other state programs.

- **Address Point-of-Sale Identification Challenges:** Given the longstanding use of virtual inventory systems by most CEs, requiring point-of-sale identification of 340B claims is impractical. We recommend that CMS devise a solution that does not rely on point-of-sale data submission.
- **Review Manufacturer Data Requirements:** CMS should carefully evaluate and regulate the data requirements imposed by manufacturers to prevent unnecessary administrative burdens on CEs.

I urge you and your team to reevaluate the proposed guidance in light of the potential impact it would have on organizations like MCHS that rely heavily on 340B revenue. I stand ready to work with you and your team, and would welcome the opportunity to provide further information at your earliest convenience.

Sincerely,

Girish G. Kaimal PharmD, MBA, FACHE
Chief Pharmacy Officer
Marshfield Clinic Health System

MASSBIO

700 Technology Square, 5th Floor
Cambridge, MA 02139
617.674.5100 | massbio.org

July 2, 2024

Submitted via email to: IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear. Dr. Seshamani:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit comments on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (the "IPAY 2027 Draft Guidance").

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,700+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

MassBio remains concerned about the impact the Medicare Drug Price Negotiation Program (the "Negotiation Program") will have on the future development of innovative and life-saving therapies, as well as on the world-leading small and emerging biotech companies based in Massachusetts. Given the potential impact on innovation and thus on vulnerable patient access to life-saving therapies, we continue to urge CMS to adopt a "do no harm" approach in implementing this program that errs on the side of mitigating against the potential disincentives created by the program's framework, and that allows the agency to make corrections as needed to preserve innovation. In particular, with respect to the IPAY 2027 Draft Guidance, we urge CMS to:

- Continue to explore opportunities to preserve incentives to develop innovative new therapies for rare disease;

- Provide additional predictability and transparency with respect to the process for establishing an MFP for selected drugs;
- Establish processes to effectuate the MFP in a manner that facilitates manufacturer compliance with statutory requirements without resulting in duplicate discounts; and
- Evaluate the impact of the IRA on the innovation ecosystem, particularly in Massachusetts.

I. CMS Should Explore Opportunities to Preserve Incentives to Develop Innovative New Therapies for Rare Disease.

MassBio remains concerned that the narrow scope of the orphan drug exclusion creates a strong disincentive for developers to continue to develop new indications and formulations for existing orphan therapies.

Rare diseases, as defined by the FDA are conditions that impact fewer than 200,000 patients nationwide, and are inherently under-researched, under-diagnosed, and under-treated. Although much progress has been made since the enactment of the Orphan Drug Act (ODA) 40 years ago, over 90 percent of known rare diseases still do not have therapies or treatments. While there has fortunately been a recent surge in the development of drugs for rare disease populations,[1] with much of this development occurring in Massachusetts,[2] these new indications still require costly clinical trials, regulatory approvals, and adherence to regulatory requirements. The narrow scope of the orphan drug exclusion creates a strong disincentive to undertake these investments, even though the science is there and could benefit vulnerable populations. Furthermore, because of the limited scope of the exclusion, companies may be disincentivized from developing therapies for rare diseases to begin with, and to instead prioritize indications with larger patient populations from the outset.

For these reasons, we are concerned that CMS appears to have walked back its commitment to "consider[] whether there are additional actions the agency can take in its implementation of the Negotiation Program to best support orphan drug development."

MassBio continues to urge CMS to implement the orphan drug exclusion in a way that promotes and is consistent with the underlying purposes and goals of the ODA: to create the necessary financial incentives to accelerate the development of rare disease drug development. Specifically, CMS should exercise its regulatory discretion to start the pre-negotiation period for orphan drugs upon loss of the orphan drug exclusion (i.e., when the product obtains approval for a new indication for a different disease or condition), rather than when the product was initially approved. In addition, once an orphan drug is selected for negotiation, CMS should ensure that

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[1] The annual number of orphan drug designation requests has steadily increased from 2012 through 2016 and has remained greater than 500 annually since 2016. In 2020, the Office of Orphan Products Development received 753 new requests for designation, a 41% increase from 2019. *See* https://www.fda.gov/news-events/fda-voices/rare-disease-day-2021-fda-shows- sustained-support-rare-disease-product-development-during-public#:~:text=The%20annual%20number%20of%20orphan,a%2041%25%20increase%20from%202019.

[2] D, Seiffert, *Massachusetts owns the orphan drug market. Here's the proof,* Boston Business Journal (Nov. 9, 2015), https://www.bizjournals.com/boston/blog/bioflash/2015/11/massachusetts-owns-the-orphan-drug-market-here-s.html.

its consideration of the statutory factors adequately values the benefit the therapy brings to patients with rare disease.

II. CMS Should Provide Additional Transparency and Predictability Regarding the Process for Establishing the MFP for Selected Drugs.

As CMS proceeds with implementation of the Negotiation Program, MassBio urges the agency to pursue an approach that creates the greatest degree of certainty for developers by adopting a predictable, transparent methodology for applying the statutory factors, which should then be updated over time to recognize the value of continued innovation. As we have explained in prior comment letters, investment in the drug development process and the innovation ecosystem is significantly impacted by the long-term market dynamics. Thus, to enable developers and their investors to make informed investments today, CMS's methodology should reflect the value that a product provides over its lifecycle and create incentives to invest in new therapeutic areas with unmet need.

MassBio is concerned that the IPAY 2027 Draft Guidance remains vague regarding certain key elements of the process for establishing an initial offer. For one, we are concerned about the lack of predictability and transparency surrounding the selection of therapeutic alternatives. Relative to the IPAY 2026 guidance, CMS is proposing to reserve even greater discretion for the agency to select a broad range of therapeutic alternatives. Given that CMS's identification of therapeutic alternatives plays an outsized role in determining the initial offer, it is critical that this selection process not only be predictable, but consistent with the statutory directive to compare selected drugs to true therapeutic alternatives. We therefore urge the agency to limit the selection of therapeutic alternatives to those products that are in the same category and class and share common clinical use. We also urge the agency to clarify how the agency will weight net prices across multiple indications and therapeutic alternatives, as applicable, in determining the starting point for the initial offer.

We are similarly concerned that CMS has provided very little information about the adjustments CMS makes to the starting point based on the various statutory factors. Manufacturers are required, as part of the Negotiation Program, to submit large volumes of information to CMS for use in establishing the MFP. However, as with the IPAY 2026 revised guidance, it remains unclear in the IPAY 2027 Draft Guidance how this information is applied. To help manufacturers of selected drugs prepare for the data submission for IPAY 2027 and beyond, and to ensure that CMS is receiving the most pertinent information, we urge CMS to provide greater detail in this regard.

III. CMS Should Establish Processes for MFP Effectuation that Facilitate Manufacturer Compliance Without Resulting in Duplicate Discounts.

MassBio appreciates CMS's efforts to support the effectuation of the MFP, including through the creation of the Medicare Transaction Facilitator (MTF). We are concerned, however, that elements of CMS's proposal may impose undue burden on manufacturers or complicate manufacturers' ability to effectuate the MFP without resulting in duplicate discounts. We therefore urge CMS to make the following revisions to the IPAY 2027 Draft Guidance:

- Make the payment facilitation function of the MTF mandatory for all parties; and
- Take proactive steps to prevent duplicate discounts between the Negotiation Program and the 340B drug discount program.

We also urge CMS to provide more information about the MTF and its functionality in a timely manner to enable manufacturers to develop informed MFP Effectuation Plans by the June 2025 deadline.

A. CMS Should Mandate Use of the MTF for Payment Exchange To Facilitate MFP Effectuation.

In the IPAY 2027 Draft Guidance, CMS reiterates that while the primary manufacturer must participate in the data exchange functionality of the MTF, "any potential payment facilitation functionality of the MTF would be voluntary for dispensing entities and Primary Manufacturers…." MassBio disagrees with this approach. Making the MTF's payment functionality optional would increase the burden on manufacturers and may compromise CMS's ability to successfully effectuate the MFP.

Notably, manufacturers have generally not had direct contractual relationships with retail pharmacies. Consolidating payment functionality in the MTF would thus avoid the need for each primary manufacturer to enter into a contractual relationship with each retail pharmacy that opts out of the MTF payment functions. However, the failure to *require* pharmacy participation undermines this benefit by nonetheless requiring manufacturers to develop a mechanism to effectuate the MFP with non-participating pharmacies.

We note that retail pharmacies would also benefit from this consolidated approach as it would streamline the payment reconciliation process across manufacturers and selected drugs—products that are, generally speaking, high-volume products. Such a requirement would also promote enrollee access to selected drugs by removing operational barriers that could affect enrollees' experience with the MNP. We note that CMS could achieve this aim by imposing contractual requirements on Part D plans that require their network pharmacies to participate in the payment functionality of the MTF.

B. CMS Should Take an Active Role in Preventing Duplicate Discounts Across the Negotiation Program and 340B Drug Discount Program.

The Negotiation Program statute exempts manufacturers from providing access to the MFP to covered entities when the 340B ceiling price is lower than the MFP for a given selected drug.[3] Although the statute requires manufacturers to provide access to the MFP if it is lower than the 340B ceiling price, this provision further requires that the MFP be offered in a "nonduplicated amount."[4] The proper implementation of this provision is necessary to ensure the proper functioning of the MNP as contemplated by Congress. However, CMS has not proposed policies that would enable MFP effectuation in accordance with these deduplication provisions.

[3] SSA § 1193(d)(1).
[4] SSA § 1193(d)(2)

In the IPAY 2027 Draft Guidance, CMS proposes that manufacturers may avoid duplication of the MFP and 340B discounts by identifying claims from the data elements transmitted by the MTF. However, CMS is not proposing to require dispensing entities to identify claims as 340B-eligible at the point-of-sale (POS) using available 340B claims modifiers. CMS instead expects manufacturers to work this out directly with covered entities. This is not a realistic proposal.

MassBio members have long been frustrated by the Health Resources and Services Administration's (HRSA's) lack of oversight the 340B program's duplicate discount prohibition. Without such oversight, covered entities have little motivation to avert the occurrence of double discounts, which can result in their loss of 340B discounts. Meanwhile, rapid growth of the 340B program and, in particular, the explosion in 340B contract pharmacy utilization complicates manufacturers' ability to prevent and identify duplicate discounts. And a growing number of states—including Massachusetts—have proposed legislation that would prohibit the use of modifiers for the identification of 340B claims in the absence of a federal mandate, undercutting the imperative for transparency.[5]

For these reasons, CMS must actively implement the 340B nonduplication provision by requiring POS identification of 340B claims. CMS can achieve this by imposing requirements on Part D plans regarding the types of claims that they may adjudicate. Specifically, CMS could designate the lack of a 340B claims modifier as a "defect" that prevents the claim from being a "clean claim" subject to the prompt payment standard.

IV. CMS Should Evaluate the IRA's Impact on the Innovation Ecosystem in Massachusetts.

We continue to urge CMS to carefully examine the impact of the law in Massachusetts. In light of Massachusetts' unique role as the hub of companies directly engaged in research, development, and manufacturing of innovative products, Massachusetts will be a "canary in the coal mine" in terms of changes to the system, and will thus be a good test case to see how IRA implementation affects the biotech industry.

As noted in prior comments above, in early 2023, MassBio surveyed its membership regarding the IRA's immediate impacts, and member perspectives regarding certain regulatory and legislative policies that could mitigate those impacts. MassBio plans to continue to survey our membership and perform other data-driven approaches to monitor the impact of the law, and we hope to have the opportunity be a resource for CMS as it begins to track the impact of the IRA. Likewise, as CMS proceeds with implementation of the law, MassBio urges the agency to similarly prioritize building the necessary infrastructure to track the impact of the IRA on the innovation ecosystem. This will be vital given the long-standing relationship between innovation and increased access to life-saving therapies, and the need for the agency to "do no harm" in the implementation of this new program. For instance, CMS could track the following metrics, using CMS's own data and certain data available from the FDA, to assess the IRA's impact over time:

- Number of new technology add-on payment applications for drugs and biologicals;

[5] States May Consider 340B Legislative Proposals in 2024, Avalere (December 1, 2023), https://avalere.com/insights/states-may-consider-340b-legislative-proposals-in-2024.

- Requests for pass-through status under the Hospital Outpatient Prospective Payment System;
- Number of new NDCs in average sales price (ASP) reporting data;
- Number of NDA/BLA submissions (tracking proportion of small-molecule vs. large-molecule over time);
- Number of supplemental NDA/BLA submissions;
- Number of applications for orphan drug designation (ODD);
- Percent of products with an ODD that are approved by FDA;
- Number of applications for breakthrough therapy designation;
- Number of applications for fast-track designation; and
- Number of applications for regenerative medicine advanced therapy designation.

We further urge CMS to publicly report these data to inform both the public and policymakers in Congress, and to establish a dynamic framework pursuant to which significant decreases in the metrics captured above trigger reconsideration of the negotiation process implemented by the agency.

V. Conclusion

MassBio thanks CMS for your consideration of our comments. Please don't hesitate to contact me at (617)-674-5148 or kendalle.oconnell@massbio.org if you have any questions or would like any additional information to consider our comments.

Best regards,

Kendalle Burlin O'Connell, Esq.
CEO & President
Massachusetts Biotechnology Council

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

MCKESSON

July 2, 2024

Meena Seshamani, M.D., Ph.D.,
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Attn: Draft Guidance on the Medicare Drug Price Negotiation Program

Sent electronically via: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear. Dr. Seshamani,

On behalf of McKesson Corporation, thank you for the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS') draft guidance on the Medicare Drug Price Negotiation Program.

About McKesson

McKesson is a global leader in healthcare supply chain management solutions, retail pharmacy, community oncology and specialty care, and healthcare information technology solutions. McKesson partners with pharmaceutical manufacturers, providers, pharmacies, governments, and other organizations in healthcare to help provide the right medicines, medical products, and healthcare services to the right patients at the right time, safely and cost-effectively. As a mission-driven company, we are focused on working with our customers and partners to advance health outcomes for *all*.

Our unique 360-degree view of the healthcare system offers a distinctive vantage point. McKesson monitors and engages in regulatory activities that present both opportunities and challenges for the company, its customers, and the patients they serve. McKesson strives to ensure that its views on improving healthcare prioritize what is best for the patient.

General Comments

McKesson appreciates CMS' commitment to implementing the Inflation Reduction Act (IRA) program in a manner that is "timely, uniform, and seamless," while minimizing disruption. We commend CMS on its consistent outreach, time and attention with industry stakeholders on operationalizing the Medicare Drug Price Negotiation Program (MDPNP) and the role of the Medicare Transaction Facilitator (MTF). CMS' most recent

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

draft guidance and reliance on the Prescription Drug Event (PDE) data to effectuate the maximum fair price (MFP) are, however, a departure from previous considerations and present several challenges not previously contemplated. Additionally, concurrent release of the MTF contractor solicitation adds complexity and confusion over the program's direction. We encourage CMS to finalize MTF operational details as soon as possible to allow supply chain stakeholders to develop and adopt the necessary solutions to minimize disruptions for patients and providers critical to implementing the MDPNP, especially independent community pharmacies. We summarize our key recommendations and concerns below.

CMS must expedite the MFP effectuation and reimbursement timeline or consider alternative models to reduce economic burden on pharmacies.

- McKesson urges CMS to consider a 2-day PDE submission requirement to prevent unnecessary payment delays across stakeholders**.** Introducing a new dependency on PDE data into the pharmacy reimbursement process results in a delay of timely payment to dispensers of MFP prescriptions. As proposed pharmacies may be forced to wait 21 – 60+ days before receiving the MFP refund. This will pose a significant cash flow challenge for pharmacies, especially independent community providers. Pharmacies should not be on the hook to prefund the MDPNP and should continue to be paid within the established 14-day timeline.
- McKesson recommends CMS consider opportunities to reduce economic burdens on independent community pharmacies. We recognize adopting an alternative MTF effectuation approach (e.g., real-time, non-PDE dependent) may no longer be perceived as feasible due to time constraints. However, CMS should consider options to provide financial support (e.g., advanced payments) to independent community pharmacies, who are not well positioned to absorb the magnitude of cash flow disruptions expected in the MDPNP.

CMS should standardize MDPNP operations to reduce ambiguity and provide supply chain stakeholders the predictability and stability necessary for the program's success.

- CMS should finalize its proposal to provide Primary Manufacturers with a Standard Default Refund Amount that would reflect the difference between a drug's wholesale acquisition cost (WAC) and MFP. McKesson believes standardization is key, and we agree with CMS that this best approximates the acquisition cost of pharmacies and offers a reliable refund amount for both manufacturers and pharmacies. CMS should ensure alternatives are reasonable and provide necessary oversight to ensure that MFP is made available in a reasonable manner that does not add complexity or increase provider burden.
- McKesson urges CMS to provide guidance on 340B non-duplication processes within the MDPNP to ensure consistency across both programs. McKesson remains concerned that lack of guidance as to the 340B program creates

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

confusion and limits industry from advancing necessary solutions to deduplicate discounts between 340B ceiling price and MFP, despite the inclusion of 340B-specific data elements in the proposed MTF data exchange capabilities. It is also critical that CMS does not disrupt current 340B processes, especially prospective application of 340B ceiling price. We caution CMS against shifting the 340B program to a credit or rebate model as this will cause significant supply chain disruptions and negatively impact cash flow for both Covered Entities and their Contract Pharmacies.

- CMS must establish a robust dispute resolution process, inclusive of 340B non-duplication. The broader Complaints and Disputes process outlined in the guidance does not provide sufficient assurance for stakeholders, especially pharmacies. There is no swift pathway for recourse in instances where the dispensing entity believes the MFP refund is inaccurate. Unique challenges of 340B non-duplication should be handled in partnership with the Health Resources and Services Administration (HRSA) to ensure consistency and reduce burden on covered entities and manufacturers.

CMS should finalize operational responsibilities of the MTF and finalize guidance on payment facilitation to ensure supply chain stakeholders have adequate time to develop, test, and adopt necessary solutions.

- CMS should finalize the retrospective approach and plan for potential prospective options in later years. Retrospective payments offer greater assurance of efficiency, standardization, and predictability in the execution of high volume, continuous payments. While the draft guidance also acknowledges the potential for prospective discounts, we believe its success is not workable for 2026 and would likely lead to unintended consequences and disruptions for dispensers, manufacturers, the MTF, and CMS.
- CMS should adopt a standardized implementation approach with a single payment facilitator across all manufacturers which would enable a central payment and reconciliation service to operate accurately and reliably for pharmacy customers. We strongly believe that payment facilitation and data exchange capabilities must be integrated within existing electronic workflows wherever possible. The MTF must be responsible for all necessary data exchanges (e.g., 835 remittance), auditing and traceability.

We remain committed to being a thought partner to CMS and provide more detailed comments below.

Detailed Comments

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6535 State Hwy 161
Irving, TX 75039

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Rich Buckley
Senior Vice President, Public Affairs

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- **§40.4.1 – Medicare Transaction Facilitator Data Facilitation**
- **§40.4.2. - Non-duplication of 340B Ceiling Price**
- **§40.4.3 - Retrospective Refund Amount to Effectuate the MFP**
- **§40.4 - Providing Access to the MFP in 2026 and 2027**
- **§40.4.4 - Options for Medicare Transaction Facilitator Payment Facilitation**
- **§40.4.5. - Medicare Transaction Facilitator Dispensing Entity Participation Requirements**
- **§40.5 – Compliance with Administrative Actions and Monitoring of Drug Price Negotiation Program**
- **§90.2.2 Negotiation Program Complaints and Disputes**

§40.4.1 – Medicare Transaction Facilitator Data Facilitation

We appreciate that CMS has proposed that Primary Manufacturers will be required to register with the MTF, including agreements that include privacy and security requirements, along with a commitment to provide an outlined set of transaction-level data for paid, Part D MTF claims to the MTF, as described in Table 2, and support data elements outlined in the draft guidance.

While we also agree that it is important for Primary Manufacturers to report to the MTF how the MFP was made available to dispensing entities, we have significant concerns that CMS' proposal to make MTF payment facilitation voluntary for dispensing entities and manufacturers paves the way for significant unintended consequences. McKesson continues to recommend a standardized implementation approach with a single payment facilitator and/or process across all manufacturers which enables a central payment and reconciliation service to operate accurately and reliably for pharmacy customers. We strongly believe that payment facilitation and data exchange capabilities must be integrated with existing electronic workflows wherever possible, given extremely condensed timeframes, and stress the importance of audit traceability requirements that all stakeholders, including CMS should want.

McKesson recommends the MTF generate electronic remittance advice to the dispensing entity for purposes of reconciling manufacturer retrospective refunds, given the complexities of these transactions. Furthermore, the MTF must have significant experience in generating remittance advice to prevent delays to dispensing entities. Additionally, the information provided by the MTF should be at the claim level so that pharmacies may properly reconcile the refund payment. We urge CMS to provide a clear understanding of requirements regarding fields needed on a refund type of remittance.

§40.4.2. - Non-duplication of 340B Ceiling Price

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6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

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McKesson remains concerned that lack of guidance regarding the 340B program creates confusion and limits industry from advancing necessary solutions to deduplicate discounts between 340B ceiling price and MFP. We appreciate that CMS intends to provide Primary Manufacturers a process to identify applicable 340B-eligible claims through the reporting of payment elements to the MTF. However, we recognize that standard 340B determination timelines may limit reporting of this information on the pharmacy claim at the point of sale (POS).

Given that very few 340B drugs are identified by pharmacies at the POS, CMS, the MTF, and consequently manufacturers will struggle to reconcile transactions without the assistance of a specialized tool or a vendor capable of adjustments for future refunds. We strongly encourage CMS to leverage the skill sets of entities experienced in resolving duplication issues. We continue to believe that MTF functionalities should roll up to a single entity handling data, payments, and 340B reconciliation to ensure a seamless experience for the supply chain and patients on upon initiation of the program.

Additionally, we encourage CMS to implement a formal Dispute Resolution process specifically for 340B duplication matters, which is separate and distinct from HRSA, as the volume of disputes could overwhelm the program, especially if the MTF entity lacks experience in timely resolution of 340B duplicate issues.

We understand that as an interim solution for Part D drugs, CMS proposes that beginning January 1, 2025, the Submission Clarification Code value of “20” and the Submission Type Code with the value of “AA” will be added to the PDE Record to indicate a 340B claim. As noted above, pharmacies may be unable to make the necessary determinations at the POS, therefore, limiting submission of these codes in a timely manner.

Other proposals in the guidance suggest that retroactively identified duplicate discounts should be reconciled by not replenishing 340B stock or only extending the difference between 340B and MFP on the replenishment order. This approach misunderstands the process by which 340B qualification is made and the extent to which manufacturers are involved in this process. By the time the 340B chargeback data is transmitted to a manufacturer, the stock has already been replenished at the discounted 340B price by a wholesaler, based on a covered entity’s 340B qualification process.

Wholesalers do not have insight into covered entity 340B qualification processes and cannot maintain prospective 340B scrubbing capabilities on behalf of manufacturers to ensure no duplicate 340B stock is replenished. Allowing manufacturers to reject a script for replenishment after the order has already been fulfilled would place undue responsibility and financial harm on wholesalers.

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

Rich Buckley
Senior Vice President, Public Affairs

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Further, 340B duplication is not the only scenario where an MFP refund may have been incorrectly paid. Therefore, McKesson urges CMS to clarify that retroactively identified invalid MFP refunds may be netted out of future period pharmacy payments, for example where a claim is adjudicated by the payer but never picked up by the patient. We encourage CMS make available to stakeholders, additional scenarios likely to occur in relation to retroactive 340B determinations and other corrections to ensure transaction-level clarity on the disposition and activities associated with a prescription for complaints, disputes, and audit processes.

Finally, in the context of the IRA, should HHS collectively ignore the 340B reconciliation issue altogether, it may unintentionally induce the supply chain into a backend credit/rebate model that will result in greater fragmentation and duplication within financial flows that will be nearly impossible for all stakeholders, including the government, to reconcile and audit. Moreover, such a model is likely to have the biggest financial impact to covered entities and pharmacies that are already struggling to keep their doors open.

§40.4.3 Retrospective Refund Amount to Effectuate the MFP

CMS proposes to provide Primary Manufacturers with a Standard Default Refund Amount that would reflect the difference between a drug's WAC and MFP. McKesson believes standardization is key, and we agree with CMS that this best approximates the acquisition cost of pharmacies and offers a reliable refund amount for both manufacturers and pharmacies. We agree that the Standard Default Refund Amount should be calculated based on WAC as published in pharmaceutical pricing database compendia on the date of dispensing but should be revisited as the program grows to include Part B drugs. We believe there is both operational and financial risk to pharmacies when it comes to negotiation alternative MFP refund methodologies between manufacturers and pharmacy.

§40.4 - Providing Access to the MFP in 2026 and 2027

McKesson understands that CMS is soliciting input on two options for manufacturers to provide access to the MFP. Given the level of complexity in the implementation of this program, retrospective reimbursement to dispensing entities for the difference between the pharmacy's acquisition cost and the MFP is the most workable solution. Retrospective payments offer greater assurance of efficiency, standardization, and predictability in the execution of high volume, continuous payments. Nonetheless, stakeholders, CMS, and the MTF will still need to determine how best to reconcile refund issues that will inevitability arise with 340B eligible drugs that are unknown at the POS.

Introducing a new dependency on PDE data into the pharmacy reimbursement process results in a delay of timely reimbursement to dispensers for MFP prescriptions. CMS'

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

guidance indicates the current 30-day window for Part D plans to submit PDE records is under consideration to be shortened to seven days, to ensure dispensing entities receive timely payment of MTF funds.

While a 7-day window is a significant reduction from the current 30-day window, McKesson urges CMS to consider a 2-day window to prevent unnecessary delays across stakeholders. We also recognize the value of the PDE file for all stakeholders concerning data validation, eligibility, and reimbursement of the MFP. We appreciate the tremendous resources required to increase the frequency of PDE submissions by plan sponsors and the CMS PDE processing contractor, as well as the increase in PDE transaction volume due to significantly more reversals and resubmissions. However, if CMS pursues this approach, we recommend CMS undertake the necessary efforts to ensure pharmacies are reimbursed according to the 14-day prompt pay window from date of dispense, which includes shortening the relevant window of time to 2 days.

The draft guidance also acknowledges the potential for prospective discounts; however, we believe that approach is not workable and would likely lead to unintended consequences and disruptions for dispensers, manufacturers, the MTF, and CMS.

§40.4.4 - Options for Medicare Transaction Facilitator Payment Facilitation

CMS has expressed concern of ambiguity in the statute around an “expressed role (within CMS) to support Primary Manufacturer effectuation of the MFP.” Consequently, CMS has opted to propose a potential voluntary role for the MTF in facilitating payment transactions between Primary Manufacturers and dispensing entities. McKesson is unsure about the feasibility of either payment facilitation option being implemented by 2026.

Many historical healthcare programs passed by Congress did not contain every detail needed for successful implementation. There are numerous examples from the Affordable Care Act, and subsequent regulatory and congressional changes that have made CMS’ authority more explicit. Given this context, we urge CMS to consider the risks posed by Option 1, given the extremely condensed timelines and current constructs of the commercial supply chain. It is neither feasible nor realistic, as manufacturers are not equipped to process payments to individual pharmacies. Therefore, we urge the agency to focus on Option 2 or a similarly streamlined approach that would involve a single payment facilitation entity and/or process, which again, should include the experience and capacity to address 340B duplication issues.

It is imperative that such a solution be highly synchronized with data facilitation processes to ensure Primary Manufacturers, pharmacies, and CMS can maintain auditable compliance processes. Multiple payment facilitation processes would introduce significant complexity, operational burdens, and inefficiency into an already complicated supply chain. Similarly, asking retail pharmacies to create new payment

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

Rich Buckley
Senior Vice President, Public Affairs

www.mckesson.com

mechanisms outside of existing workflows today is simply not possible for many pharmacies within the proposed timeline. We urge CMS to provide leadership on this issue so that supply chain stakeholders aren't put in the position of having to create workaround solutions for their customers.

McKesson urges CMS to require that MFP payment facilitation be handled by a single entity capable of aggregating data across all Primary Manufacturers and providing assurance regarding its ability to process utilization data and payments on a predetermined cadence. Additionally, any payment solution should have electronic connectivity to all pharmacies through existing electronic data interchange (EDI) workflows to help ensure the program's successful operations across the 60,000 pharmacies nationwide.

If CMS chooses to offer multiple payment facilitation options for pharmacies and Primary Manufacturers, it is critical to provide clear guidance and soon, on how to reconcile scenarios involving Primary Manufacturers and pharmacies that elect different payment processes. This issue will only be exacerbated as the program expands.

§40.4.5. – Medicare Transaction Facilitator Dispensing Entity Participation Requirements

CMS indicates that the Primary Manufacturer and pharmacy each may choose not to utilize the MTF for facilitation of retrospective refund payments. Again, as stated above, we urge CMS to reconsider this approach and to require Primary Manufacturers and dispensing entities to utilize a single entity and/or process for facilitation of retrospective refund payments. Otherwise, pharmacies could be forced to establish financial relationships with multiple manufacturers, creating unnecessary burdens that could render the process infeasible for many pharmacies. We urge CMS to minimize the choices, to ensure successful implementation on day-one of the program.

§40.5 – Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program

While CMS has indicated its plans to implement a robust program for monitoring compliance and auditing the data processes to verify the accuracy and completeness of any information provided by the Primary Manufacturer, we believe that CMS should also monitor compliance and verify that all Medicare Part D processors, including pharmacy benefit managers (PBMs), CMS' contractor-managed systems like the Drug Data Processing System (DDPS), and the MTF have the necessary data processes in place for audit and traceability purposes. These entities should be required to demonstrate that their technical infrastructure meets all requirements prior to implementation; CMS should require an official certification process. The proper implementation by these entities is vital for ensuring the accuracy and timeliness of payment to pharmacies.

McKesson Corporation
6535 State Hwy 161
Irving, TX 75039

www.mckesson.com

Rich Buckley
Senior Vice President, Public Affairs

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§90.2.2 Negotiation Program Complaints and Disputes

McKesson believes it will be critical for the MTF to have the capacity to reconcile issues with effectuation of the MFP, should they occur, and CMS needs to be explicit in its guidance to all stakeholders in its oversight mechanisms, including the timelines for notifying impacted entities. Given that the MTF will be a new entity implementing new procedures and processes, we urge CMS to develop a detailed plan for oversight, evaluation and remediation of payment and reconciliation issues that may arise under the new MTF program.

Other Areas of Consideration

While McKesson appreciates the extremely condensed timeline to establish and operationalize the IRA program, it is imperative that the MTF and any entities and or databases supporting the facilitation of the MFP program undergo CMS' Target Lifecycle Review process.[1] This includes supplying the necessary business artifacts, requirements (i.e., detailed user stories or functional specifications of the desired solution, design documents, testing, section 508 requirements, Operations & Maintenance (O&M) to be reviewed with CMS' IT Governance team, and must successfully complete testing and should be granted from CMS' Chief Information Security Officer (CISO) an Authority to Operate). This is especially important to assure all stakeholders that the MTF system complies with Information Security and Privacy requirements and has successfully passed user acceptance and accessibility testing.

Conclusion

McKesson appreciates the opportunity to provide feedback and we welcome the opportunity to be an ongoing thought partner as you implement this important program for patients. Please let us know how we can be of further assistance. Should you have any questions, please feel free to contact Fauzea Hussain, Vice President, Public Policy, Corporate Public Affairs at Fauzea.Hussain@mckesson.com or 571.567.6978.

Sincerely,

Rich Buckley
Senior Vice President, Corporate Public Affairs

[1] cms-tlc-guidance-document-2023.pdf

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

Submitted via IRARebateandNegotiation@cms.hhs.gov

RE: Comments regarding Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Brooks-LaSure:

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the draft guidance for the Medicare Drug Price Negotiation Program (MDPNP) for Initial Price Applicability Year (IPAY) 2027.[1]

MAPRx is a national coalition of more than 60 beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The coalition has championed policies in Part D that improve the affordability of medications and beneficiary access to those medications, including provisions of the Inflation Reduction Act (IRA) that establish an out-of-pocket cap in Part D and the Medicare Prescription Payment Plan. We are committed to ensuring that the implementation of these and other elements of the IRA, such as the MDPNP is informed by the experiences and needs of beneficiaries living with chronic diseases and conditions.

[1] Seshamani M. Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. Centers for Medicare & Medicaid Services. May 3, 2024. Accessed June 5, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Overview

The MAPRx coalition applauds CMS for working with us on the implementation of the IRA and we appreciate the Agency's efforts to engage the patient community and other stakeholders. We also appreciate this opportunity to provide feedback to the Agency on the draft guidance, but, as mentioned in our previous comments, encourage CMS to pursue an official Notice and Comment opportunity in the future. While we provide more detailed feedback on specific sections of the draft guidance later in these comments, we are encouraged by CMS' responses to comments for IPAY 2026 and for actively soliciting input from stakeholders on how to improve the negotiation process and, more specifically, to incorporate the perspectives of Medicare beneficiaries. As noted in our detailed comments, we urge CMS to implement specific patient-centric processes that: 1) inform Medicare negotiation and the value of medications; 2) solicit continuous input from stakeholders to identify real-world access and affordability challenges experienced by beneficiaries; 3) conduct rigorous oversight to mitigate problems and ensure those with chronic conditions have access to medications; and 4) actively monitor and publicly report changes and trends in Part D to allow CMS and all stakeholders to assess the impact of the MDPNP.

Many of our coalition member organizations were pleased to join representatives from CMS and other stakeholders in participating in the National Health Council's (NHC) January 2024 Roundtable discussion about improving patient engagement in CMS programs including the MDPNP and the listening sessions. We support the NHC's short and long-term recommendations that were included the March 2024 report, *Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement* and have noted several in these comments.

Specific Comments

Part D formulary inclusion of selected drugs (Sec. 110)

In our 2023 comments on the MDPNP and in additional comments related to IRA implementation, MAPRx has consistently emphasized the need for beneficiary protections that ensure patients have access to prescribed medications, including both negotiated and non-negotiated drugs. We are concerned that the MDPNP, in addition to other changes made by the IRA, may lead to increased utilization management, such as prior authorization and step therapy, as well as changes in formularies, tiering and cost sharing that create barriers to care. We are pleased that CMS recognizes these concerns and has indicated it will conduct formulary reviews and monitor Part D plans for these practices. However, given the potential for Part D plans to restrict access to medications, never before has CMS' role in protecting beneficiaries been more important. Therefore, we urge CMS to establish new safeguards and conduct continuous oversight to ensure that the negotiation process does not lead to unintended consequences that favor cost savings over patient care and disadvantage specific drugs or classes of drugs. This is especially needed because it is widely expected that Part D plans will increase use of prior authorization and step therapy or create new access barriers, which can lead to worse outcomes, decreased quality of life and increase overall costs.

To protect beneficiaries, CMS should establish and enforce clear guidelines that limit the excess and inappropriate use of these practices and create a system that continuously monitors not only changes in the use of these policies, but also their impacts on beneficiaries. Moreover, we recommend that CMS create a structured process that facilitates beneficiary and patient organization input on Part D formulary design and cost sharing, utilization management, and

appeals that would enable the Agency to better assess the impacts of the MDPNP and adjust policies as needed to preserve beneficiary access to appropriate care.

Patient engagement in negotiation process (Sec. 60.4)

MAPRx appreciates the Agency's willingness to explore approaches that enhance patient engagement throughout the negotiation process, including the patient listening sessions. In this section of our comments, we use patient engagement to refer to the patient listening sessions and other patient focused methods CMS may create to obtain beneficiary input. We support the recommendations outlined in the NHC's report from their Roundtable discussion that are referenced earlier in these comments and are pleased that the Agency is considering revised session formats (e.g., roundtable sessions) and speaker types (e.g., patients, caregivers, providers, health data experts) among other changes to the listening sessions. We offer the following suggestions to improve patient engagement for IPAY 2027, facilitate meaningful engagement between CMS and the beneficiary community and enable beneficiaries to more effectively inform the negotiation process.

- **Types of Information.** CMS should communicate to stakeholders the type of information that it seeks as it engages the beneficiary community via patient listening sessions or other mechanisms. This can include listing specific types of information or sharing more general categories of information related to a drug, therapeutic alternatives, the disease, unmet need, side effects, quality of life, clinical outcomes or other information related to patient experiences and preferences. This will help participants prepare for these opportunities, deliver input more efficiently and succinctly and provide input and insights most relevant to CMS. Moreover, it will help beneficiaries articulate what matters most to them.

- **How Information is Used**: CMS should communicate the objectives and goals of the patient engagement opportunities, including how and whether information shared by beneficiaries is used throughout the negotiation process, including in the Explanation for the MFP that is published by CMS and described in Sec. 60.6.1. This is critically important to assure stakeholders that their input is meaningful. It can build trust and incentivize greater, more diverse and more representative participation.

- **Format of Patient Engagement**: CMS should provide additional clarity to the stakeholder community in advance of patient engagement opportunities about the format of sessions, provide notice that allows beneficiaries and other stakeholders sufficient time to prepare to participate in these sessions, and provide sufficient time (at least 5 minutes) for participants to communicate their experiences to CMS. This can be accomplished through educational webinars or by sharing other information about the structure of engagement opportunities in addition to the types of information that is sought and how that information will be used. This additional communication not only can help ensure participants are better prepared, but also more comfortable and confident in sharing information. Moreover, this additional information, combined with sufficient lead time, can enable beneficiary communities and other stakeholders to disseminate patient engagement opportunities and help ensure more diverse and representative participation. It also can enable organizations to conduct surveys or other outreach to collect additional information of relevance to the sessions.

- **Multiple Methods of Patient Engagement:** We encourage CMS to explore multiple

different methods of obtaining beneficiary input, such as through smaller group sessions, roundtable discussions, focus groups or allowing participants to submit information following a patient engagement session. These additional approaches may allow for bi-directional conversations between CMS and participants, which can enhance information collected through other mechanisms and enable CMS to obtain additional and more specific information that is relevant to the negotiation process. In addition, these different approaches can enable the Agency to seek information from more targeted audiences and thus help ensure input to the Agency captures the heterogeneity of disease populations and different experiences, needs and preferences. Along these lines, it is important that CMS explore other methods to engage patients and provide accommodations to those who may not be able to participate in live patient engagement sessions due to employment, school or childcare commitments, privacy concerns, disability or health status, language barriers, lack of access to technology or other barriers that often can prevent diverse populations from engaging and thereby limit representative input. This could be done through written or recorded statements, translation services or other methods.

- **Participants and Selection of Participants:** CMS should communicate the process for selecting participants and allow patient organizations and other stakeholders the opportunity to provide input on the selection process to help ensure participation is diverse and representative. It is equally important for CMS to clearly communicate which stakeholders, in addition to patients, are invited to participate in patient engagement opportunities. MAPRx believes it is critical that CMS allow for a variety of stakeholder inputs, including from caregivers and family members, clinicians and others, which helps to provide a clearer understanding of the various perspectives within a community. MAPRx recommends that when identifying stakeholder audiences, CMS distinguish between a "patient" (an individual living with a disease or condition) or patient advocate (an individual or organization representing those living with a disease or condition) and a consumer (an individual or organization other than a caregiver, not living with disease or condition) or consumer advocate.

Explanation for the MFP (Sec. 60.6.1)

As noted in our comments on Sec 60.4, MAPRx believes it is critical that CMS communicate how and whether information shared by beneficiaries' is used throughout the negotiation process. This is perhaps most important when CMS publishes explanations for the MFP. This can assure beneficiaries that their input is meaningful. It can build trust and incentivize greater, more diverse and more representative participation.

Information collection request (ICR) Process. MAPRx supports CMS' efforts to collect additional information and data from the beneficiary community and other stakeholders, including information about patient experience living with a disease or condition treated by a selected drug or therapeutic alternative. However, it is critical that CMS provide more guidance and instruction about the process to enable patient organizations to submit relevant data. As we stated earlier regarding patient engagement sessions, MAPRx encourages CMS to specify what information is needed and how it will be used, which will help patient organizations collect and submit data that more effectively inform the negotiation process. We also request that CMS provide for a longer time period within which to submit data, which also will further enhance representative patient input in the negotiations process and enable organizations to collect data, including new data that is aligned with CMS' needs.

Excluding the utilization of Quality-Adjusted Life-Years in the negotiation process
MAPRx is pleased that CMS has explicitly stated that it will not use the quality adjusted life year (QALY) metric in the negotiation process. As we mentioned in our 2023 comments, any evidence that values extending the life of some individuals less than extending the life of other individuals based on disability status or age is completely inappropriate. All patients deserve to be treated equally, and thus we laud CMS' adherence to the statute and decision to separate out and exclude QALY metrics from evaluations of research that otherwise factor in QALYs. However, we remain concerned that CMS may not effectively eliminate QALYs from analysis, or that CMS may over-exclude analyses that are otherwise helpful in establishing the value of a drug. We request that CMS offer more clarity into exactly how the agency will exclude QALY-based metrics from analysis of certain evidence. We also request that CMS highlight when and how the agency removes QALY-based metrics from consideration in MFP justification documentation. Unless CMS outlines a rigorous process for how the Agency will consider evidence stemming from the use of QALY so as to not discriminate against individuals who are elderly, disabled, or terminally ill, such evidence could be inadvertently used in a manner that would disadvantage these populations.

Conclusion

The MAPRx coalition strongly encourages CMS to partner with patient advocacy organizations as it works to strengthen patient engagement throughout the negotiation process. Patient organizations are well positioned to articulate beneficiary needs, experiences and preferences, identify individuals to participate in patient engagement opportunities and collect and submit patient-centric data that not only is relevant to a selected drug or therapeutic alternative, but also is representative of a disease population. We commend CMS for its willingness to improve how the beneficiary perspective can inform the MDPNP.

Thank you for your consideration of our comments on draft guidance for the MDPNP for IPAY 2027. MAPRx welcomes opportunities to continue to work with CMS to ensure Medicare beneficiaries have access to quality and affordable care in Part D. For questions related to MAPRx or our comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

MAPRx Coalition

Robert Filippone
Vice President
U.S. Policy and Government Relations

July 2, 2024

601 Pennsylvania Avenue, NW
North Building, Suite #1200
Washington, DC 20004
T: 202-508-4559
robert.filippone@merck.com

www.merck.com

BY ELECTRONIC FILING
(IRA RebateandNegotiation@cms.hhs.gov)

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co. Inc., Rahway, NJ, U.S.A. (collectively, "Merck"), is writing to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) draft guidance on the Medicare Drug Price Negotiation Program (the Program), including draft guidance on manufacturer effectuation of the maximum fair price (MFP) for initial price applicability years (IPAYs) 2026 and 2027 (the Draft Guidance).[1]

Merck is a global research-based pharmaceutical and health care company. Through a combination of the best science and state-of-the art clinical development, Merck has produced many important medicines and vaccines. Today, the company is actively developing a broad portfolio of small molecules, vaccines, and biologic products, with the goal of improving worldwide patient access to important and life-saving therapies. Merck firmly believes that the Program is unconstitutional. Specifically, the Program coerces manufacturers under threat of severe penalties to "negotiate" and "agree" to "fair" prices, in violation of the First and Fifth

[1] CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

Amendments. If, however, manufacturers are required to participate in this unconstitutional price-setting program and provide access to the government-set price, CMS must administer the program in a way that ensures the integrity and operational feasibility of MFP effectuation.

Merck generally supports the comments of our trade associations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). As one of the manufacturers with a selected drug for IPAY 2026, Merck is deeply concerned about the feasibility of the proposed MFP effectuation and writes separately to address certain key issues related to effectuating the MFP for Part D selected drugs. Our comments are summarized as follows:

- Dispenser participation in the manufacturer's effectuation plan should be mandatory. If a manufacturer chooses to use the CMS Medicare Transaction Facilitator (MTF) or an alternate method submitted to CMS for a selected drug, dispensers must be required to access the MFP for such drug through the manufacturer's selected method. Dispensers should not be able to require alternative MFP effectuation options.
- The retrospective refund amount should be capped at wholesale acquisition cost (WAC) minus MFP. To ensure the integrity of MFP effectuation and mitigate supply chain incentives to inflate the MFP discount amount by increasing the acquisition cost, the retrospective refund amount that CMS requires manufacturers to provide to dispensers should be the lesser of the WAC minus MFP, or actual acquisition cost minus MFP. In no event should a manufacturer be required to increase the MFP retrospective refund to account for third-party fees or other costs that may increase dispenser acquisition cost above WAC.
- CMS must facilitate 340B nonduplication to enable statutory compliance. The Program statute requires manufacturers to make available the lesser of MFP or the 340B price for a selected drug, but not both. CMS has both the authority to implement the 340B nonduplication requirement and the obligation to help facilitate the statutory intent. CMS should do so by requiring dispensers to use a claim-level 340B modifier. Alternatively, if CMS is unwilling to do so, CMS and the Health Resources and Services Administration (HRSA) should jointly state that dispensers must provide manufacturers with claim-level data for selected drugs for which an MFP is in effect to enable manufacturers to implement the statutory nonduplication requirement.
- The 14-day payment window should be extended. MFP effectuation by manufacturers is new, complex, and operationally challenging. CMS should lengthen the proposed 14-day prompt MFP payment window for manufacturers to provide dispensers with the MFP retrospective refund to a timeframe more consistent with other government programs.

Additionally, while outside the scope of the current Draft Guidance, we note that many of CMS's proposals would raise substantial challenges for Part B drugs if CMS implements a similar MFP effectuation process once Part B drugs are eligible for selection.

Manufacturers May "Provide Access" to the MFP Using a Single Method, and That Method Should be Mandatory for Dispensers

CMS is evaluating options for the MTF to facilitate MFP discount payments from Primary Manufacturers to dispensers of selected drugs.[2] Merck strongly supports Option Two, which "would involve the MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating dispensing entities."[3] CMS, however, proposes that "any potential payment facilitation functionality of the MTF would be *voluntary* for dispensing entities and Primary Manufacturers."[4] The guidance explains that

> [i]n the event one or both parties choose not to utilize the MTF payment functionality..., then any MFP refund payments by the Primary Manufacturer to the dispensing entity would be provided outside of the MTF through a process agreed to by the Primary Manufacturer and the dispensing entity. Thus, there likely would still be some contracting between Primary Manufacturers and dispensing entities outside of the MTF for payment.[5]

The statute provides that "access to the [MFP]…shall be provided by the manufacturer."[6] Thus, the obligation to provide access to the MFP falls on the manufacturer, and manufacturers should be able to choose how to carry out this obligation in a reasonable manner. CMS proposes requiring manufacturers to submit their MFP effectuation plans seven months before the MFP goes into effect. During this time, the agency would have an opportunity to review the plan. If a manufacturer uses the CMS Medicare Transaction Facilitator – a CMS administered functionality – or an alternate MFP effectuation plan submitted by the manufacturer to CMS for a selected drug, CMS should find that a manufacturer will have met its statutory obligation to provide access to the MFP, so long as it does so in accordance with its submitted plan.

Merck requests greater clarity as to the process CMS will follow upon receipt of a manufacturer's MFP effectuation plan, including whether CMS will formally approve the plan or otherwise inform the manufacturer that CMS has no objection to the plan. At a minimum, CMS should announce a timeframe sufficiently in advance of required effectuation by which a manufacturer can have certainty that it may proceed with its submitted plan.

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[2] Draft Guidance § 40.4.1, 40.4.4.
[3] Draft Guidance § 40.4.4.
[4] *Id.* (emphasis added).
[5] *Id.*
[6] Social Security Act (SSA) §1193(a)(3).

Merck strongly disagrees with the Draft Guidance's suggestion that individual dispensers could choose to reject a manufacturer's plan and demand that the MFP be effectuated in a different manner. It would be extremely burdensome – if it is even possible – for a manufacturer to develop separate MFP effectuation processes for each of the up to 70,000 pharmacies that bill Part D.[7] It simply is not feasible to expect manufacturers of selected drugs to contract with thousands of individual dispensers on MFP effectuation.

Manufacturers must be able to satisfy their obligation to make the MFP available for a selected drug through a uniform MFP payment approach and dispensers must be required to participate in the manufacturer process to gain access to the MFP. Allowing dispensers to opt out and dictate their own terms would be infeasible for a single manufacturer and unsustainable for the system as the number of selected drugs and manufacturers grow. In addition, Merck is concerned that manufacturers could be placed in an untenable position of being forced to accede to a dispenser's terms (including fees imposed), even if patently unreasonable, to meet their obligation to provide the dispenser with access to the MFP. Such additional payments to dispensers, or their middlemen, were not contemplated by the statute.

The MFP Retrospective Refund Amount Should be the Lesser of WAC Minus MFP or Acquisition Cost Minus MFP

Under the Draft Guidance, the MTF would provide manufacturers with the Standard Default Refund Amount, which would be "the difference between the selected drug's WAC and MFP."[8] Merck has significant concerns about CMS's position that "the Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug."[9] CMS states that:

> [i]n this case, payment of the Standard Default Refund Amount would not be sufficient to make the MFP available to the dispensing entity consistent with the Primary Manufacturer's obligation under section 1193(a)(3) of the Act. The Primary Manufacturer could address these circumstances by making MFP refund payments that reflect the dispensing entity's higher acquisition costs for the claims.[10]

Merck believes CMS's proposal could create incentives for supply chain entities to artificially inflate the MFP discount amount, including potentially through fees and other arrangements that do not involve the manufacturer (and about which the manufacturer may lack

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[7] OIG, *Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D*, OEI-02-15-00440, at 10 (Mar. 2020), https://oig.hhs.gov/oei/reports/oei-02-15-00440.pdf. We believe that it would be even more challenging if future guidance on Part B selected drugs permits providers to reject a manufacturer's plan, given that over 1.4 million providers are enrolled in Part B. CMS, CMS Fast Facts, at 9 (Mar. 2024), https://data.cms.gov/sites/default/files/2024-03/CMSFastFactsMar2024_508.pdf.

[8] Draft Guidance § 40.4.3.

[9] *Id.*

[10] *Id.*

knowledge), but on its surface appear to increase the acquisition cost above WAC. The statute requires manufacturers to provide access to the MFP – not more.[11] Recognizing the multitude of dispensers' acquisition costs for a given drug (which may be below or above WAC), the refund amount that CMS requires manufacturers to provide to dispensers should be the lesser of: (1) WAC minus MFP, or (2) actual acquisition cost minus MFP. This would ensure integrity in the MFP effectuation process and mitigate the potential for abusive practices and incentives for supply chain entities to manipulate the MFP discount amount. Alternatively, if CMS requires manufacturers to increase the MFP refund if a dispenser's acquisition cost exceeds WAC, then the increase in the manufacturer's refund should be limited to the circumstance where the manufacturer is the entity that has charged dispensers in excess of WAC. In no case should a manufacturer be required to increase the MFP refund to offset fees or other costs charged to a dispenser by a third-party.

CMS Should Take Additional Steps to Prevent 340B/MFP Duplicate Discounts

CMS explains in the Draft Guidance that the Agency "will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP."[12] CMS asserts that the Agency "is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim."[13]

Merck disagrees with CMS's position. Section 1196 of the SSA requires CMS to administer the Program, including effectuation of the MFP. The 340B nonduplication requirement is a central part of MFP effectuation because no MFP discount is required if the 340B ceiling price is lower than the MFP. Accordingly, since CMS must administer the MFP effectuation process, CMS has the authority to implement the 340B nonduplication requirement and the obligation to help facilitate the statutory intent.

Additionally, given that the Government Accountability Office (GAO) and the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) have attributed 340B/Medicaid duplicate discount violations, in part, to "[l]imitations in federal oversight," it is important that CMS take a more active role in the de-duplication of 340B/MFP discounts.[14]

As an initial matter, CMS should *require* a claim-level 340B indicator to enable manufacturers to identify claims subject to 340B discounts. Although the Draft Guidance includes a proposal for a "voluntary" 340B identifier,[15] Merck does not believe that this will be

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[11] SSA § 1193(a)(3).
[12] Draft Guidance § 40.4.2.
[13] *Id.*
[14] GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212, at 27 (Jan. 2020), https://www.gao.gov/assets/gao-20-212.pdf (finding that "[l]imitations in federal oversight impede CMS's and HRSA's ability to ensure compliance with the prohibition on duplicate discounts"). *See also* OIG, State Efforts to Exclude 340B Drugs from Managed Care Rebates, at 16 (June 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.
[15] Draft Guidance § 40.4.1.

sufficient to enable manufacturers to identify 340B-eligible claims because studies show that, when 340B modifiers are voluntary, they are infrequently used.[16] Without a mandatory claim-level 340B modifier, and enforcement of its use, we are concerned that 340B/MFP duplicate discounts will not be able to be detected and avoided.

A mandatory 340B modifier would also align with HHS OIG and CMS's recommendations for preventing duplicate discounts in the Medicaid program. In a 2016 report, HHS OIG stated that CMS should "require States to use claim-level methods to identify 340B claims," which could include a 340B indicator, noting that this could "help States more accurately identify 340B claims, and thus reduce the risk of duplicate discounts."[17] And CMS responded to this recommendation by including a 340B claim-level modifier as one of its suggested "best practices" for States to prevent 340B/Medicaid duplicate discounts.[18]

In the absence of a mandatory 340B claim modifier, and enforcement of its use, it is unclear how manufacturers will be able to identify claims subject to the IRA's 340B nonduplication requirement. The Draft Guidance states that CMS "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price."[19] CMS "anticipates this will include utilizing data available from covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders to ensure the process is not unduly burdensome for dispensing entities, 340B covered entities, and patients."[20] CMS, however, does not explain how a manufacturer could identify whether a claim is 340B-eligible, and thus effectuate the statute's intended nonduplication, if a dispenser or other supply chain stakeholder declines to provide sufficient information in a timely manner.

Therefore, if CMS does not require a 340B claim modifier, Merck requests that CMS and HRSA jointly state that dispensers must provide manufacturers with claim-level data for all 340B-eligible utilization with respect to selected drugs for which an MFP is in effect.

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[16] IQVIA, *Can 340B Modifiers Avoid Duplicate Discounts in the IRA?* (Feb. 21, 2023), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf ("For Medicare Part B claims in 340B hospitals involving pass-through and separately payable drugs…when [340B modifier] reporting was optional, rates fell below 20%. For self-administered drugs across all payers, only 4% of branded, 340B-eligible pharmacy claims used a 340B modifier, rising to 50% for Medicaid claims at entity-owned pharmacies and falling to less than 1% at contract pharmacies.").

[17] OIG, State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates, OEI-05-14-00430, at 16 (June 2016), https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[18] CMS, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid, at 4-5 (Jan. 8, 2020), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_110.pdf.

[19] Draft Guidance § 40.4.2.

[20] *Id.*

CMS Should Lengthen the 14-Day Prompt MFP Payment Window

CMS states in the Draft Guidance that the "Primary Manufacturer's receipt of the claim-level data elements starts the 14-day prompt MFP payment window in which the Primary Manufacturer must provide access to the MFP…."[21] We are concerned that a 14-day prompt payment window will not provide enough time for manufacturers to verify MFP-eligibility. To determine whether an MFP retrospective rebate is required, a manufacturer must make a number of complicated determinations, including whether the unit is eligible for 340B discounts. And if a manufacturer determines that an MFP retrospective rebate is required, then the manufacturer must calculate the amount of the rebate. There may be a large number of daily claims for a selected drug, compounding the difficulty of providing access to the MFP within 14 days.[22]

MFP effectuation is new and highly complex. Manufacturers need more time before they are required to provide the MFP discount. CMS should look to other federal health care programs when determining the length of time that manufacturers have to provide access to the MFP. For example, the deadline for paying discounts under the Part D Coverage Gap Discount Program[23] and the new Part D Manufacturer Discount Program is 38 days after receipt of an invoice.[24] Similarly, the deadline for paying a rebate under the Medicaid Drug Rebate Program is 37 days after receipt of an invoice.[25] Manufacturers should have at least this amount of time to accurately determine whether a particular claim is eligible for an MFP discount, given the complexity of these requirements.

* * *

Merck appreciates the opportunity to comment on the Draft Guidance. Please feel free to contact us with any questions or if we may provide additional information.

Sincerely,

Robert Filippone

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[21] Draft Guidance § 40.4.3.

[22] Additionally, if CMS maintains the 14-day window after Part B drugs are subject to the Program, manufacturers would face even greater challenges, given the volume of claims and number of providers enrolled in Part B *See* CMS, CMS Fast Facts, at 9 (Mar. 2024), https://data.cms.gov/sites/default/files/2024-03/CMSFastFactsMar2024_508.pdf (showing that there were 1,484,780 Part B non-institutional providers in 2022).

[23] 42 C.F.R. § 423.2315(b)(3).

[24] CMS, Medicare Part D Manufacturer Discount Program Final Guidance § 80.1.1 (Nov. 17, 2023), https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.

[25] CMS, Interest Calculation for Late Rebate Payments, https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/interest-calculation-for-late-rebate-payments/index.html#:~:text=In%20accordance%20with%20section%201927,before%20interest%20begins%20to%20accrue.

June 25, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Baltimore, Maryland 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

The FasterCures team at the Milken Institute is honored to provide its expert response to the Request for Comments on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to solve urgent social and economic challenges to improve lives. At the heart of the Institute's work is the idea that societies prosper with an educated, healthy workforce, open and efficient capital markets, and effective social institutions. FasterCures is driven by a singular goal: to save lives by speeding scientific advancements to all patients. For the last 15 years, FasterCures has advanced patient engagement in biomedical research by bringing together diverse stakeholders to assess gaps, identify solutions, and develop the tools and resources to support decision-making. Over the past decade, considerable progress has been made toward integrating patient perspectives and input into biomedical research, as evidenced by the proliferation of legislation, regulatory guidance, and resources to expand patient-centric approaches.

The patient-centered approach in care, or person-centered care, is an established principle within the Centers for Medicare and Medicaid Services (CMS).[1] CMS realized the need to focus on patients' comprehensive, long-term needs for value-based care to work. The essence of such care is about providing tools and services to manage a person's whole health that aligns with patients' preferences and values.

CMS's authority and influence extend beyond coverage of care and quality assurance. The agency also plays a significant role in determining the coverage for medical products for the Medicare population, and its decisions often influence many private payers. Therefore, the person-centered approach should also extend to coverage decisions, and patient preferences regarding medical products should be greatly emphasized in the decision-making process.

FasterCures sees the implementation of the Medicare Drug Price Negotiation Program (MDPNP) as a critical opportunity to reflect on and expand CMS's person-centered approach. Therefore, we want to share several recommendations for integrating patients' experiences and perspectives to promote a sustainable, scientific approach to patient engagement in the future.

- Adapt best practices tested and developed by the Food and Drug Administration (FDA) and evolve them together to facilitate effective, meaningful, fit-for-purpose patient engagement to inform CMS's MDPNP.
- Develop official coordinating mechanisms with the FDA to integrate patients' preferences and experiences, which are reflected throughout the biomedical innovation ecosystem, from bench to bedside.
- Increase transparency on how the information gathered from engaging patients would inform the MDPNP processes and outcomes.
- Create a designated structure of patient engagement beyond the purview of the MDPNP that is integrated into coverage decisions for innovative medical products, such as those approved by the Accelerated Approval Pathway.
- Build staff capacity to coordinate consistent patient engagement programs for the MDPNP and other emerging technologies in medical products.

I. Scientific and Systemic Approaches to Patient Engagement

FasterCures applauds CMS's proposal to redesign patient-focused listening sessions in negotiating the price of the next round of drugs and biologics.[2] A well-prepared, coordinated, and interactive format of listening sessions will deepen the understanding of patient preferences, as patients may face direct impacts from the negotiation outcomes. Per CMS's request, we want to share recommendations to encourage the agency to create scientific and systemic patient engagement for the MDPNP.

First, CMS released its first information collection request (ICR) in April 2023 to interested companies, individuals, or organizations prior to negotiation to inform CMS of any pertinent information.[3] Under Section I—Evidence About Alternative Treatment, CMS intends to collect public input and evidence of therapeutic alternatives to the selected drugs. Questions 27 to 30 under Section I highlight the collection of patient experience, patient-reported outcomes, and patient-centered outcomes in addition to clinical outcomes. Question 31 focuses on gathering the experiences of patients and caregivers regarding the selected drugs and their therapeutic alternatives. Section I allows patients or organizations, in addition to manufacturers, to provide structured scientific and both qualitative and quantitative evidence on comparative effectiveness, which could inform drug price negotiation.

Within the ICR Section I's instruction, the agency states that it will review submitted cost-effectiveness studies and such measures "include but are not limited to quality-adjusted life-years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), and Health Years in Total (HYT)." QALY has been debated as a flawed methodology based on subjective value judgment. QALY also disadvantages the disabled, elderly, and people with chronic conditions; hence, any treatment that extends or improves their lives may score lower QALYs than the non-disabled and younger population.

Under the Inflation Reduction Act of 2022 (IRA), Sec 1194. (2) *Evidence about Alternative Treatments*, the agency is not permitted to determine the comparative effectiveness of the selected drug and its therapeutic alternatives "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[4] Therefore, Congress has essentially prohibited CMS from considering QALY for comparative effectiveness studies.

In addition, we believe that the ICR was not a proper format for gathering information from patients, patient organizations, and caregivers. The content requested in the ICR is quite technical, and most patient organizations we have spoken to have experienced difficulties responding properly. Patient groups often have significantly fewer resources and professional staff than the industry to respond quickly and robustly to requests for information and collect the appropriate data relevant to coverage and regulatory decisions. Advanced notification of data elements that are valuable to CMS consideration would be needed for successful engagement. The ICR announcement should also be communicated through multiple channels where the request can easily reach the public interested in sharing their inputs.

We recommend that CMS follow the IRA's intention by removing QALY from its consideration of ICR Section I—Evidence About Alternative Treatment. Additionally, the ICR content for patient inputs must be reconsidered to gather information from the lay audience with far advance notice for the request. Therefore, the collected information may effectively complement the listening sessions, as patients are ready to provide sufficient information to CMS.

Second, under the same section of the IRA, comparative effectiveness should be considered in the context of a drug's effect on specific populations, "such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations" learned from patients whom the negotiation outcomes will impact. Patient engagement is science.[5] The impact of patient engagement on better health outcomes and satisfaction is well-understood.[6] Like any scientific research, it requires understanding the patient population in a condition and a basic understanding of current and alternative treatments. In addition, patient engagement should have a specific focus and expected outcomes.

We want to highlight that the opportunities to gain better insights into the best practices in patient engagement are close to CMS. Its sister agency, the FDA, has worked on patient engagement in drug development for over four decades. The history of the FDA's efforts since the late 1980s can provide insight into the evolution of the science of patient engagement initiated by HIV/AIDS activists.[7] To systemically integrate patient engagement, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) created the Patient-Focused Drug Development (PFDD), the Patient Preference Initiative out of the Center for Devices and Radiological Health (CDRH), the Patient Engagement Advisory Committee (PEAC), and the FDA Patient Council. It was first mandated by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 and later supported by the 21st Century Cures Act and subsequent MDUFA and PDUFA reauthorizations.

Through this program, designated staff members are working actively on identifying best practices, robust data identification, and collection methods, as well as enhancing their understanding of patient experience and preference data along with diverse stakeholders. More importantly, the FDA's Clinical Outcome Assessment data go beyond measuring the quality of life. They encompass patients' "experiences, perspectives, needs, and priorities" for medical products, which is highly pertinent information for CMS. FasterCures believes CMS should leverage the patient engagement opportunity with the MDPNP to learn from what its sister agency has established. This will accelerate its adoption of a scientific and systemic approach to patient engagement.

We recommend that CMS consider redesigning its fundamental approach to acquiring and integrating patient input, as well as the patient-focused listening sessions. This would require closely coordinating with its sister agency, the FDA, and using its best practices tested in the past decade.

Third, transparency in decision-making builds trust in the process. It is already at the core of CMS's decision-making processes. For example, the agency maintains the Medicare Coverage Database (MCD) for all coverage decisions made for Medicare populations.[8] The public can access this web-based database to search coverage decisions for medical products and browse various coverage reports generated at national and local levels. CMS is also transparent about its Administrator's decisions to clarify and interpret the complex or ambiguous provisions in the law and regulations relevant to the agency's decisions and practices.[9]

We are confident that the information and ideas gathered from patient-focused listening sessions and the ICR will be considered and reflected in CMS's price negotiation processes. At a minimum, the agency should communicate with patients and patient organizations that shared their perspectives during listening sessions about how the agency considered the information during its negotiation processes.

We recommend that the agency consider increasing transparency in how the information gathered from patient listening sessions and ICR Section I is reflected in drug price negotiation processes.

In summary, FasterCures is eager to support CMS in advancing the recommendations below to ensure scientific and systemic patient engagement for the MDPNP.

1. Ensure the comparative effectiveness studies presented as evidence for alternative therapies are not biased against elderly, disabled, or terminally ill individuals.
2. Coordinate with the FDA's diverse patient-focused initiatives to enhance the speedy adoption of adequate, improved, and scientific patient listening sessions.
3. Increase transparency in how the information gathered from the patient listening sessions and ICR Section I would inform the MDPNP processes and outcomes.

II. Advancing Patient Engagement beyond the Medicare Drug Price Negotiation Program

Non-medical switching occurs when patients have their medication switched for reasons other than efficacy, side effects, or adherence. These reasons are often related to formulary changes and insurer coverage decisions. The practice has significant implications for patients, causing negative health outcomes and disrupting care progress and patients' lives.[10] The real-life impacts of the MDPNP remain to be seen in formulary changes; however, the concerns from patients, patient organizations, and caregivers are real.

As of March 2023, CMS makes medical product coverage decisions and reimburses for care for 65.7 million enrollees.[11] CMS has significantly improved and is committed to patient engagement regarding healthcare quality and delivery. In its strategy, the agency articulated that appreciating how patients determine preference and value is closely tied to successful long-term health management.[1]

Under the Medicare hospital quality initiative, CMS also established the Person and Family Engagement (PFE) Strategy to provide specific, actionable goals and objectives to ensure the public's involvement.[12] The agency has a Consumer Engagement program with resources and tools to encourage nursing home residents, families, and advocates to take an active role in quality care.[13] However, on the coverage determination side, patient engagement by CMS is muted. As evident during the recent FDA approvals and CMS's coverage with evidence determination of the Alzheimer's disease treatments, the public wants to be heard and involved.

Through IRA, CMS is bestowed unprecedented opportunities to engage patients meaningfully in its coverage decisions of drugs and biologics. The agency must develop and sustain its patient engagement practice and strategies beyond MDPNP through these opportunities. In order to do so, FasterCures believes that CMS must establish a structure to directly engage patients in meaningful, fit-for-purpose, and informative ways. This structure must include a dedicated and trained team of staff who can coordinate with experts and patients to implement such engagement. Patients and patient organizations must also be trained to properly engage CMS and other payers and provide valuable insights.

We recommend that CMS engage patients for its coverage decisions beyond MDPNP and build a structure and system for consistent patient engagement.

FasterCures shares this commitment to building the capacity of patients and patient organizations to help them understand the unique US payer environment that impacts their health. As an example of commitment, we want to introduce an affinity network established for over 15 years by FasterCures. The Research Acceleration and Innovation Network (TRAIN) is a network of over 160 patient organizations interested in taking a more strategic and entrepreneurial approach to their role as funders of medical research and brokers of patient participation.[14] Since TRAIN was established, FasterCures has created many resources, tools, and initiatives that help patient organizations build their capacity to advance community research efforts. Each year, FasterCures carves out a set of activities as part of TRAIN to support patient organization research capacity-building, including webinars, workshops, peer sharing sessions, networking opportunities, and resource/toolkit development[15] to target areas of patient organization priority and need as well as to provide thought leadership opportunities for TRAIN leaders to

discuss emerging issues, policies, and innovations that present both new challenges and opportunities for the biomedical R&D ecosystem.

FasterCures has a long-standing commitment to a functioning and sustainable healthcare ecosystem from bench to bedside with patients at the center.[16] We want to be a thought partner in CMS's journey toward scientific and consistent patient engagement for MDPNP and beyond. Therefore, we lay out two recommendations below.

1. Create a designated structure of patient engagement beyond the purview of the MDPNP that is integrated into coverage decisions for innovative medical products, such as those approved by the accelerated approval pathway.
2. Build staff capacity to coordinate consistent patient engagement programs for the MDPNP and other emerging technologies in medical products.

The future FasterCures envisions aligns with CMS's commitment to patient-centered health care. Our recommendations serve an instrumental purpose in advancing patient-centricity that is adequately represented in all aspects of the healthcare ecosystem. FasterCures is committed to being your partner in advancing this mission, and we stand ready to partner with CMS and provide support for developing patient engagement processes.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute

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[1] "Strategic Direction," CMS Innovation Center, accessed June 7, 2024, https://www.cms.gov/priorities/innovation/about/strategic-direction.

[2] Meena Seshamani, MD, PhD, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (Center for Medicare, Centers for Medicare and Medicaid Services, May 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[3] "Initial Price Applicability Year 2026 Policy and Public Input," Centers for Medicare and Medicaid Services, accessed June 7, 2024, https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/2026-policy-and-public-input.

[4] H.R.5376—Inflation Reduction Act, No: 117–169 (August 16, 2022), https://www.congress.gov/bill/117th-congress/house-bill/5376/text.

[5] F.I. Auwal, C. Copeland, E.J. Clark, et al., "A Systematic Review of Models of Patient Engagement in the Development and Life Cycle Management of Medicines," *Drug Discovery Today* (2023): 103702, https://doi.org/10.1016/j.drudis.2023.103702.

[6] Sima Marzban, Marziye Najafi, Arjola Agolli, and Ensieh Ashrafi, "Impact of Patient Engagement on Healthcare Quality: A Scoping Review," *Journal of Patient Experience* 9 (2022): 23743735221125439, https://doi.org/10.1177%2F23743735221125439.

[7] "Evolution of Patient Engagement at the FDA," US Food and Drug Administration, accessed June 7, 2024, https://www.fda.gov/patients/evolution-patient-engagement-fda; *Back to Basics: HIV/AIDS Advocacy as a Model for Catalyzing Chang*e (Milken Institute, June 2011), https://milkeninstitute.org/report/back-basics-hivaids-advocacy-model-catalyzing-change.

[8] "Medicare Coverage Database," Centers for Medicare and Medicaid Services, accessed June 7, 2024, https://www.cms.gov/medicare-coverage-database/search.aspx.

[9] "CMS Rulings," Centers for Medicare and Medicaid Services, accessed June 7, 2024, https://www.cms.gov/medicare/regulations-guidance/cms-rulemaking/rulings/cms.

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 1, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

The National Association of Chain Drug Stores (NACDS) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the Draft Guidance on the Medicare Drug Price Negotiation Program.

Summary of NACDS' Recommendations:

- **NACDS does support the second retrospective option proposed by CMS for Primary Manufacturers to provide access to the MFP and urges CMS to move forward with effectuating that option. Although we support a retrospective model, we have concerns about the timeliness of pharmacies receiving the MFP refund. To address these concerns, we urge CMS to pre-fund the Negotiation Program or require manufacturers to pre-fund the Negotiation Program.**
    - **CMS possesses the authority to pre-fund the Negotiation Program.**
    - **CMS possesses the authority to require manufacturers to pre-fund the Negotiation Program.**
    - **CMS does not possess the authority to require pharmacies to pre-fund the Negotiation Program.**
- **However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the Program, then we urge CMS to shorten the PDE reporting period from 30 days to 1 calendar day, and to require**

MTFs to provide only the necessary requisite data to the Primary Manufacturers on a daily (calendar) basis.

- **The IRA Requires that Pharmacies Be Reimbursed for Negotiated Drugs with No Price Concessions**

- **CMS proposes that the MTF data exchange be mandatory and that all primary manufacturers will be required to register with the MTF, sign privacy and security requirements with CMS, and maintain the necessary functionalities to receive certain claim-level data elements from the MTF. Moreover, manufacturers would be required to report to the MTF whether and how the MFP was made available to the dispensing entity. NACDS supports this CMS proposal and asks that CMS not amend this proposal.**

- **CMS proposes claim-level data elements for Part D claims for NDCs of selected drugs that the MTF will send to the Primary Manufacturer. NACDS supports this CMS proposal and urges CMS not to require any additional information beyond what has been proposed in the draft guidance.**

- **CMS should be aware that pharmacies typically do not know at the point of sale whether a claim is a 340B claim; hence, in most cases, it will be impossible for pharmacies to submit 340B clarification codes with the prescription drug claims.**

- **We urge CMS to prohibit the clawback of previously paid MFP refunds for 340B deduplication purposes. Preventing clawbacks will provide incentives for covered entities and manufacturers to develop effective means to make covered entities whole without involving contract pharmacies.**

- **Since the Part D sponsor remains responsible for ensuring that clean claims are paid within the statutorily imposed deadlines, we urge CMS to require the Part D sponsors to work with the MTF and manufacturers to ensure that this deadline is met.**

- **CMS proposes to provide manufacturers with a Standard Default Refund Amount that would reflect the difference between a drug's WAC and MFP. NACDS agrees with CMS that this best approximates the acquisition cost of pharmacies and offers a reliable refund amount for both manufacturers and pharmacies. We also agree with CMS that manufacturers and pharmacies should be allowed to negotiate whether some other amount is appropriate to make the MFP available.**

- **NACDS supports a single platform for transmitting refund payments as it would create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. Consequently, NACDS urges CMS to require only the second payment facilitation option.**

- **NACDS requests that CMS direct the MTF to create a portal that could serve a variety of functions. First, the portal could serve as an enrollment mechanism in which the pharmacy could create a profile and provide banking information and where remittance information**

could be potentially reported to or accessed by pharmacies. The enrollment process should be simplified and seamless. Second, since pharmacies otherwise would have no insight into the status of their claims for refund, the portal could serve the function of providing pharmacies with tracking and status updates at the claim level in real-time and when queried by the pharmacy.

- **CMS has proposed that the MTF be responsible for generating the remittance advice (i.e., X12 835 document)— the MTF should also be responsible for generating the EDI 820 document that relates to banking financial standards. To further emphasize, this information should be made available in the MTF portal for each pharmacy.**

- **NACDS strongly agrees that pharmacies should not be required to fund any administrative functions that manufacturers engage in to provide the MFP to pharmacies nor should pharmacies be required to provide funds for transmission or administrative functions related to the plan sponsors or PBMs providing the PDE file or any other information to the MTF as part of the Negotiation Program.**

- **CMS has requested comments on the types of documentation that currently exist in the ordinary course of business that would provide supporting information in the event of an investigation pursuant to a complaint between the manufacturer and the pharmacy regarding whether the MFP was effectuated. The documentation that currently exists, or would exist under CMS' proposal, would be the electronic remittance advice that CMS has proposed, and WAC as published in the pharmaceutical pricing database compendia on the date of dispensing.**

- **NACDS supports the Negotiation Program's Complaints and Disputes process as pharmacies should have a pathway for recourse in instances where the pharmacy or dispensing entity believes the MFP refund is erroneous or inaccurate or Primary Manufacturers of selected drugs fail to ensure access to the MFP for MFP-eligible individuals and pharmacies.**

Background

Under sections 11001 and 11002 of the IRA, the Secretary of Health and Human Services (the "Secretary") will establish Maximum Fair Prices (MFPs) for certain single-source drugs covered by Medicare Part B and Part D. Manufacturers, in turn, must ensure that the MFP is made available to pharmacies, mail order services, and other entities that dispense the selected drug to MFP-eligible individuals. (*See* Social Security Act § 1193(a)(3)(A).) Section 11004 of the IRA appropriates $3 billion for CMS to implement the Negotiation Program.

On May 3, 2024, CMS released draft guidance for implementation of the Negotiation Program.[1] CMS' guidance (at 36) proposes two mechanisms through which manufacturers can provide access to the

[1] CMS, *Draft Guidance on the Medicare Drug Price Negotiation* (May 3, 2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

MFP: by ensuring pharmacies can purchase prescription drugs at a price no greater than the MFP, or by providing retrospective payment for the difference between the pharmacy's acquisition cost and the MFP. Ultimately, the manufacturers are responsible for "calculating the appropriate amount to effectuate the MFP and ensuring that timely payment is made to the dispensing entity." (*Id*. at 38.)

CMS is seeking to contract with a Medicare Transaction Facilitator (MTF) to support CMS's administration of the Negotiation Program, monitor compliance by participating manufacturers, and facilitate retrospective reimbursements from manufacturers to dispensing entities to effectuate the MFP. Before executing a contract with the MTF, CMS is soliciting comments on two retrospective payment facilitation options that the MTF could provide. The first option involves the MTF collecting banking information from participating dispensing entities and providing that information to participating manufacturers for the manufacturers to provide payment to those accounts. The second option involves the MTF receiving aggregated refund amounts from participating manufacturers and passing through the refunds to participating dispensing entities.

Manufacturers opting to provide retrospective payment to effectuate MFPs would need to ensure that dispensing entities receive reimbursement within 14 days of when the MTF sends data to the manufacturer verifying that the drug was dispensed to an MFP-eligible individual. (*Id*. at 36-37.) This 14-day window aligns with CMS's prompt pay rules in Part D, but results in delayed payment of several weeks because the 14-day window begins only after the drug has been dispensed, a pharmacy submits a claim to a Part D plan, the plan submits prescription drug event (PDE) data to CMS, CMS verifies the data, CMS submits the data to the MTF, and the MTF submits the data to the manufacturer. (*Id.*) Under existing rules, a Part D plan has up to 30 days to submit PDE data to CMS, although CMS is considering reducing this timeframe to seven days.

Under both payment facilitation options that CMS is proposing, federal funds would not be used. Under option 1, the MTF would collect and share participating dispensing entities' bank account information with manufacturers to help facilitate the manufacturers' direct transfer of funds to those dispensing entities. Under option 2, the MTF would directly transfer funds from the manufacturer to dispensing entities, as directed by the manufacturer in the amounts authorized by the manufacturer. Under either option, pharmacies would essentially be required to pre-fund the program. Pharmacies would purchase the prescription drugs subject to the MFP at market price but would be reimbursed initially only for the MFP price. Because of the delayed payment described in the paragraph above, pharmacies would not be wholly reimbursed for several additional weeks—essentially pre-funding the program through a financial float of up to 30 days or more. NACDS urges CMS to consider other options so that pharmacies do not have to pre-fund the program—namely, that CMS pre-fund the MTF or that CMS require manufacturers to pre-fund the MTF.

CMS Possesses the Authority to Pre-Fund the Negotiation Program

CMS's authority to pre-fund the Negotiation Program hinges on whether it has both statutory authority and an appropriation to do so. We believe that CMS's $3 billion IRA appropriation may cover its prospective funding of the MTF.

1. IRA Appropriation

Whether appropriated funds are legally available for a given obligation or expenditure hinges in part on whether the purpose of the obligation or expenditure is authorized. The "purpose" statute, 31 U.S.C §

1301(a), provides: "Appropriations shall be applied only to the objects for which the appropriations were made except as otherwise provided by law." That is, public funds can be used only for the purpose for which they were appropriated. Determining the purpose for which funds were appropriated requires looking at "the common meaning of the words in the appropriation act and program legislation it funds." (GAO, *Principles of Federal Appropriation Law*, 4th ed., 2017 rev., ch. 3, §A.)

CMS could use IRA funds to carry out any provisions of the IRA even though these are not responsibilities specifically assigned to CMS. The IRA appropriation provides: "In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $3,000,000,000 for fiscal year 2022, to remain available until expended, to carry out ***the provisions of***, including the amendments made, by this part." (Section 11004 (emphasis added).) By contrast, CMS's annually-appropriated Program Management discretionary account is provided to it "[f]or carrying out, except as otherwise provided, titles XI, XVIII, XIX, and XXI of the Social Security Act, titles XIII and XXVII of the PHS Act, the Clinical Laboratory Improvement Amendments of 1988, and other ***responsibilities*** of the Centers for Medicare & Medicaid Services, ..." (Further Consolidated Appropriations Act, 2024, H.R. 2882-203 (emphasis added).)

If Congress intended for CMS's IRA appropriation to be used solely to fulfill CMS's *responsibilities* under the IRA, it would have included such an express limitation (e.g., "to carry out its responsibilities, including amendments under, this part"), as it did under the Program Management appropriation. Instead, the IRA appropriation language specifies using money to carry out the "provisions of" the IRA, which could encompass more than CMS's specific obligations under the Act. For this reason, we believe that CMS can and should pre-fund the Negotiation Program; otherwise, as proposed in the current draft 2 guidance, it would become the pharmacies' responsibility to shoulder the cost to effectuate the Negotiation Program that is intended for manufacturers.

2. Coverage Gap Discount Program

The Coverage Gap Discount Program ("CGDP") provides a framework in which CMS manages and forwards payments to Part D sponsors, and offers a model of CMS involvement in funding mechanisms similar to the above-referenced proposal. Under the CGDP, CMS provides monthly prospective payments to Part D sponsors, in order for Part D sponsors to provide coverage gap discounts to their enrollees at the point of sale.[2] After each contract year, CMS reconciles the prospective discount program payments that CMS provided to the Part D sponsor to cost, based on the actual invoiced manufacturer discount amounts made available to each Part D plan's enrollees under the Discount Program. (*Id*. at 13.)

We believe the Medicare Transaction Facilitator (MTF) as established by CMS, similar to the TrOOP facilitator, could mirror the CGDP concept to some extent. The CGDP seems to work with all relevant stakeholders to ensure that necessary processing and funding occur in real time following a pharmacy submitting a reimbursement claim. Under a CMS pre-funded model, CMS could prospectively fund the MTF each month, so the MTF could provide timely payment of the MFP refund (e.g., WAC-MFP) to the pharmacy after receiving the claims information or the PDE file (whichever makes the most sense) from

[2] CMS, *Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance*, 12 (May 21, 2010) at 12, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscount_Revised-Guidance-052110.pdf.

the plan sponsor or the pharmacy benefit manager (PBM) administering benefits on behalf of the plan sponsor. This would significantly reduce the financial burden on pharmacies to essentially float the Negotiation Program from the pharmacy counter by streamlining the process and making funds readily available at the MTF (in lieu of the TrOOP facilitator or plan sponsor) for prompt reimbursement to pharmacies. Otherwise, under the proposed options in the Draft 2 Guidance, the pharmacy would be required to wait more than roughly 24 days to receive payment as the prompt payment window doesn't start until the manufacturer receives the "MFP refund" request from the MTF. The latter approach could result in serious delays in care, possibly pharmacy store closures[3], and would exacerbate the current financial toxicities experienced by many pharmacies today due to below-cost reimbursement from PBMs.

Finally, we would highlight for CMS that the CGDP has been a success largely because it is one standard process over which CMS has authority. We believe that CMS could achieve similar success with a standardized MTF process that is prospectively funded to support timely retrospective reimbursement to the pharmacy.

CMS Possesses the Authority to Require Manufacturers to Pre-Fund the Negotiation Program

In the alternative, CMS could use its authority to require manufacturers to pre-fund the Negotiation Program. As discussed above, the IRA imposes on manufacturers the obligation to make the MFP available to dispensers. Nothing in the IRA suggests manufacturers satisfy this obligation by retrospectively refunding pharmacies and other dispensers. Thus, CMS is exercising discretion in permitting manufacturers to effectuate MFP through retrospective refunds. (*See* CMS's May 2024 guidance at 53.) As part of the retrospective process, CMS could require manufacturers to pre-fund the MTF to be able to make more immediate payments to pharmacies and other dispensers, which would be replenished when the manufacturer pays the refunds to the MTF. Most importantly, this alternative approach would also help ensure continuity of care for beneficiaries to access affordable medications under the new program and mitigate fiscal pressures on community pharmacies nationwide.

CMS Does Not Possess the Authority to Require Pharmacies to Pre-Fund the Negotiation Program

In light of the foregoing, we believe that CMS's proposed approach of giving manufacturers at least three to six weeks to reimburse pharmacies for the discounts implied in the MFP has the effect of shifting the obligation to effectuate the MFP to pharmacies, contrary to the statute.

By allowing manufacturers to provide access to the MFP by retrospectively reimbursing pharmacies, CMS would in effect be requiring pharmacies to pre-fund the MFP refund that those pharmacies would receive. Imposing such a mandate on pharmacies is misaligned with statutory intent and exceeds CMS's authority.

As noted above, the IRA obligates manufacturers – not pharmacies or other dispensing entities – to effectuate the MFP. This direct responsibility for manufacturers to ensure the provision of MFPs to dispensing entities suggests that a pre-funding requirement imposed by CMS on dispensing entities themselves would require additional legislative authorization, which currently does not exist. CMS itself notes repeatedly throughout its recent guidance that manufacturers bear the sole obligation to effectuate the MFP. Indeed, we see no statutory language or evidence of legislative intent for dispensing

[3] https://storymaps.arcgis.com/stories/21620f1e07c14d7f81adc4503faaf51e

entities to bear such a responsibility, especially when the mechanics of the retrospective refunds would require pharmacies to wait substantially longer than the 14 days they currently expect payment from Part D plans and their PBMs.

Moreover, pharmacies continue to suffer from inadequate reimbursement and Part D plan and PBM clawbacks in the Part D program. Pharmacies do not have the financial ability to pre-fund the Negotiation Program, as pharmacies are often reimbursed below cost for medications dispensed to Part D beneficiaries. As NACDS routinely comments to CMS, pharmacy DIR fees have grown exponentially in recent years to the point that pharmacies in some cases must consider whether they can even stay financially afloat. Therefore, pharmacies should not be solely responsible for pre-funding or floating the Negotiation Program and MTF as pharmacies and pharmacists have the immediate responsibility to assure optimal outcomes for all patients and sustain pharmacy clinical services considering the underwater reimbursement challenges from PBMs.

The IRA Requires that Pharmacies Be Reimbursed for Negotiated Drugs with No Price Concessions

The Inflation Reduction Act (IRA) directs the HHS Secretary to select MFP drugs and to negotiate agreements with manufacturers to set the MFPs for the selected drugs. The manufacturer is then required to "provide access to such price . . . to maximum fair price eligible individuals who . . . are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs)."[4] In addition, the basic definition of "maximum fair price" means the amount negotiated between the Secretary and a manufacturer for a selected drug—in other words, the ingredient cost of that drug.[5] **Since manufacturers must make selected drugs available for pharmacies at MFP, the IRA equates MFP with a pharmacy's ingredient cost.**

CMS should confirm that the IRA requires that pharmacies must be reimbursed by PDP sponsors at MFP (i.e., ingredient cost) plus a dispensing fee without price concessions. CMS should arrive at this conclusion for several reasons: First, as discussed above, the IRA is constructed around treating MFP as the ingredient cost, and it uses a single definition for MFP throughout. Second, the amended definition of "negotiated prices" supports this conclusion. The total amount of the negotiated price for a non-MFP drug includes (1) the ingredient cost, (2) any "price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs," and (3) "any dispensing fees for such drug[ ]."[6] In contrast, for MFP drugs, the negotiated price is simply a payment of (1) "no greater than the maximum fair price" for the drug and (2) "any dispensing fees."[7] Thus, unlike non-MFP drugs, where Congress acknowledged the existence of "concessions" in addition to ingredient costs, Congress did not provide PDP sponsors explicit authorization to extract "concessions" for MFP drugs. Again, this leads to the conclusion that PDP sponsors should reimburse pharmacies at ingredient cost plus a dispensing fee.

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[4] 42 U.S.C. § 1320f-2(a)(1) (NCPA emphasis added); *accord id.* § 1320f-2(a)(2), (a)(3).
[5] *Id.* § 1320f(c)(3); *see also id.* § 1320f-3 (describing the negotiating process for the "maximum fair price").
[6] *Id.* § 1320w-102(d)(1)(B).
[7] *Id.* § 1320w-102(d)(1)(D).

Although Congress provided that the PDP sponsors should make payments to pharmacies at an amount "no greater than the maximum fair price,"[8] which could be construed to mean that PDP sponsors could reimburse less than MFP, this is not an accurate interpretation of the IRA. The IRA consistently treats MFP as the ingredient cost, and the fact that manufacturers must provide pharmacies with access to MFP when those pharmacies dispense to an MFP-eligible individual strongly indicates that no price concessions are to be extracted from the MFP. Moreover, as noted above, if Congress had wished to allow PDP sponsors to extract additional concessions, it could have said so when it came to defining "negotiated prices" for MFP drugs. But it deliberately excluded concessions from that definition. It makes sense that Congress would have wanted to reimburse pharmacies no greater than MFP—to ensure that taxpayers are maximizing their savings—while at the same time ensuring that pharmacies at least break even on their ingredient costs while providing for a dispensing fee. NACDS has concerns that pharmacy access will become even more restricted and reimbursement will fall below the MFP without any protections from CMS, especially if DIR Fees are applied to these drugs. As of current, major PBMs often compensate pharmacies far below the acquisition cost and below the actual cost to dispense, as low as $0 or lower, by using emerging tactics and "transaction" fees.

CMS should take note that the IRA does not expressly prohibit the Secretary from ensuring that pharmacies are reimbursed at not *less* than MFP. It simply says pharmacies may not be reimbursed greater than MFP. The "not greater than" language serves a purpose, because ultimately, a PDP sponsor's costs factor into how much CMS pays it under the Part D program. Consequently, it was necessary for Congress to clarify both that manufacturers would sell MFP drugs at a maximum fair price and PDP sponsors would reimburse pharmacies no more than that same price plus a dispensing fee.

§40.4 Providing Access to the MFP in 2026 and 2027

CMS proposes two ways for manufacturers to provide access to the MFP:

- Prospectively by ensuring that the dispensing entity (e.g., pharmacy) when acquiring the selected drug is not paying no greater than the MFP; or
- Retrospectively providing reimbursement to the dispensing entity (e.g., pharmacy) for the difference between the pharmacy's acquisition costs and the MFP, unless the dispensing entity's acquisition cost is equal to or less than MFP (related to 340B discounts).

NACDS supports both options proposed by CMS and urges CMS to move forward with effectuating both options. There will be dispensers that prefer one option over another, and we appreciate CMS's recognizing that having both options will best facilitate dispensers' access to the MFP.

As noted in CMS draft guidance, Primary Manufacturers will be required to provide access to the MFP within 14 calendar days of when the MTF sends the data that verifies that the selected drug was dispensed to an MFP-eligible individual. As mentioned above, we are deeply concerned about pharmacies having to pre-fund, or provide a financial float for the Negotiation Program. As mentioned above, we urge CMS to pre-fund the program, similar to how CMS pre-funds the Coverage Gap Discount Program, or to require manufacturers to pre-fund the program.

[8] *Id*. § 1320w-102(d)(1)(D).

However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the program, then we urge CMS to shorten the PDE reporting period from 30 days to one calendar day, and to require MTFs to provide the requisite data to the Primary Manufacturers on a daily (calendar) basis. Unless the reporting time frames are reduced to daily reporting, pharmacies will not be fully reimbursed for up to 30 days or more. This would be tantamount to CMS requiring pharmacies to pre-fund the program, which it does not have the authority to do.

As a further alternative, should it be absolutely infeasible to shorten PDE reporting to one calendar day and/or infeasible for MTFs to report to Primary Manufacturers on a daily (calendar) basis, then we would urge CMS to require a percentage of claims be reported through the PDE within one calendar day and/or reported by the MTF to Primary Manufacturers on a daily (calendar) basis.

§40.4.1 Medicare Transaction Facilitator (MTF) Data Facilitation

CMS proposes that the MTF data exchange be mandatory and that all primary manufacturers will be required to register with the MTF, sign privacy and security requirements with CMS, and maintain the necessary functionalities to receive certain claim-level data elements from the MTF. Moreover, manufacturers would be required to report to the MTF whether and how the MFP was made available to the dispensing entity. NACDS supports this CMS proposal and asks that CMS not amend this proposal.

In the draft guidance, in Table 2, CMS proposes claim-level data elements for Part D claims for NDCs of selected drugs that the MTF will send to the Primary Manufacturer. NACDS supports this CMS proposal and urges CMS not to require any additional information beyond what has been proposed in the draft guidance. We agree with CMS that manufacturers should not need additional data elements as they will not need to provide additional verification and that providing additional information on individual beneficiaries that constitutes personally identifiable information or protected health information would unnecessarily increase privacy and security risks, even if the data were encrypted.

CMS proposes that beginning January 1, 2025, the Submission Clarification Code value of "20" and the Submission Code field with the value of "AA" will be added to the PDE Record to indicate a Section 340B claim. Although these indicators will be voluntary, CMS should be aware that pharmacies typically do not know at the point of sale whether a claim is a 340B claim; hence, in most cases, it will be impossible for pharmacies to submit these codes with the prescription drug claims.

CMS proposes that the MTF will provide Primary Manufacturers with data that has been verified by both the Part D plan sponsor and CMS' Drug Data Processing System (DDPS). Having the data verified by the DDPS raises the question of how pharmacies will receive their MFP refund in situations where the DDPS rejects the claim data sent by the Part D plan sponsor. In other words, in these situations, presumably, the DDPS would not pass along the data to the MTF and instead would notify the plan sponsor of the rejection. Presently, pharmacies are not implicated, nor should they be, when a plan sponsor adjudicates a pharmacy claim whose data is subsequently sent to and rejected by DDPS. Pharmacies can rely on the part D sponsor's adjudication of the claim—pharmacies are fully reimbursed, and the part D sponsor retains the responsibility for the claim. This part D sponsor responsibility should remain the same for pharmacy claims for prescription drugs subject to the Negotiation Program. The pharmacy,

having relied on the part D sponsor's adjudication of the claim, should be fully reimbursed, including the MFP; and it should be the part D sponsor's responsibility to ensure that the pharmacy is fully reimbursed, having accepted that responsibility by its adjudicating the claim. Additionally, the part D sponsor should ensure that the necessary data is still passed along to the MTF even if a claim is rejected by DDPS to help ensure the MFP refund is effectuated by the M TF to the pharmacy.

CMS is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF funds. CMS is also evaluating options for the process, timing, and frequency by which files containing claims-level data elements will be transmitted from the MTF to Primary Manufacturers. CMS is considering transmission of these files on either a daily or bi-weekly basis. 42 U.S.C. 1395w-112(b)(4) provides that Part D sponsors must make payment for clean claims within 14 calendar days of the date on which an electronic claim is received. At the same time, 42 U.S.C. 1320f-2(a)(3) requires the manufacturer to provide the maximum fair price (MFP) to the pharmacy. We do not see that the provisions of 42 U.S.C. 1320f-2(a)(3) somehow nullify or supersede the prompt pay requirements of 42 U.S.C. 1395w-112(b)(4). Consequently, these statutory provisions must be read in concert. Since the Part D sponsor remains responsible for ensuring that clean claims are paid within the statutorily imposed deadlines, we urge CMS to work with Part D sponsors, the MTF, and manufacturers to ensure that this deadline is met. This could include requiring plans to submit PDE records on a daily (calendar) basis and requiring the MTF to transmit files containing claims-level data to Primary Manufacturers on a daily (calendar) basis to help ensure that the Primary Manufacturers have sufficient time to process the reimbursement request from the pharmacy should CMS disagree with our pre-funded model recommendations.

CMS is considering having the MTF generate an electronic remittance advice to the pharmacy for purposes of reconciling manufacturer retrospective refunds. NACDS strongly supports having the MTF solely being responsible for generating remittance advice to pharmacies under either a NACDS proposed payment model where CMS or the manufacturer pre-funds the MTF and the pharmacy receives payment from the MTF or alternatively, under a model that provides a refund from the manufacturer via MTF to the pharmacy (i.e., Option 2) as proposed in the Draft 2 guidance.

However, since generating remittance advice is a complex process, we urge CMS to require that the entity generating the remittance advice have experience and be qualified to do so. Moreover, the information provided in the remittance advice should be at the claim level so that pharmacies may properly reconcile the refund payment. Finally, there should be a standardized implementation of the remittance advice, as there could be a wide variety of manufacturers providing the remittance advice information to the MTF. We recommend that CMS engage with NCPDP to define a standardized implementation of the remittance advice.

§40.4.2 Nonduplication with 340B Ceiling Price

CMS is proposing not to assume responsibility for deduplicating discounts between the 340B ceiling price and the MFP and is encouraging industry stakeholders to develop a process. CMS is also proposing to provide Primary Manufacturers a process to identify applicable 340B-eligible claims through the reporting of payment elements to the MTF, presumably from the pharmacy. Again, NACDS reminds CMS that pharmacies typically do not know whether a claim is a 340B claim at the point of sale and thus, would not be able to report this information for use by the MTF.

We support the need for the deduplication of claims; however, the current lack of system integration between pharmacy claims receivable systems and 340B systems poses a significant challenge. For instance, if a pharmacy were to have a previously paid MFP payment clawed back due to a duplicate 340B discount, it would be extraordinarily difficult to reconcile that transaction against the current 340B accounting systems. The administrative burden and financial strain of such clawbacks could jeopardize the operational viability of many contract pharmacies.

Therefore, we urge CMS to influence the industry design by prohibiting the clawback of previously paid MFP refunds for 340B deduplication purposes. Preventing clawbacks will provide incentives for covered entities and manufacturers to develop effective means to make covered entities whole without involving contract pharmacies. This approach ensures that the responsibility for resolving duplication issues rests with the parties best equipped to manage them, thereby protecting contract pharmacies from undue administrative and financial burdens. Until such time that covered entities and manufacturers develop this effective means, any 340B adjustments or resolution(s) related to a 340B claim should be handled outside of the MFP process and as appropriate through the dispute resolution process that currently is in place.

§40.4.3 Retrospective Refund Amount to Effectuate the MFP

CMS proposes to provide manufacturers with a Standard Default Refund Amount that would reflect the difference between a drug's WAC and MFP. NACDS agrees with CMS that this best approximates the acquisition cost of pharmacies and offers a reliable refund amount for both manufacturers and pharmacies. NACDS further agrees with CMS that the Standard Default Refund Amount should be calculated based on WAC as published in pharmaceutical pricing database compendia on the date of dispensing (Of note, the date of dispensing policy would need to be revisited in future guidance once the Negotiation Program expands to Part B.).

While we support a Standard Default Refund Amount, we also agree with CMS that manufacturers and pharmacies should be allowed to negotiate whether some other amount is appropriate to make the MFP available. We would like to stress that this determination of another amount should be the result of a negotiation between the manufacturer and the pharmacy and should not be solely a manufacturer's decision or determination. The draft guidance as written does not restrict a manufacturer from unilaterally deciding to use a metric that may not adequately reflect a pharmacy's acquisition cost, or otherwise may not be acceptable to a pharmacy. We ask that CMS clearly emphasize that the determination of another amount should be the result of a negotiation between the manufacturer and the pharmacy.

§40.4.4 Options for Medicare Transactions Facilitator Payment Facilitation

CMS is soliciting comments on two payment facilitation options. The first option would be for the MTF to collect banking information from pharmacies and provide that information to Primary Manufacturers in order for the Primary Manufacturer to provide payments directly to pharmacies. The second option or option 2 would be for the MTF to receive aggregated refund amounts from Primary Manufacturers and pass the refunds to pharmacies. As CMS recognizes in the draft guidance, pharmacies support a single platform for transmitting refund payments as it would create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments. Consequently, **NACDS urges CMS to require only the second option.** If CMS were to allow both options, then pharmacies could be

placed in a predicament of having some of their MFP refunds come from the MTF and other payments come from multiple other sources. This type of arrangement would be infeasible and would essentially negate the main benefit of the second option—having payment come from one source.

CMS requests comments on the most effective way to enroll pharmacies in the MTF and/or obtain their banking information. NACDS requests that CMS direct the MTF to create a portal that could serve a variety of functions. First, the portal could serve as an enrollment mechanism in which the pharmacy could create a profile and provide banking information and where remittance information could be potentially reported to or accessed by pharmacies. Second, since pharmacies otherwise would have no insight into the status of their claims for refund, the portal could serve the function of providing pharmacies with tracking and status updates at the claim level in real-time and when queried by the pharmacy. Pharmacies could also update their profile and banking information in the portal as needed to ensure the most up-to-date information is on file for payment and reconciliation purposes. The manufacturers, plan sponsors, and PBMs should not have access to the portal as this should be a closed system between the pharmacies and the MTF. However, the MTF may report data in the portal from the PDE files and other information as necessary to ensure the pharmacy receives the appropriate claims-level data for payment and remittance/reconciliation to best effectuate the MFP.

CMS comments that under no circumstances would federal funds be used to resolve or make payments. NACDS urges CMS to review our comments above that outline CMS' authority to pre-fund the program, and thus, utilize federal funds to resolve or make payment.

§40.4.5 Medicare Transaction Facilitator Dispensing Entity Participation Requirements

CMS indicates that the Primary Manufacturer and pharmacy each may choose not to utilize the MTF for the facilitation of retrospective refund payments. Again, as stated above, we urge CMS to reconsider this approach and to require Primary Manufacturers and dispensing entities to utilize the MTF for the facilitation of retrospective refund payments—otherwise, pharmacies could be forced into having to establish financial relationships with multiple manufacturers. This would be unnecessarily burdensome to the point of being infeasible for pharmacies.

Pharmacies would be willing to provide banking information in order to facilitate receiving their refunds. However, pharmacies see no need for their banking information to be provided to manufacturers if CMS were to require that the MTF be utilized for the facilitation of retrospective refund payments. CMS has proposed that the MTF be responsible for generating the remittance advice (i.e., X12 835 document)—we believe the MTF should also be responsible for generating the EDI 820 document that relates to banking financial standards. To further emphasize, this information should be made available in the MTF portal for each pharmacy.

CMS proposes that neither the Primary Manufacturer nor their contracted entities shall charge dispensing entities any transaction or other fees for the data exchanges facilitated through the MTF. NACDS strongly agrees that pharmacies should not be required to fund any administrative functions that manufacturers engage in to provide the MFP to pharmacies nor should pharmacies be required to provide funds for transmission or administrative functions related to the plan sponsors or PBMs providing the PDE file or any other information to the MTF as part of the Negotiation Program. These guardrails should be explicitly stated in the final guidance to prevent harmful PBM practices from spreading into the Negotiation Program's MTF process.

§90.2 Monitoring of Access to the MFP in 2026 and 2027

CMS proposes that if it determines through audits, investigations, or complaints from dispensing entities or other market participants, that the Primary Manufacturer has not fulfilled its obligation to make MFP available within the 14-day prompt MFP payment window, CMS will encourage the Primary Manufacturer to address any payment discrepancies as soon as possible. Failure to act in these cases may result in CMS issuing the appropriate CMPs as set forth in section 100.1 of the revised guidance for initial price applicability year 2026 or this draft guidance, as applicable. NACDS supports this proposal but also urges CMS to consider modifying its proposal to accommodate and align with a manufacturer's pre-funded model scenario as previously mentioned.

Again, NACDS further agrees with CMS that the Standard Default Refund Amount should be calculated based on WAC as published in the pharmaceutical pricing database compendia on the date of dispensing.

§90.2.1 Manufacturer Plans for Effectuating MFP

Should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the program, then we urge CMS to require option 2 which would involve the single source MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating dispensing entities via our proposed portal. Furthermore, we would support this model under a daily PDE reporting requirement to the MTF. Unless the reporting time frames are reduced to daily reporting, pharmacies will not be fully reimbursed for up to 30 days or more.

§90.2.2 Negotiation Program Complaints and Disputes

CMS has requested comments on the types of documentation that currently exist in the ordinary course of business that would provide supporting information in the event of an investigation pursuant to a complaint between the manufacturer and the pharmacy regarding whether the MFP was effectuated. We believe that the documentation that currently exists, or would exist under CMS' proposal, would be the electronic remittance advice that CMS has proposed, and WAC as published in the pharmaceutical pricing database compendia on the date of dispensing. NACDS supports the Negotiation Program's Complaints and Disputes process as pharmacies should have a pathway for recourse in instances where the pharmacy or dispensing entity believes the MFP refund is erroneous or inaccurate or Primary Manufacturers of selected drugs fail to ensure access to the MFP for MFP-eligible individuals and pharmacies.

CMS has requested recommendations for how CMS should structure its complaints and disputes process. NACDS asks that CMS develop standardized materials to educate pharmacies and pharmacists, including providing FAQs, regarding the entire Negotiation Program and MTF Reimbursement and Data Flow process, and the complaint and dispute process. As it relates to the latter, we urge CMS to clearly identify steps a pharmacy should take and whom the pharmacy should contact to address a dispute or complaint related to reimbursement or remittance advice.

Conclusion

In conclusion, NACDS thanks CMS for this opportunity to submit comments and for considering our recommendations. We urge CMS to continue to engage with NACDS, especially as CMS pursues the next steps to finalize this guidance and establish the RFP for the Negotiation Program's MTF. Moreover, we look forward to working with CMS's IRA team on helping to inform pharmacies about MTF enrollment and processes to help ensure beneficiary access and an overall smooth transition and sustainable reimbursement for the pharmacy community. If we can provide any additional information, please do not hesitate to contact Dr. Christie Boutte, Senior Vice President, Reimbursement, Innovation, and Advocacy, at cboutte@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, IOM, CAE
President and Chief Executive Officer

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

The Honorable Meena Seshamani, MD, Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Submitted Electronically: IRARebateandNegotiation@cms.hhs.gov

Re: "Medicare Drug Price Negotiation Program Draft Guidance" – Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on CMS' Medicare Drug Price Negotiation Program Draft Guidance. On May 3, 2024, CMS issued the program draft guidance to address the implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA)[1] which describes how CMS intends to implement the Negotiation Program for initial price applicability year 2027 and clarifies policies for manufacturer effectuation of the MFP in 2026 and 2027, specifying requirements that will be applicable to manufacturers of drugs that are selected for negotiation and procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (PDPs and MA-PD Plans), pharmacies, mail order services and other dispensing entities that dispense drugs covered under Medicare Part D.

As CMS works to implement the IRA drug pricing reform sections of the law, it must first acknowledge and understand the immense amount of pressure pharmacies are already under within the Medicare Part D program. CMS must ensure that the implementation of the IRA's Part D provisions, particularly the effectuation of the Maximum Fair Price (MFP), does not exacerbate the financial difficulties already faced by pharmacies. For years, pharmacies have been subject to draconian payment reductions after the point-of-sale through pharmacy direct and indirect remuneration (DIR) and other cuts, and those

[1] These Sections of the Inflation Reduction Act created Part E under Title XI of the Act (Sections 1191-1198).

cuts have persisted this year as a carryover from 2023 contract agreements. Pharmacies have experienced even worse upfront cuts at the point-of-sale ("negotiated price") through 2024 contract terms. Despite CMS implementing new Part D regulations in January 2024 that amended the definition of negotiated price to capture all price concessions at the point of sale, specialty pharmacies and the broader pharmacy community have faced significant financial uncertainty, resulting in many forced pharmacy acquisitions and closures at an alarming rate. Today, Part D reimbursement across drugs dispensed is too often far less than a pharmacy's actual acquisition cost of the drugs, and pharmacy dispensing fees are not nearly adequate to buffer the payment reductions or to afford the cost of the requisite high-touch pharmacy services needed to cover plan and/or manufacturer requirements to support a patient on a specialty drug. Some Part D sponsors and their PBMs have initiated contract practices for this calendar year that pharmacies believe are in violation of the new 2024 Medicare Part D rules, and some Plans/PBMs continue to grossly undermine the Medicare Any Willing Pharmacy statute. Congress has been working to address these concerns, but CMS also has it within its own authority to enforce existing law that is intended to ensure payments to pharmacies are reasonable. Doing so is critically important especially now, as CMS seeks to implement the IRA drug pricing reform provisions, which will most certainly result in significant additional Medicare Part D financial pressures on and processes for specialty pharmacies and the broader pharmacy community.

NASP shares the Administration's priority of ensuring patients must have affordable access to the medicines they need. With this priority, we also believe it is most important to ensure that implementation of the IRA law and CMS' related regulations and guidance ensure that patients have continued access to the specialty pharmacy of their choice and to the pharmacy-related services that are essential to support patient medication adherence and management, improve health outcomes, and reduce patient, health system, and government costs. Our comments, specifically on Guidance Sections 40, 90, and 110, seek to address implementation of the law's provisions while ensuring these specific priorities are protected for specialty pharmacies and the patients they serve.

NASP represents the entire spectrum of the specialty pharmacy industry, which includes the Nation's leading specialty pharmacies and practicing pharmacists, pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of specialty drugs, group purchasing organizations, wholesalers, distributors, integrated delivery systems, health systems, and technology and data management companies, among others. NASP's pharmacy members include specialty pharmacies of all types, including independent (non-affiliated with plan sponsors/PBMs), chain, grocery store, hospital and health system, health plan owned, and home infusion.

NASP COMMENTS ON MEDICARE DRUG PRICE NEGOTIATION PROGRAM DRAFT GUIDANCE

Section 40 – Requirements for Manufacturers of Selected Drugs

This Section requires that for the initial price applicability year 2027, the Primary Manufacturer of a selected drug is the entity that is responsible for a number of requirements, including those with implications for specialty pharmacy patients and specialty pharmacies, as follows:

- Ensuring the MFP is made available to all MFP-eligible individuals (beneficiaries) and to pharmacies and others that dispense the selected drug to those individuals;
- Responding to CMS requests within specified timeframes with documentation demonstrating compliance and remedial actions, as applicable, pursuant to reports of noncompliance or other CMS compliance and oversight activities and pays any civil monetary penalties (CMPs) for violations.

40.4 – Providing Access to the MFP in 2026 and 2027

After a Primary Manufacturer of a selected drug for negotiation enters into an MFP agreement with CMS, according to the guidance, each manufacturer for each selected drug must provide access to the MFP to MFP-eligible individuals[2] and to pharmacies/dispensing entities with respect to such MFP-eligible individuals who are dispensed a selected drug under Medicare Part D or an MA-PD plan under Medicare Part C, for all dosage forms[3] of that drug. CMS defines "providing access to the MFP" to dispensers as ensuring that the net amount paid by the pharmacy/dispensing entity for the selected drug is no greater than the MFP.

CMS also explains in the guidance that the IRA law states that the negotiated prices used in payment by each Part D plan sponsor for each selected drug must not exceed the applicable MFP plus any dispensing fees for such drug. CMS explains that this requirement ensures that Part D MFP-eligible individuals will have access to the MFP at the point-of-sale, as intended by Congress. Requiring MFP-eligible individuals have access to the MFP ensures their cost sharing will be based on the applicable MFP – a price negotiated by Medicare with manufacturers intended to reduce the drug's costs significantly and therefore improve the affordability of the drug for a beneficiary.

NASP urges CMS to interpret the MFP for the select drugs as equal to the "lowest possible reimbursement" definition of "negotiated price" as set forth in the final Part D regulation issued by CMS that went into effect in January 2024.[4] It is clear in the IRA statute that Congress directed manufacturers to provide pharmacies access to the MFP for the selected drugs and CMS, through its proposed guidance, is seeking to establish a process to ensure pharmacies pay no more than the MFP when acquiring a drug. It stands to reason that if Congress intended for pharmacies to have access to the MFP, that the MFP (plus dispensing fees) would also be considered the negotiated price at the point of sale. To permit a plan sponsor to apply further price concessions to a Medicare negotiated drug, reducing a pharmacy's point-of-sale reimbursement below the MFP would most certainly put a pharmacy underwater on the ingredient cost of the drug alone. Such unreasonable reimbursement

[2] Defined in section 1191(c)(2)(A) of the Inflation Reduction Act.
[3] Including the list of NDC-9s and NDC 11s.
[4] Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; published May 9, 2022.

would be in violation of the Any Willing Pharmacy statute,[5] and CMS must enforce the law to ensure payment to pharmacy is reasonable to permit a pharmacy to participate in network.

NASP urges CMS to explicitly prohibit any post-sale pharmacy price concessions for select drugs with an MFP to safeguard pharmacies from further financial instability. Any post-sale concessions would fail to result in a reduction to a MFP-eligible individual's cost sharing, meaning that these individuals would never benefit from post-sale concessions applied to the selected drugs, and such post-sale concessions only serve to threaten the financial viability of pharmacies, their ability to dispense certain drugs, and their continued ability to participate in pharmacy networks. While reducing beneficiary out-of-pocket drug costs is a significant goal of the IRA reforms, in implementing the law, it is critically important that CMS also seek to protect beneficiary access to their pharmacies, and as such, prohibit post-sale pharmacy price concessions (post-sale pharmacy DIR fees).

The IRA statute is clear that pharmacies are to receive a dispensing fee[6] though it did not stipulate any amounts for such fees. However, as acknowledged repeatedly by CMS in the draft guidance, all pharmacies are expected to have an increase in their operating costs to manage the new MFP process, including but not limited to: management of inventory, any reporting and reconciliation of payments through the MTF, and potentially many different manufacturer payment process requirements, etc. **NASP requests that as part of its oversight responsibilities in implementing the IRA law, CMS monitor and audit Part D plan/MA-PD dispensing fee arrangements to ensure that Plans are recognizing and covering new pharmacy operating cost requirements associated with the MFP for select drugs in addition to respecting and affording dispensing costs specialty pharmacies incur compared to their retail pharmacy counterparts, due to the extensive patient service requirements both manufacturers and plans require from specialty pharmacies.**

- ***40.4.1 – Medicare Transaction Facilitator (MTF) Data Facilitation***

The IRA statute mandates that Primary Manufacturers make the MFP for selected drugs available to both MFP-eligible individuals and pharmacies/dispensing entities. When a pharmacy/dispensing entity is not purchasing the selected drug at MFP, pharmacies/dispensing entities will need a refund from the Primary Manufacturer administered through a retroactive process. CMS acknowledges that the following data exchange elements be in place to administer such a process: 1) verification that the selected drug was dispensed to a MFP-eligible individual via certain claim-level data elements and identifying which pharmacy/dispensing entity dispensed the select drug; 2) to initiate the 14-day prompt MFP payment window for effectuating the MFP refund for each claim for each selected drug to each pharmacy/dispensing entity; and 3) to collect payment-related data for each claim for a selected drug from Primary Manufacturers to indicate when a refund was paid and the amount of the refund paid. These requirements necessitate the coordination and reconciliation of several disparate data elements, including, but not limited to:

- Part D Verification to determine patient and drug MFP eligibility;
- Identifying 340B transactions that would not be MFP-eligible;
- Calculating MFP refunds; and

[5] Section 1860D-4(b)(1)(A) of the Social Security Act.
[6] Defined in section 1198(b)(3)(D) of the Inflation Reduction Act.

- Determining total pharmacy payment across responsible entities: patients, Part D plans and manufacturers

CMS has determined that it will engage a MTF to provide a myriad of services with some of these services being mandatory to allow for the exchange of data with manufacturers and for CMS to verify data from manufacturers to ensure compliance with the law.

CMS states that a Primary Manufacturer may choose to contract with one or more third parties to perform the data exchange operations with the MTF. **NASP urges that CMS mandate a single, standardized approach for data exchange and payment processes, regardless of the involvement of third parties, to streamline operations and reduce administrative burdens on pharmacies. Otherwise, pharmacies would have to configure their operations to meet the individual needs of several manufacturers as well as potentially multiple verification systems in order to ensure they are ultimately paid correctly for the MFP.**

Effectuating the MFP should not be directly or indirectly left to the pharmacies to figure out and manage, diverting pharmacy time and resources away from serving its patients and adding significant financial and administrative burden to pharmacies that, as mentioned, are already facing numerous financial pressures within the Part D program in the absence of sufficient financial support to cover their business costs.

While NASP is pleased that CMS intends to prohibit manufacturers and any manufacturer-contracted partner from charging pharmacies fees for the retrospective MFP data/payment processes, this does not fully insulate pharmacy risk, nor does this account for the potential costs and significant burden of the many ancillary activities pharmacies may have to perform to support manufacturers with MFP effectuation outside of a required data exchange process managed by the MTF. CMS states in the guidance that it "intends to leverage existing Part D claims data in this data exchange and does not envision dispensing entities separately transmitting claims data to Primary Manufacturers." NASP asks that CMS formally establish requirements and protections for pharmacies to ensure the burden of this data exchange process is not in any way placed on pharmacies. Pharmacies simply need more assurance beyond CMS intent in guidance. Pharmacies cannot be placed at any financial risk in order for the IRA law's requirements to be carried out. Congress clearly did not intend for pharmacies to shoulder the burden of MFP effectuation.

CMS states that requiring Primary Manufacturers to exchange data with the MTF will be necessary to administer a uniform approach to the start of the 14-day prompt MFP payment window for each claim to a pharmacy/dispensing entity and to the MTF for verification purposes, saying that any failure to meet this process will be considered a violation and risk the Primary Manufacturer being subjected to civil monetary penalties (CMPs) as permitted by the statute. **CMS does not address what happens to effectuation of the MFP for a pharmacy/dispensing entity should this occur, and the Primary Manufacturer is (or opts to be) subjected to CMPs instead of participating and carrying through the data exchange process. NASP must reiterate that pharmacies cannot be left at financial risk if manufacturers do not follow through on the requirement to effectuate the MFP. Pharmacies must receive assurance and commitment from CMS that in these circumstances, the MTF will work with CMS to leverage the existing Part D claims data process to effectuate the MFP for pharmacies.**

Data Transmission, Access and Timing – An Alternative Approach

NASP is providing comments on the process CMS has proposed to effectuate the MFP to pharmacies through its proposed guidance, but NASP strongly believes an alternative approach is likely needed in the absence of addressing pharmacies' concerns. NASP strongly encourages CMS to seek not to completely "reinvent the wheel" in terms of designing a new process to ensure manufacturers are able to meet statutory MFP requirements, but rather follow to the greatest extent possible, the existing claims process system that has proven to be efficient, effective, transparent and timely for all parts of the pharmaceutical channel (all contracted entities) in the transfer of claims data for verification and payment.

The existing Part D claims management process, including the facilitation of the existing Coverage Gap Discount Process (CGDP) under Medicare Part D that largely seems to facilitate a data exchange process that, with few alterations to better support increased transparency to pharmacies, could otherwise be mirrored to support manufacturer effectuation of the MFP as required under the IRA law. Indeed, NASP understands that Congress sought to model the MFP effectuation statutory requirement after the statute that established the CGDP[7] in an effort to follow past precedent for a discount program under Part D.

CMS effectuates CGDP discounts through contracted third-party entities with the Part D plans serving as payment facilitators. In the CGDP, manufacturers are required to provide CGDP-eligible individuals discounted prices for drugs at the point of sale. Part D plans include the manufacturer-required discount amount as part of the Plan's payment obligation. The pharmacy knows its full compensation amount for related claims in real time and within the claims workflow, and payments are made within a 14-day prompt payment standard. Manufacturers repay Part D plans through the CGDP contractor. CMS, Part D plans, and manufacturers reconcile financial transactions independently without disrupting patient access or pharmacy economics.

CMS has indicated that the CGDP model will be used to operationalize the new Manufacturer Discount Program (MDP) that IRA law replaced it with, saying that the MDP will be effective under the new Part D benefit starting in 2025. CMS should strongly consider the potential overlapping needs and functions necessary to also effectuate the manufacturer MFP (drug discount) refund. Such a financing model would allow manufacturers to seamlessly pay MFP refund amounts to pharmacies at the point of sale.

If the CGDP was to serve as the model for MFP effectuation, NASP recommends that another contracted entity rather than a Plan Sponsor/PBM should serve as the data facilitator to manage access to 340B data and to also ensure trust and protect the competitive interests of pharmacies and manufacturers in relation to acquisition-related data. The CGDP includes a pre-funded account approach to managing reconciled payments to pharmacies to meet statutory payment obligations in a timely manner. Under a CGDP-like approach, CMS should have direct oversight of the MFP effectuation process as well as govern the necessary data and financial flows. CMS should also consider alternative pre-funding pathways that ultimately could reduce a manufacturer's risk and a

[7] 42 U.S. Code § 1395w–114a.

pharmacy's administrative and financial risk of no MFP retroactive payment or delayed retroactive payments.

In the absence of a CGDP-like pre-funded option, under the approach outlined by CMS in the guidance, NASP believes pharmacies will be essentially pre-funding retrospective MFP adjustments themselves and then having to pursue and track any and all MFP refund payments under potentially varied manufacturer approaches. This is unacceptable and not what Congress intended when passing the IRA law.

NASP is extremely concerned that with the various options under consideration by CMS in the proposed guidance, payment to pharmacies under a retroactive process would amount to MFP payment effectuation taking as long as 60 days or more for each claim for a dispensed selected drug. This despite the fact that the statute envisioned that pharmacies would be paid the MFP (plus dispensing fees) within a 14-day prompt payment period. This is because once claims data has been verified by the Part D plan sponsor, and the pharmacy has already received payment, CMS envisions having the plan sponsor submit complete prescription drug event (PDE) records to the Drug Data Processing System (DDPS) for secondary verification before that data is then sent to the MTF and then the MTF sends data information to the manufacturer for response. Today, in the absence of any MFP effectuation requirements, Part D plan sponsors have 30 days to submit complete PDE records to DDPS. This window of time is extremely unworkable if CMS is to require a secondary validation of Medicare Part D claims by the DDPS before data is made available to the MTF for the MTF to provide to manufacturers. **CMS states it is evaluating whether the current 30-day PDE data transfer window should be shortened to seven days to support pharmacies receiving timely MFP refunds. NASP must emphasize that is critically important that CMS shorten this window and would suggest the time window for submission of PDE records to the DDPS by plan sponsors be conducted in less than seven days, with CMS considering how this data exchange can be done in real time on a daily basis and function to capture all claims, reversals, and rebills. Under the CMS model proposed, there should likewise be very limited timing requirements for the claim-level data elements on each dispense of an NDC of a select drug to be transmitted from the MTF to Primary Manufacturers, with this also functioning in real time and on a daily basis.**

In addition to enforcing the IRA law's 14-day prompt MFP payment requirement from the Primary Manufacturer to the dispensing pharmacy, CMS is proposing to also require a Primary Manufacturer to transmit claim-level payment elements in its report with any payment-related data or information on no refunds provided to the MTF within the 14-day prompt MFP payment window. CMS explains this is to ensure CMS can appropriately administer the MFP program and to monitor compliance with the requirements of the program. CMS has outlined the following payment elements must be included in this transmission: the MFP refund transaction date; confirmation of the MFP refund to the dispensing entity; the method for determining the MFP discount/refund amount (including whether it was at the standard refund amount of WAC-MFP or another refund amount); the NPI of the entity receiving the MFP refund; the quantity of the selected drug; and the amount of payment sent as the MFP refund; whether no refund was paid (e.g., 340B claims); no refund was paid despite attempts to pay (no pharmacy response) or no refund paid (e.g., prospective access to the MFP was made to the pharmacy, etc.).

CMS states that it is also considering having the MTF generate an electronic remittance advice to the pharmacy/dispensing entity for purposes of reconciling manufacturer retrospective MFP refunds. **NASP urges CMS to have the MTF provide for electronic remittance advice with at least the same information that will be required from the Primary Manufacturers to the MTF. NASP asks that CMS ensure this information is provided electronically with payments under the 14-day prompt standard to support pharmacies in reconciling retroactive payment adjustments for all MFP selected drugs that are dispensed.**

NASP has specific concerns about the MFP payment process when there are circumstances that result in a drug being dispensed but never received by the MFP-eligible individual (e.g., a patient opts not to receive the medication due to cost, and it goes back into a pharmacy's stock); and other claim reversals and adjustments. A process under the model CMS has proposed would need to allow for a credit or at least a reasonable reversal process to be in place, if a pharmacy was in receipt of the MFP for a drug that has a claim that is ultimately reversed or not completed. The process would need to allow for information to be reported to and captured by the MTF to moderate a payment adjustment between the pharmacy and manufacturer in a non-burdensome and timely manner. NASP is discussing this issue further with its members who represent the entire channel of specialty pharmacy to understand recommendations it can offer to support a fair and non-burdensome process to address claim adjustments and reversals that occur after the pharmacy has been paid a retroactive MFP.

- ***40.4.2 – Nonduplication with 340B Ceiling Price***

The IRA law states that the Primary Manufacturer of a select drug is not required to provide access to the MFP for a select drug to MFP-eligible individuals who are eligible to be dispensed a drug subject to a 340B ceiling price under statute if the 340B ceiling price is lower than the select drug's MFP. Primary Manufacturers are required to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the select drug is lower than the 340B ceiling price.

The proposed guidance makes clear that CMS will not assume responsibility for "deduplicating" discounts and instead expects manufacturers to assume that responsibility themselves. Supplying claims data is to be voluntary by a dispensing entity while CMS works to establish a process to identify applicable 340B eligible claims through the reporting of payment elements to the MTF. **For those dispensing entities that opt to provide this information, NASP believes the effort would be immensely burdensome as dispensers seek to work with individual manufacturers through their separate data submission processes.**

CMS proposes that when a 340B price is lower than MFP, 340B entities append a modifier on the claim to identify the claim as 340B, which CMS believes would allow the manufacturer to avoid making the default payment for those claims. Yet, CMS acknowledges that most covered entities and their contract pharmacies cannot identify 340B claims at the point of sale, and likely not until days later, after the claim is submitted. **NASP believes it would be unworkable to expect pharmacies to use a separate physical inventory of 340B drugs.**

NASP is concerned that contract pharmacies for 340B covered entities will be in a very difficult situation regarding MFP implementation. Many contract pharmacies use a replenishment model,

receiving drugs from the covered entity after they have been validated as 340B eligible. This process can take over 20 days after a 340B-eligible drug has been dispensed.

CMS should develop a methodology that would enable covered entities to retrospectively submit 340B claims data to the MTF and require that the MTF use the data to identify 340B claims that should be withheld from being submitted to the manufacturer.

Absent CMS guidelines and criteria for the manufacturers' nonduplication plans, a manufacturer could require covered entities to submit large volumes of data to the manufacturer or its contractor in order to receive the 340B price or MFP as a refund. However, this would be at odds with the longstanding practice of covered entities accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B programs. Outside of a very narrow exception for AIDS Drug Assistance Programs, HRSA has never authorized manufacturers to offer 340B discounts as refunds instead of purchase prices.

NASP strongly encourages CMS to work with stakeholders to find more viable alternatives to ensure covered entities can purchase drugs at the 340B price and support efforts to address MFP refunds through a process that works with hospital and contract pharmacy processes to manage 340B drugs.

- ***40.4.3 – Retrospective Refund Amount to Effectuate the Maximum Fair Price (MFP)***

As addressed earlier in these comments, **NASP is concerned that separating the MFP financial transaction from the real-time claims processing system to be managed by the manufacturer under Part D could result in significant payment delays and disruptions for pharmacies. The best way to facilitate a retrospective MFP approach would be to create an automated, standardized, transparent, and predictable process, modeled after the Coverage Gap Discount Program (CGDP) that is aligned with current Part D claims processing systems in order to ensure timely MFP payments. Such an approach would reduce administrative burdens on pharmacies and manufacturers as well as financial risk and support a 14-day payment standard.**

For Primary Manufacturers to meet their statutory obligation under the IRA to make the MFP available to pharmacies, if on a retrospective basis, CMS has proposed a Standard Default Refund Amount that reflects the difference between the selected drug's WAC and the MFP. However, CMS is also proposing to let manufacturers opt for an alternative refund formula instead of the Standard Default Refund Amount to effectuate the MFP for a pharmacy.

NASP believes use of WAC would allow for a fair standard metric to approximate a pharmacy's acquisition costs as it is generally accepted that specialty drugs are acquired at this benchmark. NASP urges CMS to require use of this standardized metric across manufacturers for determining retrospective payments in order to allow for predictability and replication across the pharmaceutical channel to support the pharmacy refund amount. Since WAC and MFP are both publicly available data they would easily allow for an auditable MFP refund amount for all stakeholders, including pharmacies, manufacturers, and Medicare.

Permitting a variety of metrics for determining pharmacy acquisition costs would be administratively burdensome for pharmacies as pharmacies seek to reconcile their payments for selected drugs across

many manufacturers. NASP also urges CMS to prohibit manufacturers from requiring pharmacies to individually report their acquisition costs, as there are likely thousands of different acquisition costs for the same drugs as each pharmacy in the United States has different contract terms with entities in pharmaceutical channel, and sharing such information would allow proprietary pharmacy acquisition costs to be shared with others in the channel that are not privy to this information. Allowing a multitude of refund formulas could also lead to the risk of unreasonable metrics that are falsely assumed to model pharmacy acquisition costs.
The use of unreasonable metrics to address pharmacy acquisition costs in the absence of any CMS guardrails and agency oversight would only further undercut pharmacy reimbursement under Part D, contributing to the financial strain many pharmacies are already facing today.

CMS needs to provide greater oversight and a formal approval process for manufacturers if it opts not to require WAC as the standard pricing metric to be used by all Primary Manufacturers. CMS must provide information on how it will determine whether and what type of alternative pricing metrics (not WAC) ensure reasonable reconciliation payments to pharmacies that are sufficient for Primary Manufacturers to meet their obligations to make the MFP available under the terms of the law. CMS must also explain and set requirements as to how a pharmacy would be made aware of any Primary Manufacturer's decision to use an alternative metric to WAC and be provided information on that metric in advance of its use with an opportunity to appeal for reconsideration of the metric and alert CMS to its concerns.

- ***40.4.4 – Options for Medicare Transaction Facilitator (MTF) Payment Facilitation***

CMS states it has received immense stakeholder feedback that MTF payment facilitation is important to support manufacturer effectuation of the MFP. While the agency interprets the IRA law to say it is the sole responsibility of the Primary Manufacturer to provide access to the MFP and that CMS has no express role to support manufacturer effectuation of the MFP, CMS is considering how the MTF could offer some form of a voluntary payment facilitation functionality that connects the Primary Manufacturer to the dispensing entity for the purpose of providing a retrospective refund to the dispensing entity within a 14-day prompt MFP payment window.

NASP agrees that MTF payment facilitation under the model proposed by CMS in the guidance would be essential to effectuate the MFP. NASP also thinks the MTF is needed if CMS opts to support access to the MFP through an alternative approach that models the Coverage Gap Discount Program (CGDP).

NASP strongly disagrees with CMS' determination that it has no express role to support manufacturer effectuation of the MFP. CMS oversight, guardrails and review of the MTF payment facilitation process will be essential to ensure that all players in the pharmacy channel appropriately address the ultimate process CMS puts in place. At a minimum, CMS' role in this effort should include:

- **Defining roles and responsibilities for key activities and transactions in the MFP effectuation process (e.g., Part D plan required to verify MFP eligibility; MTF to assess WAC values; Primary Manufacturer to not set unreasonable acquisition metrics; pharmacy to verify accuracy of MFP payment);**

- **Clarifying which entities can play a role in effectuating the MFP based on required capabilities (e.g., only Health Insurance Portability and Accountability Act (HIPAA) covered entities are able to manage claims-based level transactions);**
- **Defining minimum data standards for core transactions (e.g., refund request must include claim number, NDC, units dispensed, etc.)**
- **Ensuring financial accountability across channel stakeholders to oversee against and mitigate against any cost shifting to pharmacies.**

In the proposed guidance, CMS solicits comment on two distinct payment facilitation options that would be voluntary to the for both Primary Manufacturers and pharmacies:

1. The MTF collecting banking information from participating pharmacies/dispensing entities and providing that information to Primary Manufacturers who want to receive that information in order to provide payments.
2. The MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating pharmacies/dispensing entities.

Technical specifications for both options have not yet been provided by CMS.

NASP believes that if CMS opts to not amend its approach to facilitate payment through existing claims processing systems similar to the CGDP, then it needs to allow for a MTF process that supports a standardized, accurate and expedited process for issuing fair and appropriate MFP payments to pharmacies. While it is difficult to completely evaluate the two options provided by CMS, NASP pharmacy members would likely be most interested in Option 2 given that, as explained in the guidance, the MTF would provide payment confirmation to both the dispensing entity and the Primary Manufacturer to demonstrate effectuation of the payment and close out the transaction while also maintaining a record of the execution of payment within the 14-day prompt MFP payment window for each transaction facilitated, which could assist in any dispute and complaint resolution process between the pharmacy and a manufacturer.

As raised previously in these comments under Section 40.4.1, CMS does not provide for any process to ensure effectuation of the MFP for a pharmacy/dispensing entity if a Primary Manufacturer is found to not meet its 14-day payment statutory requirement (intentionally or unintentionally) and is subjected to CMPs. **NASP must reiterate that pharmacies cannot be left at financial risk if manufacturers do not follow through on the statutory requirement to effectuate the MFP. Pharmacies must receive assurance and commitment from CMS that in these circumstances, the MTF will work with CMS to leverage the existing Part D claims data process and/or structure a pre-payment account with Primary Manufacturers similar to the model used in the CGDP in order to effectuate the MFP for pharmacies and protect pharmacies from financial risk.**

- ***40.4.5 – Medicare Transaction Facilitator (MTF) Dispensing Entity Participation Requirements***

The MTF is required to be used by Primary Manufacturers for data exchange as outlined in section 40.4.1; however, use of the MTF for facilitation of retrospective refund payments is at the option of both Primary Manufacturers and pharmacies as outlined in section 40.4.4. If not utilized for payment

facilitation, payments to pharmacies would be provided through a separate process agreed to by the Primary Manufacturers and pharmacies.

NASP is pleased that CMS makes clear in this section that neither Primary Manufacturers nor their contracted entities shall charge pharmacies/dispensing entities any transaction or other fees for the data exchanges facilitated through the MTF. However, such assurances are insufficient. NASP remains extremely concerned about the financial uncertainty and cash flow challenge pharmacies will face if the transaction process across all Primary Manufacturers of selected drugs and pharmacies is not uniform, standardized and seamless. Pharmacies having to manage a multitude of different payment systems among manufacturers would be untenable. CMS must require that a uniform payment transaction system be utilized regardless of whether it is administered by the MTF or administered by manufacturers and/or their contractors.

- ***40.5 – Compliance with Administrative Actions and Monitoring of the Drug Price Negotiation Program***

CMS states in the guidance that it is required by the IRA law to establish a robust program for monitoring compliance with the Negotiation Program. However, **NASP is concerned that CMS states it "may" audit any data related to the Primary Manufacturer providing access to the MFP, including where the selected drug is provided by a Secondary Manufacturer. NASP wants to emphasize the importance of CMS overseeing and requiring compliance with the process for data exchange to effectuate the MFP, and reiterate that CMS should go further to require standardization and uniformity around payments to pharmacies with CMS oversight and protections to ensure that pharmacies are not put at any financial risk for the requirements of the law addressing MFP payments. The process for the exchange of information between manufacturers and pharmacists must be part of a mandatory audit by CMS.**

Section 90 – Manufacturer Compliance and Oversight

- ***90.2 – Monitoring of Access to the MFP in 2026 and 2027***

This section of the draft guidance reiterates statutory requirements that Primary Manufacturers must meet, providing pharmacies and other dispensing entities and MFP-eligible individuals access to the MFP, and that this requirement applies to all sales of the selected drugs, including when there are Secondary Manufacturers. CMS states that if it determines through audits, investigations, and complaints from pharmacies or other market participants that Primary Manufacturers have not fulfilled their MFP obligations to make the MFP available within the 14-day prompt MFP payment window, CMS will first encourage payment discrepancies to be addressed and may then issue CMPs.

NASP would appreciate clarity from CMS on the frequency in which it will proactively audit manufacturer compliance and whether it will commit to interviewing participating pharmacies that are dispensing MFP drugs to understand concerns and options for how to address these concerns for pharmacies.

CMS states that when claims are paid at a refund amount other than the Standard Default Refund Amount (WAC), Primary Manufacturers will be required to maintain documentation demonstrating why MFP refunds were provided to an amount other than the Standard Default Refund Amount or were not provided for applicable claims.

- ***90.2.1 – Manufacturer Plans for Effectuating MFP***

Under this Section, CMS states that it will require Primary Manufacturers to submit their plans for making the MFP available, including their process for deduplicating 340B covered units for the selected drug, in writing to CMS at least seven months before the start of the first initial price applicability year for the selected drug (June 1, 2025). CMS believes this will allow the agency sufficient time to conduct outreach to Primary Manufacturers to review their plans, conducting a risk assessment for each submission. CMS also clarifies that manufacturers' plans must include description(s) of the types of documentation and data they would collect, maintain and deliver to CMS. CMS plans to publish the manufacturer plans on the CMS IRA website, making all non-proprietary information accessible to pharmacies and others.

CMS states that all Primary Manufacturer plans will be assessed for their consistency with the requirements outlined in sections 40.4-40.4.5 of this draft guidance and must include:

- Information on the plan to meet the 14-day prompt MFP payment window for reimbursing pharmacies regardless of whether the manufacturer is using the potential MTF functionality to administer payment or its own mechanism to administer payment;
- Policies and procedures for determining the methodology it will use to calculate the amount of each reimbursement due to the dispensing entity (WAC, actual acquisition cost, or otherwise); and
- Confirmation it will submit verification of reimbursement to the MTF via the requested report with payment-related data for meeting the 14-day requirement.
- Information on whether it will participate in the potential MTF payment facilitation functionality.

CMS also states that it will conduct a risk assessment for each plan submission, and when plans are identified by CMS as having a greater risk of failing in making the MFP consistently available, subject such manufacturers to increased scrutiny through CMS' monitoring and oversight activities.

CMS also states that if a Primary Manufacturer decides to make a change from proactively effectuating the MFP at the point of sale or makes any other changes to its MFP methodology, it must inform CMS within 90 days or as soon as practical.

NASP supports CMS efforts to establish an earlier deadline for manufacturer plans to be made available and agrees that this plan information should be made available to pharmacies/dispensing entities in advance of the MFP process going into effect. To support transparency and clarity of process, it is essential that pharmacies understand the process manufacturers will use to effectuate the MFP and what processes CMS will be undertaking to ensure compliance.

NASP wants to reiterate and emphasize strongly its concern about all manufacturers setting their own operational plans, requiring pharmacies to then understand and potentially set up different processes

to manage numerous manufacturer processes for a multitude of drugs as the drug negotiation program continues to grow. This would be untenable for pharmacies to manage administratively and afford. CMS also addresses directly that it will conduct a risk assessment of manufacturer plans, assuming some may be at risk of failing. This acknowledgement furthers our point on the need for standardization, uniformity and consistent oversight. We urge CMS to use its authority to enforce the law's requirements by standardizing a process. Information from the manufacturers on how they foresee managing the process should first be collected by CMS, and then a formal process outlined that all must follow.

For those plans identified by CMS to have risk, NASP would like to better understand what CMS's process to rectify concerns will be put in place, and what engagement pharmacies would have in this process, since it is pharmacies that are the ones subject to significant financial risk as any manufacturer plan is put in place.

NASP is extremely concerned about CMS' vague proposed oversight standard of a manufacturer being able to inform CMS as soon as practical of any planned change in its payment of the MFP. There is nothing in the guidance that speaks to when a pharmacy/dispensing entity would be required to be informed of any change in the payment of the MFP, and manufacturers are given flexibility to report or not report any change to CMS. The lack of a standard for manufacturer reporting of changes in effectuating the MFP to CMS and no standard requirement for manufacturers to inform pharmacies of these changes could have significant negative consequences for pharmacies to raise a complaint, dispute or appeal lack of payment or incorrect payment amounts to either CMS or the manufacturers and to have these addressed and addressed in a timely manner.

- ***90.2.2 – Negotiation Program Complaints and Disputes***

CMS states that it will establish a centralized intake system for receiving reports on complaints and disputes related to access to the MFP with respect to eligible individuals (beneficiaries) and pharmacies/dispensing entities that provide selected drugs to MFP-eligible individuals. It describes this process to have different tracks and to focus on technical issues and data matters, making clear that the MTF intake process for addressing such concerns will under no circumstances determine whether a Primary Manufacturer has provided access to the MFP or met its legal obligations (e.g., payment to pharmacies within 14-days). CMS states that the agency itself would be responsible for these issues not the MTF, and that it is still exploring options for collecting appeals/complaints and addressing them. CMS specifically states that it is still exploring the limits on the scope of disputes and complaints that the agency may remediate in the context of otherwise private transactions between Primary Manufacturers and dispensing entities.

CMS must establish a clear process for addressing any financial transaction disputes between manufacturers and pharmacies, ensuring that pharmacies have a reliable mechanism for reporting and resolving issues. It is unclear how CMS would ever be able to comply with the law's requirements to impose CMPs on manufacturers that do not effectuate the MFP for eligible individuals or pharmacies/dispensing entities if it is not able to appropriately consider proactive financial-related

complaints/disputes received or act on them. NASP would again reiterate that the law needs to be enforced by CMS, and that a standardized and required process for payment under Medicare Part D, rather than an optional and private payment process, is essential to effectuating the MFP. The amount of pressure on the channel to accurately provide access to the MFP is immense, and to establish a free-for-all system where manufacturers have carte blanche to design their own payment systems will create chaos for pharmacies and result in significant payment errors. This puts both pharmacies and manufacturers at extreme financial risk – as there is no guarantee of payment to a pharmacy, and manufacturers may be subjected to CMPs. NASP again recommends that CMS reconsider its approach entirely and instead rely on the existing claims process including the CGDP in order to support access to the MFP for pharmacies and ensure a streamlined process for all entities in the channel.

Section 100.1 – Failure of Manufacturer to Ensure Access to a Price Less Than or Equal to the MFP

CMS states that upon discovery and confirmation of a failure to make the MFP available, CMS will send the Primary Manufacturer Notice of Potential Noncompliance and establish an "informal" process allowing the Primary Manufacturer 10 business days to respond to the notice. CMS will then consider the materials and make a decision regarding manufacturer liability and any CMPs.

NASP is alarmed that such a process to assess compliance with the law's requirements is being presented as an informal process. The law requires that the MFP terms be met and met within a specifically defined window of 14-days. CMS' informal process as suggested, would allow for well over 10 days before any decision is reached on manufacturer compliance with effectuating the MFP. As this process rolls out, pharmacy payment remains non-existent, and CMS does not address what happens when the MFP is not effectuated, effectively leaving pharmacies to "hold the bag." This is a significant concern and must be addressed by CMS. CMS should establish a formal, expedited process for addressing non-compliance with MFP requirements, ensuring resolution within the already defined 14-day payment window to prevent any financial risk to pharmacies.

Section 110 – Part D Formulary Inclusion of Selected Drugs

CMS states that Medicare Part D plans must include each covered Part D drug that is a selected drug on Part D formularies during contract year 2026 (and 2027) if a MFP is in effect for that drug that year and during each subsequent year that a MFP for the selected drug. However, CMS states it does not have sufficient information to determine whether changes to the formulary inclusion policies are warranted given that it does not yet have information on plan formularies for Contract Year 2025 nor for Contract Year 2026 – the first year the law goes into effect. CMS says it intends to monitor Part D plans' compliance with formulary requirements and treatment of selected drugs and may possibly address formulary policies in the future. CMS also says that it will not implement explicit tier placement or utilization management requirements at this time. CMS does express concern that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management that is not based

on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs.

NASP is concerned about specialty patient access to the selected drugs whether for new patients or for those on current selected drug therapies, where a change in drug formulary could be extremely detrimental to their treatment. It is a very valid concern that Part D sponsors may make significant formulary changes as a result of the law, and CMS oversight and enforcement will be essential to protecting patient access to their needed specialty medications. NASP urges CMS to implement monitoring and enforcement mechanisms that ensure Part D sponsors cannot make formulary changes that disadvantage selected drugs and harm patient access.

Conclusion

NASP looks forward to continued opportunities to work with CMS as it implements the Medicare Negotiation Program. To address questions about our comments or for further information, please contact me at Sheila.Arquette@naspnet.org.

Sincerely,

Sheila Arquette, RPh.
President and CEO

Submitted electronically to: IRARebateandNegotiation@cms.hhs.gov

July 1, 2024

Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA urges CMS to implement the Medicare Drug Price Negotiation Program in a way that does not harm independent pharmacies and patient access alike. NCPA hopes to avoid a similar shock to independent pharmacy that occurred in January 2006 with the launch of the Medicare Part D program, which had significant negative effects on independent retail and LTC pharmacies, who had to float the program, and where states had to intervene with assistance.

NCPA's analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies found that if the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number

is only for year one of the MFP program, and will grow larger and larger as more drugs are added each year, resulting in devastating, irreparable impact on pharmacies serving most vulnerable and at-risk patients, especially those serving long-term care facilities.

In order to preserve patient access to MFP drugs under this program, and to insure that pharmacies are paid timely and are not floating this program, NCPA urges CMS to ensure and verify the following, among other asks in these comments:

1. That the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price;
2. That the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP;
3. That under the IRA, pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions;
4. That PBMs and plans should not be able to impose any pharmacy price concessions that would ultimately reduce patient access to MFP drugs;
5. That pharmacy reimbursement will incorporate a negotiated price that is no lower than the maximum fair price and; 2) cover acquisition cost plus commensurate professional dispensing fee in line with Medicaid fee-for-service and should be paid within Medicare prompt pay requirements;
6. That pharmacies will be paid timely within Medicare prompt pay requirements, within 14 days of adjudicating the claim;
7. That CMS will shorten the current 30-day window of the time that Part D plan sponsors have to submit complete Part D Prescription Drug Event (PDE) records to CMS' Drug Data Processing System (DDPS), to 7 days;
    a. To expedite payment to pharmacies, NCPA suggests that CMS prefund the Medicare Transaction Facilitator (MTF);
    b. However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the Program, then we urge CMS to shorten the PDE reporting period from 30 days to 1 day, and to require MTFs to provide the requisite data to the Primary Manufacturers on a daily basis.
8. That the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds; and
9. That neither plans, PBMs, manufacturers, wholesalers, CMS nor any other entity assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever, and that any EFT fees should be borne by the manufacturer and not the pharmacy.

CMS Must Address Part D Plan Sponsor/PBM Payments to Pharmacies for MFP Drugs to Ensure Beneficiary Access to MFP Drugs

NCPA is concerned that the Draft Guidance does not address Part D plan sponsor/PBM payment for MFP drugs. NCPA requests confirmation from CMS that the MFP is the ingredient cost for a selected MFP drug, and that CMS has the authority to ensure that pharmacies are paid at that specific price.

Under the Inflation Reduction Act, there is a process by which the Secretary selects MFP drugs. Once a drug is selected, the Secretary is required to enter into agreements with manufacturers to set the MFP for particular drugs. The manufacturer is then required to "provide access to such price . . . to maximum fair price eligible individuals who . . . are dispensed such drug (and to pharmacies, mail order serves, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs)."[1] In addition, the basic definition of "maximum fair price" means the amount negotiated between the Secretary and a manufacturer for a selected drug—that is, for the ingredient cost of that drug.[2] **Given the above, NCPA believes that the IRA equates MFP with ingredient cost, because manufacturers have to make selected drugs available for purchase by pharmacies at MFP.**

NCPA submits that the Inflation Reduction Act means that pharmacies are to be reimbursed by PDP sponsors at MFP for their ingredient costs, plus a dispensing fee, with no extraction of further concessions. There are a few reasons that CMS should arrive at this conclusion. First, as discussed above, the IRA is constructed around treating MFP as the ingredient cost, and it uses a single definition for MFP throughout. Second, the amended definition of "negotiated prices" supports this conclusion. For non-MFP drugs, the total amount of the negotiated price for a non-MFP drug includes (1) the ingredient cost, (2) any "price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs," and (3) "any dispensing fees for such drug[ ]."[3] *In contrast, for MFP drugs* [emphasis added], the "negotiated price" is simply a payment (1) "no greater than the maximum fair price" for the drug and (2) "any dispending fees."[4] Thus, unlike non-MFP drugs, where Congress acknowledged the existence of "concessions" in addition to ingredient costs, Congress did not provide PDP sponsors explicit authorization to extract "concessions" for MFP drugs. Therefore, PDP sponsors should reimburse pharmacies at ingredient cost plus a dispensing fee.

To be sure, Congress provided that the PDP sponsors should make payments to pharmacies at an amount "no greater than the maximum fair price,"[5] which implies that PDP sponsors could reimburse less than MFP, but that is not the best reading of the statute. For one thing, the IRA consistently treats MFP at the ingredient cost, and the fact that manufacturers must provide pharmacies with access to MFP when those pharmacies dispense to an MFP eligible individual

[1] 42 U.S.C. § 1320f-2(a)(1) (NCPA emphasis added); *accord id.* § 1320f-2(a)(2), (a)(3).
[2] *Id.* § 1320f(c)(3); *see also id.* § 1320f-3 (describing the negotiating process for the "maximum fair price").
[3] *Id.* § 1320w-102(d)(1)(B).
[4] *Id.* § 1320w-102(d)(1)(D).
[5] *Id.* § 1320w-102(d)(1)(D).

strongly implies that the pharmacies will then be reimbursed by PDP sponsors at MFP plus any dispensing fee. For another, as noted above, if Congress had wished to allow PDP sponsors to extract additional concessions, it could have said so when it came to defining "negotiated prices" for MFP drugs. But it deliberately excluded concessions from that definition.

This is also consistent with the reality of the IRA. For MFP drugs, manufacturers are being forced to provide access to certain drugs at below their customary price for eligible individuals and the pharmacies that dispense those drugs. It makes sense that Congress would have wanted to reimburse pharmacies no greater than MFP—to ensure that taxpayers are maximizing their savings—while at the same time ensuring that pharmacies at least break even on their ingredient costs while providing for a dispensing fee. Further, the IRA intended to only extract price concessions from the manufacturers, not the providers; therefore, any attempt to pay pharmacies less that MFP would be against the legislative intent of the IRA.

NCPA anticipates that PDP sponsors and their PBMs may argue that depriving them of the ability to reimburse at less than MFP would read "no greater than" out of the statute. However, such an argument is not persuasive, because the statute does not expressly prohibit the Secretary from ensuring that pharmacies are reimbursed at not *less* than MFP. It simply says pharmacies may not be reimbursed greater than MFP. The "not greater than" language also continues to serve a purpose, because ultimately, a PDP sponsor's costs factor into how much CMS pays it under the Part D program. So, it was necessary for Congress to clarify both that manufacturers would sell MFP drugs at a maximum fair price and PDP sponsors would reimburse pharmacies no more than that same price plus a dispensing fee.

40.4 Providing Access to the MFP in 2026 and 2027

40.4.1 Medicare Transaction Facilitator Data Facilitation

Privacy. The draft guidance states that each Primary Manufacturer will be required to sign privacy and security agreements with CMS and comply with privacy and security requirements to protect the data elements received from and transmitted to the Medicare Transaction Facilitator (MTF), and that CMS is evaluating the data privacy and security implications of collecting, holding, and, if applicable, sharing interested parties' financial and securities information for purposes of MTF payment facilitation. **CMS should require that each Primary Manufacturer ensure the privacy and security of data provided to them by pharmacies, which shall not exceed the information under Table 2: MTF Claim-Level Data Elements (see chart below) and the "information disclosures" under 40.4.4 of these comments.**

Table 2: MTF Claim-Level Data Elements

MTF Data Elements List	Purpose	Data Source
Record ID	Used to identify the type of record, such as new claim, adjustment, reversal, etc.	MTF
MTF Internal Claim Number (ICN)	Used to identify the internal unique MTF ID to support claim adjustments	MTF
MTF XRef ICN	Used to link an adjustment to original MTF ICN	MTF
Process Date	Used to identify MTF processed date	MTF
Transaction Code	Used to indicate original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Used to identify coverage under Medicare Part B or Part D	MTF
Date of Service	Used to verify MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Used to verify MFP eligibility	PDE Record
Service Provider Identifier	Used to verify MFP eligibility	PDE Record
Prescription/Service Reference Number	Used to verify MFP eligibility	PDE Record
Fill Number	Used to verify MFP eligibility	PDE Record
Product /Service Identifier	Used to verify MFP eligibility	PDE Record
Quantity Dispensed	Used to assist the manufacturer in calculating a refund	PDE Record
Days' Supply	Used to verify MFP eligibility	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Used to verify MFP eligibility	PDE Record
Contract Number	Used to verify MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) at time of dispensing	Used to calculate the Standard Default Refund Amount	MTF
Maximum Fair Price (MFP) at time of dispensing	Used to assist the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (WAC-MFP)	Used to assist the manufacturer in calculating a refund	MTF
Service Provider MTF Enrollment Status	Used to indicate if dispensing entity opted in to MTF payment facilitation	MTF

340B claims identification. NCPA notes that in the draft guidance, the 340B Claim Indicator in Table 2 of the MTF claim-level data elements is labelled "as voluntarily reported by [the] dispensing entity." **NCPA supports CMS not requiring pharmacies to identify 340B claims, and re-emphasizes the infeasibility of pharmacies identifying those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems.** For NCPA's full comments on this matter, see our March 2023 feedback on CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

Manufacturer calculating and paying dispensing entity. According to the draft guidance, "[r]egardless of whether the Primary Manufacturer uses the potential MTF payment facilitation functionality, the Primary Manufacturer bears responsibility for calculating and paying an appropriate amount to the dispensing entity to effectuate the MFP." **CMS should require that the manufacturer pay the difference between Wholesale Acquisition Cost (WAC) and MFP.**

14 days prompt pay. **NCPA stresses that pharmacies need to be paid timely, within 14 days of adjudicating the claim.** As CMS acknowledges, under 42 C.F.R. § 423.520 (Prompt Payment by Part D Sponsors), Part D sponsors are required to pay pharmacies within 14 days after receiving an electronic Part D claim that is a clean claim.[6] **At the outset of the Part D program and before this provision was put in place, independent pharmacies were closing rapidly due to delays in payment that caused significant impacts on cashflow. Independent pharmacies operate on small margins and are presently closing at the rate of over 1 per day, decreasing beneficiary access to care in their local communities. While NCPA appreciates CMS's effort to incorporate a 14-day prompt payment requirement for Primary Manufacturers, the proposed trigger for that window can vary widely depending on when data is transmitted to the Primary Manufacturer. NCPA stresses that pharmacies need to be paid amounts owed for the MFP within 14 days of adjudicating the claim.**

Part D plan sponsors have 30 days to submit complete PDE records to DDPS. Once those records are sent, the MTF would then need to send the data to the Primary Manufacturers. Depending on the frequency of the transmission, this could result in pharmacies waiting more than several days to receive the amounts owed to them. CMS states that it is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. **CMS must shorten the current 30-day window to 7 days, to ensure pharmacies receive prompt payment. However, in the alternative, should CMS not agree with us that it has the authority to pre-fund the Negotiation Program or to require manufacturers to pre-fund the Program (see below), then we urge CMS to shorten the PDE reporting period from 30 days to 1 day, and to require MTFs to provide the requisite data to the Primary Manufacturers on a daily basis.**

Even if the 7-day window for submitting PDE records is implemented, pharmacies will still be waiting longer than 14-days to receive MFP related payments. In the draft guidance, CMS stated that the MFP must be passed through to the dispensing entity within 14 days of the MTF sending claim-level data elements that verify that the selected drug was dispensed to an MFP-eligible individual. **Given the 7-day window that NCPA recommends that CMS should implement to submit PDE records, plus the 14-day manufacturer prompt pay window, this means pharmacies will be waiting at a minimum of 21 days for payment. This is unsustainable for independent pharmacies. Pharmacies need to be made whole within 14 days of adjudicating the claim at the pharmacy, period. Pharmacies must pay their wholesalers on an approximate two-week payment cycle, and cannot float the MFP program. Payment to pharmacies should in no circumstances exceed the 14-day prompt pay requirement under Medicare Part D.**

Manufacturer prefunding MTF. **To expedite payment to pharmacies, CMS should prefund the MTF.** CMS has the authority to direct manufacturers to prefund the MTF, in addition to requiring DDPS to submit PDE claims quicker, potentially once to twice a day at the very least. Furthermore, CMS has the authority to prefund the MTF and to require the manufacturer to

[6]See 42 C.F.R. § 423.520, available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.520.

prefund the MTF. At the same time, CMS has no authority to require pharmacies to effectively prefund the MTF, and pharmacies should not be prefunding the MFP. **The current proposal essentially places an unfunded mandate on the pharmacy to prefund the MFP program.**

Electronic remittance advice. **NCPA strongly supports CMS's proposal to require electronic remittance advices be provided to dispensing entities showing MTF reconciliation and suggest that CMS mandate a provision of requiring that the MTF generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy for purposes of reconciling manufacturer retrospective MFP refunds.** Additionally, NCPA asks that CMS mandate standardization of 835s. While the 835 is a standard, there are multiple variations in use today by PBMs which complicates the work of reconciliation vendors. Manufacturers could use a standard implementation of the 835 for MFP payments that could be fleshed out in an NCPDP task group. Further, CMS must collect the delivery address for the 835s. Additionally, CMS should ensure that the MTF should be responsible for generating the EDI 820 document that relates to banking financial standards. This information should be made available in the MTF portal for each pharmacy.

40.4.2 Nonduplication with 340B Ceiling Price

In the draft guidance, CMS states that

> If it is subsequently determined that the individual who is dispensed a selected drug was a 340B-eligible patient and received access to the MFP, and the 340B ceiling price for the selected drug is determined to be lower than the MFP, then the Primary Manufacturer will need to promptly provide to the 340B covered entity dispensing the 340B drug the difference between the MFP (which was already provided by the Primary Manufacturer to the dispensing entity) and the 340B ceiling price.

CMS has encouraged wholesalers, along with other drug supply chain stakeholders, to collaborate with manufacturers and covered entities to address this issue with potential industry solutions. It is important to note that duplicate discounts will occur at contract pharmacies if the Covered Entity (or its contracted administrator) follows the current practice of shipping replacement products to the contract pharmacy after retrospectively designating a Medicare claim as 340B eligible.

We believe all affected parties are motivated to prevent duplicate discounts up front to eliminate the need for retrospective de-duplication and complex audits. This can be accomplished by patterning the processes in place today to ensure Medicaid claims are not dispensed using product purchased at the 340B price.

NCPA understands from the Revised Guidance that the Medicare Transaction Facilitator will not perform the deduplication of 340B claims and is encouraging industry stakeholders to develop a process. Many of our members serve as 340B contract pharmacies and should not bear the brunt

of this complex process, especially given their critical role in expanding access to medications for underserved populations.

While NCPA acknowledges the need for the deduplication of claims, the current lack of system integration between pharmacy claim receivable systems and 340B systems poses a significant challenge. For instance, if a pharmacy were to have a previously paid MFP payment clawed back due to a duplicate 340B discount, it would be highly difficult to reconcile that transaction against the current 340B accounting systems. The administrative burden and financial strain of such clawbacks could jeopardize the operational viability of many contract pharmacies. Therefore, NCPA urges CMS to influence the industry design by prohibiting the clawback of previously paid MFP refunds for 340B deduplication purposes. Preventing clawbacks will push covered entities and manufacturers to develop effective means to make covered entities whole without involving contract pharmacies. This approach ensures that the responsibility for resolving duplication issues rests with the parties best equipped to manage them, thereby protecting contract pharmacies from undue administrative and financial burdens.

40.4.3 Retrospective Refund Amount to Effectuate the MFP

WAC as benchmark. In this draft guidance, while CMS stated that it "intends" for the MTF to use WAC as the standardized pricing metric to calculate the Standard Default Refund Amount, it does not expressly require the Primary Manufacturer to use WAC for reconciliation purposes. The MTF will provide the Primary Manufacturer with the Standard Default Refund Amount (i.e., WAC minus MFP) as part of the transmitted data elements. The Primary Manufacturer may elect to use the Standard Default Refund Amount, as appropriate, to calculate and make the retrospective MFP refund payment to dispensing entities. WAC, as defined by section 1847A(c)(6)(B) of the Act, is the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including any non-guaranteed purchasing incentives, such as prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data. WAC is a widely available pricing metric, published and regularly updated in large pharmaceutical pricing database compendia that would be accessible and transparent to interested parties in the MFP effectuation process, and that does not require the sharing of confidential, proprietary data, such as contracted pricing, discounts, and rebates between parties. **NCPA believes that pharmacies need protection from manufacturers arbitrarily imposing refund amounts other than the Standard Default Refund Amount (WAC minus MFP) that do not appropriately effectuate the MFP. NCPA thanks CMS for stipulating in the guidance that the claim-level data elements that the Primary Manufacturer will receive from the MTF will include a Standard Default Refund Amount that will reflect the difference between the WAC and the MFP of the selected drug at time of dispensing based on the quantity dispensed. NCPA prefers using WAC as the standardized metric.**

We have concerns that it is voluntary for manufacturers to adopt WAC, given that manufacturers and dispensing entities can "agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost," and

therefore agree to a different benchmark. In other words, the MTF sends the amount as part of the minimum data elements to the manufacturer, which is WAC-MFP. If the pharmacy and the manufacturer have agreed on a different amount other than WAC, then when the manufacturer sends the data elements back to the MTF, the MTF would send a different amount because that is the indicator that the standardized refund was paid. **NCPA strongly urges CMS to require the use of WAC as the standardized metric and that any difference between WAC and MFP is the Standard Default Refund Amount.**

Pricing for drugs based on WAC is wildly variable, and WAC discounts quoted by wholesalers are not guarantees, but instead are non-guaranteed purchasing incentives that are often contingent on volume, payment terms, generic brand ratio, and many other factors. Manufacturers are unlikely to provide discounts to wholesalers on MFP drugs, and pharmacies in turn are unlikely to receive any discounts downstream.

When WAC is higher than acquisition costs. The draft guidance states that the Primary Manufacturer can choose to refund an amount different than the Standard Default Refund Amount if the Primary Manufacturer determines some other amount is appropriate to make the MFP available**.** For example, CMS states that the Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug. In this case, payment of the Standard Default Refund Amount would not be sufficient to make the MFP available to the dispensing entity. CMS suggests that the Primary Manufacturer could address these circumstances by making MFP refund payments that reflect the dispensing entity's higher acquisition costs for the claims. **NCPA's members occasionally will have acquisition costs higher than WAC in instances of major shortages, and when they are buying from secondary wholesalers.**

Beneficiary access to Community and LTC pharmacy will suffer if pharmacies are not reasonably reimbursed for MFP drugs. NCPA, in conjunction with industry partners, conducted an analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies. The analysis reviewed actual dispensing trends from January 1, 2024 – May 31, 2024, and contained several enlightening data points that reveal the true nature and scale of the impact of MFP.

The average community pharmacy dispenses 58 prescriptions for MFP drugs each month for Medicare recipients, which represents 30 percent of the brand name medicines that they fill for Part D recipients. These 58 medications represent $44,000 each month in drug acquisition cost. If the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number is only for year one of the MFP program, and will grow larger and larger as more drugs are added each year to the program.

The most vulnerable and at-risk patients are in Medicare Part D, and if there is no viable margin on these drugs, pharmacies have no business incentive to stock these drugs. The most at-risk

patients will subsequently lose access to the most needed drugs in Medicare Part D. Independent and LTC pharmacies will be at the greatest risk for decreased access to these drugs. Because so many pharmacies are combination shops (both LTC and retail locations combined), the negative effects on the MFP program on both LTC and retail pharmacy will in turn continually negatively impact each other.

LTC pharmacies that service long-term care facilities have a regulatory obligation to dispense drugs for their patients. While 42 CFR 483.45 requires that these facilities provide or obtain routine and emergency medications and biologicals in order to meet the needs of each resident,[7] most LTC pharmacies interpret this to mean that the pharmacies should dispense within 4 hours for an emergency medication and within 24 hours for a maintenance medication. Therefore, floating the MFP program would put LTC pharmacies at significant risk for not being able to continue to service their long-term facility patients, and in turn threaten the viability of LTC pharmacy itself. Further, it is unlikely that long-term care facilities will be able to find other pharmacies for their patients.

The decrease in availability of these drugs could also create situations where elderly patients will need to travel long distances and go to multiple pharmacies to find them. If these patients ultimately are able to obtain them at another pharmacy, it is likely that the original dispensing pharmacies will be greater removed from the care of the patient, and thus not be able to check for drug interactions or duplicity, creating greater risks of adverse events and hospitalizations. These concerns demonstrate the infeasibility of pharmacy floating the MFP program given zero or extremely small margins for pharmacy under this program, and the necessity that manufacturers must use WAC as a benchmark for payment.

Reimbursement from Part D Plan Sponsors/PBMs for MFP drugs must be reasonable to ensure beneficiary access. Part D plans are required to provide "reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." According to Medicare Part D regulations:

> To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:
>
> (i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.
>
> (ii) Providing a copy of a standard contract to a requesting pharmacy within 7 business days after receiving such a request from the pharmacy.[8]

[7] 42 CFR 483.45 -- Pharmacy services.

[8] 42 CFR §423.505(b)(18). Available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-K/section-423.505.

CMS must ensure that payment for MFP drugs be reasonable and relevant. For MFP drugs, Part D plan sponsor/PBM pharmacy reimbursement should be no lower than the maximum fair price and include a commensurate professional dispensing fee in line with Medicaid fee-for-service. Additionally, PBMs and plans should not be able to impose any pharmacy price concessions on MFP drugs that would ultimately reduce patient access to MFP drugs or reduce pharmacy reimbursement. Price concessions are commonly assessed on Part D drugs today by PBMs on a per claim basis and serve no other function than to enrich the PBMs. Since HHS is negotiating the price of MFP drugs, PBMs have no role in their pricing, and therefore, should not be able to extract any monetary value from the dispensing of MFP drugs.

40.4.4 Options for Medicare Transaction Facilitator Payment Facilitation

No fees. CMS stated in the draft guidance that "…any potential payment facilitation functionality of the MTF would be voluntary for dispensing entities and Primary Manufacturers, and neither party would have to pay any fees to participate as CMS would bear the cost of operationalizing the MTF." We support CMS' re-iteration in the draft guidance that pharmacies cannot be charged any fees to participate as CMS would bear the cost of operationalizing the MTF. **CMS must ensure that plans, PBMs, manufacturers, wholesalers, CMS nor any other entity be allowed to assess any fee on pharmacies to effectuate the MTF or any aspect of the Medicare Drug Price Negotiation Program whatsoever. Any EFT fees should be borne by the manufacturer and not the pharmacy.**

"Option 1" and "Option 2". CMS is seeking comment on the two MTF payment facilitation functionality options it is considering. Under "Option 1," the MTF would not transfer funds between parties directly. Instead, the MTF would collect and share participating dispensing entities' bank account information with participating Primary Manufacturers as part of the data elements transmitted by the MTF to facilitate the Primary Manufacturer's direct transfer of funds itself (or through a contracted third-party) to participating dispensing entities. Dispensing entities would only be required to provide bank account information, such as account numbers and bank routing information, to the MTF if they elected to opt-in to the MTF payment facilitation.

NCPA does not prefer Option 1. Under this option, both CMS and the MTF do not have as much control of the process, as the MTF is just giving banking information to manufacturers who transfer funds directly to pharmacies.

Under "Option 2," CMS would receive aggregated MFP refund amount payments from participating Primary Manufacturers and pass through such payments to participating dispensing entities utilizing bank account information collected by the MTF. CMS states that this option is intended to address concerns that manufacturers typically do not interface directly with dispensing entities, and to create a single platform for transmitting refund payments to create greater efficiency, standardization, and predictability in the execution of a high volume of continuous payments.

NCPA favors Option #2, as this option gives CMS more control and standardization. **That being said, NCPA recommends that CMS maintain flexibility to receive pharmacy banking information from a variety of sources, including PSAOs, GPOs, or directly from the pharmacies. Additionally, CMS should be aware that some pharmacies have multiple NCPDP/NPI numbers, especially LTC pharmacies, so CMS and the MTF should be prepared to accommodate these when compiling pharmacy banking information.**

Regardless of the mechanism for distributing payments, NCPA again emphasizes its position that the Standard Default Refund Amount must be paid automatically.

Voluntary MTF facilitation. While NCPA supports CMS' proposed Option 2, as stated above, it is concerned with CMS' suggestion that any potential MTF payment functionality will be voluntary. Making use of an **MTF payment facilitation functionality voluntary for Primary Manufacturers voluntary could result in many manufacturers electing not to use the MTF, which could impact access to certain drugs for pharmacies that do not have a direct relationship with that drug's manufacturer. NCPA is concerned that if payment does not flow through the MTF for everyone, some manufacturers will stop selling drugs to certain pharmacies that they do not have a direct contract/financial relationship with to avoid having to set up MFP payment mechanisms.**

CMS also discusses that "the Primary Manufacturer would also need to indicate whether it would participate in the MTF payment facilitation functionality in its written plan for making the MFP available." **NCPA is disappointed that CMS has chosen to allow manufacturers to voluntarily effectuate the MFP via the MTF.** This leads to greater uncertainty and potential administrative burden on independent pharmacies. We have grave concerns that manufacturers may not utilize Option 2. **NCPA requests clarity from CMS as to what other options would there be for independent pharmacies to continue to dispense these drugs if manufactures do not opt-in?**

Information disclosures. CMS states that information collected from the participating dispensing entity in order to facilitate payment between the Primary Manufacturer and the dispensing entity could include but would not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or National Provider Identifier (NPI); (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) depositor account number with financial institution; and (6) type of registered financial account. Participating dispensing entities would need to certify that information provided is accurate and up to date. **NCPA members do not see any issues with sharing the listed data to facilitate payment. However, we are concerned by the breadth of the language "would not be limited to," and request that CMS explain what additional data Primary Manufacturers could require from dispensing entities. NCPA believes that the enumerated data set above is sufficient, and that Primary Manufacturers should not require dispensing entities to disclose more information than what is enumerated in this list, as data minimization, in light of the UGH/Change cybersecurity incident, should be paramount.**

90.2.2 Negotiation Program Complaints and Disputes

CMS states that one type of complaint may include operational issues with the MTF system originating from interested parties participating in MTF data or potential payment facilitation functionality. For this type of complaint, CMS expects that the MTF contractor would provide helpdesk functions and resolve these types of issues promptly to ensure that the system operates smoothly without input or further evaluation from CMS, including communicating the solution to the submitting party. CMS envisions that the MTF helpdesk would be a way for the MTF contractor to quickly provide answers to Primary Manufacturers and dispensing entities regarding daily operations of the MTF. **NCPA is concerned that the MTF contractor "helpdesk" is suggested and not required. CMS should mandate that the MTF contractor has a non-automated helpdesk and that it be responsive to any concerns from dispensing entities during normal business hours accounting for all U.S. time zones.**

Under the guidance, CMS further states that Complaints related to a lack of MFP availability would not necessarily require a specific resolution but will be reviewed by CMS and may trigger an investigation under CMS' obligation to administer the Negotiation Program and to provide monitoring and oversight of MFP availability. **NCPA believes that CMS's stipulation that a lack of MFP availability does not necessarily require restitution and investigation to be troubling. The voluntary nature of WAC as a benchmark is especially concerning for dispensers, considering that pharmacies need to be reasonably compensated for these MFP drugs. NCPA advises CMS to require that the manufacturer provide the MFP and that dispensers have sufficient protections for reasonable reimbursement and to make complaints.**

Additionally, CMS states that it is still exploring the limits on the scope of disputes and complaints that the agency may remediate in the context of an otherwise private transaction between the Primary Manufacturer and dispensing entity. In addition, CMS is currently exploring the most efficient way to receive reports of complaints and disputes and welcomes comment.

NCPA provides the following additional suggestions:

CMS must ensure that all Medicare Part D processors, including the MTF, DDPS, PBMs and plans, and manufacturers demonstrate compliance and validation of their technical and security infrastructure before implementation, or else they cannot participate in the MTF payment process. Improper technical infrastructure and implementation by these entities will likely negatively impact and delay payment to pharmacy.

Additionally, CMS must establish a portal for the pharmacy to locate the status of MTF payments at the claim level. This portal could be read-only that pharmacies could log into with the MTF to research claims, for example that outlines the following: claim has been received, claim is being reviewed by the Manufacturer, claim has been paid, or claim has been rejected due to 'x' reason. Additionally, NCPA asks that this portal be accessible by GPOs and PSAOs and that they and pharmacies be able to download data through Electronic Remittance Advice, ASC X12N 835 files.

NCPA advises CMS that pharmacy enrollment with the MTF can be streamlined, eliminating the need for individual enrollment forms/portal access for every pharmacy location. **NCPA recommends that the MTF leverage the NCPDP Pharmacy file for pharmacy demographics.**

Additionally, NCPA has concerns that the dispute/complaint process seems to limit issues to transaction data visible to the manufacturer. This creates concerns as the process could break in any one of the following steps:

- If the Medicare Part D plan or PBM: misapplies an MFP price (differences in MFP or WAC effective dates and/or price); lack of MFP identifier on claim response and/or PDE; timing or gaps in processing reversals; claim submissions (transaction date > date of service).
- If the DDPS: rejects PDEs that prevent the Medicare D claim from being forwarded to MTF, timing or gaps in processing reversals, claim submissions (transaction date > date of service)

CMS must provide guidance to ensure pharmacies are made aware by plans/processors if the PDEs are rejected on an MFP claim and cannot be corrected by the plans/processors. For example:

- MTF - misapplication of an MFP price (differences in MFP or WAC effective dates and/or price), lack of manufacturer WAC information, timing gaps in processing manufacturer MFP data files
- Manufacturer – if the manufacturer is the ultimate responsible party, will all the above concerns have to be resolved/supported by the manufacturer? At a minimum, the manufacturer will need to establish dedicated resources and processes to research and resolve disputes in a timely manner. Manufacturers also need to publish their process to identify 340B duplicates.
- Manufacturer Payment Codes (between manufacturer and MTF) will need to be mapped to existing (or request new 835 CARC and RARC codes) and provide pharmacies a payment manual to use for reference.

Additionally, CMS should establish a Task Force to establish the applicable Manufacturer MFP response codes that can map to 835 CARC/RARC codes, allowing for existing payment reconciliation processes to be used, and to create a standardized payment manual to be used by the MTF if option 2 is selected.

<u>RFQ Process Not Transparent</u>

NCPA is also concerned that the RFQ process to select the MTF is not transparent. The RFQ is posted on the GSA MAS schedule, but only those with user access to that schedule can access the RFQ. This precludes many stakeholders, including NCPA and its membership, from reviewing and/or commenting on the RFQ. Further, we need to understand how the RFQ works in tandem with this draft guidance. **We ask that CMS open the RFQ process to be more transparent moving forward.**

Conclusion

NCPA thanks CMS for the opportunity to provide feedback, and we stand ready to work with the agency to offer possible solutions and ideas. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact Ronna Hauser, Senior Vice President, Policy & Pharmacy Affairs, at ronna.hauser@ncpa.org or (703) 838-2691, and Steve Postal, Director of Policy and Regulatory Affairs, at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

B. Douglas Hoey, Pharmacist, MBA
Chief Executive Officer
National Community Pharmacists Association

National Government Services, Inc. (NGS) appreciates the opportunity to submit comments in response to Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027, herein after "Guidance". We recommend Medicare Transaction Facilitator (MTF) Payment Facilitation Option 2 (as depicted on Page 58 in Figure 3: Diagram of the MTF Payment Flow Option 2), with some modifications, as the best approach for ensuring the Maximum Fair Price (MFP) is made available to drug dispensers, and, by extension, Medicare beneficiaries.

Specifically, through NGS payment program experience, we recommend utilization of the MTF is made mandatory for manufacturers and dispensing entities rather than voluntary payment facilitation. Mandatory use of the MTF for financial transactions ensures standardization, greater CMS oversight and provides a predictable cadence of payments. In contrast using multiple options for providing access to the MFP promotes a fragmented landscape that introduces complexity by requiring tracking of which manufacturer/dispenser combination uses which method. Utilizing the MTF to issue the payments would bring additional benefits. First, data security would be enhanced by storing all payee (dispenser) banking information in one location rather than sharing it with multiple entities. It would also reduce the burden on the payees by issuing one payment at a time rather than their receiving payments from multiple manufacturers, increasing time and effort spent on reconciling the payments.

The MTF issuing payments could be handled in two different ways. The first, and simplest, would be a single bank account into which manufacturers would deposit funds to be used for rebate payments. Funds would be tracked on a "by manufacturer" basis and would be visible to the manufacturers and CMS on the MTF Payment Portal/GUI. This also will combine all payments from different manufacturers to a payee into a single transaction. Fees associated with the account would be allocated across all manufacturers and paid for with the funding deposited by the manufacturer. Alternatively, separate bank accounts could be used for each manufacturer but that would increase banking fees and increase the number of payments the payees receive since each payment would be manufacturer- specific.

NGS recommends the use of a MTF Payment Portal/GUI which would support multiple financial functions including, but not limited to, the following:

1. Dispenser Bank Account Management (including the onboarding of the authorized/designated official)
2. Detailed Remittance Advice for both manufacturers and dispending entities
3. Financial Dispute Management (e.g. Guidance Page 45, Determining MFP Discount/Refund Amount)

Using only a single MTF Payment Portal will increase standardization, encourage MFP compliance, and increase predictability of financial audit results.

On page 47 of the Guidance, CMS mentions claim adjustments and reversals. As CMS outlines, adjustments would require additional data elements for review and determination of overpayment/underpayment. NGS recommends that these inquiries/disputes be managed by an experienced contractor skilled with payment facilitation capabilities as these escalations require research, analysis, and financial acumen.

NGS also recommends the standard default rebate amount approach mentioned in the Guidance (page 51). This will provide predictability for both manufacturers and dispensers in their determination of rebate amounts. To resolve pricing discrepancies mentioned in the Guidance, retrospective reconciliations would be performed by the MTF on a routine basis to "true up" rebate amounts. This predictability, in combination with mandatory utilization of the MTF, should reduce the number of

disputes between manufacturers and dispensing entities. The reduction in the number of disputes will lessen both the dissatisfaction of and the administrative burden on the entities involved.

Lastly, so long as the contractor is sufficiently experienced with the Data Module work and the Payment Module work and can perform both simultaneously, having that work performed by the same contractor avoids the complexity of adding increased coordination (e.g., another layer of file transfers). Also, managing disputes could be more challenging with one entity acquiring the banking information and calculating the refund while the other contractor issues payments. Two entities processing MTF transactions could result in delays, putting the 14-day prompt pay window at risk.

NGS greatly appreciates the ability to provide comments to help ensure the success of the Medicare Drug Price Negotiation Program.

NATIONAL HEALTH COUNCIL

July 2, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (2027 draft guidance).

Created by and for patient organizations more than 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of 170 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

General Comments

The NHC appreciates CMS' commitment to actively engaging with stakeholders, including patients, consumer advocates, and health experts, in implementing the Medicare Drug Price Negotiation Program (DPNP). We believe that patient-centric engagement is essential to ensure that the negotiation process leads to outcomes that genuinely benefit patients. As noted in our previous communications, while the NHC would prefer a more traditional Notice and Comment rulemaking opportunity that would ensure the Agency directly responds to stakeholder feedback, we welcome this opportunity to express our reactions to CMS' thinking on the negotiation program.[1] And

[1] National Health Council. (2023). NHC comments on IRA guidance response. Retrieved from https://nationalhealthcouncil.org/wp-content/uploads/2023/04/NHC-IRA-Guidance-Response.pdf

we appreciated CMS' thorough responses to comments for IPAY 2026 and hope the Agency will replicate this for this comment opportunity. Our comments below highlight specific areas where we believe additional improvements can be made to ensure all Medicare beneficiaries, particularly those with chronic diseases and disabilities, have increased access to affordable, high-value, equitable, and sustainable health care.

Patient Engagement

The NHC recognizes and commends CMS' willingness to improve the listening sessions and the data submission processes. It is encouraging to see CMS' commitment to actively engaging with patients and patient organizations to ensure their voices are heard and considered in the DPNP. The NHC provides the following comments to CMS to improve on the steps it has already taken to date.

Improving the Listening Sessions. In our effort to enhance opportunities for patient input, the NHC held a Roundtable discussion that included patients, caregivers, patient organizations, and CMS representatives. The goal of this Roundtable was to chart a course for improving patient engagement in the DPNP and ultimately in other programs and activities of the Agency. The discussion focused on CMS' 2023 listening sessions during implementation of the first round of negotiations and identified lessons learned to inform future listening sessions and broader patient engagement strategies. Based on the discussions and insights from the Roundtable, the NHC offers the following recommendations to:

Improve Clarity and Communication about the Intent of the Listening Sessions.

- Clarify What Information is Sought from Speakers
- Report on Data Utilization
- Host Educational Webinars Before Listening Sessions
- Market as Stakeholder Listening Sessions if They Have Broader Representation

Improve the Structure of the Listening Sessions.

- Enhance Dialogue-Based Engagement
- Clarify Required Disclosures
- Allow HIPAA Waivers if Feasible
- Clarify Speaker Selection Process
- Allow for Data Submissions After Sessions

Increase Engagement.

- Increase Ways for Stakeholders to Engage
- Provide More Advance Notice
- Enhance Efforts to Engage Diverse Speakers
- Partner with Patient Organizations
- Record Listening Sessions

Improve the Speaker Experience.

- Provide Accommodations
- Allow More Speaking Time and Use a Timer
- Show CMS Representatives on Screen

Our report, *Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement*, offers greater detail and specificity on these recommendations. We also include additional information later in this letter when responding to Section 60.4.

Improving the Data Collection (ICR) Process. The NHC supports the focus on patient-centered data and emphasizes the importance of clear guidelines and support to help patient organizations navigate the data submission process. We appreciate CMS' stated willingness to improve this process to make it more relevant for patients and patient organizations.

We were especially pleased to see CMS indicate that they may make clearer that they are seeking detailed descriptions of what it is like to live with a medical condition treated by the selected drug or its therapeutic alternatives, and the factors that matter most to patients when assessing the value of a drug. We feel this is an optimal use of the ICR process and recommend that this framing also be used as part of the description of the listening sessions.

We also support CMS' potential grouping of questions related to manufacturer input, patient or caregiver experience, clinical experience, and health research, which can streamline the data collection process, aligning information more closely with respondents' areas of expertise. However, it is essential to ensure that the complexity and nuances of patient experiences are not oversimplified. Pilot testing this format with various stakeholders can help identify potential challenges and refine the process accordingly.

To enhance the ICR process, clarifying what qualitative and quantitative information is needed and how it will be used in determining the MFP will help patient organizations better prepare and ensure their data is relevant. Hosting educational webinars to prepare patient groups and stakeholders on information requirements will also be beneficial.

Finally, we encourage CMS to consider a longer time horizon for the submission of data. While some organizations may have access to existing data, others may want to collect new data through surveys or other activities that may be more fit for CMS' needs. Further, if this period is extended beyond the listening sessions, there may be gaps identified during the sessions that can be filled by additional research. While we understand this timing may not allow for the data to be incorporated into CMS' initial offer, it can still be useful during later stages of the negotiation process.

Utilization of Patient Experience Data. The NHC commends CMS for acknowledging the importance of patient experience data in the negotiation process. It is crucial that this data is given significant weight in determining the MFP. Patient

experience data provides valuable insights into how medications impact patients' daily lives, including their ability to manage symptoms, maintain independence, and improve their quality of life.

We urge CMS to consider a broad range of patient experience data, including both clinical and non-clinical outcomes. Factors such as treatment adherence, patient-reported outcomes, and quality of life measures should be integral to the negotiation process. Additionally, CMS should engage with patient organizations to identify the most relevant and impactful data points. By doing so, CMS can ensure that the MFP reflects the true value of medications from the patient's perspective. Furthermore, ongoing dialogue and reporting on how patient engagement information is incorporated into negotiations and establishing a feedback loop with patient organizations will reinforce CMS' commitment to truly patient-centered care.

Clarification on QALY Metrics

The NHC appreciates CMS' commitment to excluding Quality-Adjusted Life Years (QALYs) from the negotiation process as outlined in the 2027 draft guidance. Valuing life differently based on disability status, age, or other special populations is inappropriate. All patients deserve equal treatment, and we applaud CMS' decision to exclude QALY metrics. However, we are concerned about the potential use of studies with QALY-related data from secondary sources or the over-exclusion of valuable analyses. The NHC requests more clarity on how CMS will exclude QALY-based metrics and highlight when they have been removed from consideration in MFP justification documentation. Additionally, we recommend that CMS be more transparent regarding the forms of cost-effectiveness analysis it is considering using, as many approaches are not well understood or tested.

Patient value is multi-faceted and attempts to distill important dimensions of patient value and benefit into a single number are problematic. While QALYs are excluded by statute, CMS should not rely on a single metric and instead use a wide variety of sources for a holistic approach. Multi-criteria decision analysis (MCDA) is one such approach that considers a wide range of factors, including patient preferences and quality of life.[2] By adopting a holistic approach to value assessment, CMS can ensure that the negotiation process is fair and inclusive of all patient populations.

Continuous Improvement and Feedback Mechanisms

The NHC supports the establishment of a robust infrastructure for continuous patient engagement, including a patient ombudsman and regular public roundtables with patient and disability communities. Continuous improvement is essential for adapting the negotiation program to changing needs and ensuring that it remains effective and patient-centered over time.

Creating a patient ombudsman position would provide patients with a dedicated advocate within CMS who can address their concerns and ensure that their voices are

[2] National Health Council. (n.d.). Patient-centered multi-criteria decision analysis. Retrieved from https://nationalhealthcouncil.org/additional-resources/patient-centered-multi-criteria-decision-analysis/

heard. This role would be instrumental in facilitating ongoing dialogue between CMS and the patient community, helping to identify areas for improvement and ensure that patient feedback is integrated into policy decisions.

Regular public roundtables and advisory committees can also provide valuable insights into the patient experience and help CMS stay informed about emerging issues. These forums should include diverse representation from various patient communities to capture a wide range of perspectives. Additionally, CMS should establish clear processes for incorporating feedback from these engagements into the negotiation program, ensuring that patient input leads to tangible changes.

Comments on Specific Sections of the 2027 Draft Guidance

Transparency and Stakeholder Engagement (Section 30)

The NHC emphasizes the need for CMS to maintain a high level of transparency in its negotiation processes. This includes providing detailed justifications for the MFP and ensuring that patient input, especially through patient listening sessions, is transparently incorporated into decision-making. Moreover, stakeholder engagement should be a continuous process, with CMS actively seeking input from diverse patient organizations and other stakeholders at every stage. Aggregation of stakeholder feedback should be methodical and comprehensive, ensuring that no significant patient perspectives are overlooked. These elements were previously highlighted in our comments in response to the IPAY 2026 guidance, and we continue to stress their importance for the 2027 draft guidance.

Active Moiety and Single Source Qualifying Drugs (Section 30.1)

The NHC remains concerned about the effects that the aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research.[i] We want to ensure that manufacturers are not discouraged from developing new indications, forms of administration, or combination products that may improve patient adherence and outcomes. Without appropriate guardrails, CMS' broad definition of drugs eligible for negotiation may discourage these types of improvements. While manufacturers would ideally bring products to market with as many indications as possible, one potential consequence could be a significant delay in initial market entry and access. The NHC aligns with CMS' desire to eliminate potential gaming of extending patent life or time before negotiation. However, we fear this may be an overly broad approach that does not consider the patient perspective on whether new formulations, combination products, or forms of administration improve patient care.

We believe there are better approaches to address this issue, including using patient engagement to determine whether new formulations, combination products, or routes of administration are considered by patients to be important improvements. For example, innovations in biologic drugs used to reduce inflammation in autoimmune diseases like arthritis have made injections much less painful, significantly improving the quality of life for patients. Similarly, long-acting insulin analogs provide more stable blood sugar control and reduce the number of daily injections needed for diabetes patients. Extended-release psychotropic formulations for mental health conditions improve

treatment adherence and overall patient outcomes by reducing the frequency of dosing. Combination products, such as fixed-dose combinations for hypertension or HIV, simplify treatment regimens and enhance adherence.

Such innovations underscore the importance of encouraging new forms of administration, combination products, and other advancements that enhance patient experience and adherence. Therefore, incorporating robust patient engagement practices is essential to accurately capture the value and necessity of these advancements from the patient's perspective. This ensures that the negotiation process genuinely aligns with patient needs and preferences, ultimately leading to better health outcomes and improved quality of life.

Medicare Transaction Facilitator (Section 40.4.1)

The NHC appreciates the opportunity to provide feedback on the role of the Medicare Transaction Facilitator (MTF) within the Medicare DPNP. The MTF plays a critical role in ensuring that the negotiated MFPs are effectively implemented and that all stakeholders, including patients, manufacturers, and dispensing entities, experience minimal disruption during the transition. To achieve this, it is essential that the MTF operates with consistency, uniformity, and transparency while ensuring robust data security measures.

Standardization and uniformity are essential for the nearly 70,000 pharmacies that bill for Medicare Part D.[ii] Implementing a standardized process will streamline operations, reduce administrative burdens, and enhance patient access to the program. By ensuring consistency and transparency, CMS can facilitate the efficient and equitable implementation of the MFPs, enabling all parties involved to operate smoothly and effectively. This approach will ultimately lead to better patient outcomes and reduced administrative burdens for manufacturers and dispensing entities.

To maintain impartiality and integrity, it is crucial to consider the nature of any potential conflicts of interest from entities involved in the pharmaceutical supply chain. These conflicts can significantly influence formularies and patient access to medications.[iii] Transparency and careful evaluation of these conflicts are essential to ensure trust and fairness in the process for all stakeholders. By prioritizing transparency and conflict mitigation, CMS can help ensure that the MTF operates in a manner that is trusted by all stakeholders and that the negotiation outcomes are unbiased and equitable. Ensuring that the selected MTF does not have inappropriate conflicting business interests is vital for maintaining stakeholder confidence.

The NHC supports prioritizing specific MTF functions that can yield immediate benefits and alleviate the burdens faced by beneficiaries, manufacturers, and dispensing entities. Timely reimbursement is of critical importance to ensure uninterrupted access to essential drugs for beneficiaries. When pharmacies are compelled to hold onto funds for extended periods as part of the retrospective payment process, it can strain their financial resources, potentially leading to difficulties in maintaining sufficient medication supplies and disrupting patient access.[iv] This delay or uncertainty in reimbursement

may result in increased costs, potentially impacting patients through higher co-pays or out-of-pocket expenses, potentially limiting their ability to afford necessary medications.[v]

The NHC also underscores the utmost importance of implementing robust data security measures to safeguard patient data throughout the MTF process. To this end, we recommend that CMS clarify that the MTF is designated as a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), ensuring full compliance with patient data privacy and security laws. The NHC recommends the implementation of advanced encryption to secure all data exchanges and prevent unauthorized access to sensitive patient information. Additionally, strict access controls should be implemented to restrict data access exclusively to authorized personnel, fortifying data confidentiality. It is also crucial to maintain comprehensive data audit trails to monitor data access and modifications, enhancing accountability and data integrity. Furthermore, conducting regular security audits and assessments is essential to systematically identify vulnerabilities and proactively address them. The NHC firmly believes that these security measures will not only protect patient data but also foster trust in the MTF process among all stakeholders involved.

Evaluation Criteria and Patient-Centered Metrics (Section 50.2)

The NHC reemphasizes the need for comprehensive evaluation criteria that prioritize patient-centered metrics. These metrics should include patient-reported outcomes, quality of life measures, and other indicators that reflect the real-world impact of medications on patients' lives. The inclusion of such metrics will ensure that the negotiation process genuinely reflects the value of treatments from the patient's perspective.

To this end, the NHC recommends that CMS consider non-QALY-related models that focus on the quality of evidence and strength of recommendations, which can provide a more nuanced and patient-centered assessment of treatment value. Furthermore, the NHC suggests that CMS utilize the NHC's patient principles and rubric as a checklist to ensure that any methodology considered is patient-centered. The *National Health Council Rubric to Capture the Patient Voice: A Guide to Incorporating the Patient Voice into the Health Ecosystem* was developed through a multi-stakeholder process to elevate meaningful patient engagement. This rubric encompasses seven domains of patient-centered engagement and methodological practices: 1) patient partnership; 2) transparency; 3) representativeness; 4) diversity; 5) outcomes patients care about; 6) patient-centered data sources and methods; and 7) timeliness. By incorporating these domains, CMS can prioritize patient experience data in the negotiation process and develop a standardized methodology for incorporating this data into decision-making. This methodology should outline how patient experience data will be collected, analyzed, and weighted against other factors, such as research and development costs. Transparency in this process is essential to build trust and ensure that patient perspectives are genuinely influencing the outcomes.

Standardized Methodology and Real-World Evidence (Section 50.4)

We also highlight the importance of a standardized methodology for applying therapeutic alternatives data, as outlined in Section 50.4. The methodology should be

transparent and consistent, leveraging real-world evidence to provide a comprehensive understanding of treatment benefits and risks. This approach aligns with our previous calls for a holistic evaluation that incorporates diverse data sources and patient experiences.

Use of Clinical Guidelines (Section 50.6)

Clinical guidelines provide evidence-based recommendations that can help ensure treatments align with the best available scientific evidence. **The NHC supports CMS' use of these guidelines as one of many evidence sources to ensure therapies are selected and valued based on clinical efficacy and appropriateness for patients.** Emphasizing clinical guidelines and other evidence-based recommendations helps prevent the inappropriate use of cost considerations as the primary driver of decision-making, which could undermine patient care by prioritizing cheaper treatments that may not be the most effective or suitable for patient needs. CMS should balance the use of clinical guidelines with patient-centered outcomes and real-world evidence and ensure evidence is as current as possible to keep the negotiation process focused on what is best for patients. **As CMS works to achieve this balance, the NHC would like to emphasize several limitations associated clinical guidelines**:

- **Off-Label Usage:** Clinical guidelines typically do not cover off-label uses of medications, which can be significant for many patient populations, especially those with rare or complex conditions. Off-label usage often emerges from real-world clinical practice and patient experiences, which might not be reflected in the guidelines. It is crucial to consider how off-label uses will be evaluated and incorporated into the negotiation process. Ignoring these uses could lead to decisions that do not fully capture the value of a medication for all patients. CMS should develop a framework to evaluate and include off-label uses in the negotiation process. This could involve consulting with clinical experts, patient organizations, and reviewing peer-reviewed literature and real-world evidence that supports off-label use cases.
- **Pace of Guideline Updates:** The process for updating clinical guidelines can be slow, often lagging behind the latest clinical research and real-world evidence. This delay can result in outdated recommendations that do not reflect current best practices or emerging treatment options. CMS should ensure that the negotiation process is flexible enough to incorporate new evidence and adapt to changes in clinical practice swiftly. CMS should establish mechanisms to expedite the integration of new clinical evidence into the guidelines used for negotiation. This could involve setting up rapid review panels or interim updates to guidelines based on emerging data.
- **Lack of Patient Input**: Clinical guidelines often lack robust patient input, focusing predominantly on clinical outcomes rather than patient-centered outcomes such as quality of life, treatment adherence, and patient preferences. Incorporating patient perspectives into the guideline development process is essential to ensure that the recommendations reflect what matters most to patients. CMS should work with stakeholders to increase patient involvement in guideline development and consider patient-reported outcomes in the negotiation process and ensure that patient-centered outcomes are given significant weight

in the evaluation of treatments. There are some notable instances of clinical guidelines developed in collaboration with patient organizations that emphasize patient-centered outcomes in atrial fibrillation and arthritis (specifically osteoarthritis and juvenile idiopathic arthritis) that showcase models of how patient engagement can enhance the development and implementation of clinical guidelines.[vi,vii,viii]

Patient Engagement during the Negotiation Process (Section 60.4)

The NHC appreciates CMS' detailed outline in Section 60.4 regarding the patient-focused listening sessions and the overall negotiation process for determining the MFP. We commend CMS for its commitment to improving these sessions and provide the following detailed recommendations.

First, CMS should specify the type of information it seeks from speakers during patient-focused events. Clear communication about the objectives and desired outcomes will help participants prepare more effectively and contribute valuable insights. For example, CMS could outline the specific aspects of patient experiences and therapeutic alternatives it is interested in, which will enable participants to provide more targeted and relevant input. It is also essential for CMS to report on how the patient engagement information and qualitative data collected during these sessions are incorporated into the negotiations. This transparency will build trust and demonstrate that patient voices are genuinely influencing the outcomes, which can lead to greater and more representative participation moving forward. Hosting educational webinars in advance of the listening sessions can further ensure stakeholders are well-prepared. These webinars can provide detailed information on the structure of the sessions, the types of data CMS is seeking, and how this data will be used in the negotiation process. If CMS continues to include stakeholders other than patients, they should be marketed as stakeholder listening sessions. This will make it clear that the outreach includes all members of a disease community, including patients, caregivers, and practitioners. This inclusive approach will help gather a diverse range of perspectives and experiences, enriching the data collected.

CMS should focus on creating opportunities for real-time dialogue with smaller groups of patients rather than merely holding listen-only events. This approach can help gather deeper insights and foster a more interactive and engaging approach. For instance, roundtable discussions and focus groups could facilitate more meaningful interactions among participants. The required disclosures should be clarified in a manner that explains why they are needed and how they affect the testimony. This will help participants understand the necessity of these disclosures and provide informed consent. CMS should also allow patients and speakers the ability to waive HIPAA requirements, if legally permissible. This flexibility can facilitate more open and honest sharing of experiences, which is crucial for understanding the real-world impact of medications. Additionally, CMS should clearly communicate the process for selecting speakers and ensure diversity in the selection process to include a broad spectrum of voices and perspectives. Allowing for data submissions after the listening sessions can enable participants to provide additional insights that may arise from the discussions, ensuring that all relevant information is captured.

CMS should increase ways for patients and other relevant stakeholders to engage, such as through written statements or recorded testimonies for those who cannot participate in live sessions due to job constraints, privacy concerns, or lack of broadband access. Providing more advance notice for listening sessions will allow organizations time to identify relevant patients and conduct surveys to gather insights. Enhancing efforts to engage speakers from diverse backgrounds is essential, and this can be achieved by working with the Office of Minority Health and minority-led patient organizations to ensure that the sessions reflect the diversity of the patient population. Partnering with patient organizations to monitor the program's impact, especially on access to treatments, will help ensure that the program is meeting its goals. Recording the listening sessions will allow stakeholders to review the testimony and ensure that all voices are heard and considered. Sharing redacted transcripts can help maintain transparency while protecting privacy.

To improve the speaker experience, CMS should provide accommodations for patients with disabilities and non-native English speakers to ensure that all participants can engage fully. This includes providing translation services, accessible venues, and other necessary support. Allowing speakers more time (at least five minutes) and including a timer on the Zoom screen to help manage pacing can make the experience more comfortable and effective, ensuring that participants do not feel rushed and can share their experiences thoroughly. Showing CMS representatives on the Zoom screen can make speakers feel more comfortable and ensure they feel heard. This visual presence can help build rapport and foster a sense of engagement and interaction.

Explanation for the MFP (Section 60.6.1)

It is crucial that CMS provides clear and detailed explanations for the MFP, explicitly explaining how patient listening sessions and patient-submitted data are utilized. Transparency in these justifications will build trust and ensure that the negotiation outcomes are genuinely patient-centered. The NHC urges CMS to release the justifications for 2026 before starting the 2027 process, despite the statutory timeline requiring publication by March 1 of the year prior to the initial price applicability year. Early release will allow for better preparation and more informed stakeholder engagement. Furthermore, CMS might also consider releasing a template for these explanations in advance and soliciting feedback on that template to ensure the information meets the guidance's transparency goals.

Part D Formulary Inclusion of Selected Drugs (Section 110)

Finally, we reiterate our concerns regarding Part D formulary inclusion of selected drugs, as expressed in our previous letters. Ensuring that negotiated drugs are included in formularies without undue restrictions is critical for maintaining patient access to essential medications. Additionally, it is important to consider how negotiation could impact access to competitors of selected drugs, potentially affecting the overall availability of effective treatments.

To protect patients from potential negative consequences of the negotiation program, such as increased utilization management or formulary restrictions, CMS should establish clear guardrails and conduct ongoing oversight. It is essential that the

negotiation process does not inadvertently create barriers to accessing necessary medications. Patients must be assured that cost-saving measures will not come at the expense of their health and well-being.

One key area of concern is the potential for increased utilization management practices, such as prior authorization and step therapy, which can delay or deny access to necessary treatments.[ix,x,xi,xii,xiii,xiv] CMS should establish stringent guidelines to ensure that these practices are not used excessively or inappropriately. Additionally, CMS should monitor the impact of these practices on patient access and adjust policies as needed to protect patients from undue burden.

CMS' recent interoperability and prior authorization final rule emphasizes the need for streamlined prior authorization processes and enhanced transparency, which was supported by many stakeholders, including patient organizations, providers, health plans, and pharmaceutical groups.[xv] The NHC urges CMS to consider developing parallel rules specifically for prescription drugs to ensure comprehensive coverage and protection for patients.

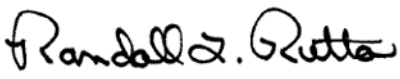
Ongoing oversight is critical to ensuring that the goals of the negotiation program are achieved without compromising patient care. CMS should implement a robust monitoring system to track the program's impact on drug prices, access, and patient outcomes. This includes collecting data on utilization management practices, formulary changes, and patient experiences. Patient organizations are willing and able to assist in collecting information from their populations to share with CMS if the appropriate structure is established to allow for this reporting. Regular reporting and public transparency will help identify any unintended consequences and allow for timely corrective actions.

Conclusion

The NHC strongly believes that a patient-centered approach is vital for the success of the DPNP. We urge CMS to consider these recommendations to ensure that the program not only achieves cost savings but also enhances access to high-value, life-saving medications for Medicare beneficiaries.

We appreciate the opportunity to provide input on this important issue and look forward to continuing our collaboration with CMS. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, at egascho@nhcouncil.org if you have any questions or require further information.

Sincerely,



Randall L. Rutta
Chief Executive Officer

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National Pharmaceutical Council®

1717 Pennsylvania Avenue, NW, Suite 800, Washington, DC 20006 Phone: 202.827.2100 Web: www.npcnow.org

July 2, 2024

The Honorable Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
U.S. Department of Health and Human
Services 7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically via: IRARebateandNegotiation@cms.hhs.gov

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Guidance, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (Guidance or the Guidance).

NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation. We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients. Our research helps inform important healthcare policy debates and supports the achievement of the best patient outcomes in the most efficient way possible.

NPC's research and that of others have found that public policies that reduce the incentives to invest in research and development result in less innovation, fewer treatment options, and lower life expectancy.[1] The Inflation Reduction Act (IRA or the Act) creates a new price-setting mechanism that will change the economic incentives for bringing new medicines to market, and evidence shows manufacturers are already responding to those incentives.[2] There are growing concerns about the potential unintended

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consequences of the IRA and the Medicare “Drug Price Negotiation Program”(DPNP). Using the term "Negotiation" in thisstatute and Guidance is misleading becausethere is not a genuine opportunityto negotiate (quotation marks around the words “negotiate” and “Negotiation” to specify that these are terms used by the agency in their publications). NPC research highlightsthatthese consequences will likely include delay of access to new medicines, and fewer diseases getting additional approved treatment options.[3]

An important goal in implementation of the Act should be to set guidance that, to every extent possible, minimizes the deleterious impact of the IRA on the incentives for the development of innovative therapies as well as patient access. In its second year of issuing guidance on the DPNP, CMS continues to take steps that do the opposite.

The price-setting mechanism described in the Guidance, incorrectly portrayed as “Negotiation,” lacks clear standards for the evidence that will be used in the process and the transparency necessary for the public to reproduce or evaluate CMS’s process and decisions. Although CMS has recognized the need to improve the approach to its patient-focused listening sessions, we remain concerned that even with the specific recommendations we outline below for patient engagement that this process minimizes the opportunity for patients, providers and other clinical experts to continuously inform and participate.
Furthermore, the effectuation of the Maximum Fair Price (MFP) and Part D formulary inclusion of selected drugs are built on a chassis ripe with perverse incentives and opportunities for fraud and abuse and provide minimal opportunity to prevent and detect unsavory activities.

The importance of implementing the price-setting provisions of the IRA in a manner that accurately values medicines and maintains patient access cannot be overstated. This process forces manufacturers to accept CMS’s final price, face an unreasonable excise tax, or exit the market – all of which threaten the development of, and patient access to, new treatments or cures.

We understand that CMS has a statutory requirement to implement the IRA. We also note that many NPC members have long argued that the underlying structure of the “Negotiation” program, as set forth by the statute and implemented here by CMS, is legally flawed. In review of the punishing penalties for non-compliance, and the general inflexibility of the process for product selection and maximum fair price (MFP) implementation, these legal flaws cannot be overcome through general guidance clarity at this stage.

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already-impacting-rd-decisions; Powaleny, Andrew. (2023). IRA Impacts: Cancer treatment research and development. PhRMA. Available at: https://catalyst.phrma.org/ira-impacts- cancer-treatment-research-and-development; Longo, N. (2023). WTAS: Inflation Reduction Act already impacting R&D decisions. PhRMA. Available at: https://catalyst.phrma.org/wtas-inflation-reduction-act-already-impacting-rd-decisions; IRA survey: Biotechs bracing for impact. Biocentury. March 16, 2023. Slabdokin, Greg. IRA Drives Pfizer’s Decision to Focus on Biologics, Not Small Molecules. BioSpace. March 4, 2024. Available at: https://www.biospace.com/article/ira-drives-pfizer-s-decision-to-focus-on-biologics-not- small-molecules/. US IRA May Weigh on Long-Term Global Pharma Growth. FitchRatings. September 2023. https://www.fitchratings.com/research/corporate-finance/us-ira-may-weigh-on-long-term-global-pharma-growth-22-09-2023.

[3]Patterson J, Motyka J, O’Brien JM. Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications *Am J Manag Care. 2024;30(2):82-86. https://doi.org/10.37765/ajmc.2024.89495*
"How The IRA Could Delay Pharmaceutical Launches, Reduce Indications, And Chill Evidence Generation", Health Affairs Forefront, November 3, 2023. DOI: 10.1377/forefront.20231101.123865

Nevertheless, NPC appreciates the opportunity to provide input and provides herein several suggestions for CMS to consider that might be helpful to the agency as it implements this program. None of these resolve the more fundamental legal infirmities of the overall program, nor could they, but they can improve transparency and incorporation of the patient perspective. NPC's recommendations are summarized on the following pages:

I. Improving Transparency in the Implementation Process

- The implementation of the Inflation Reduction Act (IRA) is being closely followed by those who invest in, research, and develop new cures. Though the IRA text permitted implementation of the price-setting process via guidance, this Guidance opens CMS to criticism for creating an opaque process giving the agency maximum flexibility and latitude while failing to provide adequate clarity and details about how it will implement important provisions. We urge CMS to make comments in response to this Guidance publicly available, as it did for IPAY 2026 guidance.

II. (Section 40) Requirements for Manufacturers of Selected Drugs

- Address concerns related to manufacturer effectuation of MFP, and ensure processes are in place to prevent MFP-340B duplication of discounts. Manufacturers should not be the only stakeholders (e.g., pharmacies, mail order services, and other dispensers) in the supply chain responsible if an MFP is not made available to beneficiaries. Without CMS intervention to rectify these serious operational issues, manufacturers must have flexibility to compliantly implement MFP effectuation.
- Abandon the burdensome and unworkable Primary/Secondary Manufacturer policy.

III. (Sections 50 and 60) Negotiation Factors and Process

- Implement these sections with maximum transparency to provide manufacturers and other stakeholders the opportunity to inform, evaluate, and predict CMS's process and priorities in the overall Negotiation process and the individual Negotiations for selected drugs.
- Provide clarity on the choices of therapeutic alternative for each approved indication of selected drugs and ground those choices in current, evidence-based clinical practice. CMS should focus on clinical benefits and cost offsets when comparing treatments and determining value, and not reduce the preliminary price by information unrelated to the value of a treatment (e.g., cost-recovery, remaining exclusivity, etc.).
- Develop, communicate, and more clearly define the factors CMS considers when determining unmet need consistent with relevant patient populations' needs for each indication of selected drugs.
- Engage with patients and caregivers throughout the process to gain insights into the value, preferences for appropriate treatment, and the indirect costs that patients and their families bear, to inform the evaluation of the clinical benefit of a selected drug (evaluation process). It is essential to gain patient input to identify unmet needs, therapeutic alternatives, clinical and humanistic benefits.

- Create and implement a consistent framework that provides more information about how CMS will make decisions during the Negotiation process, including the identification of therapeutic alternatives, stakeholder involvement, and the evidence used to support CMS decisions. While CMS did not create and implement a framework with more information for IPAY 2026, CMS can improve upon the process for IPAY 2027 by establishing this framework.
- Apply well-established best practices for evidence evaluations from organizations including the Innovation and Value Initiative and ISPOR, the Professional Society for Health Economics and Outcomes Research. Provide clarity into the evidence standards that CMS will use at all steps of the process, including when working with external organizations.

IV. (Section 110) Part D Formulary Inclusion of Selected Drugs

- While we appreciate CMS's inclusion of additional detail regarding what the agency will monitor with regard to formulary compliance, we remain concerned that patient formulary access may be reduced as a result of IRA implementation and urge CMS to implement additional safeguards and improved oversight and standards for Part D formularies to protect patient access and prevent discriminatory behavior.

V. General Comments

- Encourage CMS to broadly interpret the IRA statute to exclude orphan drugs from Negotiation and when determining the number of designations and indications that exempt an orphan product from selection.
- Incorporate the value of novel formulations in its price determination and Negotiation process.

I. Improving Transparency in the Implementa2on Process

The implementation of the Inflation Reduction Act (IRA) is the most significant Prescription drug pricing intervention in the history of the Medicare program. As we approach the announcement of set prices for IPAY 2026, it is being closely followed by those who invest in, research, and develop new cures. It is also being closely watched by health policy experts, pharmacoeconomic researchers, patient advocates, and others. CMS has a long history of publishing and responding to information provided by stakeholders when implementing new policies. This Guidance opens CMS to criticism for creating an opaque process giving the agency maximum flexibility and latitude while failing to provide adequate clarity and details about how it will implement important provisions (e.g., identification of therapeutic alternatives, weighting of factors for initial offer, etc.). We appreciate that CMS made comments on the IPAY 2026 guidance publicly available and urge CMS to continue this approach for IPAY 2027 as an important step in maintaining transparency.

II. (Sec2on 40) Requirements for Manufacturers of Selected Drugs

A. Decreasing the Potential for Payment Errors, Fraud, and Perverse Incentives

CMS should also provide flexibility for manufacturers with MFP agreements to provide access to the MFP, particularly given the new systems needed to effectuate MFP. As CMS heard in comments provided in response to the Office of the Inspector General's regulations to remove the safe harbor protection for Prescription drug rebates, it is important to contemplate the workability of these new mechanisms.

NPC has a deep understanding of the pharmaceutical supply chain. As such, we have concerns and suggestions about the flow of funds and lack of data described in Section 40.4. The Guidance robustly describes manufacturer noncompliance yet offers nearly no information about dispenser noncompliance.

While CMS is requiring the use of the Medicare Transaction Facilitator (MTF) data exchange, which is intended to facilitate the exchange of claims-level data and payment elements for selected drugs, manufacturers should not be the only stakeholders (e.g., pharmacies, mail order services, and other dispensers) in the supply chain responsible if an MFP is not made available to beneficiaries. As CMS is requiring manufacturers to submit plans for effectuating MFP, supply chain entities should be required to participate in the process laid out by manufacturers. If CMS does not fix the critical issues outlined below in advance of January 1, 2026, CMS must allow manufacturers maximum flexibility to maintain compliance with MFP effectuation requirements. Additionally, CMS should monitor compliance across supply chain entities as it proceeds with establishing its intake system for receiving complaints and disputes (Section 90.2.2).

i. Manufacturer Effectuation of MFP

The pharmacy's actual acquisition cost is not known to or controlled by manufacturers, and the existing chargeback payments and rebate mechanisms are currently inadequate to effectuate the MFP. As such, NPC supports CMS's proposed Standard Default Refund Amount (SDRA) of Wholesale Acquisition Cost (WAC) – MFP. However, while CMS asserts that the MTF is intended to support verificaGtion that the selected drug was dispensed to an MFP-eligible and to facilitate this process, NPC remains concerned about the potential for errors. If a Prescription was filled, billed, and returned to stock within the 14-day Time frame proposed by CMS, the Part D plan would have the information necessary to reverse their payment to the pharmacy, but the manufacturer would not be aware of the need to reverse the MFP effectuation payment. This creates a significant economic incentive that could encourage inadvertent duplicate discounts or outright diversion or fraud that threatens the integrity of IRA implementation.
While CMS notes that it is considering how to address claim adjustments and reversals (Section 40.4.1), NPC is concerned that no solution has been put forth yet for manufacturer and supply chain stakeholder feedback, particularly as we approach IPAY 2026. Moreover, manufacturers of selected drugs for IPAY 2026 will be required to submit their plans to make MFP available by June 1, 2025, six months sooner than announced in the Revised Guidance for IPAY 2026. Manufacturers need sufficient Time to make their plans, which could be better informed with information on how CMS plans to address claims adjustments and reversals.

NPC is also concerned about the potential for perverse incentives associated with CMS's Guidance on scenarios where SDRA may be inappropriate. In Guidance, CMS asserts that the SDRA might be unsuitable when a dispensing entity's acquisition cost exceeds the WAC for a drug and in such scenarios,

the SDRA payment "would not be sufficient to make the MFP available to the dispensing enGty." We believe this may compromise the program's integrity and foster behaviors among dispensers and other supply chain participants to inflate profits via mechanisms that spuriously raise MFP refund amounts. This issue arises in part because manufacturers do not control the prices at which dispensers obtain drugs from supply chain middlemen, including wholesalers. We urge CMS to implement safeguards to protect against these issues.

ii. *Verification of 340B Discounts and 340B Nonduplication*

Numerous factors create a significant potential for MFP and 340B duplicate discounts. These include a lack of transparency in the 340B Drug Pricing Program, the potential for mixing mechanisms of chargebacks and rebates of 340B and MFP on the same National Drug Code (NDC), and the inconsistent Timeframe and methods by which pharmacy claims are determined as 340B eligible. Without additional verification from CMS, manufacturers will be required to validate that 340B entities are only providing the MFP to eligible individuals, without standard processes to do so or the required participation of 340B covered entities (or entities acting on their behalf) to provide sufficient information to determine whether a 340B or MFP discount is owed.

To avoid duplication of 340B and MFP prices, one option is for CMS to require identification of 340B units at the point of sale at the Time of dispensing (when the claim is created) and prohibit identification of 340B units after that point for MFP drugs. If this approach is used, we ask the agency to develop a cutoff for 340B identification to avoid duplicates. As part of this, the agency should also commit to ensuring that providers report a "minimally necessary" data set to the manufacturer or its vendor to be entitled to access the MFP and for the purposes of validating their right to access in a Timely manner, according to standard business practices and consistent with non- duplication requirements. While the MTF will provide some of this data, NPC remains concerned about the limited information required from dispensing entities, and the data burden required of manufacturers in this scenario.

Given the complex interactions of the processes described above, CMS should establish a 340B clearinghouse, which would act as a claims verifier, reviewing Part D PDE data as well as data submitted by 340B covered entities (or entities acting on their behalf) to confirm whether a claim is subject to a 340B agreement, similar to the role played by 340B third-party administrators (TPAs) and split-billing vendors today.

If this clearinghouse is not established, at minimum, CMS should incorporate 340B-related transaction data from 340B covered entities or their third-party administrators into the MTF for IPAY 2026, rather than in the future as it suggests in the guidance. In the guidance, the agency itself notes that the process of facilitating access to the lesser of MFP or the 340B ceiling process will involve using data from multiple stakeholders, and providing this information via the MTF could improve this process if a clearinghouse is not used. For drugs dispensed to 340B-eligible patients, the use of a 340B identifier should be mandatory to facilitate the provision of this data. Additionally, CMS should also consider aligning data elements used in this process with data elements from CMS guidance on avoiding duplicate discounts for

Medicaid.[4] CMS should also expressly acknowledge that manufacturers will establish, receive, review, and, as necessary, audit MFP validation data to ensure MFP access is provided in accordance with the statute. If CMS does not establish a clearinghouse, manufacturers may need to collect data from covered entities to validate 340B status and avoid duplicates and will need accurate PDE data to confirm this information.

B. *Primary/Secondary Manufacturer Definition*

NPC maintains, as it commented last year, that CMS should abandon the Primary/Secondary Manufacturer policy. The primary and secondary manufacturer concept developed by CMS is unworkable, impractical, and not supported by the statute. Requiring one manufacturer to enter into an agreement with CMS that holds them responsible for the actions of another manufacturer (and potentially a competitor) unnecessarily complicates implementation and exposes manufacturers to potentially significant burden.

III. (Sections 50 and 60) Negotiation Factors and Process

As stated earlier, many stakeholders are closely watching CMS's IRA implementation process. The price- setting process is being studied not just by manufacturers, but by the broader pharmacoeconomic, health policy, and patient advocacy communities. The credibility of CMS's process will be judged by the agency's use of good evidence and appropriate methods in a transparent and patient-centered process.

CMS has described a domestic reference price-setting mechanism that begins by identifying a therapeutic alternative and using its price as an initial starting point. This initial starting point is then adjusted for clinical benefits to achieve a preliminary price that is further adjusted by a variety of other factors unrelated to the value of a treatment.

We do not believe the Guidance describes a satisfactory process to determine the value of a medicine or set its price and note that it resembles, with less transparency, processes used by countries outside of the United States that face significant delays in accessing Innovation. We believe that only clinical benefit, health improvement, including public health and societal benefits, and cost offsets associated with the treatment may be used to determine the value ofa medicine. Adjusting reimbursement by the elements described in the manufacturer data elements, which are unrelated to drug benefits, (e.g., R&D costs, cost of production, prior Federal financial support) ignores the complexity of drug development and the multitude of costs across the pharmaceutical supply chain for patients to receive their medicines. Doing so will have disastrous effects on Innovation and deny patients future treatments or future indications for existing treatments. Beyond our concerns about potential adjustments to the initial starting point based on factors unrelated to the value of a medicine, NPC is concerned about CMS's definition of the starting point itself. CMS's decision to use the net price of therapeutic alternatives, incorporating discounts paid under the Medicare Part D Manufacturer Discount Program, is an inappropriate metric to use for the Medicare population. It is not a standard price reporing measure

[4] Lynch, C. CMCS Informational Bulletin. SUBJECT: Best Practices for Avoiding 340B Duplicate Discounts in Medicaid. January 8,

2020. Available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cib010820_252.pdf

found elsewhere, which will increase burden, and Discount Program payments are highly variable and depend on the mix of drugs patients are taking.

The statute requires CMS to use a "consistent methodology and process" for Negotiation.[5] More clarity is needed than is provided in the Guidance to achieve that goal, especially related to the identification of therapeutic benefit and the weighting of factors used to determine the preliminary price and initial offer. Only when such clarity is provided can manufacturers and external stakeholders build their own models to anticipate, inform, and evaluate the process CMS operationalizes. Manufacturers in particular need more clarity to accurately prepare their submissions and meaningfully participate in the process. Clarity has not been provided to manufacturers for the first round, which does not allow manufacturers subject to subsequent rounds of Negotiation to apply lessons learned based on experience. While CMS will publish a narrative explanation of the Negotiation process and MFP of selected drugs for IPAY 2026 and share non-proprietary information, including information submitted by other interested parties and related to the selected drug and its therapeutic alternatives, this information will not be published until after comments are due for the IPAY 2027 draft guidance and may not be published until manufacturers must sign agreements to participate in the Negotiation Program for IPAY 2027 or face steep "excise tax" penalties . The deadline by which CMS must publish these explanations and by which manufacturers and the public must submit data to CMS for consideration in the Negotiation process are the same day. Both sets of stakeholders will need to submit information without understanding what CMS valued in the price-setting process for IPAY 2026. This delay in information hinders manufacturers' ability to comment more granularly on the information that should be included in CMS's public rationale for each MFP and to leverage insights from the first cycle of the price-setting process as it enters its second cycle. Our specific recommendations are below.

A. Development of a Transparent and Rigorous Evaluation and Price-setting Process

NPC encourages CMS to implement a transparent and inclusive evaluation process to promote credibility and support for their price-setting and counteroffer process. The agency is introducing comparative effectiveness to the Medicare program and making value determinations when establishing a "preliminary price" for selected drugs, yet provides limited, far from sufficient transparency or predictability around this process. Transparency and methodological rigor are paramount during value assessment.[6]

CMS should pursue analytic transparency by carefully considering data assumptions and highlighting the limitations and uncertainties of analyses to the public. By providing robust information about its evaluation criteria and the factors considered during the price-setting process, CMS can help build trust with all stakeholders and allow others to evaluate their process. Specifically, NPC encourages:

[5] SSA § 1194(b)(1). https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf

[6] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at:

- **Engagement with key stakeholders throughout the assessment process** to ensure all perspectives are considered and have the opportunity to inform the assessment.[7] CMS should specifically seek and incorporate stakeholder feedback about their choice of therapeutic alternatives for each selected drug; the benefits of a selected drug to each stakeholder (including patients, clinicians, caregivers, manufacturers and other scientists); the meaning of unmet need to each stakeholder and the extent to which a selected drug meets that unmet need.

  CMS should seek patient input via a variety of mechanisms and tailor requests to facilitate this input. CMS has recognized that the Information Collection Request (ICR) form and patient- focused listening sessions for IPAY 2026 were not organized to best collect stakeholder input. NPC will review the revised ICR and appreciates CMS intends to take additional steps to improve it, but the ICR process in general may not be the best way to reach this important stakeholder community. It is vital that CMS improve its patient engagement strategy based on participation and engagement in the patient-focused listening sessions for IPAY 2026. The structure CMS used did not promote quantity or quality of engagement, as we will detail further below. For quantity, notably, out of an anticipated 200 speaker slots, there were 106 total speakers, indicating that CMS must change its approach to maximize participation.[8] Given the important perspectives of patients and caregivers, we provide additional recommendations on meaningful patient input to the CMS process determining clinical benefit throughout this comment. Furthermore, manufacturers should be able to inform the selection of evidence about their products and verify information provided about their products from others; to do this, we recommend that CMS issue a confidential report to the manufacturer regarding evidence from stakeholders about the selected drug either with or prior to the initial offer.

- **The use of transparent and reproducible methods and results to the extent possible**, given the confidentiality required for proprietary information, methods, models (including all calculations). Assumptions should be transparent to interested stakeholders. This transparency, combined with the ability to reproduce results, are prerequisites to building credibility and trust in the process.[9] NPC reiterates that CMS should create and publish any decision-making framework it develops– both generally and for selected drugs – which should include, at a minimum, information on:

  1. the therapeutic alternative(s) considered for each indication for selected drugs and the rationale for selection;

[7] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf

[8] Patterson J, Wagner T, Salih, K, Shabazz G, Campbell, D. Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. Available at: https://www.npcnow.org/sites/default/files/2024- 05/Poster_ISPOR%202024%20Patient-Focused%20Listening%20Sessions%20FINAL.pdf

[9] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at:

2. the definition(s) of unmet need for each indication of selected drugs;
3. the full range of benefits and impacts considered for each indication;
4. the internal process and rationale for determining which benefits and impacts were included;
5. a list of each stakeholder consulted;
6. the source(s) of evidence considered, particularly clinicians and patients;
7. how each benefit and impact considered influenced the final MFP, to include any algorithms, calculations, or modeling that related to MFP determination, as well as rationale for evidence that was not considered; and
8. the limitations of the data collected and uncertainties in CMS's decision-making. As is common in any rigorous, evidence-based process, this information should also be made clear when reported to the public.

These elements of CMS's evaluation and MFP determination should be made public at disGnct phases of evaluation. First, this draft framework should be made public as a scoping document prior to initiating stakeholder engagement and beginning data Collection for CMS's evaluation process. Secondly, preliminary results should be shared with manufacturers of selected drugs at least 60 days prior to when CMS issues its initial offer. Finally, results of this framework should be revealed to the public to explain the final MFP. While these comments are for the IPAY 2027 draft guidance, it would be valuable to have this information for the IPAY 2026 MFP explanations before the IPAY 2027 Negotiations begin.

- **Robust engagement with manufacturers,** consistent with the practices and policies of other payers and regulators.[10] Given their vast knowledge of their products and therapeutic areas, pharmaceutical manufacturers and their pharmacoeconomic researchers are critically important sources of information on the value of treatments for payer decision-making. Recognizing this, Congress and the U.S. Food and Drug Administration (FDA) have provided guidelines on how healthcare economic information (HCEI) can be provided to payers' pharmacy and therapeutics committees.[11] We encourage CMS to similarly provide opportunities for meaningful engagement with manufacturers.

  While CMS currently offers a maximum of three meetings between the manufacturer of the selected drug and CMS, CMS is requesting feedback on whether three meetings are necessary and if it would be preferable to have an additional written offer in lieu of one or more meetings.

[10] Smith JC, Snider DE, Pickering LK; Advisory Committee on Immunization Practices. Immunization policy development in the United States: the role of the Advisory Committee on Immunization Practices. Ann Intern Med. 2009 Jan 6;150(1):45-9.; Payer Engagement in HEOR. Ispor.org. Available at: https://www.ispor.org/strategic-initiatives/payer-engagement-in-heor

[11] Section 3630, "Facilitating Exchange of Product Information Prior to Approval" of H.R. 2617, Consolidated Appropriations Act, 2023; FDA. Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions

and Answers Guidance for Industry and Review Staff.; 2018. Available at: https://www.fda.gov/media/133620/download.

NPC urges the agency to, at minimum, maintain three meetings, though existing industry best practices suggest a minimum level of engagement would extend beyond three meetings, to include meetings at: 1) after drug selection but prior to initiation of the price-setting process; 2) prior to CMS presenting the initial offer; and 3) the three meetings described by CMS as occurring after CMS presents the initial offer. Additional written offers and clear communication surrounding next steps will enhance the "Negotiation" process. However, if CMS moves forward with adding an additional written offer, such offer should not be in lieu of live meetings, and must promote the transparent exchange and evaluation of evidence on the value and clinical benefit of selected drugs.

i. Evaluation of data on product value for quality, particularly information on patient experience

The Guidance states that CMS will accept information on the benefits of selected drugs from the public and conduct its own literature reviews and database analyses. While laudable and helpful, public submission comes with a cost of sorting through and identifying studies that are both high quality and relevant to the therapeutic alternatives and patient population.[12]

The results of an assessment depend on the evidence that underlies it, and the burden is on CMS to use and develop evidence in a systematic, transparent, and robust manner. To maximize credibility and trust in the assessment process, the procedures by which evidence is identified and included in the assessment should be objective, systematic, transparent, robust, reproducible, and made public as part of the scoping process. Not following widely accepted scientific best practices erodes trust in the process.

Accordingly, we encourage CMS to develop robust, transparent standards for both submitted and internally generated data to ensure that evidence is methodologically rigorous and apply these same rigor and transparency standards to the agency's internal claims analysis and review when adjusting the MFP initial starting point based on clinical evidence. These standards can be informed by using accepted rubrics for evaluating study quality[13] that are fit for purpose and most appropriate for the type of evidence (e.g., clinical vs. economic data).[14] Procedures for evaluating evidence quality should be included in scoping documents, and the results should be made available through the value assessment.

[12] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf

[13] Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value Health. 2022 Jun;25(6):1060.; von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)statement: guidelines for reporting observational studies. Lancet. 2007 Oct 20;370(9596):1453-7.; The GRACE Checklist: A Validated Assessment Tool for High Quality Observational Studies of Comparative Effectiveness. J Manag Care Spec Pharm. 2016 Oct;22(10):1107-13;

[14] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at:

We encourage CMS to follow and tailor as necessary consensus guidance on the conduct and evaluation of comparative effectiveness research (CER) that is both submitted and internally conducted, and to adopt elements as high-quality research methods, aligned with principles of good CER.[15]

ii. Inclusion of Treatment Costs and Cost Offsets

Costs should be representative of the net price most relevant to the user. Cost offsets are a driving component of drug value and actual transaction costs, and care should be taken to ensure that costs are as representative of the actual net cost to the payer and net revenue realized by the manufacturer as possible in order to achieve an accurate assessment. For biopharmaceuticals, following ISPOR good research practices for measuring drug costs can help achieve this objective.[16] In the case of MFP, CMS must ensure that cost data reflects discounts and rebates provided to Medicare and recognize that the net cost to the payer does not always represent the net revenue realized by the manufacturer.

We encourage CMS to also include comprehensive assessments of the economic benefits of selected drugs, in addition to the costs of the treatments themselves. In any assessment of the value of medical treatments, all healthcare costs and cost offsets should be included.[17] Treatments may have up-front costs that lead to long-term improvements in patient health.

Those improvements may yield "cost offsets," or savings due to reductions in healthcare resource needs, such as reduced hospitalizations, or societal gains (e.g., improved productivity, reductions in caregiver burden). The full value of treatment can only be assessed by including both the treatment costs and other associated cost offsets it may produce, while also including clinical benefits of drugs without discretely quantifiable impacts on costs (e.g., improvements in the overall care of the patient). Only considering the treatment costs but not the potential cost offsets would lead to an incomplete assessment of value. NPC appreciates that this draft guidance now states that CMS may also request evidence related to "healthcare resource utilization and usage patterns" of the selected drugs and its therapeutic alternatives. Reviewing data related to healthcare resource utilization and usage, with consideration of evidence-based medicine, will provide insight into the economic benefits of selected drugs and their impacts on patient health. However, it remains unclear how CMS will use this information, the methods they will employ to analyze it, and how it will inform their evaluations, and transparency on these points is necessary to evaluate whether this evidence will be used appropriately.

When evaluating cost data, the Time horizon should be long enough to incorporate the benefits of the treatment and the lower costs of medications when they become generic. Many of the cost-offset

[15] Berger ML, Sox H, Willke RJ, Brixner DL, Eichler HG, Goettsch W, Madigan D, Makady A, Schneeweiss S, Tarricone R, Wang SV, Watkins J, Mullins CD. Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making. Value Health. 2017 Sep;20(8):1003-1008.; Dreyer NA, Bryant A, Velentgas P. The GRACE Checklist: A Validated Assessment Tool for High Quality Observational Studies of Comparative Effectiveness. J Manag Care Spec Pharm. 2016 Oct;22(10):1107-13; National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf

[16] Hay JW, Smeeding J, Carroll NV, et al. Good research practices for measuring drug costs in cost effectiveness analyses: issues and recommendations: the ISPOR drug cost task force report – Part I. Value Health 2010;13:3-7.

[17] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at:

benefits of treatment, such as costs of avoided hospitalizations, show up in the longer-term. To measure the full value of a treatment, the Time horizon for costs should be long enough to capture these cost offsets,[18] and to account for the lower costs of medications when generics and biosimilars are introduced.

iii. Utilization of Best Practices Relevant to CMS's Proposed Evidence Evaluation

We have cited in this response several publications on research best practices relevant to the agency's evidence evaluation proposed in the Guidance. We encourage CMS to review and, wherever possible, utilize the guiding principles listed below to ensure the transparency, validity, and credibility of the annual price-setting process. In our foregoing recommendations, we have emphasized methodological issues that are relevant to the price-setting process proposed by CMS. We encourage CMS to consider these tools to the extent that the principles are appropriate for Medicare. For example, NPC has developed or recommends the following resources:

- NPC's Guiding Practices for Patient-Centered Value Assessment includes 33 specific elements surrounding six key aspects of value assessment, including the assessment process, scientific methodology, benefits, costs, evidence, and dissemination and utilization.[19]
- The Myth of Average: Why Individual Patient Difference Mager, published by NPC, provides recommendations for ways improving the patient-centeredness of value assessment.[20]
- ISPOR and the InterNational Society for Pharmacoepidemiology (ISPE) have published good practices for real-word data studies of comparative effectiveness with the goal of providing a trustworthy foundation for use of RWE in decision-making.[21]

ISPOR, the Innovation and Value Initiative, PhRMA, and the National Health Council (NHC) have also developed resources related to the patient perspective, value assessment, and comparative effectiveness research that we ask CMS to incorporate into its process.[22]

[18] Hay JW, Smeeding J, Carroll NV, et al. Good research practices for measuring drug costs in cost effectiveness analyses: issues and recommendations: the ISPOR drug cost task force report – Part I. Value Health 2010;13:3-7.
[19] National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20PatientCentered%20Value%20Assessment%20January.pdf
[20] National Pharmaceutical Council. The Myth of Average: Why Individual Patient Differences Matter. 2022. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf
[21] Berger ML, Sox H, Willke RJ, Brixner DL, Eichler HG, Goettsch W, Madigan D, Makady A, Schneeweiss S, Tarricone R, Wang SV, Watkins J, Mullins CD. Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making. Value Health. 2017 Sep;20(8):1003-1008.
[22] Berger ML, Sox H, Willke RJ, Brixner DL, Eichler HG, Goettsch W, Madigan D, Makady A, Schneeweiss S, Tarricone R, Wang SV, Watkins J, Mullins CD. Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making. Value Health. 2017 Sep;20(8):1003-1008.; Innovation and Value Initiative. Principles for Value assessment in the US. https://thevalueinitiative.org/principles-for-value- assessment-in-the-us/; PhRMA. (2016). Principles for Value Assessment Frameworks. Available at: https://phrma.org/resource-center/Topics/Cost- and- Value/Principles-for-Value-Assessment-Frameworks; National Health Council. Domains of Patient Centeredness in Value Assessment. 2020. Available at: https://nationalhealthcouncil.org/wp-content/uploads/2020/03/NHC-One-Pagers_Domains.pdf; National Health Council. (2016). The

Patient Voice in Value: The National Health Council Patient-Centered Value Model Rubric. Available at: https://nationalhealthcouncil.org/wp-content/uploads/2020/11/20160328-NHC-Value-Model-Rubric- final.pdf; National Health Council. (2021). Value Classroom. https://nationalhealthcouncil.org/education/value-classroom/

B. *Identification of Therapeutic Alternatives*

The IRA instructs CMS to consider "the extent to which [a selected drug] represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives"; however, it does not suggest that the cost of those alternatives should be used as a benchmark for an initial offer. The Guidance diverges from the statute because CMS intends to rely on the lower of either: 1) the Net Part D Plan Payment and Beneficiary Liability, which reflects Total Gross Covered Prescription Drug Costs (TGCPD) net of direct and indirect remuneration (DIR) and Coverage Gap Discount Program (CGDP) payments, or (2) the MFP for initial price applicability year 2026 selected drugs, if applicable, "to determine a starting point for developing an initial offer."[23]

In any assessment of the relative clinical or economic benefits of a drug, the choice of the comparator is a fundamental driver in the outcomes and validity of the assessment with significant implications for patients, payers, and prescribers.[24] NPC recommends that the choice of comparators/therapeutic alternatives be driven by clinical appropriateness, informed by current treatment practices among a relevant patient population, and selected from potential comparators with the same treatment modality and class, rather than be dictated by cost, other concerns or implicit goals.[25] The draft guidance states that for its purposes "the term 'therapeutic alternative' may refer to one or more therapeutic alternative(s) or a subset of therapeutic alternatives that are clinically comparable," without further defining the type and volume of evidence used to define "clinically comparable." CMS changed this language from the IPAY 2026 guidance, which stated that "therapeutic alternative" may refer to "a subset of the most clinically comparable therapeutic alternatives." This is a change in the wrong direction, away from what is most clinically appropriate. The selection of a less-costly therapeutic alternative that is "clinically comparable" but not in the subset of "most clinically comparable" and lacks the safety, efficacy, and other clinical benefits of a selected drug – solely to lower the initial starting point of the price-setting process – fails to recognize the value of modern treatments and threatens to reverse the incentives that currently encourage Innovation and access.

The use of a comparator that is not consistent with current clinical practice for given patients injects significant biases into the results and recommendations of a comparative assessment. Real world treatment decisions are based on numerous factors associated with the underlying disease and its severity, general health status or frailty, quality of life, and patient preferences.

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[23] SSA § 1194(e)(2)(A).

[24] Berger ML, Sox H, Willke RJ, et al. Good Practices for Real-World Data Studies of Treatment and/or Comparative Effectiveness: Recommendations from the Joint ISPOR-ISPE Special Task Force on Real-World Evidence in Health Care Decision Making. Value in Health. 2017;20(8):1003-1008.

[25] Jaime Caro J, Eddy DM, Kan H, Kaltz C, Patel B, Eldessouki R, Briggs AH; ISPOR-AMCP-NPC Modeling CER Task Forces. Questionnaire to assess relevance and credibility of modeling studies for informing health care decision making: an ISPOR- AMCP-NPC Good Practice Task Force report. Value Health. 2014 Mar;17(2):174-82.; Sanders GD, Neumann PJ, Basu A, Brock DW, Feeny D, Krahn M, Kuntz KM, Meltzer DO, Owens DK, Prosser LA, Salomon JA, Sculpher MJ, Trikalinos TA, Russell LB, Siegel JE, Ganiats TG. Recommendations for Conduct, Methodological Practices, and Reporting of Cost-effectiveness Analyses: Second

Panel on Cost-Effectiveness in Health and Medicine. JAMA. 2016 Sep 13;316(10):1093- 103.

The Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care Program has produced guidance that may be helpful for CMS regarding comparator selection in observational CER.[26] AHRQ details how treatment selection bias (i.e., confounding by indication) may arise when there are differences between patients prescribed the drug being evaluated and the drug used as a comparator. Bias can be minimized by choosing a comparator that has the same indication, similar contraindications, similar adverse effects, and the same treatment modality, class, and mechanism of action.

AHRQ also notes that selection of a comparator of the same treatment modality and class may result in less bias than comparison across modalities or classes.[27] We appreciate CMS's intent to begin identifying therapeutic alternatives within the same drug class based on chemical class, therapeutic class, or mechanism of action before considering therapeutic alternatives in other classes, and encourage CMS to prioritize reducing bias in treatment comparisons by identifying therapeutic alternatives from potential comparators with the same treatment modality, class, and mechanism of action.

In the IPAY 2027 draft guidance, CMS uses the term pharmacological class whereas it previously used the term drug class in identifying therapeutic alternatives. Certain drugs are included in multiple pharmacological classes which may add complexity to the process, and we caution CMS to not let this change further detrimentally affect it.

NPC cautions against using cost to determine a selected drug's therapeutic alternative(s). Rather, during selection of therapeutic alternatives, we encourage CMS to:

- Publicly communicate proposed therapeutic alternatives and solicit feedback from manufacturers, clinicians with specific expertise in the treating the disease, patients and caregivers, and other stakeholders before proceeding with comparative effectiveness analyses that inform the initial offer.
- Ensure guidelines used in identifying therapeutic alternatives are up-to-date and incorporate the latest evidence.[28]
- Include patient preferences and priorities that inform shared decision-making between appropriate treatment options.[29]
- Invite manufacturers of the selected drug to proactively present clinical information focused on the relative clinical benefit of their products compared to therapeutic alternatives during the process of comparator selection and give manufacturers the opportunity to respond to CMS's choices of therapeutic alternatives. Early manufacturer communication is also consistent with practices employed by state Medicaid agencies, other federal agencies and commercial payers.

[26] AHRQ. Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide. Content last reviewed March 2021. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. https://effectivehealthcare.ahrq.gov/products/observational-cer-protocol
[27] AHRQ. Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide. Content last reviewed March 2021. Effective Health Care Program, Agency for Healthcare Research and Quality, Rockville, MD. https://effectivehealthcare.ahrq.gov/products/observational-cer-protocol
[28] National Health Council. A Dialogue on Patient-Centered Value Assessment: Overcoming Barriers to Amplify the Patient Voice. December 2018. Available from: https://www.nationalhealthcouncil.org/dialogue-patient-centered-value-assessmentovercoming-barriers-amplify- patient-voice
[29] Schmidt T, Valuck T, Riposo J, et al. Impact of Shared Decision-Making and Patient Decision Aids on Health Care Cost and

- Seek input from clinicians with specific expertise in treating the indication of the selected drug to define appropriate therapeutic alternatives among Medicare patient sub-populations, including patients with multiple comorbidities and varying levels of disease severity. There is a long history of guidance to gain this information, including NIH's National Center for Advancing TranslaGonal Sciences.[30]
- Limit the choice of therapeutic alternative to drugs and biologics with FDA-approved indications and exclude off-label use from being compared to FDA-approved indications of selected drugs.
- Consider the use of comparative effectiveness studies and real-world evidence to support the selection of therapeutic alternative.

C. Prioritize Patient and Caregiver Input

Patients' and caregivers' view of the drugs they take and the benefits they receive is essential to understanding "the full range of clinical and patient-centered outcomes",[31] as PCORI stated in their recent multi-stakeholder research Initiative. The centrality of direct patient input is echoed in best practices for comparative effectiveness research and value assessment that underpin the concept that the price of pharmaceuticals should be based on the value they provide to patients, caregivers, healthcare systems, and society. Value encompasses the balance of benefits and costs experienced by patients and society over Time. There are a multitude of specific benefits that constitute "value," from reducing mortality and improving patient functioning, quality of life, and productivity to outcome equity and societal value of scientific Innovation, among others.[32]

Measures of "indirect costs" such as patient productivity, caregiver Time, and treatment burden (such as travel Times for repeated hospitalization) are very important to patients and their families but are often poorly captured in administrative claims databases. This misalignment between patient concerns and priorities surrounding the impact of a disease or its treatment and the outcomes data collected in research and care is well documented.[33] As stewards of the Medicare program accountable to the health of people with Medicare, CMS should include these issues throughout discussions with patients and patient groups and seek and utilize observational studies or real-world evidence that includes these outcomes.

Systematically and rigorously incorporating patient perspectives on the value of selected drugs is essential to ensure that patients have a voice in decisions that affect their health and wellbeing.[34] We are mindful of the federal prohibition on CMS's use of QALYs in coverage and reimbursement decisions. We

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[30] Shekelle PG, Woolf SH, Eccles M, Grimshaw J. Clinical guidelines: developing guidelines. BMJ. 1999 Feb 27;318(7183):593-6. NIH National Center for Advancing Translational Sciences. Toolkit for Creating Clinical Care Guidelines: https://toolkit.ncats.nih.gov/module/after-fda- approval/creating-clinical-care-guidelines/guideline-development-process/

[31] Patient-Centered Outcomes Research Institute (PCORI). Landscape Review and Summary of Patient and Stakeholder Perspectives on Value in Health and Health Care. https://www.pcori.org/resources/landscape-review-and-summary-patient- and-stakeholder-perspectives-value-health- and-health-care

[32] Neumann PJ, Garrison LP, Willke RJ. The History and Future of the "ISPOR Value Flower": Addressing Limitations of Conventional Cost- Effectiveness Analysis. Value Health. 2022 Apr;25(4):558-565.

[33] Perfetto, E.M., Oehrlein, E.M., Love, T.R. et al. Patient-Centered Core Impact Sets: What They are and Why We Need Them. Patient 15, 619– 627 (2022). https://doi.org/10.1007/s40271-022-00583-x

[34] Oortwijn W, Husereau D, Abelson J, et al. Designing and Implementing Deliberative Processes for Health Technology

Assessment: A Good Practices Report of a Joint HTAi/ISPOR Task Force. Int J Technol Assess Health Care. 2022;38(1).

also emphasize that direct engagement with patients identifies the measures of treatment benefit that patients and their families value, and therefore can avoid the potentially discriminatory nature of aggregate and limited measures such as the QALY. Thus, CMS should take tangible steps to capture the patient voice with validity and fidelity, engaging with patient groups directly to understand their perspective on the value of different pharmaceuticals throughout the Negotiation process, particularly when defining unmet need, selecting therapeutic alternatives, and determining clinical benefit.

NPC appreciates CMS's intent to improve upon the design of patient-focused listening sessions used for IPAY 2027 and has conducted research on the patient-focused listening sessions from IPAY 2026, focusing on the breadth of patient and stakeholder input in these sessions. We believe CMS should continue to evolve towards best practices for patient engagement[35] and prioritize opportunities to hear a greater amount of patient-centered evidence directly from patients and their advocates, caregivers, and providers. Our recommendations are below:

- **Improve transparency around how patient input would be utilized in the price determination process, communicating that impact back to patients.** Patient engagement may have been hampered by a lack of transparency surrounding how input would be used in the price determination process. As CMS considers new approaches to patient engagement for IPAY 2027, we encourage CMS to delineate the process by which clinical benefits and patient impacts would be considered and influence MFPs, and to promote transparency surrounding the patient perspective CMS gleans from these listening sessions and how it is incorporated in CMS's MFP offers for each selected drug.[36] While the agency was able to obtain some perspective consistent with the intent of the sessions, the opportunity for patients to provide meaningful feedback on patient experience, including unmet need, drug benefits, and patient access, was hampered by the shortcomings outlined below. Future evolutions of patient engagement in the DPNP should prioritize opportunities for CMS to hear a greater amount of patient-centered evidence directly from patients and their advocates, caregivers, and providers.[37] For example, speakers often focused their Time on patient experience and evidence; still, the median duration of input on patient-focused evidence about therapeutic alternatives per drug listening session was less than 15 minutes. A median of only 2.5 patients participated per session, providing CMS with a total of

[35] Harrington RL, Hanna ML, Oehrlein EM, Camp R, Wheeler R, Cooblall C, et al. Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group. [cited 2024 Mar 12]; Available from: https://doi.org/10.1016/j.jval.2020.01.019; Innovation and Value Initiative. Principles for Value Assessment in the U.S. [Internet]. 2021. Available from: https://thevalueinitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf; National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment [Internet]. 2024. Available from: https://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Practices%20for%20Patient-Centered%20Value%20Assessment%20January.pdf

[36] Patterson J, Wagner T, Salih, K, Shabazz G, Campbell, D. Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. Available at: https://www.npcnow.org/sites/default/files/2024- 05/Poster_ISPOR%202024%20Patient-Focused%20Listening%20Sessions%20FINAL.pdf

[37] Patterson J, Wagner T, Salih, K, Shabazz G, Campbell, D. Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. Available at: https://www.npcnow.org/sites/default/files/2024- 05/Poster_ISPOR%202024%20Patient-Focused%20Listening%20Sessions%20FINAL.pdf; National Health Council. Amplifying the Patient Voice: Roundtable and

Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

only seven total minutes of patient input per selected drug.[38] The duration of input received from the sessions was likely attenuated because only approximately half of the anticipated speaker slots (106 of 200) were filled. The agency reported that it used a "process to randomly select" speakers from those who registered.[39] However, given that no session featured the full 20 anticipated speaker slots, and three sessions included fewer than 10 participants, uncertainty remains as to whether fewer than 20 speakers registered or whether the Agency selected only a subset of registered individuals. CMS's extension of the initial registration window by nearly two weeks suggests recruitment and registration requirements may have presented challenges.[40] Clearly specifying the purpose of patient and stakeholder engagement and how evidence provided by participants will be used in CMS's price determination process could further strengthen the sessions.

- **Prioritize diversity and a muli-modal approach in outreach.** NPC and others have emphasized

  the need for CMS to prioritize diversity and a multi-modal approach in outreach at all phases of the DPNP implementation.[41] Robust engagement with underrepresented communities through outreach and ongoing dialogue is needed to promote an equity-focused implementation process.[42] Documented heterogeneity in treatment preferences[43] and effects,[44] as well as disparities in health status and access to care, further underscore the need for diverse patient voices in informing CMS's price determinations. CMS should account for this heterogeneity in its feedback to manufacturers in addition to integrating it into the process for seeking patient input. Technological barriers to registration (e.g., requiring an email address for anonline-only

[38] Patterson J, Wagner T, Salih, K, Shabazz G, Campbell, D. Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. Available at: https://www.npcnow.org/sites/default/files/2024- 05/Poster_ISPOR%202024%20Patient-Focused%20Listening%20Sessions%20FINAL.pdf

[39] Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program Patient-Focused Listening Sessions [Internet]. [cited 2024 Mar 18]. Available from: https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation-program-patient- focused-listening-sessions

[40] Karlin-Smith S. As Medicare Drug Negotiation Patient Sessions Kick Off, Advocates Already Eyeing Improvements. Pink Sheet. 2026.

[41] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: h?ps://Nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf; Miller M, Sara Van Geertruyden B;, Saxton ; M Claire, Courtney ;, Savage Y, Weir D, et al. A summit on amplifying voices of Patients, caregivers, and people with disabilities in Inflation Reduction Act drug price Negotiations. J Manag Care Spec Pharm. 2024;30:1–5.; National Organization for Rare Disorders. NORD Recommendations: Future Medicare Drug Price Negotiation Program Patient and Provider Listening Sessions [Internet]. 2024. Available from: h?ps://rarediseases.org/wp-content/uploads/2024/01/NORD- Recommendations-for-CMS-Listening-Sessions_vf.pdf; Innovation and Value Initiative. Policy Symposium: Ensuring Equity in Implementation of IRA Drug Price Negotiations [Internet]. 2023. Available from: h?ps://thevalueInitiative.org/wp-content/uploads/2024/02/2023-IRA-Policy- Symposium-Proceedings-Report_FINAL.pdf

[42] Innovation and Value Initiative. Policy Symposium: Ensuring Equity in Implementation of IRA Drug Price Negotiations [Internet]. 2023. Available from: h?ps://thevalueInitiative.org/wp-content/uploads/2024/02/2023-IRA-Policy-Symposium-Proceedings-Report_FINAL.pdf [43] Hollin IL, González JM, Buelt L, Ciarametaro M, Dubois RW. Do Patient Preferences Align With Value Frameworks? A Discrete-Choice Experiment of Patients With Breast Cancer. MDM Policy Pract. 2020;5:238146832092801; Groothuis-Oudshoorn CGM, Flynn TN, Yoo H Il,
Magidson J, Oppe M. Key Issues and Potential Solutions for Understanding Healthcare Preference Heterogeneity Free from Patient-Level Scale Confounds. The Patient - Patient-Centered Outcomes Research. 2018;11:463–6.; Whitty JA, Fraenkel L, Saigal CS, Groothuis-Oudshoorn CGM, Regier DA, Marshall DA. Assessment of Individual Patient Preferences to Inform Clinical Practice. The Patient - Patient-Centered Outcomes Research. 2017;10:519–21.

[44] National Pharmaceutical Council. The Myth of Average Why Individual Patient Differences Matter [Internet]. Washington, DC; 2022 Jan. Available from: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf

registration),[45] a lack of accommodations for patients with disabilities,[46] and English-only materials may have further reduced participation among patients who were older and/or members of underrepresented or disadvantaged communities.

- **Strive to establish a partnership with patients, their families, and their advocates, including ongoing and two-way dialogue with critical stakeholders.** The patient-focused listening sessions were designed to provide an opportunity for one-sided communication rather than robust, two- way dialogue between CMS, patients, caregivers, providers, and patient advocacy organizations.[47] Patient engagement should communicate clear goals and strive to establish a partnership[48] with patients, their families, and their advocates, including ongoing and two-way dialogue[49] with these critical stakeholders. For example, despite CMS's initial intentions to draw lessons from the FDA's patient-focused drug development meetings[50] – which feature semi- structured, large-group facilitated discussion, follow-up questions, and polling among groups of patients, caregivers, and patient representatives[51] – it is not clear whether such methodologies informed the development of the listening session format. Patient experience dossiers have been proposed as one way to provide consolidated patient-centered evidence that informs more specific, meaningful, and two-way engagement with stakeholders during the evaluation process.[52] Future changes to the DPNP implementation process should prioritize more robust and meaningful engagement beyond Time-limited, one-sided listening sessions to improve the patient-centricity of the DPNP.
- **Optimize event logistics.** For IPAY 2027, event logistics should be improved to promote patient engagement and minimize confusion, including the disclosure and registration processes. The disclosure process for IPAY 2026 may have negatively impacted participation. Suspends from patient organizations were listed in the same manner as funding from pharmaceutical

[45] National Organization for Rare Disorders. NORD Recommendations: Future Medicare Drug Price Negotiation Program Patient and Provider Listening Sessions [Internet]. 2024. Available from: https://rarediseases.org/wp-content/uploads/2024/01/NORD-Recommendations-for-CMS- Listening-Sessions_vf.pdf; Karlin-Smith S. As Medicare Drug Negotiation Patient Sessions Kick Off, Advocates Already Eyeing Improvements.
Pink Sheet. 2026.

[46] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and- Recommendations-on-CMS-Patient-Engagement.pdf

[47] Harrington RL, Hanna ML, Oehrlein EM, Camp R, Wheeler R, Cooblall C, et al. Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group. [cited 2024 Mar 12]; Available from: h?ps://doi.org/10.1016/j.jval.2020.01.019; Innovation and Value Initiative. Principles for Value Assessment in the U.S. [Internet]. 2021. Available from: h?ps://thevalueInitiative.org/wp-content/uploads/2021/01/2021-IVI-Principles-of-VA_FINAL.pdf; National Pharmaceutical Council. Guiding Prac;ces for Patient-Centered Value Assessment [Internet]. 2024. Available from: h?ps://www.npcnow.org/sites/default/files/2024-01/2024%20Guiding%20Prac;ces%20for%20Patient-Centered%20Value%20Assessment%20January.pdf

[48] Harrington RL, Hanna ML, Oehrlein EM, Camp R, Wheeler R, Cooblall C, et al. Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group. [cited 2024 Mar 12]; Available from: https://doi.org/10.1016/j.jval.2020.01.019

[49]Miller M, Sara Van Geertruyden B;, Saxton ; M Claire, Courtney ;, Savage Y, Weir D, et al. A summit on amplifying voices of patients, caregivers, and people with disabilities in Inflation Reduction Act drug price negotiations. J Manag Care Spec Pharm. 2024;30:1–5.

[50] Seshamani M. Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 [Internet]. 2023. Available from: https://www.cms.gov/files/document/revised-medicare-drug-price- negotiation-program-guidance-june-2023.pdf

[51] Chalasani M, Vaidya P, Mullin T. Enhancing the incorporation of the patient's voice in drug development and evaluation. Res

Involv Engagem. 2018;4:10.
[52] Oehrlein EM EHHTVJ. Listening Sessions Can Help CMS Become More Patient-Centered. Here's How The Sessions Could Be More Effective. Health Affairs Forefront. 2023

companies, which was viewed as perpetuating unfair stereotypes of patient organizations.[53] Because members of the public are often not accustomed to reporing conflicts of interest and were unclear as to whether and how these conflicts would be publicly communicated,[54] the process by which CMS defined, collected, and communicated COIs may have further deterred participation. Additional consideration may also be warranted in c patient-friendly language during the speaker registration process.[55] For example, one page of the registration form asked patients if they would include real-world evidence or data in their spoken remarks, with definitions of these terms that may have lacked clarity for patients unfamiliar with them (e.g., "real-world data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources").[56] These definitions may have also conveyed to patients that CMS was not interested in qualitative accounts surrounding their lived experiences.[57]

NPC also supports CMS revising questions in the Negotiation Data Elements and Drug Price Negotiation Process ICRs when it is issued for IPAY 2027 to include "the factors a patient cares most about when assessing the value of a drug," but reiterates that the value of a drug should underpin the entire price- setting process, not only in this context.

Below, we provide considerations and best practices for patient input and value assessment when defining unmet need, selecting therapeutic alternatives, and determining clinical benefit.

i. ***Defining Unmet Need***

In the revised guidance for IPAY 2026 and in this draft guidance, CMS defines unmet medical need as "a circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition" and notes that it will consider *the extent to which* the selected drug addresses an unmet medical need [emphasis added]. This was a change from the initial IPAY 2026 guidance under which the evaluation of unmet need was dichotomous: "*whether* the selected drug meets an unmet medical need" [emphasis added]. NPC appreciates that CMS has revised this definition to align with a definition promulgated by FDA and that it will consider the nonbinding recommendations in FDA guidance when considering the extent to which a drug addresses an unmet medical for the purposes of the Negotiation Program, and notes that manufacturers will utilize this definition in communicating the scope of unmet need met by innovative

[53] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and- Recommendations-on-CMS-Patient-Engagement.pdf
[54] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and- Recommendations-on-CMS-Patient-Engagement.pdf
[55] National Organization for Rare Disorders. NORD Recommendations: Future Medicare Drug Price Negotiation Program Patient and Provider Listening Sessions [Internet]. 2024. Available from: https://rarediseases.org/wp-content/uploads/2024/01/NORD-Recommendations-for-CMS- Listening-Sessions_vf.pdf
[56] StopAfib.org. ACTION REQUESTED: Make Your Voice Heard by Medicare [Internet]. 2023 [cited 2024 Mar 12]. Available from: https://www.stopafib.org/afib-news-events/news/action-requested-make-your-voice-heard-by-medicare/
[57] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement [Internet]. 2024. Available from: https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and- Recommendations-on-CMS-Patient-Engagement.pdf

products. However, NPC remains concerned that a lack of transparency surrounding what specific factors related to unmet need that CMS will consider will result in an approach that is too narrow.

The FDA's definition of unmet need, as outlined in its guidance for expedited programs, includes improved efficacy, reduced toxicity and/or potential drug-drug interactions, and improvements in other benefits such as adherence.[58] Notably, the FDA definition of unmet need also highlights conditions for which there is significant heterogeneity in response to existing treatment options. Patients may respond differently to available treatment options due to pharmacologic differences, genetic risk, or social determinants of health, creating unmet need despite existing treatments.[59] NPC requests CMS clarify what elements of the FDA guidance it considers when determining unmet need, if they are weighted differently, and how these factors play a role in the price-setting process.

We believe assessments of unmet medical need should include a multifaceted definition informed by the patient perspective. Rigorous methods can be used to elicit consensus from clinician experts and have been used to identify unmet medical needs to achieve optimal treatment goals throughout the natural history of a disease.[60] These methods have identified patient-centered unmet needs, including patient quality of life, poor adherence, severe stages of a disease that are hard to treat, and patient preferred routes of administration.[61] Failure to capture the value of treatments that address patient-centered unmet needs disincentivizes Innovations that meet those needs, in turn exacerbating disparities in health outcomes among patients receiving treatments less Effective in their subgroups and/or unaligned with their preferences.

ii. *Selecting Alternatives*

As discussed above**,** the choice of comparator is the fundamental driver of any value assessment and its implications for patients and caregivers. Accordingly, patient preferences and priorities that inform shared decision-making between appropriate treatment options should be incorporated into CMS's process for selecting treatment alternatives.[62] Prioritizing the patient voice in defining unmet medical need promotes patient access to not only *any* treatment alternative but *satisfactory* and *appropriate* treatment options aligned with patient preferences.[63] While CMS may take steps to further gather information that is important to patients when revising questions in the Negotiation Data Elements and Drug Price Negotiation Process ICRs for IPAY 2027 through questions related to patients' conditions and requesting a description about what it is like to live with a medical condition treated by the selected drug

[58] Food and Drug Administration. Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. U.S. Department of Health and Human Services. May 2014. Silver Spring, MD. Available at: https://www.fda.gov/files/drugs/published/Expedited-Programs-for- Serious-Conditions-Drugs-and-Biologics.pdf
[59] National Pharmaceutical Council. The Myth of Average: Why Individual Patient Differences Matter. 2022. Washington, DC. Available at: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf
[60] Danese S, Allez M, Van Bodegraven AA, et al. Unmet Medical Needs in Ulcerative Colitis: An Expert Group Consensus. Digestive Diseases. 2019;37(4):266-283. doi:10.1159/000496739
[61] Danese S, Allez M, Van Bodegraven AA, et al. Unmet Medical Needs in Ulcerative Colitis: An Expert Group Consensus. Digestive Diseases. 2019;37(4):266-283. doi:10.1159/000496739
[62] Schmidt T, Valuck T, Riposo J, et al. Impact of Shared Decision-Making and Patient Decision Aids on Health Care Cost and Utilization in the US: A Systematic Review. J Clin Pathways. 2022;8(8):33-43. doi:10.25270/jcp.2022.12.0

[63] Zhang K, Kumar G, Skedgel C. Towards a New Understanding of Unmet Medical Need. Appl Health Econ Health Policy. 2021;19(6):785-788. doi:10.1007/s40258-021-00655-3

or therapeutic alternatives, NPC urges CMS to be transparent in informing patients and healthcare stakeholders of how this information is specifically used and weighted within the Negotiation process.

iii. Determining clinical benefit

We encourage CMS to make use of resources to capture the patient's voice when selecting outcomes for evaluation of relative clinical benefit and to emphasize patient-centered benefits throughout its evaluation process. People with Medicare may prioritize different outcomes, such as symptom relief, improved quality of life, or indirect benefits such as reduced caregiver burden, compared to clinical outcomes like survival or disease progression.[64] Subgroups of people with Medicare may also have different priorities. Our research has identified heterogeneous patient preferences for both treatment characteristics and outcomes,[65] demonstrating the benefits associated with novel drugs and formulations that provide patients and providers with preference-aligned treatment options.
Accordingly, patient preferences regarding the benefits and risks of a product, its available dosage forms, and any innovative delivery systems should be included early in the assessment. Patient preference information can inform many aspects of evaluation of benefit in value assessment, including defining what benefits are most important to patients, selecting measures to quantify benefits, and supplementing health state utilities.[66] The FDA has created useful backgrounders and issued guidance on Collection and use of patient preference information.[67]

In evaluating relative clinical benefit, we encourage CMS to consider patient-reported outcomes that are complete, comprehensive, and fit for purpose, as opposed to limited, QALY utility-based approaches, including QALYs in or outside of a life-extension context.[68] Fit-for-purpose tools may include disease- specific measures in addition to overarching measures, as well as other outcomes that are meaningful to patients, including productivity, treatment and caregiver burden, and downstream healthcare utilization. Societal benefits, including scientific spillover, limiting the fear and risk of contagion for infectious diseases, and increasing equity have also been recognized as important elements of value.[69] Comprehensive approaches to measuring patient-centered value, including incorporation of factors beyond effectiveness and side effects, will result in more meaningful comparisons.[70]

CMS has a longstanding commitment to beneficiary engagement. By engaging with patients through multiple forms of direct engagement, CMS can ensure that it is receiving comprehensive and representative information directly from patients. We also encourage CMS to emphasize its commitment to patient engagement by including, in its initial offer and price justification, how the patient experience

[64] Ciarametaro M, Buelt L, Dubois RW. Getting Value Right: The Case For Indirect Benefits. Published online 2020. doi:10.1377/forefront.20200310.267867
[65] Hollin IL, González JM, Buelt L, Ciarametaro M, Dubois RW. Do Patient Preferences Align With Value Frameworks? A Discrete- Choice Experiment of Patients With Breast Cancer. MDM Policy & Practice. 2020;5(1). doi:10.1177/2381468320928012
[66] Marsh K, de Bekker-Grob E, Cook N, Collacott H, Danyliv A. How to integrate evidence from patient preference studies into health technology assessment: a critical review and recommendations. International Journal of Technology Assessment in Health Care. 2021;37(1).
[67] FDA. Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers Guidance for Industry and Review Staff.; 2018. Available at: https://www.fda.gov/media/133620/download

[68] Brown J, Cryer DR. Is the QALY Fit for Purpose? Am J Accountable Care. 2021;9(2):8-13.
[69] Lakdawalla DN, Doshi JA, Garrison LP Jr, Phelps CE, Basu A, Danzon PM. Defining Elements of Value in Health Care-A Health Economics Approach: An ISPOR Special Task Force Report [3]. Value Health. 2018 Feb;21(2):131-139. doi: 10.1016/j.jval.2017.12.007.
[70] Westrich K, Lisabeth Buelt M. Current Landscape: Value Assessment Frameworks. Washington, DC: National Pharmaceutical Council; 2016.

was considered in the evaluation of unmet need, selection of treatment alternatives, and evaluation of clinical benefit.

IV. (Section 110) Part D Formulary Inclusion of Selected Drugs

The IRA requires Part D plan sponsors to include on their formularies drugs for which an MFP is available. However, the perverse incentives that remain in the ecosystem could be exacerbated because the MFP process will occur concurrently with Part D redesign; more so if selected drugs are in competitive classes and may be priced below the ceiling price. This could lead to adverse Gering impacting patient copayments and/or formulary-driven switching, increased utilization management, or other reductions in beneficiary access thwarting the intent of the MFP process and undermining the competition that has made Medicare Part D a success. What a patient pays for a medicine is a function of the insurance card in their pocket. Insurers also determine whether patients must navigate barriers such as prior authorization or step therapy. Right now, seniors have excellent access and experience few barriers to many of the first ten drugs selected — but that may change. Increased utilization management requirements, which are likely in response to the IRA, could reduce patient access — exactly the opposite of what the program intends to do.[71]

Experts have already warned that the intersection of MFP and Part D redesign provisions are likely to increase formulary exclusions.[72] The revised guidance for IPAY 2026 and this draft guidance for IPAY 2027 includes additional information about CMS's formulary review process and how it will monitor instances where Part D sponsors place selected drugs on non-preferred Gers, instances where a selected drug is placed on a higher Ger than non-selected drugs in the same class, any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug with an MFP, or any instances where Part D sponsors impost more restrictive utilization management for a selected drug compared to a non-selected drug in the same class. While we appreciate CMS's inclusion of additional detail regarding what the agency will monitor with regard to formulary compliance, we remain concerned that patient formulary access may be reduced as a result of IRA implementation and urge CMS to implement additional safeguards to protect patient access and prevent discriminatory behavior for IPAY 2026, 2027 and beyond. NPC and others will be closely monitoring changes to patient access as a result of IRA and encourages the agency to do the same.

V. General Comments

A. *(Section 30.1.1) Orphan drug development*

People with rare diseases face significantly higher health care costs,[73] and these patients and their families highly value the current and future treatments that meet their needs. Furthermore, the small

[71] Patterson JA, Wagner TD, O'Brien JM, Campbell JD. Medicare Part D Coverage of Drugs Selected for the Drug Price Negotiation Program. *JAMA Health Forum*. 2024;5(2):e235237. doi:10.1001/jamahealthforum.2023.5237

[72] Kelly C. Medicare Part D Redesign Could Expand Rebate-Driven Formulary Exclusions in Program. The Pink Sheet. January 26, 2023. https://pink.pharmaintelligence.informa.com/PS147634/Medicare-Part-D-Redesign-Could-Expand-Rebate-Driven-Formulary-Exclusions-In- Program

[73] Tisdale, A., Cutillo, C.M., Nathan, R. et al. The IDeaS initiative: pilot study to assess the impact of rare diseases on patients and

healthcare systems. Orphanet J Rare Dis 16, 429 (2021). https://doi.org/10.1186/s13023-021-02061-3

patient populations for which orphan drugs are indicated are highly sensitive to changes in the research and development landscape, and the companies that develop orphan drugs are additionally highly sensitive to changes in the reimbursement landscape – especially those that threaten their ability to bring new orphan treatment to market and conduct post-approval research and development. NPC performed a study assessing the research and develop Timelines of all small molecule drugs in the top 50 of 2020 Medicare Part D spending and found that all six drugs in its study that were initially approved for an orphan indication had subsequent indications, including 18 subsequent orphan-designated indications. The IRA's single orphan indication exclusion disincentives research towards these additional orphan-designated indications, likely resulting in fewer treatment options for patient with rare diseases.[74] The impact of the DPNP was recently acknowledged by FDA's deputy center director for strategy, policy, and legislation, Julie Tierney, who noted that the program could discourage companies from seeking approval of orphan drugs for multiple rare diseases.[75]

In our comments on the IPAY 2026 guidance, we encouraged CMS to broadly interpret the IRA statute to exclude orphan drugs from Negotiation and when determining the number of designations and indications that exempt an orphan product from selection. We believe that CMS should work to preserve incentives for orphan-drug research and development, consistent with Congress's mandate, for example, clarifying that for orphan drugs, the 7- of 11-year period that must elapse before a drug can be considered for Negotiation begins upon the date that the orphan drug exclusion no longer applies.

We continue to advocate for this outcome, acknowledging that CMS has taken the position that it lacks the statutory authority to implement it and that a change in legislation might be the path forward. We also note concerns that CMS's reliance on the databases mentioned in Guidance may not always provide an accurate reflection of whether a drug's indication falls within the scope of the orphan drug designation.

B. (Section 30.1) Identification of Qualifying Single Source Drugs for IPAY 2027

CMS takes a broad and sweeping approach to defining qualifying single-source drugs in Section 30. This definition ignores the value of novel formulations and delivery systems, which should be considered at the selection phase of the process not the MFP application phase. We hope that in permitting comments on Section 30 for IPAY 2027 CMS will change this approach.

C. (Section 60) Negotiation Process (MFP Calculations)

[74] Patterson, J, Motyka, J, O'Brien, J.M. Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications. February 2, 2024. https://www.ajmc.com/view/unintended-consequences-of-the-inflation-reduction-act-clinical-development- toward-subsequent-indications

[75] https://insidehealthpolicy.com/daily-news/cber-s-tierney-ira-could-impact-rare-disease-small-molecule-development; Chambers JD, Clifford KA, Enright DE, Neumann PJ. Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act. JAMA Netw Open. 2023;6(8):e2329006. doi:10.1001/jamanetworkopen.2023.29006

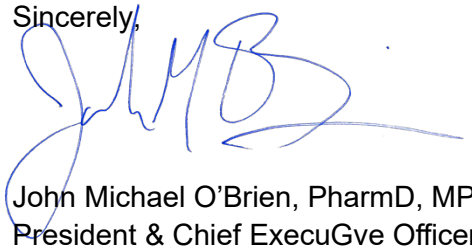
Our research demonstrates how novel formulations provide patients and providers with treatment options that account for heterogeneous patient preferences[76] and promote medication adherence through reduced regimen complexity.[77] Given the documented value of dosage form Innovation on patient-centered care and outcomes, NPC encourages CMS to incorporate the value of novel formulations in its price determination and Negotiation process. CMS provided additional detail about the calculation of 30-day equivalent supply in this draft guidance, however, we remain concerned about how calculation and implementation of MFP will incorporate and effect the use of loading doses and severity-based dosing, common clinical practices that result in the amount of medicine being used by one patient being different than that used by others. We appreciate CMS stating it will as feasible share inputs behind its methodology with the Primary Manufacturer during the Negotiation process and urge CMS to ensure it is feasible for all selected drugs, as open communication about the agency's estimation of a 30-day equivalent supply is vital for manufactures.

CMS has noted it may use an alternative methodology for calculations 30-day equivalent supply as appropriate for the therapeutic alternative(s) and suggests it may use this methodology for therapeutic alternative(s) covered under Part B. NPC asks CMS to provide examples of where an alternative methodology might be used for Part D drugs, given that IPAY 2027 will be for Part D drugs only (Section 60.3.2).

Conclusion

The National Pharmaceutical Council appreciates the opportunity to submit comments in response to this Guidance and looks forward to additional opportunities to engage with CMS as it implements the second cycle of the Medicare Drug Price Negotiation Program. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

Sincerely,



John Michael O'Brien, PharmD, MPH
President & Chief ExecuGve Officer

[76] Hollin IL, González JM, Buelt L, Ciarametaro M, Dubois RW. Do Patient Preferences Align With Value Frameworks? A Discrete- Choice Experiment of Patients With Breast Cancer. MDM Policy & Practice. 2020;5(1). doi:10.1177/2381468320928012

[77] Wertheimer AI, Santella TM, Finestone AJ, Levy RA. Drug delivery systems improve pharmaceutical profile and facilitate medication adherence. Adv Ther. 2005 Nov-Dec;22(6):559-77. doi: 10.1007/BF02849950.

July 1, 2024

Comments on Center for Medicare & Medicaid (CMS) Services Maximum Fair Prices (MFPs) and Qualifying Single Source Drug (QSSD) Interpretation

Meena Seshamani, M.D., Ph.D.,
Deputy Administrator and Director
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW., 20201

Dear Director Seshamani:

National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, appreciates the opportunity to provide comments on the recent interpretation of "qualifying single source drugs" (QSSDs) under the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program.

During the course of the Inflation Reduction Act's passage through Congress, NTU repeatedly warned of the dangers of government price controls. Price controls reduce the supply of the good in question by reducing the incentives for suppliers to come to market. This distortion is already having negative impacts even before the price controls come into effect. Estimates for the reduction in research and development spending range from a 12.3 percent to 18.5 percent cut and up to a loss of $663 billion. Depending on how the QSSD definition is finalized, the loss of R&D could be even more substantial, since the expansive draft definition would essentially combine all indications, delivery systems, and drug dosages into one QSSD. Concerning too, is the possibility that companies will not continue to develop clinical testing of drugs after initial approval. New indications could be discovered from continued research post-approval, but this proposed incentive system substantially reduces this likelihood if companies know they could be subjected to price controls.

On a more expansive view, the overall drug price control scheme introduced by the Inflation Reduction Act is likely to be harmful. Beyond reducing availability and development of drugs through an overly broad QSSD definition, as an NTU-led letter signed by dozens of economists indicates, the punitive nature of another IRA provision, a drug excise tax, is unworkable and damaging to outcomes for patients and taxpayers. As the economists noted:

> "Nonetheless, it is axiomatic that taxing a product or service at exorbitant rates tends to reduce its availability. The very existence of a 95 percent excise tax could therefore lead to shortages in the prescription drugs that patients need, as well as less innovation toward future cures as manufacturers are deterred from engaging in R&D that could carry a new 95 percent premium. Taxpayers could no longer count on as many future drug breakthroughs to bend the cost curve of more expensive treatments such as surgeries and hospital stays in government healthcare programs. The policy goal should be to encourage life-saving treatments that benefit seniors in Medicare, and ultimately, all taxpayers. This tax scheme will do the opposite."

By discouraging innovation through statute and guidance, the stated goals of the Inflation Reduction Act will not be realized. The "excise tax" (in reality a coercive mechanism) is fundamentally unserious and unworkable, while an overly broad definition of QSSDs will most likely result in even worse outcomes than projected with the IRA's passage.These and other proposed policies raise the prospects that taxpayers will not receive the value they stand to gain from prescription drug development.

NTU appreciates your consideration of the foregoing comments. Should you have any questions, I am at your service.

Sincerely,

Nicholas Johns
Senior Policy and Government Affairs Manager

NPLB No Patient Left Behind

July 2, 2024

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building Room 445-G
200 Independence Ave, SW
Washington, DC 20201
Delivered electronically via: IRARebateandNegotiation@cms.hhs.gov

Re: "Medicare Drug Price Negotiation Program Draft Guidance."

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027."

I am writing on behalf of No Patient Left Behind (NPLB), a non-profit organization comprising biotech investors, innovators, researchers, physicians, and patient advocates working together to support solutions that lower out-of-pocket costs for patients and preserve incentives for affordable innovation.

KEY ISSUES

NPLB views CMS's draft guidance from two key perspectives:

1. Will the draft guidance improve access to essential medicines for patients in need of care?
2. Will more and better medicines be developed as a result of the guidance?

In order to answer "yes" to these two critical questions, we urge CMS to incorporate NPLB's recommended improvements to its draft guidance as outlined below.

BACKGROUND

NPLB supports the IRA's $2,000 out-of-pocket cap and the Administration's efforts to expand insurance reforms beyond Medicare to commercial market segments. However, we remain concerned that the Inflation Reduction Act (IRA) will significantly reduce new small molecule R&D. NPLB would have supported the IRA altogether had it treated small and large molecules equally and imposed government negotiated price controls 13 years after FDA approval. Examples of NPLB's views on IRA's impact on beneficiary access and new R&D include:

- A response to the Congressional Budget Office's (CBO) request for information on IRA's impact on new drug development that was signed by more than 350 biotech investors, executives, and economists representing more than $320B in assets under management and 665 drug candidates in development;
- An explainer of "How the IRA makes new small molecule R&D uninvestable for diseases of the aging"; and
- A letter from more than 1,200 patients, patient advocates, researchers, biotech innovators, and investors in support of IRA's passage if Congress lowered the proposed out-of-pocket cap to $1200/year and Medicare negotiations treated small and large molecules the same.

Additional examples of NPLB's research and education resources can be found on our Fundamentals page.

NPLB IRA GUIDANCE RECOMMENDATIONS

1. **CMS should guarantee patient access to government negotiated price-set drugs on the lowest Medicare Advantage Prescription Drug (MAPD) MAPD and Prescription Drug Plan (PDP) out-of-pocket cost formulary tiers.**

   The IRA negotiation makes government price-set drugs effectively generic prior to patent expiry. Beneficiaries, not health plans, should see the benefit of savings from government-set prices. We urge CMS to require that MAPD and PDP plans put government price-set drugs on the lowest cost formulary tier to ensure affordable Medicare beneficiary access and adherence to prescribed treatments. Furthermore, the guidance should prevent MAPD and PDP plans from putting in place overly aggressive utilization management restrictions, financial barriers, or taxing administrative burdens that needlessly deny, delay, or discourage beneficiary access.

2. **CMS must not rely on faulty and outdated cost-effectiveness analysis (CEA) to set drug prices or limit beneficiary access to prescribed treatments.**

   The draft guidance seeks to allow CMS to rely on faulty and outdated conventional CEA calculations that ex-US governments use to delay, deny, or discourage patient access to prescribed innovative treatments. NPLB would recommend CMS not to rely on conventional CEAs at all to set prices. We are concerned that CMS's draft guidance seeks to circumvent Federal patient protections. We also are concerned that use of CEA leads to a precedent for setting price controls at launch versus market-based competition and choice during an innovation's time-limited, patent-protected period of market exclusivity to achieve the balance between affordability and sustainable innovation. If CMS seeks to apply CEA in approximating the societal value of an innovative medicine for any reason, particularly in IRA's price-setting process, it should instead use Generalized Cost Effectiveness Analysis (GCEA) that more comprehensively incorporates quantifiable value elements that are important to patients, caregivers, and family members that conventional CEAs omit.

   Conventional CEAs used by national or regional health technology assessment (HTA) entities in the ex-US countries like the United Kingdom's National Institute for Health and Care Excellence (NICE) and the Canadian Agency for Drugs and Technologies in Health (CADTH) and also used by the privately funded U.S.-based research organization Institute for Clinical and Economic Review (ICER) face increasing scrutiny from health economists, innovators, and patient advocates for relying on biased and incomplete math that ignores real-world, quantifiable value elements.[1]

   For example, NPLB released a report last year that illustrates how conventional CEAs featured in the assessments by ICER can underestimate the true societal value of innovative medicines and result in healthcare decisions that will hurt patient welfare. The researchers first replicated the conventional CEA models, and then developed GCEA models that accounted for dynamic pricing (e.g., market competition, loss of market exclusivity) and accounted for diminishing returns to health improvement (due to disease severity and patient risk aversion). Under ICER's biased approach, only eight of the 20 medications in the study were deemed by them at or before launch to have sufficient value to patients to justify their prices — a finding that insurance companies use to deny coverage. However, when the math is updated to model just some of the additional GCEA elements of value that medicines offer to society, the study found that at least 17 of the drugs provided good value for money.[2] This resource page and animation help explain these and other values that conventional CEAs choose to omit from their economic analysis.

   Rather than embrace conventional CEAs, CMS should proactively recognize growing concerns by health economists about the quantifiable values to patients and society that proponents of conventional CEAs omit. Using conventional CEA's faulty framework to discourage patient access to biotech innovations is likely to result in the need for more acute health services – which do not go generic – to

[1] https://www.statnews.com/2024/05/06/united-states-value-based-drug-pricing/
[2] https://nopatientleftbehind.docsend.com/view/889u6zs74tra9x4a

compensate for the loss in pharmaceutical innovations. In the long run, this will increase total healthcare spending. If CMS uses this outdated math in its decision-making, the Agency will be prioritizing short-term savings over long-term savings and patient and societal benefits.

3. **CMS should not worsen IRA's harmful innovation impact.**

   The guidance seeks to allow CMS to peg the government-set prices to therapeutic alternatives. Specifically, CMS's interpretation of the law's requirement to aggregate forms (such as a combination of active ingredients) to define a qualifying single source drug ends up sweeping in newly approved drugs. Doing so will further erode innovation that the IRA already harms by further disincentivizing research that meaningfully improves and expands existing treatment options.

4. **Guidance should not make plans and hospitals better off from government price setting than patients.**

   We are deeply concerned that the guidance makes no effort for plans, hospitals, and health systems to stop well-documented abuses of the 340B program.[3] Abuse of the 340B program burdens drug list prices that plans charge patients with hospital expenses, giving the public the impression that drugs are more expensive than their actual net prices. CMS should use its guidance to stop 340B program diversion, or at least ensure drugs acquired using government-set pricing are not marked up for eligible and non-eligible patients.

Thank you for taking into account NPLB's comments as you revise the proposed guidance.

Sincerely,

Peter Rubin
Executive Director, No Patient Left Behind

[3] https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899

July 2nd, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to comment on the Initial Pay Applicability Year (2027) Medicare Drug Price Negotiation Program (MDPNP) guidance. Millions of Medicare beneficiaries are living with a rare disease, and many struggle with high out-of-pocket prescription drug costs.[1] Implementations of the MDPNP and related programs have the opportunity to dramatically reduce patient out-of-pocket costs for rare disease patients. However, without careful consideration and intentional implementation, NORD is concerned about potential unintended consequences.

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people living with rare diseases. NORD was founded more than 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. Our mission has always been, and continues to be, to improve the health and well-being of people with rare diseases by driving advances in care, research, and policy.

The MDPNP will bring significant changes that are likely to impact rare disease patients in several complex ways, in particular given CMS' narrow interpretation of the orphan drug exclusion in the Inflation Reduction Act (IRA).[2,3] We greatly appreciated CMS' efforts to engage patients and health care providers as part of the 2026 MDPNP. We value the opportunity to recommend further changes and improvements to the solicitation and consultation processes with

[1] *Prescription Drug Affordability among Medicare Beneficiaries*. HHS- ASPE Office of Health Policy. (19 January, 2022). https://aspe.hhs.gov/sites/default/files/documents/485edf2a2d4870f88a456df61c8ff471/prescription-drug-affordability.pdf

[2] *Inflation Reduction Act of 2022*, P.L. 117-269.

[3] *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.* Section 30. CMS. (3 May, 2024). https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

1779 MASSACHUSETTS AVENUE NW, SUITE 500
WASHINGTON, DC 20036
T 202-588-5700 ▪ F 202-588-5701

55 KENOSIA AVENUE
DANBURY, CT 06810
T 203-744-0100 ▪ F 203-263-9938

1900 CROWN COLONY DRIVE, SUITE 310
QUINCY, MA 02169
T 617-249-7300 ▪ F 617-249-7301

rarediseases.org ▪ orphan@rarediseases.org

patients and health care providers through listening sessions and the Information Collection Request (ICR) for the 2027 MDPNP.

However, we remain deeply concerned about the smooth implementation of other key provisions of the MDPNP that are likely to have significant direct impacts on rare disease patients and their families. These include: formulary enforcement procedures and education; outreach efforts to ensure patients understand their co-pay liability (including their financial responsibility at the pharmacy counter and any rebates that may be applied retrospectively); and ensuring patients have the information they need to choose the Medicare plan that is right for them. Recognizing the crucial role of patient and health care provider engagement in assessing the impacts of the MDPNP on patients and families, we are pleased to also provide specific recommendations for successful engagement around program implementation. We realize the unique challenges of CMS simultaneously implementing two MDPNP years (currently for Initial Pay Applicability Years 2026 and 2027) and urge CMS to continue to prioritize assessment and evaluation as the first MDPNP program is implemented to allow for the collection of lessons learned and continuous program improvement and refinement.

Recommendation 1: Make the solicitation and consultation process with patients, caregivers, and health care providers more transparent, predictable, and inclusive and streamline the process to build and refine year-over-year capacity (Section 50).

NORD appreciated that the patient and health care provider listening sessions for the 2026 MDPNP were livestreamed and available for the public to view. Our recommendations are based on learnings from these sessions, as well as our extensive patient engagement experience and informed by a review of the relevant literature.[4] These recommendations are intended to be complementary to recommendations provided previously, including in a recent National Health Council (NHC) white paper to which NORD was honored to contribute.[5]

Our recommendations to strengthen the solicitation and consultation processes are primarily informed by three main findings with the 2026 MDPNP listening sessions:

1. The format of the listening sessions inadvertently left out some important voices in our community (*e.g., because the public format was uncomfortable for many patients; because of language, logistical, and technology barriers; because many patients were not aware of the listening sessions; because the ICR closed before the listening sessions and patients had no opportunity to submit written comments <u>after</u> the listening session, and because of questions about who was eligible to participate*).

[4] *Three Ways to Improve the Patient-Focused Listening Sessions In The Medicare Drug Price Negotiation Program.* Vandigo et. Al. Health Affairs (24 June, 2024). https://www.healthaffairs.org/content/forefront/three-ways-improve-patient-focused-listening-sessions-medicare-drug-price-negotiation

[5] *Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement.* National Health Council. (24 March, 2024). https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

2. Patient listening sessions provided limited data to directly inform the negotiation process and maximum fair price calculation (*e.g., because the 3-minute speaking slots were very short; because patient, caregivers, and health care providers lacked guidance on what insights would be most informative; and because the ridged session format prevented dialogue or clarifying questions*).

3. Patient listening sessions lacked standardization and were very heterogenous, generating inconsistent and widely varying outputs even for products in the same therapeutic area (*e.g., because listening sessions were organized by product rather than indication; included variable mixes of patients, caregivers, and providers; and because they lacked a standard set of questions*).

NORD recognizes the challenges of effective and inclusive patient engagement, exacerbated by the short timelines of MDPNP implementation and the logistical challenges of hosting the listening sessions shortly after the selected drug list is published. NORD recognizes and commends CMS' intent to host patient-focused events to seek input from patients and other interested parties and is encouraged by CMS' commitment to the most effective design and format for these sessions.

To ensure the listening sessions can help inform CMS about the true value of the selected therapies to the patient community and other select stakeholders, NORD is pleased to offer specific recommendations around three key priorities:

1. Start preparing for the listening sessions ahead of time; be transparent and standardize the outreach and engagement processes; maximize patient engagement including from historically underserved and other harder to engage communities; build long-term relationships, capacity and support in communities that are likely impacted in this and future plan years; and smooth out agency activity and workload on patient engagement over the plan year.

a. Identify therapeutic areas that are likely impacted by the selected drugs (e.g., oncology, lung, cardiovascular, diabetes); proactively begin outreach activities to these communities now; intentionally engage harder-to-reach communities; and with a goal of building long-term partnerships.

One of the most crucial elements of a successful and inclusive public participation campaign is to begin early; partnering with trusted community voices, proactively messaging important timelines, and explaining the information to be gathered (and why) as early as possible is vital to broader participation. While we commend CMS for implementing last year's iteration of the listening sessions on a tight timeline, the reality is that limited runway in advance of the listening sessions resulted in suboptimal patient and provider representation.

Although we recognize the logistical challenges CMS faces regarding proactive patient engagement, we believe this is a largely solvable problem. By the nature of the diseases that are prevalent in the Medicare population, and considering long-standing Medicare spending patterns, it appears almost certain that a limited number of therapeutic areas, including for instance oncology, lung, cardiovascular, and diabetes and related comorbidities, will likely be disproportionately represented amongst the selected products in the 2027 MDPNP as well as in future plan years.[6] CMS should proactively engage now with key stakeholder groups representing patients impacted by these diseases, and develop these relationships as long-term engagements to leverage in this year as well as future plan years.

Starting now and building out the engagement over time will allow CMS to engage a broader spectrum of diverse stakeholder groups, and to create sustainable, trusting, and fruitful partnerships over time. Moreover, approaching patient engagement by therapeutic area, rather than product, may lead to more diverse stakeholder engagement; for instance, while a given product may not be used by a specific patient group (e.g., because of label restrictions), that patient group may have valuable insights for this and future plan years. In addition, early and sustained partnerships with patient groups can have additional downstream benefits, such as helping to increase written comments and more robust participation in focus group sessions as the community builds capacity and individuals develop levels of familiarity and comfort with the process.

To ensure representation from patients, advocates, providers, and industry leaders from across the country, we encourage CMS to utilize their regional offices and ties to local communities to ensure appropriate patient engagement across different geographic regions. One effective way to do this is through in-person meetings; this would ideally include in-person outreach and education (e.g., at regional patient summits or health care provider meetings) and in-person listening sessions (e.g., at regional offices). While we recognize engaging individuals living in rural areas poses particular challenges, regional education and outreach will allow for richer, and more inclusive engagement than focusing outreach primarily nationally or on those located in, or able to travel to, the DC metro area. This is another area where year-over-year capacity building will be particularly valuable.

b. Develop educational and patient engagement materials that can be leveraged across products, therapeutic areas, and plan years; refine and revise these materials with input from the stakeholder community; and begin publicizing the listening sessions as early as possible BEFORE the selected drug list for negotiation is released.

CMS should begin developing and deploying educational materials and tools now to facilitate effective patient engagement in the drug price negotiation and refine and revise them with input from trusted partners (e.g., patient groups or providers with vested interest in the patient

[6] *Drugs likely subject to Medicare negotiation, 2026-2028.* Dickson, Sean and Hernandez, Inmaculada. National Library of Medicine. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387900/

populations utilizing the likely selected therapies). This should include outreach materials in languages other than English, and particular care should be given to ensure these materials are linguistically and culturally appropriate. These activities can and should start long before the announcement of the MDPNP 2027 selected products and build on learnings and successes year over year. Because these materials can be reused in future plan years, we urge CMS to create a feedback process that can be used to refine and revise these materials over time.

We encourage CMS to be as specific as possible in the materials about the logistics of the sessions to maximize transparency and give stakeholders a clear understanding of expectations. This transparency is vital to building trust and will mean more participants may be inclined to share their information and provide more meaningful responses. Specifically, in the lead up to the public listening sessions, we encourage CMS to be transparent with participants about how their data will be used and if / how they will be identified. Moreover, CMS should clarify how information from different population subgroups may be considered; for instance, patients who were formerly on a therapy may have inherently different experiences than the patients who are currently on it, and different patient populations may have different therapeutic alternatives available.

Information about how CMS intends to handle real or perceived conflicts of interest will be equally important. The lack of standardized processes or the required disclosure of professional or personal affiliations with interest groups led to inconsistent conflict of interest interpretation and implementation last year, which threatens to undermine trust in the process. We strongly recommend implementing a standardized mandatory disclosure process for professional or personal affiliations as a prerequisite for session participation.

Moreover, while CMS may not be able to release the names of the selected drugs until February 1, the agency can and should proactively set dates, times, structures, and locations (virtual and/or in person) for each listening session, focus group, or other engagement opportunity (preferably by therapeutic area). Scheduling these sessions early will make it easier for patients, caregivers, and providers to participate, and provide community partners more time to advertise the sessions and prepare their communities for the sessions. CMS should publicize the date and format (including speaker type) for the public engagement sessions even BEFORE the drug negotiation list is published. We encourage CMS to publish whether the sessions will include indication specific reviews, and if so, which of the sessions will be reserved for less common indications (including rare diseases).

A common challenge in the rare disease space is small patient populations. In addition, many rare disease patients experience several comorbidities which can make it harder to travel or rearrange pre-planned health care appointments. Announcing which sessions will be reserved for less common indications will make it easier for rare disease communities to plan, maximizing the chance of robust participation. This will allow for tailored outreach based on the therapeutic area and speaker type and allow umbrella organizations and other key stakeholders to begin socialization of the sessions as early as possible to maximize awareness.

2. Reconsider the session format; provide more options to meet patients where they are; include opportunities for patient engagement that protect patients' privacy and make it easier for all relevant patient populations to engage; better integrate the written and verbal opportunities for feedback and make the written process easier to navigate.

Following the success of the first year, we hope CMS will develop a process to continue to identify incremental improvements for future years. To ensure success of the program in future years, we encourage CMS to create a variety of virtual and in-person engagement opportunities, including smaller focus group style sessions targeted at both patients and caregivers and health care providers (we recommend separate focus groups for health care providers and for patients/caregivers); provide opportunities for more meaningful engagement between CMS staff and participants during the listening session; and provide opportunities for anonymous or closed-door engagement to lower the bar to participation for patients or caregivers who do not feel comfortable sharing their information with the public; provide opportunities for engagement specifically for patients or caregivers whose primary language is not English and those that need other types of accommodations (including opportunities for asynchronous input for those in our community who cannot take off time from work or school to participate during the scheduled times).

a. Streamline the public comment opportunities; provide opportunities for audio-only participation and for patients whose primary language is not English (e.g., Spanish-language listening sessions or real-time translation services); work with the patient advocacy groups and other key stakeholders to prepare patients better for the sessions; and continue to refine and revise the format for the listening sessions year over year.

As last years' experience clearly showed, not all patients feel comfortable sharing highly personal information about their disease or other aspects of their daily life on camera in publicly recorded settings. Furthermore, providing English-only engagement opportunities threatens to leave out important parts of the community. Establishing a system where participants can provide responses that will be deidentified and/or aggregated before being publicly posted has been shown to improve the quality of responses.[7] We urge CMS to continue to work with the affected communities to provide options that meet their needs.

b. Simplify and better integrate the written and verbal comment process to provide patients with a range of options to engage and share feedback without having to engage publicly.

After last year's data submission process, we are pleased to see there will be additional opportunities to strengthen written public comment. To ensure the public data submission process is captured in a meaningful way, we encourage CMS to increase timelines for

[7] *How Transparency Affects Survey Responses.* Connors, et. Al. Public Opinion Quarterly. (18 June 2019). https://academic.oup.com/poq/article/83/S1/185/5520299

participation, standardize the data capture process, and increase accessibility for patients with lower literacy comprehension and/or who need other accommodations to navigate the process (e.g., because of chronic diseases or physical or mental disabilities). Specifically, in our opinion, last year's public written comment process was terminated prematurely by closing it before the listening session. By failing to leave the written comment process open throughout the duration of the listening sessions, patients were forced to comply with tight timelines and opportunities for engagement were missed. Although we recognize that CMS was given a herculean task to accomplish within a short period of time, the short process was a significant barrier to participation for many patients, together with the complexity of navigating the process.

For this upcoming year, we recommend clearly publishing the timeline for public participation well in advance of the opening, alongside the questions that will be asked during the submission process. To our point on transparency above as well, we encourage CMS to share how the written submission will be considered differently than or in addition to the oral participation.

Moreover, we urge CMS to simplify and streamline the data submission process. Last year's data submission process included a complex series of mandatory forms with complicated and potentially concerning language utilizing terms that were not patient friendly. We encourage CMS to use short, simple forms at no greater than an eighth grade reading level to ensure language comprehension is less of a barrier. We view the written submission as a vital opportunity to supplement and complement the other engagement methods, including the collection of information from patient groups who may have difficulty (or wish not to) participating in oral sessions, such as individuals who speak English as a second language, or those who are impacted by audio-visual or physical challenges. All forms should be read with this in mind, and we strongly urge CMS to make the forms available in languages other than English.

To better understand who leverages the written process for future years we encourage CMS to collect voluntary demographic information from participants and/or to collect some of this information from stakeholder partners as appropriate. Moreover, we recommend streamlining the data collection process and prioritizing the information that is most important to CMS. Specifically, NORD recommends prioritizing the collection of plain-language information on:

- Demographic information, such as age, gender, race/ ethnicity, zip code
- Diagnosis and time since diagnosis
- Degree of disease progression
- If the information is provided by a patient or a caregiver
- What therapies the patient uses to manage their disease and for how long
- If the patient has tried other therapies in the past
- Degree of disease progression on treatment
- Most significant challenges in accessing medications
- How the patient feels and functions on the disease, and what symptoms remain unaddressed

- Challenges patient experienced associated with switching from one therapy to another
- What therapeutic alternatives the patient may have considered or may consider

It is also important for CMS to be clear about how written and oral submissions will be analyzed. For a variety of reasons, some patients may prefer submitting a written statement over participating in a live session. CMS may also not be able to find representatives for each of the indications that a selected product covers and the written responses may provide meaningful ways to substantiate and expand upon the data collected in the listening sessions. However, without clarification on how patient and stakeholder submission will be analyzed, we are concerned that components of the patient populations that are more difficult to survey may fall through the cracks during the negotiation process, and that the written submission form will not be used to its maximum extent. Certain types of patients, such as those with psychiatric conditions, cognitive limitations, and sight deficiencies, are often particularly difficult to include in surveys; specific, intentional efforts will be required to allow for meaningful inclusion of these populations.[8]

Additionally, we are concerned that without clarification of how the oral and written submissions are processed, patients could feel that submitting written comments would be a less valuable contribution. Establishing a system where participants are assured that their (deidentified) responses will be publicly posted has been shown to improve the quality of responses.[9] Even if exact weights for each of the types of responses relative to other factors cannot be shared or may vary by drug and indication, simply sharing the types of analysis used (i.e. quantitative vs. qualitative), will be helpful in how patients may structure their responses to be maximally beneficial.

c. Provide opportunities for more direct interaction with CMS through focus-group sessions in addition to the public listening sessions; this will allow the agency to ask clarifying questions and better understand varied patient perspectives on the most influential aspects of the MDPNP calculations including nuanced thinking around appropriate therapeutic alternatives (in particular in therapeutic areas like oncology or immunology where switching among products may have significant and hard-to predict impacts on long-term patient outcomes).

In our prior experience hosting patient listening sessions, NORD has found smaller focus-group listening sessions to be most effective to gain granular and nuanced input. These closed-door sessions make it more comfortable for patients to share personal details about their disease and how it impacts their daily life. We recommend sessions to be limited to five to 10 participants and set between 60 and 90 minutes. Each session should be limited to patients, providers, or caregivers, depending on the focus of the specific session – and may be further tailored (e.g., by

[8] *Barriers to Participation in a Patient Satisfaction Survey: Who Are We Missing?* Gayet-Ageron, et. Al. National Library of Medicine. (26 October, 2011). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202588/

[9] *How Transparency Affects Survey Responses.* Connors, et. Al. Public Opinion Quarterly. (18 June 2019). https://academic.oup.com/poq/article/83/S1/185/5520299

geographic area, population subgroup, or to explore specific questions such as patients' experience switching across therapeutic alternatives).

Maintaining independence of each of the sessions and limiting them to a single stakeholder type will allow participants to develop a greater level of trust, both with one another and with the moderator, and help guard against issues like halo and bandwagon effects. Including different stakeholder types risks changing the power dynamic, where some participants feel their commentary is less worthy than others, or may become more deferential, rather than all participants viewing each other as equals. In addition, we recommend each focus group to be facilitated by a skilled facilitator knowledgeable in appropriately handling group dynamics in scientifically rigorous ways.

After participants have been selected for each of the respective sessions, we encourage CMS to proactively communicate expectations and solicit requests for accommodations. Some individuals may require additional time to process the questions in advance; sending around what each of the participants will be asked is helpful in ensuring all are able to respond on time and feel comfortable doing so. We also encourage CMS to ensure the participants understand what expectations for timing are, and to help stakeholders navigate the timekeeping requirements. While the first year of the listening sessions successfully kept the conversation within the confines of time requirements, the abrupt cut off while patients were telling their stories and no response permitted from CMS staff was suboptimal. Informing participants of the time limits and setting expectations for types of follow-up questions from CMS staff will be crucial in improving the quality of responses from participants moving forward.

We also encourage CMS to consider protecting participant privacy by exclusively releasing a redacted transcript after the conclusion of these focus group sessions. Potential participants may feel dissuaded from taking part in the sessions, or not feel comfortable fully participating in the session, if their identifiable information were to be released to the general public. As we saw in the first sessions, some patients are willing to share sensitive information, and we commend the patients who were willing to share their stories. To encourage participants to share their perspective, however, and to provide more granular responses with the nuance necessary to ascertain the true value of the selected products, extending privacy protections is crucial.

3. <u>Develop a standardized set of questions that are most relevant to CMS; develop a process to tailor these questions to each given therapeutic area, product, or patient group as needed; and focus on the key insights CMS needs most to inform the MDPNP; partner with key stakeholders to optimize the phrasing of these questions for clarity and consistency and explain how this data informs the negotiation process.</u>

We urge CMS to introduce more structure into the sessions compared to last year. While last year's sessions included some general guidelines for how participants should respond to questions, we encourage much more specificity to standardize the feedback the agency receives and ensure the agency can utilize participant answers.

a. Determine which data elements are most meaningful to CMS (e.g., therapeutic alternatives, remaining unmet medical need), both in general and specific to each therapeutic area; prioritize the written and verbal data collection for these critical data elements, and partner with relevant patient groups and other stakeholders to educate the patient community and collect the most meaningful input on these negotiation factors.

Not all data elements that can be informed by patients, caregivers, and health care providers will be equally important to CMS or have the same impact on the negotiation or maximum fair price calculation. Given the large number of products and indications CMS must consider, we strongly urge CMS to prioritize what insights will be most impactful and to be clear and transparent in communication and education to targeted stakeholders. We encourage CMS to clearly communicate how patient experience data informed the drug price negotiation and the final offer for each negotiated product.

b. Standardize the data collection efforts to ensure robustness and comparability across products and plan years while providing for sufficient flexibility to address the unique aspects of each product, therapeutic area, or patient population.

We encourage CMS to consider consistently asking questions specific to three thematic areas: 1. how the patient feels, functions and survives (on the treatment, an alternative treatment, or without any therapy); 2. cost and access; and 3. therapeutic alternatives. We recognize that these questions cannot be meaningfully answered in three minutes and appreciate CMS' flexibility to reconsider the session format. We also recognize that some of these questions may vary in pertinence based on therapeutic area, patient population, or other factors, and we encourage CMS to work with the relevant stakeholder community to prioritize and refine these questions as needed; however, we believe that this is a useful starting point for CMS' listening sessions.

Thematic area 1: How the patient feels, functions and survives:

- How does this disease impact you?
- How has your disease changed since you have been using this treatment?
- How long have you been using this treatment?
- What side effects have you been experiencing with this treatment?
- What formulation do you use for this treatment (if applicable)?
- Does this formulation best fit your needs?
- Rank the importance of the different characteristics of the treatment?
- What symptoms remain unresolved, and how is this impacting your day-to-day life?
- How does this product impact your social and emotional well-being?
- What would it mean to your daily life to no longer have access to the therapy?

Thematic area 2: *Cost and access:*

- Do you find this medication to be affordable? What does affordable mean to you?
- How much do you pay out of pocket annually for this medication?
- Did your insurance company make you try any other medications before agreeing to pay for this medication? If so, how many alternative medications were you required to try?
- Has this medication caused you any financial problems?
- Have you ever skipped a dose of this medication because you could not afford it?
- Have you ever skipped a dose of another medication because this medication was too expensive?
- What would cause you to stop taking this medication?
- Does your insurance company require prior approval before you fill this medication?

Thematic area 3: Therapeutic alternatives:

- What would you consider a therapeutic alternative to your current therapy? What characteristics make it a therapeutic alternative?
- Have you tried using any other medication to treat your condition? What has been your experience?
- How have you felt or functioned on the other therapy, and how does that differ from how you feel or function on the current therapy? Has that changed over time?
- Why did you switch / stop using that medication? Or why have you not tried other therapeutic options?
- How effective do you feel this other medication was compared to the medication you are using now?
- How does the price of your other medication compare to the medication you are using now?
- How were the side effects of the other medication compared to the medication you are using now?
- Did you find the other product(s) easier or harder to use than your current medication?
- What was your experience switching from one product to another?
- Would you consider switching products? Why or why not?

To further refine these questions, we encourage CMS to work with the impacted patient communities, as well as FDA and other stakeholders who have conducted successful patient engagement sessions to identify strategies best able to accomplish the goals of the patient listening sessions. FDA's Voice of the Patient Sessions are a crucial component of FDA's Patient Focused Drug Development (PFDD) sessions. To date, over 200 sessions have been completed on a wide variety of conditions, including both rare and non-rare conditions, and may

be a strong resource to supplement listening sessions and focus groups, particularly for rare conditions where participants may be more challenging to source.

Part of FDA's success with the Voice of the Patient Sessions derives from individual modifications made to each session reflective of each of the diseases under consideration. We encourage CMS to individualize each of the patient listening sessions towards both the indications under consideration and the population involved in the sessions. Tailoring individual indications under consideration while adhering to a common structure will allow patients to speak directly to their own experience and provide valuable feedback on the product's value for patients in specific situations.

We urge CMS to further refine and revise these questions with input from key stakeholders for future plan years and to establish a process to consistently learn from and revise these questions with each subsequent plan year. We are particularly concerned about how CMS will select therapeutic alternatives for consideration. As CMS considers how to best identify therapeutic alternatives, it is crucial to solicit information from patients, caregivers, health care providers, and other key stakeholders on when, and when not, certain therapies can be identified as an alternative. We also want to raise two areas of concern regarding information gathering on therapeutic alternatives: prohibitions on medical switching and off-label use of products.

As the listening sessions last year clearly showed, for many diseases, particularly immune conditions and cancers, the use of a treatment can have significant impacts on the effectiveness of other treatments, because of, for instance, emerging tumor resistance or a secondary loss of response due to antibody formation to the drug.[10,11] This raises concerns about the prospect of therapeutic alternatives. Although there may be alternatives available on the market, if they are not available to the patient for medical reasons, they should be given consideration independent of therapeutic alternatives for other indications.

Due to the lack of treatment options available for so many rare diseases, both providers and patients frequently rely on prescription medications without an FDA-approved indication for their condition on the label, known as off-label use. Physicians frequently rely on clinical compendia to make decisions about whether treatment options would be appropriate for their patients. Off-label use accounts for up to one third of all prescriptions, and up to 97% in certain populations.[12] We recognize that CMS has indicated their intent to conduct literature reviews on therapeutic alternatives for each of the selected products in the past; to ensure all relevant

[10] *What to Do When Biologic Agents Are Not Working in Inflammatory Bowel Disease Patients*. Dalal, et. Al. National Library of Medicine. (October, 2015). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849518/

[11] *Clone Wars: Quantitatively Understanding Cancer Drug Resistance.* Yates, et. Al. JCO Clinical Cancer Informatics. (28 October, 2020). https://ascopubs.org/doi/10.1200/CCI.20.00089

[12] *Off-Label Use vs Off-Label Marketing of Drugs.* Van Norman, Gail. National Library of Medicine. (27 February, 2023). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9998554/#:~:text=Off%2Dlabel%20use%20of%20drugs%20is%20common%2C%20constituting%20up%20to,off%2Dlabel%20use%20of%20drugs.

therapeutic alternatives, we strongly recommend CMS consider including off-label uses of products.

Recommendation 2: Prioritize monitoring of unintended consequences associated with the MDPNP implementation; engage patients, caregivers, and health care providers in this monitoring activity; and refine and revise the monitoring activity over time (Section 110).

NORD appreciates CMS' commitment to monitoring plan formularies to ensure negotiated products are kept accessible to patients. Since plans benefit from drugs with higher rebates, for products with therapeutic alternatives, manufacturers may be incentivized to seek better formulary tier placement by offering increased rebates. When rebates are reduced, plan sponsors may increase the formulary tier, increasing patient cost sharing and decreasing access. Therefore, we have concerns that without requiring plans to place negotiated products on a preferred formulary tier, plans may place these products on a less preferred tier, and/or erect additional utilization management barriers, resulting in higher patient cost sharing for negotiated products.

Rare disease drugs are frequently already placed on the non-preferred or specialty tiers of Medicare Part D plan formularies, resulting in increased patient out-of-pocket liability and access delays. A 2020 study found that 85% of orphan drugs on a Part D formulary were placed on the highest cost-sharing tier.[13] A KFF analysis of 2023 Medicare Part D plans found that in 12 of the 16 national prescription drug plans, co-insurance amounts for non-preferred drugs range from 40-50 percent, with similar trends in prior plan years.[14] While we recognize that patient out-of-pocket costs for Medicare Part D are set to be capped at $2,000 beginning in 2025, high out-of-pocket costs remain a barrier for many patients, particularly those just above the qualification level for the low-income subsidy, and the MPNPP is expected to have far-reaching implications beyond Medicare plans.

We encourage CMS to think critically about how best to balance patient out-of-pocket cost and access with potentially misaligned incentives. While 95 percent of rare diseases have no FDA approved treatment, some rare disease areas, such as rare cancers, have more than one treatment available. Certain therapies, particularly those that have been on the market for a significant number of years, may not be as clinically applicable as newer therapies, which may provide more benefit, a preferable route of administration, or fewer or lesser side effects. Inadvertently incentivizing physicians and patients to choose an inferior therapy due to cost and ensuring patient access to necessary medication is a delicate balance for which there is no easy solution.

[13] *Predictors of Orphan Drug Coverage Restrictions in Medicare Part D.* Yehia, et. Al. American Journal of Managed Care. (September, 2020). https://www.ajmc.com/view/predictors-of-orphan-drug-coverage-restrictions-in-medicare-part-d

[14] *Medicare Part D: A First Look at Medicare Drug Plans in 2023.* Cubanski et. Al. KFF. (10 November, 2022.) https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-drug-plans-in-2023/

NORD believes health care providers, and their patients, are best positioned to choose the medication that is right for them. Yet, patients trying to access medications on higher formulary tiers frequently run into utilization management barriers, such as prior authorization and step therapy. A 2020 study found that 76 percent orphan drugs on Medicare Part D formularies were subject to prior authorization.[15]

To rectify these cost and access issues for rare disease patients trying to access medications, we encourage CMS to consider implementing a requirement that significantly reduces or eliminates step therapy and prior authorization requirements for negotiated products. Additionally, we recommend requiring that formularies place negotiated therapies on more preferential tier, to reduce patient cost and access burdens.

However, we also realize that monitoring and surveillance of formulary placement and utilization management will be key. We urge CMS to work with the patient, caregiver and provider communities to understand trends and changes in formulary placement, the use of utilization management, or other ways that may impact availability and access to these products.

Recommendation 3: Reconsider CMS' interpretation of orphan drug exclusion provision (Section 30.1.1).

Although we recognize that CMS has established their interpretation of the orphan drug exclusion set forth in accordance with Section 1192(e)(3)(A), we remain greatly concerned that the agency's narrow interpretation could have significant negative ramifications for the future of rare disease drug development. Today, about 60 percent of all orphan drugs have a single FDA-approved orphan indication, whereas only about 20 percent are FDA-approved for both orphan and non-orphan indications.[16] Among the drugs that only have orphan indications, fewer than a 25 percent have more than one FDA-approved indication and fewer than 10 percent have three or more approved indications.[17] Similarly, among the drugs that have both orphan and non-orphan indications, less than 20 percent have three or more orphan indications.

Still, developing already-approved therapies to treat additional rare diseases is a critical strategy to address the rare disease community's significant unmet need because these drugs have already proven to be safe for humans. In fact, according to a recent analysis, over 3,000 unique drugs have been FDA designated as rare disease drugs and studied, with about a 25 percent of these

[15] *Predictors of Orphan Drug Coverage Restrictions in Medicare Part D.* Yehia, et. Al. American Journal of Managed Care. (September, 2020). https://www.ajmc.com/view/predictors-of-orphan-drug-coverage-restrictions-in-medicare-part-d

[16] *Orphan Drugs in the United States.* IQVIA. (2019). https://rarediseases.org/wp-content/uploads/2022/10/orphan-drugs-in-the-united-states-NRD-2020.pdf

[17] Ibid

drugs being designated for more than one rare disease.[18] Serial innovation and the investigation and development of multiple rare disease indications of use is an increasingly important dimension of orphan drug development, making the preservation of incentives to further develop drugs to treat additional orphan diseases after they have entered the market particularly important.

Orphan drug development is a lengthy and difficult process. Due to the complexity and long timeline from initial drug discovery and early research and development to FDA approval, drug sponsors are making decisions today that will impact their investments and drug development pipeline for decades to come. A typical orphan drug takes over 15 years to go from first patent filing to product launch, 18% longer than the average time for all new drugs.[19] Another study found that drugs with an orphan designation take over 550 days longer than drugs without an orphan designation.[20] Remaining uncertainty about if, when, and how rare disease drugs will become negotiation eligible creates strong disincentives to develop drugs for the limited populations impacted by rare diseases. Therefore, as part of the negotiation process, NORD urges CMS to make clear that research and development efforts in support of orphan therapies that address unmet needs will be treated favorably in the price negotiation process.

We again urge CMS to consider the language in Section 1192(e)(3), "the drug or biological drug must (1) be designated as a drug for only one rare disease or condition under section 526 of the FFD&C Act and (2) be approved by the FDA for only one or more indications within such designated rare disease or condition" as a two-prong test, rather than considering each clause independently. This interpretation is consistent with Congressional intent and has more limited implications for research and development into the rare disease space. Considering each of the two clauses independently inadvertently disincentivizes manufacturers of rare disease products and reduces incentives in repurposing products, an effort the Biden administration granted $50M through ARPA-H to support earlier this year.[21]

Disincentivizing manufacturers to seek additional designations has the unintended consequence of pushing manufacturers to pursue research into new molecular entities (NMEs) rather than

[18] Miller, KL, Kraft, S, Ipe, A, and Fermaglich, L. Drugs and biologics receiving FDA orphan drug designation: an analysis of the most frequently designated products and their repositioning strategies. Expert Opin Orphan Drugs. 2022 Mar 1;9(11-12):265-272. doi:10.1080/21678707.2021.2047021.

[19] *Facing Many Challenges, Orphan Drugs Take 18% Longer to Develop.* Tufts. (14 May, 2018). https://www.centerwatch.com/articles/12603-tufts-facing-many-challenges-orphan-drugs-take-18-longer-to-develop

[20] *Clinical development times for innovative drugs.* Brown, et. Al. National Library of Medicine. (1 November, 2023). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9869766/

[21] *ARPA-H awards AI-driven project to repurpose approved medications.* ARPA-H. (28 February, 2024). https://arpa-h.gov/news-and-events/arpa-h-awards-ai-driven-project-repurpose-approved-medications

repurposing additional products.[22] Though NMEs play a crucial role in identifying treatments and cures for rare diseases, drug repurposing is a crucial part of the treatment ecosystem. Drug repurposing takes less time, is less expensive for the manufacturer and the system, and is successful in bringing a treatment to market more frequently than NME development.[23] CMS' current interpretation of the orphan drug exclusion runs contrary to the intent of the Medicare drug price negotiation program, as it may result in increased systemic costs and increased patient out of pocket costs. As such, we urge CMS to reconsider their interpretation of the orphan drug exclusion to protect incentives to continue innovation for existing products.

We thank CMS again for the opportunity to comment on this guidance and look forward to working with CMS to ensure rare disease patients can fully participate in and benefit from the Medicare Drug Price Negotiation Program. For questions related to this letter, please contact Karin Hoelzer, Director of Policy and Regulatory Affairs at KHoelzer@rarediseases.org or Mason Barrett, Policy Analyst at MBarrett@rarediseases.org.

Sincerely,

Karin Hoelzer, DVM, PhD
Senior Director, Policy and Regulatory Affairs
National Organization for Rare Disorders

Mason Barrett
Policy Analyst
National Organization for Rare Disorders

[22] *Does Therapeutic Repurposing in Cancer Meet the Expectations of Having Drugs at a Lower Price?* Fierro et., al. National Library of Medicine. (8 March, 2023). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10097740/#:~:text=The%20total%20cost%20of%20bringing,repurposing%20averages%20US%248.4%20million.

[23] Ibid

Novartis Services, Inc.
One Health Plaza
East Hanover, NJ 07936

Courtney Piron
US Country President and Head,
US Public Affairs

July 1, 2024

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington DC 20201

BY ELECTRONIC DELIVERY to *IRARebateandNegotiation@cms.hhs.gov*

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

Novartis Services, Inc. submits this letter on behalf of Novartis Pharmaceuticals Corporation and its affiliates, referred to collectively herein as "Novartis." We appreciate the opportunity to comment on the draft guidance regarding the Medicare Drug Price Negotiation Program ("DPNP") issued by the Centers for Medicare & Medicaid Services ("CMS") on May 3, 2024 (the "Draft Guidance").[1]

Novartis discovers and develops innovative medicines that address the evolving needs of patients and societies worldwide. We are concentrated on the core therapeutic areas of cardiology, immunology, neurology, and oncology. Through innovative science and technology, we address some of society's most challenging health care issues. We work to discover and develop breakthrough treatments and find new ways to deliver them to as many people who would benefit from them as possible. At Novartis, we are united by a single purpose: to reimagine medicine to improve and extend people's lives.

Novartis remains very concerned that the DPNP, as prescribed by the Inflation Reduction Act of 2022 ("IRA"), will have profoundly detrimental effects on the development of innovative medicines in the U.S.[2] The program is not a true negotiation, akin to the market-based negotiations that occur under Medicare Part D today, but rather is a blunt price-setting tool arbitrarily applied to innovative medicines after a certain number of years on the market. The far-reaching consequences of the IRA go well beyond impacts on the Medicare program and risk threatening the innovation ecosystem that has brought life-changing medicines to the U.S. market. By establishing arbitrary price caps, the IRA discourages the R&D that plays a large role in driving progress in fighting diseases. These disincentives are already impacting the research and investment decisions that determine which medicines are brought to market for patients.

Overview of Novartis' Comments

We recognize that the statute directs CMS to implement the DPNP. However, given the complexity of this program, its size and scope, and the significant consequences across the multitude of stakeholders in the prescription drug supply chain and the patients they serve, it is critical that CMS proceed carefully and

[1] CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024), *available at:* https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[2] Novartis believes that relevant aspects of the IRA are unlawful and by making this submission does not waive its rights with regard to any current or future legal challenges to the statute or guidance.

deliberately in its approach to implementation. A thoughtful approach that reflects stakeholder feedback will ensure a smooth "maximum fair price" ("MFP") effectuation process and avoid further exacerbating the negative effects the law is already having on future innovation and access to medicines in the U.S.

Novartis' recommendations seek meaningful policy changes to protect innovation, ensure patients have broad access to selected drugs, construct robust safeguards to avoid diversion and duplicate discounts, and facilitate access to the MFP as required under the law. Our comments are focused on ensuring that the MFP effectuation process works efficiently through collaboration with all affected stakeholders and that CMS reconsiders policies with respect to drug selection and the negotiation process.

As detailed below, Novartis makes the following recommendations:

- CMS should identify distinct qualifying single-source drugs based on distinct New Drug Applications ("NDAs") or Biologics License Applications ("BLA") instead of active moiety or active ingredient, regardless of whether there is a common NDA or BLA holder;
- CMS should abandon its bona fide marketing standard for determining if a generic or biosimilar is on the market and instead use the market date used for the Medicaid Drug Rebate Program ("MDRP");
- CMS should not apply its calculation of the single ceiling per 30-day equivalent supply to any selected drug where the single ceiling is self-evident;
- CMS should consider only clinically comparable therapeutic alternatives as comparators, not finalize its proposal to include Coverage Gap Discount Program ("CGDP") payments when determining the price of therapeutic alternatives for the purposes of setting the MFP, and reconsider whether the MFP of a therapeutic alternative is an appropriate starting point;
- CMS should continue to offer three negotiation meetings with manufacturers of selected drugs;
- CMS should revise the format of the patient and provider "listening sessions" to elicit more useful information from these stakeholders;
- CMS should prohibit plans from using utilization management beyond a product's Food and Drug Administration ("FDA") approved label through its Part D formulary review process; and
- CMS should revise key aspects of its proposed approach to effectuating the MFP, including by:
    - Extending the proposed 14-day prompt MFP payment window to at least 30 days;
    - Providing batch claims data every other week;
    - Requiring the use of the Standard Default Refund Amount ("SDRA") in most instances;
    - Requiring dispensers to use the Medicare Transaction Facilitator's ("MTF's") payment facilitation process, including "Option 2" in which payment is directly remitted through the MTF;
    - Taking a greater role in identifying 340B claims in order to prevent duplicate discounts;
    - Limiting the portions of a manufacturer's plan to effectuate the MFP that are made publicly available to only those necessary for dispensers to receive payment; and
    - Providing a more robust complaints and disputes process.

I. Identification of selected drugs and the negotiation process

CMS should change its approach to identifying qualifying single source drugs based on active moiety or active ingredient.

As we noted in our comments on CMS's initial guidance for Initial Price Applicability Year ("IPAY") 2026,[3] CMS's approach to identifying a qualifying single source drug by reference to common active moiety or common active ingredient is irreconcilable with the statute and will have devastating effects on innovation

[3] CMS, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (Mar. 15, 2023), *available at:* https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.

and patient access.

Under section 1192, only "qualifying single source drugs" are eligible for selection for the program. Subject to certain exclusions, "qualifying single source drugs" are drugs or biologics for which there is no generic or biosimilar on the market and for which a statutorily prescribed time period has elapsed since approval or licensure. For drugs, "at least 7 years [must] have elapsed since the date of . . . approval" as of the selected drug publication date.[4] And, for biologics, "at least 11 years [must] have elapsed since the date of . . . licensure" as of the selected drug publication date.[5]

The statute clearly defines a "qualifying single source drug" by reference to a "covered Part D drug," as that term is defined in the Medicare statute. The definition of a "covered Part D drug," in turn, cross-references the definition of a "covered outpatient drug" in the Medicaid Drug Rebate Program ("MDRP") statute. And, under such definition, whether a single source drug is a distinct "covered outpatient drug" is based on whether the product is approved pursuant to a distinct NDA or BLA. The only exception to this rule under the MDRP comes in context of line extensions. There, Congress specifically amended the MDRP statute to enable line extensions to be grouped with innovator products across distinct NDAs or BLAs. In contrast, Congress chose not to group drugs across distinct NDAs or BLAs under the DPNP.[6]

In addition, the statutory definition of a "qualifying single source drug" specifies that a qualifying product is subject to a statutory seven- or eleven-year clock tied to each "approval" or "licensure" of a product. It follows, then, that each qualifying single-source drug corresponds to a distinct approval or licensure, i.e., a distinct NDA or BLA. Any other reading—including one based on common active moiety or common active ingredient—contradicts the plain text of the statute.

Finally, the statutory "qualifying single source drug" definition is grounded in the FDA's framework for approving and licensing drugs and biologics, and such framework distinguishes among drugs and biologics via distinct applications. The FDA has spoken directly to the types of changes to an approved product that should be approved via a supplement to an existing NDA or BLA, and those that should be approved via a new NDA or BLA. By expressly cross-referencing the FDA framework in the "qualifying single source drug" definition, Congress clearly intended that CMS rely on such framework in distinguishing among qualifying single source drugs.

The use of NDAs and BLAs as the standard for distinguishing among qualifying single-source drugs helps balance the twin interests in pharmaceutical and biotechnology innovation and lowering prescription drug prices. The statute seeks to ensure that the latter does not unduly outweigh the former by, among other things, establishing a period of time after approval or licensure during which a drug or biologic is not eligible for selection for negotiation, thereby preserving an incentive for manufacturers to research and develop next-generation products that will ultimately benefit patients. In contrast, CMS's policy will greatly exacerbate the disincentive to develop next-generation therapies inherent in the DPNP, to the detriment of patients in need.

CMS should abandon its bona fide marketing standard for determining whether a generic or biosimilar product is on the market.

In the Draft Guidance, CMS proposes to maintain the standard by which a drug or biologic is rendered ineligible for selection for negotiation due to a generic or biosimilar product entering the market. CMS states that it intends to review prescription drug event ("PDE") and average manufacturer price ("AMP") data to determine whether a generic or biosimilar satisfies a "bona fide marketing" standard, under which the agency makes a subjective judgment as to whether the degree of utilization of the generic or biosimilar represents "meaningful competition."[7] Novartis is deeply concerned with this approach, which lacks a logical nexus to the actual date of marketing and introduces unnecessary complexities and confusion into the DPNP. CMS should abandon the bona fide marketing standard and instead specify that both (1) the date on which an approved generic or biosimilar is marketed and (2) the date on which CMS

[4] Social Security Act ("SSA") § 1192(e)(1)(A)(ii).
[5] *Id*. § 1192(e)(1)(B)(ii).
[6] Notably, Congress did do so as to another provision of the IRA: The Part D inflation rebate provision specifically directs CMS to establish an inflation rebate formula for line extensions consistent with the formula under the MDRP.
[7] Draft Guidance at 115.

determines that an approved generic or biosimilar has been marketed are the product's "market date" for MDRP purposes.

As a definitional matter, marketing is "[t]he act[] . . . of bringing or sending a product or commodity to market."[8] As such, once the "action of buying or selling" has occurred, a product has necessarily been "marketed."[9] CMS itself has recognized that when a product is "marketed" is an objective point-in-time determination based on when the product enters the commercial marketplace for sale. For purposes of the IRA's Part D inflation rebates, CMS determines when a product is "marketed" by reference to its "market date" as reported under the MDRP. In turn, CMS's longstanding policy under the MDRP has been to define "marketed" by reference to the date on which a product enters commercial distribution. In fact, it would be impossible to report AMP data to CMS until after a drug is marketed as only then will there be units sold as to which the manufacturer can calculate AMP. And, under the Part D program, which sources the PDE data on which CMS relies in effectuating its bona fide marketing standard, CMS has recognized that the date on which a product is "release[d] onto the market" triggers certain coverage-related obligations[10]—which means that CMS will have already recognized that a product has been released onto the market by the time PDE data show product utilization.

There is no basis for CMS to override the clear bright-line test imposed by the statute in favor of a subjective standard that effectively gives the agency unlimited discretion to determine whether and when a product is subject to an MFP. This is especially so given Congress has demonstrated that it knows how to establish a subjective "bona fide" standard yet declined to do so here.[11] "[W]here Congress knows how to say something but chooses not to, its silence is controlling."[12]

CMS's unlawful bona fide marketing standard also necessarily results in a delay between the actual date of marketing and the date of CMS's determination, because it takes time for sales to be reflected in PDE and reported AMP data. Indeed, as CMS permits Part D plan sponsors 180 days after a newly approved drug is released onto the market to determine whether to add the drug to their formulary, PDE data rarely reflect when the drug came to market with accuracy. Many Part D plan sponsors will not add a newly approved drug to their formulary until the 180-day mark (or may not add it at all), and, thus, the first six months of PDE data following the market entry of the drug necessarily reflect only very limited uptake. Even where plan sponsors add the drug to their formulary, there is typically a gradual transition by providers and patients to such product as they become increasingly familiar with its benefits relative to alternatives. Such a product is in fact marketed during this uptake period, but CMS's standard ignores this fact and focuses instead on whether the product is sufficiently utilized.

It may similarly take time for broad utilization of a newly launched product to show up in AMP data, as AMP represents an average of sales in the commercial market and utilization in that market will follow coverage and reimbursement for a drug by commercial and other health plans. Purchases of the drug thus may be more limited until such time as the purchaser is assured that sufficient reimbursement for the drug is available. Such changes in utilization patterns over time do not mean that the market is not working as intended.

CMS's standard is all the more concerning given that the agency reviews PDE and AMP data only once per month for purposes of determining when the MFP terminates, which compounds the lag between the actual date of marketing and the date of CMS's determination.

It is especially critical that CMS equate the date of CMS's determination of marketing with the MDRP's "market date." If there is a lag of even one day between the date of CMS's determination and the actual date of marketing, the selected drug may be subject to the MFP for an additional twelve months. This risk

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[8] Oxford English Dictionary, Definition of Marketing, *available at:* https://www.oed.com/view/Entry/114186?rskey=36dfg4&result=2&isAdvanced=false#eid (last accessed Jun. 10, 2024).
[9] *Id.*
[10] CMS requires that Part D plan sponsor Pharmacy and Therapeutics committees "make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days of its release onto the market and . . . make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met." CMS, Prescription Drug Benefit Manual, ch. 6 § 30.1.5.o.
[11] SSA § 1927(k)(1)(B)(i)(II) (as amended by Pub. L. No. 111–148, § 2503(a) (2010)) (amending the MDRP statute to specify that only "bona fide" service fees are exempt from the calculation of average manufacturer price).
[12] *Animal Legal Def. Fund v. U.S. Dep't of Agric.*, 789 F. 3d 1,206, 1,217 (11th Cir. 2015).

materially disincentivizes generic and biosimilar entry because a potential generic or biosimilar manufacturer has reason to be concerned about its product's ability to compete with the selected drug's MFP for an unduly extended time. This outcome runs contrary to Congress's objective in promoting generic and biosimilar market competition under the DPNP.

CMS should not apply its calculation of the single ceiling per 30-day equivalent supply to any selected drug where the single ceiling is self-evident.

CMS indicates that it intends to calculate a single ceiling per 30-day equivalent supply to negotiate a single MFP, which is then converted to an as-applied MFP for each dosage form and strength. Specifically, with respect to the calculation of the single ceiling, CMS states that it intends to "[u]s[e] the 30-day equivalent supply to calculate [the single ceiling price to] facilitate[] aggregation across dosage forms and strengths of a selected drug *where units (e.g., mg versus ml) and treatment regimens (e.g., daily consumption of tablets versus monthly injections of solutions) differ*."[13]

Where the distinct national drug codes ("NDCs") of a drug have distinct unit types, treatment regimens (such that different patients may receive different doses per day), and wholesale acquisition costs ("WACs") per unit, this calculation of a single ceiling price may be appropriate. However, this is neither necessary nor appropriate where all NDCs of the selected drug share the same unit type, treatment regimen, and WAC per unit.

In fact, under these circumstances, CMS's ceiling calculation could distort the true ceiling on account of incorrect coding of the days' supply on a claim for the drug as compared to the amount that is actually dispensed to the patient, which is then reflected in the PDE data. Although such errors can distort the calculation of the ceiling for any product, CMS can easily prevent any such distortion where the NDCs of the selected drug should share the same 30-day equivalent supply because there the single ceiling will be self-evident.

In these instances, CMS's single ceiling methodology would generate lesser rather than greater accuracy, and CMS should not apply it under such circumstances.

CMS should consider only appropriate therapeutic alternatives as comparators, not finalize its proposal to include CGDP payments when determining the price of therapeutic alternatives for the purposes of setting the MFP, and reconsider whether the MFP of a therapeutic alternative is an appropriate starting point.

As we have noted in prior comments, CMS should clarify the processes and criteria used for selection of therapeutic alternatives. The criteria and processes should be based solely on the scientific consensus around which products are truly therapeutically comparable in both clinical effectiveness and patient treatment burden. This will help to ensure that patients' access to needed medications is driven by balanced clinical considerations and not based solely on cost differences between medications that are not truly equivalent. Novartis encourages CMS to clarify that therapeutic alternatives to a selected drug are only those that are in the same drug class, have the same methods of action, and are approved for the same indications and patient populations. Additionally, they should have comparable efficacy and safety, and be administered through the same route of administration with similar dosing schedules. Finally, proposed therapeutic alternatives should have comparable real-world patient use to that of the comparator product. All of these factors are highly relevant to ensuring that the therapeutic alternatives that serve as comparators for purposes of the MFP negotiation are truly appropriate for price-setting purposes.

With respect to the process of selecting specific therapeutic alternatives for individual drug negotiations, Novartis strongly encourages CMS to provide a fully transparent process, including with respect to the criteria used to select therapeutic alternatives. CMS should specifically seek input from multiple stakeholders including patients currently on those medications, patient advocacy groups, health care providers, health care guidance committees, manufacturers, and other key stakeholders on the appropriateness of the comparators. In addition, the processes should include providing the manufacturer

[13] Draft Guidance at 72 (emphasis added).

of the selected drug a written justification of the therapeutic alternatives that CMS proposes to select, including an explanation of the criteria used to develop such proposal and affording the manufacturer a meaningful opportunity to comment on the proposal. This should occur *prior* to manufacturer submission and patient/provider listening sessions in order for manufacturers and other stakeholders to be best positioned to submit relevant data, provide informed feedback and allow CMS time to reconsider its selected alternative(s).

Further, CMS should not finalize its proposal to consider CGDP discounts and MFPs, if applicable, when considering the price of therapeutic alternatives as the starting point for the initial offer of a selected drug, where it has determined that a therapeutic alternative is available. CMS indicates that it intends to use the negotiated price under Part D, net of CGDP discounts, as the starting point on the grounds that selected drugs will not be subject to discounts under the CGDP's successor Manufacturer Discount Program.[14]

Congress has determined that selected drugs should not be subject to both the MFP and the discount that manufacturers offer on the negotiated price under Part D; the statute expressly excludes selected drugs from the Manufacturer Discount Program, which will succeed the CGDP in 2025, before any MFP is in effect under the DPNP in 2026.[15] To use the price of a therapeutic alternative net of the CGDP discount as a starting point for negotiations would be a backdoor way to subject a selected drug to both the MFP and the discount manufacturers offer on the Part D negotiated price, contrary to Congress's express intent.[16] For this reason, using the price of therapeutic alternatives, net of CGDP discounts, is an arbitrary way to lower the MFP that is inconsistent with the statute.

Moreover, CMS indicates that it also intends to use the MFP of a therapeutic alternative previously or concurrently selected for negotiation as the basis for an initial offer. As with the CGDP, the MFP is not actually a price negotiated under available market conditions given that it is subject to a cap and a prescriptive process, compliance with which is done at risk of significant civil monetary penalties ("CMPs") and excise taxes. Moreover, if the MFP for a therapeutic alternative to a selected drug is already published and available, that MFP will have already exerted downward pressure on the pricing of the newly selected drug, with such pricing reported to CMS through the manufacturer data submission process, given that the newly selected drug will have had to compete with the MFP of the therapeutic alternative. For these reasons, Novartis believes that the MFP of a therapeutic alternative is not an appropriate starting point for negotiations.

CMS should not reduce the frequency of negotiation meetings with manufacturers of selected drugs, as doing so would exacerbate the current lack of transparency in the negotiation process.

CMS seeks feedback on whether the agency should conduct fewer negotiation meetings with manufacturers of selected drugs with respect to IPAY 2027. As a manufacturer with a selected drug on the IPAY 2026 list, Novartis strongly believes that CMS should be focused on improving transparency and engagement rather than decreasing the frequency of touchpoints with manufacturers.

CMS cites the increased number of drugs that must be selected each year as a reason to potentially scale back the frequency of negotiation meetings, but this actually places *greater* importance on the interactions that occur during these meetings given that CMS staff may not have sufficient time to understand the critical and unique details of each selected drug outside of such meetings. In addition, given that CMS's interactions with outside clinical experts are limited, it is critical that CMS staff have an opportunity to directly ask questions of company medical personnel to have the most robust understanding of a medicine's clinical profile.

CMS should revise the format of the patient and provider "listening sessions" to elicit more useful input from these important stakeholders.

Novartis appreciates that CMS attempted to solicit patient and provider feedback via "listening sessions"

[14] *Id.* at 82.
[15] SSA § 1860D-14C(g)(2)(B).
[16] *United States v. Jackson*, 143 F. 783, 786 (9th Cir. 1906) ("Courts should search out and follow the true intent of Congress and adopt 'the sense of the words which harmonizes best with the context, and promotes in the fullest manner the apparent policy and object of the legislation.").

for IPAY 2026. Unfortunately, the structure of these meetings created real barriers to robust participation, and CMS did not transparently articulate whether or how feedback received from patients and providers would be used during individual drug reviews.

The limitations of these sessions between CMS and patient and provider organizations were driven by a few key structural flaws in the way the sessions were organized:

- First, making these sessions "listen only" from the CMS perspective shut down any opportunity for robust and dynamic dialogue about selected drugs, their benefits, and the costs of managing their diseases.
- Second, the types of questions asked demonstrated a lack of understanding of the types of input that an individual beneficiary can reasonably provide. For example, asking a patient to comment on the effects of a drug compared to its therapeutic alternatives assumes that the patient is even aware of what the "therapeutic alternatives" are.
- Third, the questions were not tailored for specific audiences. Providers, individual beneficiaries, and patient organizations were all asked the same questions. These stakeholders have different perspectives to bring to bear as CMS seeks to gather feedback about selected drugs.

For the next round of provider and patient engagement, we suggest that CMS continue to structure feedback sessions on a drug-specific basis but change these sessions to allow for greater participation and more impactful conversations. We suggest that CMS design separate sets of questions appropriate for different stakeholder groups. For example, patient advocacy groups are well-positioned to comment on access trends and community concerns, while individual beneficiaries can answer questions about how a selected drug impacted their quality of life and clinicians are better positioned to answer questions about how a selected drug compares to therapeutic alternatives.

In addition, CMS should conduct separate meetings with guideline-writing specialty societies, which would enable a clearer understand of how the written guidelines translate to clinical practice, including whether the therapeutic alternatives that CMS is considering are clinically appropriate in light of the guidelines. Lastly, greater transparency and visibility into how patient and provider feedback is being used in actual drug reviews by including such information in the MFP offer explanations would be a critical step to encouraging future participation in the process.

CMS should ensure broad access to selected drugs for Medicare Part D beneficiaries through its formulary review process.

While the statute requires Part D plans to place selected drugs on formulary,[17] CMS must take additional steps to ensure that patients have meaningful access to these drugs. Without these steps, the DPNP has the potential to disrupt the competitive landscape in Part D and cause beneficiaries to face higher—not lower—barriers to accessing selected drugs.

Novartis is disappointed that CMS has not proposed to clarify that selected drugs not only must be on formulary but that they must not be disadvantaged relative to other drugs in the category and class. Novartis reiterates that, while formulary coverage is essential for providing beneficiaries access to selected drugs, CMS can and must go beyond the minimum requirements in the IRA in order to ensure that beneficiaries retain access to selected drugs. Specifically, we urge CMS to make clear that Part D plans should not impose utilization management requirements that go beyond a selected drug's FDA-approved label. Such utilization management requirements stand in the way of patients seeking to access selected drugs. Part D plans and their pharmacy benefit managers are likely to favor drugs with higher prices over the selected drugs and will structure formulary benefits to encourage patients to prefer higher cost alternatives, which tend to have higher rebates. This approach to formulary design runs counter to the intent of the DPNP. In order to prevent this outcome, CMS should make clear that utilization management restrictions should not be imposed on selected drugs beyond the drug's FDA-approved label, and that a selected drug should not be disadvantaged in its formulary position relative to other drugs in the same category and class. Failure to ensure formulary safeguards for selected drugs may impede beneficiary access to these drugs, including through increased cost-sharing obligations, and may

[17] *See* SSA § 1860D-4(b)(3)(I).

result in other unintended consequences.

If CMS chooses to maintain its position that additional formulary protections are not necessary for patients under Medicare Part D, the agency should be more explicit regarding the formulary review process for selected drugs. The agency's current formulary review and outlier testing processes do not include necessary steps to verify appropriate coverage of selected drugs, and CMS should clarify how it will add to these processes to ensure continued access to selected drugs.

II. Effectuation of the MFP in 2026 and 2027 (Sections 40.4 – 40.4.4)

CMS should revise key aspects of its proposed approach to effectuating the MFP.

The principal roles of biopharmaceutical innovators in the health care system include developing treatments to meet unmet patient need, educating patients and providers about these novel options, and ensuring that patients have access to a reliable supply of essential medicines for the management of their disease. Over time, changes in the health care system have increasingly required greater manufacturer engagement in health care payment processes, including claims data validation and payment processing, but these processes are *not* among the core functions that manufacturers provide to the system. Furthermore, manufacturers, positioned at the start of the pharmaceutical supply chain, are typically disconnected from the financial transactions that occur when a prescription is dispensed to a patient. For these reasons, processes and timelines for effectuating the MFP that may be workable and appropriate for some stakeholders (i.e., plan sponsors, pharmacy benefit managers, and 340B third-party administrators) are not for manufacturers.

Novartis supports a retrospective model to make MFPs available, however the proposed 14-day prompt MFP payment window is unfeasible given the multi-step process manufacturers use today to validate and pay claims.

CMS intends to require Primary Manufacturers to provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is not greater than the MFP, or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. Under the retrospective model outlined in the Draft Guidance, Primary Manufacturers must ensure that the dispensing entity receives reimbursement in an amount that provides access to the MFP within 14 calendar days, known as the "14-day prompt MFP payment window."[18] Should the MFP not be made available to a dispensing entity or if payment-related data are not provided to the MTF within this 14-day timeframe, Primary Manufacturers may be liable for CMPs.

With this context in mind, Novartis appreciates CMS maintaining the option for Primary Manufacturers to effectuate the MFP as a retrospective rebate. A retrospective option is the most commonsense and operationally straightforward approach given stakeholders are well familiar with this model for rebate payments to both commercial and Part D payers and the current CGDP. Additionally, a retrospective model is the only way to reliably safeguard against diversion of MFP units to ineligible individuals.

Nevertheless, Novartis is concerned that the proposed 14-day prompt MFP payment window to make the MFP available to dispensers is operationally unfeasible given manufacturers' current workflows and systems. Currently, manufacturers have extensive processes in place to validate claims, ensure multiple payers are not claiming payment for the same prescription, and deduplicate 340B claims. Furthermore, many manufacturers are publicly traded companies and must uphold rigid internal controls and audit requirements to comply with the Sarbanes-Oxley Act.[19] These statutorily required processes represent an added layer of financial reporting for publicly traded companies and should be accounted for as CMS

[18] Draft Guidance at 37.

[19] Sarbanes-Oxley Act of 2002, Pub. L. 107–204 (July 30, 2002), *available at:* https://www.govinfo.gov/content/pkg/COMPS-1883/pdf/COMPS-1883.pdf. To implement certain requirements of SOX, the Securities and Exchange Commission ("SEC") adopted Rules 13a-15 and 15d-15 of the Securities Exchange Act of 1934 (the "Exchange Act"), which require companies with a class of securities registered under Section 12 of the Exchange Act that have filed an annual report pursuant to Section 13(a) or 15(d) of the Exchange Act for the most recently completed fiscal year to maintain "internal control over financial reporting," which include, among other things, "policies and procedures that . . . provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the [company] are being made only in accordance with authorizations of management and directors of the [company]".

establishes the timeframe for MFP payment.

For manufacturers, there are currently multiple steps to validating and paying claims. In a typical end-to-end payment process, manufacturers receive a data file and format it for uploading into internal systems for validation. Claims are then validated against several factors that include the following:

- Product
- Quantity
- Valid dispensing entity
- Duplicate script within file
- Reversals and/or prior period adjustments
- Coordination of benefits
- Rebate amount
- Identification of 340B claims

Further complicating this process, payer data often include duplicate claims—due to errors in claims data or abandoned prescriptions that are later filled—that must be removed. Once validation is complete, a multi-step internal review process must be followed before approval, which could include multiple levels of approval based on the payment value. Once approved, payment is sent for processing.

Novartis recommends that CMS allow for a prompt MFP payment window of at least 30 days from the receipt of claims data from the MTF to complete this validation process, which is consistent with the current industry-standard.

The IRA does not mandate the timeframe for effectuating the MFP and certainly does not require the 14-day timeframe proposed by CMS. For that reason, industry standards aligned with other government programs are the most appropriate basis for determining the timeframe for this process. Other government programs provide windows to facilitate payment of at least 30 days, including 37 days for the MDRP and 38 days for the CGDP. Given (1) our multi-step internal validation and payment processes, (2) legal requirements to comply with certain financial standards, and (3) the commonsense approach to align with payment terms of other government programs, a payment period of at least 30 days is the most reasonable timeframe to facilitate MFP payment and transmit required data elements to the MTF while also ensuring dispensers are paid accurately and within a reasonable timeframe. This would allow manufacturers to accurately perform the necessary validation—including identification of 340B claims—and issue payments within the current confines of manufacturer systems and to comply with all other statutory financial reporting requirements.

Furthermore, it is not clear from the Draft Guidance if the proposed prompt MFP payment window starts when claims-level data are *sent* to the Primary Manufacturer or when the Primary Manufacturer *receives* the claims-level data, which in some instances could be different dates. CMS should clarify that the proposed prompt MFP payment window during which payment must be made will not be initiated until the Primary Manufacturer *receives* claims-level data verifying the selected drug was dispensed to an MFP-eligible individual. In addition, a manufacturer should be considered to have complied with the prompt MFP payment window based on the date(s) on which the manufacturer *sends* payment to the pharmacy, via the MTF (as described below) and *transmits* the payment-related data to the MTF.

Data should be transmitted no more frequently than every other week to the manufacturer from the MTF to ensure an efficient payment process.

CMS is proposing to engage an MTF to facilitate the exchange of certain claims-level data elements between Primary Manufacturers and dispensing entities. Data received by the MTF would be verified by both the Part D plan sponsor and the CMS Drug Data Processing System (“DDPS”) before the MTF transmits the data to Primary Manufacturers. To optimize payment facilitation, CMS should allow manufacturers to request supporting claims information to determine eligibility or verify the payment amount should the limited data set received by the MTF be inadequate to validate a claim.

CMS is asking for input from Primary Manufacturers on the preferred frequency of data transmitted from the MTF. Given that the batch data will be voluminous and will require multiple iterations of scrubbing to

validate as described above, Novartis suggests that manufacturers receive the data no more frequently than every other week. We believe this frequency strikes the right balance, in that it will limit the number of claims reversals and adjustments between batches while also allowing more time to deduplicate 340B claims. It is imperative that there be sufficient time between receiving data file batches to allow the Primary Manufacturer to scrub the data and issue payment before the next batch is received. Processing multiple files in various stages would create an unnecessarily complex and challenging workflow, particularly given the need for payments to pass through security controls in internal financial reporting systems as outlined above.

CMS should require the use of the Standard Default Refund Amount (WAC minus the MFP) unless a Primary Manufacturer has negotiated a contracted price directly with the dispenser.

CMS proposes that the MTF use the WAC when a unit is dispensed as the standardized pricing metric to calculate the SDRA. Novartis agrees that the SDRA should be based on WAC, because this reflects a manufacturer's price when a product enters the supply chain and is publicly available and widely published.

However, we strongly urge CMS to simplify payment options by requiring the use of the SDRA as a true default and clarifying that manufacturers need only offer an alternative rebate amount in the limited circumstances described below. While some dispensers may prefer to base the MFP refund on their actual acquisition cost, if higher than WAC, any such higher price is not a price charged by the Primary Manufacturer and therefore should not be the basis for the refund calculation, as it would require the Primary Manufacturer to pay a rebate based on a price it did not charge and revenue it did not receive. Primary Manufacturers generally have no knowledge or control over these acquisition costs as they reflect a *wholesaler's price* based on a dispenser's arrangements with that wholesaler. A rebate amount based on acquisition cost in these circumstances would, moreover, be contrary to statute as it would require the manufacturer to offer a rebate amount that is *more* than the MFP, as the rebate amount would be based on a higher, non-manufacturer price.

In addition, using acquisition cost as the basis of the MFP rebate amount would create perverse incentives in wholesaler-dispenser negotiations in which the parties could prefer higher, not lower, prices in order to maximize the payments from manufacturers. Not only would the use of acquisition cost overextend a Primary Manufacturer's obligation to "provide access to" the MFP beyond that authorized by the IRA, but it could actually run counter to the IRA's stated objective to lower prices.[20] Furthermore, the use of multiple formulas for determining the payment amount would create significant administrative complexity for manufacturers and could potentially delay payment.

The only instance in which the SDRA should not be required is where the Primary Manufacturer has a contract price agreement with a dispensing entity for a price below WAC. In these circumstances, the contracted price does reflect the price charged by a Primary Manufacturer and should be used to determine the MFP rebate amount. Furthermore, these contracted prices are known and negotiated by both parties, ensuring sufficient transparency and accountability in rebate calculations and limiting administrative burden.

If CMS chooses to permit dispensers to pursue higher rebates than those based on the SDRA, we request that CMS establish an express enforcement safe harbor for Primary Manufacturers that make the MFP available to the dispensing entity using the SDRA and subsequently make a good faith effort to correct the payment amount in a timely manner, i.e., the Primary Manufacturer should be permitted to do so without facing CMPs.

CMS should require bilateral use of the MTF to facilitate MFP payment through "Option 2".

Novartis appreciates CMS's proposal to utilize the MTF for payment facilitation. Centralized administration of public programs has numerous benefits, many of which CMS outlines in the Draft Guidance, including standardization, predictability, and limitation of burden on stakeholders. In light of these benefits, Novartis is concerned that CMS is not proposing mandatory participation in the MTF payment facilitation process

[20] Draft Guidance at 35.

for dispensers. Given that there are over 60,000 pharmacies in the U.S.,[21] the proposed voluntary nature of the MTF could lead to a chaotic, fragmented approach to making the MFP available. Therefore, Novartis strongly encourages CMS to require bilateral use of the MTF to facilitate MFP payment.

CMS proposes two options for facilitating payment between Primary Manufacturers and dispensing entities: (1) MTF facilitates the sharing of banking information between the Primary Manufacturer and dispensing entity; and (2) payment passes through the MTF from the Primary Manufacturer to the dispensing entity. Novartis strongly recommends that CMS pursue "Option 2" payment facilitation to help ensure that dispensers receive MFP refund amounts within a prompt MFP payment window. Central, coordinated payment from manufacturers to dispensers through the MTF improves transparency and accountability for all stakeholders and limits unnecessary payment errors and delays.

In contrast, manufacturers establishing direct payment relationships with a larger number of individual dispensing entities outside of "Option 2" would present significant risk of payment errors and delays, particularly for high volume medicines, as it would require manufacturers to integrate new dispensers into payment systems, process numerous one-off payments, reconcile transactions, and handle disputes. For these reasons, mandating participation for dispensers through "Option 2" would almost certainly lead to a more efficient and streamlined process.

If CMS declines to mandate the use of "Option 2" MTF payment facilitation, it should permit dispensers to "opt out" of "Option 2," but still require dispensers to provide bank information, and provide an extended prompt payment period for manufacturers.

Should CMS choose not to mandate the use of "Option 2" by dispensers, we recommend that CMS automatically enroll dispensers in "Option 2" and allow dispensers to *opt out* before the beginning of the year should they decide not to participate. Furthermore, should a dispenser opt out of "Option 2", we ask that the dispenser then be immediately prompted to provide bank account information, which would be included in the claims-level data that must be provided to the MTF and then shared with the Primary Manufacturer, similar to "Option 1". This would streamline payment processes for all parties and encourage the use of "Option 2". In this scenario, we recommend that Primary Manufacturers be notified of dispensers who opt out of "Option 2" and urge CMS to require that dispensers maintain their chosen method of payment facilitation throughout the full calendar year**.**

Further, if a dispenser "opts out" of "Option 2," it would be unreasonable for the dispenser to be entitled to payment within the same prompt MFP payment window as those who opt into "Option 2." Processing payment directly to the dispenser would require Primary Manufacturers to complete additional steps to validate the dispenser and integrate the dispenser into their payment systems. For example, if an entity has not received prior payments from a manufacturer, up to 5 additional days of processing time may be needed from receipt of the entity's banking information in order to establish the entity in the manufacturer's payment system. Additionally, if CMS declines to mandate the provision of banking information and a dispensing entity refuses to provide banking information for electronic payment such that the manufacturer must send a written check, an additional 10 days from the receipt of invoice may be necessary. Just as pharmacies that participate in the Part D program as network pharmacies must meet certain flow-down requirements as well as claims submission requirements in order to obtain prompt payment for Part D claims, CMS should require dispensers that want to receive prompt payment for MFP to participate in the MTF through "Option 2."

CMS should provide a safe harbor for manufacturers that have engaged in a good faith effort to make the MFP available.

We strongly urge CMS to establish an express enforcement safe harbor for Primary Manufacturers that in good faith attempts to make the MFP available through the process outlined in their plan for effectuating the MFP. Specifically, a manufacturer that has complied with any CMS-established payment pathway, including payment through the MTF, and then makes a reasonable effort to work with the dispensing entity to resolve any underpayments, should be considered to have acted in good faith and not be liable

[21] Lucas A. Berenbrok, et al. Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-sectional Analysis. 62 J. of the Ame. Pharmacists Ass'n 1816 (Jul. 12, 2022), *available at*: https://www.japha.org/article/S1544-3191(22)00233-3/fulltext.

for CMPs. This will be particularly important should CMS finalize a prompt MFP payment window that is less than 30 days.

CMS should take a broader role in collecting 340B claims data and providing them to Primary Manufacturers through the MTF for the purpose of determining MFP payment.

By statute, a Primary Manufacturer of a selected drug has no obligation to offer both the MFP and the 340B ceiling price on the same unit.[22] The Primary Manufacturer is obligated only to offer the lower of the two prices. Specifically, the IRA specifies that the manufacturer of the selected drug, *where the drug is subject to 340B price and*:

- *The MFP is greater than the 340B ceiling price,* cannot be required to provide access to the MFP; or
- *The MFP is less than the 340B ceiling price,* can only be required to provide the MFP in a nonduplicated amount to the 340B ceiling price (which amount would be calculated as the 340B ceiling price less the MFP) as opposed to the full MFP rebate.

CMS cannot bypass these limitations on its enforcement authority by establishing a rebate process that does not provide for the data needed to effectuate the statutory MFP-340B non-duplication requirement. Given that there is no existing way for manufacturers to access 340B data today, CMS should require dispensers to provide this data to enable compliance with the MFP-340B non-duplication guarantee as described below.

Today, a large share of 340B ceiling price transactions are performed through a replenishment model, where covered entities seek to access the 340B discount often weeks or months *after* dispensing. The replenishment model necessarily creates significant barriers to identifying and tracking 340B units for the accurate payment of MFP discounts because, as proposed, the MFP discounts must be offered closer to the point of dispensing and within a prompt MFP payment window, but the replenishment model adjudicates 340B eligibility only well after the fact. Specifically, under the replenishment model, a pharmacy intermingles 340B and non-340B units in its inventory and tracks the units of a product that are dispensed to 340B patients (often well after the actual dispenses occur). Once the accumulated units dispensed to 340B patients exceed the package size of a product, the 340B covered entity places an order for replacement inventory with the manufacturer (via its wholesaler) at the 340B ceiling price.

Several aspects of the replenishment model run directly counter to CMS's proposed approach for MFP effectuation:

1) 340B replenishment orders reflect units dispensed to many individuals, some of whom are MFP eligible individuals and some of whom are not.
2) Manufacturers do not typically receive any underlying pharmacy claims data for any individual replenishment order.
3) Replenishment orders can occur at any point after units are dispensed to 340B patients and sometimes occur months, if not years, post-dispense (and therefore well after the close of the proposed prompt MFP payment window).
4) 340B units can be dispensed not just at 340B covered entity pharmacies but also through a large network of contract pharmacies.

For these reasons, Primary Manufacturers alone lack the ability to identify and track 340B units dispensed to MFP eligible individuals and prevent the payment of duplicate discounts, as guaranteed by the IRA. Furthermore, Primary Manufacturers are unlikely to have willing partners in enforcing the statute among covered entities and their third-party administrators ("TPAs") and contract pharmacies—in fact, these stakeholders stand to derive substantial financial benefit from the payment of duplicate discounts.

Moreover, MFP-340B deduplication cannot readily occur after the fact via a pricing true-up. Unless, where a contract pharmacy arrangement is concerned, CMS intends for the MTF to facilitate payment of the MFP to the covered entity, the MFP is owed to the *pharmacy* and the 340B ceiling price is owed to the *covered entity*, and the manufacturer is obligated to provide only the lesser of these two prices. If a

[22] SSA § 1193(d).

manufacturer has already provided the MFP to the pharmacy within the proposed 14-day prompt MFP payment window and, then, under the 340B replenishment model, the covered entity places an order for a replenishment unit at a lower 340B ceiling price months later, that manufacturer cannot readily avoid the duplicate discount, given that the 340B ceiling price is owed to the covered entity, and there is no apparent mechanism for clawing back the MFP from the pharmacy. (Note that the manufacturer cannot make the covered entity whole by offering the covered entity only the difference between the 340B ceiling price and the MFP, as the pharmacy, not the covered entity, received the MFP.)

In order for CMS to stay within its statutorily imposed enforcement parameters, it is therefore vital that CMS put in place a robust mechanism to identify 340B units and prevent 340B-MFP duplicate discounts as a necessary condition of any prompt MFP payment window. This mechanism is critical to the successful implementation of the DPNP as well as being necessary to avoid duplication of the Part B and Part D inflation rebates with drugs subject to the 340B ceiling price. Therefore, we are disappointed that, in its proposed Draft Guidance, CMS proposes to take on no role in identifying 340B units and deduplicating the 340B ceiling price and MFP discounts.

The statutory guarantee against 340B-MFP duplicate discounts, described above, obligates CMS to establish a meaningful mechanism for identifying 340B units and otherwise enabling MFP-340B non-duplication, as a condition of its enforcement of the MFP payment obligation.[23] Such a mechanism is especially critical given the long and well-documented history of widespread 340B covered entity non-compliance with the separate 340B-MDRP duplicate discount prohibition.[24] And, unlike 340B-MDRP duplicate discounts, there is no statutory audit, dispute resolution, or penalty process to remediate 340B-MFP duplicate discounts.[25] Given that the risk of 340B-MFP duplicate discounts therefore is even higher than that of 340B-MDRP duplicate discounts, we encourage CMS to recognize it is that much more vital to establish a meaningful mechanism to protect against such duplicate discounts. To that end, CMS should ensure that non-duplication—and therefore eligibility for the MFP—can be validated by providing for two categories of data.

First, CMS should require the use of a 340B or non-340B claims modifier, as applicable, to identify whether a unit is 340B or non-340B, use of which should be supported by the maintenance of records showing that eligibility or ineligibility for the 340B ceiling price has been validated with the covered entity. Further, CMS should condition the start of the prompt MFP payment window, and Part D reimbursement, on receipt of complete data, including these modifiers.[26] While CMS has already taken welcome steps to require the use of a 340B claims modifier for drugs reimbursed under Part B starting on January 1, 2024, and is proposing to require the same for Part D drugs, we reiterate our previous comments that no comparable steps have been taken for Part B drugs reimbursed under Medicare Advantage ("MA") or otherwise to protect against 340B-MFP duplicate discounts. As noted above, 340B units may be identified well after they are dispensed and often are not identified by the pharmacy that dispensed the unit and received reimbursement. Therefore, 340B claims modifiers that are voluntary for pharmacies or not robustly monitored and audited by the agency are unlikely to be accurate. Mandatory claims modifiers, however, are a useful tool to identify 340B units.

Second, where the 340B ceiling price is lower than the MFP, manufacturers must be able to verify whether the 340B ceiling price has already been provided on the unit or whether it will be provided either through the MTF or on a replenishment unit. Under the replenishment approach, the necessary data would include some means of confirming that the unit at issue has not been subject to the MFP rebate to be sure that non-duplication requirement is met.

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[23] *See United States v. Markgraf*, 736 F.2d 1179, 1183 (7th Cir. 1984) ("An administrative agency cannot abdicate its responsibility to implement statutory standards under the guise of determining that inaction is the best method of implementation.").

[24] *See, e.g.*, Government Accountability Office ("GAO"), Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (2018), *available at:* https://www.gao.gov/assets/gao-18-480.pdf. *See also* Public Health Service Act ("PHSA") § 340B(a)(5)(A).

[25] *Compare* SSA § 1193(d) *with* PHSA § 340B(a)(5)(C), (d)(2)(v), (3).

[26] CMS may condition Part D payment on the appropriate use of 340B and non-340B modifiers. To effectuate the Part D inflation rebates under Section 1860D-14B of the SSA, CMS must have a means of identifying whether a unit of a selected drug is subject to the 340B ceiling price, as opposed to the MFP, in order to exclude it from the inflation rebate calculation. *See* SSA § 1860D-14B(b)(1)(B). CMS may require the appropriate use of 340B and non-340B modifiers to acquire such information. *See* SSA § 1860D-12(b)(3)(D) (general authority to add Part D contract terms); *see also* SSA §§ 1871(a), 1102(a) (general rulemaking authority). Such data may then be included in the claims data provided to the manufacturer through the MTF. *See* SSA § 1860D-12(b)(8).

As CMS considers incorporating 340B-related transactional data from 340B covered entities or their TPAs into the MTF processes, Novartis urges CMS to mandate the provision of the data described above, by making such provision of data a prerequisite to triggering the prompt MFP payment window.

Absent CMS mandating the provision of the data described above, and absent CMS defining the start of the prompt MFP payment window as the date on which the manufacturer has received complete MFP eligibility validation data, including data showing whether the unit is or is not a 340B unit, any enforcement at the end of the prompt MFP payment window raises significant legal concerns because, at that point in time, it will not be knowable whether (1) the unit is subject to the 340B ceiling price or the MFP and therefore, (2) the manufacturer must pay the full MFP rebate or only the non-duplicated amount, consistent with the statutory non-duplication guarantee.

We note that, if CMS fails to mandate the provision of the data described above, it is imperative that the agency provide for an enforceable claw back mechanism under which a manufacturer can readily recover the MFP in the event that a covered entity receives a lower 340B ceiling price on the same unit after the payment of the MFP.

CMS should limit public disclosure of information in Primary Manufacturer plans for effectuating the MFP to those elements necessary for dispensers to receive MFP rebates and should provide more clarity on how it plans to review manufacturer plans.

While we understand that many stakeholders should have access to certain information contained in manufacturer plans to effectuate the MFP, Novartis is concerned that proprietary information such as claim validation methodology and reasonable assumptions could be made public and used by other stakeholders. Manufacturers should be able to designate information in their plans that is confidential, consistent with existing Freedom of Information Act ("FOIA") standards and the specific confidentiality provision contained in the IRA itself at Section 1193(c), with only non-designated information being made available to the public. Such an approach would ensure CMS's proposed approach for effectuating MFP access is not inconsistent with statutory protections for manufacturer proprietary and confidential information.

CMS should develop robust complaints and disputes processes, including associated timelines.

Novartis appreciates CMS's intent to establish a centralized intake system for complaints and disputes related to MFP availability and the MTF functionality. However, we are concerned about the lack of specificity and clear timelines provided for resolution. We recommend that CMS look to existing dispute resolution processes such as those that work well for the CGDP[27] and the Tricare Retail Refund Program.[28] Specifically, the CGDP and the Tricare Retail Refund Program allow manufacturers to file an initial dispute with CMS within 60 or 70 days of receiving the information that is the subject of the dispute. Sixty days would be a reasonable timeline for a Primary Manufacturer to initiate a dispute under the DPNP after receiving data from the MTF. Dispensers should also be held to the same timeline of 60 days from when they were due an MFP payment to initiate a dispute. Sixty days would also be a reasonable timeframe for CMS to issue a decision upon initiation of the dispute.

Additionally, CMS should establish a dispute mechanism that allows for a correction to payment amounts based on additional validation that is performed or additional data that are received after a payment has been made. Should a discrepancy be identified after a Primary Manufacturer makes payment, this would allow for an opportunity for reconciliation and would align with processes provided by all commercial and government payers for post-payment reconciliation. CMS should also provide a mechanism for the manufacturer to claw back an overpayment in instances in which a dispute resolution finds that the Primary Manufacturer was *not* obligated to provide the MFP or to provide a lesser MFP amount.

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[27] Medicare Coverage Gap Discount Program Agreement, Section V, Audit and Dispute Resolution (2010), *available at:* https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/downloads/ManuAgreement.pdf.
[28] Tricare Retail Refund Program, Section 7 (Sept. 2022), *available at:* https://health.mil/Reference-Center/Publications/2023/06/12/Manufacturer-Policy-and-Procedure-Guide.

Novartis appreciates the opportunity to comment on CMS's draft guidance regarding the DPNP and MFP effectuation in 2026 and 2027. We welcome the opportunity to answer any questions you may have about the information provided above. Please contact me at courtney.piron@novartis.com.

Sincerely,

Courtney Piron
Head, US Public Affairs

July 2, 2024

VIA ELECTRONIC FILING TO: IRARebateandNegotiation@cms.hhs.gov
Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
PO Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Novo Nordisk Comments on Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani,

Novo Nordisk Inc. (Novo Nordisk) appreciates the opportunity to provide comments in response to the memorandum issued by the Centers for Medicare & Medicaid Services (CMS, the Agency), entitled Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter, the Guidance).

Novo Nordisk is a global health care company committed to improving the lives of those living with serious chronic conditions, including diabetes, rare bleeding disorders, growth disorders, and obesity. The Novo Nordisk Foundation, our majority stakeholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and sustainability of society.

Novo Nordisk is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA). We are supportive of their comments and incorporate them here by reference. In addition, we'd like to specifically underscore our concerns with the following key areas addressed in the Guidance:

- *Negative implications of CMS' interpretation of Qualifying Single Source Drug (QSSD)*
- *Harmful impact of CMS' price setting and "single MFP" approach on incentives for future discovery*
- *Formulary management practices on selected drugs and access risks for Part D beneficiaries*
- *Need for a more streamlined MFP effectuation process across the supply chain*

I. CMS' decision to aggregate products subject to price controls violates the text of the Inflation Reduction Act (IRA) and will undermine efforts to discover new treatments for unmet needs.

CMS' approach circumvents the IRA's requirements for which products are subject to price controls under the Medicare Drug Price Negotiation Program.

The IRA limits the number of products that CMS is permitted to subject to price controls. It authorizes CMS only to regulate individual drug or biological products, and requires that a drug or biological product be marketed for a minimum number of years before it can be subject to CMS-imposed price controls. The statute makes clear that a product is not subject to price controls if it is either (1) "a drug that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval; for which, as of the selected drug publication date with respect to such initial price applicability year, *at least 7 years will have elapsed since the date of such approval*" [emphasis added] or (2) "a biological product that is licensed under section 351(a) of the Public Health Service Act and is marketed under section 351 of such Act for which, as of the selected drug publication date with respect to such initial price applicability year, *at least 11 years will have elapsed since the date of such licensure"* [emphasis added].[1]

Despite the statute's plain language, CMS has tried to expand its authority to impose price controls not on a limited number of individual products, but rather (1) "for drug products, all dosage forms and strengths of the drug with the *same active moiety* and the same holder of a New Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs*…" [emphasis added] and (2) "for biological products, all dosage forms and strengths of the biological product with the *same active ingredient* and the same holder of a Biologics License Application (BLA), *inclusive of products that are marketed pursuant to different BLAs"* [emphasis added].[2] Rewriting the statutory requirements and the products subject to price controls, CMS has indicated that it "will use the earliest date of approval or licensure of the initial Food and Drug Administration (FDA) application number assigned to the NDA/BLA holder for the active moiety/active ingredient" to determine the date of approval or licensure for a potential QSSD.[3]

As stated in our comment letter on CMS' draft guidance for IPAY 2026,[4] Novo Nordisk opposes these improper changes to the statutory requirements. The Agency's approach is contrary to the IRA's plain language and circumvents the limits imposed by Congress on which products are properly subject to price controls. The IRA's price-control provisions do not contemplate

[1] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1839 (August 16, 2022).
[2] Seshamani, M. (Center for Medicare, Centers for Medicare & Medicaid Services, Baltimore, MD). Letter to: Interested Parties re: the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. 2024 May 3. IPAY 2027 Draft Guidance at 8.
[3] IPAY 2027 Draft Guidance at 10.
[4] Novo Nordisk, Inc. (Plainsboro, NJ). Letter to: Meena Seshamani (Center for Medicare, Centers for Medicare & Medicaid Services, Baltimore, MD). 2023 Apr 14. Comment letter on Draft IPAY 2026 Guidance.

aggregating broad groupings of drug products for price controls, nor do they mention the terms "active moiety" or "active ingredient" anywhere in the text. However, the IRA statute *does* clearly impose a time on market requirement, which the Guidance willfully ignores.

By aggregating all drugs or biologicals across NDAs or BLAs that have the same active moiety or active ingredient and focusing on the earliest date of approval of any such product in the group, distinct new drug or biological products that would otherwise not be eligible for price controls are wrongfully swept into the process and subject to an MFP, potentially even at launch. CMS' approach violates the letter, purpose, and spirit of the IRA. As explained further below, this will cause irreparable harm to patients who will have access to fewer life-saving and life-sustaining drugs because it will no longer be viable for manufacturers to invest in research and development for an active moiety or active ingredient beyond the initial approval of a product that contains that active moiety or active ingredient.

In the absence of relevant statutory language, CMS tries to justify its overbroad interpretation by looking to Section 1192(d)(3)(B) and the "Use of Data" provision. That provision indicates that "the Secretary shall use data that is aggregated across dosage forms and strengths" in determining which products to subject to price controls. But that provision only permits CMS to aggregate against dosage forms and strengths after identifying which products are subject to price controls and does not permit CMS to aggregate by other product characteristics.

CMS' approach erroneously paints all post-approval research with the same broad brush.

As written in the "Summary of Public Comments on the Initial Medicare Drug Price Negotiation Program Memorandum and CMS' Responses" in the finalized guidance for IPAY 2026, CMS justifies its approach to aggregating products as a solution to so-called "product hopping."[5] While we reject the premise that the Department of Health and Human Services (HHS) uses in seeking to identify "product hopping," HHS nonetheless defines it as an "anti-competitive practice" that "occurs when a brand manufacturer makes a minor change to its product before a generic competitor enters…"[6] The Federal Trade Commission has also sought to characterize "product hopping" as "modest non-therapeutic changes to a product that offer little or no apparent medical benefit to consumers…"[7] In its finalized guidance for IPAY 2026, CMS rationalizes its sweeping approach using the "Use of Data" provision by claiming that its interpretation will reduce product hopping.[8]

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[5] Seshamani, M. (Center for Medicare, Centers for Medicare & Medicaid Services, Baltimore, MD). Letter to: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. 2023 Jun 30. IPAY 2026 Final Guidance at 11.

[6] Office of the Assistant Secretary for Planning and Evaluation. Medicare Drug Price Negotiation Program: Understanding Development and Trends in Utilization and Spending for the Selected Drugs [Internet]. Washington, DC: US Department of Health and Human Services; 2023 Dec 14 [cited 2024 Jun 30]. Available from: https://aspe.hhs.gov/sites/default/files/documents/4bf549a55308c3aadc74b34abcb7a1d1/ira-drug-negotiation-report.pdf

[7] Federal Trade Commission. Report on Pharmaceutical Product Hopping [Internet]. Washington, DC: Federal Trade Commission; 2022 Oct [cited 2024 Jun 30]. Available from: https://www.ftc.gov/system/files/ftc_gov/pdf/p223900reportpharmaceuticalproducthoppingoct2022.pdf

[8] IPAY 2026 Final Guidance at 11.

However, CMS' purported rationale for aggregating products based on "active ingredient/moiety" *undermines* competition by discouraging future investment in the scientific discovery of treatments for new patient populations, therapeutic areas, and conditions. Conducting post-approval research into new treatment areas – and the substantial investment of time and money that this entails – is distinctly different than "modest non-therapeutic" changes to a product that the Agency suggests would impede generic competition. Additionally, preserving manufacturer incentives to invest in new disease areas and subpopulations after an initial approval does not preclude generic manufacturers from market entry for the original use. To the contrary, it expands patient choice and access to medicines that could provide a therapeutic benefit for conditions with significant unmet needs.

CMS' rationale also ignores the fact that treatments with the same active ingredient are often researched and approved for completely different patient populations, new diseases, and distinct therapeutic areas relative to the original indication. These separate treatments often require new FDA applications altogether, resulting in a substantial financial investments and the development of unique clinical trial programs – again, changes that go far beyond "modest non-therapeutic changes" with "little or no medical benefit." CMS' unlawful approach paints all post-approval research with the same broad brush, leading to a gross over-correction that will have a chilling effect on incentives for ongoing scientific discovery. Subjecting multiple drugs that have been wrongfully grouped together to the same MFP—even if they are distinct and provide different health benefits to different patient populations—will harm patients the most by depriving them of future treatments that never had a chance to be developed in the first place.

CMS' approach will discourage post-approval drug research by prematurely cutting off the continuum of drug discovery and development.

CMS' approach to aggregating distinct drug and biological products will have significant downstream implications on the development of new treatments by curbing incentives to invest in the discovery of new products that share a similar active moiety or active ingredient with a selected product. As has been widely documented in peer-reviewed literature,[9] the drug development process is a multi-faceted, complicated, and risky undertaking that does not conclude once a drug receives its initial regulatory approval. Scientists, researchers, and others employed by manufacturers work tirelessly for years and sometimes decades—all without a guarantee of success—to discover and develop drugs with the goal of improving health for patients. After approval, as a drug is prescribed and used by patients in "real world" settings, new data are often generated about safety, efficacy, and potential new uses. If a drug or biological product shows promise in a new disease area or patient population, a manufacturer may decide to pursue additional clinical testing, making investments into continued development of the drug. Such investments are a ubiquitous part of the lifecycle of beneficial pharmaceutical

[9] See, e.g., DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ [Internet]. 2016 May [cited 2024 Jun 30];47:20-33. Available from: https://www.sciencedirect.com/science/article/pii/S0167629616000291

innovation. An analysis of all new molecular entities launched in the United States between 2003 and 2011 found that approximately 60 percent were approved for multiple uses, many of which were vastly different from one another.[10] Another more recent study found that for more than half of all small molecule medicines approved from 2006 through 2012—many of which treat serious chronic diseases—manufacturers engaged in additional research that led to additional approved uses.[11]

This type of continued research and progress is far from linear; rather, it is a series of starts and stops as a drug is tested in new conditions and patient populations, in search of successive breakthroughs informed by the insights that came before. Often, promising lines of scientific inquiry end up in dead ends with significant sunk and lost costs. As noted by the Congressional Budget Office, only around 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA, and the process can take a decade or more during which a manufacturer will not see a return on the investment.[12] Additionally, a recent study found that for every medication that advances to human testing, 90 percent still fail during phase I, II, and II clinical trials.[13] Including drug candidates in the preclinical stage would increase the failure rate to even higher than 90 percent.[14]

Despite these odds, manufacturers continue to invest in additional research and clinical trials to uncover new discoveries long after an active moiety or active ingredient's first approval. Before making these extraordinary investments, manufacturers consider a range of factors, including the magnitude of resource investment required, the risks involved, the likelihood of gaining approval in a new therapy area or among a new patient population, and the benefits to patients of a new therapy or cure. Resource investments are often significant – the median Phase III clinical trial alone costs more than $40,000 per enrolled patient[15] with an average cost of approximately $138 million[16] depending on the patient population, with widely varying costs. For each potential new indication, manufacturers must fund a new set of large studies to demonstrate safety and efficacy. These trials often enroll tens of thousands of patients and often take between three and six years to complete. They also have lower probabilities of success than

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[10] Ciarametaro M, Abedi S, Sohn A, Ge CF, Odedara N, Dubois R. Concerns around budget impact thresholds: Not all drugs are the same. Value Health [Internet]. 2017 Feb [cited 2024 Jun 30];20(2):230-3. Available from: https://www.sciencedirect.com/science/article/pii/S1098301516341717

[11] Partnership for Health Analytic Research. Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines [Internet]. Cambridge, MA: Partnership for Health Analytic Research; 2023 Jun [cited 2024 Jun 30]. Available from: https://www.pharllc.com/wp-content/uploads/2023/05/Implications-of-the-IRA-on-Post-Approval-Small-Molecules-2006-2012_Final.pdf

[12] Austin D, Hayford T. Research and Development in the Pharmaceutical Industry [Internet]. Washington, DC: Congressional Budget Office; 2021 Apr [cited 2024 Jun 30]. Available from: https://www.cbo.gov/publication/57126

[13] Sun D, Gao W, Hu H, Zhou S. Why 90% of clinical drug development fails and how to improve it?. Acta Pharm Sin B [Internet]. 2022 Jul [cited 2024 Jun 30];12(7):3049-62. Available from: https://www.sciencedirect.com/science/article/pii/S2211383522000521

[14] Ibid.

[15] Moore TJ, Zhang H, Anderson G, Alexander GC. Estimated costs of pivotal trials for novel therapeutic agents approved by the US Food and Drug Administration, 2015-2016. JAMA Intern Med [Internet]. 2018 Nov [cited 2024 Jun 30];178(11):1451–7. Available from: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2702287

[16] Stengel K, Von Eisenberg M, Brantley K, Frazier, L. An Assessment of Regulatory Interpretation of Qualifying Single-Source Drugs in Medicare Negotiation [Internet]. Washington, DC: Avalere Health; 2024 Apr 22 [cited 2024 Jun 30]. Available from: https://avalere.com/wp-content/uploads/2024/04/202404119_Avalere_Novo_IRA-QSSD-White-Paper_Final_Update-002.pdf

trials for initial indications. However, the prospect of all future treatments being assigned an MFP immediately upon FDA approval will severely alter the risk/reward calculus that goes into such investment decisions.

In general, the effects of the IRA (specifically, its Medicare negotiation provisions) on research and development into innovative therapies will be negatively disruptive with real consequences for patients in the form of fewer lifesaving and life-sustaining treatments. One study has quantified this impact, estimating that over the next ten years, 139 drugs are at risk of not being developed, amounting to 40 percent fewer new drugs brought to market than if the program were not in effect.[17] Researchers at the University of Chicago found that IRA policies will decrease manufacturer research and development spending by $663 billion by 2039.[18] Yet another study used lessons learned from economies that engage in price setting to conclude that the IRA would cut the number of new products launched in the US by between 29 and 44 percent.[19]

Certainly, the effects of the IRA in totality on research and development will be distortionary, but that was a policy judgment made by Congress. CMS attempts to exacerbate this dynamic through its improper Guidance, leaving patients with even fewer options. These actions could result in a new treatment being subject to an MFP immediately upon FDA approval, discouraging manufacturers from conducting research into expanded uses of a drug beyond its initial approval. A recently published series of case studies reviewing drugs originally approved to treat chronic diseases, rare diseases, and cancer illustrated the potential impact of CMS' approach to aggregation on patient access to new treatment options. The analysis showed that of the six drugs examined, 15 separate NDAs/BLAs were approved after the initial approvals. The new applications included therapies to treat chronic diseases with millions of addressable patients, in addition to new populations with rare or pediatric conditions.[20] One case study for a product that was originally approved for a type of cancer showed that three additional applications were approved *after* it would have been eligible for selection. This includes one application for a treatment that addresses a rare, pediatric population.[21]

With its Guidance, CMS effectively sets a price for all current and future applications of an active moiety or an active ingredient. In so doing, it prematurely cuts off the continuum of discovery and development to the detriment of patients who will be deprived of new treatments, many of whom live with conditions for which there are no good treatment options and substantial unmet

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[17] Gassull D, Bowen H, Schulthess D. IRA's Impact on the US Biopharma Ecosystem [Internet]. Washington, DC: Vital Transformation; 2023 Jun 1 [cited 2024 Jun 30]. Available from: https://vitaltransformation.com/2023/05/iras-impact-on-the-us-biopharma-ecosystem/

[18] Philipson TJ, Durie T. Issue Brief: The Impact of HR 5375 on Biopharmaceutical Innovation and Patient Health [Internet]. Chicago, IL: University of Chicago; 2021 Nov 29 [cited 2024 Jun 30]. Available from: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf

[19] US Chamber of Commerce Global Innovation Policy Center. The True Cost of Price Controls: Patient Access Report 2024 [Internet]. Washington, DC: US Chamber of Commerce; 2024 Jan 31 [cited 2024 Jun 30]. Available from: https://www.uschamber.com/assets/documents/GIPC-2024-Patient-Access-Report.pdf

[20] Stengel K, Von Eisenberg M, Brantley K, Frazier, L. An Assessment of Regulatory Interpretation of Qualifying Single-Source Drugs in Medicare Negotiation [Internet]. Washington, DC: Avalere Health; 2024 Apr 22 [cited 2024 Jun 30]. Available from: https://avalere.com/wp-content/uploads/2024/04/202404119_Avalere_Novo_IRA-QSSD-White-Paper_Final_Update-002.pdf

[21] Ibid.

medical need. Novo Nordisk strongly urges CMS to revise its approach as the Agency finalizes the IPAY 2027 Guidance to ensure consistency with the statute and to mitigate the unintended consequences of government price setting on drug development, and patients who rely on it.

II. CMS' approach to setting the MFP will jeopardize scientific progress, particularly in the treatment and prevention of chronic diseases which most impact population health.

By setting "a single MFP" across a selected drug's active moiety or ingredient, CMS undervalues drugs that bring significant benefits to patients.

As articulated above in Section I of this comment letter and in our comments on the guidance for IPAY 2026,[22] Novo Nordisk believes that CMS has improperly violated the statute's plain language by aggregating products containing the same active moiety or active ingredient and subjecting all of the different products to price controls. Compounding this problem is CMS' interpretation of the statutory language that it must set a "single price for a selected drug with respect to its price applicability period"[23] across the active moiety or active ingredient of the selected drug, even though that price would apply to treatments for entirely different disease areas or patient populations, potentially with vastly different (and differently priced) treatment alternatives. In the first step of the MFP setting process, CMS asserts that it will identify therapeutic alternatives for each selected drug per indication.[24] Though CMS provides a brief discussion about how it will approach selected drugs for which there are multiple therapeutic alternatives,[25] the Guidance language is ambiguous as to whether CMS intends to apply the approach within a single indication *only* or more broadly. Put differently, CMS states that it will consider the full range of net prices for therapeutic alternatives as well as the Medicare "utilization of each therapeutic alternative relative to the selected drug,"[26] implying a volume-weighted approach to arrive at the starting point. It does *not,* however, clarify whether its approach will also apply *across* multiple indications within the active moiety or active ingredient.

Though it is yet unclear whether the Agency will do so, several peer-reviewed articles have suggested that CMS intends to extend this volume-weighting approach across indications within the active moiety or active ingredient to develop the starting point.[27] If that is the case, Novo Nordisk is concerned that such an approach would significantly and arbitrarily undervalue a drug with multiple approved uses, for several reasons:

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[22] Novo Nordisk, Inc. (Plainsboro, NJ). Letter to: Meena Seshamani (Center for Medicare, Centers for Medicare & Medicaid Services, Baltimore, MD). 2023 Apr 14. Comment letter on Draft IPAY 2026 Guidance.
[23] IPAY 2027 guidance at 70.
[24] IPAY 2027 guidance at 81.
[25] IPAY 2027 guidance at 83.
[26] Ibid.
[27] See, e.g., Lin JK, Barnes JI, Doshi JA. The Medicare Drug Price Negotiation Program: Considerations for therapeutic alternatives. Health Aff Forefront [Internet]. 2023 Jul 18 [cited 2024 Jun 30]. Available from: https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiation-program-considerations-therapeutic-alternatives

- *Utilization may be wholly disconnected from the value a drug brings to patients living with a particular condition.* A drug may provide significant clinical benefit to patients with a certain disease though its overall use is low; that is the case, for example, with drugs that treat rare diseases, which by the US definition affect fewer than 200,000 people. On the other hand, therapies that provide little health benefit to patients may be overprescribed, as evidence suggests may be the case with self-administered antibiotics for upper respiratory infections.[28] In the case of opioids, high utilization may even be commensurate with increased patient harm.[29]

- *Volume weighting inappropriately devalues recently approved products and indications within a selected drug's active moiety or active ingredient, though they may bring significant improvements in health outcomes.* CMS' faulty approach to aggregating different drug and biological products means that products or indications that fall within the selected drug's active moiety or active ingredient that are *recently approved* are subject to price controls. Such products have not spent the requisite 7 years (for products approved via an NDA) or 11 years (for products approved via a BLA) on the market and thus may not have reached full market potential as reflected by utilization data. A volume weighted approach would thus skew the starting point for the entire active moiety or active ingredient.

- *Utilization changes over time and there are no apparent opportunities for adjustment after the MFP-setting process concludes.* Once an MFP is set, there are few opportunities for adjustments. According to Section 60.6 of the Guidance, the MFP will be adjusted based on inflation annually, or potentially renegotiated if the Secretary determines that "material changes" have occurred. In the absence of program guidance on renegotiation, however, it is unclear whether significant changes in utilization will constitute a "material change." Regardless of whether renegotiation is "triggered" or not, the existing MFP will have set an artificial reference point that is disconnected from the value the drug brings to patients.

- *Accurate volume weighting across indications is operationally challenging because Prescription Drug Event (PDE) data does not provide insight into the condition for which a drug was prescribed.* If CMS relies on PDE utilization data (as it states that it will throughout its explanation of the MFP-setting process in the Guidance), CMS will be unable to directly correlate it with the condition or indication for which health care providers prescribe a drug, which could lead to an incorrect assessment of actual utilization by indication. This would occur, for example, if a drug with a single National Drug Code (NDC) were indicated for two or more conditions.

Importantly, a single MFP will significantly devalue drugs that are deemed to be part of the active moiety or active ingredient *and that are currently in clinical development for a new use*. In Section

[28] Mafi JN, Reid RO, Baseman LH, Hickey S, Totten M, Agniel D, Fendrick AM, Sarkisian C, Damberg CL. Trends in Low-Value Health Service Use and Spending in the US Medicare Fee-for-Service Program, 2014-2018. JAMA Netw Open [Internet]. 2021 Feb 16 [cited 2024 Jun 30];4(2):e2037328. Available from: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776516
[29] Ibid.

60.5.1, CMS states that if a manufacturer of a selected drug receives approval under a new NDA or BLA that is deemed to be within the active moiety or active ingredient or a supplement to an existing NDA or BLA of the selected drug *after* drug selection, the MFP will *apply at launch*. That is flatly contrary to the statutory requirements, for all the reasons explained in Section I of this letter. Though the statutory language of the IRA specifies that the approval of a new indication would constitute a "material change" and thus trigger renegotiation,[30] CMS has yet to release guidance on program implementation of the renegotiation process. Renegotiation is also not statutorily permitted until 2028. Therefore, absent any additional guidance on renegotiation, and at the very least until after 2028, none of the data about the 1194(e)(1) or 1194(e)(2) factors for the drug's new use will be reflected in the MFP. Critically, neither will the net prices of its therapeutic alternatives. This is a serious flaw in CMS' MFP-setting approach that will undercut the value of selected drugs with multiple indications and/or ongoing clinical development programs.

To illustrate the flaws of this approach, consider the following scenario: Drug X is a selected drug for a given IPAY before 2028 the MFP of which is set based on therapeutic alternatives in a highly competitive class of drugs with many treatment options and relatively low net prices. CMS makes no upward adjustment for 1194(e)(2) factors. Following the conclusion of the negotiation process and effective date of the MFP, the manufacturer of Drug X receives approval under a new NDA for a drug that CMS considers to contain the selected drug's active moiety. This new drug treats a disease that disproportionately affects the Medicare population, meets a serious unmet medical need, and has one therapeutic alternative the list price of which is significantly higher than those that formed the basis of Drug X's MFP starting point considering the data from the drug's initial indication. In this scenario, the price for the new drug that CMS considers to be part of an aggregated group of products containing the same active moiety would be entirely divorced from the value it brings to patients. This scenario and others like it directly impact manufacturer decisions to invest in research and development into new conditions and populations for drugs that have already been approved.

An MFP that is not rooted in the patient perspective could threaten access to critical therapies.

Throughout Section 60.3 of the Guidance, CMS outlines how it will solicit patient experience information during the MFP setting process, noting that for IPAY 2027, it will be reformatting the events during which it will collect such feedback from patients. While this is an important first step, the changes suggested by the Agency in the Guidance do not go far enough. The process of establishing an MFP should not be a strictly academic exercise; patients' or caregivers' assessments of the value a drug brings to the overall experience of managing their disease or condition can be easily overlooked in a subjective review of available clinical research. At the same time, patient input cannot be tangential to the price setting process or collected arbitrarily. The patient perspective must be integrated into the MFP in a *systematic* way. Otherwise, the real-

[30] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1848 (August 16, 2022).

world experiences of patients living with and managing a particular disease or condition will not be appropriately captured, and selected drugs will be consistently undervalued in the process.

- *Patient preferences must drive which factors CMS considers most important when setting an MFP for a selected drug.* CMS is required to consider a long list of factors as prescribed in the IRA statute when arriving at the MFP. However, as the Agency acknowledges in Section 50 of the Guidance, it has discretion as to the sources it uses to inform its decision-making on the 1194(e)(2) factors.[31] Patients should serve as an essential source of information for CMS on the overall value of selected drugs, the most appropriate treatment alternatives, and the factors that should be prioritized based on their individual experiences living with the disease(s) or condition(s) the selected drug treats.

- *Patient input must be reflected quantitatively in the MFP.* As CMS' MFP setting methodology retains "flexibility" by design, the Agency should have the ability to channel patient experience information directly into its adjustments of the MFP's starting point – for example, by adding an upward adjustment for selected drugs that are valued higher by patients over their therapeutic alternatives. This is critical to ensure that patient outcomes not captured in formalized literature reviews or other sources (e.g., patient quality of life, caregiver perspectives, factors that impact health equity, etc.) but which CMS nonetheless cites as important in the Guidance are fully incorporated into the MFP.

In totality, the IRA's price-setting scheme will threaten discovery of future treatments and cures, particularly those for serious chronic diseases that affect population health.

A series of layered policy choices, reflected not in the IRA's statutory text but in CMS' attempt to rewrite that text through the Guidance, are likely to have a disproportionate impact on incentives for research into products approved under an NDA, which tend to be small molecule products that treat serious chronic diseases. Investment into new treatments for chronic diseases is already on the decline – a recent analysis by the National Academies of Sciences, Engineering, and Medicine of the drugs in development in 2021 (before passage of the IRA) found that relatively small percentages of products were in development for indications encompassing prevalent chronic diseases (e.g., neurology at 12 percent, endocrine/metabolic conditions at 6.4 percent and cardiovascular indications at 3.8 percent).[32]

[31] IPAY 2027 Guidance at 65.

[32] March A, Gee AW, Pool R, Shore C. Innovation in Drug Research and Development for Prevalent Chronic Diseases [Internet]. Proceeings of a workshop hosted by Forum on Drug Discovery, Development, and Translation, Board on Health Sciences Policy, Health and Medicine Division, National Academies of Sciences, Engineering, Medicine. 2021 Feb 22, Mar 1, Mar 8; virtual. Washington, DC: National Academies Press; 2021. Available from: https://nap.nationalacademies.org/catalog/26291/innovation-in-drug-research-and-development-for-prevalent-chronic-diseases

Serious chronic diseases are responsible for 7 in 10 deaths each year in the US[33] and are the primary reason for Americans having a lower life expectancy when compared to peer nations.[34] Despite such diseases causing significant morbidity and mortality and accounting for 90 percent of the annual health care expenditures,[35] policymakers have shifted focus away from tackling these public health threats in favor of funding other priorities. Despite this deprioritization, pharmaceutical discoveries resulting from over a century of investments in research and development have had a significant impact on patients' health outcomes and quality of life. One recent study found that medicines were responsible for more than a third of the improvement in life expectancy from 1990 to 2015,[36] with many of these gains coming from advancements in the treatment of chronic diseases impacting mortality. For example, the study found that 52 percent of improvements in mortality for patients with heart disease were attributable to pharmaceutical innovations.[37] Due in large part to the development of more effective medicines, diseases – especially chronic diseases – that once were considered death sentences are now able to be treated and managed, improving patients' quality of life and reducing the economic burden on the health care system.

By aggregating products containing the same active ingredient or active moiety, CMS has arbitrarily disadvantaged small molecule products with a differentiated time requirement for negotiation eligibility for products approved under an NDA (7 years) versus a BLA (11 years). Early signs about manufacturer responses to this policy change indicate that they are looking to discontinue projects or reprioritize clinical programs away from small molecule drugs.[38] The impact of CMS' approach thus fundamentally changes manufacturer considerations about investments into post-approval research and is incompatible with the long term focus necessary to uncover scientific breakthroughs and an understanding of new disease pathways. And CMS' approach to setting the MFP, as discussed above, is an inadequate model for appropriately defining value for drugs that have multiple uses, which tend to be small molecule drugs, further eroding incentives for investment into research and development.

These policy choices will jeopardize additional medical progress to treat and prevent chronic diseases by forcing manufacturers to reassess how they invest in research and development. This could eventually lead to access challenges for patients similar to those faced by patients in other

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[33] CDC Foundation. Safeguarding Americans' Health [Internet]. Atlanta, GA: CDC Foundation; 2024 [cited 2024 Jun 30]. Available from: https://www.cdcfoundation.org/safeguarding-americans-health

[34] Achenbach J, Keating D, McGinley L, Johnson A, Chikwendiu J. An Epidemic of Chronic Illness is Killing Us Too Soon. Washington Post [Internet]. 2023 Oct 3 [cited 2024 Jun 30]. Available from : https://www.washingtonpost.com/health/interactive/2023/american-life-expectancy-dropping/

[35] Benavidez GA, Zahnd WE, Hung P, Eberth JM. Chronic disease prevalence in the US: Sociodemographic and geographic variations by zip code tabulation area. Prev Chronic Dis [Internet]. 2024 Feb 29 [cited 2024 Jun 30];21:230267. Available from: https://www.cdc.gov/pcd/issues/2024/23_0267.htm

[36] Buxbaum JD, Chernew ME, Fendrick AM, Cutler DM. Contributions of public health, pharmaceuticals, and other medical care to US life expectancy changes, 1990-2015. Health Aff [Internet]. 2020 Sep [cited 2024 Jun 30];39(9):1546-56. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.00284?journalCode=hlthaff

[37] Ibid.

[38] See, e.g., Becker Z. Genentech CEO Alexander Hardy warns of 'unintended consequences' from the Inflation Reduction Act. Fierce Pharma [Internet]. 2023 Jul 6 [cited 2024 Jun 30]. Available from: https://www.fiercepharma.com/pharma/genentech-ceo-alexander-hardy-unintended-consequences-inflation-reduction-act

countries that have enacted similar policies. Many European and OECD countries have been setting prices of medicines to lessen budgetary pressures since the 1980s. Such regulation has resulted in access to fewer new medications at a slower pace in these countries as compared to the US. Of all new medicines launched globally between 2012 and 2021, 85 percent of new medicines launched are available in the US while only 52 percent are available in France, 45 percent in Canada, and 34 percent in Australia.[39] Additionally, on average, new medicines launch in the US within four months of first global launch as compared to the OECD average of 21 months.[40]

III. CMS should consider current Part D market dynamics that may disproportionately impact patients taking heavily rebated drugs and take steps to ensure patient access to selected drugs is not impeded.

Part D market dynamics may disproportionately impact patients taking heavily rebated drugs.

In the draft Guidance for IPAY 2027, CMS expressed concern that Part D Plan sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing them on less favorable tiers compared to non-selected drugs, or by applying formulary and utilization management practices to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs. Such perverse outcomes, i.e., when plans give preferred formulary placement to products with higher list prices over lower-priced competitors, are more likely to occur in classes with high manufacturer rebates. Unfortunately, in the 2024 Medicare Advantage and Part D Final Rule,[41] CMS chose to interpret federal statute in a way that ranked selected drugs based on gross drugs costs (which exclude rebates) rather than net drug costs, increasing the likelihood that highly rebated drugs will be selected for negotiation and intensifying the risk of formulary access barriers. Below, we summarize these concerns in greater detail and urge the Agency to consider the unintended consequences of setting an MFP on highly rebated drugs that are already heavily negotiated in the Part D market today. Additionally, CMS should take additional steps to ensure that patient access to selected drugs is not impeded.

As the Agency is aware, research has consistently shown that plans tend to prefer highly rebated products over lower priced alternatives, given the impact of rebates on keeping plan liability and premium pressure low. A recent Government Accountability Office report highlighted that "Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which

[39] Pharmaceutical Research and Manufacturers of America. Global Access to New Medicines Report [Internet]. Washington, DC: Pharmaceutical Research and Manufacturers of America; 2023 Apr 11 [cited 2024 Jun 30]. Available from: https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report
[40] Ibid.
[41] Centers for Medicare & Medicaid Services. Medicare Program; Contract year 2024 policy and technical changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and programs of all-inclusive care for the elderly. Final rule. Fed Regist. 2023 Apr 12;88(70):22120-345.

generally had lower rebates."[42] A more recent paper argued that the same dynamic was likely to play out as a result of IRA policies, indicating that "drugs in the Medicare Price Negotiation Program will be at a disadvantage in Part D plans because their lack of manufacturer rebates and discounts will mean lower profits for plans and more pressure on premiums relative to competitors."[43] And in the recently released Board of Trustees Report for 2024, the authors note that in the Part D program, "many of the gains from negotiated prices and lower trends are initially more than offset by increased benefits and decreased manufacturer rebates."[44]

This dynamic can perpetuate a cycle of perverse outcomes for patients, specifically when plan preferences for highly rebated products (and higher list prices) result in greater out-of-pocket (OOP) spending for beneficiaries. Barriers to access may also result as insurers and pharmacy benefit managers (PBMs) seek to drive utilization to products with higher rebates by adding prior authorization, adverse tiering, and utilization management practices that interfere with patient and provider choice.

Recent history within Medicare Part D demonstrates that this not a purely theoretical concern. In 2020, the drugmaker Viatris launched the biosimilar Semglee® at a substantially lower wholesale acquisition cost (WAC) than its reference product, Lantus®. After realizing very modest formulary uptake, Viatris launched a higher priced version of Semglee®, with the flexibility to offer manufacturer rebates to plans and PBMs. The relaunch of Semglee® at a higher WAC resulted in greater formulary access and increased market volume.[45] Novo Nordisk observed similar trends with our own unbranded biologic for NovoLog®, which launched at a 50 percent reduction from the branded list price to address policymaker interest in lower list prices and to provide an additional option to lower OOP costs for some patients. Plan uptake of the unbranded version was tepid. In 2023, formulary access of the insulin aspart unbranded biologic stood at 4 percent, while it was 58 percent for branded NovoLog®.[46]

To be sure, the opportunity for plans to collect rebates on higher priced options remains a key driver behind these coverage trends. Reporting has shown that a significant portion of revenue from vertically integrated insurers/PBMs/group purchasing organizations (GPOs) is driven by rebates and fees. In the insulin class alone, PBM rebates increased by 154.6 percent between 2014 and 2018, with a concurrent 30.8 percent reduction in net prices received by manufacturers

[42] Government Accountability Office. CMS Should Monitor Effects of Rebates on Drug Coverage and Spending: Statement of John E. Dicken, Director, Health Care Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives [Internet]. 2023 Sep 19 [cited 2024 Jun 30]. Available from: https://www.gao.gov/assets/gao-23-107056.pdf

[43] Kelly, C. Medicare-Negotiated Drugs May Not Get Favorable Coverage In Part D: Will CMS Intervene? [Internet]. Pink Sheet. 2024 Apr 16 [cited 2024 Jun 30]. Available from: https://pink.citeline.com/PS150091/Medicare-Negotiated-Drugs-May-Not-Get-Favorable-Coverage-In-Part-D-Will-CMS-Intervene

[44] Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (Washington, DC). Letter to: Mike Johnson (Speaker of the House of Representatives, Washington, DC) and Kamala D. Harris (President of the Senate, Washington, DC) [Internet]. 2024 May 6. Sending the 2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. Available from: https://www.cms.gov/oact/tr/2024

[45] Fein AJ. How Health Plans Profit—and Patients Lose—From Highly Rebated Brand-Name Drugs [Internet]. Philadelphia, PA: Drug Channels Institute; 2019 Feb 20 [cited 2024 Jun 30]. Available from : https://www.drugchannels.net/2019/02/how-health-plans-profitand-patients.html

[46] Novo Nordisk internal data on file.

over the same period.[47] At the same time, patients continued to struggle to pay for insulin because these rebates were not being applied to their OOP costs at the pharmacy counter.

Unfortunately, price-setting under the IRA is not likely to improve the affordability picture for many beneficiaries. In fact, OOP spending could actually *increase* for a certain subtype of highly rebated selected drugs, according to new research on products that will have an MFP in effect in 2026.[48] For many of these products – which are commonly prescribed for chronic diseases such as cardiovascular disease and diabetes – patients are assessed a flat copay under current plan benefit designs. Under price-setting, the MFP is not likely to change this copay amount, but the lower prices on selected drugs *will* slow beneficiaries' progression through the Part D benefit under current program rules, making it less likely that they reach their annual OOP maximum. In aggregate, millions of Part D beneficiaries who currently pay a fixed monthly copay on selected drugs will have to wait longer before reaching the new OOP cap, thereby increasing their total costs for the year.[49]

Congress did not intend for selected drugs to be costlier or less accessible to patients when seeking passage of the Medicare Price Negotiation Program under the IRA. However, these trends serve as a cautionary tale for CMS as it pursues MFP setting in the Medicare program. Specifically, if CMS sets the MFP too low, especially in competitive drug classes, patients may not have access to Medicare negotiated drugs and Part D may not realize projected savings. Further, this may result in manufacturers (including biosimilar developers) delaying entry or abandoning new research and development in certain therapeutic areas, as prevailing formulary management practices make these markets less attractive to new competitors.

CMS must take steps to ensure that patient access to selected drugs is not impeded.

In the proposed Guidance, CMS states that the Agency will not impose explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies. Rather it intends to utilize the existing statutory and regulatory restrictions on formulary design to preserve access. In a recent guidance memorandum, CMS stated its intention to reject "a (plan) bid if it finds that the design of the plan and its benefits (including formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan."[50] While Novo Nordisk supports the Agency's goal, CMS fails to affirmatively preclude plans from enacting formulary or utilization management restrictions. Indeed, a recent analysis of formulary

[47] Van Nuys K, Ribero R, Ryan M, Sood N. Estimation of the share of net expenditures on insulin captured by US manufacturers, wholesalers, pharmacy benefit managers, pharmacies, and health plans from 2014 to 2018. JAMA Health Forum [Internet]. 2021 Nov 5 [cited 2024 Jun 30];2(11):e213409. Available from: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932
[48] Cline M, Holcomb K, Robb M. Expected Impact of Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program on Medicare Part B Beneficiary Out-of-Pocket Costs [Internet]. Seattle, WA: Milliman. 2024 Jun 25 [cited 2024 Jun 30]. https://www.milliman.com/-/media/milliman/pdfs/2024-articles/6-25-24_expected-oop-cost-impact-drug-price-negotiation_summary.ashx?la=en&hash=FAE783DB2B66AF0568DF06602860D05E.
[49] Ibid.
[50] Centers for Medicare & Medicaid Services. Final CY 2025 Part D Redesign Program Instructions at 4.

restrictions in Medicare Part D found that Part D plans became significantly more restrictive over time, rising from an average of about 32 percent of drugs restricted in 2011 to over 44 percent restricted in 2020.[51] The authors found that the frequency of exclusions and prior authorization or step therapy restrictions was successively greater each year during the study period, and concluded that "the large and increasing number of drugs subject to review or excluded from coverage raises concerns of the impact on patient health."[52] We share these concerns and urge CMS to take additional action to ensure that their oversight of plans' tiering and utilization management is thorough and that patients do not experience barriers to accessing drugs subject to an MFP.

IV. A streamlined approach to effectuating the MFP is necessary to prevent disruptions to pharmacy supply chain flows, increased financial volatility, and prohibited drug diversion and duplicate discounts.

To ensure the successful implementation of MFP effectuation, CMS should implement a process modeled after the Coverage Gap Discount Program (CGDP).

Given the onus on manufacturers to effectuate the MFP with over 60,000 dispensers, and the significant penalties for failing to do so in a manner that it consistent with CMS Guidance, it is essential that CMS take appropriate action to establish a system that is operational from a manufacturer's perspective, minimizes burden for all of the supply chain stakeholders, and mitigates against diversion and duplicate discounts. It is in CMS' interest to ensure that effectuation of the MFP is seamlessly implemented. A fragmented system where manufacturers face the possibility of having to contract and manage payments to tens of thousands of pharmacies and other dispensers when they have never done so before will lead to uncertainty, chaos, and disgruntled pharmacies, plans, and manufacturers.

Successful implementation of MFP effectuation requires balancing the timely payment of dispensers, on one hand, with sufficient devotion of time necessary for plans and manufacturers to perform rigorous validation processes. This is essential to minimize the numbers of adjustments, reversals, and credits resulting from payments based on inaccurate data. A system that is fraught with errors and in need of continuous correction from the outset puts an enormous strain on that system and its workforce. It also increases the possibility of noncompliance with the law, subjecting stakeholders to both financial and legal risk. Accordingly, CMS should reconsider a CGDP-like model to ensure that (1) pharmacies are paid in a timely manner and (2) plans and manufacturers have adequate time to perform proper validation and compliance checks before payments are made. The size of the Medicare Negotiation Program and number of MFP eligible prescriptions (now and particularly in the future) demands a

[51] Joyce G, Blaylock B, Chen J, Van Nuys K. Medicare Part D plans greatly increased utilization restrictions on prescription drugs, 2011–20. Health Aff [Internet]. 2024 Mar [cited 2024 Jun 30];43(3):391-97. Available from: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999
[52] Ibid.

streamlined and consistent approach – which must include a robust dispute and appeals process – across each of the pharmacy supply chain actors.

With modifications, CMS' framework could streamline and stabilize MFP effectuation across the supply chain and provide a more seamless benefit for Medicare beneficiaries.

Novo Nordisk appreciates CMS' queries throughout the proposed Guidance to gain more insight into what is needed to ensure a successful roll-out of MFP effectuation. The success of that process will turn on both the exchange of accurate data between the supply chain actors, including the Medicare Transaction Facilitator (MTF), and a manufacturer's ability to operationalize a novel system involving new validation processes, substantial financial investments, transfers of capital, and complicated payment functions to potentially more than 60,000 dispensers. It is an extremely complex endeavor that, if improperly established, could severely disrupt the flow between patients, pharmacies and other dispensers, and plans and PBMs. Significant operational inconveniences and enormous administrative burdens could follow. Poor implementation by CMS could expose a manufacturer to substantial financial penalties, significant drug diversion, and prohibited duplicate discounts. An MFP effectuation program built on ambiguous and weak standards threatens the viability of this component of the Medicare Negotiation Program.

Absent a process like the CGDP, the following recommendations, summarized below and explained in more detail in the Appendix, would provide a solid framework under which a manufacturer could accurately provide access to the MFP, eliminating many unnecessary errors and the need for additional remediation processes.

- *Sufficient time must be built into plan and manufacturer claims-data validation check-points; failure to do so guarantees a system built on error and administrative burden*. To ensure proper payments are made to dispensers with as little disruption as possible, CMS should retain the 30-day timeframe for plans to submit PDE data to the Drug Data Processing System (DDPS). A shorter timeframe would likely result in more prescriptions being returned to stock and unavailable for patients when they present at the pharmacy counter. CMS also should permit manufacturers 38 days to remit payments to dispensers once invoices are received from the MTF. The 38 day deadline is consistent with that of the Medicaid Rebate Program, the CGDP, and the Manufacturer Discount Program starting in 2025. A 38 day timeframe is well-established across multiple federal healthcare programs for a reason – it takes time for manufacturers to perform necessary validation processes before authorizing payments.

- *The operability and stability of MFP effectuation is dependent on requiring dispensers to participate in a manufacturer's reasonable effectuation plans*. The MTF should include a payment facilitation function. Manufacturers should have the option to utilize this function and, in doing so, be deemed compliant with MFP effectuation obligations by CMS. Dispensers should be required to agree to a manufacturer's reasonable mechanism of

payment, whether that is through the MTF or some other entity engaged by the manufacturer. Similarly, given CMS' refusal to implement policies to prevent 340B duplication, CMS should at a minimum clarify that a 340B covered entity will forfeit its right to the MFP if it does not participate in a manufacturer's reasonable process to address the intersection of MFP and 340B. Further, CMS should guarantee that manufacturers will be held harmless in such cases.

- *Guardrails are needed to prevent misaligned incentives that may drive the price of a selected drug sold to dispensers above a manufacturer's WAC.* The IRA requires manufacturers to "provide access to" the MFP to eligible individuals and their dispensing providers.[53] CMS' proposed Guidance would require manufacturers utilizing a rebate mechanism to ensure that rebates reduce a dispenser's net acquisition cost down to MFP, even if a portion of the dispenser's acquisition cost is imposed by wholesalers and distributors. The costs of distribution are not part of the price that is required to be offered and cannot be shifted to manufacturers on top of the already enormous discounts imposed by MFP. CMS should not adopt an approach that incentivizes wholesaler/provider manipulation of distribution costs. An MFP rebate calculated at WAC (or actual acquisition cost, if lower than WAC) less the MFP is a necessary guardrail to prevent gaming by supply chain actors that drive the price of the selected drug sold to dispensers above WAC for purposes of generating profit.

- *A robust dispute resolution process, which allows manufacturers to dispute claims during the prompt payment window, must be established*. CMS must establish a robust dispute and complaint process, with clear procedures and timelines. Manufacturers should be allowed to dispute claims, provided there is a reasonable basis for doing so, during the payment period. This would help prevent payment of erroneous claims, which would then be subject to an adjustment and credit or claw back process.

A detailed explanation of these recommendations, as well as responses to CMS' questions throughout the proposed Guidance, are provided in the Appendix.

Thank you for considering Novo Nordisk's comments on the draft IPAY 2027 Guidance. We would be pleased to discuss our comments with you in further detail. If you have questions, please contact Jennifer Duck, VP, Public Affairs at JEDK@novonordisk.com.

Sincerely,

Jennifer Duck
Vice President, Public Affairs

[53] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1841 (August 16, 2022).

Appendix: MFP Effectuation and 340B Nonduplication[54]

Section 40.4: Providing Access to the MFP in 2026 and 2027

A primary manufacturer should not be held responsible for the effectuation of MFP by a secondary manufacturer.

As a threshold matter (and consistent with our previous comment letter), Novo Nordisk does not believe the primary manufacturer and secondary manufacturer framework is required or substantiated by the IRA. It is not operationally possible for a manufacturer to ensure that some *other* manufacturer provides the MFP to the latter's patients and purchasers. A primary manufacturer cannot control the price at which a secondary manufacturer sells its drugs.

Furthermore, under CMS' IPAY 2027 Guidance, only the primary manufacturer has access to the MTF and the claims-level data elements contained therein. There is no mechanism for a primary manufacturer to share this data with a secondary manufacturer, or to collect the required information that must be reported back to the MTF on the secondary manufacturer's behalf.

The Guidance would require this information exchange between a primary and secondary manufacturer (and critical validation processes) to occur within the 14-day payment window. This is not even feasible for the primary manufacturer with its own products, let alone on behalf of another manufacturer. Compliance with manufacturers' rebating obligations under such a compressed and restricted timeline is nearly impossible, placing manufacturers at risk of significant fines and penalties. There are also concerns about the sharing and protection of confidential and proprietary information between the manufacturers and with the MTF. CMS should rescind this requirement in its final Guidance and require any secondary manufacturer of a selected product to comply with the IRA and final Guidance on its own accord.

Section 40.4.1: Medicare Transaction Facilitator Data Facilitation

The time period for Part D plans to submit PDE data to the DDPS should remain at 30 days (and not be shortened to seven days).

Novo Nordisk recommends keeping the timing of submissions of PDE data by Part D plans to the DDPS at longer intervals (preferably 30 days) rather than seven days as proposed in the Guidance. Longer intervals between PDE submissions will reduce the credits due to reversals that occur after seven days. Many pharmacy policies keep a filled prescription in the will call bin to allow the patient time to pick up the prescription for a defined time period, typically 12 to 14 days after adjudicating the claim. After the defined time period, if the patient has not picked up the prescription, the pharmacy reverses the claim and returns the product to stock. Reversals occur

[54] Novo Nordisk is a member of PhRMA, and we incorporate by reference its comments related to MFP effectuation, except where they might slightly diverge as discussed in this Appendix.

for many reasons, including patient willingness or ability to pay for the prescription, patient vacation or hospitalization, patient switching pharmacies, therapies, and doses, and unapproved quantities (e.g., insurance will only pay for 90 days, not 30 days).

Submitting claims data before this evaluation can occur is very disruptive to the current system and could result in many clawbacks – where manufacturers have prematurely paid the MFP discount only to try to recover the misapplied discount from the dispenser. Although pharmacies and other dispensers may face slightly longer data submission timeframes and waits for MFP reimbursements, the longer time period for the plan to submit data to DDPS will result in fewer disruptive and unnecessary reversals and clawbacks. In addition, if CMS decreases the data submission time period to seven days, pharmacies may need to change their policies regarding return-to-stock timing to seven days (or fewer), rather than the current 12 to 14 days. This would impose a significant administrative burden on pharmacies, given the large number of prescriptions that would have to be returned to stock and then refilled once the patient comes to pick up their medicine. If pharmacies change their return-to-stock timing, patients may experience delays in receiving their medication if they arrive at the pharmacy after that seven day window and their prescription has been returned to stock.

The MTF should provide the manufacturer with raw, not aggregated, data preferably on a monthly basis, but no more frequently than every two weeks.

The MTF should transmit data to manufacturers on a monthly basis, which would then trigger the prompt payment window for that batch of claims. Daily receipt of data from the MTF would be too burdensome from a validation and payment processing standpoint. In no event should the frequency of data submission from the MTF be more than every two weeks. Manufacturers will need access to the raw data (including but not limited to the date of service, quantity, and National Provider Identifier) at the prescription level in order to perform its own internal validation and compliance functions – specifically, to validate for duplicate discounts and 340B status. If the MTF sends the data in an aggregated form, the manufacturer loses visibility and there is no way for it to complete its own evaluation and verification of the invoices for payment. The raw data should come in the National Council for Prescription Drug Programs (NCPDP) format with all fields recommended by NCPDP.

The MFP payment window should be increased from 14 to 38 days to ensure sufficient time for a manufacturer to validate MFP eligibility and refund amounts.

Novo Nordisk agrees that dispensers should be timely reimbursed when they are entitled to MFP rebates. The 14-day interval recommended in the Guidance, however, is too short and is operationally infeasible. Manufacturers must perform their own internal validation checks before authorizing payments, including verifying the correct quantity, ensuring no duplicate claims, and identifying whether a discounted price was offered prospectively (e.g., 340B price, GPO price). Once validated, the invoice moves into the payment system, which could take several days to

process and authorize. Moreover, the 14 day time period does not provide sufficient time for backup systems to be utilized in the event of system failures.

The IRA does not require a 14-day payment requirement. CMS should align the payment timeline with other government programs that also require eligibility verification and rebating, such as the Medicaid Drug Rebate Program and the Part D Coverage Gap Discount Program, both of which allow 38 days to effectuate rebates or refunds after verification of the data. Novo Nordisk suggests that CMS require the manufacturer to pay the rebate (or issue a credit) to the dispenser within 38 days of receipt of the complete MFP and 340B validation data from the third party administrator (TPA). The manufacturer should have the flexibility to handle claim adjustments/reversals that occur outside of the payment window as either credits to future MFP refunds or as refunds to dispensers. While most reversals would be handled as a credit, there are some circumstances where a refund is more appropriate. Regardless of which mechanism is employed, the revisions to claims should restart the payment window timeline. Disputed or incomplete claims should be held pending resolution or completion. A manufacturer should not be put in the position of paying rebates on invalidated or questionable claims and then having to issue numerous credits or chase refunds when the payment should never have been made in the first place.

Additional claim-level data elements are needed to properly effectuate MFP and protect against diversion and duplicate discounts.

Novo Nordisk appreciates the proposed claim-level data elements listed in Table 2 of the Guidance that would be provided by the MTF to manufacturers. However, additional elements are needed to enable manufacturers to perform their own validation assessments and protect against diversion and duplicate discounts. Specifically, we request that the dispenser provide the following information to the MTF, which should then be shared with the manufacturer (or alternatively, directly with the manufacturer):

- *Covered and Non-Covered Status Indicator:* For selected drugs that have both Medicare covered and non-covered indications, manufacturers need a mechanism to verify that the drug was prescribed for a covered indication, given the IRA's clear requirement that the MFP apply only to covered Part D drugs. This is necessary given that Medicare Advantage plans are permitted to add non-covered Part D drugs to their formularies as a supplemental benefit. Currently, plans utilize the Drug Coverage Status Codes "C" vs. "E" to delineate between covered drugs and non-covered drugs, respectively, within Medicare's PDE data. CMS should require plans to accurately use and report this field in the PDE to indicate coverage for Part D covered indications vs. supplemental coverage for non-covered uses and include this field among the list of data elements that the MTF must share with manufacturers. Without this indicator there is an increased risk of ineligible claims being submitted for MFP payment.

- *Bank Identification Number (BIN)/Processor Control Number (PCN) of the Beneficiary's Prescription Drug Insurance:* The BIN/PCN data allows the manufacturer to verify that the claim is a Part D claim, and which Part D plan paid the dispenser. This is an essential data point for manufacturers to verify that the drug was in fact paid under Part D.

- *NPI of the Dispensing Entity:* The Guidance indicates that the MTF would share the Service Provider Identifier, but this data element does not always indicate which pharmacy dispensed the drug. The "service provider" is normally linked to the medical provider but not the dispensing entity, which are not likely the same in most cases. As such, the datapoint should be expanded to specifically include both service (medical) provider NPI *and* the NPI of the dispensing entity. By providing both data points, manufacturers can ensure the accurate mapping of eligible claims, and reconciliation of payments. This additional data also directly supports the identification of 340B transactions and the prevention of duplicate discounts.

- *Drug Enforcement Agency (DEA) ID/Health Industry Number (HIN):* The DEA and HIN identifiers tell a manufacturer where the product was dispensed and whether it was purchased under a GPO contract. These fields will help connect the MTF claims-level data to entities receiving GPO discounts for the purposes of duplicate discount scrubbing and prevention.

- *Mechanism to Link the Dispense to a Purchase:* CMS must ensure that manufacturers have access to a data point that allows the manufacturer to link a dispense to a particular purchase. This will be critical if the dispenser's purchase price is more or less than WAC and the manufacturer offers the MFP prospectively or pays a rebate amount other than the standard default rebate amount (WAC-MFP).

- *Deidentified Medicare Beneficiary Identifier:* Manufacturers will need a way to link a beneficiary to a claim in order to prevent duplicate discounts, while still maintaining patient privacy. The best way to achieve this is through the use of a deidentified Medicare beneficiary identifier that is unique to each patient.

CMS should also require the MTF to perform an additional data scrub to eliminate duplicate prescriptions and claims with errors (e.g., unusual quantities). CMS should regularly audit the MTF functions to identify and remedy any system errors.

The MTF should provide an electronic remittance to the manufacturer that confirms payment of the MFP refund.

The MTF should provide manufacturers with an electronic remittance that confirms payment to the dispensing entity and specifies the amount of the payment, the dispenser's NPI and banking/routing number, and the refund transaction date. The remittance document should be one file reflecting how a manufacturer's aggregated lump sum payment to the MTF was paid out

to dispensers. For example, if a manufacturer provides a lump sum of $1 million to the MTF to disperse, the MTF should send a remittance including the data elements discussed above for each unique NPI once that lump sum of $1 million was fully dispersed. The MTF should not send a remittance for every payment made to every pharmacy, as that would be overly burdensome to receive and verify.

Section 40.4.2: Nonduplication with 340B Ceiling Price

A manufacturer should be held harmless if a covered entity refuses to comply with a manufacturer's reasonable process to provide a discount when the 340B ceiling price is less than the MFP.

CMS has indicated that it will not take a role in preventing duplication of 340B and MFP pricing. Even if CMS does not facilitate the calculation or payment of a refund owed to covered entities when the 340B ceiling price is less than the MFP, Novo Nordisk still believes that there is an important role for the MTF or a neutral 340B clearinghouse in identifying and validating 340B eligible claims and sharing the claims-level data with manufacturers for its own verification. This function would also be helpful to CMS in its identification and removal of 340B units from the Part D inflation rebate calculations as required by the IRA. We urge CMS to continue to explore this option.

Under the current Guidance, manufacturers are expected to employ their own processes to ensure covered entities get the difference between the 340B ceiling price and MFP, when the ceiling price is lower, and to prevent duplicate discounts (where both a 340B price and MFP discount are provided). Given that many units of drug are identified as 340B after (sometimes many weeks or months after) the point of dispense, we appreciate the Guidance clarifying that for claims identified as 340B where the 340B ceiling price is less than the MFP, after the 14-day window, the manufacturer must "promptly" provide the difference between the MFP and 340B ceiling price; the manufacturer would not need to replenish that "full stock" for the 340B covered entity or contract pharmacy at the 340B ceiling price.

Given that CMS is not "assuming responsibility for deduplicating discounts between the 340B ceiling price and MFP" and will not require covered entities to include 340B modifiers on claims, it is critical that manufacturers be given flexibility to develop and utilize their own processes to comply with this part of the IRA. A manufacturer should be deemed to be compliant with the IRA's requirement to provide a covered entity with the MFP price (when 340B ceiling price is lower than MFP), if it utilizes a reasonable mechanism to identify 340B units, calculates any amounts owed to a covered entity, and effectuates the payment (whether upfront or as a rebate or credit). And, as discussed above, covered entities should be required to comply with a manufacturer's reasonable effectuation plan, which will address 340B duplication and be reviewed by CMS, or forfeit the right to the MFP price.

Section 40.4.3: Retrospective Refund Amount to Effectuate the MFP

CMS should limit MFP refund determinations to WAC pricing.

The IRA requires manufacturers to "provide access to" the MFP to eligible individuals and their providers.[55] CMS' Guidance proposes to require manufacturers utilizing a rebate mechanism to ensure that rebates are large enough to reduce providers' *net acquisition cost* down to MFP, even if a portion of the providers' acquisition cost is imposed by wholesalers and distributors. This interpretation of the statute is flawed for two reasons: First, the "provide access to" clause imposes a *price* obligation on manufacturers. It does not assign to them an obligation to offset costs of distribution that are not part of the price. Second, making manufacturers responsible for wholesaler markups would create an incentive for wholesalers to artificially increase their fees and costs to providers. Because those fees and costs would be borne by manufacturers in the form of increased MFP rebates, neither the wholesalers nor the providers—the only parties to the distribution arrangement—would have an incentive to constrain those costs. Indeed, one can imagine that these players would affirmatively seek opportunities to shift costs to manufacturers under the cover of the CMS Guidance.

Requiring manufacturers to provide rebates to offset distribution markups improperly reduces even further the effective MFP, a carefully (if unfairly) defined concept in the statute. It also opens manufacturer liability up to unconstrained mischief by wholesalers with regard to their fees and costs. For these reasons, CMS should require that an MFP-effectuating rebate should be calculated at WAC less MFP, not actual acquisition cost (AAC) less MFP. The costs of distribution are not part of the price and cannot be shifted to manufacturers on top of the already enormous discounts imposed by MFP.

If CMS nevertheless finalizes this approach, CMS should confirm that Best Price does *not* include wholesaler markup-offsetting amounts that may be included in the rebate mechanism as articulated in the draft IPAY 2027 Guidance. If a manufacturer reduces providers' net acquisition cost down to MFP, then the lowest price available from the manufacturer to the provider is the MFP. This conclusion aligns with the text of the IRA, which calls for *MFP* to be included in Best Price, not MFP plus any markup costs imposed by third parties in the chain of distribution.[56]

The application of MFP in the Part D benefit provides further evidence that the MFP, as defined in the IRA as the Part D negotiated price — has nothing to do with a dispenser's acquisition costs. In the Part D program, the negotiated MFP price is defined as the price the pharmacy is reimbursed at the point-of-service, which is also used as the basis for setting a beneficiary's out-of-pocket cost. There is no obligation for the Part D negotiated price to account for acquisition costs by a particular provider. The idea of the MFP being calculated based off total provider acquisition costs, including costs imposed by third party distributors, is not supported by the IRA and should not be defined as such in CMS Guidance.

[55] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1841 (August 16, 2022).
[56] 42 U.S.C. §1396r-8(c)(1)(C)(ii)(V).

Section 40.4.4: Options for Medicare Transaction Facilitator Payment Facilitation

The MTF should provide a payment facilitation option for manufacturers and dispensers should be required to participate in a manufacturer's chosen method to effectuate MFP payment, whether it is through the MTF or an outside vendor.

Novo Nordisk strongly urges CMS to move forward with the development of an MTF payment facilitation function (Option 2 in the proposed Guidance). With over 60,000 pharmacies in the U.S., it is not feasible for manufacturers to enter into contracts with and facilitate direct payments to so many entities. It will, however, be necessary for the MTF to also share with manufacturers the dispenser's banking and routing information (what is contemplated in Option 1) for internal validation of payments made in the appropriate timeframe and to the appropriate dispenser. This validation is critical given the significant penalties that can be imposed on manufacturers that fail to provide the MFP in accordance with the requirements in the final Guidance.

Manufacturers should have the option to utilize the MTF payment facilitation function and, if a manufacturer chooses to do so, dispensers should be required to utilize that mechanism to facilitate payment. Any payments made through the MTF function should be deemed to be compliant with the IRA's requirements. Further, manufacturers should be held harmless in the event of any MTF system malfunctions or other errors that result in a dispenser not receiving the MFP within the required timeframe. This default compliance determination will incentivize manufacturers to use the MTF payment facilitation function. Permitting dispensers to demand other methods of payment from manufacturers (besides that provided by the MTF) would create inconsistencies, instability, and an immense administrative burden for manufacturers.

If a manufacturer determines that the MTF payment facilitation function is not a viable option for its operations (or for certain dispenses), and it utilizes another vendor to effectuate the MFP on its behalf, dispensers should also be required to utilize the manufacturer's mechanism provided that it is reasonable and meets the requirements to effectuate MFP in the final Guidance. This approach would recognize that a manufacturer has made the MFP available by providing a reasonable process (whether it is the MTF or another mechanism) through which dispensers may access the MFP price.

Section 40.4.5: MTF Dispensing Entity Participation Requirements

Dispensers should be required to utilize a manufacturer's preferred payment mechanism provided it is reasonable and compliant with IRA Guidance.

As discussed above, dispensers should not be permitted to force a manufacturer to use a different payment option than what the manufacturer has operationalized with the MTF, or through some other mechanism. The onus is on the manufacturer to effectuate the MFP for tens of thousands of dispensers or face significant financial liability and penalties. If CMS permits dispensers to demand idiosyncratic mechanisms, which we strongly oppose, at a minimum the

dispenser should be required to utilize the payment approach agreed upon between the manufacturer and the dispenser for the plan year to minimize disruption of payments. As such, we urge CMS not to finalize the proposal that would allow dispensers to provide 90-days' notice to the manufacturer if it is opting out of the MTF process.

Section 90.2.1: Manufacturer Plans for Effectuating MFP

CMS should not publish manufacturer effectuation plans, but ensure dispensers have access to the plans through the MTF.

Novo Nordisk does not support making manufacturer MFP effectuation plans publicly accessible, even if proprietary information is redacted. To ensure dispensers have knowledge of a manufacturer's MFP effectuation plan, the dispenser should have password protected access to a page on the MTF's website that includes a manufacturer's effectuation plan with all proprietary information redacted. A manufacturer should have the right to review and approve the redacted plan before it is made available to dispensers to ensure all confidential and proprietary information has been properly removed.

Section 90.2.2: Negotiation Program Complaints and Disputes

CMS should establish a dispute process that allows manufacturers to dispute a claim during the payment window.

CMS Guidance states, "If a Primary Manufacturer believes that there is an error with the claim-level data received, it can submit a dispute following the process outlined in section 90.2.2 of this draft guidance…. If the MFP is not made available to a dispensing entity or the report with payment-related data is not provided to the MTF within the 14-day prompt MFP payment window …, the Primary Manufacturer may be liable for civil monetary penalties (CMPs)." This language suggests that a manufacturer must make an MFP payment (and report the payment to the MTF) within the 14-day window even if it has knowledge that the claim is invalid or erroneous or it will be subject to CMPs.

Novo Nordisk urges CMS to adopt a process where a manufacturer can dispute a claim during the payment window period if it has a reasonable basis for doing so. One possible way is by indicating the "Code 6 – No Refund Paid – Other" (Table 4 of the Guidance) and clarify there that the claim is being disputed. Given the breadth and scope of potential claims, it is not reasonable to expect a manufacturer to pay every claim, even if there is evidence that it is an improper or invalid claim, and then go through an extended dispute process to try to claw back that payment. CMS should work with manufacturers to develop a process or mechanism that ensures manufacturers will be made whole for improper payments. Future offsets or credits may not work in every instance—for example, if a generic comes to market or a pharmacy closes—in which case a refund from the pharmacy must be provided to the manufacturer. Currently, there

is no proposal in the Guidance that contemplates how to make manufacturers whole from improperly paid claims.

CMS should develop a robust dispute and complaint process, including a process for appeals, with clear timelines and parameters.

CMS must include clear timelines for the dispute and complaint process in its final Guidance. It is not workable or desirable for disputes to be kept open for extended periods of time. In addition, CMS should establish a process that allows manufacturers an opportunity to appeal a decision by CMS. For consistency across the federal Medicare program, we support a dispute and appeals process that mirrors the one that will be utilized by the Manufacturer Discount Program beginning in 2025.[57]

[57] Duran VS (Medicare Drug Benefit and C & D Data Group, Baltimore, MD), Shapiro JR (Medicare Plan Payment Group, Baltimore, MD). Letter to: Pharmaceutical Manufacturers; All Part D Plan Sponsors re: Medicare Part D Manufacturer Discount Program Final Guidance. 2023 Nov 17.

PATIENTS FOR AFFORDABLE DRUGS™

June 26, 2024

The Honorable Meena Seshamani
Deputy Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Patients For Affordable Drugs (P4AD) is the only national patient organization focused exclusively on system-changing policies to lower drug prices. We are bipartisan and independent. We do not accept funding from any entities that profit from the development or distribution of prescription drugs. Since we launched a little more than seven years ago, we have collected over 35,000 stories[1] from patients from all 50 states struggling to afford their prescription drugs because of high prices. We have built a community of over three-quarters of a million patients and allies supporting policies to lower drug prices.

The Medicare Drug Price Negotiation Program marks a historic step toward realigning the drug pricing system to better serve patients instead of drug industry profits. Millions of Americans who depend on Medicare for their essential medicines are already experiencing financial relief, especially those in marginalized communities who are disproportionately harmed by health disparities. These negotiated price reductions could save patients as much as thousands of dollars per medication and save taxpayers billions overall. The provision's impact extends beyond Medicare, exerting downward pressure on drug prices throughout the economy more broadly to benefit millions more Americans.

We appreciate the efforts by the Centers for Medicare and Medicaid Services (CMS) to continue to invite feedback and the opportunity to comment on the draft guidance for the Medicare Drug Price Negotiation Program. The success of the Medicare Drug Price Negotiation Program depends on patient-centered implementation. P4AD especially commends CMS's commitment to center patients' lived experiences with medical conditions treated by the selected drugs in determining a maximum fair price during the negotiation process.

[1] (2024, June 20). *Patients For Affordable Drugs Map*. Patients For Affordable Drugs. https://map.patientsforaffordabledrugs.org/

Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027 (Section 30.1)

1. Orphan Drug Exclusion from Qualifying Single Source Drugs (Section 30.1.1)

- P4AD strongly supports the current orphan drug exclusion criteria for Medicare Drug Price Negotiation, as under current criteria orphan drugs from small biotech firms and those that treat small patient populations under 200,000 are excluded from negotiations. It is highly unlikely that orphan drugs with ultra-rare designations will ever meet the spending threshold to be included in negotiations. P4AD strongly opposes any efforts to expand and abuse the orphan drug exemption in the Medicare Price Negotiation process. The current measures strike the right balance by maintaining the existing strong incentives for orphan drug development while also protecting patients from extended monopolies and unjustified high prices.

Requirements for Manufacturers of Selected Drugs (Section 40)

1. Confidentiality of Proprietary Information (Section 40.2.1)

- P4AD commends CMS's dedication to transparency throughout the negotiation process. We encourage CMS to publish as much information as is possible and appropriate during negotiations to keep the public informed throughout.

2. Termination of Agreement (Section 40.6)

- P4AD urges CMS to continue to emphasize the voluntary nature of participation in the Medicare Drug Price Negotiation Program as well as the Medicaid and Medicare programs broadly. We applaud CMS for outlining the various options that pharmaceutical manufacturers have in regard to negotiations, whether that be participating in the program, opting not to participate, or electing to remove their prescription drugs from Medicare and Medicaid entirely.

Negotiation Factors (Section 50)

P4AD strongly supports the inclusion of patients' lived experiences with the chosen drugs in determining a drug's value. However, we do acknowledge that there were considerable difficulties regarding accessibility for patients during the data collection period prior to the first round of drug price negotiations.

1. Data Collection (Section 50.2)

- With regard to the data collection process for patients, P4AD urges CMS to communicate in a simple and straightforward manner, encouraging the use of 4th-grade level language(s) on the data collection form and website while minimizing the usage of hard-to-understand technical language. This may better ensure that patients with Limited English Proficiency (LEP) or reading skills are able to more meaningfully engage in the process. Further, we suggest providing alternative options for engagement including mail-in or call-back processes for individuals who may not have easy access to the Internet.
- We encourage CMS to limit the asks made of patients, including limiting the length of the form itself and reducing the number of questions required of patients.

- P4AD strongly encourages CMS to provide materials in languages commonly spoken in the United States. A majority of those who are Spanish language dominant prefer to receive their healthcare information in Spanish.[2] Latino adults are more likely to have chronic conditions compared to their white counterparts, such as diabetes and heart disease, that are treated with costly medications.[3]
- P4AD also urges CMS to provide short "explainer" videos and/or info-graphics for patients engaging in the data collection process that clarifies *why* patients should participate and *how* the data collected could be used to lower the price of the selected drugs. The inclusion of "easy-to-understand explanations" may be critical in ensuring patients understand how their participation in the program will benefit them in a manner that is best tailored to their needs and may help reduce real or perceived barriers to access.
- P4AD applauds CMS's commitment to identifying and mitigating conflicts of interest during the data collection process. P4AD strongly supports the clear identification and explicit *naming* of conflicts of interest, especially when respondents have connections to companies or organizations that profit from the development or distribution of pharmaceutical products. We commend CMS for its continued commitment to transparency throughout public listening sessions.

Negotiation Process (Section 60)

P4AD strongly supports CMS continuing to provide public listening sessions. These public listening sessions are an important tool for uplifting patient voices and including the patient perspective in communicating the human impact of drug price negotiations for patients.

1. Public Listening Sessions (Section 60.4)

- P4AD strongly supports CMS's consideration of different event formats for the public listening sessions. We support the addition of in-person sessions and/or organizational visits with patients or communities who have historically been excluded or marginalized. Providing in-person public listening session events would allow CMS to reach communities that are disproportionately represented in the patient population for a chosen drug, but may not have the ability to join digital listening sessions.
- P4AD encourages CMS to consider the inclusion of audio-only calls for public listening sessions. Having camera-only requirements can serve as a barrier to access for patients who may not have the infrastructure necessary or the technical ability to participate in video calling but would otherwise want to share their experience with the selected drugs. Further, some patients have expressed they do not prefer to share their experiences on video and are far more comfortable sharing via other formats. We urge CMS to further diversify the formats in which CMS seeks public comments from patients, including via

[2]Cary Funk and Mark Hugo Lopez. (June 2022). *"Hispanic Americans' Experiences with Health Care."* Pew Research Center. https://www.pewresearch.org/science/2022/06/14/hispanic-americans-experiences-with-health-care/.

[3](July 2021). *How high drug prices hurt Hispanic and Latino people.* Protect Our Care. https://www.protectourcare.org/wp-content/uploads/2021/07/POC-Report-How-High-Drug-Prices-Hurt-Hispanic-And-Latino-People.pdf.

general mail-in forms, email, or phone surveys that would help reduce the barriers to access and encourage patient participation.

- P4AD strongly supports CMS's concern for patient privacy and supports the plan by CMS to publish a redacted transcript of public listening sessions. By redacting patient information, patients may feel more comfortable sharing their experiences with the selected drugs and be more likely to participate in the public listening sessions.

2. Publication of the MFP (Section 60.6)

- P4AD strongly supports efforts by CMS to maintain updated and accurate information about the MFP by updating MFPs as needed on an annual basis.

3. Explanation for the MFP (Section 60.6.1)

- P4AD strongly supports the commitment by CMS to maintaining transparency in determining the MFP and commends the plan to publish information and data on how the final MFP was reached. We believe it is crucial that the public understand exactly how the MFP was reached to discourage any efforts to delegitimize the Medicare Drug Price Negotiation Program.

4. Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect (Section 70)

- P4AD strongly supports the commitment by CMS to monitor and evaluate generic or biosimilar drugs that have disqualified a selected drug from negotiation in order to ensure that these drugs are engaging in bona fide marketing and creating *meaningful competition* for the selected brand name drug. We believe that this approach may help prevent companies from gaming the system in order to evade negotiated prices and continue to charge patients exorbitant prices for their needed medications.

P4AD thanks CMS for ensuring patients are informed about and involved in the Medicare Drug Price Negotiation Program established by the Inflation Reduction Act, and looks forward to continued engagement in the process in the coming months.

Sincerely,

Patients For Affordable Drugs

6/14/2024

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare and Medicaid Services

200 Independence Avenue, S.W.

Washington, DC 20201

Delivered via electronic mail.

RE: Draft Guidance for the Second Cycle of the Medicare Drug Price Negotiation Program

Dear Administrator Brooks-LaSure:

The Partnership to Advance Cardiovascular Health – or PACH – is a 501(c)(4) nonprofit advocacy coalition of 20 patient, provider and advocacy organizations who work together to advocate for the millions of Americans with or at risk of cardiovascular disease. Despite an almost nine-percent decrease in the cardiovascular age-adjusted mortality rate from 2010-2019, cardiovascular deaths increased by nine percent from 2019-2022, reversing a decades-worth of progress. It is not hyperbole to say that our country is in the midst of a cardiovascular health crisis.

In 2022, President Biden signed the Inflation Reduction Act into law, which mandates the Secretary of Health and Human Services to engage in price negotiations with manufacturers of specific, high-spend drugs for Medicare Part D and Part B plans. The legislation also includes provisions like the Medicare Prescription Payment Plan, which allows beneficiaries to pay their balances over the course of the year as opposed to owing the full cost in the first month of the year.

We commend the Centers for Medicare and Medicaid Services' commitment to the health and wellbeing of the country's senior citizens through the implementation of this legislation.

However, the first round of price negotiations revealed glaring issues with the listening sessions and information collection requests. Also, we are concerned about the lack of regulations regarding Part D plans restructuring formularies based on the maximum fair prices. If formularies are restructured and medications are re-tiered, patients could be left scrambling to find plans that provide proper access to their medications.

During the first round of negotiations, patients experienced an inconvenient and confusing system for feedback. Patients and providers were required to apply for listening sessions and forced to wait for weeks before learning of their acceptance or denial. Furthermore, listening sessions were only offered during a single two-hour window in the middle of a weekday. Surely, many patients and providers could not participate due to unavoidable and understandable conflicts with work and personal schedules.

During the listening sessions, testimonies were frequently cut short with inconsistent warnings and no established means for patients and providers to monitor their time. Unfortunately, we will never know the feedback lost due to brief time constraints. We encourage CMS to reevaluate the structure and methods of the listening sessions to be more flexible, allowing more patients and providers to provide their experiences and insights into the selected therapies. Methods incorporating more dialogue, like roundtables, would foster meaningful insights for CMS into these therapies from both a patient and provider perspective.

Furthermore, the information collection request system proved to be convoluted. Depending on how participants submitted information, some questions were meant to be unanswered, while other questions were required for submission. Because the form was the same for everyone regardless of affiliation or identification (e.g., patient, provider, pharmacist, etc.), the multitude of nuance resulted in both frustration for participants and a potential lack of benefit for CMS. The information collection request should only include questions that pertain to the specific respondent. For example, patients and patient advocacy groups should not have to answer questions related to the efficacy and scientific data of a therapy – those questions should be directed toward researchers and providers.

Additionally, we hope CMS will include how feedback was used during negotiations for the first cycle in their justifications of the maximum fair prices for those therapies. We encourage CMS to release those justifications prior to the next round of patient feedback for the second cycle of negotiations. By better understanding what information helps CMS and how that information is incorporated into negotiations, participants can offer information that is pertinent and beneficial to CMS.

Finally, an unintended consequence of the Medicare beneficiary plan restructure is utilization management strategies within Part D remain unchecked, leaving patients vulnerable to harmful tactics from pharmacy benefit managers and insurers, like non-medical switching.

Part D formularies should be annually reviewed to identify all instances where selected drugs are unfairly utilized after their price is negotiated. Often, two drugs in the same class are not effectively interchangeable, and the decision to switch must come from the physician. Please visit our webpage for more information on the immense harms posed by non-medical switching.

Finally, CMS must do a better job of educating patients about the Medicare Prescription Payment Plan. By having the option to "smooth" their costs over the course of a year, patients will be more capable of affording their medications. This program can only be of benefit insofar as patients are aware it exists. We urge CMS to inform beneficiaries of this option with targeted materials about how, where and when to enroll.

We appreciate the opportunity to provide input for the second cycle of price negotiations, and we commend CMS' effort to improve access for Medicare beneficiaries.

We urge you to consider and incorporate the community's feedback into the next round of negotiations and demonstrate your commitment to the millions of Americans who should have a voice in these crucial price negotiations and plan restructure.

Sincerely,

American Society for Preventive Cardiology

Heart Valve Voice US

Hypertrophic Cardiomyopathy Association

National Blood Clot Alliance

North American Thrombosis Forum

Partnership to Advance Cardiovascular Health

Stopafib.org

WomenHeart: The National Coalition for Women with Heart Disease

PARTNERSHIP TO FIGHT CHRONIC DISEASE

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

We appreciate the opportunity to share comments, concerns, and opportunities for improving the Medicare Drug Price Negotiation Program: Draft Guidance for Year 2027 (IPAY 2027). The Partnership to Fight Chronic Disease is an internationally recognized coalition of patients, providers, community organizations, faith-based groups, industry and trade, and health policy experts committed to raising awareness of the leading cause of death and disability: chronic disease.

Prescription drugs are an essential tool in the fight for better health, particularly for Medicare beneficiaries. Among U.S. adults aged 65 and older, 87.5 percent take at least one prescription medicine a month. Almost 40 percent of these adults take more than five.[1] Assuring they have access to the medicines they need is critical to lowering the burden of disease and healthcare costs overall. We also recognize that many people live with serious chronic conditions for which health needs remain unmet, poorly addressed or without any relief. It is with the mutual goals of assuring people living with chronic conditions enjoy better access to the medicines they need and addressing the yet unmet medical needs people living with many chronic conditions continue to face that we share these comments.

Acting to Avoid Limitations on Beneficiary Access to Medicines

The Inflation Reduction Act (IRA) of 2022 involves sweeping changes to Medicare including the new Medicare Drug Price Negotiation Program (MDPNP) and Part D redesign. Given the wide-

1 Health, United States, 2019. https://www.cdc.gov/nchs/data/hus/2018/fig14.pdf

ranging implications for Medicare beneficiaries today and in the future and the vulnerability of the individuals affected, care to identify and avoid unintended consequences is paramount. These changes also do not occur in a vacuum but are made more complex by challenges with workforce shortages and other access issues that adversely affect many and risk worsening existing health disparities, particularly for lower income and rural populations. We urge the Centers for Medicare & Medicaid Services (CMS) to remain vigilant and avoid unintended consequences given the significant changes implementation of the MDPNP represents.

Coverage of the medicines subject to Medicare pricing does not equate to access. Part D plans and PBMs commonly deploy utilization management techniques including, "fail first" or non-clinical step therapy, prior authorization requirements, and formulary placement that erect significant barriers to access for patients. Access barriers hinder medication adherence and fuel avoidable health crises that harm health and increase costs to Medicare and the beneficiary.

We commend CMS's recognition of these issues in the IPAY 2027 guidance but were disappointed not to see recommendations that address these access barriers in the draft. We urge CMS to take needed steps to address formulary standards and oversight, particularly on issues relating to step therapy, prior authorization, and other utilization management tools that stand between Medicare beneficiaries and the medicines their physicians recommend. Taking a "wait and see" approach risks beneficiary health and current practices provide more than enough evidence of how utilization management is increasing and creating harm.[2]

Redesigning Engagement Opportunities for Beneficiaries and Caregivers

We commend CMS for seeking comments on opportunities to learn from beneficiaries – both patients and caregivers – as a part of the Medicare drug pricing program. PFCD's Policy Director, Candace DeMatteis, participated in nine of the ten patient-focused listening sessions last fall and those experiences are reflected in these comments.

We encourage CMS to seek and allow for more significant and meaningful beneficiary, caregiver, patient, and provider engagement. Several reforms could facilitate this engagement. First, we urge you to extend the timeframe for providing written comments from beneficiaries, patients, and caregivers. The current process and timelines described significantly limit those opportunities. When comments are allowed, they involve extremely short timelines for a response. For the patient-focused listening sessions, for example, the timelines for registering to present comments verbally or to submit written comments were extremely short. To provide meaningful comments on specific patient experiences and considerations important to their health requires time. Given the time, staff, and expertise needed to respond in a detailed manner, the short timeframes for comment will disenfranchise many—particularly those who are already underrepresented and under-resourced. Providing greater transparency in the

2 American Medical Association. 2023 AMA Prior Authorization Physician Survey. Available online https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

process and building in more opportunities for engagement, including opportunities to shape data collection, analysis, policy development and ultimately implementation, should be a priority.

We also appreciate your interest in ways to improve the patient-focused listening sessions. We were disappointed, however, that CMS did not include specific recommendations for improvements in the IPAY 2027 guidance. We strongly support recommendations for improvement developed by the National Health Council[3] and participated in their information gathering efforts that supported the development of these important enhancements to the process. We also strongly recommend that CMS consult with other agencies with working models of patient and caregiver engagement, including the FDA and PCORI.

In addition to changes in the format, we suggest revisiting the registration process. From having to sign up for each session individually and navigating questionnaires that initially focused on clinical questions, the registration process was unnecessarily difficult and clunky. Also, CMS limited speakers to three-minutes each whether all the speaking spots were taken or not. That was a missed opportunity for greater engagement from those participating and would not have required any additional time from CMS. The fact that speakers were not allowed additional time though speaking spots remained unfilled left an impression that CMS was less interested in what they could learn from the people speaking than in being able to "check the box" that the sessions were held and completed.

We recognize and appreciate the softer approach CMS adopted in notifying people their time was ending after the first listening session but encourage CMS to go further to enable a greater diversity of experiences be represented in the collection of input regarding people living with the diseases the medicines treat.

We also support structuring patient-engagement sessions to allow for more interactive discussions where CMS could ask follow up questions of participants and learn more from their experiences. Ultimately, greater transparency from CMS on how the patient and caregiver information is being used in Medicare pricing would facilitate greater engagement as well as improve on the types of information CMS receives.

Redefine "Selected Drug" to Avoid Further Innovation Loss

The IPAY 2027 guidance proposes a broad definition of "qualifying single source drug", or QSSD, that will limit the availability of new indications and uses of medicines that represent important

3 National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement (2024). Available online https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

health advancements for patients living with chronic illnesses. The MPDNP includes the consideration of clinical benefits and uses of medicines that reflect clinical guidelines and usages of medicines for critically important and distinct medical needs. But the IPAY 2027 guidance in the definition of QSSD ignores these clinical distinctions reflected in clinical guidelines and medical practice. That risks patient health and the availability of treatments for patients. The first list of ten drugs selected for the MDPNP illustrates this point. CMS used an overly broad definition of QSSD to treat several distinct insulin products – each with distinct, non-interchangeable medical uses and subject to separate FDA approvals – as a single selected drug. That decision ignores the clinical realities of how these medicines are used by people with insulin-dependent diabetes and prescribed by physicians. Moreover, it serves a chilling effect on the development of new products that address unmet medical needs.

Barring Use of the Quality-Adjusted Life Year (QALY)

We appreciate CMS's recognition of the problems with QALYs and pledge to "not use any QALYs in the Negotiation Program." As the IPAY 2027 notes, the QALY undervalues interventions intended for populations with shorter life spans which includes the majority of people covered by Medicare. We strongly encourage CMS to fully adopt the prohibition to avoid using this metric in evaluating clinical effectiveness or factoring this metric into developing a maximum fair price. CMS should also take caution in using other cost-effectiveness analysis metrics beyond the QALY, as they may also have concerning discriminatory implications.

Supporting Orphan Drug Development

More than 30 million people in the U.S. live with a rare disease. For most, treatment options are limited or non-existent, making continued research and innovation essential. The IRA itself and CMS's interpretation of IRA provisions relating to exemptions of medicines for rare and orphan diseases from Medicare pricing create significant disincentives to the exploration of new indications for rare diseases.[4] That is a major detriment to the research and development of new treatments for rare diseases that CMS could but failed to address in the IPAY 2027 draft guidance. We urge you to reconsider and provide guidance that would acknowledge the issue and, to the extent allowed by law, address this disincentive for developing treatments for rare diseases through the guidance and other regulation.

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4 National Organization for Rare Disorders (NORD). NORD's Position on IRA/CMS Drug Negotiation Price Program. Available online https://rarediseases.org/driving-policy/public-policy-positions/inflation-reduction-act-ira-nord-point-of-view/

PARTNERSHIP TO FIGHT
CHRONIC DISEASE

We appreciate the complexities involved in implementing this significant shift in Medicare and financing of prescription drug coverage. We also appreciate the opportunity to provide comments we hope will aid implementation in ways that protect and enhance beneficiary access to the medicines they need to maintain and enhance their health. We stand ready to assist in that regard and urge CMS to re-evaluate the proposed process for evaluating drugs and determining pricing to allow for additional, meaningful public input and beneficiary engagement in the process.

Sincerely,

Kenneth E. Thorpe, PhD
Chairman, Partnership to Fight Chronic Disease
Robert W. Woodruff Professor of Health Policy and Chair, Department of Health Policy and Management in the Rollins School of Public Health at Emory University

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 2124401850

Dear Deputy Administrator Seshamani:

Thank you for this opportunity to comment on the draft guidance for the second cycle of the Medicare Drug Price Negotiation Program. Since passage of the Inflation Reduction Act, we have worked collaboratively as organizations representing patients and people with disabilities to amplify the perspectives of those with lived experience in the implementation of the Medicare Drug Price Negotiation Program. Our comments will focus on the agency's process for engaging patients in its decisions, including determinations related to a treatment's clinical effectiveness, unmet need and therapeutic alternatives, as well as the agency's use of value assessments.

While we appreciate that the agency is considering certain recommendations from patients and people with disabilities for improving its engagement, we are concerned that the new guidance does not put forward a concrete plan or process for developing predictable, targeted, and specific tactics for engaging patients and people with disabilities. We are also concerned that the guidance does not capture the limitations on use of quality-adjusted life years (QALYs) and similar measures explicitly described in the Affordable Care Act. Therefore, we are pleased to share the following recommendations:

- CMS should avoid **one-size fits all value metrics**.
- CMS should develop a formalized process to ensure **continuous, robust engagement** of patients and people with disabilities at multiple levels.
- Using patient insights, CMS should **clearly communicate how it intends to use the input it receives**, and how that input is reflected in the final negotiated prices.
- CMS should solicit input from **diverse communities** to ensure representation of the diversity of the patients and communities affected by the topic.
- CMS should ensure that opportunities for patient engagement are **accessible**.
- To gauge both successes and challenges, CMS should establish a structured process for **continuous review and assessment** of its engagement strategy.

CMS should avoid one-size-fits-all value metrics.

It is now widely recognized that traditional methods and metrics of value assessment such as the QALY have significant shortcomings. This has led to well-intentioned development of other measures and approaches that developers assert to be nondiscriminatory and more

patient-centered. However, each approach comes with tradeoffs, need for improvement, and inherent methodological weaknesses. No patient is average, and no measure of value should assume so.

Prior law, including the Affordable Care Act, bars use of QALYs and similar measures.

CMS made a strong, positive statement of its commitment to "learning from, collaborating with, and engaging the public, including patients, consumer advocates, health and data experts, and pharmaceutical supply chain entities in the policy-making process." The agency also expressed support for collecting real-world data and engaging patients related to its work to identify therapeutic alternatives. Yet, we are concerned that the new guidance states that CMS will "review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with section 1194(e)(2), as well as with section 1182(e) of Title XI of the Act."

The guidance narrowly references the IRA's statutory language, stating that the Medicare Drug Price Negotiation Program will not use "information that treats extending the life of individuals in these populations as of lower value," leaving out language in the Affordable Care Act (ACA) barring similar measures that "discounts the value of a life because of an individual's disability." The aim of this language was not to spur an effort to find loopholes that allow the government to use a single approach. As discussed on the Senate floor, the spirit of the provision was to protect vulnerable patients and people with disabilities from policies that "set national practice standards or coverage restrictions" and ensure research used to make decisions is focused on clinical outcomes.[1]

Also, CMS cannot assume that a value assessment does not discriminate simply because it does not use QALYs. The recent final rules governing Section 504 of the Rehabilitation Act[2], a law passed in 1973, and Section 1557 of the ACA[3] both acknowledge the potential for value assessments to discriminate. The agency interpreted the final section 504 rules as "broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment."

The data used to value health care may be discriminatory or fail to represent real-world experiences of patients and people with disabilities.

We appreciate that agency's interpretation of Section 504 that "discounting the value of quality of life on the basis of disability for purposes of denying or limiting medical

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[1] Colloquy by Senators Baucus, Enzi, Conrad, Hatch, Carper and Menendez. "Comparative Effectiveness Research Funds." Congressional Record 155:24 (February 6, 2009) p. S. 1796.
[2] HHS, "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance," May 9, 2024, https://www.federalregister.gov/documents/2024/05/09/2024-09237/nondiscrimination-on-the-basis-of-disability-in-programs-or-activities-receiving-federal-financial
[3] CMS, "Nondiscrimination in Health Programs and Activities," May 6, 2024, https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities

treatment to a qualified individual with a disability would likely violate § 84.56." The agency also stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others."

Therefore, we urge CMS to not only comply with current law, but also to consider whether the evidence used in its decision-making was developed in a manner that reliably represents the population of patients and people with disabilities impacted. Value assessments are only as good as the data used in their development. Therefore, we urge the agency to consider the following factors:

- **Health utilities:** Also known as Health State Utility Value (HSUV), they mark the health-related quality of life (HrQOL) of a patient with a specific disease. A numeric valuation is applied to a health state based on preference of being in that state relative to perfect health, assigning a number between 0 and 1 to various conditions a person's health could be in (often called "health states" in which 0=death and 1=optimal health). They are typically derived from surveys asking how much, on average, someone prefers one health state compared to another. Health states typically represent degree of impairment (not the disability or condition) such as active disease, response, remission, or mild, moderate and severe. Shortcomings include:
    - Survey data relies on average perspectives of quality of life in a health state, which are biased, inaccurate and almost never replicable. For example, there is significant research on the bias against disability among the public[4] and among providers[5].
    - The identified health states are typically not disease or condition specific, often surveying health from lens of mild, moderate or severe (such as the EQ-5D[6]) and only accounting for health improvements that move between these broad states. Only large health improvements, i.e. HrQOL, count.
    - Health utilities typically give a lower value to people living below optimal health. For example, extending the life for person living at a .5 is worth half of a person at a 1.
- **Disability weights:** Disability weights quantify health losses relating to non-fatal outcomes, expressed as years lived with disability (YLD). They typically have a value between 0 (equivalent to full health) and 1 (equivalent to death). For example, living 10 years with a 10 percent reduction in HRQoL is a disability weight of 0.10 – equal to losing one full year of good health (e.g., by dying one year before the life

[4] Ari Ne'eman et. al., "Identifying And Exploring Bias In Public Opinion On Scarce Resource Allocation During The COVID-19 Pandemic," *Health Affairs* Vol. 41 No. 10 (October, 2022), https://www.healthaffairs.org/doi/10.1377/hlthaff.2022.00504

[5] Lisa I. Iezzoni et. al., "Physicians' Perceptions of People With Disability and Their Health Care," *Health Affairs* Vol. 40 No. 2 (February, 2021), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2020.01452

[6] EUROQOL, "EQ-5D-5L," https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-5l/

expectancy). Severity of condition (morbidity) and its death rate (mortality) are expressed as the number of healthy life years lost. Shortcomings include:
    - Disability weights are elicited by surveys, often of participants that do not have experience in the studied health state. Surveys are subject to bias against disability.
    - Disability weights from different studies are often not comparable, coming from different countries or populations with differing perceptions of disease and disability.
    - Assuming same weights to different aspects of quality of life as representative of all people risks being applicable to none.[7] Triathletes may highly weigh physical function. Academics may weigh mental acuity.
- **Health outcomes data**: Cost effectiveness analysis requires data on health outcomes to measure cost of gaining health. A product's "value" combines clinical effectiveness (impact of intervention on select health outcomes) and economic value (impact of intervention on healthcare resource use and costs). Shortcomings include:
    - Patient-centered outcomes and societal value are often ignored. For example, methods may not incorporate data on economic or social consequences such as loss of ability to work or caregiver effects.
    - Reliance on average estimates based on generic survey data obscures important differences in clinical needs and preferences, particularly complex diseases and those from underrepresented communities.[8]
- **Health equity:** Cost effectiveness analyses and value assessment are intended to maximize health care efficiency. Historically, they have not explicitly incorporated equity concerns related to race, ethnicity, or socioeconomic factors, nor implicit bias or structural inequities within healthcare systems, disparities in access to healthcare services and treatments, or social determinants of health.[9]
- **Real-World Implications:** New methodologies for cost effectiveness analysis are abundant but untested. While recognition of flaws inherent in historic methods for assessing treatment value is driving innovation, literature on almost every method underscores need for extensive detailed data on patients' risk profiles, co-existing conditions, and other relevant factors currently lacking and challenging to obtain. Investment in data is needed.

Every value assessment measure has tradeoffs.

There has been longstanding protection against use of discriminatory value assessment tools in statute. Therefore, we are concerned that CMS' draft guidance explicitly expressed

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[7] Anirban Basu & David Meltzer, "Value of Information on Preference Heterogeneity and Individualized Care," *Medical Decision Making* Vol. 27 No. 2 (March-April 2027), https://pubmed.ncbi.nlm.nih.gov/17409362/
[8] Michael J DiStefano et. al., "Alternative approaches to measuring value: an update on innovative methods in the context of the United States Medicare drug price negotiation program," *Expert Review of Pharmacoeconomics & Outcomes Research* Vol. 24 No. 2 (February 2024), https://pubmed.ncbi.nlm.nih.gov/37961908/
[9] No Patient Left Behind, "The Value of Medicines," https://www.nopatientleftbehind.org/value-of-medicines

interest in using alternative approaches as part of drug price negotiations. Every cost effectiveness measure has tradeoffs between conditions advantaged and disadvantaged:

- **Quality-adjusted life year (QALY):** Less value to life-extending treatments among patients whose baseline health-related quality of life is low, particularly people living with disabilities. More value to treatments achieving maximum quality of life.
- **Equal value of life year gained (evLYG):** Less value to treatments improving quality of life in extended life years. Same value as QALYs for treatments that do not extend life years regardless of quality-of-life improvements. More value to treatments extending life years.
- **Generalized Cost Effectiveness Analysis (GCEA):** Less value to treatments for common conditions to manage symptoms. More value to treatments for severe and disabling conditions.
- **Generalized risk-adjusted cost effectiveness (GRACE):** Less value to treatments for common conditions to manage symptoms. More value to treatments for severe and disabling conditions.
- **Disability adjusted life year (DALY):** Less value to treatments for people with disabilities due to focus on life years lost. More value to conditions leading to an early death without treatment.
- **Health years in total (HYT):** Less value to treatments that improve quality of life without increasing life expectancy. More value to treatments that extend life.
- **Life years gained (LYG)**: Less value to treatments for patients with fewer years left to live (e.g., older adults or those with disabling conditions) and for largely non-fatal conditions (e.g., blindness, depression, rheumatoid arthritis. More value to treatments extending life.

<u>Recommendation</u>: We urge CMS to avoid use of one-size-fits-all value metrics, like the QALY or evLYG, as part of its decision-making, consistent with current Medicare law and regulations governing nondiscrimination. CMS should also identify and be transparent about the types and sources of research, data, and assessments considered in its decision-making process. In addition, CMS should ensure it and other entities are exercising adequate oversight over the Medicare Drug Price Negotiation Program to ensure decisions do not rely on data from studies relying on one-size fits all metrics, like the QALY or evLYG.

Engaging Patients and People with Disabilities

We urge the Centers for Medicare & Medicaid Services (CMS) to create a systematic engagement process that goes beyond written comment periods and ad hoc listening sessions. Drawing on robust frameworks from leading organizations including PCORI, National Health Council (NHC), the PATIENTS Program at the University of Maryland, the Innovation and Value Initiative (IVI), and AcademyHealth, we are pleased to provide the following recommendations through which CMS would prioritize authentically involving patients and people with disabilities in agency decisions. We urge CMS to incorporate these best practices to foster meaningful dialogue with patients, caregivers, and people with

disabilities across the agency. The insights from their lived experience will allow CMS to ensure advancement of policies and practices that improve health care value and patient outcomes.

Our recommendations for enhancing CMS' patient engagement strategies are grounded in the expertise of organizations dedicated to improving health care value through meaningful engagement with patients and individuals with disabilities. These organizations have developed substantial recommendations to foster and guide patient engagement across the health care sector, emphasizing the crucial role of meaningful and authentic patient and caregiver engagement in research processes.

In response to CMS' 2023 listening sessions on the Medicare Drug Price Negotiation Program, NHC convened a roundtable discussion to provide a platform for the patient community to share their experience engaging with the agency.[10] Stakeholders outlined valuable insights gleaned from these sessions, which can contribute to shaping CMS' broader patient engagement strategies. The PATIENTS Program at the University of Maryland School of Pharmacy adopted a similar approach by hosting a Town Hall, bringing together stakeholders to gather insights and recommendations.[11] Their aim was to ensure that patient perspectives are being represented in the agency's decision-making.

Furthermore, the PCORI-developed Foundational Expectations for Partnerships[12] and IVI's Economic Impacts Framework[13] also informed our recommendations. PCORI's six expectations serve as a framework to guide meaningful, effective, and sustainable engagement to advance patient-centered comparative clinical effectiveness research (CER). Meanwhile, IVI's framework, along with the principles used to develop it, encourages partnerships between patients, caregivers, and researchers to broaden the understanding and measurement of the six main economic impacts for patients.

CMS should work with an advisory group of experts from organizations representing people with chronic conditions and disabilities to develop a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels.

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[10] NHC, "Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement," published March 2024, https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf

[11] The PATIENTS Program at the University of Maryland School of Pharmacy, "PATIENTS Professors Town Hall: Recommendations for the CMS Drug Price Negotiation Program Final Report," published July 12, 2023, https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf

[12] PCORI, "Engagement in Research: Foundational Expectations for Partnerships," updated February 2024, https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf

[13] IVI and AcademyHealth, "A Research Framework to Understand the Full Range of Economic Impacts on Patients and Caregivers," published May 2023, https://thevalueinitiative.org/wp-content/uploads/2023/06/05-2023-Economic-Impacts-Framework-Report_FINAL.pdf

There is broad consensus among policymakers and leaders in the field of patient-centered outcomes research that robust engagement of people with lived experience is crucial. As part of NHC's vision for improving CMS' patient engagement over the next five years, one of three key improvements proposed is inclusion of patient perspectives at every stage of the decision-making process. To achieve this objective, both NHC and the PATIENTS Program urge CMS to establish partnerships with the patient community and formalize a process to create multiple touchpoints with people experiencing the disease or illness being studied. This aligns with PCORI's foundational expectations for partnerships, which emphasizes the importance of initiating touchpoints early, even during planning stages of a study.

Additionally, IVI highlights that continuous partnerships provide valuable context from individuals' lived experiences to shape research priorities and NHC recommends CMS develop methods for incorporating this patient experience data into its program implementation. The experts participating in the advisory group should include those with experience engaging patients and people with disabilities throughout the life cycle of chronic conditions and disabilities to elicit information about the range of burdens and outcomes that matter most to them, as well as the differences among subpopulations.

Recommendation: Based on this strong consensus and alignment of goals, we recommend that CMS develop a formalized engagement process in consultation with engaged partners in the patient and disability communities that have expertise engaging people with lived experience related to their experiences with treatment. This process should not only ensure that the agency is actively engaging early and often with patient stakeholders but also guarantee ongoing engagement, fostering sustainable partnerships and building trustworthy relationships for future endeavors.

Using patient insights, CMS should clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.

Although CMS has asked stakeholders to go through the intensive process of submitting data pertaining to selected drugs, and has made listening sessions available to them, CMS has not explained how input will be used by CMS or will inform CMS' eventual conclusions. While the process for obtaining this information is critical, equally important is how it is being used.

This issue was highlighted during the NHC's roundtable, where numerous stakeholders expressed feeling underprepared by CMS for the 2023 listening sessions, which limited their ability to meaningfully participate. They suggested that CMS could have better communicated the purpose of the information it is seeking, and how it is being used in determining prices for selected drugs. Based on this feedback, NHC recommends CMS enhance its clarity and communication about the intent of its listening sessions — a recommendation that we would apply more broadly to the agency's holistic engagement.

Similarly, the PATIENTS Program's Town Hall echoed these concerns, leading to their recommendation for CMS to provide more information to the patient community throughout the process. They emphasize trust-building through transparency, advocating that patients should understand the agency's decision-making processes and how their input is utilized. They specifically recommend the agency develop a process to share how stakeholder feedback guides decision-making. Patients and people with disabilities, as well as the organizations representing people with the chronic conditions and disabilities being reviewed, will dedicate the time and resources to being engaged partners if they know how their input makes a meaningful difference.

Recommendation: We encourage a cyclical approach, wherein patient engagement helps CMS communicate how it intends to use the information submitted by stakeholders on selected drugs and therapeutic alternatives. It is critical that this information is communicated to stakeholders to ensure they are prepared to provide appropriate feedback at listening sessions and have advance notice to gather and submit useful information throughout the process. CMS should be very explicit and transparent about the information it is seeking from patients and people with disabilities and how it will influence decisions.

CMS should solicit input from diverse communities to ensure representation of the diversity of the patients and communities affected by the topic.

The CMS Framework for Health Equity seeks to further advance health equity, expand coverage, and improve health outcomes.[14] Additionally, the Inflation Reduction Act requires consideration of the differences among subpopulations. Therefore, it is crucial for the agency to formalize an engagement process that prioritizes feedback from diverse communities.

For example, PCORI places significant emphasis on the importance of diversity in patient engagement, particularly ensuring that research partnerships reflect diverse patients and communities affected by the topic. They explain diversity is essential to adequately address the needs of the targeted population, especially those with perspectives historically excluded from research.

NHC's roundtable on CMS' Medicare Drug Price Negotiation Program listening sessions highlighted concerns about the lack of racial and ethnic diversity among speakers and the inadequate accommodations for speakers with disabilities. To enhance the diversity of future patient engagement endeavors, NHC recommends that CMS collaborate with the Office of Minority Health and engage with minority-led patient advocacy groups to promote broader participant diversity.

Recommendation: We concur with the necessity of ensuring that health care research represents the affected population and encourage CMS to take a proactive approach in

[14] CMS Office of Minority Health, "CMS Framework for Health Equity 2022-2032," published July 2022, https://www.cms.gov/media/529636

including diverse perspectives in patient engagement efforts. In addition to engaging the Office of Minority Health and minority-led patient advocacy groups, proactive engagement with PCORI and the National Institute on Minority Health and Health Disparities (NIMHD) may be useful to identify research priorities that capture diverse perspectives.

CMS should ensure that opportunities for patient engagement are accessible.

IVI and PCORI emphasize the significance of allocating dedicated funds and resources to support and compensate patient engagement. We concur with this perspective and recommend CMS take responsibility for ensuring the accessibility of their patient engagement opportunities. Patient and disability advocates have echoed these sentiments, urging CMS to allocate resources such as financial assistance, accessible materials, disability-friendly meeting arrangements, and extended input and comment periods.

The PATIENTS Program calls for accessible materials, emphasizing the use of plain language and health literacy principles to ensure patient understanding and inclusivity. They also advocate for diverse engagement approaches, recognizing that online-only methods may not be accessible to everyone. Notably, NHC recommends that Congress provide this support, along with funding and oversight, to strengthen CMS' engagement efforts.

Additionally, NHC recommends that CMS enhance its own accessibility. Communication with executive branch agencies can often be challenging due to bureaucracy and the need for institutional knowledge to communicate effectively. Streamlining the process for initiating dialogue, such as by creating an ombudsman or a clearly identified point of contact, is essential for effective engagement.

<u>Recommendation</u>: CMS should create an ombudsman for engagement of stakeholders from the patient and disability communities, dedicate funds and resources to support and compensate patient engagement, and ensure accessibility through use of plain language materials and by providing opportunities for engagement through written comments, in-person meetings and online events. We call attention to the recent regulations from the U.S. Department of Justice governing digital accessibility for people with disabilities and urge CMS' focus on compliance.

To gauge both successes and challenges, CMS should establish a structured process for continuous review and assessment of its stakeholder engagement strategy.

PCORI's final expectation for patient engagement underscores the importance of gathering input and feedback throughout projects to pinpoint areas of success and areas for improvement, enabling adjustments in future engagement strategies. PCORI emphasizes that continuous learning is essential for enhancing engagement strategies, allowing researchers to assess whether engagement is effective, equitable, and as intended. The PATIENTS Program echoes PCORI's expectation, advocating for a third-party evaluation of

patient and stakeholder engagement to ensure transparency and accountability. Similarly, IVI advocates for integration of health equity throughout research initiatives, ensuring equitable design and implementation.

Recommendation: CMS should commit to continuous learning, refining its patient engagement strategy and promoting health equity as part of a structured assessment of what works and what does not work, in collaboration with engaged patients and people with disabilities.

Conclusion

We urge CMS to finalize guidance that not only assures patients and people with disabilities that its implementation of the program will be aligned with current law governing the use of value assessment, but also provides concrete steps the agency will take to facilitate meaningful engagement of patients and people with disabilities and rely on high quality sources of evidence. We appreciate CMS' consideration of our recommendations, offering a holistic approach to improving patient engagement across the agency. Embracing these recommendations will not only strengthen CMS' relationship with stakeholders but also pave the way for more effective and equitable health care delivery, ultimately benefiting patients and the health care system.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association of Kidney Patients
American Association on Health and Disability
Autistic People of Color Fund
Autistic Women & Nonbinary Network
Biomarker Collaborative
Bone Health and Osteoporosis Foundation
Brain Injury Association of America
Buscher Consulting
Cancer Support Community
Cancer*Care*
Caregiver Action Network
Caring Ambassadors
Cystic Fibrosis Research Institute
Davis Phinney Foundation for Parkinson's
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Disability Rights California
Disability Rights Oregon

Epilepsy Alliance America
Epilepsy Foundation
Exon 20 Group
Familia Unida Living with MS
Family Heart Foundation
FORCE: Facing Our Risk of Cancer Empowered
Genetic Alliance and PXE International
Global Liver Institute
GO2 for Lung Cancer
Health Hats
HealthHIV
Heart Valve Voice US
Hypertrophic Cardiomyopathy Association
ICAN, International Cancer Advocacy Network
Johns Hopkins Disability Health Research Center
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.
MET Crusaders
MLD Foundation
Multiple Sclerosis Foundation
National Association of Councils on Developmental Disabilities
National Coalition for LGBTQ
National Disability Rights Network (NDRN)
NHMH - No Health without Mental Health
Partnership to Fight Chronic Disease
Partnership to Improve Patient Care
PD-L1 Amplifieds
RASopathies Network
Rosie Bartel
The Coelho Center for Disability Law, Policy and Innovation
The Headache and Migraine Policy Forum
The Hepatitis C Mentor and Support Group-HCMSG
Tourette Association of America
TSC Alliance

Comments on CMS Draft Guidance for Medicare Drug Price Negotiation Program

To: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

Submitted by: MacKay Jimeson, Executive Director, Patients Rising

Date: July 1, 2024

Subject: Enhancing Transparency, Patient Input, and Protection Against Predatory Practices in Medicare Drug Price Negotiation

Dear Dr. Seshamani,

Patients Rising appreciates the opportunity to submit comments on the draft guidance for the Medicare Drug Price Negotiation Program (2027 applicability, 2026 & 2027 MFP effectuation). We represent a broad network of patients with chronic illnesses across America.

The American healthcare system is unnecessarily complex, opaque, and centered around the interests of the payer, not the patient. Patients Rising believes that CMS can and should lead a model approach to healthcare that is patient-centric, transparent, accountable, and avoids the conflicts of interest that are pervasive in our health system. Patients Rising's Patient Access & Affordability Project issued principles for CMS on involving patients in the implementation of the Inflation Reduction Act. We believe these principles remain relevant and should guide CMS, particularly concerning the Medicare Drug Price Negotiation Program.

Patients Rising believes the negotiation process can be much improved and there are critical steps that need to be taken to protect Medicare beneficiaries from the unintended consequences of this program. Patients Rising recommends enhancing transparency, improving the collection of patient perspectives and insights, and protecting patients from predatory formulary practices and access restrictions.

1. Transparency in Value Assessment Tools and Negotiation Processes

Too many healthcare decisions are made in secrecy or are communicated with convoluted messaging. CMS should ensure that the value assessment tools and the process used in the Medicare Drug Price Negotiation Program are fully transparent. This includes public disclosure of the criteria, methodologies, and data sources used in the assessments.

Transparency in value assessment is crucial for building trust with all healthcare stakeholders, particularly among patients and caregivers. Too many value assessment tools are overly generalized and are not sensitive enough to accurately reflect the value of treatments from the patient's perspective. Current value assessment tools often fail to capture the comprehensive clinical, economic, and social value that patients and their families experience from their treatments.

CMS should avoid generalized or discriminatory value assessment tools that are commonly used by academics and organizations like the Institute for Clinical Effectiveness Research (ICER) and Harvard's Program on Regulation, Therapeutics, and Law (PORTAL). Both ICER and PORTAL have a history of using value assessment tools that are problematic from a methodological and ethical standpoint. Both organizations have shown a minimal willingness to meaningfully innovate on their approach to value assessments.

By disclosing the assessment tools and processes, CMS can ensure that all stakeholders, including patients, caregivers, and clinicians, understand how decisions are made and can provide meaningful input.

Along with transparency, CMS should encourage universities and businesses to develop better value assessment tools that are fit for the 21st Century.

2. Improving Patient Input and Deep Insights from the Patient Perspective

To truly assess a therapy's value, it is crucial to grant patients and caregivers a meaningful voice in the process. A listening session with brief time limits for comments is not enough to truly understand the patient and caregiver's perspective on any particular medicine.

CMS should actively involve patients, caregivers, and patient advocacy organizations throughout the process to gather deep insights on what are measures of value from the patient's perspective. Patient-centric value measures should be adopted by CMS to guide drug pricing decisions. Input from disease-specific specialists who understand the therapy's impact on patients is essential.

This approach involves considering both clinical and non-clinical benefits of medications based on insights from patients, caregivers, and society, while also accounting for the varying needs of individual patients and subgroups. A comprehensive valuation should incorporate clinical trial data, safety information, long-term health outcomes, patient experiences, population health

equity, health system resource use, along with socio-economic benefits that are not traditionally captured by the health system.

Finally, a clear and transparent methodology for gathering and applying data to quantify patient experience should be established to ensure a fair and accurate assessment of a drug's value when setting prices.

By integrating patient input and real-world evidence, CMS can make more informed decisions that better align with patient needs and preferences.

3. Protecting Patients from Utilization Management and Predatory Formulary Practices

Sadly, due to the perverse incentives and anti-competitive practices that are pervasive in healthcare, the lower negotiated prices will create an incentive for health insurers to implement stricter utilization management strategies, such as prior authorization and step therapy. These measures would be used to steer patients towards treatment options preferred by health plans and their pharmacy benefit managers, potentially limiting access to the negotiated drugs.

This creates new and needless barriers for patients, who are trying to access specific medications that are prescribed by their doctor. This highlights the complex interplay between drug pricing, insurance practices, and patient access in the evolving landscape of Medicare drug negotiations.

CMS must have safeguards to protect patients from utilization management practices and predatory formulary practices that restrict access to necessary medications. This includes prohibiting practices such as lasering, adverse tiering, and excessive prior authorization requirements. By prohibiting these practices and streamlining access restrictions, CMS can ensure that patients receive timely and affordable access to the medications they need.

4. Ensuring No Conflict of Interest for the Medicare Transaction Facilitator

The Medicare Part D Transaction Facilitator plays a crucial role in the implementation of the Medicare Drug Price Negotiation Program. This entity is responsible for facilitating data exchange among pharmacies, participating drug companies, and Medicare Part D plans to ensure proper access to negotiated Maximum Fair Prices (MFPs) for selected drugs.

The Transaction Facilitator handles sensitive information, including beneficiary enrollment data, claims data, and pricing information, to support accurate calculation of True out-of-pocket (TrOOP) expenditures and non-Medicare payer payments.

To maintain the integrity of the negotiation process and ensure fair access to negotiated prices, it is essential that the Transaction Facilitator operates as an independent entity without conflicts of interest in the pharmaceutical supply chain.

This independence helps foster trust, transparency, and impartiality in the implementation of negotiated drug prices, ultimately serving the interests of Medicare beneficiaries and the healthcare system as a whole.

Conclusion

Patients Rising is dedicated to building a better healthcare system that prioritizes the long-term health and well-being of patients.

Patients Rising has several key recommendations for improving the Medicare Drug Price Negotiation Program. The patient community is very concerned that the current process is opaque and values input from academics over patients and their caregivers. CMS must substantially improve transparency in value assessment tools and negotiation processes. The patient community needs to have confidence that CMS is not using problematic methodologies used by entities like ICER and PORTAL.

The success of the Medicare Drug Price Negotiation Program will be based on the ability of CMS to gather deeper patient and caregiver insights throughout the process, incorporating both clinical and non-clinical benefits, and real-world evidence.

CMS must also protect patients from stricter utilization management strategies that health insurers and their pharmacy benefit managers will implement in response to lower negotiated prices.

Finally, Patients Rising advocates for an independent Medicare Part D Transaction Facilitator to maintain integrity in the negotiation process and data handling.

There is a great need for a more patient-centric, transparent approach that prioritizes patient needs over payer interests. CMS must lead by ensuring this program avoids conflicts of interest and ensures patient access to necessary medications.

Thank you for considering our comments. We look forward to continued collaboration with CMS to advance the health and well-being of patients.

Sincerely,

MacKay Jimeson
Executive Director,
Patients Rising

July 2, 2024

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov.

Dr. Meena Seshamani, M.D. Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Comments in Response to Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 Draft Guidance

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Initial Price Applicability Year (IPAY) 2027 draft guidance (Draft Guidance) regarding implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA),[1] as published on May 3, 2024. This Draft Guidance establishes the parameters for the second year of the Medicare Drug Price Negotiation Program (Negotiation Program) to negotiate prices for certain single source drugs and biological products.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes. PCMA's comments are informed by two overarching policy priorities that should govern CMS's implementation of the Negotiation Program.

(1) **Pharmacies should be shielded from the financial hazards associated with delays or failures in receiving the Maximum Fair Price (MFP)**. The current system employed by CMS, which retrospectively effectuates the MFP, exposes pharmacies to such risks. PCMA advocates for a shift towards a system where the MFP is effectuated prospectively. While retrospective methods may be used as interim solutions, the

[1] Available https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

ultimate goal should be to establish a permanent system that calculates the MFP prospectively.

(2) **CMS has an obligation to minimize the administrative responsibilities of Part D plans in the implementation of the MFP**. PCMA contends that CMS's current approach, which relies on the Prescription Drug Event (PDE) record, inappropriately burdens Part D plans with the operationalization of the MFP. PCMA holds the view that it is not suitable to overhaul the existing protocols that Part D plans and pharmacies use for processing and paying claims, especially for the purpose of integrating a sub-process that affects only a handful of drugs. PCMA urges CMS to explore alternative methods that would assign the responsibility for MFP effectuation solely to the drug manufacturers instead.

Our comments on CMS's IPAY 2027 Draft Guidance are laid out below.

I. Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2027

Background. Consistent with its IPAY 2026 Revised Guidance, CMS intends to identify "negotiation-eligible" drugs under the Negotiation Program by using "gross covered prescription drug costs" (GCPDC) as reinterpreted by the agency to exclude price concessions and other rebates.[2] In other words, CMS will identify and rank negotiation-eligible drugs without regards to the discounts that Part D plans currently secure on these same products.

Comment. PCMA has previously objected to CMS's reinterpretation of the GCPDC definition for purposes of the Negotiation Program. When Congress enacted the Negotiation Program and employed the GCPDC term, it did so with an understanding that CMS's longstanding interpretation of the term would also govern the implementation of the Negotiation Program. Congress did not provide any sign that it expected CMS to revise its longstanding interpretation, either in the statutory scheme of the Negotiation Program, or any other legislative history. Congress' expectation that the longstanding GCPDC definition would govern the Negotiation Program also makes sense from a public policy perspective. It is counterintuitive that, in implementing a Negotiation Program intended to reduce drug costs and improve access, Congress would rank negotiation-eligible drugs without regard to how effectively Part D plans are negotiating prices for these same drugs. Instructing CMS to negotiate prices for drugs that are already subject to substantial rebates through Part D plans is redundant and could potentially disrupt the market-driven structure that is foundational to the Part D program. Further, such a decision clearly decreases the potential actual savings the program would realize under the negotiation program.

[2] IPAY 2027 Draft Guidance at 6.

***PCMA recommendation*: CMS should reconsider its revised GCPDC definition for IPAY 2027 and revert to the longstanding definition that was in effect when the Negotiation Program was enacted.[3]**

II. Section 30.3.1 – Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

Background. The manufacturer of a biosimilar biological product may submit a request, prior to the selected drug publication date for the relevant IPAY (Feb. 1, 2025 for IPAY 2027), for CMS's reconsideration to delay the inclusion of a negotiation-eligible drug that includes the reference product for the biosimilar on the selected drug list for a given IPAY.[4] CMS must determine that there is a "high likelihood" that the biosimilar will enter the market by February 1, 2027.[5] CMS will notify the biosimilar manufacturer of its determination regarding the manufacturer's delay request no later than February 28, 2025.[6]

Before submitting an Initial Delay Request, biosimilar manufacturers face the challenge of limited information about the potential selection of the reference biological product for negotiation. CMS plans to determine the drugs eligible for negotiation for IPAY 2027 based on PDE data collected from November 1, 2023, to October 31, 2024.[7]

Comment. The optimal strategy for reducing drug prices for high-priced biologics lies in fostering competition between reference products and biosimilars.[8] This understanding underpins Congress's focus on targeting products that lack competition for the Negotiation Program, and its directive to CMS to remove products from the Negotiation Program when market competition is likely to achieve the ends desired by the statute.

PCMA suggests that CMS should directly share information with biosimilar manufacturers concerning the reference products that are likely to be eligible for negotiation. The process of submitting an Initial Delay Request demands considerable effort and coordination within a biosimilar manufacturer's organization. The uncertainty surrounding the selection of reference biological products for the Negotiation Program adds to the complexity and creates an unnecessary burden on biosimilar manufacturers. This lack of predictability also leads to inefficiencies in the Negotiation Program's execution.

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[3] *See* 88 Fed. Reg. 22120, 22261 (April 12, 2023) (amending GCPDC definition at 42 C.F.R. § 423.308).
[4] *Id.* at 19.
[5] *Id.* at 24.
[6] *Id.* at 22.
[7] *Id.* at 14.
[8] See for example Yang, J., Chaudhry, B.I., Yue, A.T. et al. The Impact of Biosimilar Use on Total Cost of Care and Provider Financial Performance in the Medicare Oncology Care Model: A Population-Based Simulation Study. Adv Ther 41, 349–363 (2024). https://doi.org/10.1007/s12325-023-02703-x.

***PCMA recommendation*: To alleviate these issues, PCMA recommends that CMS should either publish a preliminary list of selected drugs well before the official publication date, giving biosimilar manufacturers more time to evaluate whether to submit an Initial Delay Request, or CMS should engage in targeted communication with biosimilar manufacturers. For example, CMS could publish the full list of 50 drugs eligible for selection by spending without other exclusions, well in advance of the Initial Delay Request deadline. CMS uses a different time period than is otherwise publicly available when calculating total spending, creating uncertainty that biosimilar manufacturers are left to manage. This outreach would inform them in advance if their reference product was being considered for negotiation, thus aiding in their planning and decision-making processes.**

III. Section 40 – Requirements for Manufacturers

Background. Manufacturers may make MFPs available to dispensing entities prospectively, through current contract administration processes, or retrospectively, through a newly created entity. CMS describes two options for manufacturers to make discounts relative to the MFP available to dispensing entities.

To ensure the effectuation of the MFP retrospectively, CMS proposes to mandate that both manufacturers and dispensing entities engage in a data-sharing process for IPAY 2026 and 2027.[9] This process will be managed by a newly contracted intermediary, referred to as the Medicare Transaction Facilitator (MTF), whose role is to streamline the exchange of detailed claims data. This data exchange is critical in establishing instances where a manufacturer is responsible for providing the MFP to a dispensing entity, and for triggering the application of the prompt pay requirement.[10]

As described by CMS, Part D plans and their contracted PBMs are central to this data-exchange process by virtue of their role as the claims processing entity for Part D transactions. The MTF will provide manufacturers with data that has been verified by both the Part D plan sponsor and CMS's Drug Data Processing System (DDPS), resulting in dual verification for each claim being transmitted of both an individual's eligibility for Part D and Part D coverage of the selected drug.[11] CMS is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF funds.[12]

[9] *Id.* at 37.
[10] *Id.* at 38.
[11] *Id.* at 41.
[12] *Id.* at 42.

At this time, CMS states it will not be responsible for deduplicating discounts between the 340B ceiling price and the MFP.[13]

Comment: We agree with CMS that ensuring that MFPs are made available to dispensing entities is solely the manufacturer's responsibility. We conditionally support CMS's efforts to establish a data-sharing process between manufacturers and dispensing entities for IPAY 2026 and 2027, as managed by the MTF, because CMS has not made it more clear to manufacturers how to otherwise effectuate the MFP as an acquisition price for dispensing entities. As currently described, we agree that the data exchange is crucial for ensuring that manufacturers provide the MFP to dispensing entities when required.

However, we have some concerns and recommendations regarding the proposed data transmission requirements and timelines, as well as the potential for voluntary payment facilitation functionality through the MTF.

As stated in our introductory section, CMS is describing a process by which Part D plans, at their own expense, are providing significant data to manufacturers in a system through which pharmacies are left waiting for reimbursement. We strongly recommend CMS first make it clear to manufacturers that allowing dispensing entities to purchase at the MFP is the expectation, and that the MTF is for reconciliation or back-up reimbursement claims. We are specifically concerned about the proposed requirement for Part D plans to submit prescription drug event (PDE) records within seven days of the date of dispensing, instead of the current 30-day window. We believe that this would impose significant operational and administrative burdens on Part D plans, especially for claims that require coordination of benefits, prior authorization, or other complex processing. A shortened window would lead to inaccurate information being transmitted to manufacturers that heightens the administrative burden on all parties.

Our members report CMS has taken as long as six days to accept PDEs, though these are noted to be outliers, and sometimes CMS's responses to PDEs require either corrections or new files. There are also situations where PDEs are reversed – skilled nursing facility residents, hospice patients, and ESRD bundled payment patients were highlighted by members. It can take many months to clean out these records as plans work toward the payment reconciliation timeline of six months after plan year closing.

While the volume of non-seven-day one-and-done PDEs may be low, they represent real financial risk to pharmacies for retroactive repayment requests by manufacturers. Manufacturers may use the absence of a PDE on day seven to delay payment of the MFP within the statutory prompt pay framework. For PDEs submitted at 14 days, the manufacturer has no information on which to make a refund, and they could take the position that the prompt payment clock does not commence until they receive the PDE from the MTF, even though the statute's use of the word "claim" does not condition the provision of the MFP on the PDE record. Thus, we are

[13] *Id.* at 49.

concerned that CMS's reliance on the PDE may delay payments to pharmacies and make such claims "off-cycle" relative to the payments that pharmacies receive from Part D sponsors. Due to these various considerations, we also question CMS's ability to significantly change the Part D claims processing and payment processes without statutory authorization, including but not limited to narrowing the PDE submission window from 30 days to seven days. The Part D prompt payment rules were established by Congress as part of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Changes to these processes disrupt the industry's longstanding and compliant solutions to MIPPA. If Congress intended to grant CMS the authority to change the payment cycle and process, it would have done so as part of the IRA. Forcing plans to adjust the payment cycle (at great expense and risk) for a sub-process (MFP effectuation) that does not directly involve plans could represent an unlawful exercise of authority by CMS.

Second, we are concerned that the 14-day prompt payment period for manufacturers may not be sufficient time to deduplicate 340B-eligible claims, especially in the context of contract pharmacy 340B-eligible claims. CMS has opted not to consolidate the deduplication process within the MTF, which may lead to a proliferation of deduplication methods by manufacturers, potentially affecting 340B covered entities in various ways. There is a risk that manufacturers might not complete the deduplication process within the 14-day window, which could result in the issuance of duplicate discounts, in contravention of the statute. Again, under a retrospective reimbursement to pharmacy model, it is pharmacies who are most harmed by CMS's decision not to take an active role in deduplication. Rather, manufacturers who can operationalize MFP at the point of acquisition will have better data from dispensers and can more effectively reduce their 340B duplicate discount risks.

Moreover, the lack of a standardized deduplication methodology could give rise to disputes over the methods employed by manufacturers, causing inefficiencies and payment delays for the effectuation of MFP. Further, manufacturer deduplication measures may require covered entities to prospectively identify 340B prescriptions, which we understand is often not possible under prevailing replenishment models. This issue is exacerbated by the absence of CMS guidelines regarding the evidentiary standards manufacturers should meet when identifying 340B-eligible claims and determining if the 340B ceiling price is indeed lower than the MFP. The agency states that in order to avoid paying the MFP, the Primary Manufacturer must "reasonably believe" that the claim is a 340B-eligible claim and that the 340B price is lower than the MFP.[14] However, without a clear definition of what constitutes "reasonable belief," disagreements are likely to emerge between covered entities and manufacturers. Such disputes have the potential to hinder the effective rollout of the MFP. The concerns about the prompt payment time frame and the deduplication process underscore the need for more detailed guidance from CMS to ensure that the objectives of the MFP are met without undue conflict or delay. CMS should, at the very least, require manufacturers to share thorough documentation of

[14] *Id.* at 48.

their 340B-eligibility determinations with the MTF, rather than simply sharing such documentation upon request from CMS.

Third, as alluded to above with respect to CMS's PDE-related proposal, we are concerned about how CMS will handle claim adjustments and reversals after clean PDE data submission. We understand that CMS intends to use existing Part D claims data to avoid additional data transmission requirements for dispensing entities, but we are unclear how CMS will ensure that manufacturers are notified of any changes in the status or amount of claims that affect their MFP obligations. We request that CMS provide more detail on how it will track and communicate claim adjustments and reversals to manufacturers and dispensing entities, and how it will resolve any disputes or discrepancies that may arise, such as 340B-related disputes as discussed above.

Fourth, our support extends to CMS's proposal of the two payment methodologies for stakeholders that would be facilitated through the MTF. However, we strongly encourage CMS to persist in identifying and evaluating prospective methods for implementing the MFP. We emphasize that both of CMS's payment options place the financial risk associated with the difference between the pharmacy acquisition cost and the MFP on the pharmacies, as opposed to the manufacturer. Pharmacies should not be exposed to potential financial shortfalls because of a manufacturer's preference on how to implement a statutory obligation. Moreover, any friction that pharmacies encounter in accessing the MFP will necessarily be felt by beneficiaries as pharmacies may adjust their drug purchasing and inventory policies, thereby affecting beneficiary's access. Also, many PBMs operate mail and specialty pharmacies that will also be subject to these financial considerations.

Thus, while we agree that the MTF stands to act as an essential and wholly independent intermediary for bridging the gap between manufacturers and dispensing entities, thereby smoothing the implementation process of the MFP within a retrospective model, it remains the case that the most effective and error-resistant approach for ensuring that dispensing entities have access to the MFP would be for manufacturers to prospectively provide the MFP to these entities. We recommend that CMS should prioritize the development of a prospective MFP implementation strategy and consider the retrospective approach as a secondary alternative.

***PCMA recommendation*: We urge CMS to maintain the current 30-day window for PDE submission, or at least provide a reasonable grace period for claims that are delayed for legitimate reasons. We also urge CMS to more closely consider a standardized 340B deduplication method or an extension to the 14-day prompt payment standard to account for challenges in the deduplication of discounts between the MFP and 340B ceiling price. Further, we recommend that CMS prioritize the development of a prospective MFP model as it would be more efficient and error-resistant, and it would shift the financial risk associated with the MFP from pharmacies to manufacturers. Lastly, we seek more information from CMS on how to handle claim adjustments after clean PDE submissions,**

and how CMS plans to account for critical, but non-payment related functionalities of the MTF's payment facilitation responsibilities.

IV. Section 70 – Removal from the Selected Drug List Before or During Negotiation, or After an MFP is in Effect

Background: For IPAY 2027, if CMS determines that a generic or biosimilar version of a selected drug is marketed on a bona fide basis between the date that the selected drug list for IPAY 2027 is published (September 1, 2024) and the end of the negotiation period (November 1, 2025), the drug will remain a selected drug through 2027, but the MFP will not apply.[15] If CMS makes this determination between November 2, 2025 and March 31, 2027, for a drug selected for IPAY 2027, then the drug will be subject to the MFP for 2027, but will cease to be a selected drug on January 1, 2028.[16]

Comment: Based on our understanding that Congress intended the Negotiation Program to be a fallback mechanism to be utilized in the absence of market competition for high-cost drugs, PCMA has two separate but related comments about the impact of CMS's "bona fide marketing" determination on selected drugs and Part D plans' ability to negotiate pricing and formulary coverage for these products.

The first concern emphasizes the critical nature of CMS's prompt public notification when it determines that a generic or biosimilar is being marketed on a bona fide basis. This information is pivotal for Part D plans as it directly influences their ability to negotiate drug prices and manage formulary coverage for the selected drug and its competitors. The expectation is that the MFP's implementation will likely deter manufacturers from offering additional discounts. Therefore, if a selected drug is exempt from the MFP due to a bona fide marketing determination, it is imperative that Part D plans are informed promptly. This will enable them to engage in timely negotiations with the drug's manufacturer, who will no longer be bound by the MFP obligations.

The second concern necessitates that CMS provide clear guidance regarding the mandatory coverage requirement outlined in section 1860D-4(b)(3)(I)(i) of the statute. This requirement should not be applicable to a selected drug for which CMS has determined that the MFP does not apply due to the identification of bona fide marketing within the specified time frame. The statute is clear that the mandatory formulary coverage requirement applies only to a selected drug "for which a maximum price…is in effect with respect to the year."[17] In instances where CMS makes a bona fide marketing determination for a selected drug between the publication date of the selected drug list and the end of the negotiation period, the drug remains a selected

[15] *Id.* at 105.
[16] *Id.*
[17] Social Security Act § 1860D-4(b)(3)(I)(i).

drug for the initial year without the MFP being in effect for that year. Consequently, the mandatory coverage requirement should not be enforced for that drug.

PCMA recommendation: CMS should promptly notify Part D plans, such as through an HPMS memo, when "bona fide marketing" is present for a selected drug. CMS should also clarify that the mandatory formulary coverage requirement does not apply to selected drugs for which CMS makes a "bona fide marketing" determination between the selected drug publication date and the end of the negotiation period.

V. Section 90.2.2 – Negotiation Program Complaints and Disputes

Background: CMS will establish a centralized intake system for receiving reports related to access to the MFP with respect to MFP-eligible individuals and pharmacies, mail-order services, and other dispensing entities that provide selected drugs to MFP-eligible individuals.[18] The complaint and dispute system will be set up with two "tracks" within one overall system. The first track is a dispute functionality within the MTF for qualifying disputes from manufacturers or dispensing entities regarding technical aspects of the MTF process. The second track is a complaint process that will intake complaints, and will be available to the public, regardless of their degree of participation in any aspect of the MTF and will encompass any issues that do not qualify as "disputes." CMS considers a "dispute" to be a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an MFP refund).[19]

Comment: We support the establishment of a centralized intake system for receiving reports related to access to the MFP, as proposed by CMS. We believe this system will help ensure that MFP-eligible individuals and dispensing entities can obtain the MFP as required by the program, and that any issues or disputes can be resolved in a timely and efficient manner. We also appreciate that CMS will provide a dispute functionality within the MTF for qualifying disputes and a complaint process for issues that do not qualify as disputes. However, we are concerned that the IPAY 2027 Draft Guidance does not explicitly allow Part D plan sponsors to use the complaint process to report any problems they encounter that relate to the MFP under the "first track," such as the mandatory formulary coverage requirements. Part D plan sponsors are key stakeholders in the program and have a direct interest in ensuring that the MFP is available and accessible to their enrollees. We recommend that CMS clarify that Part D plan sponsors can also submit complaints through the centralized intake system and that CMS will respond to and address their concerns.

PCMA recommendation: CMS should clarify that Part D plans may avail themselves of the "first track" of the proposed complaint and dispute system.

[18] *Id.* at 113.
[19] *Id.* at 114.

VI. Section 110 – Part D Formulary Inclusion of Selected Drugs

Background: CMS has indicated its intention to maintain the formulary inclusion policies set out in the revised guidance for the initial price applicability year 2026 into contract year 2027, acknowledging the lack of sufficient information to warrant changes to these policies. Despite the upcoming changes due to the IRA Part D redesign provisions effective in 2025, CMS does not have details on plan formularies for contract year 2025 and will continue to monitor compliance with formulary requirements. CMS will not impose uniform tier placement or utilization management requirements for selected drugs in 2027 but will require formularies to include all dosage forms and strengths of selected drugs for which the MFP applies. In the contract year 2027 formulary review, CMS will scrutinize any instances where selected drugs are placed on non-preferred tiers or subjected to more restrictive utilization management compared to non-selected drugs in the same class, requiring Part D sponsors to provide justifications for their plan designs that comply with statutory and regulatory requirements. CMS will assess these justifications during the annual bid review process and approve Part D plan bids only if they meet all applicable requirements.

Comment: Consistent with our previous comments, CMS should not require Part D plans to include all dosage forms and strengths of selected drugs on their formularies, but only those that are necessary to meet the needs of enrollees. This modification would reduce the administrative burden and cost for Part D plans and align with existing formulary standards and guidance. For example, there may be Part B-covered formulations, or a wide variety of NDC configurations that are not typically stocked by pharmacies, or some NDCs are more commonly used for pediatric rather than adult patients. Moreover, we reiterate our previous comments that we interpret this guidance to say that selected drugs with MFPs should be preferred brand drugs by default.

Specifically, PCMA has long been concerned that CMS does not adequately address the potential impact of the formulary inclusion requirements on the competition and innovation in the pharmaceutical market. By requiring Part D plans to include selected drugs on their formularies, CMS may limit the ability and willingness of manufacturers of non-selected drugs to compete for preferred status or offer rebates or discounts to Part D plans. This may reduce the incentives for manufacturers to develop new or improved drugs or to lower their prices to compete with the selected drugs. Further, while CMS has provided plans and PBMs the ability to justify situations where a selected drug would not be preferred, the burden is on the plan rather than the manufacturer. Many selected drugs have been on the market for a very long time and may not represent the most recent therapeutic advances. CMS should, consistent with precedent, rely on PBM pharmacy & therapeutics committee processes to determine the best products to prefer within formularies, rather than imposing a coverage mandate for selected drugs.

We recognize that the legislation stipulates the inclusion of certain medications in formularies, but it does not dictate the specific tier placement for these drugs. Specifically, the statute only requires that Part D plans "include each covered Part D drug that is a selected drug…."[20] The statute plainly distinguishes between on-formulary coverage and the tier of coverage, such as with respect to exception requests for non-formulary drugs versus tiering exceptions.[21] Therefore, the obligation to include selected drugs should be understood as ensuring their presence on the formulary. It would be incorrect to infer from this obligation any specific tier placement for selected drugs in the absence of explicit legislative language indicating such a requirement.

We urge CMS to consider the potential unintended consequences of the formulary inclusion requirements and to allow Part D plans more flexibility in designing their formularies to reflect the needs and preferences of their enrollees, advancements in clinical care, and the market dynamics.

We also request that CMS provide clear and consistent guidance on the transition policies, formulary exceptions, and tiering exception requests that apply to selected drugs, and ensure that beneficiaries have adequate notice and access to the drugs they need.

***PCMA recommendation*: CMS should only require the formulary inclusion of dosage forms and strengths of selected drugs that are necessary to meet the needs of the Part D plan's patient population. CMS should also clarify that for selected drug dosage forms and strengths which are included on formulary, their default formulary placement should be as preferred brand status. Finally, CMS should provide guidance on the application of transition policies, formulary exceptions, and tiering exception requests to selected drugs.**

CONCLUSION

We appreciate the opportunity to comment on the IPAY 2027 Draft Guidance regarding implementation of section 11001 and 11002 of the IRA, which established the Medicare Drug Price Negotiation Program to negotiate prices for certain single source drugs and biological products.

We hope our suggestions help CMS to implement the Negotiation Program in a way that utilizes, and does not undermine, the existing market-based approach to the Part D program that has allowed Part D plan sponsors and PBMs to successfully negotiate discounts that benefit patients and the program since the inception of the program. We would welcome the opportunity to meet with the agency to discuss these or any other issues relevant to

[20] Social Security Act § 1860D-4(b)(3)(I)(i).
[21] *See id.* at § 1860D-4(g).

implementation of the Negotiation Program for IPAY 2027. If you have any questions on these suggestions and recommendations, please do not hesitate to contact me directly at tdube@pcmanet.org.

Sincerely,

Tim Dube

Timothy Dube, Senior Vice President, Policy & Regulatory Insights

Cc: Chris Ritter, CMS
Kristi Martin, CMS

PERSONALIZED MEDICINE COALITION

July 2, 2024

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Sent electronically to IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Deputy Administrator Seshamani:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on CMS' draft guidance for implementation of the Medicare Drug Price Negotiation Program for the initial price applicability year (IPAY) of 2027.[i] This draft guidance includes some improvements compared to the draft guidance for IPAY 2026. We believe, however, that it continues to lack transparency and clear descriptions for procedures and methodology that will be used to negotiate a drug's maximum fair price (MFP). Because few details are provided on how personalized medicine will be considered and in light of recent studies demonstrating the potential negative impacts of the program, our comments build upon those shared with CMS on IPAY 2026.[ii] We urge CMS to take every step possible to prevent, monitor, and correct for potential unintended impacts of the program on patients and the health care system.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine is playing an important role in transforming care and patient outcomes for a range of serious and life-threatening diseases and conditions, helping to shift patient and provider experiences away from trial-and-error medicine and toward a more streamlined process for making clinical decisions.

After initial approval of a small-molecule drug, biologic, orphan drug, or genetically targeted therapy by the U.S. Food and Drug Administration (FDA), further research can provide greater understanding of patients' responses to treatment based on results

from molecular diagnostics. This research leads to new or improved treatment indications that contribute to progress in personalized medicine.

We believe PMC and CMS share the goal of achieving better health outcomes and removing patient access barriers. We urge CMS to refine its negotiation process so that it does not disrupt the innovation ecosystem and patient access to personalized medicine by ensuring that:

- CMS establishes processes to prevent, monitor, and correct for any unintended, downstream impacts of the program on patient access to personalized medicine and on pipelines for new personalized medicine treatments and expanded indications;
- CMS' methodology to determine a selected drug's MFP recognizes the clinical and societal benefits of personalized medicine and incorporates patients' perspectives on care value;
- CMS' methodology and negotiation process establish consistency and transparency by communicating how factors considered are weighed and how external data are factored into its decisions;
- CMS establishes procedures that allow a robust exchange of information with manufacturers, patient organizations, and other stakeholders in determining the MFP throughout the negotiation process; and
- Patients do not face additional barriers in accessing negotiated medicines and their treatment alternatives, as well as non-negotiated medicines.

Statement of Neutrality

Many of PMC's members will present their own responses to the *Medicare Drug Price Negotiation Program Draft Guidance for IPAY 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027* and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the draft guidance and/or any that follows.

Monitoring Unintended Impacts on Personalized Medicine

Personalized medicines have accounted for at least a quarter of new drug approvals for each of the past nine years.[iii] Medicare's drug price negotiation program could have an outsized effect in discouraging the pharmaceutical industry from bringing additional personalized medicines and expanded indications to the market. Multiple analyses, including those from the Congressional Budget Office (CBO), have called attention to the potential consequences of the Medicare drug price negotiation program, such as canceled research and development and disincentives to invest in small-molecule medicines and therapeutic areas that require incremental innovation.[iv,v,vi,vii] Legislators have also questioned CBO's initial analysis for underestimating such impacts of the program.[viii] **CMS should take every step possible to prevent, monitor, and correct for potential impacts of the program on patients and the health care system.**

Indications for smaller patient subpopulations

Due to smaller patient subpopulations, personalized medicines that address the root causes of disease can sometimes be expensive and risky to develop. In 2023, a record 61 percent of new personalized medicines approved by the FDA were to treat rare diseases, with 27 percent indicated for certain

cancers.[ix] There are more than 10,000 rare diseases, including rare cancers, and more than 90 percent of them do not have an FDA-approved treatment.[x] With companies expected to focus on treatments for larger patient populations where return on investment can be easier, the pursuit of indications for smaller patient populations could be delayed or forgone. Thus, treatment pipelines for cancers and rare diseases could be especially impacted by Medicare's drug price negotiation program.[xi,xii] **CMS should monitor impacts of the program on the development of personalized medicines for smaller patient subpopulations, including patients with unmet medical needs.**

Small-molecule drugs

Many targeted cancer therapies that deliver personalized medicine to patients are small-molecule drugs.[xiii] According to *IRA* statute, small-molecule drugs are eligible for negotiation nine years after approval versus 13 years for biological, or large-molecule, products. PMC is concerned that implementation of these differential timelines will disincentivize investment in small-molecule over large-molecule drugs. Small-molecule drugs comprise 70 percent of the drugs selected for negotiation in IPAY 2026. Such drugs are likely to make up 93 percent of the drugs selected for IPAY 2027 and 87 percent of the drugs in IPAY 2028.[xiv] Small-molecule oncology therapies are also estimated to be predominantly affected during the program's first few negotiation cycles.

These dynamics may impact the growing pipelines of personalized medicines available to patients, including patients from communities already experiencing disproportionately high incidence and mortality rates of certain diseases like cancer. One analysis estimates 79 fewer small-molecule drugs and 188 fewer indications coming to market over the next 20 years.[xv] To reduce the impact of differential timelines for drugs and biologics on clinical development for small molecules and patients who need these critical therapies, PMC supports Congress amending the *IRA* to establish equal timelines for the negotiation of both drugs and biologics at 13 years. **CMS should also monitor impacts of the negotiation program on the development of small-molecule personalized medicines.**

Post-approval research and expanded indications

In identifying drug products for negotiation, CMS broadly interprets the statute to aggregate drugs for selection based on a single active moiety, or ingredient, across multiple New Drug Applications (NDAs) or Biologics License Applications (BLAs). As drug products age and approach eligibility for price negotiation, companies may be disincentivized to pursue additional indications, which can require additional approvals after the original NDA or BLA approval. PMC is concerned that the negotiation program will deter incremental innovation supported by post-approval research, including the development of expanded indications that provide patients with personalized medicine treatment options.

Research conducted after approval of a new drug is important for advancing personalized medicine. After initial approval of a targeted therapy by FDA, further research provides greater understanding of patients' responses to treatment based on results from molecular diagnostics. This research leads to new or improved treatment indications that contribute to progress in personalized medicine. But smaller patient subpopulations can make it difficult to recoup investment in this research, which can require additional clinical trials and NDAs or BLAs. One white paper examining six products in chronic diseases, rare diseases, and cancer found that nearly half (seven out of 15) of the applications for expanded indications were approved at about the same time or after the product could have been selected to begin negotiation (at seven or 11 years).[xvi] Another peer-reviewed analysis of 50 drugs with the highest Medicare Part D

spending in 2020 found that 30 were small-molecule drugs, and 56 percent of these small-molecule drugs received FDA approval for expanded indications more than seven years after their initial FDA approval.[xvii]

Over the past nine years, PMC has identified more than 130 expanded indications significant to advancing personalized medicine.[xviii] Notably, these expanded indications have had an upward trend in the average time since a drug's initial approval. Since these expanded indications can increase the product's aggregated utilization and risk for earlier selection, the drug price negotiation program can alter manufacturers' decision-making for investing in researching new uses for a drug post approval, potentially affecting patients with serious conditions or unmet needs. **CMS should monitor impacts of the negotiation program on post-approval research into expanded indications for both small- and large-molecule drugs. CMS should also consider opportunities to implement its statutory requirements in a way that does not undermine incentives for post-approval research critical to personalized medicine.**

Orphan drug products and additional rare designations

Currently, certain orphan drugs are excluded from the Medicare Drug Price Negotiation Program, but the exclusion only applies to orphan drugs that treat one rare disease or condition. If an orphan product has designations for multiple diseases, even if these are also orphan designations, then it loses its exclusion from negotiation. The agency will use the earliest date of approval or licensure to determine when the product is eligible for negotiation. Only about one quarter of all orphan drugs approved in the last two decades have a single indication.[xix] Researching additional orphan indications for existing rare disease treatments plays an important role in identifying new treatments for patients with rare diseases who do not have treatments available to them.

PMC is concerned that this narrow exclusion could stifle post-approval research into additional orphan indications for rare diseases. Even when making investment decisions among multiple potential orphan indications, manufacturers may be incentivized to prioritize indications for rare diseases with larger patient populations over indications for very rare diseases. PMC believes this narrow exclusion contradicts the goals of the *Orphan Drug Act* to foster the development of new treatments for rare diseases. PMC recognizes CMS is limited by the *IRA* and supports legislation to broaden the orphan drug exclusion in statute by ensuring orphan drugs treating one or more rare diseases or conditions are excluded and by clarifying that the countdown to eligibility for price negotiation would begin only when an orphan drug loses its exclusion. **Still, we encourage CMS to monitor impacts of the new program on the development of orphan products and research into additional orphan designations for patients with rare diseases.**

Genetically targeted therapies

Genetically targeted therapies (GTTs) work by either delivering healthy copies of genes to target cells, permanently changing the genetic code, or manipulating gene expression. If a GTT silences a gene, it is regulated as a drug, but if a GTT adds to a gene, it is regulated by the FDA as a biologic. Despite differences in their pathways for regulatory approval, GTTs are similar in time of development, therapeutic action, and complexity of manufacturing. As a result of the unequal negotiation timelines, GTTs regulated as drugs would be negotiated after only nine years, whereas GTTs regulated as biologics would be negotiated after 13 years. These different timelines under the *IRA* impose an artificial

distinction that could lead to a lack of parity in the development of these novel therapies.

Of the dozen or so GTTs with an approved NDA to-date, all are personalized medicines that treat patients with rare diseases. While only a limited number of GTTs are on the market now, the underlying technology is expected to generate novel therapies for non-rare diseases in the future. To ensure the even advancement of all GTTs in this promising area of personalized medicine, PMC would support statutory changes treating all GTTs as biologics that could be negotiated after 13 years. **Meanwhile, CMS should monitor for disparate impacts of the program on the development of GTTs regulated as drugs versus biologics.**

Collecting information

PMC asks CMS to collect information on the unintended impacts discussed above to ensure the negotiation program does not disincentivize the development of new treatments for unmet medical needs; research on expanded indications that provide additional benefits to patients; patient access to personalized medicine through cost-control practices, like prior authorization or step therapy; or have other impacts on health equity. Related data CMS could consider tracking include changes in NDAs and supplemental NDAs and changes in formulary placement and utilization management for negotiated versus non-negotiated drugs, as discussed below.

Recognizing the Clinical and Societal Value of Personalized Medicine

Drugs with personalized medicine treatment strategies create considerable benefits for patients and society since they are used in a manner that directs them toward patients who are most likely to benefit and away from those who are not. Value assessment frameworks (VAFs) often draw sweeping conclusions, however, about the economic worth of a particular treatment, typically based on analysis of its safety and effectiveness at a population level. In many cases, value assessment methodologies fail to adequately account for the safety and effectiveness benefits that may be realized by individual patients or patient subpopulations. When assessing value, it is important to consider the holistic benefits of a treatment at the patient, subpopulation, and societal levels, including to underserved or underrepresented populations facing inequities in access to care.

PMC appreciates CMS' reference to patient experiences in its discussion of the clinical benefits of selected drugs and their therapeutic alternatives in Sec 60.3.3 of the draft guidance, as well as CMS' proposal to evaluate health outcomes for specific populations, including through an access and equity lens. Although CMS has broadened its consideration of patient experiences to now include caregiver perspectives; changes to productivity, independence, and quality of life; and other factors of importance to patients and caregivers, it is still unclear how input from patients, caregivers, and providers will influence CMS' analysis of clinical benefit and whether CMS may consider the benefit of personalized medicine. **In general, PMC urges CMS to consider the following aspects of clinical and societal value related to personalized medicine that advance patient-centered care,** [xx] **ensuring that the value of personalized medicine to direct patients toward or away from treatments based on their likelihood to benefit from them is factored into determining the MFP for a selected drug:**

1. **Diagnostic testing strategies:** Diagnostic tests can help guide treatment decisions and determine which treatments will be most effective and safest for any given patient. Such testing is a crucial element of the personalized treatment regimen. For example, the use of companion diagnostics

can help define subpopulations of patients who may benefit from a treatment, and those who will not. The availability of diagnostic tests and consideration of test results that help inform treatment decision-making for drugs with biomarker implications must be figured into the value assessment methodology for personalized medicines. **PMC encourages CMS to consider the value of applicable diagnostic strategies in its evaluation of unmet medical need and clinical effectiveness.**

2. **Heterogeneity of treatment effects:** Some patients will experience more or less benefit from a treatment than suggested by the averages reported within clinical trials and population-based data. Health care policies based on averages misjudge and undervalue personalized medicines simply because the data required for value-based decision-making do not account for patient subpopulations or because long-term efficacy data is not yet available. **PMC encourages CMS to consider the full range of patient outcomes and benefits that may not be represented in population average-based data.**

3. **Patient values and circumstances:** Personalized medicine depends not only on the consideration of a patient's molecular and biological characteristics but also on individual values, clinical and economic circumstances, and the potential impact of a therapy for that patient over the long term. Fundamental patient values and preferences, including the impact of treatment on quality of life, quantity vs. quality of time, functional ability related to illness or treatments, cost of supportive care, and other patient costs of treatment are weighed by patients and their caregivers when deciding on a treatment in consultation with health care providers. Although CMS attempts to broaden its definition for "unmet medical need" under IPAY 2027, we believe this definition continues to be too narrow to appropriately assess the value personalized medicines provide to patients with unmet medical needs. **PMC encourages CMS to further expand its definition of "unmet medical need" proposed in guidance to formally consider a broad range of patient outcomes and impacts, including unmet medical needs unique to individual patients and to patient subpopulations.**

4. **Treatment efficiency:** Although value assessments generally focus on improvements in effectiveness, they do not generally consider avoiding ineffective or harmful treatment options and reducing the downstream expenses associated with rapid disease progression and/or adverse events. In order to capture economic as well as clinical value, value assessments need to consider costs and outcomes across health care. **As CMS evaluates the costs and benefits of personalized medicines to society, PMC encourages the agency to formally consider a broad range of economic impacts beyond just the proposed consideration of changes to a patient's productivity, including broader cost offsets and societal benefits, like treatment efficiency.**

It is clear both in the statute and in CMS' guidance that quality-adjusted life years (QALYs) will not be used as a basis for evaluations. The QALY and other similar metrics do not sufficiently account for the broad heterogeneity of clinically relevant characteristics and preferences across patients and diseases, nor do they consider aspects of value defined by patients and their families. These measures rely on population averages that do not consider the heterogeneity of patient populations, even within the same condition.

While CMS states it will follow statute, the revised IPAY 2026 guidance suggested CMS may explore

QALY-like alternatives and the draft IPAY 2027 guidance indicates that CMS still plans to separate and exclude QALY metrics from evaluations of research that otherwise factor in QALYs when such content is "relevant and allowable." PMC is concerned that this approach may not effectively separate QALYs from CMS' analysis because CMS may continue to rely on studies that employ QALY or QALY-like data from secondary sources, or that CMS may exclude analyses that are otherwise helpful in establishing the value of a drug for a patient. Regarding CMS' *Negotiation Data Elements Information Collection Request* that asks the public to submit information on a selected drug, we appreciate that CMS now asks submitters to indicate whether their submission contains information from studies that use QALYs and to provide a short description of any cost-effectiveness measures included in the research they submitted and how they believe the data avoid the use of the QALY measure. **However, PMC also requests that CMS specify how it will exclude QALY-based and other similar metrics from its analysis of such evidence, how it will determine such content is relevant and allowable, and how this evidence would be weighed. PMC also requests that CMS highlight when and how the agency removed QALY-based metrics from consideration in its public explanation of a drug's MFP.**

For IPAY 2026, CMS requested input on what alternative measures to QALYs might be appropriate or inappropriate. PMC believes the agency would be better served by focusing on the factors related to comparative clinical outcomes and unmet need that are described in statute, which can better capture the benefits of personalized medicine, rather than seeking an alternative to the QALY or using another metric based on the QALY. There is not one measure of value or one VAF that holistically captures the value and benefits of any medical treatment or outcomes important to patients in every disease area. VAFs have strengths and limitations relative to different stakeholder perspectives and circumstances that can bolster or undermine their usefulness and applicability to personalizing patient care. A single measure will not be sufficiently comprehensive.[xxi] **We continue to encourage CMS to consider a wide variety of measures consistent with CMS' statutory focus on comparative effectiveness research and unmet need, especially those driven by patient experience data, patient input, and patient-centeredness.**

Establishing a Consistent and Transparent Process for Gathering and Evaluating Evidence

CMS indicates it will consider real-world evidence, peer-reviewed research, expert reports or white papers, clinician expertise, and patient experiences when reviewing the clinical benefit of a selected drug and its therapeutic alternatives (Sec. 60.3.3). Considering that all medicines for which CMS will set an MFP will have a minimum of nine years since their original FDA approval, **PMC encourages CMS to consider as broad an array of evidence sources and outcomes as possible to help fill gaps in population-based data sources and capture the full range of personalized medicine's benefits to patients and the health care system discussed above.** We thank CMS for considering information on underserved and underrepresented populations that may be experiencing disparities in health outcomes or access to a selected drug.

Although CMS' draft guidance lists aspects related to the quality and completeness of evidence sources it will consider, such as peer review, study limitations, risk of bias, and study population, among others, CMS does not describe requirements for the quality and completeness of this data, nor how CMS would consistently evaluate this evidence in determining the MFP. For example, since studies using RWE are designed fit-for-purpose, CMS' methodology should consider the extent to which the evidence it considers was designed to answer the value questions it is asking. The approach outlined in the initial guidance is too vague to create consistency across negotiations. **To ensure that the agency is evaluating these elements in a way that considers the value of personalized medicine to patients, CMS should**

refine its methodology through notice-and-comment rule-making to provide more clarity on how the agency intends to leverage negotiation factors outlined in Sec. 50.2. For real-world evidence in particular, CMS should describe what data sources it plans to use and create guidelines to ensure that the data used are robust and correctly utilized.

Specifically, CMS should outline a consistent methodology for how it will synthesize evidence and for how data related to therapeutic alternatives will result in changes to an initial offer or final negotiated MFP. In addition, CMS should not use cost as a criterion for selecting therapeutic alternatives. While multi-criteria decision analysis (MCDA) may not be feasible for CMS because it requires extensive time, resources, and expertise, CMS may be able to incorporate elements from, for example, the cost-consequence approach model to compare evidence on outcomes for certain therapies. CMS should continue to consider opportunities to adopt elements from MCDA into its framework for evaluating evidence, as the agency identified in its revised guidance for IPAY 2026.[xxii] As part of CMS' methodology, we ask CMS to prioritize data related to the factors described above for recognizing the full range of personalized medicine's benefits to patients and the health care system. Given the discount already reflected in a selected drug's ceiling price, **we recommend that when these factors are taken into consideration, the MFP for a selected drug be set at the ceiling if it demonstrates significant patient, clinical, or societal benefit.**

Even though CMS intends to employ a qualitative approach to considering the evidence between different selected drugs, CMS' methodology should clearly explain how each data element is weighted in determining the initial offer and final MFP. **To account for the clinical and societal benefits of personalized medicine and incentivize continued research and development for this field, CMS should place more weight on the factors related to the benefits of the selected drug for patients, caregivers, and society – including evidence on its benefit to patients experiencing health disparities – over, for example, non-clinical manufacturer-specific data elements.**

Establishing a clear and consistent process for gathering and evaluating evidence, including the information provided by stakeholders during the patient-focused listening sessions, can help manufacturers, patient groups, and other third parties better understand the evidence they may need to prioritize or collect for CMS' future consideration. Transparency can also build beneficiaries' confidence that their preferences and values are important to the agency.

Facilitating Meaningful Stakeholder Engagement

PMC thanks CMS for responding to previous stakeholder feedback by establishing patient-focused listening sessions in the IPAY 2026 revised guidance. We recognize that CMS has a tight timeline for drug selection and price negotiation. However, in order to ensure MFPs adequately reflect the value of selected treatments for patients and to limit unintended consequences on patients' access to personalized medicine, **CMS must meaningfully engage patients, caregivers, providers, manufacturers, regulators, and other third parties throughout the negotiation process. Third parties, including patients and patient organizations, should be allowed ample time and opportunities to share data and experiences related to selected drugs, and they should be informed by CMS about how their input is being used during the negotiation process.**

CMS solicits comments on how to improve and potentially restructure its patient-focused listening sessions in IPAY 2027. Organizations like the National Health Council have published recommendations

for how CMS can improve patients' experiences in these listening sessions and their overall engagement in the negotiation program.[xxiii] **PMC recommends CMS consider how to foster robust, bi-directional communication between public stakeholders and the agency, and we encourage the agency to adopt recommendations from patient advocacy organizations for how they and individuals from underrepresented communities can be most meaningfully engaged in the negotiation process.** In addition, although we appreciate CMS' intention to consult with clinical and academic experts to help evaluate clinical benefit of a selected drug, **we ask CMS to outline how clinical and academic experts would be identified and consulted during the negotiation process.** For example, CMS could establish a panel of patients, clinicians, and other stakeholders to provide feedback throughout each drug negotiation.

We appreciate CMS' interest in improving the submission of information from the public through its *Negotiation Data Elements Information Collection Request*, such as by grouping and revising questions to align with a respondent's area of expertise and by soliciting information about the factors patients care about most in assessing the value of a drug. CMS' proposed timeline, however, only allows one month from when the list of selected drugs is announced for the public to provide written information on the selected drug and therapeutic alternatives to inform CMS' initial offer. We believe this short and singular timeframe for written public input does not allow a sufficient window for stakeholders who may have information on the value of a treatment to their patient population to collect and provide information that could improve CMS' decision-making. In addition, this timeframe will disadvantage patients and caregivers from or organizations working with underserved communities, who have fewer resources and may find it challenging to respond in such a short timeframe. **CMS should consider the burden of data collection and submission on stakeholders. We ask CMS to allow patients, caregivers, clinicians, and organizations representing these groups additional time to submit the requested data in writing after the list of selected drugs is published. In addition to informing CMS' initial offer for a selected drug, CMS should allow this information to be submitted during subsequent steps of the negotiation process, if initiated, to inform CMS' decision-making.** Flexibility with the submission of public information would facilitate the inclusion of a broad range of patient perspectives, including those of communities underrepresented in existing studies and published literature.

To help build public trust in the process and ensure predictability informs stakeholder participation in listening sessions and data submission during future years of the negotiation program, CMS must be transparent about how it considers information provided. We thank CMS for intending to publish an explanation of the factors that had the greatest influence in determining a drug's MFP, including a narrative explanation and redacted information regarding the negotiation data elements received, exchange of offers and counteroffers, and the negotiation meetings. (Sec. 60.6.1). We remain concerned, however, that the explanation may not provide adequate detail to be meaningful to the public and that its timing – after stakeholders will have submitted data to inform the next cycle of negotiations – will make it irrelevant for stakeholders seeking to inform CMS' next cycle of negotiations. **In CMS' explanation for the MFP, we ask the agency to explain which information submitted by the manufacturer and the public was or was not considered in the final MFP; the benefits and impacts considered; the data sources considered; how evidence influenced the MFP up or down, including the extent to which real-world evidence and patient-centered data elements like patient experience data were used; which third parties were engaged, both formally and informally by CMS; and, as discussed above, the extent to which and how any evidence used to inform the MFP was separated from a QALY-based metric. In addition, so that stakeholders understand how the information they provide in one negotiation cycle is used before they submit information to the next, we support**

CMS' efforts to publish the explanation of the MFP earlier than its statutory deadline.

Ensuring Coverage Policies Facilitate Patient Access to Negotiated Drugs

Medicare's drug price negotiation program could narrow patients' access to existing treatment options in personalized medicine. PMC has previously submitted comments to CMS on the difficulties utilization management practices, such as prior authorization and step therapy, can create for patients in accessing the latest treatments and standards of care informed by personalized medicine.[xxiv,xxv,xxvi] We share CMS' concerns that plans may be incentivized to disadvantage selected drugs with utilization management that is not based on medical appropriateness, potentially exacerbating an already growing trend in the use of step therapy and its embedding in prior authorization requirements.[xxvii,xxviii,xxix] Because negotiated drugs are being offered to plans at a lower price, **PMC believes negotiated drugs should not face additional cost-control practices that could limit eligible Medicare beneficiaries' access to them. While PMC thanks CMS for identifying several criteria the agency will use to assess whether plans meet requirements for covering negotiated drugs through its existing formulary review process, including instances where plans impose more restrictive utilization management for a selected drug compared to a non-selected drug in the same class, we disagree with CMS' proposal to defer on implementing explicit policy requirements. We request CMS clarify specifically the extent to which any utilization management will be permitted for negotiated drugs.**

Although Medicare plan sponsors will be required to include selected drugs on their formularies, without additional guardrails, plans could use restrictive utilization management or other cost-control practices to manage their increased liability by preferring non-negotiated drugs or denying coverage for negotiated products vital to a patient's personalized health care. **To ensure patients are protected from plan attempts to offset costs, CMS should establish robust guardrails and conduct oversight to ensure the clinical appropriateness of any utilization management or formulary changes and to mitigate unintended consequences on beneficiaries' access to both negotiated and non-negotiated drugs and the narrowing of patients' treatment options. In particular, CMS should ensure that patients who are stable on their current medications maintain access to these medications as the negotiation program is being implemented, whether these medications are negotiated or non-negotiated drugs.** Following CMS' recent final rules regarding nondiscrimination protections[xxx] and collecting data regarding the health equity implications of utilization management under Medicare Advantage,[xxxi] **PMC also encourages CMS to address how it plans to monitor and address the real-world impacts of any utilization management changes on health equity.**

Conclusion

As the agency continues to implement the drug price negotiation program, we urge CMS to carefully consider these comments for this and future guidance. PMC looks forward to working with you and your colleagues to ensure the program maintains the ecosystem for innovation in personalized medicine and fosters patient access to needed personalized medicine treatments. If you have any questions about the contents of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org, or David Davenport, PMC's Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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petauri
POWERING HEALTH

July 2, 2024

The Honorable Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

By email: IRARebateandNegotiation@cms.hhs.gov

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027, and Solicitation of Comments

Dear Deputy Administrator Seshamani:

Petauri LLC appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) Guidance, *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the MFP in 2026 and 2027, and Solicitation of Comments* (Guidance or the Guidance).

Petauri, a pharmaceutical services provider, is committed to promoting an environment that fosters scientific innovation, pricing based on value, and affordable access to care. Our team's extensive experience working with manufacturers, payers, and healthcare providers equips us with multifaceted perspectives on policies impacting the pharmaceutical ecosystem that have delivered extraordinary improvements in the quality and length of patients' lives.

That reductions in incentives for research and development (R&D) lead to less innovation, fewer treatment options, and lower life expectancy is well established. The Inflation Reduction Act (IRA), through the Drug Price Negotiation Program (DPNP), has introduced government price-setting that alters economic incentives to invest in R&D for new drugs, and current events indicate that manufacturers are adapting to these changes. As CMS continues to implement the DPNP, a crucial aim should be to provide guidance that minimizes the adverse effects of the IRA on incentives for developing innovative therapies and ensuring affordable access. We believe the current Guidance continues to fall short in this regard, though we acknowledge that it reflects some positive lessons from public comments and the ongoing initial price applicability year (IPAY) 2026 price-setting experience.

While recognizing CMS's obligation to implement the DPNP as outlined in the IRA, we emphasize the importance of CMS exercising discretion in minimizing the potential negative impact of price-setting provisions. The process should accurately value medicines and continue to encourage innovation, while supporting patient access.

Petauri appreciates the opportunity to provide input to the Guidance, offering several key suggestions to enhance transparency as CMS implements this program. We focus comments on our central concerns that in implementing the DPNP CMS is establishing a novel role similar to a Pharmacy & Therapeutics (P&T) committee used by Part D plan sponsors. Per CMS, Part D plan sponsors are tasked with making formulary management decisions that are "based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy"

(Medicare Part D Manual, §30.1.5, Chapter 6).[1] Yet, there is no clarity in the draft Guidance that the analyses CMS is undertaking for the DPNP are grounded in reproducible practices that could be made consistent with plan sponsor assessments or their decisions. We therefore provide several suggestions to improve clarity in the DPNP price-setting and negotiation processes. By not considering the multiple benefits of selected drugs in a manner that is transparent to all stakeholders, especially Part D plan sponsors, there is a high potential for disruptions to patient access to selected drugs. Although our recommendations cannot address some of the fundamental flaws of the IRA, they aim to improve CMS's ongoing implementation of the law as expectations for transparency and consistency will increase post-*Chevron*.

Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2027

- Impact on development of small molecules and orphan drugs. We recognize that CMS has a statutory requirement to implement the IRA as passed by Congress. We also note that CMS has considerable discretion in that implementation and, rightfully, seeks to "preserve flexibility" (§60.3.3) for itself during the negotiation process. We therefore encourage CMS to exercise that discretion and flexibility during drug selection to reduce the negative impacts on incentives to develop both small molecule drugs (§30.1)[2] and orphan drugs (§30.1).[3] These IRA provisions, as currently written, significantly reduce the likelihood that innovators will develop novel treatments that would have a high proportion of Medicare recipients among eligible patients.

Section 40 – Requirements for Manufacturers of Selected Drugs

- Design of the proposed Medicare Transaction Facilitator. The current stance of CMS places the Primary Manufacturer as the 'ultimate responsible' party for implementing the MFP (§40.4). This will likely be highly disruptive as this proposal does not correspond with the existing landscape of entities accountable for claim adjudication. Entities such as pharmacy benefit managers (PBMs) and health plans, termed as 'payers,' play a pivotal role in the adjudication process, often in collaboration with switch organizations. Consequently, there is a pressing need to clarify the role and responsibilities of these payers, particularly in ensuring the timely provision of the MFP. In the absence of a standardized definition of payer accountability, the extent to which a Primary Manufacturer can strategize and execute proper reimbursement is inherently limited, irrespective of their engagement with additional vendors. This highlights the necessity for a more comprehensive understanding and definition of payer accountability in design and implementation of the MTF.
    - In addition, we recommend that CMS clarify whether and how it has aligned the data submission and MFP payment schedules to ensure the availability of PDE data for the prescribed 14-day reimbursement period, as noted in §40.4.1. Our understanding is that plan sponsors are required to submit original PDEs within 30 days following

[1] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf[2] Daniel M. Skovronsky. The IRA's nonsensical distinction between small- and large-molecule drugs. STAT+ May 9, 2023 https://www.statnews.com/2023/05/09/ira-inflation-reduction-act-small-large-molecule-drugs/ .

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[3] The ORPHAN Cures Act's Promise for Rare Disease Patients. Health Policy Today. November 29, 2023. https://healthpolicytoday.org/2023/11/29/the-orphan-cures-acts-promise-for-rare-disease-patients/.
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the Date Claim Received or Date of Service, whichever is greater.[4] However, these timelines seem to potentially conflict with the expected reimbursement schedule. This concern is further compounded by claims that may require additional resolution, such as when a claim is initially paid but subsequently reversed.

Section 50 – Negotiation Factors

- Continuing need for greater transparency in the DPNP. Throughout the Guidance, CMS identifies multiple types of evidence that external stakeholders may submit, in addition to analyses that CMS may conduct, including literature reviews and database analyses. However, nowhere is it noted that these will be made public. All studies, accounting for any proprietary information manufacturers submit as part of the negotiation process, whether submitted by external parties or especially those generated by CMS, must be made public to ensure transparency, fairness, and credibility of the process.

- Information from patients. We appreciate that CMS is considering expanding the information it requests from patients to include patients' experience with disease burden and the aspects of effective treatments that patients most value (§50.2). Seeking information from both patient advocacy groups and individual patients would provide value to CMS, however participation from individual patients would likely benefit from clear guidance on specific information CMS is seeking. Basic good research practices[5] and specific recommendations to correct the failure of the listening sessions to elicit meaningful patient-centered information on the value of effective treatments[6] suggest that some prompts would enhance the quality, consistency and utility of information gained. We therefore encourage CMS to be systematic about these requests from patients and, for example, request information on patients' 1) experience with symptoms, 2) health-related quality of life (HRQOL) impacts, 3) physical functioning, 4) feelings and attitudes about the illness, and 5) experience of treatments.[7]

- Assessing quality of submitted evidence. We appreciate that CMS has responded that it will consider "source, rigor of the study methodology, current relevance to the selected drug and its therapeutic alternative(s), whether the study has been through peer review, study limitations, degree of certainty of conclusions, risk of bias, study time horizons" (§50.2). This is a clear improvement in CMS's initially declared process. Beyond this, we urge CMS to employ well-established rubrics to assess the quality of evidence submitted, instead of internally created schema. Specifically, the CHEERS guidance[8] for economic studies would be well-suited to CMS's needs for the DPNP. In addition, we suggest that CMS clarify how it will include some of the proposed criteria. For example, in a situation with two studies that, on their own merits, are of similar assessed "quality," will the one submitted by a manufacturer be somehow downgraded? The rationale and process for that proposed "source" criterion must be made explicit and transparent.

- Additional guidance on evidence containing QALYs and CMS use of such evidence. We agree that healthcare coverage, reimbursement, and treatment decisions must not discriminate against individuals or patient groups who are elderly, disabled, or suffering from a terminal illness. We also believe that prices for drugs should reflect the full benefits they

[4] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2012223283-le-whatarecmsfrequencyrequirementsforsubmittingdata20140416.pdf
[5] For example: Gaglio B, Henton M, Barbeau A, Evans E, Hickam D, Newhouse R, Zickmund S. Methodological standards for qualitative and mixed methods patient centered outcomes research. BMJ. 2020 Dec 23;371:m4435.
[6] Vandigo J, Edwards HA, Flanagan JH, Mattingly TJ. Three Ways To Improve The Patient-Focused Listening Sessions In The Medicare Drug Price Negotiation Program. Health Affairs Forefront. JUNE 24, 2024. 10.1377/forefront.20240620.766661
[7] For example: E.G., Forestier B, Anthoine E, Reguiai Z, Fohrer C, Blanchin M. A systematic review of dimensions evaluating patient experience in chronic illness. Health Qual Life Outcomes. 2019 Jan 21;17(1):19.
[8] Husereau D, et al. Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations. Pharmacoeconomics. 2022 Jun;40(6):601-609.

provide to patients and their families, as well as to payers and health systems. QALYs, like any analytic tool, are imperfect. As a limited measure of both the costs and benefits of medical treatments, QALYs can be valuable inputs to CEA and other CER, which in turn can be one of many tools used by multi-stakeholder, patient-centered assessment of a drug's value.[9] The current draft guidance, and what little is currently known from the IPAY 2026 evaluation and negotiation process, continues to fall far short of that goal. Nonetheless we applaud CMS in adding some language as to how CMS will consider studies that may employ QALYs.

- At the same time, we also acknowledge political activity around QALYs and respect CMS's cautious approach. Both theoretical and practical factors cloud concerns over the QALY. One can posit a scenario in which a costly treatment for a younger patient could be prioritized, based on potential QALY gains, over an equally expensive therapy for an elderly patient with a grave terminal condition. Resource allocation decisions in fixed-budget national health systems may be similar to that scenario. We agree that such uses of the QALY should not be allowed in the US, but, in the case of value assessment and in the CER demands of the DPNP, the practical use of QALYs is both more complicated and far less prone to discrimination potential. Given this situation, it is essential that CMS clearly defines a narrow use case for QALYs in CER and CEA that is appropriate for the DPNP. This suggestion supports the notion of ensuring transparency and fairness, in contrast to the current proposal of allowing those who submit evidence, manufacturers, and others, to describe why the use of QALYs is appropriate. Thus, we encourage CMS to be more prescriptive in the acceptable uses of CER and CEA, which may use QALYs. As an illustration only, a potential use case for the DPNP may include several main dimensions:
    - At the foundation, CMS should make a concerted effort to describe study design issues that are perceived to lessen the risk of discriminatory decisions within the process. For example, an RCT or observational study that compares outcomes between two or more groups that have been randomized, pseudo-randomized, or otherwise demographically comparable will pose far less risk than a study that assesses outcomes between groups that are not comparable.
    - CMS should also define parameters for generating and presenting QALY data. Studies that do not stratify results by age, disability, or life expectancy could be considered lower risk scenarios.
    - Economic models, which commonly employ assumptions or expert opinion where empirical evidence is not available, may require additional guidance. As a first principle, any model assumption or analysis scenario should not violate the above rules: no differentiation in estimated effectiveness by protected class, with any estimates generated only between patient cohorts.
    - Finally, CMS should be transparent about how it will use this information in the DPNP. This includes limiting use of CER – with/without QALYs – to evaluate the benefits of drugs within the set of therapeutic alternatives, effectively banning CER to make decisions regarding patient access, pricing, or coverage between different drug classes, disease states, or patient populations.

[9] For example: Drummond M, et al. Key Principles for the Improved Conduct of Health Technology Assessments for Resource Allocation Decisions. Int J Tech Assess Health Care. 2008. 24:3:250; and, National Pharmaceutical Council. Guiding Practices for Patient-Centered Value Assessment. 2024. https://www.npcnow.org/guidingpractices.

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Section 60 – Negotiation Process

- Generic drugs as therapeutic alternatives and price comparisons, but not as competitors. We appreciate CMS's additional insights into how therapeutic alternatives are being considered under the DPNP (§60.3.1). However, the 2024 Draft Guidance retains the logical inconsistency in the two broad ways that CMS will use generic drugs in the DPNP that represents, effectively a double standard that is deeply unfair to manufacturers of selected drugs. First, in identifying drugs eligible for selection into the DPNP, CMS is bound to a very narrow molecular definition of what constitutes a generic or biosimilar drug, essentially if the listed or reference drug is selected (§30.1). Second, in identifying therapeutic alternatives for the purpose of develop the "starting point" for the MFP, CMS allows itself to employs a much broader clinical definition of generic – when CMS believes a generic or biosimilar drug is used to treat at least one of the labeled indications of a selected drug: "In addition to brand name drugs and biological products, CMS will consider generic drugs and biosimilars when identifying a potential therapeutic alternative(s) to a selected drug" (§60.3.1). If generics or biosimilars were considered as therapeutic alternatives, their net Part D prices or average sales prices (ASPs) would be used to set the starting point for CMS's initial MFP offer (§60.3.2).
- During this public comment window, it is unknown whether CMS deployed this effective double standard against drugs selected for the IPAY 2026 DPNP negotiation, for example comparing the selected direct oral anticoagulants (DOACs) (i.e., Eliquis, Xarelto) against generic warfarin. It may be that CMS will not fall prey to the language of the IRA in this instance. Nonetheless, this situation clearly holds the potential that a drug will be selected for the DPNP due to lack of a narrowly defined generic competitor while the MFP for that selected drug would be set based on the net price of actual generic competition.
- We recognize the limits of IRA language that binds CMS to a narrow chemical definition for generics for use in selecting drugs for the DPNP. However, CMS must exercise flexibility that they have preserved elsewhere (§60.3.3) to not deploy the double-standard in setting MFPs based on the more meaningful clinical definition of generic. That is, generic drugs should not be used as a therapeutic alternative. The selection and negotiation process as currently defined in the Guidance is deeply unfair regarding this point and further erodes credibility of the DPNP.
- Use of non-value negotiation elements in the Preliminary Price. We acknowledge CMS's efforts to describe how "non-value" data elements (§60.3.4), such as R&D costs or patents, are apparently placed as secondary to cost:benefit evidence outlined in other sections. However, the information provided in the Guidance raises far more critical questions than are answered around this point. CMS must clarify exactly how this information will be used, as well as the magnitude of the adjustment made to the MFP based on this information.
    - While quite vague in the draft Guidance, the aim and impact of CMS's use of these measures in setting the preliminary price is without precedent in the US. The statements on the use of R&D cost recoupment and "current unit costs of production and distribution" clearly (§60.3.4) demonstrate how CMS is verging on setting profit-levels for manufacturers with drugs selected for the DPNP. This is an unprecedented government intervention that is not clearly identified in the IRA legislation. We recommend that CMS explicitly and transparently minimize the role of this information in MFP-setting.
    - CMS use of Patent information in adjusting the preliminary price also must be made clear (§60.3.4). For example, will the mere existence of patents be used to adjust preliminary prices up since patents capture the scientific knowledge that is placed in

the public domain? Will the contents of patents somehow be used to adjust prices; and if so, how? Will patent information trump clinical, economic, or humanistic benefits that have been demonstrated in clinical trials or observational studies? We recognize that CMS is directed by Congress to consider this information, but this does not mean the IRA suggests that CMS should invent novel, potentially confusing assessment methods without public disclosure and input.

Section 110 – Part D Formulary Inclusion of Selected Drugs

- Ensuring patient access to selected drugs. CMS currently offers no assurances to patients on selected drugs that the DPNP process will result in continued, let alone improved, access to drugs (§110). CMS does emphasize their duty to oversee plan sponsors' compliance with all relevant formulary requirements. Importantly, we acknowledge CMS's statement that it does not have sufficient information to determine whether the multiple changes to the design of Part D. Nonetheless, the Guidance itself cites 42 C.F.R. § 423.120(b)(2)(iii) which addresses "type of drugs most commonly needed by Part D enrollees" that, by design, would likely cover any drugs selected for the DPNP. Further, CMS states that its Part D formulary review process will "assess" any changes in formulary status of DPNP-selected drugs. We therefore encourage CMS to apply the tools at their disposal currently to not only "assess" such changes but to deny proposed changes to the formulary status of selected drugs on Part D plans when those changes may limit patient access to selected drugs. Without doing so we are concerned that CMS will not only be setting prices but limiting access through the DPNP.

Petauri appreciates the opportunity to submit comments on this draft Guidance and CMS's consideration of our feedback. If you have any questions about our comments, please contact us at bob.nordyke@petauri.com or joe.honcz@petauri.com.

Sincerely,

Robert Nordyke, MS PhD
Senior Advisor
Petauri Evidence

Joe Honcz, RPh MBA
Sr. Vice President
Petauri Advisors

July 2, 2024

VIA Electronic Filing – *IRARebateandNegotiation@cms.hhs.gov*

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
PO Box 8016
Baltimore, MD 21244-8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for the Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Deputy Administrator Seshamani:

Pfizer Inc. appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 (henceforth referred to as the "Guidance"). Pfizer Inc. is a research-based, global biopharmaceutical company. We apply science and our global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of medicines and vaccines.

The Inflation Reduction Act established the so-called "Medicare Drug Price Negotiation Program", which in fact, is not a true "negotiation" framework, but a dangerous price setting policy that will significantly harm patient access to medicines and threaten U.S. leadership in biopharmaceutical research and development. These threats are inherent to the law, which requires the Secretary of Health and Human Services (HHS) to disrupt the very real negotiations between manufacturers and Part D plans by setting the price for any top spend small molecule drug that has been on the market 9 years or more without generic competition and any top spend biologic that has been on the market for 13 years or more without biosimilar competition. As such, the law requires HHS to intervene in private market negotiations well before most products have reached the end of their patent and other legally provided

670 Maine Avenue, SW • Suite 1000, Washington, DC 20024 • PHRMA.ORG

July 2, 2024

VIA Electronic Filing – *IRARebateandNegotiation@cms.hhs.gov*

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for the Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027

Dear Deputy Administrator Seshamani:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS, the Agency) *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (Guidance or the Guidance) which CMS released on May 3, 2024.[1] We represent the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Our sector is one of the most research-intensive industries in the United States: over the last decade, PhRMA member companies have more than doubled their annual investment in the search for new treatments and cures, including nearly $101 billion in 2022 alone.[2]

PhRMA has longstanding concerns about the impact of government price setting on patients. Our concern is grounded in the industry's substantial and longstanding experience with price setting policies in foreign countries, where patients go without or face significant delays before accessing many important treatments.[3] We are deeply concerned that Medicare beneficiaries could see parallel access disruptions resulting from the IRA's price setting provisions. Those provisions are also creating considerable uncertainty that will hamper development of life-changing treatments and cures.

To an extent, patient access and innovation will always be under threat as long as the price setting provisions of the IRA remain in place. This is true to an even *greater* extent if policymakers are successful in their rushed

[1] CMS. (May 3, 2024). Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. Available at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.
[2] PhRMA. (July 26, 2023). 2023 PhRMA Annual Membership Survey. Available at: https://phrma.org/resource-center/Topics/Research-and-Development/2023-PhRMA-Annual-Membership-Survey
[3] PhRMA. (April 12, 2023). New Global Analysis Shows Patient Access Challenges Around the World. Available at: https://phrma.org/Blog/New-global-analysis-shows-patient-access-challenges-around-the-world

attempts to *expand* the Medicare Drug Price Negotiation Program (Program) to include additional drugs or market segments only two years following enactment of the law.[4] However, as we emphasized in our comments on the Initial Guidance for IPAY 2026, CMS has an opportunity to promote transparency, accountability, and confidentiality in the Program's operation through implementation.

We are disappointed that after more than a year of hearing concerns and feedback from stakeholders, CMS has largely[5] stayed its course in the Guidance for IPAY 2027. In this letter, we articulate our core concerns with CMS' Draft Guidance for IPAY 2027, as follows:

I. CMS is not negotiating with manufacturers; it is setting drug prices in an arbitrary manner that is highly susceptible to politicization.

II. CMS' implementation of the Program puts patient access to medicines in Medicare Part D at risk.

III. CMS' implementation of the Program undermines competitive marketplace dynamics, which successfully drives patient access to new medicines and cost containment.

IV. CMS' implementation of the Program will do irreparable harm to innovation, to the detriment of patients.

V. CMS has failed to implement proper safeguards to protect patients and clinicians in its implementation of the Program.

Aside from outlining our core concerns with the Guidance, we are attaching to this letter several Appendices that provide technical, in-depth input on specific issues. In many instances, the consensus-based recommendations outlined in the Appendices are in addition to feedback that PhRMA has previously provided to CMS in other comment letters or forums. The topics they focus on are of great importance to PhRMA's membership, and we welcome the opportunity to discuss them in more detail with CMS staff.

Appendix A: Drug Selection;

Appendix B: Effectuation of the Maximum Fair Price; and

Appendix C: Strengthening Access and Formulary Protections in Medicare Part D.

Despite our aforementioned concerns regarding government price setting, in advance of IPAY 2026, PhRMA recognized CMS' statutory obligation to implement the Program. Thus, in response to Initial Guidance for IPAY 2026[6], PhRMA articulated concrete, actionable recommendations for CMS on implementation of the Program in issue areas that were open for comment. Unfortunately, CMS disregarded most of PhRMA's recommendations, as it did with most stakeholder feedback in advance of IPAY 2026.[7] We strongly recommend CMS revisit and adopt PhRMA's prior recommendations in implementing the Program for IPAY 2027. We have attached those prior recommendations as Appendix D.

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[4] The White House. (March 7, 2024). Remarks of President Joe Biden – State of the Union Address as Prepared for Delivery. Available at: https://www.whitehouse.gov/briefing-room/speeches-remarks/2024/03/07/remarks-of-president-joe-biden-state-of-the-union-address-as-prepared-for-delivery-2/

[5] We are disappointed that CMS has, on most issues, not changed course on its implementation of the Program. However, PhRMA appreciates the significant expansion of Agency guidance covering effectuation of the Maximum Fair Price (MFP), although we continue to have concerns that the process for Primary Manufacturers to provide access to the MFP, as proposed by the Agency, creates significant financial and operational burdens on manufacturers and other supply chain stakeholders. PhRMA offers technical comments on this portion of the Guidance in Appendix B (Effectuation of the Maximum Fair Price) of this letter.

[6] PhRMA. PhRMA Comments on CMS Initial Guidance on Medicare Drug Price Negotiation Program. (April 14, 2023). Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/G-I/PhRMA-Comments-on-CMS-Initial-Guidance-on-Medicare-Drug-Price-Negotiation-Program22948.pdf

[7] CMS also intentionally did not solicit comments on foundational aspects of the IPAY 2026 guidance, such as Section 30 (discussing QSSD and bona fide marketing).

* * *

I. CMS is not negotiating with manufacturers; it is setting drug prices in an arbitrary manner that is highly susceptible to politicization.

The IRA and CMS label government price setting as "negotiation." Indeed, CMS' Guidance used this term nearly 400 times. But simply repeating the word does not make it true. In reality, the IRA provides for highly limited exchanges between manufacturers of "selected drugs" and CMS. As noted by those with experience in the negotiations that occur between insurance companies and biopharmaceutical manufacturers in the private sector, the Program in no way resembles such negotiations, and should not be mistaken for such.[8] Put simply, CMS has the unilateral, nearly unconstrained authority to both set any price it wishes below a statutory ceiling and impose severe penalties on manufacturers who do not agree to the CMS-set price, with little-to-no transparency on how CMS reached this price in the first place.

Below, we outline the specific aspects of the IRA price setting framework, and CMS' implementation of the Program, supporting our assertion that it does not constitute "negotiation."

"Negotiation" under the IRA does not in any way resemble negotiations that occur in the private market.

Manufacturer Penalties

If a manufacturer fails to agree to the price CMS sets, the manufacturer faces either exclusion from entire market segments or severe financial penalties that would be impossible for any company to sustain. Under the IRA, if a manufacturer doesn't agree to "negotiate" or agrees to negotiate but doesn't agree to the CMS-set price, it must withdraw *all* of its products from the entirety of the approximately 45 percent of the nationwide retail prescription drug market comprised of Medicare and Medicaid spending.[9] Manufacturers' only alternative is to accept an excise tax of up to 1,900 percent and, in some circumstances, civil monetary penalties. Those are not potential outcomes in actual negotiations. These penalties are severe and disproportionate to other penalties imposed by Medicare; they are clearly intended to command compliance, rather than encourage true negotiation.[10]

Moreover, the government is empowered to impose significant fines, including a $1 million dollar per day penalty on manufacturers if they do not produce an extremely broad array of information, much of it proprietary, difficult to accumulate, and not relevant to setting a Medicare price. However, manufacturers have no equivalent authority to demand information of the government related to its analysis and decision making. CMS' authority to compel a manufacturer to produce data under threat of severe penalties is another of many signs that the Program does not represent actual negotiation.

Ceiling Price

The IRA price setting framework, unlike actual negotiation, includes a ceiling, or absolute cap on a medicine's price in Medicare based in part on the time since the medicine was approved by FDA. This ceiling is not subject to negotiation and cannot be exceeded for any reason, including factors such as the drug meeting an unmet medical need, its superiority over alternative treatments, or new uses that recently obtained FDA approval or that are under development through ongoing clinical trials. We are not aware of any bona fide, private market negotiations in which the purchaser starts with a ceiling price set externally and enforces its chosen price with harsh penalties.

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[8] Shah S. (June 20, 2024). Here are four reasons Medicare drug-price 'negotiation' in NJ isn't truly a negotiation. Courier Post. Available at: https://www.courierpostonline.com/story/opinion/2024/06/13/medicare-drug-price-negotiation-in-nj-isnt-truly-a-negotiation/73896264007/

[9] CBO. (January 2022). Prescription Drugs: Spending, Use, and Prices. Available at: https://www.cbo.gov/publication/57772

[10] In fact, the Congressional Budget Office score for the IRA presumes that the excise tax will not generate any revenue independent of its effects on Medicare drug pricing through imposition of the government's MFP. See Congressional Budget Office, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14 at 5 (Sept. 7, 2022). Available at: https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf.

Renegotiation

Finally, the result of an IRA "negotiation" can always be reopened by one party – the Secretary – but not by manufacturers, and the statute purports to insulate renegotiations from administrative and judicial review. Under Section 1194(f) of the Social Security Act (SSA), the Secretary will "renegotiate" a previously set "negotiated" price whenever "the Secretary determines there has been a material change" in any of the clinical or manufacturer-specific factors.[11] To date, the Secretary has declined to provide direction regarding what would constitute a "material change," leading to uncertainty in the commercial stability of the prices the Secretary imposes when a manufacturer is first subject to an MFP, and leading to concerns that the Secretary may seek to upend these previously set prices at an unknown future time.[12]

Other Elements

Beyond the aforementioned issues, it is also notable that IRA "negotiation" has none of the hallmarks of actual negotiation over drug prices that occur in the commercial market. Based on our membership's vast experience in such negotiations (experience that CMS is notably lacking), there are numerous other examples of how the Program diametrically differs from true private market negotiation, including the following:

- **Access Tradeoffs.** In true negotiation, drug prices are balanced against patient access to the drug, including issues such as formulary tiering and utilization management; under the Program the price of a selected drug is set without reference to the terms of that drug's coverage, other than it must be offered by Part D plans. The parameters of access for selected drugs remain to be determined by Part D plans, which, in exchange for needing to cover the selected drug, receive the government-set price as a *starting point* for negotiations with manufacturers, without regard to how they cover the medicine.

- **Terms and Conditions.** In a true negotiation, the parties can offer revision, clarification, amendment, or customization of the non-price terms and conditions of a contract; under the Program, CMS publishes a "one size fits all" contract of adhesion that manufacturers must sign – and that agreement contains unilateral amendment authority for CMS, but not the manufacturer;[13]

- **Timing of Contract.** In a true negotiation, parties sign a contract after agreeing to a price term; under the Program, manufacturers must sign an agreement before CMS offers a final price;

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[11] Section 1194(f) provides for renegotiation in additional circumstances.

[12] CMS and the Department of Justice (DOJ) have stated, without further explanation, that manufacturers may simply cease selling their products to Medicare. For example, DOJ argues that there is no "mechanism to force manufacturers to actually make sales of any drug," and that "after signing the agreement with CMS, [a manufacturer]" could "refuse to transfer [a selected drug] to Medicare at all," and "that would not be prohibited by the IRA." *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-03335-ZNQ (D.N.J., Dec. 22, 2023), ECF No. 84 at 32. In the draft guidance, CMS states that a manufacturer "is not obligated to make sales of the selected drug." Draft Guidance at § 40.4. Both CMS and DOJ fail to acknowledge that manufacturers do not "transfer" drugs to Medicare – they typically sell drugs to wholesalers, who sell to a pharmacy or other dispenser. Medicare is a payer – it does not purchase an inventory of drugs directly from manufacturers (or wholesalers). Further, the manufacturer does not have knowledge of the insurance status of the patient when it sells its drugs. CMS presumably understands the pharmaceutical supply chain and yet continues to make and allow statements that willfully ignore it. At the very least, if CMS and DOJ believe that blocking sales or transfers of drugs "to Medicare" is an option, the Agency should explain the logistical and legal rationales for how manufacturers could cease selling selected drugs to Medicare beneficiaries "at all."
CMS and DOJ have also argued that CMS may read the Agency's authority to *involuntarily* terminate Part D agreements for a manufacturer's knowing or willful violation or other good cause as somehow equivalent to a manufacturer *voluntarily* withdrawing using the manufacturer's own authority. *Compare* clause (i) and clause (ii) of SSA §§ 1860D-14A(b)(4)(B) and 1860D-14C(b)(4)(B), respectively. However, CMS does not explain how its reading accords with the canon of statutory construction that a term must be understood in light of "the neighboring words with which it is associated," *United States v. Williams*, 553 U.S. 285, 294 (2008), or is anything more than pretext to paint the IRA program in the light most favorable to the Agency's litigation posture without regard to the plain language in the law.

[13] The agreement states: "CMS retains authority to amend this Agreement to reflect changes in . . . guidance. When possible, CMS shall give the Manufacturer at least 60-day notice of any change to the Agreement." Available at: https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

- **Legal Recourse.** In a true negotiation, either party may seek to redress any legal and equitable claims; under the Program, the statute purports to limit manufacturers from seeking any form of judicial or administrative review of fundamental Agency actions; and

- **Disclosure of Information.** In a true negotiation, parties may – but certainly are not required to – turn over any manufacturing or distribution costs, sales forecasts, marketing budgets, or other trade secrets or proprietary data demanded by the other party; under the Program, CMS requires the submission of extensive, highly-sensitive data in a truly burdensome manner.[14,15]

These issues are further compounded by the lack of transparency stakeholders, including manufacturers of selected drugs, have into the price setting process. This lack of transparency limits the ability of the manufacturer to produce data that will be impactful and help inform CMS decision making. As such, manufacturers of selected drugs have found interactions with CMS thus far to be lacking in the type of information sharing and dialogue that would accompany a true negotiation. CMS seeks feedback on whether CMS should conduct fewer meetings with manufacturers of selected drugs in IPAY 2027. Based on the IPAY 2026 experience, however, fewer meetings would only exacerbate the opacity of the price setting process for manufacturers. PhRMA strongly recommends that CMS meet with the same frequency with manufacturers as in IPAY 2026 but also provide insight into its thinking, processes and next steps so that manufacturers may appropriately engage.

The IRA grants CMS broad price setting authority that is highly susceptible to politicization.

Lack of Transparent Methodology for Price Setting

Instead of establishing the "consistent process and methodology" required by Section 1194 of the SSA, CMS has stated it will take a "qualitative approach" to setting and adjusting the starting price based on the "totality of the relevant information and evidence" about the medicine and the identified "therapeutic alternative(s)". That price will then be adjusted by an undefined amount based on one or more of the "manufacturer-specific" factors listed in SSA Section 1194(e)(1) [16], with the factors considered "in isolation or in combination with other factors."[17]

Unfortunately, CMS' Guidance does not provide any insight into:

- How the evidence CMS develops on its own and receives from manufacturers and the public will be converted into conclusions about the factors;

- How the factors will be weighted;

- How CMS will determine whether and by how much to adjust the price for the factors that "may" be used to adjust price, and whether to consider those factors singly or in combination; and

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[14] Internal feedback based on company survey of experience indicates that the information collection process was extraordinarily more burdensome than CMS estimated despite the extensive recommendations PhRMA provided to CMS on how to more productively facilitate collection. CMS not only requested information that was almost impossible to collect but also in a manner that significantly differed from corporate record-keeping.

[15] Of note, in the most recent Guidance outlined in "Appendix A (Definitions for Purposes of Collecting Manufacturer-Specific Data), CMS includes a new "Market Data and Revenue and Sales Volume Data" element on Manufacturer net Medicare Part D price. Specifically, CMS seeks to collect the "net Medicare Part D price as calculated by the Primary Manufacturer," and goes on to elaborate that the Agency seeks "specific data to which the manufacturer has access including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) not reflected in the sum of the plan-specific enrollment weighted amounts calculation, and utilization that may differ from the PDE data". This data element is concerning. If viewed as an attempt to aggregate price concessions from supply chain entities across the pharmaceutical supply chain, it would not represent an accurate assessment of net Medicare Part D price at the NDC-11 level. This is not only an inaccurate accumulation of discounts for CMS to require but represents significant burden upon Primary Manufacturers that would be required to track and aggregate, at the NDC-11 level, "supply chain concessions". The term also is overly broad, particularly the references to "other supply chain concessions" and "wholesale discounts" with little direction for accurate data collection.

[16] CMS. (June 30, 2023). Revised Medicare Drug Price Negotiation Program Guidance. Available at: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf, Section 60.3.3.1, pg. 149.

[17] Ibid, Section 60.3.4, pp. 150-51.

- How the evidence and factors will be translated into a specific price.

This lack of clear, objective standards or any explanation of how these criteria will be used in price setting means CMS can specify any price below the ceiling and will likely always be able to conjure a justification. Without a transparent and predefined protocol for the Agency's evidence identification and review process., experts within CMS risk targeting the wrong sources, omitting important evidence, and increased subjectivity and bias in their review – making it difficult to replicate findings. In fact, the Guidance itself contains clear examples of CMS putting its thumb on the scale to achieve lower prices beyond the authority it is granted in statute.[18]

Politicization of Price Setting

Per the IRA, Maximum Fair Prices are set by Secretary of Health and Human Services, a political appointee, who is accorded broad decision-making authority and whose decisions are purportedly exempt from administrative and judicial review for the most consequential aspects of the Program. CMS has also argued that the Agency need not engage in notice-and-comment rulemaking to consider the views and expertise of stakeholders.

Regardless of the approach taken by the Secretary, there is a significant threat that either a current or future Secretary could make predominantly political decisions regarding prices of selected drugs. For instance, a Secretary may decide that political circumstances dictate that an election year is an optimal time to renegotiate by determining a "material change" has occurred. Or the Secretary could set excessively low prices to demonstrate that an Administration is lowering seniors' costs. Although not every Secretary may be so politically motivated, the unconstitutional legislative authority delegated by the IRA (as discussed below) means that there exists broad opportunity and incentives for setting prices on a political basis, and the Program contains *absolutely no safeguards against politically set prices*. CMS appears to have declined its responsibility to address this issue in the Guidance.[19]

Unconstitutional Delegation of Authority

Indeed, the price setting authority under the IRA is so overly broad that it amounts to an unconstitutional delegation of legislative authority. CMS has already taken advantage of that unconstrained delegation, going beyond the statute to impose its own definition of what is a "Qualifying Single Source Drug" (QSSD), and its own vague standard for whether a generic drug or biosimilar product is "marketed" such that a listed or reference drug cannot be selected for price setting. CMS also has arbitrarily offered conflicting interpretations of what entities qualify as a "manufacturer" subject to price setting—imposing vicarious responsibility and liability on primary manufacturers for the information and actions of unrelated corporate entities that the Agency deems "secondary manufacturers," while simultaneously asserting that only a subsidiary corporation listed on an FDA application (and not a parent entity) has standing to sue.[20] In these ways, CMS has quickly demonstrated how

[18] CMS also proposes in Section 60.3 of the Draft Guidance to use, in certain cases, the "Part D total gross covered drug cost (TGCDC) net of DIR and CGDP [coverage gap discount program] payments . . . for the therapeutic alternative(s)," as part of establishing the starting point for developing an initial offer for a selected drug. This proposal violates the intent of the IRA and must not be finalized. Nothing in the IRA reflects a Congressional intent for CMS to consider manufacturer or coverage gap discounts in price-setting. To the contrary, the statute specifically excludes selected drugs from the definition of "applicable drugs" subject to the manufacturer discount in Part D, the successor to the CGDP. SSA § 1860D-14C(g)(2)(B). Yet, CMS' proposal would circumvent this intent by using – as the comparative starting point for establishing an MFP – a price that reflects these discounts. Effectively, CMS would be reincorporating the discounts into the MFP, when Congress specifically required that manufacturers of selected drugs are exempt from such discounts. We further note that Congress instructed CMS, as part of price setting, to include in the ceiling price the Part D "price concessions" that are received by the plan or pharmacy benefit manager on behalf of the plan and constitute direct or indirect remuneration. SSA § 1194(c)(2)(A). Congress did <u>not</u> direct CMS to include estimated Part D manufacturer or coverage gap discounts as part of this calculation.

[19] Examples of actions CMS could take to limit political influence over price setting include establishing a consistent methodology for arriving at prices for selected drugs or establishing a robust dispute resolution process.

[20] *Merck v. Becerra*, Case No. 1:23-cv-01615 (D.D.C.), ECF No. 24 at 19-20 (arguing lack of standing due to a subsidiary holding the NDA for the selected drug); *Dayton Area Chamber of Comm. v. Becerra*, Case No. 3:23-cv-00156 (S.D.Ohio), ECF No. 71 at 13-14 (arguing that Pharmacyclics, a subsidiary of AbbVie, is the only entity harmed by price setting).

unconstrained it views its authority. Indeed, CMS has even told a federal court that it is empowered to misread statutory language that is "clear as a bell," without any opportunity for judicial review.[21]

II. CMS' implementation of the Program puts patient access to medicines in Medicare Part D at risk.

In comments on CMS' Initial Guidance for IPAY 2026, many stakeholders raised concern that CMS price setting in Part D could disrupt patient access to care and result in barriers to needed medicines. The Agency acknowledged this in its IPAY 2026 Revised Guidance and repeated it again in the Draft Guidance for IPAY 2027, stating "… CMS is concerned that Part D sponsors may be incentivized in certain circumstances to disadvantage selected drugs by placing selected drugs on less favorable tiers compared to non-selected drugs, or by applying utilization management (UM) that is not based on medical appropriateness to steer Part D beneficiaries away from selected drugs in favor of non-selected drugs."[22]

CMS' concern is well-placed. Disadvantaging drugs means disadvantaging *patients* who will face more barriers to obtaining the medicine they need. To guard against the negative impacts of price setting, which are compounded by other provisions of the IRA related to Part D, it is critical that CMS maintain and improve upon existing statutory and regulatory formulary standards. Nondiscrimination and formulary standards are essential elements of Part D;[23] to the extent those standards were adequate prior to enactment of the IRA, they are no longer likely to remain adequate under pressure from the effects of the IRA. Our detailed recommendations for improvements to Part D formulary standards are provided in Appendix C (Strengthening Access and Formulary Protections in Medicare Part D).

Medicare patients need timely access to a choice of medicines to ensure effective treatment of a range of serious diseases and conditions.

Patients' access to medicines is central to our ability to effectively improve health and reduce downstream costs. For example, medicines have profoundly changed what it means for a patient to have and be treated for cardiovascular and cerebrovascular diseases, many cancers, diabetes, HIV/AIDS, and depression. Leading researchers have attributed 35 percent of the 3.3-year gain in life expectancy from 1990-2015 to pharmaceuticals, compared to 13 percent attributable to other medical care.[24]

However, to improve patient health outcomes with medicines, patients must have timely access to medicines. This involves ensuring individual patients have access to the range of medicines they may need to meet their specific needs and circumstances. As a result, it is important to ensure that formulary coverage, tiering and UM operate as tools for health plans to effectively negotiate with manufacturers and appropriately control costs, and *not as* barriers to obtaining the right medicine for a given patient. It is precisely because it is important for patients and

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[21] *AstraZeneca v. Becerra*, Case No. 1:23-cv-00931, Tr. Oral Argument at 99-100 (D. Del. Jan. 31, 2024) ("THE COURT: Let's say this is. I read the statute. It's clear as a bell . . . So let's just say I agree with AstraZeneca on that. When would a drug company be able to challenge your designation of its blockbuster product? Let's say it only makes one product. When can it do that? MR. NETTER: So it wouldn't be able to, Your Honor. THE COURT: Ever? MR. NETTER: Ever? Well, unless they could try to convince Congress to change the statutory bar. But it's Congress' prerogative. THE COURT: That doesn't bother you, that you could have -- again, imagine it was, again, that there was no other ambiguity in the statute to shed doubt on AstraZeneca's interpretation. So you're saying that an Agency can come along and can issue a regulation that absolutely contradicts the explicit statutory text of Congress? And here -- and you're saying, tough noogies, there's no review? MR. NETTER: That is the outcome of the standard analysis on judicial bars.").

[22] Section 110. Presumably CMS' concern is rooted in the possibility that Part D plans will prefer non-selected drugs with higher list prices and higher rebates to selected drugs with lower list prices.

[23] Certain Part D formulary standards were premised on the Medicare Modernization Act's nondiscrimination requirements at Section 1860D-11(e)(2)(D)(i). Research on Part D and other programs suggests formulary design can be used as a way to encourage or discourage enrollment by certain beneficiaries, https://www.nber.org/papers/w22338 and https://www.aeaweb.org/articles?id=10.1257/pol.20170014. This underscores the need for improved formulary standards and risk adjustment as existing standards are challenged by dramatic program design changes that could encourage new barriers to patient access to medicines.

[24] Buxbaum J.D., Chernew M.E., Fendrick A.M., Cutler D.M. (September 2020). Contributions of Public Health, Pharmaceuticals, and Other Medical Care to US Life Expectancy Changes, 1990-2015. Health Affairs. Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00284.

clinicians to have a choice of medicines that efforts by plans and PBMs to steer patients among drugs using strategies "not based on medical appropriateness" create cause for concern.

CMS' Guidance recognizes the fundamental principle that patients differ from one another, as do medicines, even when in the same therapeutic class. Because of differences in clinical circumstances and individual health needs and preferences, patients benefit from access to a range of treatment options, which has been repeatedly underscored by professional consensus and research.[25,26] Furthermore, a medicine's average effect will not always apply to all subsets of patients due to factors such as genetics, drug-drug interactions, age, and comorbidities.[27] For example, the American College of Rheumatology, notes that individual treatment decisions for rheumatoid arthritis patients should be made based on patients' values, goals, preferences, and comorbidities, citing 44 different recommendations.[28] As described in more detail below, the IRA is likely to exacerbate the trend of increasing formulary exclusions and coverage restrictions. Thus, it is vital for CMS to strengthen formulary standards and oversight to address this and protect beneficiary access to a range of treatment options in Part D.

The IRA puts patient access to both selected medicines and non-selected medicines at risk.

Since its inception, the Part D program has proved remarkably successful in providing Medicare beneficiaries access to a range of outpatient prescription medicines and keeping premiums low through a choice of competing health plans. Underscoring this success, beneficiary satisfaction with the program has consistently remained over 90 percent.[29] Large health plans and PBMs are able to demand substantial discounts and rebates from manufacturers that offer medicines that compete with other brand drugs or with biosimilars and generics. In some instances, rebates represent a discount of 50 percent or more off products' list price, and six of the ten drugs selected for price setting for 2026 are in therapeutic classes where the average rebate was 40 percent or more in 2021.[30]

The introduction of government price-setting for a subset of competing medicines will inevitably prove highly disruptive to this competitive dynamic and lead to unintended consequences that hinder beneficiary access to MFP-selected medicines and/or competing brand medicines. Health plans' and PBMs' continued reliance on manufacturer rebates as a source of income in Part D amplifies the disruptive effects of government price-setting, which likely will have the effect of reducing manufacturer rebates. This risk was underscored in CMS' most recent national health expenditure projection, in which the Agency estimated that government spending in Part D will *increase* by 12 percent in 2026, largely due to the loss of manufacturer rebates under IRA on MFP medicines.[31]

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[25] For instance, American College of Rheumatology. (2024). American College of Rheumatology Health Policy Statements: Remove Barriers to Patient Access to Treatment, Access to Treatment under Medicare Part D. Available at: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltd84782969d741aba/acr-health-policy-statements.pdf

[26] Kent D.M., Nelson J., Dahabreh I.J., et al. (December 1, 2016). Risk and Treatment Effect Heterogeneity: Re-Analysis of Individual Participant Data from 32 Large Clinical Trials. International Journal of Epidemiology. Available at: https://pubmed.ncbi.nlm.nih.gov/27375287/, https://pubmed.ncbi.nlm.nih.gov/15595946/

[27] Hayden CG. (September 4, 2023). IRA: Patient Access to Therapeutic Options. Available at: https://haydencg.com/ira-patient-access-to-therapeutic-options/.

[28] Fraenkel L., Bathon J.M., England B.R., et al. (July 2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Available at: https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/blt9e44ccb701e1918c/63360f6775c0be225b8d943a/ra-guideline-2021.pdf

[29] Medicare Today. (August 2023). Senior Satisfaction Survey. Available at: https://www.medicaretoday.org/resources/senior-satisfaction-survey

[30] MedPAC. (June 2023). MedPAC Report to Congress, Table 2-1. Available at: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf

[31] CMS. (June 12, 2024). Office of the Actuary in the Centers for Medicare & Medicaid Services, National Health Expenditures Projections, National Health Expenditure Projections, 2023–32. Available at: https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected. See also: Fiore J., Madison A., Poisal J, Cuckler G., Smith S., Sisko A., Keehan S., Rennie K., Gross A. (June 2024). National Health Expenditure Projections, 2023-32: Payer Trends Diverge as Pandemic-Related Trends Fade. Health Affairs. Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469

Despite CMS acknowledging the importance of patient access to a range of medicines, the sharp dislocations that the IRA brings to Part D are likely to create significant pressure on plans to strictly control utilization and maximize rebates and other discounts.[32] This could exacerbate plans' use of UM and coverage exclusions in ways that result in clinically inappropriate barriers to access. As a result of these changing dynamics, access to medicines selected for price setting as well as their non-selected competitors in the same therapeutic class may be threatened, with results varying depending on the dynamics within each therapeutic class. CMS should make use of the full extent of its authority to ensure patient access is not disrupted, including ensuring that patients who are stable on an MFP-selected drug or a treatment alternative in the same class are not inappropriately switched to a different medicine or face other barriers to continued access.

In its Revised Guidance for IPAY 2026 and the Draft Guidance for IPAY 2027, CMS proposes to remedy its concerns about access to selected drugs by requiring plans to provide a "reasonable justification" for disadvantaging selected drugs in coverage. CMS will "evaluate these justifications for compliance with applicable statutory and regulatory requirements" and only approve a plan if it complies with those requirements.[33] Unfortunately, there is no basis for knowing whether this approach will protect patients' access to selected drugs. As a group of academic leaders recently wrote, "CMS plans to assess formulary placement and use of UM tools that may influence access to negotiated drugs, but it has not yet provided guidance on how it will do so, nor on the consequences for plans' undesirable behavior."[34] Moreover, many of the underlying regulatory requirements that CMS will apply are vague, fluid and lack transparency (e.g., "best practices" and "current industry standards"[35]).

While we appreciate CMS' discussion of steps it will take to ensure beneficiary access to MFP selected medicines, we don't believe these steps are sufficient to protect beneficiaries. As CMS has acknowledged, there are circumstances in which plans and PBMs may be incentivized to establish increased access barriers for MFP selected drugs relative to competing medicines.[36] For example, in instances where CMS sets an MFP for a medicine within a competitive drug class that offers significant rebates, plans and PBMs may choose to give preferential status to a competing medicine and establish more significant UM or higher cost sharing for the MFP selected medicine.

At the same time, CMS also must recognize and address the risk of government price-setting disrupting access for Medicare beneficiaries receiving non-selected medicines that compete with the MFP drug. For example, there may be other instances where manufacturers of competing medicines are unable to match the CMS-set price of a MFP selected medicine, leading the plan to prefer the selected drug irrespective of whether it is the most clinically appropriate.

Recent research serves to reinforce concerns that beneficiaries will face increased, potentially inappropriate access barriers to clinically important treatment options as a result of government price setting.[37] For example, in one recent survey of payers, 65 percent said they expect to reduce the number of medicines covered on their formulary

[32] Kelly C. (April 16, 2024). Medicare Negotiated Drugs May Not Get Favorable Coverage in Part D: Will CMS Intervene? Pink Sheet. Available at: https://pink.citeline.com/PS150091/Medicare-Negotiated-Drugs-May-Not-Get-Favorable-Coverage-In-Part-D-Will-CMS-Intervene

[33] IPAY 2027 Initial Guidance at 123.

[34] Arad N., Hoover G., Evans R., McClellan M.B. (April 9, 2024). Medicare Drug Price Negotiations: Policy Implications of the First 10 Drugs' Features. Health Affairs. Available at: https://www.healthaffairs.org/content/forefront/medicare-drug-price-negotiations-policy-implications-first-10-drugs-features.

[35] CMS. Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf, Section 30.2.2.

[36] IPAY 2027 Initial Guidance at 122.

[37] Fein A. (April 5, 2024). Implications of the IRA: Why the IRA Will Encourage Part D Plans to Prefer High-List, High-Rebate Drugs. Drug Channels. Available at: https://www.youtube.com/watch?v=F5Rjkw7h4gk

for therapeutic classes with selected drugs, and nearly half of payers reported they are likely to exclude most non-selected drugs in the same therapeutic class as a selected drug. [38]

We urge CMS to describe the specific steps it is taking to update and strengthen its formulary standards and oversight and to ensure these safeguards are applied both to MFP-selected medicines and competing medicines in the same class. CMS price-setting under the IRA will inevitably increase the risk of inappropriate UM and formulary restrictions that compromise beneficiary access to medically appropriate care. Thus, CMS must rethink its approach to formulary review for all Part D medicines – including selected drugs, non-selected medicines, and even to ensure adequate access to medicines in the six protected classes – and must engage patients, clinicians, and other stakeholders in a formal process to achieve this.[39]

The IRA threatens to exacerbate barriers to accessing medicines under Medicare Part D.

While UM strategies like prior authorization (PA) can play a useful role in ensuring that patients receive clinically-appropriate medicines and at lower costs, research shows that excessive UM restrictions may also harm Medicare beneficiaries by delaying treatment, substituting less effective medicines, and decreasing medication adherence – potentially leading to avoidable progression of diseases and harmful health effects.[40] The potential harms call for effective standards to assure that any UM imposed by PBMs or Part D plans is clinically appropriate, not a barrier to patients receiving the medicine they need.

A study published earlier this year in *Health Affairs* underscores that cause for concern, showing that Part D formularies have become significantly more restrictive over the past decade.[41] In 2011, Part D plans excluded an average of 20.4 percent of compounds from their formularies and placed PA or step therapy restrictions on another 11.5 percent. By 2020, those numbers jumped to 30.4 percent and 14 percent respectively. Part D plans placed the greatest number of access restrictions and exclusions on brand-name-only compounds, with a total of 68.4 percent of brand-name-only compounds facing some sort of UM restriction in 2020. These data underscore the importance of improving CMS' existing formulary and UM standards as IRA threatens to diminish access further.

Prior Authorization and Step Therapy

In recent years, multiple stakeholders have conducted analysis that demonstrates the negative effects of inappropriate UM on patients. For example, the National Health Council (NHC) released a report on the burden of PA on patients with chronic diseases, noting that PA processes can result in treatment delays, including delays for necessary drugs, and harm care quality. [42] Step therapy[43] can also be implemented in ways that have a negative impact on patients' adherence to their medicine regimens.[44] Indeed, one study found that low-income Medicare beneficiaries who faced PA restrictions on a drug reduced their use of that drug by 26.8 percent – with

[38] Magnolia Market Access IRA Payer Insights Survey. (2023). Respondents (n=26) represent ~259M covered US lives. See also: Myshko D. (March 19, 2024). Payers Question CMS' Ability to Get Discounts Through Drug Price Negotiation. Formulary Watch. Available at: https://www.formularywatch.com/view/payers-question-cms-ability-to-get-discounts-though-drug-price-negotiation

[39] See Appendix C (Strengthening Access and Formulary Protections in Medicare Part D) for further recommendations.

[40] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999. See also: Weeda E., Nguyen E., et al. (October 29, 2019). The Impact of Non-Medical Switching Among Ambulatory Patients: an Updated System Literature Review. Journal of Market Access & Health Policy. Available at: https://pubmed.ncbi.nlm.nih.gov/31692904/

[41] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999

[42] Pinn A., Witting L.L.Q., Gascho E., Escontrias O,A. (November 2023). NHC Report: Exploring the Burden of Prior Authorization on Patients with Chronic Disease. National Health Council. Available at: https://nationalhealthcouncil.org/wp-content/uploads/2023/11/NHC-Report-Exploring-the-Burden-of-Prior-Authorization-on-Patients-with-Chronic-Disease.pdf

[43] The previously cited Magnolia payer survey cited suggests such programs will become more common as a result of IRA.

[44] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 4, 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999

approximately half of those beneficiaries receiving no drug at all.[45] This underscores the importance of ensuring that any UM requirements are clinically appropriate. CMS should consider whether, in addition to reviewing a formulary's overall clinical appropriateness for the Medicare population, it should also more closely review the formulary's effects on beneficiary access and adherence to clinically appropriate medicines, particularly in drug classes with one or more drugs subject to CMS price setting.

The increased imposition of UM restrictions by health plans and PBMs in Part D already has taken a toll on Medicare beneficiaries, and these impacts stand to worsen under the IRA. This is because plans likely will have a financial incentive to deter access to certain medicines (depending on the circumstances, either a selected drug or its non-selected competitors), regardless of which medicine is most clinically appropriate for a given patient. Part D plans are not required under the IRA to cover medicines not subject to price setting, and plans retain latitude to apply UM to covered drugs. In the wake of IRA, Part D plans likely will rely on even more UM and other formulary controls, resulting in plans imposing financially motivated access barriers for patients. These dynamics are likely to disproportionately hurt disadvantaged groups, exacerbating health inequities.[46] There is great concern that a patient's access to the best treatment options will be impeded.[47]

Formulary Exclusions

In addition to the increases in PA and step therapy, Part D plans have increasingly excluded medicines from plan formularies, depriving patients of critical access to their medicines. While formulary exclusions historically were applied to brand drugs with generic equivalents or drug classes with multiple brands, plans are increasingly imposing exclusions for drugs for complex conditions such as cancers and autoimmune diseases.[48] As discussed, a recent payer survey reports that nearly two-thirds of plans expect to further increase formulary exclusions in classes with drugs selected for IRA price setting, which would inevitably create more barriers between patients and the medicines they need.

Formulary exclusion is a particularly harsh tool to restrict patient access to medicines, as it requires beneficiaries to successfully navigate the complicated and cumbersome process for formulary exceptions or pay out of pocket. And the narrower formularies imposed by Part D plans have negative consequences for patients – decreased choices of medicines and a reduced likelihood of being able to obtain a medicine that's optimal for their medical condition. These consequences are expected to worsen under the IRA and must be addressed by CMS.

CMS has failed to protect patients from reduced access to medicines resulting from government price-setting.

Even before the impacts of the IRA are fully realized, CMS' current formulary review standards have not kept pace with the increase in UM restrictions. CMS' current standards are mostly focused on process and are opaque, allowing plans to erect barriers to high value treatment at the expense of patients. For example, CMS' current formulary benefit review includes looking at criteria such as existing "best practices," "industry standards," and "appropriate guidelines," and asking Part D sponsors for a "reasonable justification" for practices falling outside of those practices/standards/guidelines.[49] These terms are not defined and are insufficient to ensure appropriate oversight of UM restrictions.

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[45] Brot-Goldberg, Z.C., Burn S., Layton T., Vabson B. (January 2023). Rationing Medicine Through Bureaucracy: Authorization Restrictions in Medicare. National Bureau of Economic Research. Available at: https://www.nber.org/system/files/working_papers/w30878/w30878.pdf.

[46] Thorpe K.E. (June 27, 2024). Penny Wise And Pound Foolish: IRA Impact On Chronic Disease Costs In Medicare. Health Affairs. Available at: https://www.healthaffairs.org/content/forefront/penny-wise-and-pound-foolish-ira-impact-chronic-disease-costs-medicare.

[47] Hayden Consulting Group. (September 4, 2023). IRA: Patient Access to Therapeutic Options. Available at: https://haydencg.com/ira-patient-access-to-therapeutic-options/.

[48] Joyce G., Blaylock B., Chen J., Van Nuys K. (March 2024). Medicare Part D Plans Greatly Increased Utilization Restrictions on Prescription Drugs, 2011-20. Health Affairs. Available at: https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00999

[49] CMS. (January 15, 2016). Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements. Section 30.2.2. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

Given the changing incentives that IRA establishes, both for selected as well as non-selected medicines, and the growing risks to beneficiary access in Part D, CMS should update and strengthen current Agency oversight and standards for formulary design in Part D.

The Guidance, as well as existing CMS regulations and Part D sub-regulatory guidance, must be revised to fortify protections for patient access to medicines in the wake of the IRA. The current Guidance does little to account for the patient perspective, heterogeneity or clinical nuance and must be strengthened in these areas to better ensure medication access for patients and protect against plan adoption of increased UM. Specifically, we urge CMS to broadly establish stronger standards and oversight for Part D formularies, for all medicines in classes or categories with one or more selected drugs, as well as other therapeutic classes, including the six protected classes. For our detailed recommendations on what CMS can do to strengthen access and formulary protections in Medicare Part D, see Appendix C (Strengthening Access and Formulary Protections in Medicare Part D).

III. CMS' implementation of the Program undermines competitive marketplace dynamics, which successfully drive patient access to new medicines and cost containment.

Our health care system is designed to promote incentives for continued innovation and patient access while leveraging competition to achieve cost containment. Brand medicines face robust competition from generic drugs, biosimilars, and other brand medicines, which PBMs and insurers have historically leveraged to negotiate rebates and discounts from biopharmaceutical manufacturers. As noted above, this dynamic often occurs with multiple competing brand medicines in the same class. For example, less than a year after market entry of the first highly effective curative treatments for hepatitis C virus, multiple other products entered the market, some offering improved cure rates for patients. The resulting competition was so fierce that the average net daily cost for this class today is nearly 80 percent lower than the first product's launch price.[50] Further illustrating this point, a recent study found that new brand medicines launched between 2013 and 2017 led to an immediate decrease in the average net price of competitors already on the market.[51] As a result of competitive dynamics, medicines continue to represent just 14 percent of overall health care spending.[52]

The marketplace is also uniquely designed to promote innovation and affordability simultaneously through the product lifecycle. Underscoring this point, CBO found that the average net price per prescription in Medicare Part D and Medicaid declined between 2009 and 2018, despite the introduction of many new treatments and cures.[53] This is because over time, new medicines help to improve patient health and reduce overall health care costs while also paving the way for lower-cost generics and biosimilars. Similar cost containment mechanisms do not exist in other parts of our health care system.[54]

Unfortunately, the IRA and CMS' implementation of the Program undermine the success of this system by substituting government price setting for future competition from generics and biosimilars. Specifically, the IRA allows the government to impose such low prices on an innovator product that biosimilar and generic manufacturers may not be able to compete, discouraging them from bringing products to market in the first place. This risk is further heightened by the inability of generic and biosimilar manufacturers to predict with any

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[50] Silseth S., Shaw H. (June 11, 2021). Analysis of prescription drugs for the treatment of hepatitis C in the United States. Milliman. Available at: https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states

[51] Dickson S., Gabriel N., Hernandez I. (August 2023). Changes in Net Prices and Spending for Pharmaceuticals After The Introduction Of New Therapeutic Competition, 2011–19. Health Affairs. Available at: https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00250

[52] Altarum Institute. (July 2022). Projections of the Non-Retail Prescription Drug Share of National Health Expenditures. Available at: https://altarum.org/sites/default/files/uploaded-publication-files/ProjectionsCMS20of%20NonRetail%20Drug%20Share%20of%20NHE%202022.pdf

[53] CBO. (January 19, 2022). Prescription Drugs: Spending, Use, and Prices. Available at: https://www.cbo.gov/publication/57050

[54] For example, the price of a medicine commonly used to prevent cardiovascular disease dropped 95% between 2007 and 2017, while the average charge for a surgical procedure to treat it increased 94% over the same period. PhRMA analysis of Healthcare Cost and Utilization Project (HCUP). National (Nationwide) Inpatient Sample (NIS) database. 2007, 2017. Available at: https://www.ahrq.gov/research/data/hcup/index.html; IQVIA analysis for PhRMA. Invoice price data for atorvastatin 10mg from IQVIA National Sales Perspectives data for 2007 (branded Lipitor) and 2017 (generic). June 2020.

certainty, when they need to make their investment and development decisions, whether or when the branded reference product they are seeking to compete against will be selected for price setting under the Program.

Specifically, regarding small molecule drugs, the IRA undermines existing incentives for generic competition by implementing price setting far earlier than current timelines for generic competition. Currently the average effective patent life for small molecule drugs before generics enter the market is 13 to 14 years.[55] Under the IRA, generics manufacturers must weigh the economic viability of entering the market to compete against a brand product that may already have a low government-set price. But generics rely on the ability to offer sharply lower prices to attract market share from brand competitors. In fact, generics often enter the market immediately upon patent expiration and are often adopted rapidly because of this successful dynamic. Today, 90 percent of prescriptions filled are filled with generic medicines and many capture as much as 90 percent of the market within 3 months of entry.[56] But the IRA's price setting provisions upend incentives that currently drive market entry.

Additionally, the IRA will strongly discourage biosimilar development, as the price-setting timelines imposed under the law are at odds with the framework created under the biosimilar regulatory pathway created under the Biologics Price Competition and Innovation Act (BPCIA). Under the Program, biologics may be eligible for price setting at year 11, with the government-set price going into effect 2 years later, unless there is an approved and marketed biosimilar. However, under the BPCIA, a biosimilar cannot be approved until at least 12 years after the first licensure of the reference biologic. To mitigate against this tension, a special rule was established in the IRA, which allows for potential biosimilar manufacturers to request a "pause" in the price setting process if there's a "high likelihood" for biosimilar marketing within the requisite timeframe. Unfortunately, the biosimilar pause provisions leave too much uncertainty as to whether a drug with a marketed biosimilar can qualify.

To make matters worse, CMS has also imposed an extra-statutory "bona fide marketing" standard, entirely of its own invention, that would leave significant ambiguity as to whether it will be possible to avoid price setting even when there is a marketed biosimilar. These realities make the decision to invest in biosimilar development extremely risky and potentially financially infeasible moving forward. Biosimilar manufacturers face long development timelines and significant costs due to the complexities of biologics manufacturing.[57] As a result of the uncertainty around navigating the pause and the prospect of competing against a government price-set product, the Program – if implemented as CMS has described in Draft Guidance - is likely to serve as a significant disincentive for biosimilar manufacturers in entering the market. For our recommendations on what CMS can do to mitigate against these disincentives and improve the biosimilar pause and its interpretation of "marketed," see Appendix A (Drug Selection) to this letter, which is focused on Drug Selection and related issues.

CMS' list of drugs selected for price setting in 2026 already illustrates the risk that government price setting will undermine market competition.[58] In fact, the majority of medicines on CMS' list of selected drugs for IPAY 2026 already have anticipated generic and biosimilar competition before the IPAY.[59] However, due to the provisions in the IRA and CMS' flawed interpretation, if the pending generic and biosimilar products are unable to reach the market in time for CMS to determine by August 1, 2024 that "bona fide" marketing exists, they will be forced to compete against price-controlled products. This jeopardizes future competition and savings driven by generics and

[55] Grabowski H., Long G., Mortimer R., Bilginsoy M. (January 2021). Continuing trends in U.S. brand-name and generic drug competition. Journal of Medical Economics. Available at: https://pubmed.ncbi.nlm.nih.gov/34253119/
[56] AAM. (September 2023). The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. Available at: https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf
[57] Blackstone E.A., Joseph P.F. (September 2013). The Economics of Biosimilars. American Health & Drug Benefits. Available at: https://pubmed.ncbi.nlm.nih.gov/24991376/
[58] HHS. (August 29, 2023). HHS Selects the First Drugs for Medicare Drug Price Negotiation. Available at: https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html
[59] Analysis based on publicly available information at FDA Orange Book and Purple Book and press sources. Additional generic applications may be pending with FDA beyond the 3 noted.

biosimilars in the years ahead. These savings totaled $408 billion last year alone, including $130 billion to Medicare.[60]

IV. CMS' implementation of the Program will do irreparable harm to innovation to the detriment of patients.

The IRA and CMS' implementation of the Program have also disrupted the incentives which have driven the development of innovative medicines over the years. The price setting framework sets an arbitrary ceiling on prices and allows CMS to set the price at any level below that ceiling for drugs 9 to 13 years after initial FDA approval (and for forms of a selected drug, price setting could occur even earlier due to CMS' approach to defining QSSD). In this section, we detail the mechanisms by which price-setting shifts existing R&D incentives and jeopardizes the future development of medicines in certain therapeutic areas with very real consequences for patients. While each of these disincentives may affect biopharmaceutical companies differently given varying areas of expertise and focus, across the market, the IRA, and CMS' interpretation of the statute, is anticipated to discourage:

- **Post-Approval Innovation.** CMS' broad definition of QSSD, as well as when drugs become eligible for negotiation within their lifecycle, discourage R&D that occurs after a drug or biological is initially FDA approved.
- **Development of Small Molecule Medicines.** By affording small molecule medicines less time on the market after FDA approval prior to entering negotiation, the IRA disincentivizes their development.
- **Development of Orphan Drugs.** Although the IRA exempts certain orphan drugs from negotiation, CMS' overly narrow interpretation of the exemption's eligibility criteria will further harm innovation for these diseases.
- **Development of Treatments for Chronic Diseases.** The list of drugs subject to negotiation is overwhelmingly comprised of medicines to treat common chronic illnesses, signaling that investing in these medicines may impose significant uncertainty and risk.

CMS' implementation of the Program will create disincentives to post approval R&D and the development of small molecule medicines which are critical for driving treatment advances in certain disease areas.

Under the framework, selected medicines will face price setting earlier than they may otherwise face generic or biosimilar competition. Shortening the timeframe by which manufacturers can earn revenues on medicines after initial approval and before price setting may occur is expected to upend existing R&D incentives.[61] Specifically, biopharmaceutical companies will now be forced to make difficult decisions about whether it is feasible to invest in R&D occurring after initial FDA approval that could lead to important new uses of already approved medicines. This is particularly true given it can take an additional four years or more to complete costly phase III clinical trials to support a post-approval indication, and companies must consider whether there will be sufficient time on the market to earn revenue before price setting may occur. Unfortunately, any advancements for patients are realized through continued investment in this form of R&D to bring new treatments for different diseases or patient populations.

Additionally, by affording small molecule medicines a shorter timeframe on the market relative to other medicines before price setting may occur, the "pill penalty" especially discourages the development of these critical treatments. Moreover, given the relatively shorter timeframe the pill penalty also particularly jeopardizes the post-approval R&D that is necessary to realize their full therapeutic potential. In fact, research shows more than half of

[60] AAM. (September 2023). The U.S. Generic & Biosimilar Medicines Savings Report, September 2023. Available at: https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf

[61] Philipson T.J., Ling Y., Chang R. (October 2023). The Impact of Price Setting at 9 Years on Small Molecule Innovation Under the Inflation Reduction Act. The University of Chicago. Available at: https://ecchc.economics.uchicago.edu/files/2023/10/Small-Molecule-Paper-Final-Oct-5-2023.pdf.

small molecule medicines approved a decade ago received additional indications in later years, and nearly half of those occurred seven or more years after initial approval.[62] One of the reasons small molecule medicines play such a critical role in the treatment of many diseases is their unique ability to reach therapeutic targets inside cells. For example, in diseases such as cancer where the genetic changes that drive cancer cell growth begin inside cancer cells, this feature makes these medicines an important part of the treatment arsenal. Similarly, the ability for these medicines to cross the blood-brain barriers also makes them critical in the treatment of disease with therapeutic targets inside the brain—including illnesses that impact the central nervous system, mental health conditions, neurodegenerative diseases, and many more.[63]

In disease areas where most medicines approved by the FDA are small molecules and post-approval R&D has been indispensable in driving progress for patients, the impact of price setting is expected to be substantial. For example, one study found more than 60 percent of small molecule *cancer* drugs approved between 2006 and 2012 received at least one post-approval indication, and nearly half of those occurred seven or more years after initial approval.[64] Similarly, another analysis examining *cardiovascular* medicines approved between 1995 and 2021 found 92 percent were small molecule medicines and among these, nearly half of approved indications were approved seven or more years after initial approval.[65] Unfortunately, many of these indications may be foregone moving forward. In fact, one analysis by researchers at the University of Chicago found the IRA's price setting provisions would translate to a total of 79 fewer small molecule medicines, and 188 fewer post approval indications over the next 20 years.[66]

Moreover, CMS' approach to setting that price may penalize manufacturers for having "recouped" R&D costs. Not only is this approach flawed but it is based on a fundamental misunderstanding of the biopharmaceutical investment model. As a result, biopharmaceutical companies now must not only consider R&D investment decisions in light of price setting but also how those decisions may affect the government-set price if price setting will apply. In both instances, the Program and CMS' approach to setting a price disrupt existing regulatory and market incentives which have historically aligned the R&D enterprise to drive innovation to meet the unmet needs of patients and instead realigned those incentives towards considering the application of government intervention and its consequences.

CMS' interpretation of the orphan drug exclusion threatens the development of new medicines to meet unmet needs for patients with rare diseases.

Unfortunately, CMS' interpretation of the orphan drug exclusion under the Program is overly narrow and undermines existing R&D incentives under the Orphan Drug Act (ODA) for developing new treatments for rare diseases. Congress passed the ODA in 1983 to encourage companies to develop orphan drugs when existing market incentives have historically been insufficient to encourage investments, due to small patient populations, significant R&D challenges, and limited probabilities of success relative to other therapeutic areas. Since enactment, more than 600 orphan drugs and biologics have been approved in the US compared to just 10 in the decade before passage.[67] While the IRA provides a specific exemption from price setting for medicines with a

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[62] Partnership for Health Analytic Research. (June 2023). Implications of the Inflation Reduction Act Price Setting Provisions on Post-approval Indications for Small Molecule Medicines. Available at: https://www.pharllc.com/publication/implications-of-the-ira-price-setting-provisions-on-post-approval-indications-for-small-molecule-medicines/

[63] Ibid.

[64] PhRMA. (July 2023). Emerging Value in Oncology: How Ongoing Research Expands the Benefits of Oncology Medicines. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/PhRMA_Emerging-Value-Report/PhRMA_Emerging-Value-Report_FIN-web_July2023_v2.pdf

[65] Grabowski H., Long G. (March 18, 2024). Post-Approval Indications and Clinical Trials for Cardiovascular Drugs: Some Implications of the US Inflation Reduction Act. Journal of Medical Economics. Available at: https://www.tandfonline.com/doi/full/10.1080/13696998.2024.2323903

[66] Philipson T.J., Ling Y., Chang R. et al. (August 25, 2023). Policy Brief: The Potentially Larger Than Predicted Impact of the IRA on Small Molecule R&D and Patient Health. The University of Chicago. Available at: https://ecchc.economics.uchicago.edu/project/policy-brief-the-potentially-larger-than-predicted-impact-of-the-ira-on-small-molecule-rd-and-patient-health/

[67] FDA. (May 12, 2022). Developing Products for Rare Diseases & Conditions. Available at: http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/default.htm

single orphan designation (and indications only within that designation), the exemption is far too narrow and is expected to shift R&D incentives and negatively impact orphan drug development. To make matters worse, CMS' careless implementation of the Program and disregard for the critical incentives driving orphan drug development is further evidenced by its explicit removal of a statement in this year's Guidance—noting that CMS would consider additional actions it can take in implementing the "Negotiation Program to best support orphan drug development."

Market incentives prior to the enactment of the IRA incentivized biopharmaceutical companies to choose to launch first in small populations such as rare diseases, because they could earn revenues while conducting R&D on additional patient populations. Now, based on CMS' interpretation of the orphan-drug exclusion, companies across the market must grapple with difficult decisions about whether to choose early indications with the greatest economic value. Specifically, even where a drug's initial approval qualifies for the orphan-drug exclusion, CMS has elected to "use the date of the earliest approval of the drug or licensure of the biological product" to determine whether a drug may be selected for price setting, even if the exclusion is lost years later. As a result, promising drugs may be delayed in getting to market as companies may have an incentive to start the clock first with indications impacting larger population sizes. But importantly, it also means in many cases rare disease patient populations will have to wait for post-approval indications to treat their illness or these indications ultimately may never be realized given shortened timelines to conduct R&D after initial approval. To put a finer point on this disincentive, while the IRA provided a limited exemption for orphan drugs approved to treat a single rare disease, the exemption does not eliminate the disincentives imposed by the IRA and the Program's broader price setting framework which discourages companies from conducting R&D after initial approval, and CMS' Guidance exacerbates this concern.

Historically, post-approval R&D has been critical to advancing treatments for rare diseases. In fact, a total of 35 percent of orphan drugs had multiple indications between 1990 and 2022 (20 percent were approved for rare and common diseases, and 15 percent were approved for just orphan conditions). Half of all subsequent approvals for orphan drugs came five years after initial approval.[68] As noted by a researcher at Columbia University, "The likely result [of the IRA] will be fewer orphan-first launches and, without such launches, riskier trials for broader indications."[69] For our recommendations for improving implementation of the Orphan Drug Exclusion to mitigate against R&D disincentives for patients with rare diseases see Appendix A (Drug Selection).

CMS' treatment of medicines containing the same active ingredient or moiety as one drug under the Program discourages the post-approval R&D that results in new drugs and biological products.

CMS' interpretation of QSSD for the purposes of price setting under the IRA is untethered from the statute and will stifle the development of innovative and lifesaving treatments. CMS' overbroad approach treats new dosage forms and formulations containing the same active ingredient or moiety as the same drug, even if the drug was approved under a different marketing application. As a result, biopharmaceutical companies will have to reconsider the economic feasibility of investing in new drug or biological products that could provide meaningful new treatment options for different diseases or patient populations, or provide a new method of administration, jeopardizing the development of these critical treatments moving forward. As noted by a former FDA official, CMS' broad definition of QSSD will undoubtedly discourage post-approval R&D.[70]

Whether improving adherence for vulnerable patient populations or providing new treatment options for an entirely different disease or patient population, post approval R&D that leads to new drugs and biological products provide meaningful treatment advances for patients. For example, long-acting injectable formulations of antipsychotics have significantly improved patient adherence and treatment outcomes. These medications have

[68] Miller, K.L., Lanthier M. (January 2024). Orphan Drug Label Expansions: Analysis Of Subsequent Rare And Common Indication Approvals. Health Affairs. Available at: https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00219.
[69] Masia N. (2024). Will Potential IRA Price Limits Delay Drug Launches? Health Capital Group. Available at: https://www.ispor.org/docs/default-source/intl2024/ispor24masiapt4poster138000-pdf.pdf?sfvrsn=2450c107_0
[70] Lumanity. Potential Impact of the IRA on the Generic Drug Market. Available at: https://lumanity.com/perspectives/potential-impact-of-the-ira-on-the-generic-drug-market/

been available for many years and were initially made available in oral dosage forms that patients were required to self-administer daily. Unfortunately, non-adherence rates to antipsychotic medications are relatively high among those with schizophrenia, ranging from 34 percent to 81 percent.[71] [72] [73] Poor adherence is associated with severe consequences, including greater risk of relapse, hospitalization, and suicide.[74] [75] [76] [77] Today, many of these medications are available as long-acting injectables (LAIs) that can be administered every two weeks to as little as every 6 months, depending on the drug. Real world use studies have shown that LAI antipsychotics improve medication adherence and patient outcomes leading to lower odds of hospitalization and fewer emergency room visits. Among Medicaid beneficiaries with schizophrenia, improved adherence due to LAI antipsychotics generated annual net savings of up to $3.3 billion, or $1,580 per patient per year, driven by lower hospitalizations, outpatient care, and criminal justice system involvement.[78] [79]

Unfortunately, the first set of drugs selected for price setting demonstrates CMS' disregard for the value these medicines provide and for the patient populations that rely on these treatment advances. While CMS was permitted to select 10 drugs for price setting, CMS adopted an overly broad interpretation of QSSD to sweep in a broad range of dosage forms and formulations, including those submitted under entirely different marketing applications. The selection of these drugs and biological products, for which the government-set price will go into effect in 2026, sends a clear signal discouraging any future research on improved dosage forms and formulations to meet unmet needs for various patient populations, including patients outside of Medicare. For example, one selected cancer medicine was originally approved for adults with a form of chronic leukemia. Many years later it was approved for use in a new dosage form for an entirely different disease for pediatric patients: graft versus host disease. The new oral suspension form for this patient population provided an important option for those with difficulties swallowing. While this new dosage form was also approved under an entirely different drug application in 2022, for an entirely different disease and patient population, the drug will nonetheless be treated as the same QSSD and subject to price setting just a year after the drug was approved by the FDA.[80]

Given the IRA's price setting framework and CMS' treatment of new dosage forms and formulations under the framework, the economic incentives driving investment in these types of drugs and biological products will be significantly limited moving forward given they may be swept into government price setting shortly after reaching the market. For our recommendations on how to appropriately identify QSSDs in line with the IRA and mitigate

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[71] Lacro J.P., Dunn L.B., Dolder C.R., et al. (October 2022). Prevalence of and Risk Factors for Medication Nonadherence in Patients with Schizophrenia: A Comprehensive Review of Recent Literature. Journal of Clinical Psychiatry. Available at: https://pubmed.ncbi.nlm.nih.gov/12416599/

[72] Lafeuille M.H., Frois C., Cloutier M., et al. (October 2016). Factors Associated with Adherence to the HEDIS Quality Measure in Medicaid Patients with Schizophrenia. American Health & Drug Benefits. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5123648/

[73] Greene M., Yan T., Chang E., et al. (February 2018). Medication Adherence and Discontinuation of Long-Acting Injectable Versus Oral Antipsychotics in Patients with Schizophrenia or Bipolar Disorder. Journal of Medical Economics. Available at: https://pubmed.ncbi.nlm.nih.gov/28895758/

[74] Sher L., Kahn R.S. (July 10, 2019). Suicide in Schizophrenia: An Educational Overview. Medicina (Mex). Available at: https://www.mdpi.com/1648-9144/55/7/361

[75] Ventriglio A., Gentile A., Bonfitto I., et al. (June 27, 2016). Suicide in the Early Stage of Schizophrenia. Front Psychiatry. Available at: https://pubmed.ncbi.nlm.nih.gov/27445872/

[76] Albert M., McCaig L.F. (September 2015). Emergency Department Visits Related to Schizophrenia Among Adults Aged 18-64: United States, 2009-2011. National Center for Health Statistics. Available at: https://www.cdc.gov/nchs/products/databriefs/db215.htm

[77] Higashi K., Medic G., Littlewood K.J., et al. (August 2013). Medication Adherence in Schizophrenia: Factors Influencing Adherence and Consequences of Nonadherence, a Systematic Literature Review. Therapeutic Advances in Psychopharmacology. Available at: https://pubmed.ncbi.nlm.nih.gov/24167693/

[78] Predmore Z.S., Mattke S., Horvitz-Lennon M. (April 1, 2015). Improving Antipsychotic Adherence Among Patients With Schizophrenia: Savings for States. Psychiatric Services. Available at: https://pubmed.ncbi.nlm.nih.gov/25555222/

[79] Bera R., Offord S., Zubek D., et al. (February 2014). Hospitalization Resource Utilization and Costs Among Medicaid Insured Patients With Schizophrenia With Different Treatment Durations of Long-Acting Injectable Antipsychotic Therapy. Journal of Clinical Psychopharmacology. Available at: https://pubmed.ncbi.nlm.nih.gov/24135840/

[80] Analysis of FDA labels of products on selected drug list. Drugs@FDA. Available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm

against the disincentives described here see Appendix A (Drug Selection).

The IRA and CMS' implementation of the Program will jeopardize our ability to bend the cost curve and reduce health disparities in the years ahead.

Six in ten Americans have one or more chronic conditions and 42 percent have 2 or more.[81] Chronic conditions, including mental illness, are the largest drivers of healthcare costs accounting for 90 percent of the $4.5 trillion spent on health care each year.[82] In the years ahead, the number of individuals with 3 or more chronic conditions is projected to nearly double by 2030, greatly increasing the burden of these illnesses and pressures on public programs. Much of this impact is expected to disproportionately affect underserved and marginalized populations, leading to widening health disparities.[83,84,85,86,87]

Better disease management achieved through use of medicines has long been credited with avoiding health complications and spending on other costly health care services. These features in turn have been shown to have the effect of curbing overall Medicare spending growth. For example, between 1999 and 2012, there was a significant reduction in Medicare spending growth for cardiovascular disease, one quarter of which was due to greater use of cardiovascular medicines over this period.[88]

Yet, just as chronic illness is expected to impose an increasing burden on our health care system and public programs, CMS' implementation of the Program is moving our healthcare system in the opposite direction by discouraging investment in chronic disease medicines which offer the best opportunity to reduce healthcare spending. CMS' initial list of drugs eligible for price setting illustrates this disincentive in action as the entire list is comprised of medicines to treat common chronic illnesses such as heart disease, diabetes, cancer and autoimmune diseases.[89] Moreover, CMS is expected to continue to select medicines that treat chronic disease for price setting in the years ahead—ironically due in large part to the high burden chronic illness imposes on the Medicare population.

Research shows these types of shortsighted policies can be expected to reduce the number of medicines developed in the future, including those that offer potential to reduce or eliminate spending on other costly medical care. One study from economists at the University of Chicago estimated that IRA price setting policies would increase overall healthcare spending by $50.8 billion over a 20-year period due to the lost opportunity to realize savings in

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[81] Benavidez GA, Zahnd WE, Hung P, Eberth JM. (February 29, 2024). Chronic Disease Prevalence in the US: Sociodemographic and Geographic Variations by Zip Code Tabulation Area. Preventing Chronic Disease. Available at: https://www.cdc.gov/pcd/issues/2024/23_0267.htm

[82] CDC. (May 2023). Fast Facts: Health and Economic Costs of Chronic Conditions. Available at: https://www.cdc.gov/chronic-disease/data-research/facts-stats/index.html#:~:text=The%20impact%20of%20chronic%20diseases,significant%20health%20and%20economic%20benefits.

[83] Partnership to Fight Chronic Disease. What Is the Impact of Chronic Disease on America? Available at: https://www.fightchronicdisease.org/sites/default/files/pfcd_blocks/PFCD_US.FactSheet_FINAL1%20%282%29.pdf

[84] Buttorff C., Ruder T., Bauman M. (May 26, 2017). Multiple Chronic Conditions in the United States. Rand Corporation. Available at: https://www.rand.org/pubs/tools/TL221.html

[85] U.S. Department of Health and Human Services, Office of Minority Health. Heart Disease and African Americans and Hispanic Americans, Diabetes and African Americans and Hispanic Americans, Obesity and African Americans and Hispanic Americans, Asthma and African Americans and Hispanic Americans, Cancer and African Americans and Hispanic Americans.

[86] Ndugga N., Hill L., Artiga S. (June 11, 2024). . KFF. Available at: https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/Key Data on Health and Health Care by Race and Ethnicity. KFF. Available at: https://www.kff.org/racial-equity-and-health-policy/report/key-data-on-health-and-health-care-by-race-and-ethnicity/

[87] Partnership to Fight Chronic Disease. (November 2, 2022). Advancing Health Equity, Improving Health Outcomes for All Could Save U.S. $3.8 Trillion. Available at: https://www.fightchronicdisease.org/latest-news/advancing-health-equity-improving-health-outcomes-all-could-save-us-38-trillion

[88] Cutler D.M., Ghosh K., Messer K.L., et al. (February 2019). Explaining the Slowdown in Medical Spending Growth Among the Elderly. Health Affairs. Available at: https://pubmed.ncbi.nlm.nih.gov/30715965/

[89] HHS. (August 29, 2023). HHS Selects the First Drugs for Medicare Drug Price Negotiation. Available at: https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html

medical care that medicines generate.[90] Unfortunately, the IRA undermines the most effective tool we have to bend the cost curve and reduce health disparities in Medicare moving forward.

V. CMS has failed to implement proper safeguards to protect patients and clinicians in its implementation of the Program.

CMS has failed to meaningfully include key stakeholders, such as physicians and clinicians, in the price setting process.

We appreciate CMS' acknowledgement in the Guidance that it must revisit its approach to engaging stakeholders. It is clear to many that CMS' efforts to solicit and incorporate feedback on both the Program itself, as well as on the selected drugs for IPAY 2026 of the Program, have been seriously deficient. CMS offered two primary opportunities for stakeholders to engage and provide input into the price setting process in IPAY 2026: the Negotiation Data Elements Information Collection Request (ICR), and the Stakeholder Listening Sessions. Both were riddled with fundamental substantive, as well as operational, issues. CMS efforts likely led to the opposite effect of what CMS intended – *discouraging* rather than encouraging a diverse group of stakeholders with robust subject matter expertise from engaging in the IPAY 2026 process.

First, the Data Elements ICR was not an appropriate or complete mechanism to solicit input from patients, clinicians, or caregivers on the factors CMS must consider in determining prices for selected drugs. CMS asked for a significant amount of highly complex and technical data that posed a significant burden on patients and other key stakeholders – especially those from underrepresented or disadvantaged communities. To simply submit data to the Agency, these stakeholders needed to learn how to navigate a structurally complex form, decipher and answer highly technical questions in writing, and collect and provide data on the selected drug and potential therapeutic alternatives all within 30 days. Even worse, CMS declined to meaningfully solicit feedback on topics that are important to patients, clinicians, and caregivers – including clearly asking for their experience with a selected drug and the potential therapeutic alternative(s)[91] – while also imposing arduous word limits on the responses CMS did solicit. Together, these factors impeded a patient's, clinician's, or caregiver's ability to relay a complete narrative regarding their experience with a selected drug or therapeutic alternative.

Second, the Stakeholder Listening Sessions hosted by CMS for IPAY 2026 selected drugs, while perhaps well intended, were ill-conceived and poorly executed. This has been noted not only by patients themselves, but by experts in the field of patient engagement.[92] Issues highlighted by PhRMA and other stakeholders (including participants) include:

- **Lack of transparency into participant selection.** For each session, participation was limited to 20 speakers, though it was unclear to participants and the public how the speakers were selected, whether at random or based on certain criteria and each session only featured an average of 11 speakers per drug.[93]

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[90] Philipson T.J., Di Cera G. Issue Brief: The Impact of Biopharmaceutical Innovation on Health Care Spending. The University of Chicago. Available at: https://ecchc.economics.uchicago.edu/2022/08/03/the-impact-of-biopharmaceutical-innovation-on-health-care-spending/

[91] While CMS included new questions on the patient and caregiver experience in the revised ICR, the questions in Section H of the revised ICR were unnecessarily narrow and worded in a way that may have made it difficult for patients to clearly understand what specifically CMS was seeking in each question. For example, when defining "Therapeutic Alternative" in Questions 27 and 28, CMS used terms such as "drug class," "chemical class," and "therapeutic class," without defining these terms.

[92] Vandigo J., Edwards H.A., Flanagan J.H., Mattingly T.J. (June 24, 2024). Three Ways To Improve The Patient-Focused Listening Sessions In The Medicare Drug Price Negotiation Program. Health Affairs. Available at: https://www.healthaffairs.org/content/forefront/three-ways-improve-patient-focused-listening-sessions-medicare-drug-price-negotiation

[93] Patterson J., Wagner T.D., Campbell J. (November 2023). Three Takeaways from CMS's Patient-Focused Listening Sessions: Toward Improved Patient Engagement. National Pharmaceutical Council. Available at: https://www.npcnow.org/resources/three-takeaways-cmss-patient-focused-listening-sessions-toward-improved-patient

This is disappointing as the selected speakers were primarily white (88 percent) and below the age of 65 (63 percent) which may have obscured the views of Medicare patients and those from underserved or traditionally underrepresented communities.[94] CMS has provided no clarity into if these sessions were smaller than expected because of limited response or interest, or resulting from a decision by the Agency.

- **No meaningful dialogue between the Agency and the participants.** Staff remained in listening mode the entire time and did not provide information for participants to respond to or ask questions or provide feedback after participants spoke. CMS even asked at least one speaker to "reconsider" their statements on the IRA's impact to innovation the week of their listening session,[95] signaling that it may have even been trying to prevent any discussion on the flaws of the IRA.
- **Lack of clarity into conflict-of-interest disclosures.** CMS required participants to disclose "conflicts," though the purpose of those disclosures and what should be disclosed was unclear. Although funding from pharmaceutical companies was named as a potential "conflict," funding from other interested or biased parties – including payers, pharmacy benefit managers (PBMs) or other stakeholders with a vested interest in profiting off lowered drug prices – was not. This could have discouraged participation and confused the audience about participants' potential conflicts (or lack thereof).
- **Lack of accommodation of persons with disabilities.** In general, there were few apparent accommodations of persons with disabilities. At one point, CMS staff appeared to cut off a speaker with a speech impediment because the three-minute time limit had been reached.[96]

CMS has also failed to engage (or publicly disclose how they plan to engage) clinicians at critical junctures in the process. As PhRMA discussed at length in our comments on the IPAY 2026 Guidance, clinicians can offer valuable, real-world experience and insight into the selected drugs and key CMS decision points, including but not limited to identification of therapeutic alternatives, whether a selected drug or therapeutic alternative represents a therapeutic advance or meets an unmet need, and key subpopulations for selected drugs. As noted by physicians, CMS' failure in this regard could have very real consequences for patient access to treatment. Physicians are also in the best position to minimize the negative consequences Program implementation might have on formulary access. A structured process for receiving their input can ensure appropriate clinical reviews are considered in both evidence gathering and evaluation as well as monitoring the extent to which selected drugs and their competitors are appropriately covered on formularies.[97] As one physician has stated, "The [A]gency is required to consider a drug's clinical benefit, whether the drug addresses unmet needs, and what alternative treatments exist. But it's hard to make these determinations without a deep dive into the kind of observations and clinical evidence that physicians acquire from extensive, everyday experience."[98]

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[94] Patterson J., Wagner T.D., Salih R., Shabazz G., Campbell J. (June 2024). Breadth of Patient and Stakeholder Input in CMS's Drug Price Negotiation Program: A Content Analysis of the 2023 Patient-Focused Listening Sessions. Value in Health, Volume 27, Issue 6, S1. Available at: https://www.ispor.org/heor-resources/presentations-database/presentation/intl2024-3898/137099

[95] Czwartacki J.(November 30, 2023). After Participating in CMS's IRA Listening Sessions, I Remain Skeptical of IRA Implementation. RealClearHealth. Available at: https://www.realclearhealth.com/blog/2023/11/30/after_participating_in_cmss_ira_listening_sessions_i_remain_skeptical_of_ira_implementation_995832.html

[96] CMS cut off multiple patients throughout the sessions. For an example, please see the redacted transcript for "Speaker 3" during the Eliquis listening session on October 30th. Available at: https://www.cms.gov/files/document/eliquis-transcript-103023.pdf

[97] Fendrick A.M. (December 14, 2023). CMS Must Obtain Clinician Input Today to Prevent Part D Access Barriers Tomorrow. Health Affairs. Available at: https://www.healthaffairs.org/content/forefront/cms-must-obtain-clinician-input-today-prevent-part-d-access-barriers-tomorrow

[98] Fonseca R. (July 2, 2024). Without Doctor Input, the IRA Could Hurt Patients and Cost Them More. RealClearHealth. Available at: https://www.realclearhealth.com/blog/2024/07/02/without_doctor_input_the_ira_could_hurt_patients_and_cost_them_more_1041650.html.

CMS' lack of engagement is certainly not due to lack of feedback or ideas from stakeholders for how best to engage. To the contrary, principles to conduct patient-centered research have existed for years[99] and there is a wide range of academic and thought leader research[100] on methods to better understand and collect patient and caregiver feedback. In response to CMS' implementation of the IRA, experts in patient engagement, including both academics and patients themselves, have been increasingly vocal and concrete regarding how CMS should best receive information from patients, clinicians, and caregivers, and how they should use that information. [101] For example, NHC hosted a roundtable and subsequently released detailed, actionable recommendations to CMS on how to improve engagement with patients; these recommendations were developed in concert with over thirty different stakeholder groups. Because CMS received such thoughtful input, it is even more deeply disappointing that the Agency did not include a detailed engagement roadmap in the Guidance. Instead, it appears CMS will simply finalize a strategy (a strategy which will hopefully be based on feedback received from stakeholders in response to this Guidance) and move forward. Before that happens, PhRMA strongly encourages CMS to speak with stakeholders who should remain at the center of this process – patients, clinicians, and caregivers.

CMS has failed to articulate a patient-centered approach to setting prices or implement the few patient protections that were included in the IRA.

As previously noted, PhRMA strongly believes that CMS has an obligation to mitigate the potential harm to patients caused by the IRA. One way CMS can do this is by ensuring that all aspects of its price setting methodology are centered on the needs of patients. This includes adhering to the few explicit patient protections in the IRA. Unfortunately, there is very little evidence in the Guidance that CMS has taken that important step.

As previously mentioned in Section I of this letter, CMS is required by the IRA to develop a consistent methodology for determining prices for selected drugs. It is safe to assume that development of such a methodology would include, at a minimum, public release of certain aspects of the Agency's decision making. However, CMS has failed to disclose to the public (including in the "negotiations" with manufacturers) sufficient detail surrounding many aspects of its methodology.

CMS' apparent failure to adhere to the requirement that it develop a "consistent methodology" is concerning for a number of reasons, but primarily because it is unclear whether the evidence CMS is relying upon or generating, the manner in which CMS is interpreting the factors, or the methodology itself is centered on the perspective of patients, caregivers and society. If CMS is truly committed to a patient-centered approach, at minimum, the Agency needs to transparently articulate how the feedback gathered from the ICR process, the listening-sessions, and any other form of engagement is being used directly and quantitatively in setting the MFP. Without a formalized methodology, any improvements to data collection will fall flat and prices for selected drugs will not reflect the inherent value patients derive from the selected drugs. A failure to emphasize the needs of patients

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[99] For examples, please see principles from the National Health Council (available at: https://nationalhealthcouncil.org/blog/the-nhcs-new-value-classroom-tools-to-help-patient-group-staff-engage-on-a-value-assessment/), the National Pharmaceutical Council (available at: https://www.npcnow.org/sites/default/files/2021-04/npc-guiding-practices-for-patient-centered-value-assessment.pdf), the Patient-Centered Outcomes Research Institute (available at: https://www.pcori.org/engagement/engagement-resources), and PhRMA (available at: https://phrma.org/en/resource-center/Topics/Cost-and-Value/Principles-for-Value-Assessment-Frameworks#:~:text=Clearly%20state%20the%20intended%20use,and%20reporting%20costs%20and%20economic)

[100] Examples of patient engagement research CMS should reference include: dosReis S., Butler B., Caicedo J., et al. (October 2020). Stakeholder-Engaged Derivation of Patient-Informed Value Elements. Patient. Available at: https://pubmed.ncbi.nlm.nih.gov/32676998/. See also: Slejko J.F., Hong Y.D., Sullivan J.L., et al. (September 2021). Prioritization and Refinement of Patient-Informed Value Elements as Attributes for Chronic Obstructive Pulmonary Disease Treatment Preferences. Patient. Available at: https://pubmed.ncbi.nlm.nih.gov/33554310/

[101] Vandigo J., Edwards H.A., Flanagan J.H., Mattingly T.J. (Jume 24, 2024). Three Ways To Improve The Patient-Focused Listening Sessions In The Medicare Drug Price Negotiation Program. Health Affairs. Available at: https://www.healthaffairs.org/content/forefront/three-ways-improve-patient-focused-listening-sessions-medicare-drug-price-negotiation

could lead to significant consequences to patient access to drugs in Medicare Part D, or the ongoing development of future treatments, as discussed earlier in this letter.

Another issue on which CMS has remained silent is how it intends to weigh the two sets of factors against each other. Per the IRA, CMS must consider two sets of factors when setting prices for selected drugs. An emphasis on the factors in Section 1192(e)(2) (related more closely to the value a selected medicine brings to patients) may somewhat mitigate inherent disincentives for continued innovation.[102] However, if CMS places too much importance on factors in Section 1194(e)(1) (related to "manufacturer-specific data"), the result could be a price that entirely disregards the value that medicines bring to patients, and have catastrophic consequences for both patient access and innovation. In the Guidance, CMS has declined to discuss the issue entirely, creating considerable uncertainty for manufacturers and jeopardizing patient access to current and future treatments.

One issue CMS does discuss in Guidance, but only superficially, is the use of cost effectiveness analysis (CEA) methodologies to arrive at prices for selected drugs. Given that the protection against use of discriminatory value metrics is one of the few explicit patient safeguards contained in the IRA, CMS' failure to fully explain how it intends to implement the safeguard is disappointing. CMS states that, "CMS will review cost-effectiveness measures used in studies relevant to a selected drug to determine whether the measure used is permitted in accordance with Section 1194(e)(2), as well as with Section 1182(e) of Title XI of the Act. CMS may use content in a study that uses a cost effectiveness-measure if it determines that the cost-effectiveness measure used is permitted in accordance with the law." However, CMS does not elaborate on specifically what specific methodologies it is considering. Transparency regarding specific methodologies is critical – the issue of what qualifies as discriminatory is currently not only a subject of debate among stakeholders, but also the subject of recent rulemaking within HHS' Office of Civil Rights.[103] And as noted in PhRMA's comments on the IPAY 2026 Initial Guidance, regardless of the specific approach taken, reliance on CEA, whether it is rooted in the quality-adjusted life year (QALY) or another similar metric, as the basis for policy decisions risks further discriminating against the elderly, the disabled, and underserved and underrepresented people of color who are already at higher risk of not receiving the care they need.

* * *

PhRMA appreciates your consideration of these comments. Please feel free to contact Elizabeth Carpenter (ecarpenter@phrma.org) and Jim Stansel (jstansel@phrma.org) if there is any further information we can provide or if you have any questions about our comments.

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Elizabeth Carpenter
Executive Vice President
Policy & Research
PhRMA

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James C. Stansel
Executive Vice President and General Counsel
PhRMA

[102] We note, however, that the mitigation is limited by the fact that the statutory ceiling price applies even when a higher price would be set based on the factors related to the therapeutic benefits medicines offer to patients.

[103] HHS Final Rule, 89 Fed. Reg. 40066 (May 9, 2024) (value assessment prohibition codified at 45 CFR 84.57); HHS Final Rule, 89 Fed. Reg. 37522 (May 6, 2024).

PLASMA PROTEIN THERAPEUTICS ASSOCIATION

June 26, 2024

Meena Seshamani, M.D., Ph.D
Deputy Administrator and Director of Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ELECTRONIC DELIVERY TO IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

The Plasma Protein Therapeutics Association (PPTA) is pleased to have this opportunity to comment on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 2024 Guidance) issued by the Centers for Medicare & Medicaid Services (CMS).[1] PPTA is the standard setting and global advocacy organization that represents plasma donation centers and manufacturers of plasma protein therapies. Our U.S. membership includes ADMA, Grifols, Kedrion SpA, and Takeda. PPTA strives to ensure that Medicare beneficiaries continue to have appropriate access to life-saving plasma protein therapies. To that end, we write to underscore the critical importance of ensuring that these plasma protein therapies are excluded from the Drug Price Negotiation Program, which the May 2024 Guidance rightly continues.

[1] The May 2024 Guidance is available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

BACKGROUND

Plasma protein therapies are made from human plasma[2] donated by healthy individuals or by using recombinant technology.[3] It is essential that plasma protein therapies have adequate reimbursement due to their unique nature. Manufacturers of plasma-derived therapies depend upon donated plasma from healthy, committed individuals as the raw material for therapeutic production. The process for collecting donated plasma is highly regulated, resource-intensive, and time-consuming, with a production process spanning seven to ten months. Individual proteins within plasma are isolated for therapeutic use through distinct fractionation processes. The result is plasma protein therapies that are sole source biologicals that produce different therapeutic outcomes depending on the patient.

Many patients struggle to access providers who have sufficient expertise to treat their conditions, and patients may experience challenges in accessing treatment both geographically and at the appropriate site of care. An analysis of access issues by the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning & Evaluation[4] found that previous changes in Medicare reimbursement policy resulted in access challenges, treatment delays, and shifts in site of service for individuals who use plasma protein therapies. Another study[5] and a data analysis reached a similar conclusion.[6] The risks to patient health outcomes underscore the need for a reimbursement framework that ensures access to all therapies.

DISCUSSION

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[2] Human plasma is the clear liquid portion of blood that remains after the red blood cells, leukocytes, and platelets are removed. Due to its human origin, complexity, and richness in therapeutically useful proteins, human plasma is a unique biological material. *See* Thierry Burnouf, *Plasma Proteins: Unique Biopharmaceuticals – Unique Economics*, *in* 7 PHARMACEUTICALS POLICY AND LAW, BLOOD, PLASMA AND PLASMA PROTEINS: A UNIQUE CONTRIBUTION TO MODERN HEALTHCARE 209 (2005, 2006).

[3] Recombinant therapies are only available for clotting factors and C1 esterase inhibitors; plasma-derived therapies are the only life-saving treatment for most plasma protein deficiencies.

[4] HHS, Office of the Assistant Secretary for Planning and Evaluation, *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)*, Final Report (February 2007) at pp. 4-31 (ASPE Report).

[5] Tomas Philipson & Anupam B. Jena, *The Impact of Medicare Modernization Act Reimbursement Changes on the Utilization of Intravenous Immune Globulin*, The University of Chicago; The Irving B. Harris Graduate School of Public Policy Studies. This study found that after a reduction in Medicare reimbursement rate for intravenous immune globulin (IVIG) at the start of 2005, the average number of IVIG claims among Medicare eligible individuals grew more slowly than in the non-Medicare eligible population, despite growing at the same rate in the previous three years. There was a significant reduction in the share of IVIG claims for Medicare beneficiaries originating in the physician office with no accompanying change in the non- Medicare population. Changes in the Medicare reimbursement of IVIG negatively impacted access to IVIG.

[6] The Moran Group, 2003-2010 IVIG [Intravenous Immune Globulin/SCIG [Subcutaneous Immune Globulin] Utilization by PID [Primary Immune Deficient] Patients by Site of Service (Dec. 21, 2012) (noting a significant shift in the site of service of IVIG utilization after implementation of reimbursement cuts as a result of the Medicare Modernization Act).

Consistent with the Medicare Drug Price Negotiation Program statute and CMS's revised guidance for IPAY 2026,[7] under the May 2024 Guidance, CMS proposes to exclude plasma-derived products when identifying qualifying single source drugs as described in section 30.1.3 of the May 2024 Guidance.[8] Under the guidance, a plasma-derived product is a licensed biological product that is derived from human whole blood or plasma, as indicated on the approved product labeling, with CMS referring to certain Food and Drug Administration (FDA) websites to determine if a product is subject to the exclusion.[9] Consistent with section 30.1.3, all plasma protein therapies are rightfully subject to the exclusion. This result is an essential one to align with Congress's intent in creating this exception and ensure continued patient access to these critical therapies, for reasons detailed below, and thus we commend CMS for the exclusion of plasma protein therapies from the Medicare Drug Price Negotiation Program.

Plasma protein therapies, as a class, have a longstanding history of special recognition by federal policymakers in acknowledgement of the non-interchangeability, complex sourcing and production process for plasma medicines. These biological products treat patients who predominantly have rare diseases, and most are orphan drugs. The starting material for plasma derived medicines is human plasma collected from donors. The amount of source plasma needed to manufacturer enough product to treat only one patient annually can exceed 1,300 donations for certain therapies. Furthermore, these products take 7 to 12 months from the time of plasma donation to the delivery of treatment to a patient.

Since 2019, CMS and FDA have had continuing concerns over availability and access to these life-saving therapies and maintaining sufficient collections of plasma. Plasma protein therapies are often subject to various external influences that can affect plasma donation and collection. Plasma protein therapies are, by nature, intrinsically fragile and difficult to fractionate into medicine. The starting material collection process for all plasma protein therapies is influenced greatly by donor concerns like pandemics and man-made problems such as an international border crossing ban. Due to this unique starting material and production process, the cost structure for plasma therapies is significantly different than more traditional small molecule pharmaceuticals. For plasma products, the raw materials and manufacturing costs make up 57% of overall costs, compared to 14% for small molecule drugs. This divergent cost structure means that drug price negotiation models are not well suited to this class of products.

Federal policymakers have previously recognized this by exempting this class of therapies from certain Medicare policy proposals, including:

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[7] Social Security Act § 1192(e)(3)(C); CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 at 104 (June 30, 2023).
[8] May 2024 Guidance at 14.
[9] *Id.*

- In 2020, In the Most Favored Nation interim final rule, CMS exempted IVIG from the model based on potential supply impacts[10];

- In 2005, CMS attempted to implement a third-party vendor model for Medicare Part B drugs, but exempted plasma products because of the importance of maintaining patient access to all products[11]; and

- In 2006, in response to concerns about access to IVIG after implementation of the Medicare Modernization Act, CMS established a temporary pre-administration service payment to compensate providers for services required to locate and acquire adequate product.[12]

The May 2024 Guidance properly continues the recognition of the importance of plasma protein therapies and the unique nature of the plasma protein therapy industry be excluding these products from the Medicare Drug Price Negotiation Program.

CONCLUSION

We are grateful for this opportunity to offer comments to CMS on the May 2024 Guidance, focusing specifically on the exclusion of plasma-derived products when identifying qualifying single source drugs. CMS has correctly included plasma protein therapies within this exclusion and that should continue to be the case throughout CMS's implementation of the Medicare Drug Price Negotiation Program for the reasons discussed above. Thank you for considering our comments, and please feel free to contact Thomas Lilburn, Senior Director of Government Relations at (443) 458-4682 or tlilburn@pptaglobal.org if you have any questions.

Sincerely,

Thomas B. Lilburn
Senior Director, Government Relations

[10] 85 Fed. Reg. 76180, 76191 (Nov. 27, 2020).
[11] 70 Fed. Reg. 39022, 39029 (Jul. 6, 2005).
[12] 70 Fed. Reg. 70116, 70220 (Nov. 21, 2005).

VIA ELECTRONIC DELIVERY

July 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Brooks-LaSure:

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to submit feedback, including input from our patient communities, on the Centers for Medicare & Medicaid Services' (CMS') draft guidance for the Medicare Drug Price Negotiation Program (MDPNP) for initial price applicability year 2027 (the Draft Guidance).

PIRC is a collaborative, multi-stakeholder, patient advocacy coalition focused on improving access to and affordability of existing treatments while preserving the incentives required to advance future innovations in rare cancers. The coalition seeks to fulfill an important role in exchanging information and collaborating toward educating both our rare cancer communities and policymakers on the impact the Inflation Reduction Act (IRA) might have on access to existing Part D drugs and development of new therapeutic options.

As you are likely aware, cancer patients can face significant challenges in not only finding the best treatment option but being able to afford their prescribed treatments. Individuals fighting rare cancers typically have a limited set of effective therapeutic options and treatment affordability can be a matter of life and death. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with enabling Part D enrollees to opt into Medicare's new payment program and spread out-of-pocket costs over the plan year will greatly reduce the risk that Medicare's cancer patients must choose between paying for their medications and maintaining access to food and housing.

Given the typical cost of anti-cancer treatments and the impending cap on Part D out-of-pocket costs, any MDPNP savings on anti-cancer treatments will likely accrue to the Medicare program

rather than patients utilizing those treatments. While this may not be the result our patients anticipated from the IRA, it is consistent with Congress' expectation that MDPNP savings would offset the estimated $30 billion increase in Medicare spending due to Part D benefit redesign.[1]

Our comments are intended to aid CMS in ensuring that the MDPNP delivers on its promise of improving the health and lives of Medicare beneficiaries, including those with rare cancers. We believe that to achieve this goal, CMS must proactively consider downstream impacts of broad reaching initiatives like the MDPNP and mitigate any risk that an "unintended" consequence might erode benefits patients anticipate from the initiative. As more fully articulated below, PIRC and its member organizations:

- Appreciate that CMS seeks to refine its stakeholder engagement approach to enable more robust and meaningful patient participation.
- Urge CMS to reconsider its definition of qualified single source drug for negotiation eligibility purposes.
- Acknowledge that the contours of the orphan exemption are statutorily defined and urge CMS to use its available discretion and work with stakeholders, internal teams, and Congress to ensure that the MDPNP does not erode incentives for new rare disease approvals of existing treatments.
- Urge CMS to remove ambiguity and inconsistencies with respect to considering off-label uses of selected drugs as it prepares an initial offer.
- Recommend that CMS enforce Part D plan requirements to base utilization management tools on evidence and include all or substantially all products within protected classes on plan formularies.

PIRC appreciates that CMS seeks to refine its stakeholder engagement approach to enable more robust and meaningful patient participation.

Patient advocacy organizations often struggle to fully participate in the processes CMS uses to solicit feedback on proposed Agency action due to time constraints, lack of awareness of opportunities to contribute, and uncertainty on the information CMS seeks. The 30-day timelines for input on CMS' draft guidance and other MDPNP implementation documents for IPAY 2026 were too tight for patient organizations to digest the documents and respond in advance of the comment period. PIRC was, however, able to gather input from our patient communities on the model documents for the Medicare Prescription Payment Program (MPPP) and contribute meaningful feedback within the 60-day comment period. We appreciate that

[1] Congressional Budget Office. Estimated budgetary effects of Public Law 117-169, to provide for reconciliation pursuant to Title II of S. Con. Res. 14. Published 2022. https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf

CMS has responded to feedback from stakeholders by extending the comment period for the Draft Guidance for IPAY 2027 to 60 days.
PIRC similarly appreciates that CMS intends to include enhanced opportunities for patients, patient advocacy organizations, and other stakeholders to contribute information on selected drugs within the negotiation process. We had several concerns with the "listening session" format for patient engagement during IPAY 2026, including that:

- The demographic of patients contributing during the listening sessions was not representative of the Medicare patient demographic.
    - People of color were substantially underrepresented.
    - Some contributors were outside the Medicare population and appeared to believe that the MDPNP would reduce out-of-pocket costs for all patients.

- The format was uncomfortable for patients. Participating patients shared very personal information on their experience with cancer and other serious, life-threatening conditions, and CMS staff remained silent other than to let the individual know that their time was up. The overall impression was one of cold detachment on CMS' part.

- The patient and patient advocacy community did not have a clear understanding of the information CMS sought or how that information would be used within the negotiation process.
    - Some participants believed that the negotiated price would apply beyond Medicare.
    - Most believed that the savings from negotiation on Imbruvica would be passed on to patients.
    - Many patients expressed a belief that Part D plans pay an inflated "sticker price" for drugs and remained unaware of the role of PBMs, rebates, and other price concessions currently in use to reduce net price to manufacturers.
    - Few participants in listening sessions were aware of the parallel paths of Part D redesign and IRA drug price negotiation.

- The lack of back-and-forth dialogue likely deprived CMS of information that might have been helpful toward CMS' understanding of the patient perspective on the selected drug and its therapeutic alternatives.

- Participation was likely hampered by CMS' use of the Federal Register to "get the word out."

PIRC fully supports CMS' stated intention to create additional opportunities for stakeholder engagement and to include formats that enable a meaningful dialogue among participants as well as between participants and CMS staff. We similarly urge CMS to:

- Work with patient advocacy organizations to ensure robust and meaningful participation from impacted patient communities. This might be particularly helpful when multiple selected drugs share an indication and/or are used to treat a particular condition.

    - Patient advocacy organizations are not only trusted messengers within their patient communities, but they have access to impacted patient populations that might ensure more representative participation.

- Clarify both the information CMS seeks and how it expects to use that information.

- Retain flexibility during the stakeholder engagement period of the negotiation process. For example, CMS could make MDPNP staff available for a dialogue organized by one or more patient advocacy organizations.

- Provide more advance notice of CMS-sponsored stakeholder engagement opportunities.

- Allow for submission of data and other information after the stakeholder engagement event.

Finally, while PIRC is pleased that CMS has responded to feedback from stakeholders and plans to respond to that feedback with improved engagement mechanisms, these changes in process will not have a meaningful impact on patients unless CMS also hears and responds to feedback on the more substantive aspects of its Draft Guidance for IPAY 2027. PIRC and its member organizations are particularly concerned that CMS has not mitigated the risk that Medicare cost savings from the MDPNP will come at a price for rare cancer patients and other individuals with significant unmet needs. These concerns are informed by our experience and understanding that new laws and policy initiatives can exert a considerable and increasing force on access to existing treatments and the development of new therapeutic options.

There is little doubt that the MDPNP will become an integral factor for investors and manufacturers calculating the feasibility of pursuing a particular drug candidate for a specific indication. Our patient communities fear that CMS' approach to implementing the MDPNP will inadvertently tip the scales away from innovation in cancers that lack a sufficient patient population to ensure relatively rapid return on investment and profit potential. We urge CMS to proactively consider approaches that achieve savings without disrupting or neutralizing the incentives for innovation that have driven scientific advances and fueled hope among rare cancer patients.

PIRC urges CMS to modify its definition of qualified single source drug (QSSD).

PIRC strongly urges CMS to reconsider its decision to identify a qualifying single source drug (QSSD) and its dosage forms and strengths, by referring to common active moiety (drugs) or common active ingredient (biologics). CMS' approach is not clearly mandated by the statutory language directing that the Agency include all doses, formulations, and dosage strengths of a particular drug as a single QSSD. The statutory language and the process for arriving at an initial offer, in fact, provides greater support for a QSSD definition based on NDA or BLA. For example, the determination of negotiation eligibility turns on how much time has elapsed since approval of an NDA/BLA yet CMS' definition would include NDA/BLA approvals that have not met the negotiation eligibility requirements. If Congress had intended that CMS include all ***indications*** **approved with a common active moiety/active ingredient**, it could easily have included those terms in the statute.

Similarly, the process of examining therapeutic alternatives to a selected drug in determining an initial offer could be rendered virtually meaningless if divergent conditions with variable 30-day supplies and diverse sets of therapeutic alternatives are somehow aggregated. The resulting calculation could easily fail to capture the cost of therapeutic alternatives for ***all*** uses of the selected drug. The biologic denosumab provides a good example of the potential unintended consequences of CMS' active moiety/active ingredient approach and its avoidable unintended consequences for rare cancers and other rare conditions. Denosumab is FDA approved as Prolia for post-menopausal osteoporosis and administered as 60 mg subcutaneous injection every 6 months. It is also approved as Xgeva for bone metastasis, multiple myeloma (approximately 37,000 cases per year) and in giant cell tumors of the bone (an extremely rare (1 in 1,000,000) predominantly noncancerous condition that destroys the bone). The recommended dose of XGEVA is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm with additional 120 mg doses on days 8 and 15 of treatment of the first month of therapy.

CMS may be able to avoid having to calculate a single price for denosumab if progress on marketing a biosimilar is sufficient to exempt it from selection, but this type of problem is certainly not unique to denusomab. CMS' definition of QSSD creates problems that make it all but impossible to utilize the statutory process and arrive at any initial offer that reflects use in any indication due to differential dosing and extremely divergent therapeutic alternatives.

In addition, our patient communities have significant concerns that CMS' QSSD definition will make new FDA rare cancer approvals for existing drugs unattractive from a financial perspective. A recent article[2] authored by scientists at the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center. The authors note that:

[2] Chambers JD, Clifford KA, Enright DE, Neumann PJ. Follow-On Indications for Orphan Drugs Related to the Inflation Reduction Act. JAMA Netw Open. 2023 Aug 1;6(8):e2329006. doi: 10.1001/jamanetworkopen.2023.29006. PMID: 37581890; PMCID: PMC10427936.

> Efforts to address prescription drug costs must balance the benefits of lower drug prices with downsides in terms of reduced future innovation. We provide new data to help understand the potential consequences of incentives inherent in the IRA for drug companies to curtail efforts to pursue future follow-on indications for orphan drugs. FDA approved roughly one quarter of orphan drugs from 2003 to 2022 for at least 1 follow-on indication, and the agency considered the majority of these indications in expedited review programs.
>
> How much the IRA will affect future innovation is unknown and a source of controversy. . .. The law may lead pharmaceutical manufacturers to develop more single-indication orphan drugs (which are not subject to negotiations) rather than follow-on indications. Our analysis suggests that the potential foregone follow-on indication approvals for serious illness and unmet needs could be nontrivial. Such potential losses should be considered against the gains to consumers and society that come with lower drug prices.[3]

For the initial year of the Medicare Drug Price Negotiation Program (MDPNP), Imbruvica® was the only cancer treatment selected for negotiation. Imbruvica® is a Bruton's tyrosine kinase (BTK) inhibitor that initially received accelerated approval in 2013 for the treatment of mantle cell lymphoma (MCL, voluntarily withdrawn in 2023) in patients who had received at least one prior therapy. It was subsequently approved for chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) with 17p deletion, Waldenström's macroglobulinemia (WM), (a rare form of non-Hodgkin lymphoma), marginal zone lymphoma (MZL, voluntarily withdrawn in 2023), and chronic graft versus host disease (cGVHD) after failure of one or more treatments. The indication with the highest impact to the Medicare program is chronic lymphocytic leukemia (CLL), which is a chronic blood cancer of a type of white blood cell called the B-lymphocyte. CLL is the most common leukemia in adults in the United States, and is also classified as a type of non-Hodgkin's Lymphoma (NHL).

Imbruvica was the first Brutons Tyrosine Kinase (BTK) inhibitor and first oral treatment option for chronic lymphocytic leukemia and small cell lymphoma (CLL/SLL). Targeted therapies such as BTK inhibitors and the BCL2 inhibitor known as venetoclax have offered substantial efficacy against CLL/SLL and have transformed care for patients.

Although most CLL/SLL patients can expect a response to initial therapy, nearly all current treatment options are palliative and not curative. Most patients will experience one or more relapses during the course of their disease, and many are forced to either change treatments, take a "drug holiday," or adjust dosing due to drug intolerance. For patients with relapsed or refractory disease (or treatment intolerance), treatment decisions are highly individualized based on prior therapies, prior response, the reason for discontinuation of previous therapy, comorbidities, biomarker characteristics, patient preference, and therapeutic goals. Patients

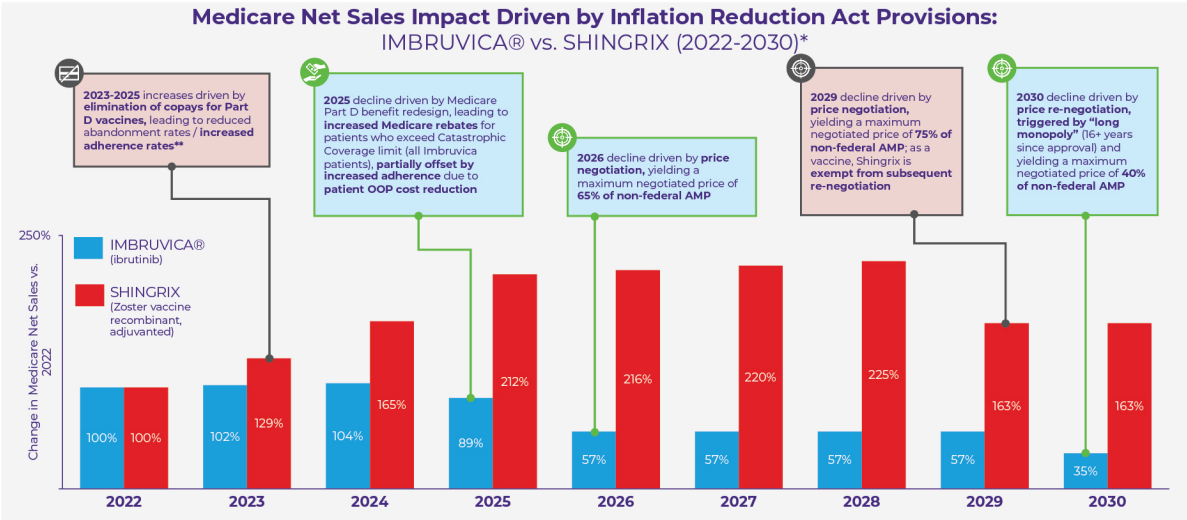
[3] Id.

can experience serial relapses and may be treated with all available agents at some point during their disease course.

The unfortunate reality is that despite significant progress in treating CLL/SLL, it remains an incurable cancer. Patients progressing after both BTK and BCL2 inhibitors face a poor prognosis with few treatment options other than PI3K inhibitors. There is, therefore, a significant unmet need for CLL/SLL patients. The primarily Medicare-age demographic for CLL/SLL, however, could exert pressures on manufacturers to steer away from product candidates, particularly small molecules given the shorter timeframe for negotiation eligibility and high likelihood that the patient demographic could drive disproportionately high costs to the Medicare program.

Rare cancer patients have serious concerns that CMS' negotiated prices will act as a signal deterring innovators from studying new treatment classes due to the combined risks of diminished market share from new in-class competitors and aggressive price negotiation through the MDPNP. An analysis comparing the MDPNP impact on Shingrix and Imbruvica illustrates the risk investors and manufacturers will assume if they develop new treatments or new uses of existing treatments in rare cancers that, like CLL/SLL have a significant Medicare population.[4] We strongly urge CMS to recognize the inherent uncertainties the MDPNP presents for innovation and access in rare cancers and that it diverge from the ceiling price only when there is a strong justification for doing so and no unmet treatment needs in the impacted disease state(s).

A Tale of Two Drugs: How the Inflation Reduction Act of 2022 Impacts Pharmaceutical Classes Differently



Trademarked names are used for illustrative purposes and remain property of their respective owners
*Directional estimate only based on publicly available data; Excludes impact of any market changes not driven by the IRA (e.g., disease epidemiology, product preference share, indication expansion, etc.); Assumes 2% price increases that do not trigger inflation penalties; **Assumes Shingrix adherence rates rise from 34.5% to 69.0% based on 65+ pneumococcal vaccination rates as an analog; Source: Inflation Reduction Act of 2022 (H.R.5376 – 117th Congress); Lu et al, *Surveillance of Vaccination Coverage Among Adult Populations* (2018); Putnam Medicare Price Negotiation Database 2022; Putnam Analysis 2022

[4] The Inflation Reduction Act: A tale of two drugs - Putnam (putassoc.com)

Over an eight-year period, revenue from Medicare sales of Imbruvica are anticipated to decline by 65%. It is generally anticipated that each of the newer BTK inhibitors will be selected in the first year of negotiation eligibility and experience similar revenue losses. This financial picture is not only likely to deter some investors from developing products in CLL/SLL but to deter investment in research such as combination therapy protocols that could lead to improved patient survival. The narrow orphan exemption (discussed below) combined with CMS' intention to refer to a product's first NDA/BLA in determining selection eligibility likely exacerbate the financial downside of product development in this cancer.

PIRC is also concerned that CMS' implementation strategy and QSSD definition create the potential that the Primary Manufacturer/Secondary Manufacturer construct will drive a substantial set of burdens on Primary Manufacturers that were not envisioned when the IRA was enacted. Under this construct, the NDA/BLA holder is the Primary Manufacturer even if a Secondary Manufacturer holds exclusive commercialization rights on a separate indication approved under a separate NDA/BLA. The Secondary Manufacturer has no IRA-related obligations, yet its activities or omissions could place the primary manufacturer in legal jeopardy in the form of substantial fines and penalties. Manufacturers could not have foreseen the new landscape CMS' definition of a qualifying single source drug has created, and there may be no recourse available to Primary Manufacturers under the contractual relationship between the parties. We urge CMS to reconsider its definition of QSSD.

PIRC urges CMS to use its available discretion in implementing the Orphan Drug Exclusion and work with stakeholders, internal teams, and Congress to ensure that the MDPNP does not erode incentives for new rare disease approvals of existing treatments.

Last year, CMS solicited stakeholder feedback on ideas for implementing the Orphan Drug Exclusion that preserve incentives facilitating orphan drug development. We were disappointed that CMS' Draft Guidance for IPAY 2027 reinforces the narrowest interpretation of the statutory exclusion.

The sets of incentives encouraging the development of treatments for small-population diseases have generally worked well to expand treatment options and improve survival for patients with CLL/SLL and other blood cancers. The IRA's narrow exclusion for orphan drugs, however, creates a landscape in which multiple designations for a promising therapy will negate eligibility for the exclusion, thereby substantially complicating analyses on the potential for favorable return on investment which, in turn, may delay or reduce development of potentially effective and life-saving treatments for patients. Manufacturers may face pressures to focus on an orphan indication with the largest patient population rather than the disease state that is most suitable for clinical trials. This could impact the time it takes to move a product from bench to market, increase costs associated with securing a first approval, and deter studies leading to FDA approvals in cancers with extremely small patient populations.

We do not believe Congress or the Administration sought to limit research and development in orphan diseases generally or in rare cancers. Manufacturers secured orphan designations well before the IRA was enacted and could not have considered that a relatively narrow designation would later drive consequences to research and development in other indications. PIRC is concerned that as the drug price negotiation program becomes a tangible reality for manufacturers and investors, it will drive decisions on the drug candidates and/or indications manufacturers and investors are willing to pursue.

We believe researchers, investors, and manufacturers should be rewarded, not penalized, for investing in research and development to secure FDA approval for new indications (rather than relying on off-label use). It would be a tremendous tragedy if Congress' efforts to improve healthcare affordability created an environment in which future treatments would never be indicated for use in rare cancers despite their potential to transform patient care. PIRC also expects that our concerns could be greatly mitigated if CMS reconsidered its QSSD definition. This is particularly true within the context of the impact that loss of Orphan Drug Exclusion status would have on the date of selection eligibility. CMS stated:

> In the event that a drug or biological product loses Orphan Drug Exclusion status, pursuant to sections 1192(e)(1)(A)(ii) and (B)(ii) of the Act, CMS will use the date of the earliest approval of the drug or licensure of the biological product (as described above in section 30.1) to determine whether the product is a qualifying single source drug that may be selected for negotiation

Finally, PIRC urges CMS support for Congressional action to broaden the orphan exclusion to align with public policy favoring development of new and existing orphan treatments to address unmet needs in rare diseases. The statutory language as it stands leaves manufacturers with a lose/lose proposition and jeopardizes patient access to promising therapies. Moreover, it is unlikely to benefit the Medicare program or society as a whole.

PIRC urges CMS to remove ambiguity and inconsistencies with respect to considering off-label uses of selected drugs as it prepares an initial offer.

Section 60.3.1 "Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication" provides that:

> For initial price applicability year 2027, for the purpose of identifying indications for the selected drug, CMS will identify the FDA-approved indication(s) not otherwise excluded from coverage or otherwise restricted under section 1860D-2(e)(2) of the Act for a selected drug, using prescribing information approved by the FDA for the selected drug, in accordance with section 1194(e)(2)(B) of the Act. ***CMS may consider off-label use*** when identifying indications if such use is included in nationally recognized, evidence-based guidelines and listed in CMS recognized Part D compendia. (emphasis added)

Although PIRC and its member organizations strongly believe that FDA approval is the best way to ensure that **all** patients have equitable access to the best treatment options for their particular cancer, off-label use remains an important part of cancer care. We are concerned that CMS' use of the term "may" conveys an intent to determine the set of uses for a selected drug on a case-by-case basis. This ambiguous standard creates an additional layer of uncertainty to an already-uncertain process. We urge CMS to either provide an explanation for excluding off-label uses or include those uses in its decision processes.
PIRC recommends that CMS enforce Part D plan requirements to base utilization management tools on evidence and include all or substantially all products within protected classes on plan formularies.

PIRC appreciates that the MDPNP is one part of a broader set of changes to the Part D program and that CMS "does not have sufficient information to determine whether changes to the formulary inclusion policies described in CMS' revised guidance for initial price applicability year 2026 are warranted." We are, however, concerned that patients could face immediate and potential harmful access constrictions as Part D redesign changes converge with implementation of negotiated prices for selected drugs.

Our concerns appear to be valid in light of a 2023 double-blind, web-based survey distributed through Cencora's Managed Care Network to pharmacy directors, medical directors, and contracting managers/directors. This survey and its analysis provide insight into how managed care entities perceive and will likely react to the IRA drug provisions[5]. We are especially concerned that most respondents expect that the IRA's Part D changes will lead to narrower formularies in comparison to pre-IRA formulary design.

In addition, most payers are acutely aware of the increased liability for Part D plans and expect:

- greater use of utilization management tools
    - 42% anticipated greater utilization management overall.
    - 32% expect greater utilization management for high-cost medications.
    - 10% (n = 5) anticipate no change
- Increased Part D plan premiums
    - 8% anticipate a premium increase greater than 10%.
    - 40% expect an increase from 5% to 10%.
    - 18% anticipate an increase up to 5%.
    - 12% believe Part D plan premiums will remain at their current levels.
    - No payers expect that premiums will be lower than current levels.

As negotiated drug prices are implemented, plans will face downstream impacts to their bottom line as the traditional rebates (reflected after the point of sale) are replaced by the MFP

[5] Ford C, Westrich K, Buelt L, Loo V. Payer reactions to the implementation of the Inflation Reduction Act: forecasting future changes to Medicare Part D plans. Presented at: AMCP Nexus 2023; October 16-October 19, 2023; Orlando.

(reflecting discounted cost at the point of sale). The dynamics are uncertain and will likely vary based on whether there are other available drugs within the same category and class as the selected drug, as well as the PBM's and/or plan's ability to contract with manufacturers for favorable rebates on non-selected drugs.

PIRC is concerned that simply "monitoring" plan activities will not sufficiently protect Medicare beneficiaries. Without CMS intervention and/or oversight, it is likely that plans will determine which drug(s) are associated with the lowest financial liability and steer patients toward that drug through formulary inclusion/exclusion and tier placement. A selected drug might be the only available alternative for beneficiaries despite competing products that may offer improved effectiveness and/or greater tolerability.

As the first anti-cancer treatment for which a negotiated price will be implemented, Imbruvica serves as a good example of how the MDPNP and Part D redesign could impact patient access to prescribed treatments. According to NCCN Guidelines, the most appropriate frontline treatment for CLL and SLL depends on patient-specific factors, including characteristics of the cancer and mutation status, age, and comorbidities. Subsequent lines of therapy are chosen based on the previous treatment as well as the factors outlined above. BTK inhibitors offer considerable improvements in care for patients but can result in drug intolerance requiring interruption, dose reduction, and even treatment discontinuation. Although clinical guidelines and recommendations recognize that newer BTK inhibitors have greater tolerability that would tend to improve outcomes, there is still much to learn about the various BTK inhibitors through real world data generated over time. BTK inhibitors are also increasingly being studied in combination with other treatment options, and these uses should also be covered by Part D plans when the patient and their clinician determine that it is the best treatment option.

It is, therefore, vital that Part D plans, including MA-PD plans, include all available treatment options on their formularies, without imposing step therapy protocols, so that clinicians and patients are able to make treatment decisions based on what will enable the patient to achieve a durable treatment response while maintaining their quality of life. There is substantial concern that if Imbruvica is priced in a way that encourages health plans to insist on it as a first step, more patients will be steered away from care reflecting NCCN guidelines. Moreover, failure on one BTK inhibitor likely precludes use of other BTK inhibitors – making step therapy particularly inappropriate and potentially dangerous for patients given the limited lines of treatment available. At the same time, patients need to have access to all viable treatment options and those using Imbruvica successfully for their cancer are unable to take an alternative BTK inhibitor that may be more financially advantageous to a plan due to rebates and other price concessions.

We urge CMS to:

- Increase its oversight to ensure that plan formularies include all necessary medications and that expedited formulary exception processes enable access when patients need treatments not included on formulary.
- Provide Part D plans with clear guidelines on coverage, formulary tiers and utilization management (UM) tools, including enforcement of requirements that formulary process be transparent and utilization management strategies be based on clinical evidence.
- Proactively monitor the impact of the Manufacturer Discount Program, the MDPNP, and Part D redesign on formulary decisions and UM practices.
- Identify and mitigate in a defined timely manner any access constrictions, on the plan and sponsor levels as well as program wide.
- Establish a formal mechanism for patients and patient advocacy organizations to communicate their experiences, including any barriers to getting their prescribed medications when they need them, directly with CMS. We urge the Agency to create a dedicated communication channel as well as a set of proactive forums for patients and clinicians.

We are also gravely concerned that the protections that have been codified since 2006 for Part D drugs within the six "protected" classes, i.e., immune-suppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics, have eroded from one year to the next. CMS' rationale for designating these classes of drugs as requiring plans to include all or substantially all drugs within the class was designed to ensure that formulary designs do not disadvantage and discriminate against the vulnerable patients requiring access to specific drugs or combinations of drugs. That rationale is as valid today as it was when the protected classes were created.

Conclusion

PIRC appreciates the opportunity to contribute the perspectives of those within the rare cancer patient and caregiver community as CMS implements the drug price negotiation provisions of the IRA. We look forward to a continuing dialogue throughout the IRA implementation process and welcome the opportunity to discuss our comments or the experience of rare cancer patients generally.

Bag It Cancer
Biomarker Collaborative
CancerCare
Cancer Support Community
Chondrosarcoma Foundation
CLL Society
Cutaneous Lymphoma Foundation
Desmoid Tumor Research Foundation
Exon 20 Group
Hairy Cell Leukemia Foundation

ICAN, International Cancer Advocacy Network
MET Crusaders
No Stomach for Cancer
Ovarian Cancer Research Alliance (OCRA)
PD-L1 Amplifieds
The Healing NET Foundation
The National Pancreas Foundation

PUBLIC CITIZEN 50
People • Power • Progress YEARS

Meena Seshamani, M.D., Ph.D
CMS Deputy Administrator and Director of the Center for Medicare
Transmitted via IRARebateandNegotiation@cms.hhs.gov

July 2, 2024

Public Citizen Comments Regarding Medicare Drug Price Negotiation Guidance

Dear Dr. Seshamani,

Thank you for the opportunity to provide stakeholder feedback as CMS works to enact the new drug price negotiation and inflationary rebate systems established through the Inflation Reduction Act.

Public Citizen is a nonprofit consumer advocacy organization with more than 500,000 members and supporters. The Access to Medicines program advocates for access to prescription drugs in the United States and internationally.

Public Citizen and health care access proponents across the nation invested tremendous energy into supporting Medicare drug price negotiation becoming law. We share CMS' goal of making this program a success to help prevent prescription drug manufacturer price gouging of seniors and people with disabilities with Medicare, and taxpayers who support the program.

Below, we outline several comments and recommendations in response to CMS' solicitation of stakeholder feedback on initial guidance regarding implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169).

In summary of our highest priority comments to this guidance:

1a) We strongly urge CMS against continuing to adopt a negotiation starting point using existing prices of therapeutic alternatives, all or some of which have not been negotiated by Medicare, as doing so will lead to inappropriately high maximum fair prices for Medicare beneficiaries and taxpayers.

1b) Instead, we urge CMS to adopt a modified cost-plus approach, under which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement, plus the marginal cost of production and distribution.

2) Retain CMS' proposed approach of considering all dosage forms and strengths of a drug with the same active moiety as a qualifying single source drug. Doing so is vital to preserving program integrity and consistent with the intent of the legislation.

3) Provide greater transparency around R&D costs and other data. CMS' overly expansive interpretation of what information shall be held confidential would severely limit the impact of the legislation on industry drug pricing practices and the ability of the public to assess whether the Medicare drug price negotiation program is successfully negotiating "the lowest maximum fair price for each selected drug", as required under the Act, which would instill greater public confidence in the program.

Thank you again for this opportunity and for your consideration of these comments as CMS works towards implementing the Act.

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Recommendation 1a: Do not use the existing prices of therapeutic alternatives as the starting point for developing an initial price offer in drug price negotiations.

Section 60.3 outlines the proposed methodology from CMS for developing an initial price offer in drug price negotiations. CMS proposes in section 60.3.2 to take as a starting point for developing its initial negotiated price offer the average prices available for therapeutic alternatives for the selected drug. Below, we articulate two major concerns with this approach.

I. Starting with the prices of therapeutic alternatives will lead to ongoing inappropriately high prices.

Evidence shows that drug prices paid under Medicare Part D are significantly higher than those paid under other health programs in the United States, including Medicaid and the Department of Veterans Affairs, as well as those paid in other wealthy countries.[1,2,3]

Current inappropriately high prices, which burden Medicare beneficiaries and taxpayers, are the underlying reason that Congress passed and President Biden signed a law to empower Medicare to negotiate in the first place.

These prices are set by drug corporations under monopoly conditions to maximize profits, while plans face broad coverage obligations under Medicare Part D. Taking prices of therapeutic alternatives set under these conditions as the starting point for developing negotiated price offers would in turn bias the system towards inappropriate high, unfair prices.

This would be inconsistent with the IRA requirement that CMS develops a methodology and process for drug price negotiation "that aims to achieve the lowest maximum fair price for each selected drug."[4]

II. Starting with the prices of therapeutic alternatives would be a missed opportunity for the law to provide virtuous systemic impact.

In support of its negotiated price offer starting point proposal, CMS has previously argued that "[the prices of therapeutic alternatives] is an important factor when considering the overall benefit that the treatment brings to Medicare beneficiaries." In the draft guidance for initial price applicability years 2027 and 2028, CMS states that it plans to use a largely similar methodology for developing its initial offer starting point,

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[1] Government Accountability Office, *Prescription Drugs: Department of Veterans Affairs Paid About Half as Much as Medicare Part D for Selected Drugs in 2017*, GAO-21-111, January 14, 2021.
[2] Mulcahy AW, C.; Tebeka, M.; Schwam, D.; Edenfield, N.; Becerra-Ornelas, A. International Prescription Drug Price Comparisons. 2021; https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf.
[3] Government Accountability Office, *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France*, GAO-21-282, April 28, 2021.
[4] 42 U.S.C § 1320f–3 (b)(2).

but with consideration for coverage gap discount program payments and maximum fair prices of therapeutic alternatives.

We agree that pricing of a medicine and its therapeutic alternatives impact Medicare beneficiaries, but we do not believe it follows that prices of therapeutic alternatives should dictate the starting point of prices CMS negotiates. Moreover, while section 1194(e)(2)(A) of the Act requires CMS to consider the prices of therapeutic alternatives in developing a maximum fair price offer, there is a multitude of ways to incorporate that information that do not inordinately prejudice the process toward entrenching current high prices, which are often multiples higher than those paid in other high-income countries. At the end of recommendation 1b in these comments, we provide an alternative that will situate the maximum fair price in the context of the prices of therapeutic alternatives, but, crucially, without reinforcing the current regime of excessive prices.

Rather than provide virtuous systemic impact, the current process CMS is considering would reduce incentives for manufacturers of therapeutic alternatives to lower their prices. Using existing drug prices, especially those that have not been negotiated by CMS, as the basis for negotiations risks building inertia for higher prices into the system. By instead negotiating a maximum fair price through alternate methods, such as those we propose below and other organizations have proposed separately, CMS' negotiation process could help reduce the prices of the alternative therapies, since the manufacturers of the alternatives may try to compete on price with that of the negotiated product.

Recommendation 1b: Instead, to calculate a maximum fair price, take a modified cost-plus approach, under which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement, plus the marginal cost of production and distribution.

When negotiating prices, CMS can deliver access and protect innovation by calculating the maximum fair price using the baseline of risk-adjusted research and development (R&D) costs.

Medicines are information goods. R&D costs—not other welfare metrics like "value"—should form the core basis for negotiating prices because R&D costs can help answer the inquiries central to information economics: how much does innovation cost, and how much compensation is necessary to induce innovation?

Exclusive rights allow prescription drug corporations to charge prices that are not linked to the cost of innovation. As one drug executive noted, "We all look at each other and keep pace with each other. Honestly, there is no science to it."[5] Pharmaceutical industry pricing practices reduce social welfare by limiting access and create massive inefficiencies in the form of deadweight loss. Governments tolerate this static (short-term) inefficiency in the name of protecting dynamic (long-term) incentives for

[5] https://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html

innovation. HHS can help challenge this false dichotomy by negotiating lower prices that appropriately reward true R&D costs.

The IRA lists a series of negotiating factors to help determine the maximum fair price offers and counteroffers.[6] To calculate the maximum fair price for a unit of drug for Medicare, CMS should take a modified cost-plus approach, under which drug corporations are paid a fair portion of the revenue necessary to recover risk-adjusted R&D costs, accounting for therapeutic advancement, plus the marginal cost of production and distribution. We explain each factor below.

Suggested Formula for HHS to Arrive at Maximum Fair Price Offers:

$$Maximum\ Fair\ Price\ Offer\ =$$

$$\frac{\left(\begin{array}{c}\text{Risk-adjusted R \& D Costs}\\ \times \\ \text{Therapeutic Advancement Multiplier}\end{array}\right) - \left(\begin{array}{c}\text{Net revenues from all payers}\\ + \\ \text{Expected net revenues excluding Medicare}\end{array}\right)}{\text{Expected Medicare utilization over remaining product life (units)}} + \text{Marginal production and distribution cost}$$

I. Risk-Adjusted Research and Development Costs, Accounting for Federal Investment

The cost of innovation should be central in determining the maximum fair price assessment. Unfortunately, section 60.3.4 shows that CMS intends to deprioritize manufacturer-specific data, which represent more than half of the total number of factors provided under statute for CMS to consider in determining its maximum fair price offers and counteroffers.[7] Section 60.3.4 of the guidance goes so far to suggest that CMS may not even incorporate consideration for this information in its maximum fair price offer. This would seem to represent a failure to meet the obligations set forth for the Secretary under statute, that "the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) of the drug[.]"[8] The statute does not direct CMS to pick and choose which factors enumerated in statute it will consider.

Under the IRA, manufacturers are required to submit information "in a form and manner specified by the Secretary" that CMS requires to carry out the negotiation. To determine actual R&D costs, CMS can require granular information. Drawing on expert reviews[9] and prior legislative proposals[10], we recommend that total expenditures on R&D are itemized by direct and indirect costs, including for:

- Basic and preclinical research;
- Clinical research, reported separately for each clinical trial, per patient, per year, comprising
    - Personnel costs (including salary and benefits)
        - Administrative staff
        - Clinical staff
    - Materials and supplies

[6] 42 USC § 1320f-3(e)(1) and 42 USC § 1320f-3(e)(2).
[7] 42 USC § 1320f-3(e)(1)
[8] 42 USC § 1320f-3(e)
[9] NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH
[10] S.909 - Prescription Drug Price Relief Act of 2021, https://www.congress.gov/bill/117th-congress/senate-bill/909/text

    - Clinical procedures
    - Site management
        - Site monitoring costs
        - Site retention
        - Other
    - Central laboratory
    - Equipment
    - Other direct costs
        - Publication Costs
        - Subawards/Consortium/Contractual Costs
        - Other;
- Development of alternative delivery systems, dosage forms, strengths or combinations; and
- Other development activities, such as post-approval testing and record and report maintenance.

In Appendix A of the guidance, CMS appropriately delineates a wide array of information that will be required to be disclosed by manufacturers, pursuant to section 1194(e)(1) of the IRA.[11] To the extent that any ambiguity remains, we recommend CMS clarify that this information, described under definitions relating to R&D costs in Appendix A, should be provided in an itemized and disaggregated fashion. This is particularly important with regard to reporting costs separately for each clinical trial, as there are significant differences in risk depending on trial phase, as described further below.

Obtaining disaggregated, detailed information offers two advantages over relying only on more generalized and potentially misleading research and development information disclosed pursuant to SEC requirements. First, CMS can risk-adjust R&D figures in a more sophisticated way, including by stage of clinical development, and better account for federal investment. For example, researchers have estimated success rates across clinical trials, including by drug class, disease and indication.[12] Together with the cost of trials and federal investment, CMS can use these figures to determine the cost of trial failures—and hence, risk-adjusted trial costs incurred by the manufacturer.

Table 1: Drug Development Success Rates (Hay et al., 2014)[13]

Stage	Phase Success	Likelihood of Approval
Phase 1 to Phase 2	64.5%	10.4%
Phase 2 to Phase 3	32.4%	16.2%
Phase 3 to NDA/BLA	60.1%	50.0%
NDA/BLA to Approval	83.2%	83.2%

Second, the granularity of R&D costs can increase the integrity of the data and help prevent gaming of R&D cost figures. Aggregate figures, like the ones reported by firms in financial filings, capture many different kinds of expenses that inflate the real cost of R&D, making them less useful. For example, firms can include the costs of acquiring a candidate as an R&D expense, even if the acquisition cost was based on the expected revenue the candidate could generate—not necessarily the money that was spent in

[11] 42 USC § 1320f-3(e)(1)
[12] Michael Hay et al., Clinical development success rates for investigational drugs, 32 Nature Biotechnology (2014).
[13] Michael Hay et al., Clinical development success rates for investigational drugs, 32 Nature Biotechnology (2014).

research and development.[14] (In the case of a drug that was acquired part way through its development, it should be incumbent on drug corporations to disclose disaggregated information on actual R&D expenditures on the drug candidate prior to its acquisition to the extent they want such costs considered by CMS.) Successful drug development organizations, like the Drug for Neglected Diseases Initiative, have shown that reporting real R&D costs is possible, and provide crucial insights on how that reporting might be structured.[15]

Furthermore, a three-year House Oversight Committee investigation into drug pricing, initiated by the late Rep. Elijah E. Cummings, found that drug corporations can also include in bulk R&D figures "non-innovative R&D expenditures." The Committee found that the corporations reviewed in their investigation "dedicated a significant portion of their R&D expenditures to research that was intended to extend market monopolies, support the companies' marketing strategies, and otherwise suppress competition."[16] A recent study from Department of Health and Human Services officials and coauthors indicates that R&D estimates touted by industry are significantly higher than what a transparent analysis of public data provides – an average of less than $900 million, including costs of capital and failed candidates, rather than more than $2.5 billion.[17]

Under a pure cost-plus payment model, sellers may have a perverse incentive to inflate costs incurred and reported, knowing that higher costs will result in increased payment. If pharmaceutical reimbursement is linked to actual costs reported, then drug corporations could inflate expenditures, especially to the extent they are risk adjusted for payment considerations. CMS is well positioned to overcome this obstacle and better incent efficient drug development by using data-driven proxies for R&D and production and distribution costs.

Importantly, the law requires manufacturers to submit information regarding "[p]rior Federal financial support for novel therapeutic discovery and development with respect to the drug." The extent to which R&D has been supported and subsidized by the Federal government and other public sources is a key factor in determining privately borne risk in developing a medicine. In addition to requiring companies to report and acknowledge all relevant public R&D contributions in all forms, HHS should work across government to gather such information and make it public.

In collaboration with U.S. Government entities that conduct and fund clinical trials, within HHS as well as elsewhere within the federal government, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, the Department of Defense, and the Department of Veteran Affairs, CMS can supplement manufacturer-provided information to develop an R&D cost database and form proxies using average costs of R&D for different categories of therapies, using representative

[14] An analysis of 10-K filings by Knowledge Ecology International showed that pharmaceutical corporations sometimes include the costs of acquiring licenses and other assets as research costs. *See* https://www.keionline.org/wp-content/uploads/KEI-Written-Testimony-OR-SB793.pdf

[15] DNDI, Transparency of R&D Costs, https://dndi.org/advocacy/transparency-rd-costs/

[16] U.S. House of Representatives Committee on Oversight and Reform, Majority Staff Report: Drug Pricing Investigation, December 2021, https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf

[17] Aylin Sertkaya, PhD; Trinidad Beleche, PhD; Amber Jessup, PhD; Benjamin D. Sommers, MD, PhD. Costs of Drug Development and Research and Development Intensity in the US, 2000-2018. JAMA. June 28, 2024. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2820562

samples of R&D costs for different products. HHS can then use the appropriate category of proxy of demonstrated R&D costs for calculating the maximum fair price offer of a given drug. Optimally, HHS would also obtain as much data as possible on costs of failed clinical trials to best inform its calculation of risk-adjusted R&D costs. HHS and other agencies taking action to increase and systematize compliance with the Stevens Amendment, which requires disclosure of the total costs of programs or projects paid for with federal funds "[w]hen issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs," can also provide greater insight into federal support for pharmaceutical R&D.[18]

Using the risk-adjusted, true R&D cost can help provide a fairer baseline from which to reward innovation. This can be adjusted to account for clinical benefit, as described in the following section.

II. Therapeutic Advance Multiplier

To promote meaningful innovation, manufacturers that produce drugs with new, clinically meaningful benefit should receive robust rewards, including the ability to make a reasonable profit on risk-adjusted R&D investments that they incur. Manufacturers of products that do not show evidence of improving health outcomes, relative to other therapies at the time of approval, should not be excessively rewarded. A therapeutic advancement multiplier (TAM) can be applied to the risk-adjusted R&D costs. The TAM can be based on the magnitude and certainty of evidence of net clinical benefit[19] compared to other therapies available at the time of approval, taking into account the factors enumerated in the IRA, including unmet medical needs.[20]

The value of the multiplier would be less than one if there is a lack of or only very weak evidence of increased value compared to other therapies at the time of FDA approval or licensure, and greater than one, potentially significantly, if there is clear evidence of increased therapeutic value relative to other available therapies for the conditions for which the drug is indicated. A similar categorization of therapeutic benefit is used in Germany.[21]

Table 2: Therapeutic Advancement Multiplier (TAM)

Strength of Evidence	**Added Value**		
	Minor	**Significant**	**Major**
Low-to-Moderate	potentially higher than 1	probably higher than 1	higher than 1
High or Proof	higher than 1	higher than 1	highest possible multiplier
No Data	below 1	below 1	below 1
High or Proof Against	lowest possible multiplier	below 1	below 1

[18] Government Accountability Office, Grants Management: Agency Action Required to Ensure Grantees Identify Federal Contribution Amounts, March 2019, https://www.gao.gov/assets/gao-19-282.pdf
[19] Taking into consideration both potential benefits and risks.
[20] 42 USC § 1320f-3(e)(2).
[21] Skipka et al., Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5034755/

Multiplying the risk-adjusted R&D cost with the therapeutic advancement multiplier provides the size of the full reward the pharmaceutical manufacturer should obtain from the drug over the entire life of the product. The table above provides general guidance for determining the size of TAMs that will prevent inappropriately subsidizing corporations for medicines that lack evidence of improving health outcomes and allow for negotiated prices that reward genuine advancements. The appropriate TAM for a medicine with strong evidence of providing major added health benefit may be significantly higher than one, but should conform to the principle stated at the beginning of this section: *how much does innovation cost, and how much compensation is necessary to induce innovation?*

By ensuring that drug manufacturers are well rewarded for true, novel therapeutic advancements and, importantly, avoiding inappropriately subsidizing corporations through excessive prices paid by patients and taxpayers for products that are required by statute to be included in formularies but that do not show increased benefit relative to other therapies, IRA drug price negotiations can promote an R&D ecosystem better aligned with serving unmet health needs.

While we take strong exception to CMS' proposed approach for reaching a starting point for a maximum fair price offer, discussed in recommendation 1a above, the approach CMS takes to analyzing comparative effectiveness between a selected drug and its therapeutic alternatives (described in section 60.3.3 of the guidance and its subsections) could be consistent with this element of our proposal in development of a Therapeutic Advancement Multiplier and its rationale.

III. Net and Expected Net Revenues

Determining Medicare's fair share requires assessing how much additional reward the manufacturer needs to obtain the full appropriate reward during the remaining product life, taking into account the net and expected revenues from other payers. CMS can obtain information about how much the manufacturer has already recouped so far, estimate how much the manufacturer expects to make from other payers over the remaining product life, and then divide the difference over the expected product volume sold to Medicare over the remaining product life to determine a Medicare price. Because pharmaceutical corporations operate in a global marketplace and are not bound only to market products in the United States, global sales should be included in this calculation. The first factor for consideration for the purpose of negotiating the maximum fair price of a selected drug in the IRA includes "the extent to which the manufacturer has recouped research and development costs," which necessarily implicates the extent to which such costs have been recouped through U.S. *and* non-U.S. sales. CMS has previously taken this approach of considering global revenues, and we encourage it to continue to do so.

IV. Marginal Production and Distribution Cost

Finally, beyond rewarding medical innovation, CMS should pay for the marginal cost of production and distribution for medicines used by Medicare beneficiaries. Using the marginal cost of production and

distribution—rather than the average total—is the most precise way to determine minimum costs. It precludes the manufacturer from adding other costs into the figure.[22]

V. Note on Negotiation Delay Periods

While our proposed formula for CMS to calculate maximum fair price offers is constructed to arrive at appropriate prices consistent with promoting medicines access and innovation regardless of how long a product has been on the market, currently negotiations are permitted only for older medicines. Specifically, CMS is allowed to negotiate prices only for drugs and biologics that will have been on the market for at least 9 or 13 years by the time such prices take effect.

Since CMS will only be negotiating prices of high spend drugs and biologics for which drug corporations have had many years to recoup risk-adjusted R&D costs, and they will likely have done so many times over prior to the initial price applicability year, even with a very large therapeutic advancement multiplier, it may be appropriate for the maximum fair price offer from CMS to approach the marginal production and distribution cost per unit. CMS should not shy away from approaching marginal cost pricing of medicines that have been super-blockbusters, such as those that have already generated tens-of-billions of dollars in revenues since entering the market.

By applying this calculation to determine maximum fair price offers and counteroffers, CMS can create a predictable system for rewarding medical innovation and ensuring reasonable prices. Indeed, to preserve the integrity of the system, CMS should only adjust its response to a manufacturer counteroffer if refinements to the input data are presented. Consistent use of the calculation can help realign incentives for pharmaceutical corporations and promote more meaningful medical innovation.

VI. Note on Consideration of Prices of Therapeutic Alternatives

While section 1194(e)(2)(A) of the Act requires CMS to consider the prices of therapeutic alternatives as one of several factors in developing a maximum fair price offer, it certainly does not require it to form the underlying basis for developing a starting point for such an offer. There is nothing in the Act that says or suggests that this or any other factor should be prioritized over or emphasized more than any of the others CMS is required to consider in developing a maximum fair price. As discussed above, it is our strong view that such an approach will inappropriately prejudice CMS toward inappropriately high offers, entrenching the existing regime of price gouging.

Rather than the approach articulated in section 60.3.2 of the guidance, under which prices of therapeutic alternatives form the starting point for CMS' negotiated price offer, CMS should instead take the approach we have articulated above, and as a final step in the process, compare the maximum fair price reached to the prices of therapeutic alternatives. The maximum fair price CMS plans to offer should be reduced to a price that is no higher than the lowest price of a therapeutic alternative that has demonstrated safety and efficacy matching that of the selected drug, including generic and biosimilar versions of therapeutic alternatives marketed in the United States, if the planned offer is not already below this price. A similar

[22] CMS could also consider forming proxies with consideration of pricing information of generic drugs in the same category of therapy, where available, to avoid perverse incentives to inflate marginal costs of production and distribution to obtain higher prices.

approach to internal, therapeutic reference pricing has been incorporated in Denmark's pharmaceutical reimbursement regime since 2005.[23,24]

Recommendation 2: Retain CMS' proposed approach of considering all dosage forms and strengths of a drug with the same active moiety, inclusive of products marketed pursuant to different New Drug Applications (NDAs) and Biologics License Applications (BLAs), as a qualifying single source drug.

Section 30.1 of the guidance correctly cites section 1192(d)(3)(B) of the IRA, which requires CMS to aggregate sales across dosage forms and strengths of a qualifying single source drug in determining whether such drug is negotiation eligible.[25] Additionally, section 1192(b) of the IRA[26] requires CMS to select drugs for negotiation based on the rankings of total expenditures under Medicare Part D for negotiation-eligible drugs, as clarified under section 1192(d)(3)(B) to include spending "data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug."

This language clarifies the intent of policymakers of applying negotiated prices across dosage forms and strengths of a selected drug, which necessitates the approach CMS proposes in the guidance to take for identifying potential qualifying single source drugs.

Further, the approach proposed by CMS will prevent gaming and abuse of the Medicare drug price negotiation program that may occur if prescription drug corporations were able to prevent a high-revenue product from qualifying for negotiation through product hopping and obtaining new NDAs and BLAs, effectively resetting the clock on the statutory 7- and 11-year delay periods before a drug or biologic may qualify for negotiation.[27]

We appreciate that CMS plans to continue to take this approach.

Recommendation 3: Provide greater transparency around R&D costs and other data to amplify the impact on industry pricing practices and instill public confidence in the Medicare drug price negotiation program.

[23] Ulrich Kaiser, Susan J. Méndez, Thomas RØnde, Hannes Ullrich. "Regulation of Pharmaceutical Prices: Evidence from a Reference Price Reform in Denmark." February 2013. https://docs.iza.org/dp7248.pdf

[24] It is difficult to estimate the impacts of this policy in isolation strictly by looking at the Danish experience, as there are other significant differences in their pharmaceutical system from that of the United States, including operating under a universal health care system and an obligation for pharmacists to first offer a patient the lowest-price product within a group of substitutes for a drug unless prohibited by the prescription.

[25] 42 USC § 1320f-1(d)(3)(B)

[26] 42 USC § 1320f-1(b)

[27] 42 USC § 1320f-1(e)(1)(A)(ii) and 42 USC § 1320f-1(e)(1)(B)(ii)

Section 40.2.1 of the guidance indicates that "CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary."

This overly expansive interpretation of what information collected by CMS through the drug price negotiation program shall be held confidential would severely limit the impact of the legislation on industry drug pricing practices and the ability of the public to assess whether the Medicare drug price negotiation program is successfully negotiating "the lowest maximum fair price for each selected drug", as required under the Act, which would instill greater public confidence in the program.[28]

CMS can achieve the lowest maximum fair price for drugs and amplify the impact of the IRA on industry pricing practices by collecting detailed, disaggregated figures around R&D costs, and openly publishing the data. CMS has a unique opportunity to examine the assumptions of the industry business model. Sunshine on this business model would further aid the public discourse and policymakers beyond CMS working to advance measures supporting access to medicines and innovation. Greater disclosure would also be consistent with the U.S.-supported World Health Assembly resolution WHA72.8, "Improving the transparency of markets for medicines, vaccines, and other health products."[29]

As described above under recommendation 1b, CMS can collect an array of information about R&D costs under the IRA. Critically, IRA grants CMS authority to determine whether the submitted information is "proprietary" and hence subject to any disclosure limitations.[30] CMS is also required to publish "the explanation for the maximum fair price" with respect to the factors used to determine it, which include data about R&D costs, production costs, and patents and exclusivities.

The IRA provides no additional guidance on what information should be considered proprietary. CMS may be guided by trade secrets law. In federal statute, the Defend Trade Secrets Act defines the term "trade secret" as information that:

> *(A)the owner thereof has taken reasonable measures to keep such information secret; and*
>
> *(B)the information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use of the information[.]*[31]

While detailed R&D costs may be kept "secret", they may not hold independent economic value to others, especially years after the costs have accrued.[32] Historically, NIH has disclosed some cost data in response to Freedom of Information Act requesters, further suggesting such information is not considered by NIH

[28] 42 USC § 1320f-3(b)(1)
[29] Seventy-Second World Health Assembly, WHA72.8, 28 May 2019, https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R8-en.pdf
[30] 42 USC § 1320f–2 (c). ("Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.")
[31] 18 USC § 1839
[32] Curbing Unfair Drug Prices, A Primer for States (2017), Yale Global Health Justice Partnership Policy Paper, https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf

to be trade secret or confidential commercial information.[33] CMS can also aggregate information on a case-by-case basis. Moreover, CMS can share even information that is considered trade secret if it does so under a license for noncompetitive purposes, or limits disclosure to a subset of recipients who are not competitors.[34]

By more critically scrutinizing whether the information it receives is proprietary, CMS can publish much of the data it collects as part of its explanation for pricing determinations. This can help inform the public debate about the benefits and limitations of the current industry business model and have a transformative impact beyond the IRA.[35]

Recommendation 4: Solicit Information from Patients, Consumers and Other Interested Parties While Promoting Transparency Around Financial Conflicts of Interest with Drug Corporations

In Section 60.4 of the guidance, CMS indicates its plans to once again "host patient-focused events to seek verbal input from patients and other interested parties." In the sign-up form for patient-focused listening sessions for each of the selected drugs for initial price negotiation year 2026, applicants were asked to voluntarily disclose whether they had a conflict of interest, and the disclosure of a conflict was announced during the sessions. We thank CMS for taking this modest step towards promoting transparency and encourage it to go further.

Public Citizen research has found that drug manufacturers and their affiliated foundations and industry groups maintain vast networks of financial relationships with patient advocacy groups, universities, and professional associations, identifying more than $6 billion in grants dispersed by the trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA), and its members from 2010 through 2022.[36]

In the context of a virtual ocean of drug corporation money flooding stakeholder groups that may speak at patient-focused listening sessions or other events, it is essential that disclosures of conflicts of interest resulting from financial relationships with drug corporations or other participants in the prescription drug supply chain are required to be disclosed. This includes financial relationships held by the individuals participating in stakeholder sessions as well as organizations they represent. Moreover, rather than only disclosing the existence of a conflict, the nature of the conflict should also be described. For example, CMS might announce that a participant in a stakeholder session represents an organization that has received funding from drug corporation A, drug corporation B, drug corporation C, and industry group Z.

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[33] See NYU Law, Clinical Trial Cost Transparency at the NIH: Law and Policy Recommendations (2020), https://www.law.nyu.edu/centers/engelberg/pubs/2020-08-17-Clinical-Trial-Cost-Transparency-at-the-NIH at footnote 178

[34] See Amy Kapczynski, The Public History of Trade Secrets, UC Davis Law Review, Vol. 55, at 1438-1440 https://lawreview.law.ucdavis.edu/issues/55/3/articles/files/55-3_Kapczynski.pdf; See also Christopher J. Morten, Amy Kapczynski, The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines, Columbia Law Review, Vol. 109:493, at 552-555, https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=3814&context=faculty_scholarship

[35] See e.g., the Senate Finance Committee report on hepatitis C medicines and its impact.

[36] Mike Tanglis. Mapping the PhRMA Grant Universe. Public Citizen. December 15, 2023 https://www.citizen.org/article/mapping-the-phrma-grant-universe/

We also encourage CMS to closely scrutinize public information available on conflicts of interest held by stakeholders that participate in patient-focused events in order to appropriately weigh the information provided, especially when it is consistent with positions espoused by manufacturers of selected drugs.

In response to questions related to patient-focused events presented by CMS in the guidance:

- Any stakeholder session, regardless of format or scope, must be made as public and transparent as possible, including by livestreaming the event. Publication of event summaries or redacted transcripts should only be supplements to making the event available to the public through livestreaming, not as replacements for it.
- We support CMS holding sessions which allow CMS to ask participants clarifying questions, to better elucidate understanding of stakeholder perspectives.
- To the extent that CMS hosts events that invite discussion between stakeholders, it is essential that it is fully transparent whether participants have conflicts of interest with drug corporations or other participants in the prescription drug supply chain. It is essential that patients and other stakeholders without conflicts of interest have the opportunity to have their views heard without being undermined by participants with conflicts of interest.

Additional Recommendations:

- ***As CMS considers information submitted[37] on selected drugs and their therapeutic alternatives, critically scrutinize the quality of the evidence and weight it accordingly.***
  Well-designed randomized clinical trials with tight statistical confidence intervals confirming clinically meaningful safety and effectiveness should be weighted more heavily in CMS' consideration than information from less rigorous sources.

- ***Continue to use "both the Primary Manufacturer's global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug", as stated in Appendix A of the guidance.***
  As stated under recommendation 1b, because pharmaceutical corporations operate in a global marketplace and are not bound only to market products in the United States, global sales should be included in this calculation. The first factor for consideration for the purpose of negotiating the maximum fair price of a selected drug in the IRA includes "the extent to which the manufacturer has recouped research and development costs," which necessarily implicates the extent to which such costs have been recouped through U.S. *and* non-U.S. sales.

- ***We encourage CMS to adjust its price offer downward to the extent R&D costs have been recouped by a manufacturer and up to the extent they have not been recouped, as considered in section 60.3.4 of the guidance.***
  This recommendation comes with the caveats of criticisms provided under recommendation 1a and the strong encouragement towards taking the more comprehensive approach described in

[37] Section 50.2 of the guidance states that "[t]he Primary Manufacturer and members of the public, including other manufacturers, Medicare beneficiaries, academic experts, clinicians, caregivers, and other interested parties, may submit information on selected drugs and their therapeutic alternatives […]"

recommendation 1b. Our proposed formula for CMS to use in determining a maximum fair price would have this result.

- ***We recommend CMS clarify that the information described under definitions relating to R&D costs in Appendix A should be provided in an itemized and disaggregated fashion, to the extent the guidance leaves ambiguity on this point.***[38]
  This is particularly important with regard to reporting costs separately for each clinical trial, as there are significant differences in risk depending on trial phase, as described further in recommendation 1b.

- ***As CMS considers manufacturer-specific data provided under section 1194(e)(1) of the IRA, it must critically scrutinize the assumptions and calculations provided in manufacturers' narrative texts.***
  Section 60.3.4 of the guidance indicates that CMS may use "the assumptions and calculations in the accompanying narrative text" submitted by the manufacturer in its consideration of this data. Manufacturers may make unrealistic assumptions about cost of capital and risk and otherwise seek to use this narrative to inflate the price implicated by the data it provides under section 1194(e)(1) of the Act. CMS must remain vigilant to prevent such mischaracterizations from leading to inappropriately high maximum fair prices.

- ***Take a more holistic approach to considering federal financial contributions to drug development, including with consideration for other forms of support, such as critical scientific contributions to underlying inventions, upstream research and funding thereof, and other support from public sector research institutions and publicly supported research programs.***
  The FY2024 NIH budget is approaching $50 billion dollars, the vast majority of which funds "extramural research through grants, contracts, and other awards to universities and other research institutions."[39,40] For decades, the NIH and the public have played an integral role in drug development and the NIH role in basic research is understood by many. Researchers recently found that "[o]verall, NIH funding contributed to research associated with every new drug approved from 2010-2019, totaling $187 billion."[41]

  While traditionally the NIH is understood to provide support for foundational basic research, increasingly, the public sector is providing more contributions later in drug discovery. A recent review of patents associated with all drugs having a new molecular entity approved by FDA over a 10-year period found that 19% of the drugs had origins in publicly supported research and development and 6% originated in companies spun off from a publicly supported research program.[42] An earlier study showed that over 40 years, 153 new FDA-approved drugs, vaccines, or new indications were

[38] This a reiteration of a point included in recommendation 1b, to avoid it being lost in the wider-ranging recommendation above.
[39] Specifically, nearly 83% of the FY2024 NIH budget goes towards these purposes.
[40] CRS Reports. National Institutes of Health (NIH) Funding: FY1996-FY2025, Updated June 25, 2024. https://sgp.fas.org/crs/misc/R43341.pdf
[41] Ekaterina Cleary, et. al. Government as the First Investor in Biopharmaceutical Innovation: Evidence From New Drug Approvals 2010–2019. Institute for New Economic Thinking Working Paper Series No. 133. https://doi.org/10.36687/inetwp133
[42] Rahul K Nayak, Jerry Avorn, Aaron S Kesselheim. "Public sector financial support for late stage discovery of new drugs in the United States: cohort study." BMJ 2019; 367 doi: https://doi.org/10.1136/bmj.l5766 (Published 23 October 2019)

discovered by public sector research institutions, more than half of which were used in the treatment or prevention of cancer or infectious diseases.[43] CMS should account for these vital public contributions as it develops maximum fair price offers.

Additionally, when pending and approved patent applications disclose U.S. government scientists as inventors, or it is the position of an agency of the U.S. Government that its scientists should be listed as coinventors,[44] this should be considered in-kind financial support and the maximum fair price offer from CMS should be adjusted downward to take account for this public support, which de-risks drug development.

- ***Do not use inflated value metrics for coupons, goods donated, or other forms of voluntary access concessions when calculating the global, total lifetime manufacturer net revenue for the selected drug.***

  Appendix A of the negotiation guidance indicates that CMS intends to consider coupons and donated goods in its "Global, including U.S., Total Lifetime Manufacturer Net Revenue for the Selected Drug" definition. Manufacturers may seek to argue for aggressively high offsets to their revenues from such coupons and donations, such as the full list price that would have been paid for a donated product, or the difference between such price and a coupon price and the amount paid by an insurer. It would be more appropriate to understand such price concessions, including any provided through patient assistance programs, as voluntary. They should not be considered in the net revenue calculation.

  If CMS declines to take this position, it should use the cost of goods donated and should not use a hypothetical price a party may have paid for the product absent such voluntary concession(s).

[43] Ashley J. Stevens, et. al., "The Public Role of Public-Sector Research in the Discovery of Drugs and Vaccines." N Engl J Med 2011; 364:535-541. DOI: 10.1056/NEJMsa1008268 https://www.nejm.org/doi/full/10.1056/nejmsa1008268

[44] In a recent dispute with the biopharmaceutical corporation Moderna, the NIH correctly argued that as part of its four-year partnership with Moderna, NIH scientists coinvented the NIH-Moderna vaccine sequence. Moderna refused to name NIH scientists as coinventors and instead quietly abandoned these patents earlier this year. See *Sheryl Gay Stolberg and Rebecca Robbins. "Moderna and U.S. at Odds Over Vaccine Patent Rights" New York Times.* *https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html* and Public Citizen's Letter on the Moderna Vaccine Patent Dispute https://www.nytimes.com/interactive/2021/11/09/us/public-citizen-nih-moderna-vaccine.html

RARE ACCESS ACTION PROJECT

July 1, 2024

VIA ELECTRONIC DELIVERY to IRARebateandNegotiation@cms.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244–1850

RE: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027, and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Administrator Brooks-LaSure:

The Rare Access Action Project, (RAAP) appreciates this opportunity to comment on the initial guidance regarding the Drug Price Negotiation Program (Negotiation Program) under the Inflation Reduction Act of 2022 (IRA) issued by the Centers for Medicare & Medicaid Services (CMS or Agency) on May 3, 2024 (Initial Guidance).[1]

RAAP is a registered 501(c)(4) non-profit organization that is a coalition of life sciences and patient stakeholders that explore creative policy solutions to address structural issues in access and coverage. Our priorities are twofold. First, we advocate for policies that stimulate the development of therapies that treat rare diseases. Second, we advance initiatives that ensure rare disease patients have access to the care and treatments they need.

As detailed further, RAAP is extremely concerned about the impact that CMS' final definition of qualified single source drug (QSSD) will have on patients.[2] With history as a guide, RAAP believes that CMS' final definition of QSSD will have a significant chilling effect on investment in clinical development of orphan drugs.

I. Background: Rare Diseases and Orphan Products

[1] CMS, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (May 3, 2024), (IPAY 2027) available at https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

[2] Id. at page 8.

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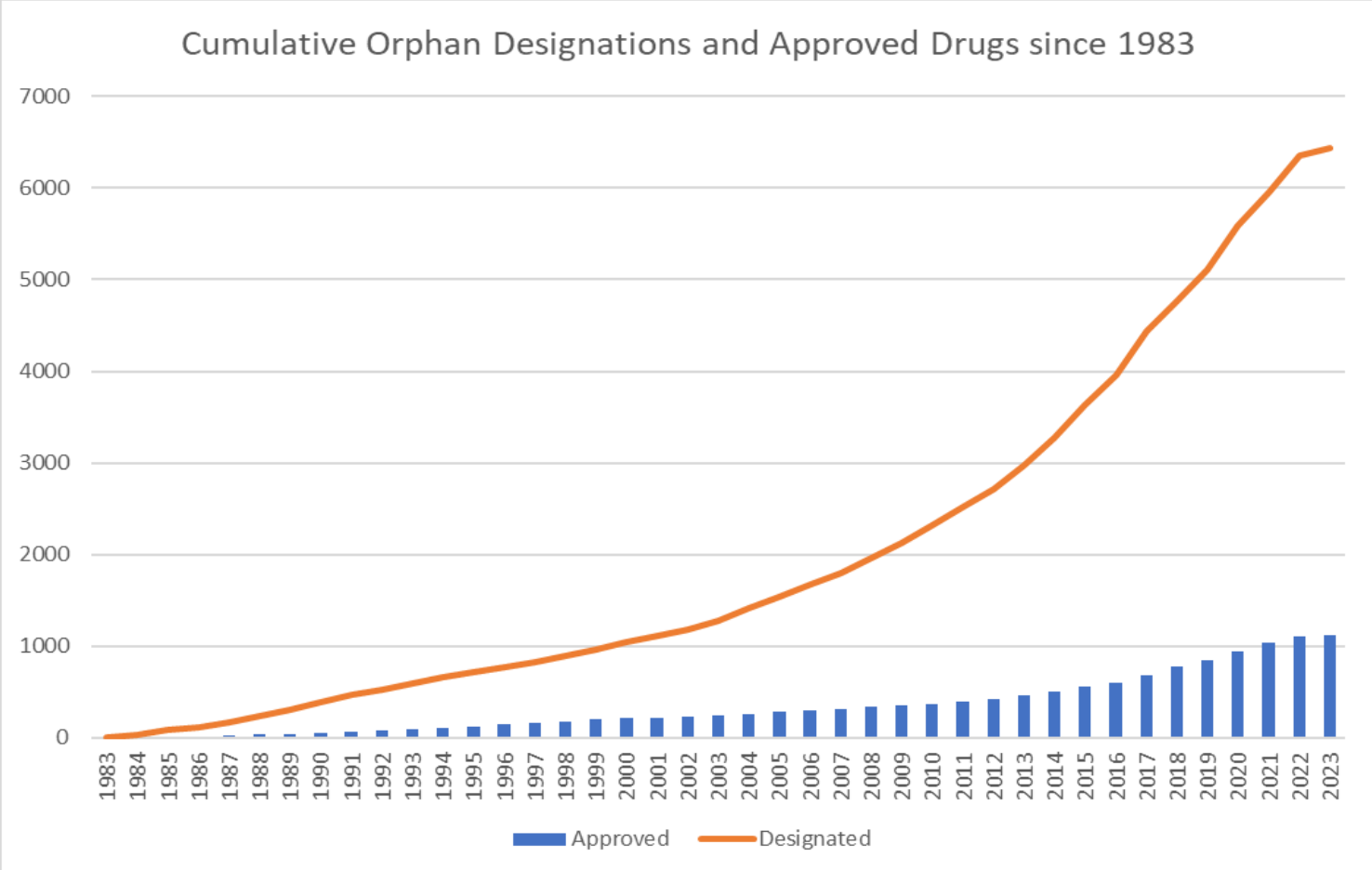
RARE ACCESS ACTION PROJECT

Over 7,000 rare diseases affect more than 30 million Americans.[3] The Orphan Drug Act (ODA), enacted in 1983, provides financial incentives to encourage the development of drugs to treat, diagnose, or prevent rare diseases or conditions that affect fewer than 200,000 people in the US. The ODA has resulted in manufacturers developing orphan drugs that have provided benefit to previously overlooked populations, including new drugs offering breakthrough therapies and existing drugs providing medical benefits for new populations. Since 1983, 6,371 drugs and biologics have received the Orphan Drug designation, and the FDA has approved 1,110 drugs and biologics for orphan indications, as shown in the figure below[4]:



[3] https://www.fda.gov/patients/rare-diseases-fda
[4] FDA. Search Orphan Drug Designations and Approvals. Accessed March 28, 2023. https://www.accessdata.fda.gov/scripts/opdlisting/oopd/

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Whereas, from 1973-1983, manufacturers marketed only 34 orphan products, 10 of which were developed by the pharmaceutical industry and 24 were developed from research and funding by the federal government.[5] This is a stark and distinguishing difference from today that further reinforces the tremendous positive impact of the ODA. Further, from 1983 to 2014, 843 new molecular entities were approved by the FDA, 25% of those were orphan drugs. A study in *Health Affairs* found that the average number of orphan New Molecular Entities (NMEs) approved per year was 7, but from 2010-2014, the average increased to 12.5 further showing the power of the ODA.[6]

Specifically, the ODA has transformed treatments for rare cancers. Between 1983 and 2015, 177 drugs were approved to treat rare cancers. The 177 approvals originated from 1,391 orphan drug designations.[7] By almost any measure the ODA has successfully achieved its policy objectives—to stimulate the development of orphan therapies.

Rare diseases include more familiar conditions, such as cystic fibrosis, Lou Gehrig's disease, and Tourette's syndrome, as well as less familiar conditions, such as aromatic L-amino acid decarboxylase (AADC) deficiency, Duncan's Syndrome, Madelung's disease, and acromegaly/gigantism. These conditions are complex and often not well understood, which causes great challenges to the diagnosis and treatment as well as research efforts. Rare disease treatments range from curing the disease, modifying how the disease functions, or treating the symptoms. Truly curative treatments are rare. Disease-modifying therapies target the underlying pathology of a disease to prevent it from worsening. Symptomatic treatments seek to temper symptoms or to maintain physical, emotional, and mental functioning. Only 5% of rare diseases have a treatment approved by the Food and Drug Administration (FDA) and for one-third of individuals with a rare disease, it can take between one and five years to receive a proper diagnosis.

The successes mentioned above resulted from significant clinical investment within the backdrop of the financial incentives of the ODA and a healthcare system that could provide equal access to these life altering therapies. Manufacturers invested knowing that there was a potential of seven years of market exclusivity to recoup the billions of dollars of investment.[8] Companies relied on the ODA to partner with patients to develop the next generation of orphan therapies and now, however, due to CMS' nearsighted definition of QSSD and the Orphan Drug Exclusion from being a QSSD, the future of orphan drug discovery is bleak.

[5] https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/RS20971.pdf
[6] https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0921
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4828121/
[8] https://www.fda.gov/patients/rare-diseases-fda

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II. CMS' Final Definition of Qualified Single Source Drugs Could Irreparably Stunt the Development of Therapies that Treat Rare Disease

In Section 30.1.1 of CMS' proposed Guidance for IPAY 2026, entitled, "Orphan Drug Exclusion from Qualifying Single Source Drugs" CMS states that it "is considering whether there are additional actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development."[9] RAAP appreciates this statement and hopes that the Agency reverses its final decisions regarding definition of QSSD and the Orphan Drug Exclusion clock from IPAY 2026 that it gain proposes in IPAY 2027.[10] Specifically, CMS again proposes to identify "qualifying single source drugs" at the active moiety/active ingredient level and to set the seven or eleven-year clock for purposes of the qualifying single source drug definition on the date of initial FDA approval. RAAP disagrees with CMS statutory interpretation of QSSD and the initiation period for the negotiation clock. RAAP urges CMS to reverse these decisions because they could stunt manufacturer development of orphan drugs as it it will force manufactures to choose between developing an orphan indication or a non-orphan indication.

A. CMS' Overreach Of Defining QSSD based on Active Moiety/Active Ingredient will Disincentivize Orphan Drug Development

In its Initial Guidance, CMS states that "[i]n accordance with the statutory language (section 1192(e)(1) of the Inflation Reduction Act (IRA)) cited above for purposes of the Negotiation Program, CMS will identify a potential qualifying single source drug using: For drug products, all dosage forms and strengths of the drug **with the same active moiety** (emphasis added) and the same holder of a New Drug Application (NDA) inclusive of products that are marketed pursuant to different NDAs. For biological products, all dosage forms and strengths of the biological product **with the same active ingredient** (emphasis added) and the same holder of a Biologics License Application (BLA) inclusive of products that are marketed pursuant to different BLAs."[11] In other words, the potential qualifying single source drug will also include all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s).[12] RAAP believes that Agency's final policy of combining drugs by active moiety and biologicals by active ingredient is inconsistent with the plain reading of the statute that in turn will harm orphan drug development.

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[9] IPAY 2026, proposed guidance at page 11. https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

[10] IPAY 2027 at page 7. https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

[11] https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf at page 8.

[12] Id.

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Specifically, the plain text of section 1192(e)(1) references FDA action in the singular, not the plural by using word approval or licensure, not approvals or licensures. The law states that "qualifying single source drug" is defined for products approved under an NDA by reference to whether seven years has elapsed since "such approval." Similarly, the term is defined for products licensed under a BLA by reference to whether eleven years has elapsed since "such licensure." These clauses are written in the singular, it therefore requires products to be treated as the same qualifying single source drugs only where they share the same NDA or BLA. The use of "such license" and "such approval" is intentional and unambiguous. Congress used this language to denote that a qualifying single source drug is distinguished by a distinct approval or licensure—i.e., a distinct NDA or BLA. CMS must give effect to the plain language of the statute by distinguishing among qualifying single source drugs based on their FDA application and reverse its final decision to group QSSD by active moiety or active ingredient.

Biopharmaceutical innovation is incremental, relying on sustained and continuous improvements to molecules, pathways, and modes of administration to achieve maximum clinical benefit for patients. For patients living with a rare disease or disorder this development process is particularly necessary because of the rarity of their condition. Science cannot take significant leaps and develop new active moieties with each generation of treatment. By combining drugs at the active moiety or active ingredient level, CMS is likely cutting of hundreds of investments into new orphan disease indications.

B. CMS' Decision of Starting the Negotiation Clock at FDA Approval will Prevent Clinical Development for Rare Therapies

CMS states that to determine the date of approval or licensure for a potential qualifying single source drug with more than one FDA application number, CMS intends to use the earliest date of approval or licensure of the initial FDA application number assigned to the NDA/BLA holder for the active moiety / active ingredient. Consistent with CMS' request on actions it could take to best support orphan drug development, RAAP strongly urges CMS to reverse this decision and or clarify that for orphan drugs, where a drug loses eligibility for the orphan drug exclusion, the clock starts on the date the drug loses such eligibility, not the date of FDA approval for purposes of the qualifying single source drug definition.

Manufacturers typically seek indications and orphan designations sequentially as new clinical evidence is developed, and thus starting the clock at FDA approval regardless of clinical sequencing will hurt orphan drug discovery. For example, the U.S. Department of Health and Human Services Office of Inspector General,

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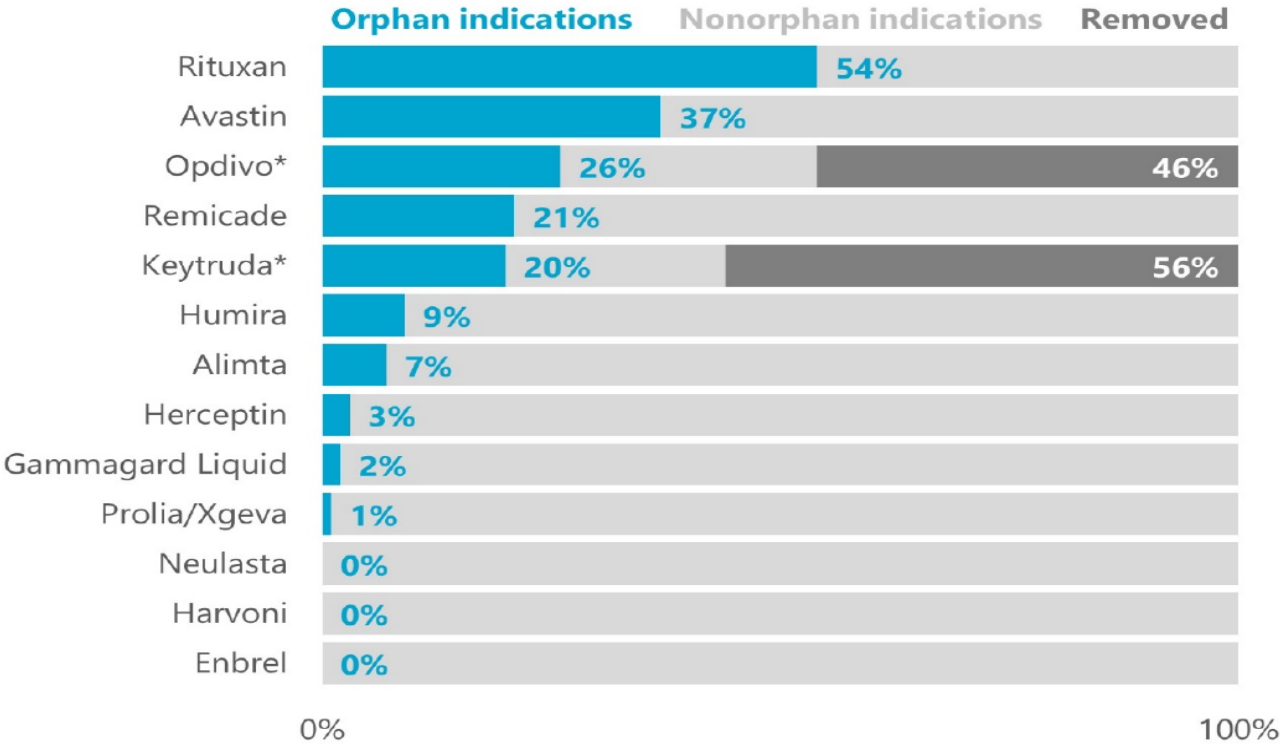
published a report in 2021 that demonstrates the potential impact that this policy could have on orphan drug discovery. Specifically, based on the graph[13] below the orphan indications for the top drugs on the list would likely not have been developed. It is reasonable to believe that the manufacturer of these blockbuster drugs may have chosen only the larger indications.

Exhibit 6: Drugs with both orphan and nonorphan approvals were much less likely to be used for their orphan indications.



Source: OIG analysis of 2018 Medicare Part B claims and Part D PDE records.
*Note: Opdivo and Keytruda both have FDA approval for orphan indications to treat small cell lung cancer (SCLC,) as well as nonorphan indications to treat non-small cell lung cancers (NSCLC). Because ICD-10 diagnosis codes do not distinguish between SCLC and NSCLC, we removed units related to any form of lung cancer from our analysis.

RAAP believes that the statute[14] is clear, for so long as a drug qualifies for the orphan drug exclusion, the product is entirely exempt from the QSSD definition and all its implications. Therefore, the 7- or 11-year pre-negotiation period cannot start for a QSSD until the first day after the orphan drug no longer qualifies for the orphan drug exclusion. Any other interpretation would contradict the intent of

[13] Id.
[14] Social Security Act (SSA) §1192(e)(3)(A).

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excluding eligible drugs from the QSSD definition and negatively impact on drug development decisions for rare disease treatments.

RAAP urges CMS to continue the work of the Congress and the ODA and continue to help stimulate the development of orphan drugs. Through the ODA, Congress devised a regulatory infrastructure that carefully balances incentives in favor of the development of orphan drugs. This history is repeated by Congress in the IRA as evidenced by the orphan drug exclusion. Congress again recognized the special nature of orphan drug discovery. RAAP is disappointed that CMS does not recognize this continued Congressional theme of protecting orphan drug discovery in its final definitions.

As such, RAAP urges CMS to promote orphan drug development by clarifying that the seven- or eleven-year clock for purposes of the qualifying single-source drug definition starts on the date on which a drug loses its status as an excluded orphan drug.

III. Other Issues Related to Implementing the Orphan Drug Exclusion

In the spirt of implementing policies that continue to stimulate orphan drug development, RAAP urges the Agency to implement, at a minimum, the following recommendations that will better support ongoing development of and access to drugs targeting patients living with rare diseases.

First, CMS should establish a process that enables manufacturers to submit evidence that an indication falls within an orphan drug designation to account for situations where CMS is unable to determine eligibility for the orphan drug exclusion based on a review of FDA's orphan drug databases. Second, CMS proposes that if a selected drug "has patents and exclusivities that will last a number of years," CMS may adjust the "preliminary price" downward. RAAP is very concerned by this implication for orphan drug development. Specifically, this could mean that drugs that have orphan exclusivity could have a lower MFP than would otherwise apply further disincentivizing the pursuit of orphan indications.

IV. Conclusion

Based on the policies stated in the Initial Guidance, RAAP anticipates that some if not many of the current drug discovery programs for orphan diseases will unfortunately be discontinued. Therefore, we urge CMS to implement the above changes in order to mitigate the risk that the Initial Guidance will deter the development of these orphan drugs and many more in the future.

1012 14th Street NW, Suite 500, Washington DC, 20005

RARE ACCESS ACTION PROJECT

Thank you for the opportunity to submit these recommendations on which actions CMS can take in its implementation of the Negotiation Program to best support orphan drug development. RAAP is significantly concerned that without changing the definition of QSSD and starting the clock from when a nonorphan indication is approved that orphan drug discovery will significantly dimmish. RAAP believes that CMS owes it to future patients to preserve the intentions and benefits of the ODA and reverse these final decisions regarding the definition of QSSD.

We look forward to working with CMS to further develop policies that maximize access to therapies treating rare diseases. Please feel free to contact me at 202-631-5752 or by email at mike@rareaccessactionproject.com

Sincerely,

Michael Eging

1012 14th Street NW, Suite 500, Washington DC, 20005

RxParadigm

New Paradigm For Modern Pharmacy Solutions

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

RxParadigm's Comments: CMS' Draft Guidance on the Medicare Drug Price Negotiation Program

CONTACT

650 Naamans Rd,
Claymont, DE, 19703

302-524-4179

timothy.neylan@rxparadigm.com

PREPARED FOR:

Center for Medicare and Medicaid Services

PREPARED BY :

Timothy Neylan
Chief Operations Officer

Contents

RxParadigm, an innovative pharmacy solutions and technology firm, formally submits comments to the CMS Draft Guidance on the Medicare Drug Price Negotiation Program. The CMS' efforts to provide clarity, transparency, and accountability in the Medicare Program align with RxParadigm's core values and initiatives. Our proprietary technology Tungsten+ PLUS is already built with the purpose of serving as a reimbursement platform with the ability to ingest, identify, and address 340B duplicate discounts, reducing the Medicare Transaction Facilitator (MTF) initiative's go live implementation window for January 1, 2026. Our leadership team brings a wealth of experience in serving government entities to inform our responses. Key highlights of our leadership team's expertise include:

1. Extensive Government Experience: Our executives have over four decades of collective experience in working with government agencies, understanding their requirements, and implementing successful pharmacy solutions tailored to their needs.

2. Deep Knowledge of Regulatory Landscape: We have a thorough understanding of the regulatory environment governing pharmacy in the public sector. Our team ensures compliance with all relevant regulations while maximizing cost savings and improving health outcomes for program beneficiaries.

3. Experience in Reimbursement Negotiation and Administration Using Innovative Solutions: RxParadigm team boasts over 25 years of experience in drug reimbursement negotiation and administration for government–funded programs as well as commercial payers. Leveraging innovative technology and data analytics, our company provides actionable insights to inform drug contracting decisions, maximizing resource utilization while optimizing patient outcomes. Specifically, for the 340B program, RxParadigm has integrated unique functionality into its technology platform, Tungsten+ PLUS. This platform can identify 340B claims, serving as a neutral 340B clearinghouse technology that fulfills all stakeholders' requirements including IRA.

Our founder and CEO, Mesfin Tegenu, has been a stalwart in the managed care industry for three decades, contributing innovative solutions and driving positive outcomes for our valued clients. A key strength of RxParadigm lies in our extensive experience in negotiating and administering reimbursement programs. This expertise led us to develop an all-inclusive end-to-end blockchain-powered administration technology. This technology plays an essential role in today's intricate administration processes, both in private and government-managed programs.

Furthermore, our proprietary technology platform offers robust functionalities for reimbursement tracking, monitoring, validation, and reporting. With state-of-the-art systems ensuring accurate and timely processing, we have laid the groundwork to build elements that ensure MTF compliance.

Our unwavering commitment to leveraging innovative technology enables us to streamline administrative processes and deliver actionable insights, empowering our clients to make informed decisions. Our comments aim to help craft the most practical and useful guidance to implement IRA flawlessly.

During this comment period, our organization is enthusiastic about the opportunity to showcase our expertise in Medicare Transaction Facilitator (MTF) initiatives, utilizing our proprietary technology, Tungsten+ PLUS and how to meet CMS' need for a platform and contractor that has claims adjudicator, reimbursement administrator, and 340B identifier competencies. In our response, we have recorded or paraphrased CMS' current guidance to each topic in bolded text, and RxParadigm's relevant comments below.

340B De-Duplication – Section 40.4

340B Identification into MTF Processes

Certain parts of this section are paraphrased to make this document more readable and shorten the page length. In light of numerous factors such as those outlined below, CMS will not, at this time, assume responsibility for deduplicating discounts between the 340B ceiling price and MFP. As described above, CMS intends to provide Primary Manufacturers with a process to identify applicable 340B eligible claims through the reporting of payment elements to the MTF, as described in section 40.4.1 of this draft guidance. CMS will rely on such indications when determining the extent to which the obligation to provide access to the MFP has been discharged. CMS will continue to explore the feasibility of incorporating 340B-related transactional data from 340B covered entities or their TPAs identifying claims eligible under 1193(d)(1) into MTF processes in the future and welcomes comments on this approach.

CMS' draft guidance outlines the obligations of Primary Manufacturers regarding access to the Medicaid Federal Upper Limit price and the 340B ceiling price for selected drugs dispensed to MFP eligible individuals in Section 40.4.2 - Nonduplication with 340B Ceiling Price. According to section 1193(d)(1) of the Act, if the 340B ceiling price is lower than the MFP for a selected drug, the PM isn't obligated to provide access to the MFP for that drug to 340B-covered entities. However, under section 1193(d)(2), if the MFP is lower than the 340B ceiling price, the PM must provide access to the MFP to 340B covered entities.

The draft guidance clarifies that if the PM provides access to the MFP for a drug, they aren't required to offer the 340B ceiling price for the same claim. It's emphasized that the ingredient cost of all Part D prescriptions filled for a drug should not exceed its MFP. While CMS currently won't deduplicate between the 340B ceiling price and the MFP, it may explore this in the future. CMS encourages collaboration among stakeholders to ensure access to the lower of the MFP and the 340B ceiling price without undue burden. Additionally, CMS acknowledges coordination with HRSA regarding compliance with their respective program requirements, seeking comments on the outlined policies.

RxParadigm Comments:

Manufacturers providing the MFP discount need a fair opportunity to identify 340B claims to prevent duplicate discounts. The 340B indicator included in the claim from the Plans has been proven to be unreliable. Analysis by IQVIA and others show that claim modifiers are not reliable, even when required, and are even less reliable when voluntary, as suggested by CMS in this draft guidance. Additionally, only a small percentage of the Manufacturers participating in the 340B program have implemented solutions to obtain 340B information from covered Entities (CEs) and their agents, such as Third-Party Administrators (TPAs). Without addressing 340B duplicate discounts, significant challenges are inevitable.

The following measures can be implemented to tackle these challenges.

1) Creating a direct Transfer Conduit:

a. Establish a conduit within the MTF to facilitate the direct transfer of 340B claims from CEs to Manufacturers. CEs already have established processes with third-party vendors for submitting 340B claims, and leveraging this infrastructure minimizes additional effort.
b. By implementing this approach, CMS and the MTF are relieved of the burden of matching claims from diverse sources (DDPS or 340B claims from CEs) or managing inevitable claims timing issues. This approach ensures that CEs can securely submit claims without multiple intermediaries, reducing the risk of compromising Medicare patient data. There are solutions in the market capable of facilitating this integration.

2) Mandating CMS Requirements:

a. CMS should mandate that the MTF platform has the capability to analyze and flag 340B claims, supporting a clean and complete claims reimbursement process.
b. This should be future proofed to manage potential future 340B integration needs, avoiding the need for time-consuming RFP/RFQ procurement processes.
c. Access to this data would also benefit CMS by resolving disputes between pharmacies and Manufacturers, enabling informed decision-making, and minimizing patient and provider dissatisfaction.

MTF Claim-Level Data Elements – Section 40.4.1

The MTF will have additional data elements (i.e., MTF internal claim number (ICN), Record ID, MTF XRef ICN, Process Date, Transaction Code, and Medicare Claim Type) that will assist in the facilitation of information on claim adjustments and reversal.

Table 2: MTF Claim-Level Data Elements

MTF Data Elements List	Purpose	Data Source
Record ID	Used to identify the type of record, such as new claim, adjustment, reversal, etc.	MTF
MTF Internal Claim Number (ICN)	Used to identify the internal unique MTF ID to support claim adjustments	MTF
MTF XRef ICN	Used to link an adjustment to original MTF ICN	MTF
Process Date	Used to identify MTF processed date	MTF
Transaction Code	Used to indicate original claim, adjustment, reversal, etc.	MTF
Medicare Source of Coverage	Used to identify coverage under Medicare Part B or Part D	MTF
Date of Service	Used to verify MFP eligibility	PDE Record
Service Provider Identifier Qualifier	Used to verify MFP eligibility	PDE Record
Service Provider Identifier	Used to verify MFP eligibility	PDE Record
Prescription/Service Reference Number	Used to verify MFP eligibility	PDE Record
Fill Number	Used to verify MFP eligibility	PDE Record
Product /Service Identifier	Used to verify MFP eligibility	PDE Record
Quantity Dispensed	Used to assist the manufacturer in calculating a refund	PDE Record
Days' Supply	Used to verify MFP eligibility	PDE Record
340B Claim Indicator (as voluntarily reported by dispensing entity)	Used to verify MFP eligibility	PDE Record
Contract Number	Used to verify MFP eligibility	PDE Record
Wholesale Acquisition Cost (WAC) at time of dispensing	Used to calculate the Standard Default Refund Amount	MTF
Maximum Fair Price (MFP) at time of dispensing	Used to assist the manufacturer in calculating a refund	MTF
Standard Default Refund Amount (WAC-MFP)	Used to assist the manufacturer in calculating a refund	MTF
Service Provider MTF Enrollment Status	Used to indicate if dispensing entity opted in to MTF payment facilitation	MTF

RxParadigm Comments:

Without incentives or regulatory guidance from CMS, stakeholders are unlikely to collaborate effectively to address the issue of duplicate discounts. As mentioned in the 340B de-duplication section above, an optional 340B indicator field, although proposed, would yield suboptimal results. Historically, optional fields tend to remain empty unless there is a compelling incentive. Moreover, Plans adjudicating claims at the point of sale often overlook the designation of a claim as 340B. Third-party administrators (TPAs) and Covered Entities (CEs) typically retroactively identify claims as 340B, creating a timing discrepancy and further complicating the accurate and consistent use of the 340B indicator.

To mitigate these challenges, the MTF should be equipped to capture additional required fields. This capability would enable the MTF to analyze claims thoroughly and flag 340B drugs, supported by relevant evidence such as tags or textual information. Leveraging enhanced 340B claims interrogation techniques, the MTF could identify prescriptions affiliated with 340B covered entities accurately. Covered entities must be required to be fully compliant in providing relevant information and Manufacturers who have implemented contract pharmacy restrictions must share information about approved 340B pharmacies with the MTF to incorporate into its logic. Additional fields should include:

- Prescriber ID
- Submission Clarification Code (to be added to PDE record starting January 1, 2025)
- Basis of Cost Determination

Capturing these fields is essential to realizing the benefits outlined in our response to the 340B De-duplication section, ensuring transparency, accuracy, efficiency, and seamless implementation of IRA.

Data Transmission from DDPS to MTF Section

CMS is evaluating whether the current 30-day window for Plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds.

RxParadigm Comments:

RxParadigm aligns with CMS's recognition of the importance of prompt reimbursement for pharmacies, particularly considering that many pharmacies lack sufficient cash reserves to endure prolonged reimbursement cycles, a factor critical to the program's efficacy. It is crucial that reimbursement payment cycles adhere to standard PBM reimbursement timelines, typically falling within 14 to 21 calendar days. Additionally, States' timely pharmacy payment laws often require pharmacy reimbursements to fall within 14-day cycles. The CMS requirements lead to, at best, a 21-day cycle, meaning state laws may need to be carved out of the MTF requirements. The capability of claims adjudication systems to furnish claims data within or equal to a 7-day timeframe underscores the feasibility of expediting reimbursement processes; many systems routinely extract claims data daily or weekly for integration into other operational facets.

In light of the shortened claims window, the consideration of additional field values within the PDE record, such as paid/reversals, emerges as a pertinent discussion point. If these values are not already provided in some form, the MTF platform could incorporate them into its processes to assist Manufacturers in fulfilling their reimbursement obligations effectively. However, the efficacy of these measures is contingent upon the commencement point of the 14-day window. To allay pharmacy concerns and accommodate a shortened PDE submission window, considerations must be made. The transmission of claims from the Drug Data Processing System (DDPS) to the MTF similarly poses no insurmountable technical obstacles; leveraging modern technology solutions already on the market can address concerns regarding frequency and volume.

Data Transmission from MTF to Primary Manufacturers

CMS is also evaluating options for the process, timing, and frequency by which files containing these claim-level data elements will be transmitted from the MTF to Primary Manufacturers. CMS is considering transmission of these files on either a daily or bi-weekly frequency and is soliciting comments on the process, timing, and frequency of these file transmissions.

RxParadigm Comments:

RxParadigm's proposed solution of sharing claims data in the NCPDP file format aligns with Manufacturer practices concerning standard rebate payments and maintains consistency. Manufacturers possess robust, established processes capable of managing substantial volumes of claims from Payers/PBMs, enabling them to configure their tools and procedures to accommodate MFP reimbursement, which, from their perspective, resembles a type of rebate. Utilizing the latest NCPDP file format (version >=07.04) ensures compatibility and consistency with industry standards.

Given the lead time involved in claims transitioning from Plans to the DDPS to the MTF, the backend of the MTF to Manufacturer reimbursement process must be expedited. Daily transmission of files is imperative to afford Manufacturers adequate time for claim review and reimbursement determination, considering factors such as 340B or prospective MFP status already provided. Similarly, reimbursements from Manufacturers to the MTF and subsequently to pharmacies should adhere to a similarly rapid timeframe, either daily or weekly, to streamline the reimbursement process effectively.

Although Manufacturers may not be accustomed to daily claims and swift payments within the Payer/PBM rebate realm based on our experience, their systems can be configured to facilitate such processes for Medicare Plans and MFP-scoped drugs, ensuring timely and efficient reimbursement operations.

Pharmacy Payment – Sections 40.4 and 90.2

Prospective Pricing vs. Retrospective Reimbursement

A Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP (the requirements for which are further described in sections 40.4.1 and 90.2 of this draft guidance), or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP (the requirements for which are further described in section 40.4.3 of this draft guidance). That is, unless the dispensing entity's acquisition cost for the selected drug is equal to or less than the MFP, or, as detailed in section 40.4.2 of this draft guidance, the Primary Manufacturer establishes that section 1193(d)(1) of the Act (related to 340B discounts) applies.

RxParadigm Comments:

There are benefits and drawbacks to both retrospective and prospective payments for stakeholders. For Manufacturers, prospective payments are more prone to duplicate discount claims and operational issues due to the need for collaboration with wholesalers. Retrospective payments, from a Manufacturer's perspective, offer better management of duplicate discount claims, although operational issues remain. For pharmacies, prospective payments provide more beneficial cash flow, while retrospective payments require timely data and prompt pharmacy payments. Regarding the reference price issue, using a benchmark is ideal, but WAC will inflate the final payment. Using NADAC is more accurate, but not required.

Nonetheless, it is imperative that reimbursement remains retrospective, as pharmacies typically serve a diverse patient population across various Lines of Business (LOBs) such as Medicare, Commercial, and Medicaid. Introducing prospective reimbursement would introduce numerous downstream challenges and complicate the overall process. A unified retrospective reimbursement approach proves more effective, simplifying operations for pharmacies and ensuring consistency across their reimbursement processes, thereby enhancing efficiency and ease of management.

Payment Reporting Elements from Primary Manufacturers to MTF

Payment elements will include the MFP refund transaction date, the method for determining the MFP discount/refund amount, the NPI of the entity receiving the MFP refund, and the amount of payment sent as the MFP refund. CMS is soliciting comments on the required payment elements to be reported to the MTF by the Primary Manufacturer, including whether to add other specific categories.

CMS anticipates that Primary Manufacturers and their contracted third parties may automate the process of reporting payment elements and welcomes comment on any data needs or limitations to facilitate such operations.

RxParadigm Comments:

It is imperative to remain consistent with Manufacturer practices around standard rebate payment. Manufacturers have well formed, stable processes to manage large rebate claims volumes from Payers/PBMs and can configure their tools and processes to handle MFP reimbursement, which is a "type of rebate" from their perspective. Reports and reporting data elements Manufacturers use when paying rebates today include:

- ECP Outlier Detail
  - This file contains all claims identified to be ineligible for payment by the Manufacturer.
- Payment Summary
  - This file contains a summary of total payment made based on drug NDC and pharmacy.
- Payment Detail
  - This file contains information on payment eligible drug NDCs with total dispensed quantity and payment per pharmacy.

Pharmacy Electronic Remittance Advice

After the Primary Manufacturer makes payment to the dispensing entity and sends the report with payment-related data to the MTF, CMS is considering having the MTF generate an electronic remittance advice to the dispensing entity for purposes of reconciling Manufacturer retrospective MFP refunds. CMS welcomes comment from interested parties on the concept of the MTF creating and sending an electronic remittance advice to dispensing entities to reconcile the payment provided by the Primary Manufacturer's retrospective refund payments. Additionally, CMS welcomes feedback on other methods for electronic remittance advice, including Primary Manufacturer electronic remittance advices, and specific data elements for such electronic remittance advices to ensure that accounts receivables can be closed for dispensing entities.

RxParadigm Comments:

RxParadigm fully supports the suggested framework. Implementing new standards alongside the existing 835 system would impose a significant burden on pharmacies, potentially making it unfeasible. Given the diverse array of pharmacy systems, each potentially requiring a unique form apart from the 835, the task becomes daunting. Modifying the existing practice poses a risk that could escalate costs for CMS. Delaying pharmacy payments beyond 14 days exposes them to financial vulnerability and shifts the burden onto manufacturer funding. Pharmacies would then require insurance policies, further increasing costs for CMS.

Claims Adjustments and Reversals

CMS is considering how to address claim adjustments and reversals. As noted earlier, CMS Plans to explore shortening the time in which Part D Plan sponsors submit PDE data to DDPS to facilitate timely payment. CMS expects some time to elapse between the dispensing entity billing the Part D Plan and submission of clean PDE data to the MTF, and this time could allow for timely adjustments to submitted claims, such as reversals. However, CMS recognizes that adjustments and reversals could occur after the 14-day prompt MFP payment window has concluded. CMS envisions claim adjustments or reversals would entail transmission of additional data elements and reports with payment-related data when a change to original payment is warranted, based on an adjustment claim. These elements would inform the Primary Manufacturer of payments it owes or that are due based on claim adjustments. CMS has included these additional data elements (i.e., MTF internal claim number (ICN), Record ID, MTF XRefICN, Process Date, Transaction Code, and Medicare Claim Type) in Table 1 above, and believes they will assist in the facilitation of information on claim adjustments and reversals. CMS invites comments on whether CMS should recognize a certain timeframe for paying or collecting claim adjustments, whether these should be considered as offsets to future claims to a dispensing entity that was overpaid, and any additional approaches commenters may wish to see from the MTF data functionality for addressing claim adjustments.

RxParadigm Comments:

There are several methods available for handling overpayments in this scenario. Initially, the MTF and Manufacturer processes are used to track overpayment records. When new claims from the pharmacy are received, the payment for the new claim can offset the overpayment, accompanied by a corresponding 835 notification sent to the pharmacy. If the overpayment remains unresolved over a specified period (e.g., three months), existing processes within claims adjudication systems and pharmacies allow for issuing a negative bill to the pharmacy to recover the funds. To facilitate this, the pharmacy must register with the MTF, provide their banking information, and agree to the negative billing process during setup, including acceptance of legally enforceable terms and conditions.

In the standard process, pharmacies typically refrain from reversing claims for 14 to 30 days if a claim remains unpicked. Once a claim is paid, it should be treated as if the patient intends to collect the prescription imminently. Provided that reversals and adjustments are accurately documented, the 14-day prompt payment period is adequate. Any reversal should be used to offset future claims. However, if there are no future claims to offset the amount on the balance sheet for more than six months, the sum will be deducted from the dispensing entity's account.

Retrospective Pharmacy Reimbursement Calculation

If the Primary Manufacturer and a dispensing entity agree to make the MFP available via a retrospective refund that is calculated based on a reasonable proxy for the dispensing entity's acquisition cost (e.g., WAC as used in the Standard Default Refund Amount), as opposed to the dispensing entity's actual acquisition cost for that particular unit of the selected drug, then CMS will consider a retrospective refund paid pursuant to that calculation to be sufficient for the Primary Manufacturer to meet its obligation to make the MFP available to the dispensing entity. CMS is considering approaches to allow parties to notify each other and CMS that they agree a retrospective payment of the Standard Default Refund Amount is sufficient to provide access to MFP on a particular claim or category of claims. To calculate the retrospective MFP refund amount owed by the Primary Manufacturer to a dispensing entity, the parties may use a reasonable, standardized pricing metric as the dispensing entity's acquisition cost in the MFP refund amount payment calculation (as reflected below).

MFP Refund Amount = Standardized Pricing Metric – MFP

The Standard Default Refund Amount may not be appropriate when the acquisition cost of a dispensing entity is greater than the WAC of a selected drug. In this case, payment of the Standard Default Refund Amount would not be sufficient to make the MFP available to the dispensing entity consistent with the Primary Manufacturer's obligation under section 1193(a)(3) of the Act. The Primary Manufacturer could address these circumstances by making MFP refund payments that reflect the dispensing entity's higher acquisition costs for the claims. CMS is soliciting comments from interested parties on which dispensing entities may be impacted by this scenario, when the described scenario may occur, and evidence a Manufacturer and dispensing entity might review to determine acquisition costs higher than WAC.

RxParadigm Comments:

The wholesaler and pharmacy are considered qualified parties to report drugs sold over the Wholesale Acquisition Cost (WAC). There should be a mechanism allowing the pharmacy to report instances of high acquisition costs to the Manufacturer for review. If an error is identified, it will be rectified either at the Manufacturer or wholesaler level. If no error is found, the Manufacturer will be responsible for reimbursing the extra amount charged above the Wholesale Acquisition Cost (WAC) to the wholesaler and pharmacy.

Payment Facilitation

CMS has received numerous requests from various stakeholders advocating for payment facilitation, citing reasons such as standardization, predictability, and reducing burden. In Section 40.4. 4 - Options for Medicare Transaction Facilitator Payment Facilitation, CMS acknowledges that while under the Act, the Primary Manufacturer bears the sole responsibility to provide access to the MFP, CMS is considering the role the MTF could play in facilitating transactions between Primary Manufacturers and dispensing entities.

CMS is contemplating two voluntary payment facilitation options outlined in the draft guidance. The first option involves the MTF collecting banking information from dispensing entities and sharing it with Primary Manufacturers for direct payment facilitation. The second option entails the MTF receiving aggregated refund amounts from Primary Manufacturers and passing them to participating dispensing entities. CMS emphasizes that participation in MTF payment facilitation would be voluntary for both parties, and no fees would be incurred. However, CMS stresses that regardless of the option chosen, the Primary Manufacturer remains responsible for ensuring MFP availability. Interested parties are invited to provide feedback on these options, including operational concerns and additional considerations.

In Section 90.2.1, "Manufacturer Plans for Effectuating MFP" CMS outlines guidelines for Primary Manufacturers to ensure the availability of the MFP for selected drugs, including to 340B covered entities and their contract pharmacies. Primary Manufacturers must submit Plans detailing their approaches for MFP availability to CMS, at least seven months before the start of the initial price applicability year for a selected drug. CMS assesses these Plans for risk and compliance, and Plans to publish them for transparency, redacting proprietary information. Deadlines for Plan submissions are specified, with adjustments made in this draft guidance. Plans should encompass methods for reimbursement, data collection, compliance with privacy laws, and engagement with the MTF payment system if opted for. Additionally, CMS emphasizes ongoing oversight, record-keeping obligations, and procedures for updates or amendments to the Plans, ensuring compliance with the requirements set forth in the guidance.

RxParadigm Comments:

Manufacturer payment systems are set up primarily for significant monthly or quarterly payments. As such their systems are not optimized for numerous, smaller payment transactions across a wide range of entities. To offset operational hurdles if Manufacturers manage payments independently, the MTF should serve as an intermediary that mitigates the burden of managing countless different pharmacy reimbursements.

When a pharmacy chooses to participate, it should upload information regarding the designated location for payment and reconciliation file delivery in a secure server. If a Manufacturer underpays a claim or fails to pay the MTF within the 14-day payment window, the 14-day cycle must halt as a result of Manufacturer error, absolving the MTF of responsibility or fault. A

process must be built to acknowledge back receiving file and payment, then the 14-day clock starts again.

Payment Information

Information collected from the participating dispensing entity in order to facilitate payment between the Primary Manufacturer and the dispensing entity could include but would not be limited to: (1) legal business name and address; (2) Tax Identification Number (TIN) and/or National Provider Identifier (NPI); (3) financial institution details, including address and contact information; (4) financial institution routing number; (5) depositor account number with financial institution; and (6) type of registered financial account. Participating dispensing entities would need to certify that information provided is accurate and up to date. CMS would further outline contractual requirements for collecting, using, sharing, and safeguarding financial information in the effectuation of MFP refund payments for parties who voluntarily elect to participate in MTF payment facilitation and would protect interested parties' data in accordance with applicable laws. CMS is evaluating the data privacy and security implications of collecting, holding, and, if applicable, sharing interested parties' financial and securities information for purposes of MTF payment facilitation. CMS is soliciting comments on what information would be required by interested parties in either of the two options in order to efficiently facilitate payments.

RxParadigm Comments:

Implementing a secure, CMS-run website or platform where pharmacies can easily sign up and manage their banking details would enhance efficiency and streamline operations when onboarding a new pharmacy. Any updates to the pharmacy's credentials or bank account information will be uploaded to the platform. Negative billing, as described in the "Pharmacy Billing" section of our response, will also be implemented through the CMS-run website and platform. Proactive measures should be in place, where pharmacies either initiate updates themselves or are promptly contacted if a transfer fails due to outdated information.

This platform must adhere to stringent security measures, including proper IT certifications such as HIPAA, HITRUST, and PCI compliance. Since this platform will operate with the MTF, there should be a mechanism to reach out to pharmacies if payments fail due to outdated banking information. Primary and secondary contact information from pharmacies will be required for effective communication.

Complaints, Disputes and Violations – Sections 90.2 and 100.2

In Section 90.2.2 "Negotiation Programs Complaints and Disputes," CMS Plans to establish a centralized intake system to address complaints and disputes related to the MFP availability for MFP-eligible individuals and the entities providing selected drugs to them. This system is tailored to handle specific issues regarding the MFP and MTF functionality, distinct from broader feedback on the Negotiation Program. Complaints and disputes will be categorized into two tracks: disputes concerning technical aspects of the MTF process, and general complaints encompassing various concerns. CMS will review disputes and issue findings based on evidence provided, while complaints will trigger investigations into MFP availability. CMS may request supplementary information and documentation to assess complaints, with potential enforcement actions for non-compliance. The agency is exploring the scope of remediation and efficient reporting mechanisms, inviting feedback on improving the process.

CMS has the authority to impose Civil Monetary Penalties (CMPs) on Primary Manufacturers of selected drugs for noncompliance with requirements set forth in their agreements with CMS, necessary for administering and monitoring the Negotiation Program, as outlines in Section 100.2 "Violations of the Agreement". These CMPs may amount to $1,000,000 for each day of violation. Examples of substantive violations include failure to submit required data, omission of critical information, or failure to make the MFP available to eligible individuals and dispensing entities. CMS will engage in outreach and corrective action processes before considering CMP imposition. If CMPs are pursued, they will accrue for each day of violation until compliance is achieved. CMS may request additional information for compliance monitoring, with failure to comply potentially resulting in CMPs. CMS provides reminders and notifications of potential noncompliance to support compliance. Submission of false information may also result in CMPs, with the violation period calculated from the day after the established deadline for submission until compliance is achieved.

RxParadigm Comments:

Establishing a Help Desk is essential to address inquiries and provide support for stakeholders navigating the complexities of the MTF system. Additionally, the MTF can assist CMS in identifying areas potentially susceptible to auditing or penalties, enhancing compliance and accountability. For effective calculation processes, the MTF would require access to the 340B pricing database, enabling accurate assessments and informed decision-making. This collaborative approach ensures transparency, efficiency, and regulatory adherence within the reimbursement ecosystem.

SANDOZ

July 2, 2024

Submitted Electronically via IRARebateandNegotiation@cms.hhs.gov

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human & Human Services
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Comments in Response to Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 Draft Guidance

Dear Deputy Administrator Seshamani,

Sandoz Inc. (Sandoz) appreciates the opportunity to comment on the Centers' for Medicare & Medicaid Services (CMS's) draft guidance for Initial Price Applicability Year (IPAY) 2027 and manufacturer effectuation of the Maximum Fair Price in 2026 and 2027 (Draft Guidance).

Sandoz is a global leader in generic drugs (generics) and biosimilar biological products (biosimilars), committed to pioneering access to high-quality, affordable, off-patent medicines for patients. Our medicines—spanning important therapeutic areas including anti-infectives, oncology, ophthalmology, immunology, endocrinology, and multiple sclerosis—reach approximately 500 million people each year, generating substantial savings to the health-care system.

Sandoz endorses the Association's for Accessible Medicine (AAM) and The Biosimilars Forum's (Forum) comments in response to the Draft Guidance, including with respect to CMS's *ultra vires* interpretation of "marketed" in the Inflation Reduction Act (IRA). As a biosimilar developer, Sandoz is uniquely situated to discuss additional adverse consequences of CMS's position, and we submit this comment to specifically highlight how the agency's approach improperly rewards the contracting practices of reference biological product manufacturers, which are designed to wall off competition to their products.

Consistent with its IPAY 2026 Revised Guidance, CMS affirms its position that to disqualify the reference biological product from the Qualifying Single-Source Drug (QSSD) definition (and to off-ramp the product once selected), the [biosimilar] must be engaged in "meaningful competition" and the [biosimilar] manufacturer must demonstrate that it is engaged in "bona fide marketing" of the biosimilar.[1] In making such a determination, CMS may consider "whether the generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain and whether any licenses or other agreements between a Primary Manufacturer and a generic drug or biosimilar manufacturer limit the availability or distribution of the selected drug."[2] In

[1] IPAY 2027 Draft Guidance at 115.
[2] *Id.* at 116.

addition, CMS will analyze the share of generic drug or biosimilar units identified in prescription drug event (PDE) data as a percentage of total units of Part D expenditures, as well as whether manufacturers are reporting units of the selected drug as part of their average manufacturer price (AMP) reporting responsibilities under section 1927(b)(3)(A) of the Act, and the trend in reporting of such AMP units. CMS reserves the right to also use other available data and informational sources on market share and relative market competition of the generic drug or biosimilar.[3]

CMS's position on the term "marketed" is incongruent with market realities that empower reference biological product manufacturers in stifling the successful adoption of biosimilars even when they are aggressively "marketed" by biosimilar manufacturers. One of the most discussed contracting practices is the use of "rebate traps" or "rebate walls". This involves the reference biological product manufacturer, once a biosimilar competitor launches, offering substantially higher rebates on the reference biological product or even the reference biological product *plus* a portfolio of additional drugs / biological products to payers / plans sponsors, often through their contracted pharmacy benefit managers (PBMs), on the condition that the payer / plan sponsor favors their reference biological product over the competing biosimilar. In other words, the reference biological product manufacturer might offer substantially higher rebates on the reference biological product plus (hypothetically) 10 other drugs / biological products when a biosimilar competitor launches. These rebates (and again, not just for the associated reference product) can make it financially disadvantageous for payers / plan sponsors to cover biosimilars, even if the list price of the biosimilar is lower.[4] Consequently, the approach taken by CMS effectively perpetuates the existing distortions within the biological product marketplace. This is achieved by incenting manufacturers of biological products to set high list prices, which are then offset by substantial rebates, a strategy that helps them retain market share. In contrast, this approach disadvantages biosimilars, which tend to be priced more competitively with lower list prices.

Experts have further suggested that the success of this contracting approach is attributable to a systemic problem: the lack of competition in the PBM market. In a competitive market, the structure of the PBM contract would not matter as PBMs would compete for a payer's / plan sponsor's business rather than capturing a larger share of surplus in the market.[5] This indicates that the core issue may not be the contract design per se, but rather the absence of robust competition within the PBM service sector.

Whether due to exclusionary contracts between reference biological product manufacturers and PBMs, or the lack of PBM competition that enables the capture of this arbitrage by dominant PBMs, the biosimilar market faces unique challenges. CMS's current interpretation of what constitutes "marketed" is a regressive interpretation, reinforcing the very obstacles that have historically hindered the successful commercialization of biosimilars.

In short, the way CMS construes the term "marketed" deviates from the ordinary meaning of the term, improperly endows the agency with a discretionary role, and fails to acknowledge the actual conditions of the marketplace. Furthermore, CMS's own regulatory requirements – such as

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[3] *Id.*

[4] Margolis Center for Health Policy, biosimilars: Overcoming Rebate Walls (2022**),** *Duke-Margolis Center for Health Policy*, https://healthpolicy.duke.edu/sites/default/files/2022-03/biosimilars%20-%20Overcoming%20Rebate%20Walls.pdf (last visited June 8, 2024).

[5] Craig Garthwaite, The Effects of Changes to the Health Care System on Workers and Their Employers: Hearing Before the H. Comm. on Education and Labor, 116th Cong. (2019) (testimony of Craig Garthwaite), https://democrats-edworkforce.house.gov/imo/media/doc/GarthwaiteTestimony0926

limitations on mid-year formulary changes for biosimilar products without the interchangeability designation – may limit the ability of biosimilars to secure timely market penetration. Despite biosimilar manufacturers' vigorous marketing efforts, they continue to be challenged in capturing market share from the reference biological products. This difficulty is largely due to the restrictive contractual agreements that reference biological product manufacturers establish with PBMs.

Finally, CMS should base its determination with respect to biosimilar marketing on real-time information (e.g., transaction data at the "switches"), to avoid making critical decisions based on statistics such as PDE data, which are further complicated by PBM contracting practices and delays associated with formulary access policies and claims "cleaning" / submission processes.

Sandoz appreciates the opportunity to comment on CMS's Draft Guidance. We look forward to continuing to work with the agency on implementation of the Medicare Drug Price Negotiation Program to help ensure Medicare beneficiaries' timely access to high-quality, affordable, off-patent medicines. If you have any questions about these comments, please do not hesitate to contact Mary Jo Carden, Heady of Policy at mary_jo.carden@sandoz.com.

Sincerely,

DocuSigned by:
Leslie Pott
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Leslie Pott
VP, Corporate Affairs
Sandoz, North America

3800 Kilroy Airport Way
Suite 100, P.O. Box 22616
Long Beach, CA 90801-5616

TEL 562.989.5100
FAX 562.989.5200

VIA ELECTRONIC SUBMISSION TO IRARebateandNegotiation@cms.hhs.gov

July 1, 2024

Deputy Administrator Meena Seshamani, M.D., Ph.D.
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Deputy Administrator Seshamani:

SCAN Health Plan, Inc. (SCAN) is pleased to submit comments in response to the Draft Guidance on the Medicare Drug Price Negotiation Program. We appreciate CMS seeking feedback as you consider implementation of the 2026 MFPs along with the negotiation process for IPAY 2027.

SCAN Group is a mission-driven, non-profit organization deeply committed to developing and implementing new ways to deliver evidence-based, patient-centered care to older adults. Founded in 1977 by seniors determined to improve access to needed care and services, SCAN's mission is Keeping Seniors Healthy and Independent.

SCAN is Committed to Keeping Seniors Healthy and Independent

SCAN Group executes on our mission across our organization, including Independence at Home (a SCAN community service), and myPlace Health (a Program for All-Inclusive Care for the Elderly, known as PACE, center launched in partnership with Commonwealth Care Alliance), and SCAN Health Plan.

SCAN Health Plan, one of the nation's foremost not-for-profit Medicare Advantage (MA) plans, serves nearly 280,000 members across California, Arizona, New Mexico, Nevada, and Texas. In a market dominated by national, for-profit Medicare Advantage plans, SCAN Health Plan provides seniors a mission-driven, non-profit alternative focused on meeting their individual needs. SCAN proudly offers over a dozen plan options, including the country's first plan specifically designed for LGBTQ+ members (SCAN Affirm), a plan designed for women by women (SCAN Inspired), and California's only fully integrated dual-eligible special needs plan.

SCAN Health Plan determines our own formulary to ensure our members have access to the right treatments at the right time. Our high quality ratings reflect this effort, with SCAN's largest contract earning 4+ stars on antidiabetic, antihypertensive, and statin adherence measures in addition to 5 stars on completion of medication therapy management.

SCAN's Response to the Draft IPAY 2027 Medicare Negotiation Guidance

3800 Kilroy Airport Way
Suite 100, P.O. Box 22616
Long Beach, CA 90801-5616

TEL 562.989.5100
FAX 562.989.5200

40.4.1 Medicare Transaction Facilitator Data Facilitation

CMS states that it is evaluating whether the current 30-day window for Part D plans to submit PDE records should be shortened to seven days. CMS is also considering how to address claim adjustments and reversals, recognizing that they could occur after the 14-day MFP payment window has concluded.

SCAN Comments: SCAN currently submits PDEs to CMS every seven days. We believe that other plans will likely be able to operationalize a seven-day reporting timeframe as well.

To implement a seven-day PDE reporting timeframe, however, CMS would need to adjust other PDE requirements. Specifically, CMS currently requires plans to submit the reimbursement date in the PDE, effectively requiring claim payment prior to PDE submission. As claim payment occurs weekly or biweekly, requiring a payment date prevents submission of all PDEs within seven days. If CMS removed the PDE data field requiring a reimbursement date, or if CMS allowed plans to fill in future dates, SCAN could operationalize a seven-day PDE reporting timeframe.

40.4.2 Nonduplication with 340B Ceiling Price

CMS states that it will not require 340B covered entities or dispensing entities to proactively indicate on a submitted claim that the claim is 340B-eligible.

SCAN Comments: Currently, identification of 340B claims is highly ambiguous, requiring aggressive negotiation and contracting with PBMs and other entities. **SCAN recommends that CMS mandate dispensing entities submit all 340B claims with an indicator.** Plans would include this indicator in the PDE submission process, and the 340B eligibility of a claim would be shared with manufacturers for reconciliation with their obligation to provide access to the MFP. Including a claims indicator would ensure the smoothest, most transparent, possible process such that manufacturers and dispensing entities would abide by the statutory prohibition on duplicate discounts between 340B and MFP.

110 Part D Formulary Inclusion of Selected Drugs

Medicare Part D plans like SCAN are required to include covered Part D drugs selected for negotiation on Part D formularies. Because the selected drug includes all dosage forms and strengths to which the MFP applies for initial price applicability year 2027, CMS states that formularies must include all such dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect. CMS also indicates that for contract year 2027, it will not impose explicit tier placement or utilization management requirements that apply uniformly across selected drugs in all formularies. However, CMS states that it will use its formulary review process to assess: (1) any instances where Part D sponsors place selected drugs on non-preferred tiers; (2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class; (3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or (4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class.

As part of the contract year 2027 Part D formulary review and approval process, CMS states that it will expect Part D sponsors to provide a reasonable justification to support the submitted plan design that includes any of the practices noted above during the annual bid review process. This justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of

3800 Kilroy Airport Way
Suite 100, P.O. Box 22616
Long Beach, CA 90801-5616

TEL 562.989.5100
FAX 562.989.5200

the selected and non-selected drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements. CMS states that it will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will approve a Part D plan bid submitted by a Part D sponsor only if the plan benefit package complies with those requirements.

SCAN Comments: Medicare Part D coverage decisions are first and foremost based on clinical factors. When SCAN designs our formularies, we prioritize drugs that are safer and more effective than others in their class. For example, SCAN has designed a formulary with a sixth tier. On this tier, we ensure that our members have access to highly utilized, highly effective drugs at a copay of no more than $11 for a 30-day supply. SCAN also tailors its formulary to meet the needs of specific populations, such as our SCAN Affirm LGBTQ+-focused product and our SCAN Inspired women-focused product.

SCAN's personalized, affordable drug benefit is only possible thanks to CMS's long held position that plans know how best to serve their members. Accordingly, we support CMS not implementing explicit tier placement or utilization management requirements applying uniformly across selected drugs in all formularies for 2027. This decision is consistent with statute, which requires only that all selected drugs be on formulary, not imposing any specific limitations on plans.

CMS not having explicit tier placement or utilization management requirements is also in accordance with SCAN and other plans' duty to prioritize clinical effects of various therapies. While plan formularies are required to include all dosage forms and strengths of the selected drug that constitute a covered Part D drug and for which the MFP is in effect, selected drugs may not be the clinically preferred treatment in all indications. Given that negotiation eligibility is based, in part, on the time a drug has been on the market, many of the negotiated drugs may be older and no longer be the preferred standard of care or the best option for new patient initiation.

In circumstances with minimal clinical differentiation between similar products, affordability becomes a vital consideration for plans trying to preserve low-cost access to important drugs. Rebates on Part D drugs, which plans receive in exchange for preferred formulary placement or decreased utilization management, lower Part D premiums and counter increased list prices for Part D drugs. SCAN, for example, has already reduced out of pocket costs to no more than $11 for over a dozen popular drugs with our Tier 6 benefit. We also have addressed affordability through deprescribing recommendations, maximizing safety and minimizing complexity for SCAN beneficiaries with over 50,000 recommendations. SCAN's affordability efforts have lowered costs in an environment in which drug prices continue to increase.

SCAN is concerned that CMS will require plans to cover selected drugs in ways that are not clinically beneficial and that are detrimental to member access and affordability. For example, some selected drugs have indications for which they are not clinically the best product, yet plans will have to cover them for these indications under current guidance. Plan P&T committees have statutory latitude to determine how best to abide by clinical guidelines for selected drugs; CMS requiring coverage of *all* forms and dosage strengths could put these P&T committees in a position where they must give non-clinically-based access determinations.

Additionally, SCAN is concerned that while CMS indicates a test for plan coverage of selected drugs, the agency has not committed to a standardized, quantitative methodology. We are concerned that different formulary review pharmacists will interpret CMS's test differently, leading to unfair distinctions between plans. Finally, SCAN is very concerned that CMS coverage requirements, especially ambiguous ones like these, will lead to higher premiums as net price becomes a smaller consideration.

In future guidance, SCAN encourages CMS to propose for comment the criteria it will use for the clinical justification process. Transparency and standardization in CMS evaluations of clinical

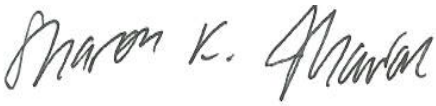
3800 Kilroy Airport Way
Suite 100, P.O. Box 22616
Long Beach, CA 90801-5616

TEL 562.989.5100
FAX 562.989.5200

justifications associated with formulary placement of selected drugs versus non-selected drugs will help ensure consistency in its formulary review and approval process.

Again, thank you for the opportunity to provide input as CMS continues to implement the Medicare Drug Price Negotiation Program. Please consider SCAN a resource as CMS evaluates how to improve access and affordability for seniors, and please do not hesitate to contact me with any questions regarding these comments.

Sincerely,



Sharon Jhawar, PharmD, MBA, BCGP
Chief Pharmacy Officer
sjhawar@scanhealthplan.com

SENIOR CARE PHARMACY COALITION
1700 Pennsylvania Avenue, NW
Suite 900 | Washington, DC 20006
202.827.9987

July 2, 2024

Submitted via Electronic Filing: ***IRARebateandNegotiation@cms.hhs.gov***

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

The Senior Care Pharmacy Coalition ("SCPC") appreciates the opportunity to provide comments on the May 3, 2024 memorandum issued by the Centers for Medicare & Medicaid Services ("CMS"), entitled *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (the "Draft Guidance"),[1] particularly §§ 40 and 90 which concern Medicare Transaction Facilitators (MTFs) and the process by which manufacturers must make payments to pharmacies to reconcile the difference between acquisition costs and MFP. We appreciate the agency's thoughtful consideration of our comments, given the complexities of ensuring that manufacturers meet their obligation to pharmacies under the Inflation Reduction Act (IRA), the challenging financial and operational circumstances which LTC pharmacies face, and the adverse financial impact the IRA will have on LTC pharmacies.

About SCPC: SCPC is the only Washington-based organization exclusively representing the interests of long-term care (LTC) pharmacies. SCPC's membership includes 75% of all independent, closed-door LTC pharmacies. Our members serve one million residents daily in LTC facilities across the country. Given the distinct characteristics of the LTC patient population and the enhanced clinical and other responsibilities of LTC pharmacies, we offer unique perspectives on CMS' initiatives and proposals, particularly how Medicare Prescription Drug Benefit (Part D) policies and requirements impact Part D enrollees with institutional level of care needs and the LTC pharmacies that serve them.

[1] 88 Fed. Reg. 37229 (May 6, 2024).

LTC Pharmacy Context: While SCPC strongly supports lower drug prices for Part D beneficiaries and other patients, we are concerned that policy-driven reductions in drug prices, particularly MFPs negotiated pursuant to the IRA, may inadvertently threaten the financial viability of many LTC pharmacies, undermining both patient access to LTC pharmacy services and the quality of LTC pharmacy services overall.

The LTC patient population is medically complex, suffers multiple impairments in activities of daily living (ADLs), has a high incidence of cognitive impairments, and relies disproportionately on prescription drugs to maintain both quality of health and quality of life. Nearly 60% of Medicare beneficiaries residing in LTC facilities have four or more cognitive impairments. More than 75% have impairments in three or more activities of daily living, and 75% suffer from cognitive impairment. These beneficiaries rely heavily on prescription drugs, with Medicare beneficiaries residing in federally defined LTC facilities averaging 12 prescriptions per year.[2] Given these needs, the Medicare and Medicaid Requirements of Participation for skilled nursing facilities (SNFs), nursing facilities (NFs), and intermediate care facilities (ICFs) impose detailed pharmacy services requirements on facilities, which they fulfill through contracts with LTC pharmacies.[3] Medicare beneficiaries with LTC needs who reside in assisted living facilities (ALFs) have similar patient characteristics.[4] In addition, CMS requires that PDPs demonstrate LTC pharmacy network adequacy independent of retail pharmacy network adequacy.[5] PDPs must demonstrate enough pharmacies capable of providing distinct LTC pharmacy services to assure that each Part D Plan's enrollees will have adequate access to LTC pharmacy services if needed.[6]

Since LTC pharmacies are closed door pharmacies that do not serve the general public and do not sell "front of store" items directly to consumers, they must rely on reimbursement from various payers to maintain financial viability. LTC pharmacies disproportionately rely on Medicare Part D, with 75% of revenues coming from Medicare Part D. Regardless of payer, LTC pharmacies have three revenues streams:

- **Generic drugs.** While generics account for more than 90% of the prescriptions LTC pharmacies dispense, the difference between acquisition costs and reimbursement for generic ingredient costs generates very little margin for LTC pharmacies. Most generics LTC pharmacies dispense are inexpensive. Although reimbursement often is higher than acquisition costs, payments are only marginally higher. Given the disproportionate market power pharmacy benefit managers (PBMs) wield on behalf of PDPs, in many cases reimbursement for generics is lower than acquisition costs.

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[2] See, ATI Advisory & Senior Care Pharmacy Coalition, Understanding the Long-Term Care Needs of the Medicare Population and the Role of Long-Term Care Pharmacies in Addressing this Need (July 2021).
[3] 42 U.S.C. § 1395i-3 (pertaining to SNFs participating in the Medicare program) & 42. U.S.C. § 1936r(b)(4)(a)(iii) (pertaining to NFs and ICFs participating in the Medicaid program). CMS has promulgated enabling regulations, 42 C.F.R. §§ 483.1-482-95.
[4] Id.
[5] Medicare Prescription Drug Benefit Manual, Chapter 5, § 50.5 [Long-Term Care (LTC) Pharmacy Access.
[6] Id., at § 50.5.2 "Performance Criteria for Network Long-Term Care Pharmacies (NLTCPs)."

- **Dispensing Fees.** Regardless of payer, dispensing fees are consistently lower than the cost of providing LTC pharmacy services. Recent third-party analyses which SCPC has sponsored conclude that it costs LTC pharmacies about $15/prescription to meet the LTC pharmacy service requirements which CMS imposes, but PDPs pay less than $4/prescription. Essentially, LTC pharmacies lose roughly $11 for each prescription they dispense to a Part D beneficiary. The gap is even greater for other payers.
- **Brand Name Drugs.** While 5% or less of prescriptions LTC pharmacies dispense are branded drugs, margins on these drugs sustain LTC pharmacies financially. This reality is yet another example of the hidden cost-shifting which unfortunately is all too prevalent across the nation's healthcare system. Eight of the ten drugs subject to price negotiation for 2026 are heavily prescribed to the LTC patient population. SCPC estimates that, if CMS negotiates 2026 MFPs at the highest amount the IRA allows, more than 90% of LTC pharmacies are likely to have negative operating margins in 2026.

While LTC pharmacies rely on margins from branded drugs to maintain economic viability, LTC pharmacies are not high margin businesses. There are an estimated 1,200 LTC pharmacies in the country. Ten or fewer have annual revenues greater than $500 million and have net operating margins of less than 10%. Fifty or fewer have annual revenues between $100 million and $500 million and have net operating margins of less than 5%. Roughly 1,100 – more than 90% of all LTC pharmacies - have net operating margins of less than 2%.

SCPC strongly supports lower drug prices for consumers and understands that major legislation like the IRA may have unintended consequences. We also appreciate that the IRA may not grant CMS the statutory authority to address the potential impact on LTC pharmacies directly. Nonetheless, CMS must recognize the challenges LTC pharmacies face due both to ongoing and increasing PDP/PBM abuses and the impact of policy-driven price reductions like those required by the IRA. Given the broader context, it is essential that the process CMS requires to assure that manufacturer payments to pharmacies to reconcile the difference between acquisition costs and MFP be as streamlined and expedited as possible.

Specific Comment and Recommendations

Prospective v. Retrospective Payment Resolution. The Draft Guidance suggests that there could be two options available to manufacturers to ensure payments at MFP prices: (1) the manufacturer may sell the drug to the pharmacy at the MFP, in which case no reconciliation is needed; or (2) the manufacturer may sell the drug to the pharmacy at WAC, in which case the manufacturer must pay the pharmacy the difference between WAC and MFP once the drug has been dispensed to a Part D beneficiary. Draft Guidance at 36. It is highly unlikely that manufacturers will sell drugs subject to negotiation at MFP since the negotiated price applies only to Medicare Part D beginning in 2026 and to Medicare Part B beginning in 2028 because manufacturers have incentives to sell at higher prices to other payers and disincentives to sell at different prices based on anticipated buyers. In addition, as CMS notes in the proposed guidance, if manufacturers continue to sell at WAC then it will remain possible that wholesalers and group purchasing organizations will negotiate discounts with manufacturers, a portion of which will be

shared with pharmacies. We recognize that the IRA may not have given CMS statutory authority to require that manufacturers sell drugs subject to negotiated prices at WAC rather than MFP. **We therefore recommend that CMS finalize the guidance in ways which incentivize manufacturers to sell drugs at WAC rather than MFP.**

The MTF Role. CMS proposes to establish its own MTF (the "CMS MTF") to facilitate manufacturer payments to pharmacies to reconcile the difference between the pharmacy's acquisition cost and the MFP. Since the Draft Guidance pertains only to 2026 and 2027, it is unclear whether CMS intends to maintain the CMS MTF in subsequent years.

The CMS MTF would provide manufacturers with information sufficient to determine that an MFP drug has been dispensed to an individual eligible to receive MFP at the point of sale (i.e., a Part D enrollee). All manufacturers would be required to work with the CMS MTF for this purpose. In addition, the Draft Guidance proposes that the CMS MTF could serve two additional roles: (1) to collect banking information from pharmacies and share it with manufacturers so that the manufacturers can directly pay pharmacies the difference between WAC or actual acquisition cost and MTF; or (2) to serve as the "bank," with manufacturers depositing funds into the MTF, and the MTF reimbursing pharmacies as claims are presented. Draft Guidance at 53, 55-58. We understand that CMS has interpreted the IRA as preventing the agency from requiring that manufacturers use the CMS MTF for either of these additional roles.

SCPC strongly supports creation of the CMS MTF and requiring, to the fullest extent allowed by statute, and otherwise aggressively incentivizing manufacturers to use the CMS MTF to assure that manufacturers receive timely notice that a drug subject to MFP has been dispensed to an eligible Part D enrollee, that pharmacies provide banking information so manufactures may make timely payments to pharmacies, and to serves as the "bank" that will process payments from manufactures to pharmacies. Multiple MTFs in addition to the CMS MTF will create chaos for LTC pharmacies that will add confusion and delays that LTC pharmacies simply cannot sustain. Simply put, it would be a logistical nightmare for individual manufacturers to use multiple MTFs to process reconciliation payments to more an estimated 45,000 retail pharmacies and 1,200 LTC pharmacies and would impose a substantial and costly administrative burden on pharmacies.

The Draft Guidance makes clear that CMS will bear the cost of operating its MTF and that, if manufacturers use the CMS MTF, pharmacies may not be charged for processing payments. The Draft Guidance does not discuss whether pharmacies may be assessed transaction fees if manufacturers do not use the CMS MTF to process payments. We strongly recommend that CMS clarify that, if manufacturers choose to process payments through MTFs other than the CMS MTF, they nonetheless must assure that pharmacies are not charged for processing reconciliation payments.

Finally, we note that the Draft Guidance pertains only to 2026 and 2027, such that CMS provides no clarity regarding the longevity of the CMS MTF. It is essential to the efficient operation of the reconciliation process that, once established, the CMS MTF be maintained beyond 2027.

We therefore recommend that CMS (1) finalize the Draft Guidance require, to the fullest extent possible, that manufacturers use the CMS MTF to confirm that an MFP drug has been dispensed to an eligible enrollee, to collect relevant banking information, and to manage payments from manufacturers to pharmacies; (2) clarify that pharmacies may not be charged transaction or processing fees regardless of the MTF on which a manufacturer relies; and (3) that the CMS MTF will remain operational after 2027.

Timing of Reconciliation Payments. The IRA requires that manufacturers make reconciliation payments to pharmacies within 14 days of receiving confirmation that an MFP drug was dispensed to a patient eligible for MFP. The Draft Guidance acknowledges this requirement, with the caveat that the 14-day payment requirement must be consistent with other Part D prompt pay requirements. Draft Guidance at 37. CMS warns that the operational aspects of MFP reconciliation may differ from Part D payment systems, and payment may be delayed, resulting in a 45-day or longer process due to the delay in the Part D Plan submitting the Prescription Drug Event (PDE). Draft Guidance at 42-43. SCPC is deeply concerned that the potentially substantial delay between the date on which a PDP approves a claim and the date upon which manufacturers must provide reconciliation payments will create significant cash flow problems for LTC pharmacies that could threaten timely patient access to essential medications, and urge CMS to take all administrative steps within its statutory authority to streamline the process and accelerate reconciliation payments to LTC pharmacies.

We strongly urge CMS to rearrange its proposed reconciliation process, eliminating the need to await the Part D Plan (PDP) submission of a PDE file, and instead require the PDP to directly submit a transaction to the MTF as soon as the claim is adjudicated, so that payment can be made from the manufacturer (through the MTF) to the pharmacy within seven (7) days. In this era of Part D electronic claims submission, including CMS's recent adoption of the new NCPDP 2023011 Script by January 1, 2025, there is no reason the MTF must await CMS receiving a PDE from a Plan and verifying the PDE before the MTF process can begin. Rather, in the same way that a Plan receives an electronic claim from the pharmacy, the Plan can readily submit that claim once adjudicated to the MTF which can initiate payment. We urge CMS to adopt such a streamlined process to mitigate the significant cash-flow challenges that LTC (and other) pharmacies will experience due to the delays in the reconciliation process.

CMS proposes a convoluted process whereby manufacturers will determine that an MFP drug has been dispensed to an eligible individual. Currently, once a PDP approves a Part D claim, it has 30 days to submit a PDE to CMS' Drug Data Processing System (DDPS). CMS proposes that, once the DDPS verifies a claim, the DDPS will send information presumably sufficient to demonstrate that a drug subject to MFP has been dispensed to an individual eligible for the MFP. CMS also proposes that the CMS MTF will share such information with the manufacturer. [7] The manufacturer then must conclude that it has information sufficient to determine that a drug subject to MFP has been dispensed to an eligible individual. The manufacturer's determination

[7] CMS notes that patient-specific information will not be submitted to the CMS MTF, such that manufacturers only will receive aggregate dispensing information but not patient-specific utilization data. Draft Guidance at 42. Using the field numbers indicated above specific to each claim will not disclose patient-specific information.

is the event which triggers the 14-day payment period. CMS acknowledges that, in a best-case scenario, the time period between a PDP approving a claim and the manufacturer making a reconciliation payment to a pharmacy is as long as 44 days.

However, the Draft Guidance proposes a series of intermediate steps that could lengthen this best-case scenario significantly. We note with concern that the Draft Guidance is silent on the timeframes within which (1) DDPS must verify a claim after it receives the PDE from a PDP; (2) DDPS must transmit relevant information to the CMS MTF once it verifies a claim: (3) the CMS MTF must transmit relevant information to the manufacturer; and (4) the manufacturer must determine that the information received from the CMS MTF is sufficient to determine that a drug subject to MFP has been dispensed to an individual eligible to receive MFP pricing. SCPC urges CMS to establish specific deadlines by which each actor – DDPS, the CMS MTF, and the manufacturer – must complete each step in this process. We also urge that CMS assure that all relevant exchanges of information be done such that the process is instantaneous for routine claims.

We appreciate that CMS has specifically asked for comments on shortening the period within which a PDP must submit PDE data from thirty days to seven days. SCPC strongly supports shortening this period to no more than seven days. However, while this could shorten the timeline significantly, and SCPC supports the proposal, it would not eliminate the other delays inherent in the proposed process, underscoring the importance of streamlining the process as discussed above. Therefore, we also recommend that, instead of the cumbersome process of waiting until the PDP submits the PDE to the DDPS, which must then verify the claim and send appropriate information to the CMS MTF, which in turn sends appropriate information to the manufacturer, CMS should require that the PDP submit the PDE to both the DDPS and the CMS MTF simultaneously, thereby eliminating unnecessary and potentially time-consuming intermediate steps that could slow the period between the PDP approving a claim and the manufacturer making a reconciliation payment to a pharmacy. Shortening the period within which the PDP must submit a PDE to seven days, coupled with simultaneous submission to the CMS MTF and instantaneous electronic transmission to manufacturers of information sufficient to confirm that a drug eligible for MFP pricing was dispensed to an individual eligible to receive MFP pricing would address the cash flow concerns of LTC pharmacies to the fullest extent allowable under the statutory authority the IRA grants to CMS. We urge the agency to exercise full authority to protect all pharmacies from unnecessary process-driven delays in receipt of reconciliation payments.

We therefore recommend that CMS simplify the process by which the manufacturer receives information sufficient to conclude that an MFP drug has been dispensed to an eligible enrollee such that the period between PDP approval of a claim and manufacturer payment to the dispensing pharmacy be as short as possible. In particular, we recommend that CMS (1) require PDPs to submit PDEs to the DDPS and the CMS MTF simultaneously; (2) require PDPs to submit PDEs to both DDPS and the CMS MTF within seven days of approving the claim; and (3) require the CMS MTF to submit information to manufacturers immediately upon receipt of PDEs from PDPs.

Standard Default Payment Amount. The IRA specifies that manufacturers must pay pharmacies the difference between acquisition cost of the drug and the MFP. Although the IRA did not grant CMS the statutory authority to determine acquisition cost, the Draft Guidance nonetheless acknowledges that manufacturers sell most branded drugs at WAC and recommends that manufacturers use WAC as the default basis for reconciliation rather than actual acquisition costs. Draft Guidance at 40-41. We urge CMS to adopt this default approach and incentivize manufacturers to use the default approach.

It would be difficult, time-consuming, administratively burdensome, and costly for pharmacies to determine the actual acquisition cost of a particular drug dispensed to a specific individual. Acquisition costs may vary over time due to the vagaries of the prescription drug supply chain. Pharmacy inventory management systems may not be equipped to determine acquisition costs of the specific pills, tablets, or capsules dispensed to a specific person at a specific time. CMS acknowledges this reality. Draft Guidance at 50. Even if such information were readily available, no systems are in place for pharmacies to provide such information to PDPs, MTFs, CMS, or manufacturers, since there is no NCPDP data field that contains this information. CMS would have to develop a separate process whereby pharmacies would report such information, and as noted CMS already has acknowledged that pharmacies simply cannot obtain such information. Were such a process viable, moreover, it undoubtedly would impose significant and costly administrative burdens on pharmacies and would result in additional delays that would exacerbate the cash flow problems discussed above. The only practical reconciliation metric is the "default refund amount" – the difference between WAC and the MFP at the time the drug is dispensed. Draft Guidance at 51. We urge CMS to require all reconciliation payments to be at the Standard Default Refund Amount – WAC minus MFP.

CMS has also suggested that it may allow a primary manufacturer to "choose to refund an amount different than the Standard Default Refund Amount. Draft Guidance at 52. We strongly urge the agency to withdraw that suggestion. For the reasons stated above, all reconciliation payments should be at the Standard Default Refund Amount.

CMS also asks whether there should be a process which would require manufacturers to use actual acquisition cost when acquisition cost is greater than WAC. In the experience of SCPC members, such situations are rare. We therefore urge CMS to use the Standard Default Refund Amount (i.e., WAC) in these situations, rather than attempt to create a process by which pharmacies would be required to determine and report actual acquisition costs. As noted above, it could prove impossible to create such a system, regardless of whether actual acquisition costs be above, below or at WAC.

We therefore recommend that, to the fullest extent legally permissible, CMS require that manufacturers use the Standard Default Refund Amount (i.e., WAC) as the basis for making payments to pharmacies to reconcile the difference between acquisition costs and MFP in all circumstances.

Claims Reconciliation. The Draft Guidance offers little insight into a pharmacy's ability to track and reconcile manufacturer payments to actual claims. We appreciate that: "CMS anticipates the introduction of new NCPDP values on claim responses from Part D plan sponsors that will allow dispensing entities to be made aware of specific claims that were priced at or below the MFP amount and therefore be able to create an accounts receivable for anticipated manufacturer retrospective refund payments, as applicable," Draft Guidance at 47. However, NCPDP has not yet created such codes and there is no certainty that they will be in place before January 1, 2026, and the degree to which such codes will prove sufficient for pharmacies to determine whether manufacturers have paid appropriately is unknown and it is uncertain. We also acknowledge that the Draft Guidance contemplates an expected MTF "electronic remittance advice" that will be sent to dispensing entities, Draft Guidance at 60, but the Draft Guidance provides no details concerning the information to be included in such a remittance advice. Assuming that pharmacies can even create a necessary "accounts receivable" in their systems (which will be a significant administrative burden created by the IRA), moreover, it is unclear how the manufacturer payment will ever be able to be linked to that receivable or claim because the manufacturer will not have a claim number to reference or whether the anticipated "electronic remittance advice" will allow for information to be exchanged.

Regardless of the processes used or developed, however, it is essential that the pharmacy have access to information sufficient to determine whether it has received an appropriate manufacturer reconciliation payment for instance in which it dispenses an MFP drug to an eligible beneficiary. Absent such information, it will be impossible for a pharmacy to determine whether it has been reimbursed appropriately for MFP drugs dispensed to eligible beneficiaries.

We also believe that it would be more efficient and effective to use existing data fields rather than relying on a third party to create new fields. Currently, each individual pharmacy claim includes a specific set of NCPDP fields unique to each claim that allows the claim to be identified once the prescription is dispensed. The relevant NCPDP D.0 fields are:

Field #	Description
201-B1	Service Provider ID (NPI)
401-D1	Date of Service
402-D2	Prescription Number
403-D3	Fill Number

The pharmacy currently reports these fields to the PDP. Once the PDP approves a claim, the PDP could report these fields directly and immediately (whether through an expedited PDE or otherwise) to the CMS MTF or other MTFs. Similarly, an MTF could use the same fields to advise the pharmacy that the manufacturer has made a reconciliation, which would expedite the process allowing the pharmacy to "close out the open transaction." Draft Guidance at 57. At minimum, pharmacies, manufacturers, and an MTF, should have information sufficient to track and reconcile payments at the individual claims level. Using the existing fields noted above as described would efficiently allow the MTF and the pharmacy to reconcile payments and close the claim.

We therefore recommend that CMS use existing data fields and streamline the reporting process as described above to assure that pharmacies have information sufficient to reconcile manufacturer payments at the individual claims level, to streamline the manufacturer-pharmacy reconciliation process most effectively, and to reduce the delay between PDP approval of a claim and manufacturer payment to pharmacies.

Transaction Costs. The Draft Guidance clarifies that if manufacturers use the CMS MTF, pharmacies may not be charged for processing payments. Draft Guidance at 53. The Draft Guidance, however, does not discuss whether pharmacies may be assessed transaction fees if manufacturers do not use the CMS MTF to process payments. CMS must clarify that, regardless of the MTF a manufacturer selects to process payments, pharmacies may not be charged any administrative, transaction, "switch" or service fees by manufacturers, MTFs, or other entities that may be required to provide information or perform services pursuant to implementation of the manufacturer reconciliation provisions, specifically but not exclusively including PDPs and the PBMs with which they contract to administer Part D coverage.

We therefore recommend that CMS clarify that MTFs, manufacturers, PDPs or PBMs may not impose any fees or charges on pharmacies to process reconciliation payments from manufacturers to pharmacies.

Reliance on PDEs. We have noted in the context of other recommendations that CMS need not and should not rely on PDEs as part of the process by which manufacturers receive information sufficient to conclude that an MFP drug has been dispensed to an eligible beneficiary. The Draft Guidance proposes that a PDP's submission of PDE to the DDPS should be the first step in the reconciliation process. Draft Guidance at 40. We urge CMS to abandon PDE submission for this purpose, not only for the reasons discussed earlier but also because an estimated 10% of PDEs contain errors that require reconciliation between CMS and PDPs. Simply stated, pharmacy reimbursement should not be dependent upon how accurately a PDP completes a PDE and whether it timely submits the PDE to CMS. Rather, CMS should require PDPs to transmit the relevant information directly to the MTF immediately upon approval of a claim for an MFP drug. There is no reason such transmission could not occur instantaneously upon approval of a claim, particularly following adoption of the NCPDP 2023011 standard. There is an existing set of discrete codes that could readily be used for the MTF process, such that PDE reports are not needed.

We therefore recommend that CMS abandon reliance on PDEs to trigger the manufacturer reconciliation process in favor of the more streamlined approach detailed in the foregoing comments.

Audits. PBMs administering PDPs frequently conduct audits of LTC pharmacies, and such audits may result in retroactive denials of paid claims, thereby requiring pharmacies to reimburse PDPs for those claims. Audits typically do not occur during the relevant plan year, and PBMs may conduct such audits well after the close of a plan year. The Draft Guidance is silent on manufacturer reconciliation payments for claims that are reversed on audit.

CMS should consider carefully how to address this issue. While some claims undoubtedly are mistakenly approved, PBMs routinely abuse the audit process to force LTC pharmacies either to incur administrative burden and substantial cost to contest claims reversed during audit, or simply accept reversals as less costly than contentious engagement with unresponsive auditors and inevitable arbitration necessary to challenge improper reversals. If LTC pharmacies must also repay manufacturers for reconciliation payments when PBMs reverse payment for claims PDPs previously approved, it would require a similar and similarly cumbersome and costly process which LTC pharmacies could ill-afford.

We therefore recommend that CMS specify how reconciliation payments will be handled with respect to PDP/PBM audits and assure that LTC pharmacies are not subject to burdensome and time-consuming processes as a result.

Dispute Resolution. The Draft Guidance addresses cases where the manufacturers fail to make timely payment or reconcile between acquisition cost and MFP. Draft Guidance at 54, 113-114. CMS proposes a centralized "complaint process" by which pharmacies may submit unresolved claims to CMS or the MTF, such that the MTF may determine whether a payment was late or not made at all. However, CMS suggests it does not have the legal authority to compel manufacturers to timely make payment or any payment, such that the dispute process will only monitor general compliance. The Draft Guidance does note that CMS has the legal authority to issue civil monetary penalties (CMPs) of up to $1 million per each day of violation. This is a cramped and insufficient approach to assuring that manufacturers make timely reconciliation payments to pharmacies and would create substantial opportunities for manufacturers to subvert the intent of the IRA.

First, CMS does have the statutory authority to compel manufacturers to make timely reconciliation payments. The IRA gives the Secretary authority to establish "procedures to carry out the provisions of this part, as applicable, with respect to—(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title," which clearly encompasses the provisions of Section 1193(a)(3)(A) and includes manufacturer reconciliation payments.[8] Under this statutory authority, CMS could create procedures to ensure timely payments to pharmacies. In addition, CMS could require that any contracts or agreements between a manufacturer and an MTF include a provision by which manufacturers agree to make timely payments to pharmacies and could grant CMS the authority to assure prompt payment through guidance.

Second, use of CMPs is inadequate to assure that pharmacies receive the reconciliation payments that the IRA requires. The Draft Guidance offers no criteria pursuant to which CMS would impose CMPs. Should CMS do so, of course, the manufacturer could appeal the imposition of CMPs, adding potentially substantial delay before payment of penalties. CMPs, moreover, are paid to the federal government, not directly to pharmacies, such that pharmacies would not receive reconciliation payments from manufacturers, contrary to the specific language and clear intent of the IRA.

[8] 42 U.S.C. § 1196(a)(3)(A),

We therefore recommend that CMS rely on its statutory authority under § 1196(a)(3)(A) to establish procedures to require that manufacturers make timely reconciliation payments to pharmacies.

MTF Transparency. While CMS may incentivize or encourage manufacturers to use the CMS MTF for claims payment purposes, the Draft Guidance underscores the fact that manufacturers may choose to use alternative MTFs for these purposes. To assure that pharmacies receive prompt and accurate reconciliation payments from manufacturers and to minimize potential abusive practices akin to those employed by PBMs on behalf of PDPs, we urge CMS to make all MTF information and processes transparent to pharmacies which would better empower pharmacies to track claims and payments. CMS should create a "read only" portal allowing pharmacies access to information at an individual claims level to afford pharmacies the ability to determine status of manufacturer payments and to otherwise track claims.

We therefore recommend that CMS provide MTF transparency to pharmacies.

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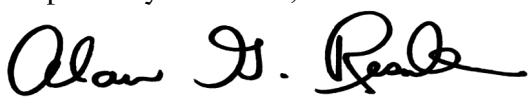
Thank you for your consideration. If you have questions or wish to discuss our comments, please feel free to contact me at arosenbloom@seniorcarepharmacies.org or (717) 503-0516.

Respectfully submitted,



Alan G. Rosenbloom
President & CEO
Senior Care Pharmacy Coalition

SUBMITTED IRARebateandNegotiation@cms.hhs.gov

June 24, 2024

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Supernus Pharmaceuticals ("Supernus" or "The Company") appreciates the opportunity to submit these comments in response to the Medicare Drug Price Negotiation Program Draft Guidance for 2027. Supernus is a biopharmaceutical company with 30 years of experience focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. Supernus strives to be a leader in the CNS industry by specializing in medicines in neurology and psychiatry to improve the lives of patients suffering from diseases of the central nervous system.

Supernus appreciates the efforts of the Centers for Medicare and Medicaid Services (CMS) in implementing the various provisions of the Inflation Reduction Act (IRA), including this draft guidance for the Medicare Drug Proce Negotiation Program and urges CMS to ensure beneficiary access to needed medications is not jeopardized by the use of inappropriate utilization management requirements by Part D sponsors. Supernus believes this can be achieved through increased transparency during the development of formularies and tiering placements of medications by Part D sponsors during the annual bidding process. This includes requiring Part D sponsors make formulary justification statements submitted to CMS during the formulary review process available to manufacturers directly impacted by a formulary and/or tiering determination.

We provide the following comments for your consideration.

Grant Manufacturers Access to Plan Sponsor Formulary Justification Statements

In "Part 110. Part D Formulary Inclusion of Selected Drugs" of the Medicare Drug Price Negotiation Program Draft Guidance for Initial Price Applicability Year 2027, CMS states that the CMS formulary review process is used to assess "Medicare Part D plans' compliance with all applicable formulary requirements." Relevant to the drugs selected for negotiation, "CMS will use its formulary review process to assess:

1) any instances where Part D sponsors place selected drugs on non-preferred tiers;
2) any instances where a selected drug is placed on a higher tier than non-selected drugs in the same class;
3) any instances where Part D sponsors require utilization of an alternative brand drug prior to a selected drug (i.e., step therapy); or
4) any instances where Part D sponsors impose more restrictive utilization management (i.e., step therapy and/or prior authorization) for a selected drug compared to a non-selected drug in the same class."

Part D plan sponsors who include any of these practices within their plan design will be expected to "provide a reasonable justification to support the submitted plan design." Supernus supports a robust formulary review process by CMS for all Part D sponsor formulary determinations, including for those drugs selected for negotiation as the changing dynamics in the Part D program brought about by the IRA could inadvertently lead to formulary decisions based on non-clinical reasoning. Such decisions could negatively impact the ability of beneficiaries to access the most clinically appropriate medication as determined by their prescriber, leading to increased wait times and prescription costs, poorer medication adherence and reduced health outcomes.

Formulary determinations that do not include an appropriate clinical justification also impact manufacturers' insight into formulary decisions, which may adversely affect beneficiaries. Manufacturers may have reduced ability to anticipate beneficiary needs and pursue responsive innovation due to the influence of formulary decisions on the utilization of a drug. Additionally, manufacturers do not have control over formulary designations and may incur unfavorable treatment solely for being a negotiation selected drug. Increased transparency surrounding formulary decision making would encourage Part D sponsors vigilance in making appropriate formulary determinations.

To ensure a more transparent formulary review process, Supernus is requesting that pharmaceutical manufacturers have access to these formulary justification statements for which a manufacturer's negotiation-selected drug is the subject of any of the previously listed formulary tiering practices.

Clarify within the Final Guidance that Manufacturers will be Granted Access to Plan Sponsor Formulary Justification Statements

Supernus Pharmaceuticals requests that CMS clarify within the Final Guidance that pharmaceutical manufacturers will be granted access to the plan sponsor formulary justification statements for which their negotiation-selected drug is the subject of unfavorable formulary placement. The Draft Guidance does not explicitly grant or deny pharmaceutical manufacturers access to these formulary justification statements; as written, CMS is the only designated recipient of the formulary justification statements. CMS has the authority to expand this language within the Final Guidance to include pharmaceutical manufacturers as recipients. Making this clarification would communicate to plan sponsors and stakeholders that CMS is committed to conducting a thorough and transparent formulary review process.

Revise the Final Guidance to Grant Manufacturers Access to Plan Sponsor Formulary Justification Statements

If CMS finds that the Draft Guidance cannot be interpreted to grant pharmaceutical manufacturers access to the formulary justification statements, Supernus Pharmaceuticals requests that CMS revise the Final Guidance to grant this access. CMS and pharmaceutical manufacturers share interest in drugs' placement within plan sponsor formularies and the specific considerations used to justify their placement. Pharmaceutical manufacturers also have specialized knowledge of their drugs' clinical performance which is particularly relevant to formulary placement decisions. Granting pharmaceutical manufacturers access to the plan sponsor formulary justification

statements for their negotiation-selected drugs will increase transparency and partnership amongst CMS and pharmaceutical manufacturers.

Supernus Pharmaceuticals urges CMS to grant pharmaceutical manufacturers access to the formulary justification statements from Part D sponsors who are found to use unfavorable formulary tiering placement for their negotiation-selected drugs during the CMS formulary review process.

Supernus Pharmaceuticals thanks CMS for the opportunity to submit comments to the Medicare Drug Price Negotiation Program Draft Guidance for Initial Price Applicability Year 2027 and looks forward to working with the Agency in the future on this and other issues impacting beneficiary care.

Sincerely,

Bill Soucie

Bill Soucie
VP, Market Access
Supernus Pharmaceuticals, Inc.

SurvivorsFor Solutions

June 19, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
The Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

I write to you on behalf of my organization, Survivors for Solutions, to express our concerns about the impact of the Inflation Reduction Act (IRA) on medical innovation. I also would humbly like to provide feedback on how your agency can improve its listening sessions and enable patients to have a voice when discussing the Medicare Drug Price Negotiation Program that is heard.

As a more than thirty-year survivor of multiple sclerosis (MS), I understand the value and importance of medical innovation better than most. Throughout my time living with this disease, I have been fortunate to have access to cutting-edge medication as my illness progressed. I have relied on four different breakthrough drugs over time —none of which were available at the time of my diagnosis. Centers for Medicare and Medicaid's recent announcement of draft guidance for the continuance of the IRA's drug negotiation program through Initial Price Applicability Year 2027 (IPAY) is devastating in its thoughtlessness and cruelty for patients like me. The guidance itself is riddled with questions and largely fails to address the key concerns with the program.

Without waiting to see the longer-term impacts – or any impact – of the drug price "negotiation" program on patient health, the Biden administration is blindly pushing ahead with the next round. No study or assessment of whether it helps or hurts, ignoring common sense and history – price controls lead to shortages and worse access to medicines.

Just when America needs thoughtful solutions, you press ahead with the unproven and risky threats to our most vulnerable citizens. It's already happening; this policy will further weaken America's once-thriving innovation ecosystem. Just the program's announcement back in 2022 drove drug researchers to pull back development initiatives, denying patients potential treatments and cures. This will only continue as more drugs are added to the program. In addition to removing the incentive to discover new treatments, the program also discourages further research into the capabilities of existing drugs, which can be used to treat a variety of conditions.

While patients can only hope that the IRA is pulled back before it destroys medical innovation as we know it, CMS can at least improve upon the patient listening sessions that it hosted in 2023.

As one of the handful of patients and advocates who participated in the “patient listening sessions” for the initial round of drug price negotiations, I saw an opportunity to express to CMS my initial concerns about the IRA. Unfortunately, this experience fell short of my expectations.

What should have been an open, constructive dialogue was instead a cold, one-way Zoom call with a government official. There were no exceptions to the rules, including the strict three-minute timeslots, even for patients like me who suffer from diseases that impact our ability to speak or hand mobility. The bureaucrats we spoke to did not give any indication that they could hear us. It felt like we were speaking into a void with no way of knowing that our words were resonating with decision-makers. For this next round, CMS can and must do better by way of providing ample, accessible opportunities for patients to provide their input on this program that will greatly impact their lives.

In this same vein, the registration process for these feedback opportunities must be simplified to make the entire experience more accessible. This will ensure every patient who has input to share can do so and is not stopped by bureaucratic red tape inhibiting them from giving their feedback.

On that note, these sessions are essentially meaningless if there is no explicit guidance on how CMS will consider and implement patient feedback. Requesting that a patient recount their struggles and experiences with their disease and associated medication is a big ask. Patients deserve to know that their feedback will be considered and incorporated in a meaningful way. CMS should release official guidance outlining precisely what the agency will do to ensure patients’ statements are taken into account this next round.

Lastly, I was disappointed to see intimidation tactics used in the last round of feedback. CMS warned me by email to reconsider my carefully thought-out statements, which were nearly identical across all listening sessions. I still believe these statements to be true; the drug price negotiation program will deliver “blunt-force trauma to a delicately balanced medical discovery ecosystem.” Intimidation from a governmental agency is wrong and will undermine the critical patient testimony that provides much-needed insight into the impacts of this program. CMS should avoid any communication with participants that may persuade them to alter or rescind their statements.

I firmly believe that the IRA will decimate the US medical innovation ecosystem and will, therefore, destroy hope for patients in need of treatments and cures across the world. I’ve experienced firsthand the power that hope for a brighter future can inspire in survivors. This next round of price negotiations must not take place without proper feedback from key stakeholders, who will be impacted by the decrease in key research and development and patient access restrictions resulting from IPAY 2027.

Sincerely,

John “CZ” Czwartacki
Founder & Chairman, Survivors for Solutions

Sutter Health

2200 River Plaza Drive
Sacramento, CA 95833

July 2, 2024

Meena Seshamani
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani:

Sutter Health is a not-for-profit, integrated health delivery system that provides comprehensive care throughout California. Sutter Health delivers exceptional and affordable care through its hospitals, medical groups, ambulatory surgery centers, urgent care clinics, telehealth, home health, and hospice services. Currently serving nearly 3.5 million patients, thanks to our dedicated team of more than 57,000 employees and clinicians, and 12,000+ affiliated physicians, with a unified focus on expanding care to serve more patients.

Sutter Health is committed to enhancing the well-being of its patients by transforming care to achieve the highest levels of quality, access, and affordability for its communities,[1] and we share CMS's vision to drive value-based care transformation, advance health equity, and promote health care quality and access.

Comments on Medicare Drug Price Negotiation Program Draft Guidance

On May 3, 2024, the Centers for Medicare & Medicaid Services (CMS) issued draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price (MFP) provisions. Sutter Health is very concerned that the guidance, if implemented as proposed, would impermissibly interfere with hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on 340B hospitals, would recommend that 340B hospitals share their claims data directly with manufacturers, and would force hospitals to float greater drugs costs until they receive a refund from a manufacturer in instances where a drug's MFP is lower than its 340B ceiling price.

Sutter Health is committed to serving its patient community by providing access to cost-effective drugs, as the 340B program intended. However, Sutter Health's commitment to our patients extends beyond providing accessible medications to those who cannot afford needed

[1] https://www.sutterhealth.org/about/mission

therapies. Our organization has re-invested 340B program savings in capital improvements, such as new specialty clinics to offer needed care to patients in rural communities. For example, Sutter was able to establish an oncology care clinic for patients in a rural community on the border of Oregon and California. Without the establishment of this clinic, patients would have been required to travel over 100 miles for access to oncology care. Such investments have expanded services and improved the healthcare infrastructure, ensuring that underserved populations have access to critical care. Additionally, Sutter Health's integration of primary care services within clinics exemplifies how the 340B program can enhance the delivery of comprehensive care.

We commend Congress for establishing the 340B Drug Discount program in 1992 with the aim of extending federal resources, expanding access to comprehensive services, and reaching more eligible patients. As a committed participant in the 340B program, we appreciate the opportunity to contribute our insights and recommendations to CMS on the implementation of this program to ensure its continued success.

Conclusion

We appreciate your consideration of our comments. Should you have questions, please do not hesitate to contact Jonathan Williams, Vice President of Government Affairs at Sutter Health, by phone at 916-718-2085 or email at Jonathan.Williams@sutterhealth.org.

Sincerely,

Ryan Stice
Chief Pharmacy Officer
Sutter Health

UNIVERSITY of WASHINGTON
SCHOOL OF PHARMACY
The Comparative Health Outcomes, Policy, & Economics (CHOICE) Institute

July 2, 2024

VIA ELECTRONIC DELIVERY
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington DC 20201
IRARebateandNegotiation@cms.hhs.gov

Re: Medicare Drug Price Negotiation Program Guidance (May 2024 Guidance)

Dear Administrator Brooks-LaSure:

We are submitting this letter as independent health economists with a long history of collaboration on pharmaceutical policy analysis. In the interests of transparency, we declare that this work has been supported in part by pharmaceutical companies and their industry association. We appreciate the opportunity to submit comments on the Medicare Drug Price Negotiation Program (MDPNP): Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 and Solicitation of Comments posted on the Centers for Medicare & Medicaid Services (CMS) website on May 3, 2024 (**May 2024 Guidance**).

Our comments are specifically relevant to the following guidance sections:

- 50.2 Evidence About Therapeutic Alternatives for the Selected Drug
- 60.3.1 Identifying Indications for the Selected Drug and Therapeutic Alternatives for Each Indication
- 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternative(s)

A common theme emerges across both of these sections: CMS intends to lead a thorough review of relevant literature—as cited in the May 2024 Guidance as a "CMS-led review"—and we have practical suggestions to help support your team. While we recognize that a guidance document is not required to specify all methods and plans, we think it is incredibly important for the MDPNP team to provide additional information regarding the methods for current and future CMS-led reviews. Also, please consider our comments from the perspective of health economists who have experienced challenges in attempting to do these types of reviews, so we sympathize with the MDPNP team in tackling the enormous challenge by the tasks placed on them by Congress.

We make three main points.

Box 357630 1959 NE Pacific St., H-375, Seattle, WA 98195-7630
206.427.0798 fax 206.543.3835

First, CMS does not need to "reinvent the wheel" per se by developing a new process for evidence generation in this CMS-led review. We highly recommend that the MDPDP team consider the ISPOR Good Practices Task Force co-chaired by Lena Mandrik, Hans Severens, and Jeremy Goldhaber-Fiebert.[1] The ISPOR Task Force process for report preparation is comprehensive and inclusive of perspectives across different stakeholder groups and countries. In this report, Mandrik et al. recommend six practical stages for evidence synthesis for the type of evidence that could support CMS decision-making.[1] To assist in linking this to the MFP negotiation process, we have drafted—for your consideration—general best practices corresponding to the six stages for your team to consider as part of the MFP negotiation process (**Table 1**). Following best practices for evidence synthesis will help guide companies in developing their evidence submissions to ensure all literature reviews supporting the MFP negotiation process are repeatable.

Table 1. Best practice recommendations for an evidence synthesis process.

Task Force Staging of Process	**Recommendations for CMS based on best practices**
Stage 1: Planning and development	A predefined protocol for evidence identification and review should be established by the literature review team in order to reduce the risk of subjectivity bias, and enable other researchers to replicate findings.
Stage 2: Searching for evidence	A robust evidence search strategy should be defined that specifies what types of evidence may be included, how study quality will be judged, and whether and how patient, clinician, or other stakeholder perspectives will be considered.
Stage 3: Study selection and eligibility	Once a search strategy is finalized, eligibility criteria for including evidence and a process for screening evidence based on these criteria must be established.
Stage 4: Critical appraisal of included studies	A plan must be established for critical appraisal of the included studies using appropriate checklists for methodologic quality and reporting.
Stage 5: Data extraction and synthesis	Standards for data extraction along with methods for narrative synthesis or meta-analysis need to be established with specific considerations for handling different study types and evaluating the heterogeneity of outcomes included.
Stage 6: Presentation and reporting	CMS should provide sufficient detail and standardize review reporting to facilitate comparability between different CMS-led literature reviews and improve replicability.

Challenges will remain. The established tools of clinical evidence synthesis have focused on indirect treatment comparisons and network meta-analyses of randomized controlled trials (RCTs) most often developed for product registration. Comparisons based on real-world data after a product has been on the market for seven years or more are another matter: the methods for synthesizing information of RCT and real-world data are still developing, and there is not a strong methodological consensus or a set of widely-accepted guidelines.[7-9] The health economic and outcomes research field as a whole is doing more and more to gather and use of real-world data: this MDPNP need should help to accelerate these needed developments.

Furthermore, after a product has been on the market for many years, there are often numerous indications and multiple comparators. CMS has not specified how the process with handle this complexity. Reviewing this situation, Hernandez et al. (2024) commented: "What remains unclear is precisely how CMS will identify, weigh, and scientifically judge the clinical evidence; select outcomes of interest for the comparative effectiveness assessment; and integrate that information with

net price and other factors to inform the initial price offer. Much like the selection of alternatives, this step remains opaque, as CMS will follow what they indicate is a "qualitative approach" to the integration of data."[10] Clearly, this lacks the rigor and transparency that leading HTA agencies currently apply in evaluating an initial price.

Second, we believe it is absolutely critical that CMS employ a transparent process throughout these evidence synthesis stages. In the private insurance market, commercial insurers negotiate with pharmaceutical manufacturers using proprietary processes and do not routinely disclose the information that ultimately led to their coverage decision or negotiated rebates (or net price). Consumers, however, have choice in terms of responding to a private insurer's decision to change coverage or prices (e.g., premium rates or out-of-pocket costs) as they can enroll in a different plan in the following year. CMS price negotiation under the IRA will apply to all Medicare beneficiaries, providing them with limited options if they are unhappy with the resulting benefit changes. Ideally, a government-led process that affects the public (including both Medicare beneficiaries and taxpayers) would embrace or develop processes that are more transparent that those observed in the private market. While this sounds straightforward, the implementation of transparent processes in value assessment presents significant challenges: for example, other countries with established value assessment processes have been inconsistent in determining what information was made publicly available.[2] A review of 11 value assessment organizations (both public and private) in North America and Europe found substantial differences in evidence source selection, with few explicitly referencing peer-reviewed sources.[2]

Transparency in this process is crucial for CMS to gain the public's trust and support future expansion of drug price negotiation. Additionally, transparency helps improve reproducibility[3,4] and will support CMS's ability to update and revise its assessments quickly in response to new research. Process transparency by CMS will also enable external organizations to replicate its methods, providing CMS with valuable cross-validation from other experts to help confirm or improve CMS's findings.[5]

Third, CMS needs to be more clear on whether it intends to reward value or whether the focus is primarily to lower costs for Medicare. Some have argued that there seems to be implicit "value framework" in the guidelines for negotiating MFP.[6] But there is some lack of clarity here as well since—in addition to requesting information on the prices, comparative effectiveness, and safety of therapeutic alternatives—information on R&D and production costs is also requested: this suggests some interest in a cost-based approach which is fundamentally different to one based on clinical value.

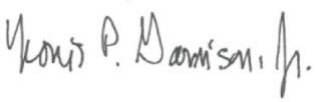
Summary Recommendations:

1. **Use established guidelines and best practices for evidence synthesis.**
2. **Prioritize transparency to gain the public's trust.**
3. **Clearly articulate whether the intent is "value" or "cost reduction" as these two different objectives will affect the methods used in evidence generation differently.**

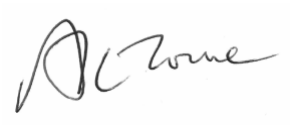
We appreciate your consideration of our comments as you develop and refine the MDPNP and its policies and practices. We look forward to continuing to try to support and work with CMS to ensure that this program is implemented to promote more efficient development of and equitable access to innovative medicines for all Americans, while producing knowledge that is beneficial for the health and well-being of all persons globally.

Please contact us if you have any questions regarding our comments.

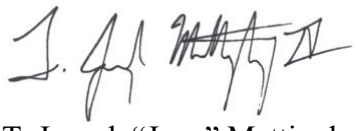
Yours sincerely,



Louis P. Garrison, Jr., Ph.D.
Professor Emeritus, The CHOICE Institute
Tel: 206-427-0798
Email: lgarrisn@uw.edu



Adrian Towse, M.A., Mphil
Emeritus Director & Senior Research Fellow
Office of Health Economics
Tele: 44 (0) 207 747 1407
Email: atowse@ohe.org



T. Joseph “Joey” Mattingly II
Associate Professor and Vice Chair of Research
Department of Pharmacotherapy
University of Utah College of Pharmacy
Tel: 502-552-5104
Email: joey.mattingly@utah.edu

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3. Wang SV, Schneeweiss S, Berger ML, et al. Reporting to Improve Reproducibility and Facilitate Validity Assessment for Healthcare Database Studies V1.0. *Value in Health*. 2017/09/01/ 2017;20(8):1009-1022. doi:https://doi.org/10.1016/j.jval.2017.08.3018
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UnityPoint Health

Government and External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Department of Health & Human Services
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1859

RE: Draft Guidance on the Medicare Drug Price Negotiation Program

Submitted electronically via IRARebateandNegotiation@cms.hhs.gov

Dear CMS Deputy Administrator and Director of the Center for Medicare Seshamani,

UnityPoint Health appreciates this opportunity to provide comments on CMS' draft guidance implementing the Inflation Reduction Act's (IRA) maximum fair price provisions released May 3, 2024. UnityPoint Health is one of the nation's most integrated healthcare systems. Through more than 29,000 employees and our relationships with 370+ physician clinics, 36 hospitals in urban and rural communities, and 13 home care areas of service throughout our 8 markets, UnityPoint Health provides care throughout Iowa, west-central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health is responsible for a service area of over 2.3 million people and has generated $344.6 million in community impact.

As a nonprofit, integrated healthcare system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provides vital access to healthcare services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. *Not including our affiliated 18 critical access hospitals, we have 12 hospitals (9 covered entities) under the 340B Drug Pricing Program*. **We respectfully offer the following input limited to the impact of the draft guidance on the 340B Drug Pricing Program.**

IRA'S MAXIMUM FAIR PRICE (MFP) IMPACT ON 340B CEILING PRICE

The IRA requires the Primary Manufacturer to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price if the MFP for the selected drug is lower than the 340B ceiling price for the selected drug. CMS acknowledges the intersection between the IRA requirement under the Negotiation Program for manufacturers to provide access to the MFP and Health Resources and Services Administration (HRSA) requirements for manufacturers to make the 340B ceiling price available to 340B covered entities.

Comment: **While UnityPoint Health agrees that covered entities should not receive duplicate**

discounts, the draft guidance proposes to address this through an arduous process that places unreasonable burdens upon 340B covered entities and ultimately adversely impacts Medicare beneficiaries. As proposed the draft guidance would impermissibly interfere with hospitals' ability to use 340B drugs for Medicare Part D beneficiaries, would put a tremendous and unreasonable burden on 340B hospitals, would recommend that 340B hospitals share their claims data directly with manufacturers, and would force hospitals to float greater drug costs pending manufacturer refunds in instances where a drug's MFP is lower than its 340B ceiling price. CMS has failed to meet its statutory obligation to ensure that 340B covered entities (CEs) receive the lower of the 340B ceiling price or MFP when purchasing covered outpatient drugs that are subject to the MFP.

We urge CMS to abandon its current proposal to make the MFP available in a nonduplicated amount to the 340B ceiling price and instead work with 340B CEs to develop a workable means for CEs to continue purchasing at the 340B price without identifying a claim at the point of sale, regardless of whether a drug's 340B ceiling price is lower or higher than MFP. Challenges created by this proposal include:

Default Payment Methodology: CMS' proposal requires providers to purchase drugs at prices significantly higher than MFP and wait weeks to receive a payment from the manufacturer to net the purchase cost to MFP ("default payment"). This essentially requires providers to float revenue to manufacturers. Applying this to 340B CEs, CMS proposes that when the 340B ceiling price is lower than MFP, 340B CEs voluntarily append a modifier on the claim to identify the claim as 340B. This modifier would allow manufacturers to avoid making the default payment for those claims. Yet, CMS acknowledges that most CEs use a virtual inventory system in which 340B claims cannot be tagged until after the claim is submitted. The virtual inventory model has been in use since the 340B Drug Pricing Program was enacted more than 30 years ago, and it is the model used by our CE hospitals. It would be unworkable to expect our CE hospitals to use a separate physical inventory of 340B drugs. Instead, **we recommend that CMS develop a methodology to enable CEs to retrospectively submit 340B claims data to CMS' Medicare Transaction Facilitator (MTF) and require that the MTF use the data to identify 340B claims and withhold them from being submitted to the manufacturer**. This process has been used successfully by Oregon Medicaid for more than a decade.

Claims Submission to Manufacturers: Recognizing the issues with point-of-sale identification, CMS urges that CEs submit their 340B claims data directly to the manufacturers for drugs subject to the MFP. This would involve individual CEs separately submitting data to individual manufacturers, each of which could have its own separate data requirements and processes. While CMS does not mandate that CEs share data, the draft guidance sets up processes for manufacturers to use such data. **We strongly oppose CMS allowing manufacturers to mandate 340B claims data submission through their own deduplication policies**. Ceding this responsibility to numerous drug manufacturers:

- ***Conflicts with CMS' explicit authority*** in section 1193(d)(1) of the Social Security Act to develop a process in which manufacturers do not provide the MFP for drugs sold at the 340B price and, per sections 1193(a)(5) and 1196(b), that process be one that CMS can "administer" and for which CMS can ensure compliance. CMS can neither administer nor ensure compliance with unclear and vague statements about what the parties should agree to outside of, and separate from, the

government's stated process, especially when there could be numerous different policies.

- ***Creates significant barriers to CEs*** accessing the lower of the 340B ceiling price or MFP for numerous manufacturers and will be tremendously burdensome for CEs to manage. We are especially concerned because CMS provides no guidelines for the plans or criteria for how the agency will evaluate these plans, including manufacturers responsibilities. Absent evaluation guidelines and criteria for the manufacturers' nonduplication plans, manufacturers plans and processes will likely vary. There is no govern on manufacturers as to scope of claims data, reporting methodology, or additional restrictions (e.g., CE assurance of 340B compliance). For example, a manufacturer could (1) assume all outpatient claims attributed to a CE's NPI are 340B eligible; or alternatively, (2) require CEs to submit large volumes of data to receive the 340B ceiling price or MFP as a refund. Either would be at odds with the longstanding practice of CEs accessing the 340B discount as a purchase price and would be highly disruptive to how hospitals manage their 340B programs. It is also not difficult to imagine that numerous and varying requirements will increase operational burdens for CEs (especially small CEs), add to oversight complexity for CMS and HRSA, and insert unnecessary delays in receiving 340B payments.

  These assertions are based on the experiences and frustrations of our CE hospitals who currently share 340B claims data with drug manufacturers through the vendor ESP in connection with 340B contract pharmacy restrictions. The process of obtaining and preparing 340B claims data for submission to ESP imposes a significant administrative burden. CEs must download claims data reports from the portals of every 340B third-party administrator (TPA) with which they contract and for every contract pharmacy arrangement administered by each TPA. There is wide variation around reinstatement of 340B pricing at hospitals' contract pharmacies after they have submitted claims data to ESP. It has been our experience that 340B pricing is made available for only some NDCs, but not all, and only at some contract pharmacy locations, but not all. Our CE hospitals have devoted extensive time and staff resources to follow up on notifications in ESP's portal that claims submissions are incomplete to ensure 340B pricing is preserved. It is commonplace to send multiple emails to ESP in support of issues and fixes in the portal. To add to the frustration, manufacturers can and do change restrictions/rules at will and sometimes without notice, yet CE hospitals may only change their single contract designation once every 12 months.

MFP Relationship to 340B Ceiling Price: **We also oppose the draft guidance's proposed implementation of MFP when it is lower than the 340B ceiling price**. The draft guidance effectively prohibits use of the 340B benefit in those instances, expecting CEs to purchase drugs for 340B-eligible patients at a non-340B price. This requires safety-net hospitals participating in the 340B Drug Pricing Program to float more upfront drug costs. This would substantially disrupt our CE hospitals' longstanding practice of purchasing and using 340B drugs for patients and will impact our virtual inventory systems. CEs should be able to use the 340B benefit for all 340B-eligible patients, as permitted under the 340B statute, and not amended by the IRA. **Additionally, we suggest that CMS establish a clear process for manufacturers to make CEs whole by providing the difference between the two price points**.

As a 340B stakeholder, we appreciate this opportunity to offer input on this draft guidance and its impact on our hospitals and health system, our beneficiaries, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Cathy Simmons, JD, MPP
Executive Director Government & External Affairs

USPIRG.org
Info@USPIRG.org

July 1, 2024

Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244
IRARebateandNegotiation@cms.hhs.gov

RE: Draft Guidance on the Medicare Drug Price Negotiation Program

Dear Director Seshamani:

On behalf of U.S. PIRG and our two dozen state based affiliates, I write to offer the following feedback on the Draft Guidance on the Medicare Drug Price Negotiation Program. We appreciate your call for feedback on all aspects of the program and in particular on the draft guidance which will apply to prices beginning in 2027. As a 50 year old grassroots consumer advocacy organization, PIRG seeks to improve the value of health care by promoting policies that improve the quality of care and contain cost for government programs and American families.

We know that too often, patients and consumers have difficulty finding ways to influence policies that directly influence their day to day life. With (FACT) Americans needing at least one medication, and (FACT) needing four or more medications to live their best lives, the prices of drugs have a huge impact on family budgets. The breakthrough policy that allows CMS to negotiate lower drug prices for the Medicare program has the potential to save money not only for our federal and state health programs but also for individuals and families directly.

Overall comments

Throughout the process, anytime public feedback is allowed (such as Sec 60.4 “patient-focused events”, Sec 50.2 Evidence about Therapeutic Alternatives for the Selected Drugs and section 1194(e)(2) factors), it is important for CMS to clearly understand who is submitting the information. CMS should be made aware of any potential bias from commenters.

Most importantly, we urge CMS to require all people and entities who submit evidence or information to CMS to clearly disclose their sources of information and funding. For example, there are many “patient groups” that purport to represent patient viewpoints, but are funded by the companies that could financially benefit from the recommendations and input submitted by those patient groups.

As a public interest group that accepts no funding from pharmaceutical companies, we know this disclosure is important to help regulators weigh the input of patient groups with this kind of conflict of interest and possible/likely bias. Patient experiences should be communicated free from the influence of the drug company that supplies them their medications. But at a minimum, patients who receive funding from pharmaceutical companies should disclose that information and explain the connections they have with the industry CMS is regulating.

Comments on patient-focused events for initial price applicability year 2027

We commend CMS for considering additional formats and venues for patient and caregiver input. Medical conditions, medication usage and dealing with family financial struggles are very personal and private issues that many feel uncomfortable sharing in a public way. Fear of retaliation and/or humiliation, especially when it comes to health status and medical debt is real. We urge CMS to offer a variety of venues so as to:

- Allow patients and consumers to react to industry assertions and raise questions to be considered by regulators.
- Allow patients and members of the public to provide feedback and comments in a more comfortable setting that is not as intimidating as a public hearing or requiring a computer with camera
- Provide accommodations to patients and consumers so they can communicate in a way that works for them, based on their varying degrees of health and disability.
- Allow patients/consumers an opportunity to have more intimate conversations which might solicit new insights that patients may not feel comfortable providing in a more public setting.
- Offer a variety of ways for individuals to share their personal experiences without fear.

Thank you for the opportunity to offer our suggestions for improving the process for the Medicare Drug Price Negotiation Program.

Sincerely,

Patricia Kelmar
Senior Director, Health Care Campaigns
pkelmar@pirg.org

July 1, 2024

VIA ELECTRONIC SUBMISSION —

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year (IPAY) 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

ViiV Healthcare Company (ViiV) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid's (CMS) IPAY 2027 proposed guidance, which once finalized, will take effect on January 1, 2027.[1] ViiV reasonably believes that one or more ViiV products may be directly impacted and subject to price setting under the Inflation Reduction Act (IRA) statute and guidance. Given those potential implications, ViiV has a vested interest in the development, interpretation, and application of the final IPAY 2027 guidance that will be issued by CMS. As CMS undertakes the process of finalizing this guidance, ViiV appreciates CMS's willingness to solicit comments and offer listening sessions to understand stakeholder impacts and concerns related to implementation.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV and those who could benefit from prevention of HIV. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

An estimated 1.2 million people in the United States are living with HIV, with at least 13 percent unaware of their HIV status.[2] HIV is a unique area of health as both an infectious disease and chronic condition that when effectively managed cannot be transmitted to others. HIV began as an epidemic that disproportionately affected younger people, but with the development of new ARV treatments that enable long-term management of the disease, the age distribution of people with HIV has shifted higher. Today, over 40 percent of people with HIV are now aged 55 or older, with the average age expected to continue

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[1] Center for Medicare. Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. May 3, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. Accessed June 24, 2024.

[2] HIV.gov. U.S. Statistics. December 7, 2023. https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics. Accessed June 26, 2024.

rising.[3,4] In addition to treatment, ARVs can also be used as pre-exposure prophylaxis (PrEP) to prevent acquisition of HIV. Today there are an estimated 1.2 million people in the United States who could benefit from PrEP.[5]

The health of people affected by HIV depends on access and innovation. CMS has recognized the need for access by identifying ARVs as one of six protected classes that must be covered by all Medicare prescription drug plans. CMS must also recognize the need for innovation. New ARV treatments and prevention tools are critical for staying abreast of an evolving virus. Only three major manufacturers continue to invest in HIV research and development, and ViiV is concerned that ARV price setting could have long-term detrimental impacts on innovation and achieving the nation's goal of *Ending the HIV Epidemic*.[6]

ViiV encourages CMS to account for how HIV is a unique and evolving area of health care and how policies in this guidance could inadvertently impact access and innovation toward future prevention tools, treatments, and a cure. ViiV supports the comments provided by GSK, its majority shareholder, and offers the following more targeted recommendations in response to the guidance:

I. CMS Should Consider the Impact of MFP on AIDS Drug Assistance Programs (ADAPs) (Section 40.4)
II. CMS Should Highly Weight Product Value, Including Preventive Value, in Developing Initial Price Offers (Sections 50, 60).
III. For Therapeutic Alternative Selection for HIV Treatments, CMS Should Limit Selection to Antiretrovirals, Account for Dosing Requirements, and Account for Last-Line ARVs with No Therapeutic Alternatives (Sections 50, 60)
IV. CMS Should Enable Participants to Privately Participate in Patient-Focused Listening Sessions or Create an Alternate Opportunity for Comment that Allows for Privacy (Section 60.4)
V. CMS Should Create a More Systematic and Continuous Patient Engagement Process (Section 60.4)

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I. CMS Should Consider the Impact of MFP on AIDS Drug Assistance Programs (ADAPs) (Section 40.4)

ViiV is concerned that once operationalized, the implementation of MFP for HIV treatments could threaten the sustainability of AIDS Drug Assistance Programs (ADAPs) and their ability to cover treatments for individuals covered by Medicare.

ADAPs are a critical component of the Ryan White HIV/AIDS Program, statutorily mandated to provide U.S. Food and Drug Administration (FDA) approved medications for the treatment of HIV and opportunistic infections to eligible, low-income individuals with HIV. Over half of people with HIV have

[3] AIDSVu. Location Profile: United States. 2021. https://map.aidsvu.org/profiles/nation/usa/overview#0-2-Demographics. Accessed June 24, 2024.
[4] Althoff KN, Stewart CN, Humes E. The shifting age distribution of people with HIV using antiretroviral therapy in the United States. AIDS. 2022 Mar 1;36(3):459-471. Accessible at https://pubmed.ncbi.nlm.nih.gov/34750289/.
[5] HIV.gov. Expanding PrEP Coverage in the United States to Achieve EHE Goals. October 18, 2023. https://www.hiv.gov/blog/expanding-prep-coverage-in-the-united-states-to-achieve-ehe-goals. Accessed June 25, 2024.
[6] Centers for Disease Control and Prevention (CDC). About Ending the HIV Epidemic in the US. March 20, 2024. https://www.cdc.gov/ehe/php/about/index.html. Accessed June 27, 2024.

some portion of their care and treatment needs met through the Ryan White HIV/AIDS Program.[7] In 2021, nearly 300,000 people living with HIV received medication assistance (either direct purchase of medications or healthcare coverage premiums and/or cost sharing assistance) from an ADAP.[8] Over 70 percent of ADAP beneficiaries who received cost-sharing or deductible assistance from ADAP were age 50 or over.[9] This figure is expected to increase as the population of people living with HIV live long, healthy lives and age into Medicare.

ADAPs operate using multiple funding streams. Federal grants, state appropriations, program income, and the 340B Drug Pricing Program are all important to ADAP budgets. While the role of grants and appropriations are straightforward, how MFP will affect the 340B Drug Pricing Program is not yet clear, and ViiV believes these two programs will not be operational together with the way the guidance is currently drafted. Ultimately, ViiV is concerned that ARV price setting will unintentionally affect 340B-generated program revenue for ADAPs and impact the ability of the program to serve patients.

II. CMS Should Highly Weight Product Value, Including Preventive Value, in Developing Initial Price Offers (Sections 50, 60)

In developing initial price offers, ViiV encourages CMS to weight negotiation factors for product value ("Evidence About Alternative Treatments") more heavily than factors focused on cost recovery ("Manufacturer-Submitted Data."). When assessing product value, ViiV strongly encourages CMS to consider data that demonstrates how access to medication can mitigate costs through prevention for an individual beneficiary's care, conditions averted, and community health.

Greater prevention of HIV benefits Medicare. People with HIV represent a large patient population that is aging into Medicare, and prevention keeps this population from expanding. As of 2021, 40 percent of people with HIV and 10 percent of new HIV diagnoses were among people aged 55 or older in the United States.[10] The health care system saves an estimated $939,946 (2022 US$) for every case of HIV prevented.[11,12,13]

HIV ARVs reduce individual health care costs and prevent HIV transmission. When taken as prescribed, ARVs prevent disease progression, reduce health care utilization, and enable people with HIV to live full, healthy lives.[14,15] ARVs also benefit public health by reducing HIV in the blood to levels undetectable by

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[7] Health Resources and Services Administration. Program Overview: HRSA's Ryan White HIV/AIDS program. https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/resources/program-factsheet-program-overview.pdf. Accessed June 27, 2024.

[8] Health Resources and Services Administration. Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP) Annual Client-Level Data Report 2021. September 2023. https://ryanwhite.hrsa.gov/data/reports. Accessed June 25, 2024.

[9] Health Resources and Services Administration. Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP) Annual Client-Level Data Report 2021. September 2023. https://ryanwhite.hrsa.gov/data/reports. Accessed June 25, 2024.

[10] Centers for Disease Control and Prevention (CDC). HIV Surveillance Report, 2020; vol. 33. May 2022. Accessible at: https://stacks.cdc.gov/view/cdc/121127. Accessed June 25, 2024.

[11] Brogan AJ, Davis AE, Mellott CE, Fraysse J, Metzner AA, Oglesby AK. Cost-effectiveness of cabotegravir long-acting for HIV pre-exposure prophylaxis in the United States. Pharmacoeconomics. 2024 Apr;42(4):447-461. Accessible at: https://pubmed.ncbi.nlm.nih.gov/38267806/.

[12] Cohen JP, Beaubrun A, Ding Y, Wade RL, Hines DM. Estimation of the incremental cumulative cost of HIV compared with a nonHIV population. Pharmacoecon Open. 2020;4(4):687–96. Accessible at: https://pubmed.ncbi.nlm.nih.gov/32219732/.

[13] US Bureau of Labor Statistics. Consumer price index for Medical Care. 2022. https://data.bls.gov/cgi-bin/surveymost?cu. Accessed June 28, 2024.

[14] HIV.gov. Viral Suppression and Undetectable Viral Load. February 1, 2023. https://www.hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/viral-suppression. Accessed June 27, 2024.

[15] Cohen CJ, Meyers J, Davis KL. Association between daily antiretroviral pill burden and treatment adherence, hospitalisation risk, and other healthcare utilisation and costs in a US medicaid population with HIV. BMJ Open. 2013 Aug 1;3(8):e003028. Accessible at https://pubmed.ncbi.nlm.nih.gov/23906955/.

lab tests which prevents transmission of HIV to others. This is commonly referred to as Treatment as Prevention (TasP),[16] or Undetectable = Untransmissible (U=U).[17]

In addition to TasP, ARVs are also a primary prevention tool when used as PrEP, which protects individuals without HIV from acquiring the virus. In 2023, the U.S. Preventive Services Task Force (USPSTF) assigned a Grade A Recommendation for PrEP as a highly effective preventive intervention.[18] PrEP has been shown to reduce the risk of acquiring HIV from sex by 99 percent and from injection drug use by 74 percent.[19] CMS has also recognized PrEP as an effective preventive service in the draft National Coverage Determination released in July 2023, expected to be finalized in late September 2024.[20]

For these reasons, CMS should consider the preventive value of ARVs as both treatment and PrEP for direct and indirect healthcare costs averted when developing initial price offers.

III. For Therapeutic Alternative Selection for HIV Treatments, CMS Should Limit Selection to Antiretrovirals, Account for Dosing Requirements, and Account for Last-Line ARVs with No Therapeutic Alternatives (Sections 50, 60)

ViiV recommends CMS restrict its therapeutic alternative selection for HIV products to ARVs. ViiV is concerned that the IPAY 2027 draft guidance would allow CMS to compare MFP-selected HIV treatments to therapeutic alternatives that are inappropriate for benchmark price comparisons when considering outcomes and value.

In the draft IPAY 2027 guidance, CMS states that it will identify potential therapeutic alternatives by using "drug classification systems commonly used in the public and commercial sector for formulary development [and] CMS-recognized Part D compendia."[21] In many public and commercial compendia, HIV ARV treatments are categorized as antivirals alongside products for different indications that would be inappropriate comparisons for developing initial offers.

If CMS uses the US Pharmacopeia (USP) Medicare Model Guidelines (MMG), for example, within the MMG, HIV ARV treatments are categorized as antivirals alongside anti-hepatitis C agents, antiherpetic agents, antiviral coronavirus agents, and anti-influenza agents.[22] Comparing HIV treatments to these other product areas is inappropriate as there are clear differences in outcomes and value for patients.

ViiV is especially concerned that in its proposed guidance, CMS opens the door to an even more expansive methodology for identifying therapeutic alternatives beyond a drug's class. When compared to

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[16] Centers for Disease Control and Prevention (CDC). HIV Treatment as Prevention. August 9, 2023. https://www.cdc.gov/hiv/risk/art/index.html. Accessed June 27, 2024.

[17] National Institutes of Health (NIH). HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention. May 21, 2019. https://www.niaid.nih.gov/diseases-conditions/treatment-prevention. Accessed June 27, 2024.

[18] US Preventive Services Task Force. Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. August 22, 2023. https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Accessed June 27, 2024.

[19] Centers for Disease Control and Prevention (CDC). HIV Risk and Prevention: PrEP (Pre-Exposure Prophylaxis). July 5, 2022. https://www.cdc.gov/hiv/risk/prep/index.html. Accessed February 2, 2024.

[20] Centers for Medicare & Medicaid Services. Proposed Decision Memo: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection. July 12, 2023. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310. Accessed June 25, 2024.

[21] Center for Medicare. Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. May 3, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. Accessed June 24, 2024.

[22] US Pharmacopeia. USP Medicare Model Guidelines v9.0. September 29, 2023. https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines. Accessed June 24, 2024.

IPAY 2026, the more expansive methodology proposed in the draft IPAY 2027 guidance suggests that CMS is downgrading reliance on clinical appropriateness by considering products outside of a drug's class.[23,24]

ViiV is opposed to this proposed change and strongly recommends that CMS restrict HIV treatment therapeutic alternative selection to ARVs. Benchmarking the price of a selected MFP HIV treatment to non-ARV therapeutic alternatives within the broader antiviral class, or beyond, would be inappropriate when considering patient outcomes and value.

ViiV also recommends that CMS limit therapeutic alternative selections to products that have the same dosing requirements (e.g., once daily). CMS should consider the ramifications of comparing products that are not fully equivalent—such as once daily oral ARVs and long-acting injectable ARVs—and how that practice could stifle future therapy innovation.

Finally, ViiV recommends that CMS use a patient-focused approach when identifying therapeutic alternatives and determining a product's comparative value. When people with HIV develop resistance to ARVs, they may be prescribed a non-first-line ARV treatment with no therapeutic alternative. This should be reflected in that product's comparative value.

IV. CMS Should Enable Participants to Privately Participate in Patient-Focused Listening Sessions or Create an Alternate Opportunity for Comment that Allows for Privacy (Section 60.4)

ViiV thanks CMS for hosting patient-focused listening sessions and its proposal to improve the design of the sessions, including through alternative formats. ViiV recommends that CMS provide an option to participate privately or create an alternate opportunity for comment that allows for privacy. If left unchanged, the public forum format used for IPAY 2026 could have discouraged people affected by HIV from participating if they were concerned about disclosing their HIV status or their likelihood of acquiring HIV (for those who may benefit from PrEP). Despite advances that demonstrate Undetectable = Untransmissible (U=U),[25] HIV remains a highly stigmatized condition. Furthermore, populations disproportionately affected by HIV are also often stigmatized for their sexual orientation, gender identity, race/ethnicity, drug use, and other factors.[26]

ViiV supports a change in the format of the listening sessions to promote more meaningful and insightful feedback from people affected by HIV—those who benefit the most from advances in treatment and prevention. ViiV recommends that CMS allow opportunities for public comment by patients via writing and an option to provide comment anonymously.

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[23] Center for Medicare. Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. June 30, 2023. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf. Accessed June 27, 2024.

[24] Center for Medicare. Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. May 3, 2024. https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf. Accessed June 24, 2024.

[25] National Institutes of Health (NIH). HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention. May 21, 2019. https://www.niaid.nih.gov/diseases-conditions/treatment-prevention. Accessed June 27, 2024.

[26] HIV.gov. Standing Up to Stigma. July 18, 2023. https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma. Accessed June 27, 2024.

V. CMS Should Create a More Systematic and Continuous Patient Engagement Process, Including for Determining Therapeutic Alternatives (Section 60.4)

ViiV aligns with recommendations from the Partnership to Improve Patient Care (PIPC) encouraging CMS to deepen its patient engagement beyond written comment periods and ad hoc listening sessions toward a more systematic and continuous process. ViiV encourages CMS to use and build upon the patient-engagement frameworks developed by the Patient Centered Outcomes and Research Institute (PCORI),[27] the National Health Council (NHC),[28] the PATIENTS Program at the University of Maryland,[29] the Innovation and Value Initiative and AcademyHealth,[30] and the Milken Institute.[31]

To make its patient engagement meaningful, CMS should incorporate patient input and data into the selection of therapeutic alternatives and the development of initial price offers—and to be transparent in how it develops pricing when setting MFP.

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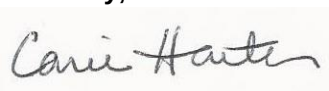
ViiV Healthcare appreciates CMS's consideration of these comments. Please feel free to contact Carie Harter at (770) 710-9620 or carie.a.harter@ViiVhealthcare.com should you have any questions.

Sincerely,



Carie Harter
Senior Director, Government Relations
ViiV Healthcare

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[27] Patient-Centered Outcomes Research Institute. Engagement in Research: Foundational Expectations for Partnerships. February 2024. https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf. Accessed June 26, 2024.

[28] National Health Council. Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement. March 2024. https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf. Accessed June 26, 2024.

[29] The PATIENTS Program at the University of Maryland School of Pharmacy. PATIENTS Professors Town Hall: Recommendations for the CMS Drug Price Negotiation Program Final Report. July 12, 2023. https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf. Accessed June 27. 2024.

[30] Innovation and Value Initiative and AcademyHealth. A Research Framework to Understand the Full Range of Economic Impacts on Patients and Caregivers. May 2023, https://thevalueinitiative.org/wp-content/uploads/2023/06/05-2023-Economic-Impacts-Framework-Report_FINAL.pdf. Accessed June 26, 2024.

[31] Awo Osei-Anto H, Puerini R. The Current Landscape of the Science of Patient Input. The Milken Institute. November 28, 2022. https://milkeninstitute.org/report/science-patient-input-current-landscape. Accessed June 26, 2024.

799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

July 2, 2024

Submitted via email to: IRARebateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., PhD.
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

Vizient, Inc. appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter the "Draft Guidance").[1] Also, Vizient thanks CMS for hosting listening sessions regarding the Draft Guidance to better understand stakeholder perspectives regarding implementation of the drug price negotiation provisions of the Inflation Reduction Act (IRA). While Vizient is not commenting on all questions posed in the Draft Guidance, Vizient urges CMS to better ensure that implementation of the IRA will not have unintended consequences for providers and that significant effort is made to ensure access to the MFP is provided prospectively. Further, Vizient recommends that CMS work closely with providers, particularly hospitals and health systems, to ensure implementation of the IRA's drug negotiation provisions do not cause harm, disruption, and administrative burden on providers.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics and consulting services, as well as a contract portfolio that represents $140 billion in annual purchasing volume. Solutions and services from Vizient improve the delivery of high-value care by aligning cost, quality and market performance. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Recommendations

Vizient appreciates the willingness of CMS to consider stakeholder feedback regarding the Draft Guidance which provided additional information regarding manufacturer effectuation of the Maximum Fair Price (MFP) in calendar years 2026 and 2027. While Vizient thanks CMS for clarifying that for 2026 and 2027, the agency "does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan"[2], we do have concerns that the Draft Guidance could negatively impact hospitals and other providers, especially if such policies continued for future years or if there is disruption to the 340B Program.

40.4 Providing Access to the MFP in 2026 and 2027

Voluntary Facilitation of the Retrospective Payments

In the Draft Guidance, CMS is soliciting comment on two distinct payment facilitation options which would be optional for dispensing entities and involve a Medicare Transaction Facilitator (MTF). The first option would involve the MTF collecting banking information from participating dispensing entities and providing that information to Primary Manufacturers electing to receive such information for the Primary Manufacturer to provide payment to those accounts. The second option would involve the MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating dispensing entities.

Should CMS continue to develop a retrospective model despite our continued and prior concerns, we believe that the second option would be less harmful than the first option, and we provide additional considerations for the agency. In addition, Vizient notes our strong opposition to the first option as we are extremely concerned that it could lead to unintended consequences for providers, particularly as it is unclear whether manufacturers would find alternative uses for any data obtained to the detriment of providers, and there would be even less transparency and oversight to manufacturer practices, while also adding complexity for providers.

Vizient believes that second option is preferable since it would help minimize burden on dispensing entities as they would need to ensure only one entity, the MTF, has accurate banking information and the dispensing entity would need to track fewer transactions. Further, option two would limit variability in how Primary Manufacturers could provide payment to accounts. Also, Vizient believes option two provides greater transparency and assurance that dispensing entities would be reimbursed as CMS, through the MTF, could more easily consider this information when evaluating compliance.

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[2] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Also, in the Draft Guidance, CMS provides that if a dispensing entity chooses to utilize the MTF payment facilitation functionality and later decides to no longer utilize it or modifies the selection of drugs for which it will use the MTF payment facilitation, the dispensing entity must notify CMS of this decision at least 90 calendar days prior to the effective date of the change. Given the MTF payment facilitation functionality has yet to be tested, implementation challenges could emerge that result in excessive payment delays to dispensing entities. As CMS is aware, providers often operate on extremely narrow margins, thus delays in payment can be highly disruptive to operations. Vizient is concerned that the 90 calendar day notice period could result in significant financial challenges for providers, especially if issues emerge with the MTF, such as a cybersecurity incident, that delay payment. Providers would effectively be forced to endure such challenges for an excessively long period of time. **Vizient urges CMS to consider opportunities to shorten the notice requirements for dispensing entities if they decide to no longer utilize the MTF payment functionality.**

In addition, in the Draft Guidance, CMS is soliciting comments on other potential considerations for facilitation services that may be provided through the MTF for dispensing entities. **To help minimize burden associated with identifying 340B claims, Vizient recommends that CMS ensure 340B third party administrators (TPAs) acting on behalf of covered entities can integrate with the MTF to identify 340B-eligible claims.** The automated process supported by the TPAs addresses the inherent risk and burden of the manual process for claim indicators. TPAs can identify 340B-eligible claims within 24 hours of prescription processing for inclusion in the Prescription Drug Event (PDE) submission to the Drug Data Processing System (DDPS) and supporting the 14-day prompt-MFP payment window. **Vizient believes including TPA functionality with the MTF process to effectuate the MFP price will be the least disruptive to the current prescription dispensing and support integrity for the IRA and 340B programs.**

<u>30-day Window for Plans to Submit Prescription Drug Event Records</u>

In the Draft Guidance, CMS indicates it is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. As CMS considers shortening the 30-day window to a 7-day window, Vizient suggests that the agency also consider policy for when unclaimed prescriptions must be returned to stock, which is often 14 days from the fill date and can result in an adjudicated claim being reversed. Vizient thanks the agency for considering opportunities to better ensure dispensing entities receive timely payment.

Also, in the Draft Guidance, CMS notes that it is evaluating options for the process, timing, and frequency by which files containing claims-level data elements will be transmitted from the MTF to Primary Manufacturers. As providers operate on slim margins and cannot afford to wait to be made whole on medications that are eligible for MFP pricing, including for several weeks or months, **Vizient urges CMS to transmit data from the MTF to Primary Manufacturers on a daily basis to prevent delays in processing.**

Further, additional attention should be paid to ensure the MTF promptly reviews data received. As provided in the Draft Guidance, delays on the part of the MTF will also delay the start of the

14-day prompt payment window, ultimately delaying when a dispensing entity would be made whole, among other potential concerns. **Vizient recommends that CMS require the MTF to promptly review received data, in addition to sending data to the MTF daily.**

Payment Elements

In the Draft Guidance, CMS provides that Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted parties, will be required to include in the report with payment-related data the corresponding data elements previously transmitted by the MTF in addition to the payment elements listed in Table 3 of the Draft Guidance for all claims that are transmitted by the MTF to the Primary Manufacturer regardless of whether a refund was paid. Also, these payment elements would be submitted to the MTF with the corresponding information from the MTF claim-level data elements file. Notably, in Table 3, CMS indicates that leaving certain payment elements blank will also have a meaning (e.g., If "MFP Refund Transaction Date", "Confirmation of MFP Refund to Dispensing Entity", and "Amount of Payment Sent as the MFP Refund" is left blank then that would mean the claim was prospectively purchased or a refund was not sent). Vizient discourages CMS from permitting any fields from being left blank, particularly where different inferences could be drawn if a field is left blank as this could create unnecessary confusion. In addition, it is unclear how CMS would interpret circumstances where only one field is left blank. **Vizient suggests that CMS refrain from allowing fields to be left blank to promote greater clarity and consistency.**

Electronic Remittance

In the Draft Guidance, CMS welcomes comment on the concept of the MTF creating and sending an electronic remittance advice to dispensing entities to reconcile the payment provided by the Primary Manufacturer's retrospective refund payments. Vizient provider members have expressed concerns regarding the administrative burdens that could emerge as a result of the Drug Price Negotiation Program, including efforts to ensure refunds have been appropriately provided. Vizient believes that having the MTF create and send electronic remittances in advance to dispensing entities may help minimize administrative burden. Vizient suggests that electronic remittance advice be provided at the same time payment is provided to the dispensing entity.

Additionally, CMS welcomes feedback on other methods for electronic remittance advice, including Primary Manufacturer electronic remittance advices, and specific data elements for such electronic remittance advices to ensure that accounts receivables can be closed for dispensing entities. Vizient suggests that such information should be standardized and compatible with current systems and processes providers, such as hospitals, utilize for similar processes. Vizient would have concerns if each Primary Manufacturer followed different approaches for electronic remittance as this would increase burden. As noted above, utilizing the MTF for this process may help minimize administrative burden on the part of providers.

Also, regarding claim adjustments and reversals, CMS invites comments on whether CMS should recognize a certain timeframe for paying or collecting claim adjustments, whether these should be considered as offsets to future claims to a dispensing entity that was overpaid, and

any additional approaches commenters may wish to see from the MTF data functionality for addressing claim adjustments. Vizient supports the use of the MTF for claims adjustments and reversals as this could avoid scenarios where manufacturers try to claw back or withhold funds from providers. Vizient anticipates that we would have additional comments regarding the role of the MTF should additional information about the MTF be made available, including real-world testing of different processes. **We encourage CMS to work with providers and share information about the MTF, and any related testing or pilots, before finalizing the scope of roles the MTF will perform.**

Nonduplication with 340B Ceiling Price

In the Draft Guidance, although CMS recognizes the various functions of TPAs in the context of the 340B Program, the agency does not provide guidance to enable the integration of TPAs with the MTF to identify 340B-eligible claims. Rather, CMS only "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price".[3] Vizient members, many of which are 340B covered entities, recognize the need for nonduplication of a covered entity's access to both the 340B ceiling price or MFP for a given claim. TPA software programs (e.g., stand-alone split billing systems or functionality within pharmacy dispensing systems) are currently integral in the 340B program to identify 340B-eligible claims vs. non-340B-eligible claims. Their performance has been proven to support program compliance by 340B covered entity internal audits as well as Health Resources & Services Administration (HRSA) audits for 340B program integrity. **Vizient urges CMS to enable the integration of covered entities' TPAs with the MTF to identify 340B-eligible claims irrespective of the use of claim indicators**.

As noted in the Draft Guidance, CMS would allow the Primary Manufacturer to calculate the difference between MFP and 340B price to support the nonduplication efforts. Vizient is concerned this approach introduces another complex process and burden for 340B covered entities, particularly when each primary manufacturer can establish their own process.
In the Draft Guidance, CMS outlines a retrospective refund model to effectuate access to the MFP, however, by enabling this method of accessing 340B discounts, CMS may be unintentionally altering how the 340B discount is provided to covered entities that goes beyond MFP drugs and therefore beyond CMS's authority. **Vizient urges CMS to avoid final guidance that enables a retrospective payment of the 340B discount.** In other words, CMS should clarify that a manufacturer would not be permitted to utilize information obtained through the MTF or as otherwise required to comply with the Drug Price Negotiation Program for other purposes, including providing access to 340B pricing. Further, CMS should emphasize to manufacturers that the statutory requirement to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price does not mean that manufacturers can delay providing access to 340B pricing.

[3] Draft Guidance at pg. 50

Also, the Draft Guidance's 340B refund model does not include detail regarding transparency and oversight in how the 340B refund is returned to the covered entities in the same way that this is created for the MFP refund with the MTF. Without this transparency or oversight, this model could result in manufacturers conditioning 340B sales or discriminating 340B access. This would result in additional labor, time, and costs, which could strain safety net providers even further.

Furthermore, there is no time-limit specified in the Draft Guidance that requires prompt payment by the primary manufacturer. This lack of a time-limit and the varied methods for implementing 340B refund models may lead to increased Administrative Dispute Resolution (ADR) suits and loss of transparency for HRSA.

It is important to consider these potential challenges and burdens that may arise from implementing the Draft Guidance. Safety net providers rely on the 340B program to support their services to underserved populations. Vizient urges CMS to include and financially support HRSA's Office of Pharmacy Affairs in meeting the statutory requirement for Nonduplication with 340B Ceiling Price and MFP so that both drug pricing programs can meet their congressional intent. Also, Vizient recommends that CMS work more closely with covered entities to identify alternative policies that would not harm covered entities or cause disruption.

90.2 Monitoring of Access to the MFP in 2026 and 2027

<u>340B Program</u>

As noted in the Draft Guidance, CMS is exploring the scope of disputes and complaints that the agency may remediate in the context of an otherwise private transaction between the Primary Manufacturer and dispensing entity. Regarding disputes related to the 340B Program, Vizient believes the HRSA 340B ADR process is appropriate to use when the 340B price is not made available by the Primary Manufacturer. To help streamline these cases, providers and HRSA would need access to the documentation indicating that the Primary Manufacturer did or did not provide the MFP refund in the case of a 340B-eligible drug. As such, Vizient encourages CMS to finalize policy that sets a clear expectation that Primary Manufacturers must demonstrate their justification of nonpayment of MFP because the claim was 340B eligible when the 340B price is less than MFP. The requirement for the Primary Manufacturers to justify their rationale for the nonpayment promotes transparency and accountability for CMS and dispensers.

Given the potential increase in the number of 340B disputes as a consequence of the negotiation program, Vizient believes that HRSA will require financial support, such as support from CMS, to effectively handle these disputes. Also, Vizient anticipated that such collaboration can help ensure that covered entities have a clear and efficient pathway to either obtain the 340B price or receive an MFP refund when appropriate.

Vizient believes it is important for CMS to work with HRSA to establish clear processes for dispute resolution, ensuring that dispensers receive the appropriate drug price and promoting transparency and accountability in both the 340B Program and Medicare Drug Price

Negotiation Program. Also, given dispensers eligible for 340B will likely have multiple dispute resolution processes to obtain either the 340B price or MFP, a clear framework is needed to prevent redundancy and confusion.

Reports of Complaints and Disputes

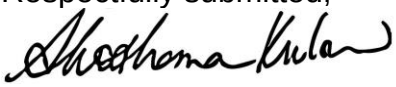
Should a dispute emerge that is not related to the 340B program, Vizient urges CMS to ensure that such a process is accessible to dispensing entities without unnecessary burden. We encourage the agency to learn from other dispute resolution processes involving providers. For example, as seen in the context of surprise billing, an extremely large volume of disputes has been brought, resulting in a backlog and several of the disputes may be missing elements to advance the resolution process. Vizient cautions CMS from providing a dispute resolution process that is too complex and burdensome for providers as they effectively face financial risk with each transaction involving a product selected for negotiation and when filing a dispute (e.g., delays in payment, financial and administrative burdens associated with collecting data to file a claim, potential fees associated with filing a claims). Therefore, Vizient urges CMS to work closely with providers to streamline any dispute process and to utilize the MTF where appropriate to proactively address circumstances where manufacturers are slow to provide refunds.

Also, Vizient suggests that CMS provide opportunities for providers to issues complaints and disputes. Such information could be used to inform enforcement activity, in addition to helping support the prompt resolution of disputes. For example, should a complaint be issued regarding a new issue impacting the program, CMS could proactively share steps that manufacturers could take to promptly resolve such issues.

Conclusion

Vizient thanks CMS for the opportunity to share feedback in response to the Draft Guidance. Vizient emphasizes the importance of minimizing provider burden, including avoiding disruptions to current purchasing and reimbursement practices. Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on the Draft Guidance. Please feel free to contact me or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,



Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.

July 2, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

We Work for Health appreciates the opportunity to share comments on the Medicare Drug Price Negotiation Program: Draft Guidance for Year 2027 (Initial Price Applicability Year [IPAY] 2027). We Work for Health brings together national and local business leaders, including labor, biopharma, patient advocacy, and other healthcare-related stakeholders to support policies that foster innovation and facilitate the delivery and lifesaving and life-enhancing medicines. As such, we share your goals of making prescription medicines more accessible and affordable to Medicare beneficiaries, but caution that implementation of the sweeping changes represented by the MDPN directly threaten those shared goals without significant diligence to avoid those harms. It is with those concerns in mind that we share the following comments on IPAY 2027.

Do More to Protect Beneficiary Access to Medicines

We are concerned by the "wait and see" approach CMS proposes in terms of protecting beneficiary access to medicines subject to the MDPN. In the IPAY 2027 draft guidance, CMS expresses concern regarding the potential for Part D plans to accelerate the use of restrictive formulary placement and utilization management techniques including step therapy and prior authorization to limit beneficiary access to medicines. Simply requiring that plans "cover" medicines subject to the MDPN is not sufficient to assure beneficiaries have access to them. We

urge you to do more to protect beneficiary access to these medicines in the final IPAY 2027 guidance and avoid the predictable harms that will follow if such protections are not put into place.

Improve Transparency in the Pricing Process

In the IPAY 2027 guidance, CMS maintains the current "black box" of its decision making in the drug pricing process. Not only does CMS plan to maintain secrecy around how it will set medicine prices until months after it makes those decisions, but CMS also proposes to *reduce* the number of times it will meet with drug manufacturers during the process. That reduction in meetings coupled with the serious issues that limited to impact of the patient-focused listening sessions last Fall casts significant doubt on whether CMS is concerned with the clinical benefits and overall value of these medicines at all. CMS is not a scientific agency well-versed in the practice of medicine or pharmaceutical development, much less the specific knowledge needed to understand the diseases being treated. These proposals raise serious concerns about whether a medicine's benefits and overall value to the patient, the healthcare system, and society as a whole are being appropriately evaluated. We strongly recommend that CMS build greater transparency into the decision-making process and allow for both more and more meaningful opportunities for stakeholder input, including reforms that facilitate input from beneficiaries, patients, caregivers, and providers who live with the realities of disease every day and will bear the brunt of the consequences of reduced access and less innovation.

Refine Criteria for "Selected Drug"

CMS proposes to continue using an overly broad definition and approach in identifying selected drugs for the MDPN. Specifically, CMS asserts that *any form* of a drug from the same manufacturer with the same active ingredient will be grouped together for price setting based on the earliest approval of any drugs in that group. This action ignores the significant contribution of follow-on treatments that may be used entirely differently, involve separate FDA approvals, and be used in clinical practice to address different health concerns. It also serves as a chilling effect on future research into new treatments whose only similarity is a shared active ingredient or moiety. That represents a huge loss for patients today and in the future. We urge CMS to reconsider and narrow the definition of "selected drug" to promote continued innovation.

Promote Biosimilar Competition by Removing Vague Marketing Condition

Provisions in the IRA fail to recognize differences in the timeline for selection for price setting and typical timelines for generic or biosimilar competition when exempting drugs with approved generic or biosimilar competitors from pricing. This flaw will severely limit the availability of generics and biosimilars but is made even worse by CMS's addition of poorly defined criteria to evaluate the nature of that competition. Specifically, CMS proposes to evaluate whether a generic or biosimilar competitor is engaged in "bona fide marketing". That concept fails to understand the market dynamics that have limited biosimilar access to date: insurers and PBMs determine whether these competitor drugs are covered. Forcing potential generics and biosimilars to compete with government set prices will reduce the incentives for market entry of these competitors that help significantly to lower prices and provide patients with treatment

options. We strongly encourage CMS to remove the poorly defined concept of "bona fide marketing" in the evaluation of generic or biosimilar competition.

We appreciate the opportunity to share these comments and look forward to seeing these concerns addressed in the final IPAY 2027 guidance.

Sincerely,

Dan Leonard
Executive Director
We Work For Health
www.weworkforhealth.org

Comment on Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted by:
Omar Qureshi, BS
Reshma Ramachandran, MD, MPP, MHS
Melissa Barber, PhD
Joseph S. Ross, MD, MHS
Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT) at Yale School of Medicine

Introduction

Thank you for the opportunity to comment on the updated draft guidance for the upcoming 2027 negotiations under the Medicare Drug Price Negotiation Program (Negotiation Program), facilitated by the Centers for Medicare and Medicaid Services (CMS). We are members of the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), an interdisciplinary initiative aligning research on medical product evaluation, approval, and coverage with the goal of advancing policies that improve patient outcomes.

On behalf of CRRIT, we laud CMS for the detailed proposed guidance document, which provides significant clarity into CMS's negotiation process with manufacturers, addresses concerns from manufacturers and the general public regarding the Negotiation Program, and once again reiterates CMS's commitment to reducing drug expenditure for the benefit of patients and the sustainability of the Medicare program. We agree with many aspects of the updated guidance, particularly sections that address ambiguity surrounding certain Negotiation Program clauses that could have been exploitable by manufacturers (such as the Exception for Small Biotech Drugs or the Application of the MFP Across Dosage Forms and Strengths), sections that provide further clarity into CMS's negotiation process with manufacturers, and sections that reiterate CMS's commitment to ensuring that manufacturers are encouraged to participate in the Negotiation Program fairly.

As clinicians and health policy researchers, we are optimistic that the Negotiation Program will lower Medicare drug expenditures for both the government and patients. However, as detailed in our prior research[1] and writing[2], there may be opportunities to further strengthen the program to better enable affordable access to expensive medicines. In our comments below, we offer suggestions to strengthen specific sections of the guidance document and also offer support for sections we believe to be critical to the Negotiation Program's effectiveness at a time when U.S. patients are increasingly facing challenges with prescription drug affordability.

Section 30.1 – Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

CMS clarifies the definition of a qualifying single source drug as it pertains to selecting drugs for consideration in the Negotiation Program to be: a drug which is approved and marketed under either the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act for small molecule and biologic drugs, respectively; a drug has been FDA-approved for ≥7 or ≥11 years for small molecule and biologic drugs, respectively; a drug which is neither approved under an Abbreviated New Drug Application nor the reference product for any biological product that is licensed and marketed under section 351(k) of the PHS Act for small molecule and biologic drugs, respectively. These clarifying points are well taken, especially with regards to the additional clarification that the active marketing of an authorized generic drug does not disqualify a branded drug from consideration from the Negotiation Program so long as the authorized generic drug is the only marketed alternative to a branded product. However, we urge CMS to consider what course of action to take if an authorized generic drug commands an outsized share of sales for a particular medication even when traditional generics are also simultaneously marketed, as is seen in the case of the drug aliskiren, a drug used to treat high blood pressure. Aliskiren, an authorized generic for the branded drug Tekturna launched by the manufacturer of Tekturna, was launched and marketed before any generic drugs produced by other manufacturers were allowed to come to market so that Tekturna's manufacturer could secure a first mover advantage in the drug's generics market.[3] As a result, even after other manufacturers launched independent generics to Tekturna, the aliskiren authorized generic remained the best-selling version of Tekturna despite having a higher price than other independent generics.[3] This situation is not unique. Research conducted using Medicaid prescription drug data from 2014-2020 found that 35% of authorized generics launched during this period were marketed for ≥1 year before independent generics had launched and that authorized generic drugs commanded accounted for disproportionately large market share in the first 3 years in which a branded drug faces competition from independent generics.[4]

Given the current treatment of authorized generics under the Negotiation Program, certain branded drugs and their authorized generic counterparts from the same manufacturer may be exempt from the negotiation program if independent generics are marketed, even when the independent generics do not pose any real commercial competition to the branded or authorized generic equivalent. We recognize that the guidance may have been constructed this way by design, but nonetheless encourage CMS to consider the inclusion of additional measures which may include branded and authorized generic drugs for consideration for the Negotiation Program if traditional generics do not provide material competition to a manufacturer's branded and authorized generic drug.

Section 30.2.1 – Exception for Small Biotech Drugs

CMS clarifies the terms and conditions of the Exception for Small Biotech Drugs (SBE), including the stipulation that that "a qualifying single source drug is not eligible for an SBE if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer." We strongly support the inclusion and clarification of the SBE as it would disincentivize large drug manufacturers from acquiring manufacturers of biotech drugs that meet the definition of a specified manufacturer solely for the purpose of

acquiring drug products which would be exempt from eligibility for the Negotiation Program. We agree with CMS's approach in evaluating on case-by-case basis the applicability of the SBE and definition of a qualifying manufacturer for each instance of a drug manufacturer acquiring another manufacturer with biologic drugs in its portfolio in order to determine whether an acquisition is occurring for the sole purpose of acquiring biologic drug products to ensure exemption from the Negotiation Program. We also support this approach because we believe it would not disincentivize mergers and acquisitions activity conducted by drug manufacturers for other reasons such as to achieve economies of scale or diversify their drug product portfolio, as these may represent legitimate reasons for mergers and acquisitions which may drive value for patients.

Section 30.4 – Publication of the Selected Drug List

CMS specifies that the Selected Drug List for 2027 will "include the 15 (or all, if such number is less than 15) drugs covered under Part D." We appreciate that CMS recognizes that less than 15 drugs may be eligible for 2027 negotiations under the Negotiation Program's drug eligibility criteria and also appreciate the clarification that if such is the case, CMS will include less than 15 drugs on the Selected Drug List. We recently published a study that simulated the number of drugs, and attributable drug expenditure from those drugs, that would be eligible for the Negotiation Program from 2016-2019.[1] Our findings corroborate what CMS has recognized: current drug eligibility criteria made approximately two-thirds of drugs with ≥$200 million in annual expenditure ineligible for the Negotiation Program, which may prevent CMS from filling all spots on the Selected Drug List in some years. We encourage Congress and CMS to consider expanding eligibility requirements for price negotiation to ensure there are a sufficient number of high-expenditure drugs eligible for negotiation or make certain ineligible drugs contributing to significant annual Medicare spending eligible for negotiation on a case-by-case basis.

Moreover, we encourage Congress and CMS to consider modifying eligibility requirements pertaining to launch date recency or consider aligning the post-launch timeframes for small molecule and biologic drugs to consist of the same number of years post-launch of 7 years or less rather than the distinct periods of >7 and >11 years for small molecule and biologic drugs, respectively. Prior work investigating pre-market development times for small molecule and biologic drugs using FDA approval and US Patent and Trademark Office data found no significant difference in pre-market development times between the two classes of drugs.[5] Additionally, this work's analysis of the Merck Index found that biologic drugs were associated with development times 2.5-2.9 years shorter than those of small molecule drugs, on average.[5] These observations corroborate our push for small molecule and biologic drugs to have identical launch date recency eligibility requirements applied to them under the Negotiation Program to enhance the Negotiation Program's ability to generate savings for Medicare by making more drugs eligible for negotiation under the Negotiation Program.

Section 40.1 – Entrance into an Agreement with CMS and Alternatives

CMS has reiterated in this draft guidance that if a manufacturer refuses to participate in the Negotiation Program, the manufacturer may "may expedite its exit from the CGDP and the Manufacturer Discount Program". While this information has been previously conveyed, we affirm CMS's decision to adhere to the decision to impose material consequences, including

inaccessibility to the Medicare market, should manufacturers opt out of the Negotiation Program. Doing so is critical to promote manufacturer participation in the Negotiation Program and achieve savings on drug expenditure.

Section 40.2.1 – Confidentiality of Proprietary Information

CMS states that it "must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information". We appreciate CMS's efforts to ensure that manufacturers retain competitiveness from proprietary information pertaining to their drug development, manufacturing, and commercial processes. However, we suggest that CMS consult experts outside the CMS and manufacturers without conflicts of interest to definitively determine whether information is truly confidential to ensure the validity of manufacturer claims around confidentiality. Such information can be critical for outside expert parties to assist CMS in their negotiations and in setting a fair price. The availability of such data can allow others to conduct studies to better understand the consequences of ensuring a fair price for negotiations while also allowing outside experts to weigh in on the validity of the figures put forward by the manufacturers to CMS.

Additionally, we support CMS's decision to deem information pertaining to Federal financial support received by manufacturers for selected drug research and development as non-proprietary. We also encourage CMS to treat any manufacturer-related information disclosed to public equity investors of manufacturers on investor calls or SEC-sanctioned documentation as non-proprietary information, if such information is not considered non-proprietary already.

Section 40.2.2 – Data and Information Use Provisions and Limitations

CMS states that it "will make public a narrative explanation of the negotiation process and share redacted information" as appropriate. As with all other measures in the guidance document that further enhance transparency surrounding the negotiation process, we support this effort. Additionally, we encourage CMS to solicit retrospective feedback on negotiation processes undertaken as part of the Negotiation Program from outside experts in order to further improve CMS's performance in negotiations with manufacturer in subsequent years.

Section 40.4 - Providing Access to the MFP in 2026 and 2027

CMS states that they will provide commercial and other payors with access to Maximum Fair Prices (MFPs) established through the Negotiation Program, allowing private payors to "to have discretion to consider Medicare payment rates, including the MFP, in establishing their own payment policies". We commend CMS for being transparent with established MFPs. Prior work has found that employer-sponsored insurance plans pay more than Medicare on common physician-administered drugs.[6] Additionally, out-of-pocket drug expenditures for patients covered by commercial payors have been found to exceed those for patients covered by Medicare[7], exacerbated further by the $2000 out-of-pocket cap established by the Inflation Reduction Act for Medicare beneficiaries. Thus, CMS releasing MFPs negotiated through the Negotiation Program to private payors may allow them to negotiate more competitive prices with manufacturers on prescription drugs, as well as physician-administered products when the Negotiation Program is expanded to drugs covered by Medicare Part B to allow for greater

pricing parity relative to that negotiated by Medicare. Should private payors leverage MFPs to negotiate more competitive prices on drugs included on the Selected Drugs List, which is comprised of some of the costliest drugs by annual expenditure, they may be able to ultimately provide greater value for the patients they insure through lower out-of-pocket expenditures or lower insurance premiums attributable to cost savings on drug expenditure.

Section 50.1 – Manufacturer-Specific Data

CMS requires that manufacturers submit information on certain factors for further consideration including, but not limited to, research & development (R&D) costs, cost of production, prior federal financial support for novel therapeutic discovery with respect to the selected drug, FDA-recognized exclusivities, among other factors, to inform considerations of a "fair profit" for the selected drug. We support CMS's aspirations to establish such a "fair profit" MFP. However, we are concerned that some potential ambiguities in the guidance may limit its usefulness and present challenges in its application.

- R&D: The guidance notes that the preliminary price may be adjusted upward in cases where R&D costs have not been recouped, and downwards where they have. Appendix A divides R&D into five categories, including acquisition costs, base pre-clinical research costs, post-investigational new drug application costs, abandoned and failed drug costs, and all other R&D direct costs. At present, it is not clear in the guidance whether manufacturers are required to report R&D costs disaggregated by these categories, or whether categories are constitutive of a simple total of R&D costs that can be reported. We strongly urge CMS to require that R&D costs be reported within the disaggregated categories proposed. Without disaggregation by category, manufacturers may be able to "double count" the same "abandoned and failed drug costs" across multiple products, if they share the same active moiety or mechanism of action. Similarly, when drugs are acquired – particularly in late-stage clinical development – the manufacturer is not taking on risk, and so related failed research should not be considered in the same way in assessing total R&D spend. The guidance should also clarify that R&D spending should be reported as out-of-pocket spending, and not be capitalized or risk-adjusted. CMS may consider providing stylized case examples, as were included in National Institute of Standards and Technology's "Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights", to further clarify acceptable reported costs.

- Unit production costs: We commend CMS for including unit production costs, which are routinely considered by health systems globally, but have thus far been used in comparatively limited contexts in the United States (for example, through some DoD cost-plus contracts). There is no standard methodology for reporting production costs, and the guidance provided in Appendix A is generally clear, detailed, and comprehensive. However, we are concerned that "allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses)" is vague. Capitalized production facility costs could be interpreted to include investments in a given facility. To avoid double-counting across products, the guidance should be updated so that capitalized production facility costs are proportional to their volume or revenue across the full facility.

- Prior federal financial support: In addition to definitions that financial support include "tax credits, direct financial support, grants or contracts, [and] in-kind contributions", we suggest that federal financial support also include some measure of the value of incentives such as priority review vouchers (PRVs). PRVs in many cases constitute the largest federal investment, valued between by Ridley and Régnier (2016) to be worth between $67.5 million (July 2014) and $350 million (August 2015).[8] Uncertainty in the value of the voucher is related to the number of total vouchers on the market, and to the profitability of the drug to which it is applied. Ridley and Régnier's method for estimating the value of a given PRV combines the number of months of acceleration in approval with fifth-year sales for the product to which the PRV is applied.[8] This model has been applied to a range of other drugs, and could be included within this guidance to facilitate the inclusion of federal investments through PRVs. We are also concerned that the window of included federal investments should be longer than the proposed 52 months in cases where manufacturers cannot calculate the length of the basic pre-clinical research period. In practice, we anticipate most manufacturers will default to 52 months where beneficial, as there is no universally defined measure of what the pre-clinical phase should include. According to the guidance, 52 months was chosen as the average reported in reviewed studies on R&D costs and timelines. An average is not appropriate in this context: public investment in research is in most cases undertaken in the earliest and riskiest phases of research. We would therefore anticipate that federal investments be skewed earlier, and any *average* measure of the duration of pre-clinical research therefore disproportionately exclude federal versus manufacturer investments. As one example, in the case of blockbuster GLP-1 drugs, estimated to cost CMS $166 billion per year if used by all eligible adults on Medicare and Medicaid, federal investments stretch back to the 1970s and 1980s for semaglutide, for which an Investigational New Drug (IND) application was filed only in 2019.[9,10]

The inclusion of these factors is an important step forward in achieving both fairer prices for CMS, but also generates valuable transparency and insight into costs across the value chain. At present, even the Congressional Budget Office (CBO) does not have access to R&D and clinical trial costs, and instead relies on industry-reported figures from anonymous surveys collected in industry-funded research studies.[11] This has curtailed the objectivity and accuracy of models assessing the impact of legislation such as the IRA on future innovation. We encourage CMS to continue to work with stakeholders and expert to develop and refine methodologies used for reporting costs of R&D, production, and the value of federal funding and incentives. To ensure the accuracy and completeness of data provided, CMS could contract a third party auditor to review a random sample of submissions.

Section 50.2 Evidence About Therapeutic Alternatives

CMS states that they will "consider evidence about alternative treatments to the selected drug" during Negotiation Program negotiations which is to be submitted by manufacturers, members of the public, clinicians, academic experts, and other interested parties. We support CMS's efforts in this regard, as the identification of clinically interchangeable drugs or therapies would allow for more productive and informed negotiations with manufacturers. However, we

encourage CMS to work alongside other agencies on this effort, such as international agencies which assess drugs' clinical interchangeability or Veterans Affairs, which assesses drugs' clinical interchangeability to some extent to determine drugs' tier placement and applicable utilization management strategies on drug formularies. These agencies that likely have extensive data and expertise regarding drugs' real-world and post-approval efficacy and safety profiles including comparative effectiveness data, may help CMS to develop even more well-informed stances on therapeutic alternatives for selected drugs prior to negotiations with manufacturers.
Moreover, CMS could not only partner with these agencies, but also payors, to proactively generative evidence around the negotiation-eligible drug and other alternative treatments should such data not be available. Payors may prove to be effective partners in such evidence generation given their vested interest in determining which therapeutics are most effective and the ability to use payers' extensive claims data as a source of real-world evidence for drug efficacy and safety.[12] Being able to confidently assess selected drugs' clinical interchangeability with alternative therapeutics through the generation of such evidence would allow CMS to make appropriate decisions regarding selected drugs' formulary tier placement and utilization management on Medicare formularies after MFPs are negotiated. Our previous research regarding 2016 Medicare prescription drug plan formularies found that a substantial portion of Medicare formularies did not fully capitalize on opportunities to incentivize prescribing of generic drugs over their more expensive branded drug counterparts due to suboptimal branded drug tier placement and utilization management.[13] After negotiating MFPs, there is room for CMS to further decrease Medicare drug expenditure by choosing appropriate formulary tier placement and implementing appropriate utilization management strategies for drugs selected for the Negotiation Program on Medicare formularies.

Additionally, we encourage CMS to consider making drug efficacy and safety analyses between selected drugs and identified therapeutic alternatives publicly available. Making these analyses public would not only allow outside experts to provide insight on CMS's conclusions but also potentially allow clinicians to enhance clinical care provided to patients by informing them of selected drugs' efficacy and safety relative to alternative therapeutics.

Section 60.4 – Negotiation Process

CMS states that they will host patient-focused events to seek verbal input from "patients, beneficiaries, caregivers, and consumer and patient organizations" to inform negotiations. We support CMS's aspiration to integrate varied perspectives into the negotiation process. However, our previous research demonstrated that among the 50 highest-revenue PAOs in the US, three-fourths had board members, senior paid staff, or executives with prior or current ties to the pharmaceutical and medical device industries.[14] Additionally, a report by Patients for Affordable Drugs found that several patient advocacy groups actually oppose drug pricing reforms, such as those included in the Inflation Reduction Act and the Negotiation Program, despite their claims to fight for improved patient access to healthcare.[15] These groups receive millions of dollars in funding from the pharmaceutical industry, have leadership with significant ties to the pharmaceutical industry, and support policy paradigms which would undoubtedly worsen patient access to care, such as policies which would provide unfettered pricing power to drug manufacturers.[15] Given that representatives at patient-focused events may have conflicts of interest pertaining to selected drugs, we encourage CMS to ensure parity of voices and perspectives among those represented at these events. Additionally, we encourage CMS to

include the voices of clinicians at these events, including generalist physicians, as they often assist patients in navigating access challenges to their medications and finding strategies to manage prescription drug costs.

Section 60.5 – Application of the MFP Across Dosage Forms and Strengths

CMS states that they will "apply the MFP across different dosage forms and strengths of the selected drug and not based on the specific formulation or package size or package type of such drug." We support CMS's treatment of different dosage forms and strengths with regards to MFP given the prevalence of strategies employed by branded drug manufacturers to extend drugs' market exclusivity protection or delay generic launches, and thus protect revenue associated with drugs, such as "evergreening" or "product hopping". We found that between 1995 and 2010, approval of new formulations was 4 times more likely among blockbuster drugs and 5.5 times more likely among drugs granted accelerated approval, indicating that manufacturers likely launch new drug formulations or dosage forms for commercial reasons.[16] We believe that by applying the MFP across all dosage forms or formulations of a selected drug, CMS is taking steps to disincentivize manufacturers from launching products which repackage an existing drug into a new dosage form or formulation for commercial gain, and instead incentivizes manufacturers to do so only if it truly improves patients' experience or care.

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