Draft CY 2026 Part D Redesign Program Instructions

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10. Introduction

The purpose of these Draft Calendar Year (CY) 2026 Part D Redesign Program Instructions (Draft CY 2026 Program Instructions) is to provide interested parties with draft guidance regarding the implementation of section 11201 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, which made several amendments and additions to the Social Security Act (the Act) that affect the structure of the defined standard (DS) Part D drug benefit. These Draft CY 2026 Program Instructions also provide interested parties with draft guidance on the successor regulation exception to the IRA's formulary inclusion requirement for selected drugs, a topic relevant to the Medicare Part D program that relates to the implementation of sections 11001 and 11002 of the IRA, which establish the Medicare Drug Price Negotiation Program (Negotiation Program) to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products.

These Draft CY 2026 Program Instructions contain a detailed description of, and guidance related to, all IRA-related changes newly in place for CY 2026 made by sections 11201(a) and (b) of the IRA to the Part D benefit and certain changes in place for CY 2026 made by sections 11201(c) and (e) of the IRA. These Draft CY 2026 Program Instructions are being published

concurrently with the Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, which announces updates to Part D parameters for CY 2026. Some of those updates are impacted by provisions discussed in this document.[1]

Section 11201(f) of the IRA directs the Secretary of the Department of Health and Human Services (the Secretary) to implement section 11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. In accordance with the law, the Centers for Medicare & Medicaid Services (CMS) is issuing these Draft CY 2026 Program Instructions for implementation of section 11201 of the IRA for 2026. Changes made by section 11201 of the IRA specific to CY 2023 are described in separate guidance.[2] Changes specific to CY 2024 are discussed in the CY 2024 Advance Notice and Rate Announcement.[3] Changes to the Part D benefit for CY 2025 are discussed in the Final CY 2025 Part D Redesign Program Instructions (Final CY 2025 Program Instructions).[4] For detailed guidance on the Medicare Part D Manufacturer Discount Program (Discount Program), see the Medicare Part D Manufacturer Discount Program Final Guidance and the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers.[5, 6]

As noted above, these Draft CY 2026 Program Instructions also contain guidance on the successor regulation exception to the IRA's formulary inclusion requirement for selected drugs, a topic relevant to the Medicare Part D program that relates to the Negotiation Program and implementation of sections 11001 and 11002 of the IRA. Sections 11001(c) and 11002(c) of the IRA direct the Secretary to implement the Negotiation Program provisions in sections 11001 and 11002 of the IRA, including amendments made by such sections, for 2026, 2027, and 2028 by program instruction or other forms of program guidance. In accordance with the law, CMS is including guidance regarding the successor regulation exception in these Draft CY 2026 Program Instructions to implement certain provisions in sections 11001 and 11002 of the IRA for 2026. For detailed guidance on the Negotiation Program, see the Medicare Drug Price Negotiation

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[1] Please see the Advance Notice of Methodological Changes for Calendar Year (CY) 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

[2] Refer to CMS' Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin memorandum.

[3] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

[4] Refer to the Final CY 2025 Part D Redesign Program Instructions: https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.

[5] Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance and Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers memoranda.

[6] Unless otherwise specified, all references in this memorandum to the "Discount Program" and any relevant terminology refer to the new Manufacturer Discount Program beginning on January 1, 2025, consistent with section 1860D-14C of the Act.

Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026[7] and the Medicare Drug Price Negotiation Program: Final 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.[8]

10.1 Final CY 2025 Part D Redesign Program Instructions

Changes to the Part D benefit for CY 2025 are discussed in the Final CY 2025 Program Instructions. The policies described in the Final CY 2025 Program Instructions also apply in CY 2026 unless otherwise stated in these Draft CY 2026 Program Instructions. These Draft CY 2026 Program Instructions only include policies updated or modified from CY 2025 and new polices for CY 2026.

Sections in these Draft CY 2026 Program Instructions that update or modify policies stated in the Final CY 2025 Program Instructions include the following:

- Section 20: Redesigned Part D Benefit in CY 2026 (in the Final CY 2025 Program Instructions: "Section 20: Detailed Description of the Redesigned Part D Benefit")
- Section 30: Creditable Coverage (in the Final CY 2025 Program Instructions: "Section 90: Creditable Coverage (§ 423.56)")
- Section 40: Definition of Enhanced Alternative Benefit Design (in the Final CY 2025 Program Instructions: "Section 120: Definition of Enhanced Alternative Benefit Design (§ 423.104(f))")
- Section 50: PDP Meaningful Difference (in the Final CY 2025 Program Instructions: "Section 130: PDP Meaningful Difference (§ 423.265(b)(2))")
- Section 60: Non-Calendar Year (NCY) EGWPs (in the Final CY 2025 Program Instructions: "Section 140: Non-Calendar Year (NCY) EGWPs")
- Section 80: Medical Loss Ratio (MLR) (in the Final CY 2025 Program Instructions: "Section 160: Medical Loss Ratio (MLR) (§§ 423.2420 and 423.2460)")

[7] For purposes of these program instructions, CMS refers to this guidance as the Revised Guidance for Initial Price Applicability Year 2026. The Revised Guidance for Initial Price Applicability Year 2026 is available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[8] For purposes of these program instructions, CMS refers to this guidance as the Final Guidance for Initial Price Applicability Year 2027. The Final Guidance for Initial Price Applicability Year 2027 is available at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

Sections in these Draft CY 2026 Program Instructions that are newly in place for CY 2026 and were not included in the Final CY 2025 Program Instructions include the following:

- Section 70: Selected Drug Subsidy
- Section 90: Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs

For those topics addressed in these Draft CY 2026 Program Instructions, CMS explains, where applicable, how specific policies from the Final CY 2025 Program Instructions apply or do not apply for CY 2026. For policies that continue to apply for CY 2026, but are not addressed in these Draft CY 2026 Program Instructions, interested parties should refer to the Final CY 2025 Program Instructions at https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.[9]

In addition, Sections 11202(c), 11401(e), and 11406(d) of the IRA direct the Secretary to implement sections 11202 pertaining to the maximum monthly cap on cost-sharing payments under standalone prescription drug plans (PDPs) and Medicare Advantage prescription drug (MA-PD) plans (i.e., the Medicare Prescription Payment Plan), 11401 pertaining to coverage of adult vaccines recommended by the Advisory Committee on Immunization Practices under Medicare Part D, and 11406 pertaining to appropriate cost-sharing for covered insulin products under Medicare Part D, respectively, by program instruction or other forms of program guidance through CY 2025. Because such program instruction authority does not apply to CY 2026, any specific provision of the Final CY 2025 Program Instructions that implements sections 11202, 11401, and 11406 of the IRA is not applicable to CY 2026. Interested parties should refer to the proposed rule titled "CY 2026 Contract Year 2026 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," which was issued on November 26, 2024, for proposed rulemaking related to sections 11202, 11401, and 11406 of the IRA for CY 2026 and subsequent years.

Furthermore, the Final CY 2025 Program Instructions contain references to the CY 2025 Part D benefit parameters as described in the CY 2025 Advance Notice and CY 2025 Rate Announcement. Each year, in the Advance Notice, CMS updates the statutory parameters for the DS Part D drug benefit and provides information on any changes to the payment methodology for the Part D benefit. As such, the specific CY 2025 benefit parameters referenced in the Final CY 2025 Program Instructions do not apply in CY 2026. Rather, for CY 2026, for policies described in the Final CY 2025 Program Instructions that also apply in CY 2026, the CY 2025 benefit parameters discussed in the Final CY 2025 Program Instructions should be read as the

[9] A summary of key comments and changes for Final CY 2025 Program Instructions can be found in Section B (pp. 3-4) of the Final CY 2025 Program Instructions: https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf.

corresponding CY 2026 benefit parameters, as updated in the CY 2026 Advance Notice. For example, the $2,000 annual out-of-pocket (OOP) threshold for CY 2025 discussed in the CY 2025 Program Instructions should be read to be $2,100 for the purposes of CY 2026, as specified in the CY 2026 Advance Notice. Interested parties should refer to the appendix at Section 100 of these draft program instructions and Attachment III Section A of the CY 2026 Advance Notice for updated benefit parameters.

10.2 Request for Comment on Draft CY 2026 Part D Redesign Program Instructions

As was the case for the Draft CY 2025 Program Instructions, CMS is voluntarily soliciting comment on these Draft CY 2026 Program Instructions, including on policies originally adopted in the Final CY 2025 Program Instructions that will continue to apply in CY 2026 as described in section 10.1 of this document. Please send comments to PartDRedesignPI@cms.hhs.gov with the subject line "Draft CY 2026 Part D Redesign Program Instructions." CMS will consider comments received by 11:59 PM Eastern Time on February 10, 2025. CMS will issue final program instructions for CY 2026 after considering the public comments received in response to these draft program instructions. In the final program instructions, CMS may change any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues. Policies established in the final program instructions for CY 2026 are subject to change in subsequent years.

If any provision of these program instructions, once finalized, is held to be invalid or unenforceable, CMS intends that it shall be severable from the remainder of these program instructions, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances. CMS has determined that all relevant provisions of the guidance could function independently from one another.

20. Redesigned Part D Benefit in CY 2026

The IRA has already made significant changes to the Part D benefit and to the payment obligations of enrollees, Part D plan sponsors, manufacturers, and CMS, which took effect in CYs 2023, 2024, and 2025. Beginning in CY 2026, with the maximum fair prices negotiated under the Negotiation Program beginning to take effect on January 1, 2026, the IRA makes further changes to payment obligations in Part D related to selected drugs (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act).[10]

[10] For more information, see: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf and https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

The DS benefit for CY 2026 will consist of the following phases and liabilities, with the CY 2026 changes reflected in bolded and italicized font:

- **Annual deductible**. The enrollee pays 100 percent of their gross covered prescription drug costs (GCPDC) until the deductible is met.
- **Initial coverage.** The enrollee pays 25 percent coinsurance for covered Part D drugs. The Part D plan sponsor typically pays 65 percent of the costs of applicable drugs and selected drugs[11] and 75 percent of the costs of all other covered Part D drugs. The manufacturer, through the Discount Program, typically covers 10 percent of the costs of applicable drugs. ***In the initial coverage phase, CMS will pay a 10 percent subsidy for selected drugs during a price applicability period.*** This phase ends when the enrollee has reached the annual OOP threshold of $2,100 for CY 2026.
- **Catastrophic**. The enrollee pays no cost sharing for Part D drugs. Part D plan sponsors typically pay 60 percent of the costs of all covered Part D drugs. The manufacturer pays a discount, typically equal to 20 percent, for applicable drugs. CMS pays a reinsurance subsidy equal to 20 percent of the costs of applicable drugs, and equivalent to 40 percent of the costs of all other covered Part D drugs that are not applicable drugs. ***In the catastrophic phase, CMS will provide 40 percent reinsurance for selected drugs during a price applicability period.***

Please see the appendix for a diagram of the DS benefit in CY 2026 relative to the CY 2025 DS benefit.

30. Creditable Coverage (§ 423.56)

Under section 1860D-13(b) of the Act, Medicare beneficiaries may incur a Part D late enrollment penalty (Part D LEP) if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period during which the individual was eligible for Part D but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage. Under § 423.56(c), the entities described in § 423.56(b) (with certain exceptions) that offer prescription drug coverage must provide a written disclosure to Part D eligible individuals enrolled in, or seeking to enroll in the coverage, whether the coverage is creditable prescription drug coverage, subject to notification and timing requirements specified at § 423.56(f). If the coverage is not creditable prescription drug coverage, the disclosure must also meet the requirements under § 423.56(d).

[11] An applicable drug under the Discount Program is a Part D drug approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA), but does not include a selected drug (as defined in section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to that drug. Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

As discussed in section 90 of the Final CY 2025 Program Instructions, the changes made by the IRA required CMS to revise the regulatory definition of creditable prescription drug coverage in § 423.56(a). The revised definition that became effective January 1, 2025 remains in place for 2026 and reads as follows:

> Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount provided under section 1860D-14C of the Social Security Act, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

Since the start of the Part D program in CY 2006, an entity offering a group health plan[12] that is not applying for the retiree drug subsidy (RDS) under section 1860D-22(a) of the Act has been permitted to use either actuarial equivalence testing or the creditable coverage simplified determination methodology,[13] which CMS released as part of the "Updated Creditable Coverage Guidance" on September 18, 2009, to determine whether its prescription drug coverage is creditable.

In the Draft CY 2025 Program Instructions, CMS stated that, because of the IRA changes to the Part D benefit, the simplified determination methodology would no longer be a valid methodology to determine whether such an entity's prescription drug coverage is creditable as of CY 2025. The increased plan liability in the catastrophic phase of the DS benefit requires sponsors to pay more than the 60 percent specified in the current simplified determination methodology and, therefore, continuing to use 60 percent would not satisfy requirements for actuarial equivalence for creditable coverage. CMS received several comments on the Draft CY 2025 Program Instructions that raised concerns about the potential risk that a large number of Part D eligible individuals would no longer have creditable coverage through their group health plan if the existing simplified determination methodology were no longer available for CY 2025. Commenters were also concerned that group health plan sponsors would not have sufficient time to consider the impact of the Part D benefit changes made by the IRA to make decisions about their benefit offerings in time for CY 2025 coverage. In the Final CY 2025 Program Instructions, in response to those comments, CMS indicated that we would continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for group health plan sponsors not applying for the RDS. We also noted that, by permitting continued use of the creditable coverage simplified determination methodology for CY 2025, CMS has additional time to better assess the various impacts of the

[12] "Group health plan" as used in this Section refers to a group health plan described at § 423.56(b)(3). It does not include EGWPs, which are Part D plans, and, as such, cannot use the creditable coverage simplified determination methodology.

[13] Refer to CMS' Creditable Coverage Simplified Determination.

Part D redesign in CY 2025 and evaluate the modifications to the methodology that may be needed in future years to ensure that Part D eligible individuals with creditable coverage continue to have prescription drug coverage that is at least as good as DS Part D coverage. Finally, we stated that, for CY 2026, we would re-evaluate the continued use of the existing simplified determination methodology or establish a revised one.

Section 1860D-13(b)(5) of the Act requires creditable prescription drug coverage to have an actuarial value that equals or exceeds the actuarial value of standard Part D coverage (as determined under section 1860D-11(c) of the Act). Because of the changes made by the IRA to enhance the DS Part D benefit, we do not believe the existing simplified determination methodology meets this requirement; therefore, non-RDS group health plans are not permitted to use it to determine whether prescription drug coverage under their CY 2026 plans is creditable.

Instead, for CY 2026, CMS will permit non-RDS group health plans to use the revised simplified determination methodology described below to determine whether their prescription drug coverage is creditable. Under the revised simplified determination methodology, the coverage will be deemed to provide prescription drug coverage with an actuarial value that equals or exceeds the actuarial value of DS Part D coverage if it meets all of the following standards:

- Provides reasonable coverage for brand name and generic prescription drugs and biological products;
- Provides reasonable access to retail pharmacies; and
- Is designed to pay on average at least 72 percent of participants' prescription drug expenses.

The revised simplified determination methodology retains some parameters of the existing methodology, such as a requirement for reasonable coverage of brand and generic prescription drugs and reasonable retail pharmacy access. We have revised the requirements to add coverage of biological products due to changes in the prescription drug landscape since the existing methodology was developed and made other updates for accuracy. We removed the requirements related to annual and lifetime benefit maximums because changes to the health insurance landscape under the Affordable Care Act have essentially eliminated such limitations among group health plans. We also removed requirements related to an annual deductible, because outside of the Medicare program, it is unusual for health and drug coverage to be separate benefits, and integrated health and drug plans could have a significantly higher deductible than standard Part D coverage but still offer comparable drug coverage. Although plans with higher annual deductibles (including high deductible health plans) might appear less likely to meet the requirement to pay at least 72 percent of prescription drug expenses, such risk may be mitigated through other aspects of the benefit such as not applying a deductible to preventive (i.e., maintenance) medications, a reasonable and supportable allocation of the deductible attributable

to prescription drug expenses, or offering lower cost sharing than standard Part D coverage once the deductible is met.

Under the revised methodology, the group health plan coverage must be designed to pay at least 72 percent of participants' prescription drug expenses, versus 60 percent under the existing methodology. CMS made this revision because of program changes in Part D—in particular, the benefit changes mandated by the IRA, which significantly enhanced the Part D DS benefit. These changes—which include a $35 cost sharing cap on a month's supply of each covered insulin product, access to recommended adult vaccines without cost sharing, the implementation of an annual OOP threshold ($2,100 for CY 2026), and the elimination of the coverage gap phase of the benefit—increase the proportion of drug costs paid by the Part D plan sponsor. In light of the more robust Part D benefit under the IRA, CMS has determined that the 60 percent value is no longer an accurate representation of the value of the Part D benefit and that group health plan coverage must be designed to pay on average at least 72 percent of participants' prescription drug expenses in order to provide coverage the actuarial value of which to the individual equals or exceeds the actuarial value of standard Part D coverage, as required by section 1860D-13(b)(5) of the Act. We estimated the actuarial value of the DS benefit in 2026 using 2023 Part D claims experience adjusted to the projected 2026 benefit levels. This estimate confirmed that the actuarial value increased to 72 percent, primarily as a result of the changes made by the IRA to the Part D DS benefit.

Consistent with the statutory and regulatory requirements referenced in this section, non-RDS plans may make the determination of creditable coverage either by (1) determining whether the actuarial value of the coverage equals or exceeds the actuarial value of DS Part D coverage, demonstrated through generally accepted actuarial principles, or (2) using the revised simplified determination methodology. In accordance with the requirements at § 423.884(a)(1), any entity applying for the RDS cannot use the revised simplified determination methodology, and instead must make an annual determination of actuarial value in accordance with the requirements at § 423.884(d).

CMS is seeking comment from interested parties, including actuarial firms, consulting companies, employee benefit managers, employers, and others with direct involvement in making determinations of creditable coverage, regarding the following:

- The prevalence with which non-RDS group health plans use the existing simplified determination methodology in lieu of actuarial equivalence testing;

- The prevalence with which non-RDS plans currently meet creditable coverage requirements (through either the simplified determination methodology or actuarial equivalence testing) and the anticipated impact on such plans if the policies discussed in this section are finalized for CY 2026;

- Specific impacts of the changes to the Part D benefit and the corresponding revisions to the simplified determination methodology described above, including data reflecting such impacts on the populations of Part D eligible individuals who have maintained non-RDS creditable coverage, e.g., how many of those individuals or what percentage of that population would continue to have access to creditable coverage if the policies in this section are finalized for CY 2026;

- Anticipated changes, if any, to group health plan offerings to maintain plans that offer creditable coverage (RDS or non-RDS);

- Other feedback or data relevant to this section of these draft program instructions.

We also are seeking comment from any groups that may have experience assisting beneficiaries with issues related to creditable coverage and the loss of creditable coverage, whether such issues are prevalent, and, if so, if there are any trends in the types of beneficiaries that are disproportionately impacted.

40. Definition of Enhanced Alternative Benefit Design (§ 423.104(f))

Part D plan sponsors have the flexibility to offer non-DS plans, under which they can modify certain benefit parameters. This includes two types of basic plans—Actuarially Equivalent and Basic Alternative— in addition to Enhanced Alternative (EA) plans. EA coverage must meet the requirements of alternative prescription drug coverage and, in accordance with § 423.104(f), include both required basic prescription drug coverage and supplemental benefits.

Because the IRA did not modify the list of permissible supplemental benefits in section 1860D-2(a)(2)(A)(i) of the Act to include a reduction in the annual OOP threshold, Part D plan sponsors may not lower the annual OOP threshold below $2,100 for CY 2026. Thus, under § 423.104(f)(1)(ii), the following supplemental benefits remain as possible enhancement features for CY 2026: coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100 and/or

- Reduction (or elimination) of the DS deductible.

- Reduction of cost sharing in the initial coverage phase.

We note that, historically, we have not considered the waiving of a plan's deductible for a subset of its formulary tiers as an enhancement; however, we believe this does represent an increased value for enrollees. As such, we will consider the waiving of a plan's deductible for a subset of its formulary tiers as an enhancement. Despite this additional flexibility, we note that limited options remain for EA plans to increase the value of the benefit above that of DS coverage. Therefore, CMS believes it is critical to continue using a process for ensuring that beneficiaries receive value relative to the DS benefit when they enroll in an enhanced plan in terms of out-of-

pocket costs (OOPC) and in light of the supplemental premiums they may pay for these enhanced plans.

As noted above, EA plans may offer excluded drug coverage as an enhancement, but CMS is not establishing a requirement for the value of such coverage at this time. We note that CMS' Part D OOPC model does not include the excluded drug benefit in the OOPC estimate values. CMS will continue to perform separate reviews of individual drugs offered under excluded drug coverage, such as comparing drug prices to the cost sharing submitted, and working with Part D plan sponsors to make changes to benefits under our negotiation authority under § 423.272(a) if a plan's proposed benefit does not appear to offer enhanced value. Our reviews in recent years suggest that excluded drug offerings have not demonstrated a significant benefit, and we are considering prohibiting the option of *only* offering excluded drugs as a means to meet EA benefit design requirements. We seek comment on eliminating this option for meeting EA design requirements beginning with CY 2026. CMS will also consider the comments received in developing policies for CY 2027 and subsequent years.

For CY 2026, CMS will again utilize the Part D OOPC model as a mechanism to estimate the value of EA plans relative to the value of the DS benefit. The Part D OOPC model estimates the relative OOPC (i.e., the estimated beneficiary cost per month) for beneficiaries in Part D plans and, as discussed in Section 60 of this document, this value is used to evaluate meaningful differences between standalone PDP offerings during annual bid reviews. Consistent with our policy in CY 2025, CMS will not be reviewing PACE organization or EGWP plan benefit packages (PBPs) for purposes of implementing this requirement. For CY 2026, CMS will also exclude Dual Eligible Special Needs Plan and Medicare-Medicaid Plan PBPs from the review, as the value reflected in the OOPC model does not account for LIS cost sharing which would be available to the majority, if not all, beneficiaries in these plan types. We seek comment on any additional plan types that should be excluded from this analysis.

For the purpose of evaluating EA plan value for all Part D plan sponsors, as illustrated in Table 40, CMS will calculate an OOPC estimate for each submitted Part D EA plan that has indicated a reduction (or elimination) of the deductible, a waiver of the plan deductible for a subset of at least one tier, and/or a reduction in cost-sharing in the initial coverage phase. Using the same formulary that is submitted for the EA plan, CMS will also calculate an OOPC estimate for that formulary using the DS benefit. We subtract the OOPC value for the EA plan from the OOPC value that represents the DS benefit, for its submitted formulary, to determine the absolute OOPC difference. We then calculate the percent difference between the EA plan and DS plan by dividing the calculated absolute difference by the DS OOPC value. While CMS did not establish a specific threshold for CY 2025, we did analyze the submitted bid data. Using the CY 2025 bids, we calculated the percent difference for all plans, except for those plan types noted above, and then prepared distributions. For CY 2026, CMS is establishing a threshold of 15 percent, which represents the fifth percentile of the percent difference calculation, based on this analysis of CY 2025 bids. This threshold strikes a balance between ensuring value for beneficiaries while

maintaining a feasible approach for Part D plan sponsors. To assist Part D plan sponsors in bid preparations ahead of the CY 2026 bid deadline, the CY 2026 Bid Review OOPC Model will incorporate functionality for plans to run the formulary tied to the EA plan through a DS benefit design.

Table 40. Calculation to Evaluate EA Plan Offerings

Value	Source	Description	Calculation	CY 2026 Requirement	Example
[A] EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan (formulary and intended plan design)	N/A	N/A	$70
[B] DS EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan's formulary run through DS benefit	N/A	N/A	$105
[C] Difference	Calculation	Represents the absolute OOPC difference between the EA plan as compared to the EA formulary applying the DS benefit	[B] – [A]	N/A	$35
[D] Percent Difference	Calculation	Represents the proportion of additional value attributed to the EA plan as compared to the EA formulary applying the DS benefit	([C] / [B]) x 100	**For CY 2026, this value must be ≥ 15%**	33%

The CY 2026 PBP will include options, that can be selected via checkboxes-, available to increase the actuarial value of the benefit (i.e., reduced deductible, waived plan deductible for at least one tier (new for CY 2026), and/or reduced initial coverage phase cost shares). When the "Reduced Initial Coverage Phase cost shares" check box is selected, the PBP will activate a field where Part D plan sponsors must describe how their intended benefit design lowers cost sharing for beneficiaries in the initial coverage phase. Part D plan sponsors should use the free-text field in the Rx section of the PBP in HPMS to describe the specific features of their supplemental benefit that contribute to an increased value. The CY 2026 PBP must be approved by the Office

of Management and Budget (OMB) through the Paperwork Reduction Act (PRA). OMB has approved the current version (CMS-R-262; OMB control number: 0938-0763) until March 31, 2027.

Examples of best practice entries from CY 2025 include:

- $0 cost sharing for generic tiers;
- Placement of drugs on the lowest cost share tier; and
- Reduced cost sharing for tier 1 drugs at preferred pharmacies.

Part D plan sponsors should avoid non-specific language and language that pertains to non-Part D benefits. Examples of entries to avoid include:

- "Placeholder";
- Reduction of cost sharing in the initial coverage phase; and
- Entry of Part A/B or MA supplemental benefits (e.g., dental benefits).

We believe the approach outlined in this section is an important step toward ensuring that beneficiaries who choose a Part D EA plan with supplemental benefits are receiving value relative to the value they would receive from a DS benefit and experiencing improved transparency to find the plan that best meets their needs. This approach is also consistent with CMS efforts to ensure healthy competition in the plan market.

50. PDP Meaningful Difference (§ 423.265(b)(2))

The IRA's amendments to section 1860D-2 of the Act impact Part D plan benefit design by capping enrollees' annual OOP costs, eliminating the coverage gap phase, and eliminating cost-sharing in the catastrophic phase. As a result of these changes to the benefit, CMS adopted a new approach to assessing meaningful difference between an EA plan and a basic plan for standalone PDPs in CY 2025.

CMS has the authority under section 1857(e)(1) of the Act, incorporated into Part D by section 1860D-12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds "necessary and appropriate," as well as authority, under section 1860D-11(d)(2)(B) of the Act, to propose regulations imposing "reasonable minimum standards" for Part D plan sponsors. Under this authority, we can deny bids that are not substantially different from other bids submitted by the same organization in the same service area with respect to the benefit package or plan costs (§ 423.272(b)(3)(i)). This is an important protection, as it ensures beneficiaries are able to better distinguish between the plans available to them and ultimately make the best plan choice for their needs.

CMS has used a Part D OOPC model since CY 2012 to conduct the annual PDP meaningful difference evaluation and has refined it over the years based on experience and stakeholder feedback. The Part D OOPC model estimates the relative OOPC (i.e., the estimated beneficiary cost per month) for beneficiaries in PDPs. Annually, CMS has determined meaningful difference thresholds for the upcoming contract year by evaluating the Part D OOPC estimates using the prior year's approved bid and formulary data.

After consideration of the statutory changes under the IRA and the comments we received, we established an absolute percent threshold approach for evaluating PDP meaningful difference for CY 2025. This approach aligns with a longstanding CMS goal to move the meaningful difference evaluation from an absolute dollar differential to a percent differential. Once established, a percent differential will not require annual updates for inflation and will establish a stable, consistent requirement from year to year. This approach also considers the richness of the comparator basic plan in the evaluation; for instance, a basic plan with an OOPC of $100 will not be held to the same dollar threshold as a basic plan with an OOPC of $150.

For CY 2025, we required a 15 percent differential between a PDP organization's basic and EA plan(s). Despite concerns expressed by some commentors about the 15 percent differential threshold, all organizations were able to meet or exceed the requirement. For CY 2026, CMS will maintain this differential threshold of 15 percent, but we will continue to evaluate whether this threshold is appropriate beyond CY 2026. For CY 2026, Part D plan sponsors must demonstrate that each EA plan's Part D OOPC value generated from the OOPC model is at least 15 percent better than the basic plan offered by the same parent organization in the same region.

In addition to this requirement, CMS will continue to conduct a sub-analysis to determine the proportion of meaningful difference derived from formulary robustness as opposed to benefit design/tier placement for the enhanced plan. Based on past CMS experience in bid review, there are instances in which a Part D plan sponsor's EA plan within a region has offered higher cost sharing for individual formulary tiers when compared to its basic plan in that region. Such Part D plan sponsors achieve an adequate OOPC differential by adding drugs to the formulary without offering a richer benefit (e.g., lower deductible or lower copays) compared to the basic plan. CMS does not consider this type of enhancement to be entirely transparent to the beneficiary. We also note that such an enhancement is of limited scope, given that only beneficiaries who utilize the added drugs benefit from the enhancement. Further, in responding to CMS meaningful difference review concerns, we often find that Part D plan sponsors respond by simply adding drugs to their formularies, particularly those that are high cost but with low utilization, rather than improving on the benefit. Our intent is not to discourage plans from adding Part D drugs to their formularies and, while plans will receive credit in the OOPC model for adding drugs to their formulary, our methodology will not rely on formulary robustness alone to achieve a meaningful difference value.

To address this issue, the sub-analysis allows CMS to differentiate between the two metrics of formulary robustness and benefit design/tier placement. To assess these two metrics, CMS runs each plan's formulary (basic and enhanced) through the Part D OOPC model using a DS benefit design, allowing us to determine the proportion of meaningful difference that is attributed solely to formulary robustness. By subtracting this calculated value associated with formulary robustness from the overall Part D OOPC difference, CMS can estimate the proportion of meaningful difference resulting from benefit design/tier placement. We provide a description of the calculations in Table 50. For CY 2025, CMS required that each metric—formulary robustness and benefit design/tier placement—be no worse for the EA plan compared to the basic plan. All organizations were able to meet this requirement, with an average of 19.4 percent of the meaningful difference attributable to formulary robustness and 80.6 percent to benefit design/tier placement. For CY 2026, CMS will require the percentage attributed to formulary robustness be a positive value (greater than or equal to 0 percent, and the proportion attributed to benefit design/tier placement be greater than 50 percent.

As illustrated in Table 50, values [A] – [D] are outputs from the Part D OOPC Model. Values [E] – [H] will be calculated by Part D plan sponsors when preparing bid submissions and by CMS when evaluating bid submissions.

Table 50. Output from Part D OOPC Model and Calculations to Evaluate Part D Meaningful Difference

Value	Source	Description	Calculation	CY 2026 Requirement	Example
[A] Basic OOPC	Output from the Part D OOPC model	OOPC value of basic plan (formulary and intended plan design)	N/A	N/A	$100
[B] DS Basic OOPC	Output from the Part D OOPC model	OOPC value of the basic plan's formulary run through DS benefit	N/A	N/A	$110
[C] EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan (formulary and intended plan design)	N/A	N/A	$70
[D] DS EA OOPC	Output from the Part D OOPC model	OOPC value of the EA plan's formulary run through DS benefit	N/A	N/A	$104

Value	Source	Description	Calculation	CY 2026 Requirement	Example
[E] Meaningful Difference	Calculation	The differential in OOPC between the EA plan and the basic plan. This value must be positive, indicating the EA plan is better (i.e., lower) than the basic plan	[A] − [C]	N/A	$30
[F] Formulary Component (%)	Calculation	The proportion of meaningful difference attributed to formulary robustness	$\frac{[B]-[D]}{[E]} \times 100$	**For CY 2026, this value must be ≥ 0%**	20%
[G] Benefit Component (%)	Calculation	The proportion of meaningful difference attributed to benefit design / tier placement	100% - [F]	**For CY 2026, this value must be greater than 50%**	80%
[H] PDP Meaningful Difference (%)	Calculation	The percent difference between the enhanced plan and the basic plan	$\frac{[A]-[C]}{[A]} \times 100$	**For CY 2026, the EA plan must offer at least 15% more value than the basic plan**	30%

In summary, for CY 2026, in addition to meeting the 15 percent overall differential between PDP basic and EA plan(s), as calculated and represented in Table 50 as [H], CMS will also require that the share of meaningful difference attributed to benefit design/tier placement, as calculated and represented as [G], be greater than 50 percent and the share of meaningful difference attributed to formulary robustness, as calculated and represented as [F] be greater than or equal to 0 percent.

To assist Part D plan sponsors ahead of the CY 2026 bid deadline, the CY 2026 Bid Review Part D OOPC Model will continue to incorporate the ability for Part D plan sponsors to run each of their plan's formularies through a DS benefit. We believe this approach will be transparent for

beneficiaries and ensure that those who choose an EA plan are paying for value relative to a basic plan offered by the same Part D plan sponsor in the same region.

60. Non-Calendar Year (NCY) EGWPs

The CY 2025 Final Program Instructions addressed how Part D plan sponsors offering NCY EGWPs operating on an NCY basis were to implement IRA changes that took effect on January 1, 2025 during the middle of their NCY plan years. The IRA changes, including the decrease in the annual OOP threshold to $2,000 and the transition to the new Discount Program, required us to revise existing guidance specific to NCY plan years that began in 2024 and continued into 2025. With those IRA changes now in place, we are providing these draft program instructions for NCY plan years that begin in 2025 and continue into 2026.

Background

A CMS waiver permits Part D plan sponsors offering EGWPs to establish NCY plan benefit packages in HPMS that allow employer groups to determine benefits (including deductibles, OOP limits, etc.) on an NCY basis.[14] As a result of this waiver, a small proportion of EGWPs currently have NCY plan benefit packages, meaning their NCY plan year will start during 2025 and continue into 2026.

Since January 1, 2014, supplemental benefits provided by EGWPs beyond the parameters of the DS benefit are always considered non-Medicare other health insurance (OHI). (See 77 FR 22072 (April 12, 2012); and 80 FR 7912 (February 12, 2015).) This section provides guidance for EGWPs' DS benefit. Employer contributions can result in EGWP benefits of greater value than the DS benefit; however, EGWPs should follow current rules and guidance unless modified by these program instructions.

As specified on page 204 of the "Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," dated April 4, 2016, EGWP benefits, including NCY EGWP benefits (meaning, the Part D benefits, taking into consideration employer OHI), must continue to meet the following actuarial standards in § 423.104(e):

- Deductible is limited to no greater than the DS deductible;
- Total benefit is at least actuarially equivalent to the basic benefit; and
- Catastrophic benefit is at least actuarially equivalent to the basic catastrophic benefit.

[14] See Prescription Drug Benefit Manual; Chapter 12, section 20.13 at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/dwnlds/r6pdbpdfpdf

Section 20.13 of Chapter 12 of the Prescription Drug Benefit Manual specifies that an NCY EGWP must:

- Satisfy these actuarial requirements for the portion of its NCY plan year that falls in a given calendar year; or
- Satisfy the actuarial requirements for the calendar year in which the NCY plan year starts as long as no design change is made for the remainder of the NCY plan year. In no event can an NCY plan increase the TrOOP threshold at which catastrophic coverage begins during the NCY plan year.

Since 2014, we have required all EGWPs to "map" PDEs to the DS benefit. Any difference in cost sharing from the DS benefit constitutes OHI. OHI, including supplemental coverage provided by EGWPs, became TrOOP-eligible starting January 1, 2025.

General Rule

A Part D plan sponsor offering an NCY EGWP with an NCY plan year that begins in 2025 and continues into 2026 that operates on an NCY basis will:

- Map PDEs to the 2025 Part D DS benefit for the 2025 and 2026 portions of its NCY plan year using the 2025 DS deductible and annual OOP threshold;
- Not increase the plan deductible during its NCY plan year; and
- Utilize the 2025 DS deductible and annual OOP threshold for the entirety of the NCY plan year for purposes of applying discounts under the Discount Program.

Application of Discount Program Phase-Ins for Specified Manufacturers and Specified Small Manufacturers

Under the Discount Program, sections 1860D-14C(g)(4)(B) and (C) of the Act establish lower percentages for applicable discounts for certain applicable drugs of participating manufacturers that meet the definition of a specified manufacturer or a specified small manufacturer during a multi-year phase-in period. For NCY EGWP plan years that begin in 2025 and continue into 2026, Part D plan sponsors must apply the phase-in percentage specified in sections 50.1.1 and 50.1.2 of the Medicare Part D Manufacturer Discount Program Final Guidance based on the calendar year in which the relevant date of service occurred. For example, on a claim for an applicable drug for an applicable beneficiary with a date of service of January 1, 2026 that is eligible for the specified small manufacturer phase-in, the NCY EGWP must apply the 2 percent manufacturer discount that applies in 2026.

70. Selected Drug Subsidy

Section 11201 of the IRA added section 1860D-14D to the Act, creating a new selected drug subsidy program, which begins in CY 2026. Under the program, the Secretary must, periodically and on a timely basis, provide Part D plan sponsors with a subsidy for selected drugs equal to 10 percent of the drug's negotiated price.[15] The selected drug subsidy applies to a covered Part D drug that would otherwise meet the definition of an applicable drug but for being a selected drug[16] during a price applicability period.[17] The subsidy is paid on behalf of an applicable beneficiary[18] who is enrolled in a PDP or an MA-PD plan, has not incurred costs that are equal to or exceed the annual OOP threshold,[19] and is dispensed a selected drug.

Under the selected drug subsidy program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D-2(b)(1) of the Act, that is, the deductible under the DS benefit, the selected drug subsidy is available in the initial coverage phase of the benefit. The selected drug subsidy lowers Part D plan sponsor liability on the negotiated price of the drug.

Policy for Drugs Not Subject to the Defined Standard Deductible

TrOOP-eligible costs for drugs not subject to the DS deductible, specifically covered insulin products, as well as TrOOP-eligible costs for drugs not subject to a non-DS plan deductible or drugs subject to a reduced deductible under non-DS plans, all count towards a beneficiary's satisfaction of the DS deductible. As such, it is necessary to apply the policy for drugs not subject to the DS deductible established at Section 40 of the Final CY 2025 Program Instructions to drugs subject to the selected drug subsidy program.

Under that policy, which continues to apply for CY 2026, if a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the DS deductible, they will be both an applicable beneficiary under the Discount Program, as defined at section 1860D-14C(g)(1)(C) of the Act, and be deemed to have satisfied their plan deductible. With respect to a selected drug during a price applicability period, such an applicable beneficiary will be eligible for the selected drug subsidy.

If a plan offers a non-DS plan deductible—whether that be a lower deductible than the DS deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the DS deductible amount, the selected drug subsidy is

[15] "Negotiated price" is defined in section 1860D-14C(g)(6) of the Act.

[16] "Selected drug" is referred to under section 1192(c) of the Act.

[17] "Price applicability period" is defined in section 1191(b)(2) of the Act.

[18] "Applicable beneficiary" is defined in section 1860D-14C(g)(1) of the Act.

[19] The annual OOP threshold is specified in section 1860D-2(b)(4)(B)(i) of the Act.

not available for selected drugs during a price applicability period. As such, for a selected drug during a price applicability period, the plan is responsible for covering the portion of costs that would be covered by the selected drug subsidy if the beneficiary were an applicable beneficiary until the beneficiary's TrOOP exceeds the DS deductible and they become an applicable beneficiary.

For example, an EA plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20 percent coinsurance for drugs in that tier. A beneficiary's first fill of the year is for a $200 tier 1 drug, meaning they pay $40 out of pocket. The beneficiary has not incurred sufficient TrOOP-eligible costs to satisfy the DS deductible of $590 (and has $390 remaining TrOOP eligible costs before they satisfy the deductible) and does not meet the definition of an applicable beneficiary under the Discount Program. Therefore, the plan must cover the 10 percent of costs that would be covered by the selected drug subsidy if the beneficiary were an applicable beneficiary.

Selected Drug Subsidy Prospective Payments

Because certain actual expenses can only be fully known after all costs have been incurred for a payment year, CMS currently makes monthly prospective payments of certain estimated costs submitted with bids, including reinsurance costs and low-income cost-sharing subsidy (LICS) costs, in order to mitigate cash-flow concerns that plans could experience if such payments were made wholly on a retrospective basis. CMS makes final payment for these costs after a coverage year after obtaining all of the information necessary to determine the amount of payment.

CMS believes that similar concerns suggest that we should also make monthly prospective payments for the selected drug subsidy program. As such, Part D plan sponsors will be required to submit estimates of selected drug subsidy payment amounts with their CY 2026 bids. CMS will use the actual selected drug subsidy amounts that Part D plan sponsors report on PDE data to determine actual costs incurred for selected drug subsidy payments.[20]

After the deadline for PDE submissions for a year (typically at the end of June of the following coverage year), CMS will calculate the difference between the prospective payments made by CMS to the Part D plan sponsor and the actual payments made by the Part D plan sponsor to determine a selected drug subsidy reconciliation amount. Part D plan sponsors will be paid dollar for dollar for the selected drug subsidy. CMS will make a lump-sum adjustment to monthly payments based on the calculated reconciliation amount in the same manner as is done for other Part D reconciliation payments. Specifically, CMS will recover payments made for a coverage year if prospective selected drug subsidy payments exceed the selected drug subsidy costs

[20] See HPMS memorandum entitled "New 2025 Prescription Drug Event (PDE) FINAL File Layouts - FIELD UPDATES, October 31, 2023" and HPMS memorandum entitled "2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations, March 8, 2024" for additional information.

actually incurred by the plan or if the Part D plan sponsor does not provide the data requested by CMS to verify the plan's actual selected drug subsidy amount; similarly, CMS will make a lump sum payment if the actually incurred subsidy amount exceeds the prospective selected drug subsidy payments.

In general, we intend the reconciliation timeline and payment process for the selected drug subsidy to work like that for other Part D reconciliation payments.

Reinsurance Methodology

As noted in the Final CY 2025 Program Instructions, the IRA significantly modified the reinsurance subsidy under the Part D benefit in CY 2025. In the Final CY 2025 Program Instructions, CMS established reinsurance methodologies for applicable and non-applicable drugs respectively. Those policies continue to apply in CY 2026.

For CY 2025, under section 1860D-15(b) of the Act, as amended by section 11201(b) of the IRA, the reinsurance payment amount for a Part D beneficiary decreased from 80 percent of the allowable reinsurance costs incurred after the beneficiary exceeds the annual OOP threshold to 40 percent for covered Part D drugs that are not applicable drugs. For CY 2026, covered Part D drugs that are not applicable drugs include selected drugs (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act), as well as non-applicable drugs (as defined in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance).[21]

Table 70.1 Reinsurance Categories for CY 2026

Category	**Definition**	**Reinsurance Percentage**
Applicable Drug	An applicable drug under the Discount Program is a Part D drug approved under a new drug application (NDA) under section 505(c) of the	20% of allowable reinsurance costs after a beneficiary exceeds the annual OOP threshold.

[21] As defined at section 1860D-14C(g)(2) of the Act and in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance, an applicable drug under the Discount Program is a Part D drug approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA), but does not include a selected drug (as defined in section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to that drug. As defined in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance, non-applicable drug means any Part D drug that is not an applicable drug and not a selected drug (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug. Selected drugs for the first year of the Medicare Drug Price Negotiation Program will enter a price applicability period on January 1, 2026.

Category	**Definition**	**Reinsurance Percentage**
	Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA), but does not include a selected drug (as defined in section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to that drug.	
Non-Applicable Drug	Non-applicable drug means any Part D drug that is not an applicable drug and not a selected drug (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug.	40% of allowable reinsurance costs after a beneficiary exceeds the annual OOP threshold.
Selected Drug (during a price applicability period)	Selected drug has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance. A price applicability period is defined in section 1191(b)(2) of the Act.	40% of allowable reinsurance costs after a beneficiary exceeds the annual OOP threshold.

Accordingly, in this Section, CMS is updating the reinsurance subsidy calculation methodology that we established in the Final CY 2025 Program Instructions to include the calculation of allowable reinsurance costs and final reinsurance subsidy for selected drugs.

For CY 2026, CMS will calculate the reinsurance subsidy separately for applicable drugs. Because the percentage of allowable reinsurance costs to calculate the reinsurance payment amount for a Part D beneficiary will be the same for non-applicable and selected drugs, the reinsurance subsidy for non-applicable and selected drugs will be calculated together. CMS will allocate the share of direct and indirect remuneration (DIR) for applicable drugs and non-applicable and selected drugs based on their respective share of gross drug costs that fall in the catastrophic phase. This methodology otherwise aligns with the historical approach for apportioning DIR.

After the end of the coverage year, CMS will reconcile reinsurance subsidies for non-applicable and selected drugs as follows:

- Identify incurred reinsurance costs for non-applicable and selected drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for non-applicable and selected drugs at the plan level.
- Allocate DIR for non-applicable and selected drugs to incurred reinsurance costs for non-applicable and selected drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as "reinsurance DIR.")
- Subtract reinsurance DIR for non-applicable and selected drugs from incurred reinsurance costs for non-applicable and selected drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable and selected drugs).

Table 70.2: Example of Reinsurance Calculation for Applicable, Non-Applicable, and Selected Drugs

	Applicable Drugs	**Non-Applicable and Selected Drugs**	**Total**
Allowed costs	$500	$200	$700
Incurred Reinsurance costs	$400	$50	$450
DIR	$200	$10	$210

	Applicable Drugs	Non-Applicable and Selected Drugs	Total
Reinsurance DIR	($210/$700) * $400 = $120	($210/$700) * $50 = $15	$135
Adjusted Reinsurance	($400 - $120) * 0.2 = $56	($50 - $15) * 0.4 = $14	$70

The calculation formulas for non-applicable and selected drugs are:

> Reinsurance DIR for non-applicable and selected drugs = (total DIR / total allowed costs) × incurred reinsurance costs for non-applicable and selected drugs, or, using the numbers in the example above, ($210/$700) * $50 = $15.
>
> Adjusted reinsurance for non-applicable and selected drugs = (incurred reinsurance costs for non-applicable and selected drugs – reinsurance DIR for non-applicable and selected drugs) × 0.40, or, using the numbers in the example above, ($50 - $15) * 0.4 = $14

The sum of the adjusted reinsurance amounts for applicable drugs and non-applicable and selected drugs will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year.

To determine the appropriate category (applicable, non-applicable, or selected) for drugs, CMS will use the 11-digit NDC submitted on each PDE record and assign it with an applicable, non-applicable, or selected designation based on the marketing category listed for that NDC in the FDA's NSDE file used for PDE processing and the list of NDCs referenced in the Medicare Drug Price Negotiation Program guidance.[22]

80. Medical Loss Ratio (MLR) (§§ 423.2420 and 423.2460)

Section 1857(e)(4) of the Act requires that MA organizations be subject to financial and other penalties for a failure to have an MLR of at least 85 percent. Since section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e), the minimum MLR requirement and sanctions also apply to Part D plan sponsors. The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately contract termination.

[22] See, e.g., section 40.4 of the Final Guidance for Initial Price Applicability Year 2027 at www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

MA organizations and Part D plan sponsors are required to report the MLR for each contract for each contract year, pursuant to the regulations at §§ 422.2460 and 423.2460. The MLR is computed as the percentage of revenue used for patient care (including incurred claims for clinical services and prescription drugs, and expenditures for activities that improve healthcare quality) rather than for such other items as administrative expenses or profit.

The MLR regulations at § 423.2420(c) specify that the following Part D plan payments from the federal government are included in the MLR denominator: the direct subsidy, prospective federal reinsurance subsidy, reconciliation adjustments to the federal reinsurance subsidy, low-income premium subsidy (LIPS) amount, which subsidizes premium payments to the plan, and risk corridor payments. In the preamble to the Medicare MLR final rule, CMS-4173-F, we explained that we view LICS, which subsidizes cost sharing, and CGDP payments as pass-through payments for which plans do not retain any liability, and that these amounts should therefore be excluded from the MLR calculation; accordingly, LICS and CGDP payments are excluded from both the MLR numerator and denominator.[23] In the Final CY 2025 Program Instructions, we stated that the Part D plan payments for the Discount Program and Inflation Reduction Act Subsidy Amount (IRASA) are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation, because excluding these payments and associated expenditures is consistent with the exclusion of LICS and CGDP payments from the MLR on the basis that they are pass-through payments collected by a plan on behalf of a third party rather than revenue to the plan. The IRASA policy announced in the Final CY 2025 Program Instructions was specific to CY 2023 MLR reporting. Given that IRASA payments were only made in CY 2023, it is not applicable to CY 2026 (or MLR reporting for years after CY 2023). The Discount Program guidance in the Final CY 2025 Program Instructions continues to apply in CY 2026.

For CY 2026, the IRA introduced a new category of Part D plan payments from the federal government: selected drug subsidy payments**.** Under the selected drug subsidy, the government provides a subsidy to Part D plan sponsors for selected drugs dispensed to enrollees in the initial coverage phase.

For CY 2026, the new Part D plan payments for the selected drug subsidy are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. Excluding these payments and associated expenditures is consistent with the exclusion of LICS, CGDP, Discount Program, and IRASA payments from the MLR on the basis that they are pass-through payments collected by a plan on behalf of a third party rather than revenue to the plan.

[23] Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 78 FR 31284, 31290-92 (May 23, 2013).

90. Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs

Section 11001(b) of the IRA added section 1860D-4(b)(3)(I)(i) of the Act, which requires that, starting in 2026, Part D plan sponsors include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP (as defined in section 1191(c)(3) of the Act) is in effect with respect to the year. Section 11001(b) of the IRA also added section 1860D-4(b)(3)(I)(ii) of the Act, which clarifies that nothing in clause (i) shall be construed as prohibiting Part D plan sponsors from removing from their formularies such a selected drug if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation. At the time the IRA was enacted, then-current § 423.120(b)(5)(iv) permitted a plan to immediately remove a brand name drug from its formulary or change the preferred or tiered cost-sharing status of the brand name drug if a newly available, therapeutically equivalent generic drug was added to the formulary at the same time and certain requirements were met, including that the generic drug was added to the same or lower cost-sharing tier and with the same or less restrictive utilization management criteria than had applied to the brand name drug and that the plan complied with certain notice requirements, such as advance general notice in communications materials and retrospective direct notice to affected enrollees.

In the CY 2025 Part C & D Final Rule (CMS-4201-F3 and 4205-F),[24] we finalized regulations related to approval and notice of changes to an approved formulary to codify longstanding guidance and to make certain policy updates. Because of the reorganization and renumbering of our regulations finalized in the rule, there is no longer a § 423.120(b)(5)(iv) in the current Part D regulations. As a result, CMS must identify the successor regulation to § 423.120(b)(5)(iv) for the purposes of the exception to the formulary inclusion requirement for selected drugs in section 1860D-4(b)(3)(I)(ii) of the Act.

Successor Regulation

As discussed above, the language in § 423.120(b)(5)(iv) at the time of the IRA's enactment addressed when Part D plan sponsors could make immediate substitutions of brand name drugs for newly available, therapeutically equivalent generic drugs and the requirements that applied to such formulary changes, including with respect to notice. Under the current Part D regulations, the approval requirements for immediate substitutions, which have been expanded to provide for the substitution of additional types of products, are now codified at § 423.120(e)(2)(i) and the corresponding notice requirements for such formulary changes are now codified at § 423.120(f)(2), (3), and (4). Under § 423.120(e)(2)(i), a Part D plan sponsor is permitted to:

[24] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 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 (PACE), 89 FR 30448, 30511 (April 23, 2024).

> make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval . . . because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of [section 423.120].

The term "corresponding drug" is defined in § 423.100 as "respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product." Under § 423.120(f)(2), (3), and (4), a Part D plan sponsor making an immediate substitution under § 423.120(e)(2)(i) is required to provide advance general notice and retrospective notice to enrollees, among others, and to ensure that written notices include specified content. Specifically, the advance general notice must be provided to all current and prospective enrollees and other specified entities, be in the Part D plan sponsor's formulary and other applicable beneficiary communication materials, and advise that the Part D plan sponsor may make immediate negative formulary changes, consistent with the regulation, at any time. The required retrospective notice must be provided to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The content of these notices is specified in paragraph (f)(4) of § 423.120.

Because these provisions encompass the amended approval and notice requirements for immediate substitutions previously located in § 423.120(b)(5)(iv), CMS is identifying § 423.120(e)(2)(i), (f)(2), (3), and (4) as the successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D-4(b)(3)(I)(ii) of the Act. Under this successor regulation, nothing in section 1860D-4(b)(3)(I)(i) of the Act shall be construed as prohibiting a Part D plan sponsor from removing a selected drug from its formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2), (3), and (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug with respect to such selected drug.

Identifying current § 423.120(e)(2)(i) as part of the successor regulation means that in addition to continuing to permit removal of a selected drug that is a brand name drug and replacement of it with a generic drug as an immediate substitution, CMS also will permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution. In other words, this successor regulation expands the types of selected drugs potentially eligible for removal as an immediate substitution from the original § 423.120(b)(5)(iv), which only permitted immediate substitutions of brand name drugs with newly available, therapeutically equivalent generic drugs, to also include

immediate substitutions of reference products with newly available interchangeable biological products.[25]

Allowing removal of selected drugs that are reference products and replacement with interchangeable biological products as immediate substitutions would be similar in kind to and consistent with the original regulation that Congress identified for the exception. This successor regulation would apply the same rules to interchangeable biological products as are applied to generic drugs, which would promote consistency across selected drugs because, regardless of whether a selected drug is a drug or biological product, the Part D plan sponsor would be able to remove a selected drug that is a brand name drug or reference product as an immediate substitution. Moreover, we note that rather than establishing a specific and static exception legislatively (e.g., by codifying the exception as the policy in § 423.120(b)(5)(iv) at the time of enactment), Congress provided CMS with the authority and flexibility to identify a successor regulation, maintaining the ability for the rules for removal to evolve over time to reflect changes in the pharmaceutical landscape, such as the emergence of interchangeable biological products.

CMS will permit, consistent with the agency's longstanding practice, including under § 423.120(b)(5)(iv) at the time of enactment of the IRA, Part D plan sponsors to immediately substitute a selected drug for which there is a generic drug or interchangeable biological product available in the same dosage form, route of administration, and strength. The exception to the selected drug formulary inclusion requirement in section 1860D-4(b)(3)(I)(ii) of the Act allows for a selected drug to be removed as permitted under § 423.120(b)(5)(iv) (or any successor regulation). Accordingly, it is consistent with the exception established under section 1860D-4(b)(3)(I)(ii) of the Act to apply this longstanding policy under the Part D program to the removal of selected drugs under the successor regulation identified pursuant to section 1860D-4(b)(3)(I)(ii) of the Act.

Corresponding Drugs Do Not Include Selected Drugs

Consistent with CMS' identification above of the successor regulation for the purposes of section 1860D-4(b)(3)(I)(ii) of the Act, a Part D plan sponsor may remove a selected drug from its formulary if, in accordance with § 423.120(e)(2)(i) and the notice requirements of § 423.120(f)(2), (3), and (4), the Part D plan sponsor adds to its formulary on the same or lower cost sharing tier and with the same or less restrictive PA, ST, or QL requirements a newly available corresponding drug with respect to such selected drug. Section 423.100 currently

[25] The section 1860D-4(b)(3)(I)(ii) exception to the IRA's formulary inclusion requirement for selected drugs addresses when a Part D plan sponsor can remove a selected drug from a formulary. Accordingly, this section 90 of these Draft CY 2026 Program Instructions applies specifically to negative formulary changes that result in the removal of a selected drug from a formulary. This section does not affect Part D plan sponsors' ability to implement negative formulary changes other than removal where a Part D plan sponsor would continue to include a selected drug on its formulary as required by section 1860D-4(b)(3)(I)(i) of the Act (e.g., moving the selected drug to a higher cost-sharing tier or adding utilization management practices).

defines "corresponding drug" as "respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product." When read in isolation, the definition might incorrectly appear to suggest that a Part D plan sponsor could remove a selected drug under section 1860D-4(b)(3)(I)(ii) of the Act if the Part D plan sponsor adds an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

However, such a removal would be inconsistent with the Part D plan sponsor's obligation under section 1860D-4(b)(3)(I)(i) of the Act to include on formulary each covered Part D drug that is a selected drug under section 1192 of the Act for which an MFP is in effect with respect to the year. As stated in section 110 of the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027, because the selected drug includes all dosage forms and strengths to which the MFP applies, the statute requires that formularies 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.[26]

As stated in section 1192(e)(2)(A) of the Act (as added by section 11001 of the IRA), and as discussed in section 30.1 of the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027, an "authorized generic drug" (as defined in section 1192(e)(2)(B) of the Act)[27] and the qualifying single source drug (as defined in section 1192(e) of the Act) that is the listed drug or reference product of that "authorized generic drug" shall be treated as the same qualifying single source drug and, thus, the same selected drug. For the purposes of the Negotiation Program, an "authorized generic drug" is defined in section 1192(e)(2)(B) of the Act as: (1) in the case of a drug product, an authorized generic drug as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act, and (2) in the case of a biological product, a product that has been licensed under section 351(a) of the Public Health Service Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark than the reference product. Consistent with the treatment of "authorized generic drugs" in section 1192(e)(2)(A) of the Act and the definition of such term in section 1192(e)(2)(B) of the Act, the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027 make

[26] See section 110, Part D Formulary Inclusion of Selected Drugs, of the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027.

[27] The definition of "authorized generic drug" in section 1192(e)(2)(B) of the Act differs from the definition of "authorized generic drug" in the Part D regulations at § 423.4. As defined in section 1192(e)(2)(B) of the Act, the term "authorized generic drug" for the purposes of the Negotiation Program encompasses both drugs and biological products that meet the statutory definition. For clarity, we have put quotations around "authorized generic drug" throughout this paragraph when referring to the term as defined in section 1192(e)(2)(B) of the Act.

clear that authorized generics of a brand name drug that is a selected drug and unbranded biological products marketed under the same license as a brand name biological product that is a selected drug are treated as the same selected drug as the respective listed drug or reference product. For example, section 30.1 of the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027 states that, for drug products, the qualifying single source drug (and, thus, the selected drug) includes "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" and "also include[s] all dosage forms and strengths of the drug with the same active moiety and marketed pursuant to the same NDA(s)…that are…authorized generic drugs that are marketed pursuant to such NDA(s)." Likewise, section 30.1 of the Revised Guidance for Initial Price Applicability Year 2026 and the Final Guidance for Initial Price Applicability Year 2027 states that, for biological products, the qualifying single source drug (and, thus, the selected drug) includes "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" and "also include[s] all dosage forms and strengths of the biological product with the same active ingredient and marketed pursuant to the same BLA(s)…that are…authorized biological products that are marketed pursuant to such BLA(s)."

Because an authorized generic of a brand name drug that is a selected drug or an unbranded biological product marketed under the same BLA as a brand name biological product that is a selected drug also qualifies as the selected drug, section 1860D-4(b)(3)(I)(i) of the Act requires the Part D plan sponsor to include each such authorized generic or unbranded biological product that is a covered Part D drug for which an MFP is in effect on its formulary. Consequently, the statute does not permit a Part D plan sponsor to remove a selected drug that is a brand name drug or brand name biological product on the basis of adding an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product. Therefore, to ensure consistency with the IRA's formulary inclusion requirement and avoid any potential confusion related to the identification herein of § 423.120(e)(2)(i) as part of the successor regulation to § 423.120(b)(5)(iv) for the purposes of section 1860D-4(b)(3)(I)(ii) of the Act, CMS is clarifying that, for CY 2026, the definition of "corresponding drug" in § 423.100 does not include a selected drug, as defined in section 1192(c) of the Act. Pursuant to the requirement in section 11001(c) of the IRA that CMS use program instruction or other forms of program guidance to implement section 11001 of the IRA, including amendments made by such section, the definition of "corresponding drug" for 2026 reads as follows with the revisions to the current definition reflected in bold and italicized font:

> *Corresponding drug* means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a

brand name biological product. ***A corresponding drug does not include a selected drug as defined in section 1192(c) of the Act.***

Consistent with the formulary inclusion requirement in section 1860D-4(b)(3)(I)(i) of the Act, this amended definition clarifies that a Part D plan sponsor cannot remove a selected drug that is a brand name product under section 1860D-4(b)(3)(I)(ii) of the Act when a Part D plan sponsor adds an authorized generic of the brand name drug or an unbranded biological product marketed under the same BLA as the brand name biological product.

Timing Clarification for Immediate Substitutions

Section 423.120(e)(2)(i), (f)(2), (3), and (4), which we are identifying as the successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D-4(b)(3)(I)(ii) of the Act, permits a Part D plan sponsor, provided it has met the notice requirements, to remove a selected drug that is a brand name drug or reference product from its formulary and replace it with a generic of the brand name drug or an interchangeable biological product of the reference product "so long as the Part D sponsor previously could not have included such corresponding drug on its formulary *when it submitted its initial formulary* for CMS approval consistent with paragraph (b)(2) of this section because such drug was *not yet available on the market*" [emphasis added]. As such, under these regulations, for Part D plan sponsors that have a selected drug for initial price applicability year 2026 on their 2025 formulary, if a generic drug or interchangeable biological product of a selected drug becomes available on the market in 2025 *after* the Part D plan sponsor submitted its initial 2026 formulary for CMS approval, consistent with our longstanding policy on immediate substitutions, a Part D plan sponsor could add such generic drug or interchangeable biological product and remove the selected drug from its formulary as an immediate substitution for 2025, as well as for 2026. In other words, where the Part D plan sponsor could not have included the generic drug or interchangeable biological product on either its 2025 initial formulary submission or its 2026 initial formulary submission, and such Part D plan sponsor removes the selected drug as an immediate substitution, the Part D plan sponsor can apply the removal to both the current year formulary as well as the already-submitted formulary for the following year. A Part D plan sponsor that does not have the selected drug on its 2025 formulary but has submitted a formulary for 2026 that includes the selected drug in accordance with section 1860D-4(b)(3)(I) of the Act could remove the selected drug as part of an immediate substitution only with respect to its 2026 formulary. That is, if a generic drug of a brand name drug that is a selected drug or an interchangeable biological product of a reference product that is a selected drug was first available on the market after the initial submission of the 2026 formulary, the Part D plan sponsor could, in the latter part of 2025, remove that selected drug from its 2026 formulary.

This application of the immediate substitutions policy to both the 2025 and 2026 formularies with respect to a generic drug or interchangeable biological product that becomes available on the market after the Part D plan sponsor has already submitted its initial formulary to CMS is

consistent with section 1860D-4(b)(3)(I) of the Act. As discussed above, the formulary inclusion requirement in section 1860D-4(b)(3)(I) of the Act applies with respect to selected drugs starting in initial price applicability year 2026 and the only permitted exception to the requirement is the "removal" of "such selected drug." The plain text of the statute contemplates that a selected drug will need to be included on the plan's formulary for the first initial price applicability year in which the MFP for the selected drug is in effect, regardless of whether the plan ever previously included the drug. Moreover, the only statutory exception to the formulary inclusion obligation is the "removal" of "such a selected drug" in accordance with § 423.120(b)(5)(iv) or its successor regulation. The references to "removal" and "such selected drug" indicate that the selected drug must first be included on the formulary for the initial price applicability year under section 1860D-4(b)(3)(I)(i) of the Act and only then can be removed under section 1860D-4(b)(3)(I)(ii) of the Act. Accordingly, as discussed above, a Part D plan sponsor that includes a selected drug with an initial price applicability year of 2026 on its initial formulary submission for 2026 could remove the selected drug as part of an immediate substitution prior to the start of 2026 if a generic drug or interchangeable biological product of the selected drug becomes available on the market in 2025 after the initial formulary submission. In such cases, the Part D plan sponsor will have included the selected drug on the formulary with respect to the initial price applicability year in which the MFP is in effect (i.e., 2026), as required by section 1860D-4(b)(3)(I)(i) of the Act, and subsequently removed the selected drug, as permitted by section 1860D-4(b)(3)(I)(ii) of the Act.

Further, we note that there may be scenarios in which a generic drug or interchangeable biological product of a selected drug becomes available on the market in 2025 (after the Part D plan sponsor has submitted its initial 2025 formulary in 2024) but *before* the Part D plan sponsor submits its 2026 initial formulary for CMS approval. Under such a scenario, a Part D plan sponsor would be permitted, assuming all requirements are met, to remove a selected drug (prior to its MFP taking effect) from its 2025 formulary under § 423.120(e)(2)(i), but would be required under section 1860D-4(b)(3)(I)(i) of the Act to include the selected drug on its 2026 formulary when the MFP takes effect. We are clarifying here that if there is a generic drug or interchangeable biological product for a selected drug with an initial price applicability year of 2026 and such generic drug or interchangeable biological product is available on the market before a Part D plan sponsor's 2026 initial formulary submission, such Part D plan sponsor would still need to include the selected drug on its 2026 formulary submission, regardless of whether the Part D plan sponsor had removed such selected drug from its 2025 formulary via an immediate substitution in 2025, to comply with the formulary inclusion requirement in section 1860D-4(b)(3)(I)(i) of the Act. Moreover, the Part D plan sponsor would not be permitted to remove the selected drug from the formulary for 2026 as an immediate substitution and replace it with the generic drug or interchangeable biological product that became available on the market prior to the initial formulary submission for 2026 because section 1860D-4(b)(3)(I)(ii) of the Act permits removal only in accordance with § 423.120(b)(5)(iv) or its successor regulation. As discussed above, the identified successor regulation includes § 423.120(e)(2)(i), which, like §

423.120(b)(5)(iv) at the time of enactment, permits an immediate substitution only if the Part D plan sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval. In this scenario, because the Part D plan sponsor could have included the generic drug or interchangeable biological product in its initial formulary submission for 2026, an immediate substitution is not available.

Further, we are clarifying that the regulatory language at § 423.120(e)(2)(i)—that a Part D plan sponsor previously could not have included the corresponding drug on its formulary when it submitted its initial formulary for CMS approval—means, in practice, that the corresponding drug is not included on the final formulary reference file (FRF) update that CMS releases before the bid submission deadline.

Comment Solicitation

As discussed above in these draft program instructions, we are identifying as the successor regulation the provisions that would allow for immediate substitutions of generic drugs and interchangeable biological products that qualify as corresponding drugs (i.e., § 423.120(e)(2)(i) and (f)(2), (3), and (4)). In this comment solicitation, we are also soliciting input on alternative approaches that would include within the successor regulation, in addition to the provisions identified above, provisions allowing for maintenance changes of generic drugs and interchangeable biological products and maintenance changes of biosimilar biological products other than interchangeable biological products. Under these alternative approaches, the successor regulation would also include § 423.120(e)(3)(i) with respect to negative formulary changes, such as removing a drug from the formulary, that meet the requirements of paragraph (1) or (2), as applicable, of the definition of maintenance change at § 423.120, as well as the timing limitation for such changes in § 423.120(e)(4) and the corresponding notice requirements for such changes in § 423.120(f)(1) and (4). Below we describe these alternative approaches.

Under one alternative approach, CMS could identify the successor regulation to also include maintenance changes for generic drugs and interchangeable biological products that are "corresponding drugs" under § 423.100. As corresponding drugs, they also could qualify to be added as part of an immediate substitution if all requirements were met. In other words, CMS could identify these additional regulatory provisions as part of the successor regulation, as applied only to paragraph (1) of the definition of maintenance change in § 423.100. Under this approach, Part D plan sponsors would be permitted to remove a selected drug that is either a brand name drug or a reference product as a maintenance change within 90 days of adding, respectively, a corresponding generic drug or interchangeable biological product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

Under another alternative approach, CMS could identify the successor regulation to include maintenance changes of generic drugs and interchangeable biological products, as in the approach described above, and also include maintenance changes of biosimilar biological

products other than interchangeable biological products. Because biosimilar biological products other than interchangeable biological products are not corresponding drugs under § 423.100, they could not be added as part of an immediate substitution. CMS could identify these additional regulatory provisions as part of the successor regulation, as applied to both paragraphs (1) and (2) of the definition of maintenance change in § 423.100. In addition to permitting Part D plan sponsors to remove selected drugs as discussed in the first alternative, under this second alternative approach, Part D plan sponsors would also be permitted to remove a selected drug that is a reference product as a maintenance change within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

With respect to either alternative approach, the successor regulation would also include the timing limitation for such maintenance changes in § 423.120(e)(4) and the corresponding notice requirements for such changes in § 423.120(f)(1) and (4). Under § 423.120(e)(4), except with respect to immediate substitutions permitted under § 423.120(e)(2), Part D plan sponsors may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period (also referred to as "Open Enrollment," which begins October 15) and 60 days after the beginning of the contract year associated with that annual coordinated election period. As set forth in § 423.120(e)(3)(i), negative change requests for maintenance changes are deemed to be approved 30 days after the Part D plan sponsor's submission of such a negative change request unless CMS notifies the Part D plan sponsor otherwise. In addition, § 423.120(f)(1) requires in part that Part D plan sponsors provide at least 30 days' advance direct notice of any substitutions that are maintenance changes to affected enrollees, and § 423.120(f)(4) describes the content of the required written notice.

We would like to ensure that we have fully considered and received input on the potential approaches to identifying the successor regulation. In sum, we seek input from interested parties on the advantages and disadvantages of identifying as the successor regulation the regulatory provisions that encompass—

- only immediate substitutions of generic drugs and interchangeable biological products;
- immediate substitutions and maintenance changes of generic drugs and interchangeable biological products; or
- immediate substitutions and maintenance changes of generic drugs and interchangeable biological products, as well as maintenance changes of biosimilar biological products other than interchangeable biological products.

As discussed above, section 11001(b) of the IRA provided CMS with flexibility in identifying a successor regulation for the purposes of section 1860D-4(b)(3)(I)(ii) of the Act. We believe that the approach that identifies only our current regulations on immediate substitutions, as well as

the alternative approaches on which we are also soliciting comment, are consistent with the purpose of the original regulation identified in section 1860D-4(b)(3)(I)(ii) of the Act as well as our authority to identify a successor regulation to account for updates to the original regulation.

100. Appendix

Part D Benefit Parameters for Defined Standard Benefit for CY 2025 and CY 2026 for Non-LIS Beneficiaries[28]

<table>
<tr><td></td><td colspan="2">2025</td><td colspan="3">2026</td></tr>
<tr><td>Deductible Phase</td><td colspan="2">Cost sharing: 100%</td><td colspan="3">Cost sharing: 100%</td></tr>
<tr><td></td><td colspan="2">Deductible: $590</td><td colspan="3">Deductible: $615</td></tr>
<tr><td>Initial Coverage Phase</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 65%
Manufacturer Discount: 10%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td><td>Selected Drugs
Cost sharing: 25%
Plan Pays: 65%
Selected Drug Subsidy: 10%</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 65%
Manufacturer Discount: 10%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td></tr>
<tr><td></td><td colspan="2">Out-of-Pocket Threshold: $2,000</td><td colspan="3">Out-of-Pocket Threshold: $2,100</td></tr>
<tr><td>Catastrophic Phase</td><td>Applicable Drugs
Plan Pays: 60%
Manufacturer Discount: 20%
Reinsurance: 20%</td><td>Non-Applicable Drugs
Plan Pays: 60%
Reinsurance: 40%</td><td colspan="2">Applicable Drugs
Plan Pays: 60%
Manufacturer Discount: 20%
Reinsurance: 20%</td><td>Non-Applicable Drugs and Selected Drugs
Plan Pays: 60%
Reinsurance: 40%</td></tr>
</table>

[28] Note that the IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022, during a multi-year phase-in period, which concludes by 2031. For drugs that are subject to a phased-in discount, plans are responsible for covering the difference between the phased-in discount and the full discount that otherwise would have applied (10 percent in the initial coverage phase and 20 percent in the catastrophic phase). As such, the liability of Part D plan sponsors and manufacturers for applicable drugs in the initial coverage and catastrophic phases may vary based on whether a drug is subject to a phase-in discount.