

Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452)

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (“the Negotiation Program”), codified in sections 1191 through 1198 of the Social Security Act (“the Act”). The Act establishes the Negotiation Program to negotiate a maximum fair price (MFP), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D (each a “selected drug”).¹ As discussed in section 20 of the [Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price \(MFP\) in 2026 and 2027](#) (“the Medicare Drug Price Negotiation Program Draft Guidance” or “draft guidance”), for initial price applicability year 2027, CMS will select up to 15 high expenditure, single source drugs covered under Part D for negotiation. Any MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2027. The negotiation period for initial price applicability year 2027 begins February 28, 2025, or when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement with CMS, whichever is sooner.

This ICR Form includes two parts: Part 1—Negotiation Data Elements ICR Form, and Part 2—Drug Price Negotiation Process ICR Form.

PART 1: NEGOTIATION DATA ELEMENTS ICR FORM

Section 1194(e) of the Act and section 50 of the draft guidance require CMS to consider two sets of factors as the basis for determining offer(s) and counteroffer(s) throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation (in section 1194(e)(1)) of the Act), and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug (in section 1194(e)(2) of the Act)).

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act and section 50 of the draft guidance, the manufacturer must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price (“non-FAMP”) for the selected drug as defined in 38 U.S.C. § 8126(h)(5) and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2), will serve as the basis for determining offers and counteroffers. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describe evidence about the selected drug and its therapeutic alternative(s).

For the purposes of this ICR, a selected drug for initial price applicability year 2027 is defined as a drug included on the selected drug list published by CMS by February 1, 2025. In section

¹ Hereinafter, “drug” includes drugs and biological products pursuant to the definition of a “qualifying single source drug” at section 1192(e)(1) of the Act.

1191(c)(1) of the Act, the statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with “the manufacturer” of the selected drug. In accordance with section 40 of the draft guidance, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for the selected drug to be “the manufacturer” of the selected drug (hereinafter the “Primary Manufacturer”).

Likewise, in accordance with section 40 of the draft guidance, CMS will refer to any other entity that meets the statutory definition of manufacturer for a drug product included on the selected drug list and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a “Secondary Manufacturer².”

CMS will collect certain data from the Primary Manufacturer, including information on non-FAMP and the data identified in section 1194(e)(1) of the Act, and will collect information on evidence about a selected drug and its therapeutic alternative(s) per section 1194(e)(2) of the Act from any interested party. This ICR Form serves as one of multiple ways that CMS will collect data per section 1194(e)(2) (see the Supporting Statement for further details). Submission of the information collected in this ICR Form is due by 11:59 PM PST on March 1, 2025.

Note: This ICR focuses on information required and optional for selected drugs for initial price applicability year 2027.

General Instructions

Overview

In accordance with section 50 of the draft guidance, the Primary Manufacturer of each selected drug must complete Sections A through H for each of its selected drug(s), which are specifically:

- [A: Selected Drug Information](#),
- [B: Non-FAMP Data Collection](#),
- [C: Research and Development Costs and Recoupment](#),
- [D: Current Unit Costs of Production and Distribution](#),
- [E: Prior Federal Financial Support](#),
- [F: Patents, Exclusivities, and Approvals](#),
- [G: Market Data and Revenue and Sales Volume Data](#), and
- [H: Certification of Submission of Sections A through G for Primary Manufacturers](#).

² As specified in section 40 of the draft guidance, a manufacturer that is not listed as a manufacturer on the NDA / BLA and without an agreement in place with the Primary Manufacturer would not be considered a Secondary Manufacturer. Examples of agreements that could result in a Secondary Manufacturer relationship may include, but are not limited to, royalty agreements, licensing agreements, revenue sharing agreements, marketing agreements, supply agreements, purchasing agreements, or parent / affiliate agreements.

The Primary Manufacturer is responsible for aggregating and reporting all necessary data on its selected drug(s) from other parties, as applicable.

Section I (“Evidence on Alternative Treatments”) collects available evidence on the selected drug and its therapeutic alternative(s), as applicable. **Any interested party, including but not limited to patients and caregivers, Part D plan sponsors and Medicare Advantage organizations, Primary Manufacturers, Secondary Manufacturers, manufacturers of therapeutic alternative(s) for a selected drug, hospitals and health care providers, wholesalers, pharmacies, researchers, and other members of the public, is permitted, but not required, to submit information for Section I.** Any interested party who submits evidence in Section I must complete Section J (“Certification of Submission of Section I for All Respondents”) as well.

Submission Method

Primary Manufacturers will submit the information for Sections A through J via the CMS Health Plan Management System (“the CMS HPMS”), which can be accessed here:

<https://hpms.cms.gov/>. Manufacturers of high-expenditure, single source drugs may register for access to the CMS HPMS, and are encouraged to do so before the questions for this ICR are available to access in the CMS HPMS. Instructions for manufacturers to gain access to HPMS can be found in the “Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)” PDF.³ Instructions for gaining signatory access to the CMS HPMS are also included in this PDF. Technical assistance will also be made available. Additional instructions will be available prior to February 1, 2025.

All respondents who are not Primary Manufacturers will use a separate web application to access the questions in Sections I and J. This application will be accessible from an entry point on CMS.gov, as well as on the CMS HPMS landing page, which is publicly accessible at <https://hpms.cms.gov>. In order to access the questions in Sections I and J through the web link, the respondent must provide an email address. A confirmation email message from CMS will be sent to the respondent-provided email address and the respondent must follow the steps contained in the email message to obtain access to the questions in Sections I and J. Additional instructions to access this public web application will be available on CMS.gov.

Submissions may be saved while work is in progress. Primary Manufacturers and interested parties may also wish to draft their submission outside of the CMS HPMS and then copy their submissions into the appropriate fields to complete the formal submission.

Questions about CMS HPMS user access should be sent to HPMS_Access@cms.hhs.gov. For technical assistance related to the submission of information in HPMS, questions should be sent to hpms@cms.hhs.gov. Technical assistance for Primary Manufacturers and other interested parties will also be made available.

Additional Instructions

- The instructions in this section apply to all Sections A through J. If a term included in this

³ <https://www.cms.gov/about-cms/information-systems/hpms/user-id-process>

ICR is also included and defined in draft guidance. The term's definition in this ICR is the same as in the draft guidance. Questions about the Medicare Drug Price Negotiation Program Draft Guidance, including questions about terms defined in this ICR, should be sent to IRAREbateandNegotiation@cms.hhs.gov.

- For Sections A through G of this form, the Primary Manufacturer must provide data **only with regard to the selected drug as identified** under section 1192 of the Act. If a Primary Manufacturer has more than one selected drug, the Primary Manufacturer is required to make a separate submission of the information required in Sections A through G of this ICR for each selected drug.
- All response fields are limited to a character count. The field and response format sections provide a character count and an estimated word count.
- Certification is required for submissions. Section H includes the Certification of Submission of Sections A through G for Primary Manufacturers. Section J includes the Certification of Submission of Section I for all respondents.
- For Sections A through G of this form, CMS will pre-populate or the Primary Manufacturer must submit, as indicated in the section, the applicable data for all dosage forms and strengths of the selected drug, including for dosage forms and strengths that were sold, labeled, or packaged by a Secondary Manufacturer.
- For non-monetary numeric amounts, include up to three decimal places.
- Response formats are indicated within any charts included in Sections A through G and Section I (e.g., # to indicate a numerical response is required).
- Primary Manufacturers must timely notify CMS if any of the information submitted changes after the initial submission of data, including as set forth in sections 40.2 and 50.1 of the draft guidance. Please timely notify CMS via the IRA Mailbox at IRAREbateandNegotiation@cms.hhs.gov if any such changes are applicable to the selected drug.
- Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. As described in section 40.2.1 of the draft guidance, CMS will treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer.⁴ In order to identify information within a response that a respondent believes should be withheld by CMS under FOIA Exemptions 3 and/or 4 (5 U.S.C. § 552(b)(3), (4)),⁵ Primary Manufacturers are instructed to complete Question 28 regarding such applicable information provided in response to Sections A through G, and any interested party is instructed to complete Question 64 regarding such applicable information provided in Section I. Sections 40.2.1, 60.4 and 60.6 of the draft guidance discuss the situations in which CMS may share section 1194(e)(2) data submitted

⁴ Specifically, as described in section 40.2.1 of the draft guidance, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

⁵ See: <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.

publicly, without sharing any personally identifiable information⁶ (PII) or protected health information⁷ (PHI), proprietary information, or information that is protected from disclosure under other applicable law.

- Definitions included in this ICR are intended for purposes related to this ICR and the Medicare Drug Negotiation Program only.

Instructions for Reporting Monetary Amounts

- When calculating and reporting monetary values, the information must be determined using the methodologies described throughout the document and consistent with the Generally Accepted Accounting Principles (GAAP), when applicable. Describe the policies and methodologies used in the calculations in the free response field for the relevant question, as well as the standard used if it is inconsistent with GAAP.
- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment.⁸ If a Primary Manufacturer uses a cost of capital adjustment below 8.1 percent, that amount should be used.
- Monetary amounts must be reported in United States dollars (USD) and include two decimal places (i.e., dollars and cents), unless otherwise specified in Section D or Section G. Use the free response field of an applicable question, when it is available, to clarify any rounding limitations or alternative rounding standard relied on.
- When converting another currency to USD, specify in the free response field of applicable question which of the following options were used:
 - (1) the exchange rate applicable at the time the costs were incurred. The Internal Revenue Service (IRS) website lists government and external sources where historical exchange rates can be found to the day.⁹ If the exact date of a sale or conversion is not known, use the yearly average exchange rate for that currency for the year the costs were incurred.¹⁰ In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in this calculation, or

⁶ Personally identifiable information (PII) is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. PII can include sensitive data, such as medical, financial, or legal information; "neutral" information such as name, facial photos, or work address; and, contextual information, such as a file for a specific health condition that contains a list of treated patients. See: <https://www.hhs.gov/web/policies-and-standards/hhs-web-policies/privacy/index.html#what-is-pii>.

⁷ Protected health information (PHI) is individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. Individually identifiable information is information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition; the provisions of health care to the individual; or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. PII includes many common identifiers such as name, address, birth date, Social Security Number, etc. See <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>.

⁸ Most studies on research and development (R&D) costs apply a cost-of-capital adjustment to each company's R&D spending to reflect the lag between investment and return on investment. The use of 8.1 percent is consistent with assumptions used by the Congressional Budget Office, see "Research and Development in the Pharmaceutical Industry," CBO (April 2021), available at <https://www.cbo.gov/publication/57126>.

⁹ See: <https://www.irs.gov/individuals/international-taxpayers/foreign-currency-and-currency-exchange-rates>.

¹⁰ See: <https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates>.

- (2) the GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies.
- Do not report the same costs in multiple places unless the additional specific instructions for that question instruct you to do so.
- Do not include any costs that are unallowable under an applicable law or costs that are otherwise expressly excluded from this ICR.
- Do not make any adjustments for inflation to any dollar amounts reported. As applicable, in the free response field, specify the applicable time period for a specific question (e.g., calendar quarter, calendar year), and report the cost and revenue per each applicable time period. CMS will make the relevant trending inflation adjustments, as necessary.

A. Selected Drug Information

Primary Manufacturer Response Required

In Section A, for each selected drug for initial price applicability year 2027, CMS will populate the CMS HPMS with the list of the 11-digit National Drug Codes (NDC-11s) marketed by the Primary Manufacturer and any Secondary Manufacturer and published in accordance with section 30.4 of the draft guidance, meaning those NDC-11s of the selected drug that:

- (1) had Part D PDE utilization in the 12-month period beginning November 1, 2023 and ending October 31, 2024, or
- (2) CMS believes are likely to have Part D PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs).

For each of these NDC-11s of the selected drug, including any NDC-11s that are marked as “discontinued,” CMS will also populate the CMS HPMS with the Product Name and the Labeler Code. If a Primary Manufacturer believes that an NDC-11 that has been populated by CMS within the CMS HPMS should not be populated, or an error has occurred, they can submit an email to IRAREbateandNegotiation@cms.hhs.gov.

Definitions for Section A:

- Average Manufacturer Price (AMP) unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Drug sample: A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug (21 C.F.R. § 205.3).
- Labeler code: The first segment of the FDA-assigned NDC. Each entity who engages in manufacturing, repackaging, relabeling, or private label distribution of a drug subject to listing under this part must apply for an NDC labeler code (21 C.F.R. § 207.33(c)(1)).
- Private label distributor: With respect to a particular drug, a person who did not manufacture, repack, relabel, or salvage the drug but under whose label or trade name the drug is commercially distributed (21 C.F.R. § 207.1).

- Total AMP Units per Package is the total number of AMP units per NDC-11 package size.
- Total National Council for Prescription Drug Programs (NCPDP) Units per Package is the total number of NCPDP units per NDC-11 package size.

Instructions for Section A:

- Review the list of NDC-11s populated by CMS, and if any NDC-11s associated with the NDA(s) / BLA(s) of the selected drug are missing from the list (e.g., because they are new NDC-11s, discontinued NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug, provide the missing NDC-11 and corresponding Product Name and Labeler Code.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, provide the NCPDP Unit, Total NCPDP Units Per Package, AMP Unit and Total AMP Units Per Package.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, indicate whether:
 - (1) any of the listed NDC-11s or additional NDC-11s are marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer,
 - (2) any of the listed NDC-11s or additional NDC-11s are distributed by a private label distributor,
 - (3) any of the listed NDC-11s or additional NDC-11s have been discontinued and the date of discontinuation, and
 - (4) any of the listed NDC-11s or additional NDC-11s are a sample package, outer package, or inner package.
- If an NDC-11 is not controlled by a Primary or Secondary Manufacturer and the Primary Manufacturer is not able to determine the information for the NDC, select “Unknown” in response to whether the NDC-11 is “Marketed and Controlled Solely by a Manufacturer that is not the Primary or Secondary Manufacturer.”

Product Name	NDC-11 Numbers	Marketed and Controlled Solely by a Manufacturer that is not the Primary or Secondary Manufacturer	Discontinued (Select if NDC-11 has been discontinued and provide date of discontinuation)	Sample Package (Select if NDC-11 is a sample package)	Inner Package (Select if NDC-11 is an outer package)	Outer Package (Select if NDC-11 is an inner package)	Private Label (Select if NDC-11 is a private label)	NCPDP Unit (EA, ML, GM)	Total NCPDP Units per Package	AMP Unit (Injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, EC, millicurie, microcurie)	Total AMP Units per Package	Labeler Code
<i>Text to be pre-populated by CMS</i>	<i>Numbers to be pre-populated by CMS</i>	<i>Yes/No/Unknown</i>	<i>Text</i> <i>Date if Applicable</i>	<i>Text</i>	<i>Text</i>	<i>Text</i>	<i>Text</i>	<i>Text</i>	<i>#</i>	<i>Text</i>	<i>#</i>	<i>Numbers to pre-populated by CMS</i>

**Primary Manufacturer to add rows and identify any NDC-11s of the selected drug that are not pre-populated by CMS*

B. Non-FAMP Data Collection

Primary Manufacturer Response Required

For Section B, the Primary Manufacturer is required to report the non-FAMP for its selected drug(s) for the four quarters of calendar years 2021 (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, the Primary Manufacturer is required to report average non-FAMP for the first full calendar year following the market entry for such drug), as well as calendar year 2024 (i.e., the calendar year prior to the selected drug publication date, February 1, 2025).

CMS plans to use the reported NDC-11s, quarterly non-FAMP, and total NDC-11 package volume in the table below to calculate the average non-FAMP for calendar year 2021 (or for the first full calendar year following the market entry of the selected drug) and calendar year 2024 for initial price applicability year 2027.

Definitions for Section B:

- Non-FAMP: Section 1194(c)(6) of the Act defines “average non-Federal average manufacturer price” as the average of the non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) for the four calendar quarters of the year involved.¹¹ For initial price applicability year 2027, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2024 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2025). When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021, the Primary Manufacturer should submit 2021 data—to the extent that it exists—for all NDC-11s of the selected drug. For a given NDC-11 of such drug, when there are at least 30 days of commercial sales but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or 2024, the non-FAMP reported by the Primary Manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2024 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.¹² Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP package: Non-FAMP package is the package unit as described in 38 U.S.C. § 8126(h)(6) and represents the NDC-11 package (e.g., for an NDC-11 that represents a

¹¹ The term “non-Federal average manufacturer price” means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account— (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount. 38 U.S.C. § 8126(h)(5).

¹² See: <https://www.va.gov/opal/docs/nac/fss/pl102585-2024-pbm-fcp-guidance-for-new-covered-drugs.pdf>.

bottle of 30 tablets, the non-FAMP package would be the bottle).

Instructions for Section B:

Please follow the instructions below when completing the following tables.

- Please complete the two tables immediately below:
 - Table 1: please fill in the information for non-FAMP for each calendar quarter of 2021 for the selected drug (or, in the case that there is not an average non-FAMP available for such drug for 2021, please fill in the information for the applicable calendar quarters for the first full year following the market entry for such drug). If the first full year following the market entry happens to be 2024, then please proceed to fill in table 2 only.
 - Table 2: please fill in the information for non-FAMP for calendar year 2024.
- Please note that when filling out Table 1 and Table 2, there may be a different number of NDC-11s with available data in Table 1 and in Table 2. As an example, if a selected drug's market entry was in the 3rd quarter of 2021, all associated NDC-11s should be reported for the four quarters of 2022 in Table 1. Table 2 will consist of all NDC-11s for the four quarters of 2024, even if an NDC-11 was available in 2024 but not available during any quarter of 2022 and therefore no data was provided in Table 1.
- Please report the non-FAMP and total non-FAMP package volume for each NDC-11 of the selected drug. Primary Manufacturers are responsible for reporting the calendar year in Table 1 as either calendar year 2021 or the calendar year of first year post market entry. If an NDC-11 was not marketed, sold, or distributed in a particular calendar quarter, enter "0" in the total NDC-11 package volume field and leave the non-FAMP field blank. In these situations, please provide an explanation in the "Explanation of why non-FAMP was not reported (if applicable)" field of why the NDC-11 had no non-FAMP for that calendar quarter (e.g., first marketed in a later calendar quarter).
- Non-FAMP and total non-FAMP package volume information must be provided by the Primary Manufacturer for its own NDC-11s and the NDC-11s of any Secondary Manufacturer(s).
- Any restatements of the non-FAMP for the four calendar quarters of 2021 (or, in the case that there is not an average non-FAMP available for such drug for 2021, for calendar quarters for the first full year following the market entry for such drug) and for 2024 made in any manufacturer non-FAMP submissions to the VA must be reflected in the table below.
- Please indicate the total number of NDC-11 packages sold during the quarter and that are used in the calculation of the non-FAMP in the total non-FAMP package volume field.

Table 1

NDC-11	Calendar Quarters of 2021 or first calendar year post market entry	Calendar Year	Total Non-FAMP package volume	Non-FAMP	Explanation of why non-FAMP was not reported (if applicable)
<i>12345-6789-01</i>	<i>QQ</i>	<i>YYYY</i>	<i>#</i>	<i>\$</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Table 2

NDC-11	Calendar Quarter for 2024	Calendar Year	Total Non-FAMP package volume	Non-FAMP	Explanation of why non-FAMP was not reported (if applicable)
<i>12345-6789-01</i>	<i>QQ</i>	<i>YYYY</i>	<i>#</i>	<i>\$</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

C. Research and Development (R&D) Costs and Recoupment

Primary Manufacturer Response Required

Section C contains five questions, related to global R&D costs incurred by the Primary Manufacturer, including acquisition costs, related to the selected drug. Each of these questions requires the Primary Manufacturer to report, as applicable: (1) dollar amounts for R&D costs, which must be reported in the numerical response field and (2) explanations of how those costs were calculated in the free response field. Section C also contains one question about the Primary Manufacturer’s global and U.S. total lifetime net revenue for the selected drug. This question requires the Primary Manufacturer to report, as applicable: (1) the dollar amount for global, total lifetime net revenue, which must be reported in the numerical response field, (2) an explanation of how global, total lifetime net revenue was calculated in the free response field, (3) the dollar amount for U.S. lifetime net revenue, which must be reported in the numerical response field, and (4) an explanation of how U.S. lifetime net revenue was calculated in the free response field.

Definitions for Section C:

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications¹³ of a drug falling into the five categories below, and excluding the following: (a) prior Federal financial support, (b) costs associated with applying for and

¹³ For purposes of this ICR, CMS distinguishes between the use of the word “indication” and the term “FDA-approved indication” such that “FDA-approved indication” refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s), and “indication” refers to the condition or disease state for which the selected drug is used. CMS will use “indication” for purposes of determining the initial offer, as described in the Medicare Drug Price Negotiation Program Draft Guidance.

receiving foreign approvals, and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Acquisition Costs
2. R&D: Basic Pre-Clinical Research Costs
3. R&D: Post-Investigational New Drug (IND) Application Costs
4. R&D: Abandoned and Failed Drug Costs
5. R&D: All Other R&D Direct Costs

CMS is calculating recoupment of R&D costs using both the global and U.S. total lifetime net revenue for the selected drug:

6. Recoupment: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

The definitions and associated time periods for these terms are included below.

Instructions for Section C:

Follow these instructions for Questions 1 through 6 when reporting R&D costs:

- For each dollar amount listed below, the Primary Manufacturer must report one dollar amount in the numerical response field and an explanation of the values, including any calculations or conversions and any assumptions made in the free response field.
- All costs in this Section C are for FDA-approved indications of the selected drug, unless otherwise specified. Do not report any costs for indications that are not FDA-approved indications.
- All dollar figures submitted to CMS must be cash-outlay costs to the Primary Manufacturer. They must exclude any costs to entities that are not the Primary Manufacturer.
- Reported costs for Questions 1 through 5 must be mutually exclusive for each question; in other words, no costs must be counted in more than one section. Similarly, reported costs for Questions 1 through 5 must be collectively exhaustive for all R&D costs; in other words, all R&D costs that the Primary Manufacturer incurred for the selected drug must be accounted for in Questions 1 through 5.
- If the Primary Manufacturer received any prior Federal financial support, as defined in Section E, for any of the costs listed in Questions 2 through 5 below (e.g., basic pre-clinical research, clinical trials, etc.), deduct such funding from the final calculated numerical amount before answering the relevant question and note that deduction in the applicable free response field. CMS will be collecting additional information on prior Federal financial support in Questions 9, 10, and 11. Please reference Section E for instructions on reporting prior Federal financial support.
- If the Primary Manufacturer shared the expenses described in Questions 1 through 5 for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report only costs the Primary Manufacturer incurred. Report how shared expenses were allocated among the Primary Manufacturer and any other entity or entities in the free response field for the relevant question.
- Follow the instructions for Reporting Monetary Amounts, including those related to converting to USD if R&D costs occurred in other countries. While R&D may occur in other countries and those costs must be included and reported in USD, costs associated with applying for and receiving foreign approvals must not be included.

Question 1: Primary Manufacturer Acquisition Costs of the Selected Drug

Please provide the information below about acquisition costs incurred by the Primary Manufacturer for the selected drug, as described in more detail below.

Definitions for Question 1:

For the sole purpose of data collection under section 1194(e)(1)(A) of the Act, acquisition costs are defined as costs associated with the Primary Manufacturer's purchase from another entity of the rights to hold previously approved or future NDA(s) / BLA(s) of the selected drug.

Instructions for Question 1:

- First, report whether the Primary Manufacturer acquired the right to hold previously approved or future NDA(s) / BLA(s) of the selected drug from another manufacturer.
- If the response is No, please skip to Question 2.

RESPONSE FORMAT
<i>Yes/No</i>

- If the response is "Yes", please report the total costs of the acquisition(s) of the NDA(s) / BLA(s) of the selected drug in the "Total Acquisition Costs for the Selected Drug" field.
- In situations where the total acquisition costs of the approved or future NDA(s) / BLA(s) of the selected drug included costs other than for acquisition of the selected drug, please (1) report those costs in the "Total Acquisition Costs" field and (2) provide a proportional allocation of the total acquisition costs for the selected drug in the "Total Acquisition Costs for the Selected Drug" numerical field.

FIELD	RESPONSE FORMAT
Total Acquisition Costs for the Selected Drug	\$
Total Acquisition Costs	\$

If the "Total Acquisition Costs for the Selected Drug" numeric field does not apply, indicate N/A.

If the "Total Acquisition Costs for the Selected Drug" numeric field is populated, then please provide an explanation of the allocation of "Total Acquisition Costs for the Selected Drug," in the free response field below.

FIELD	RESPONSE FORMAT
Explanation of Allocation of Total Acquisition Costs for the Selected Drug	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 2: Basic Pre-Clinical Research for All FDA-Approved Indications of the Selected Drug

Provide the following information about total R&D costs incurred by the Primary Manufacturer for all FDA-approved indications for the selected drug related to basic pre-clinical research, as described in more detail below.

Definitions for Question 2:

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each FDA-approved indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that FDA-approved indication of the selected drug went into effect.^{14,15} The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.¹⁶
- Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect basic pre-clinical research costs and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending

¹⁴ CMS acknowledges that the exact date of initial discovery might not be known, but Primary Manufacturers should use their best estimate.

¹⁵ For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug, use the earliest date of acquisition for any NDA / BLA of the selected drug.

¹⁶ CMS believes that 52 months represents a solid average across studies. For example, one study reported that the pre-clinical phase takes 52 months on average. See DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. *Journal of Health Economics*, 2003, <https://dukespace.lib.duke.edu/items/746bd624-1fbd-44ae-b348-73edc80b073f>. Another study estimated that the pre-clinical phase can take 31 months on average. See DiMasi, J, Grabowski, H, Hansen, R. Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, 2016, as cited by the Congressional Budget Office (CBO) in Research and Development in the Pharmaceutical Industry, April 2021, <https://www.cbo.gov/publication/57126>. Other estimates have found that the pre-clinical phase ranges from three to six years. See PhRMA, “Biopharmaceutical Research & Development: The Process Behind New Medicines,” 2015.

allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.^{17, 18} For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs for that period of time, then *indirect* costs should be allocated proportionally. Thus, for the selected drug, they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Instructions for Question 2a:

- The amount reported for basic pre-clinical research costs in the numerical response field for Question 2a must be the sum of (1) direct research expenses and (2) a proportion of indirect research expenses. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.
 - If the Primary Manufacturer acquired the right to hold the most recent NDA / BLA of the selected drug after the last IND application submitted to the FDA went into effect, enter "\$0" for Question 2a.
 - If there were basic pre-clinical research costs incurred after the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug, the basic pre-clinical research costs must be reported in the numerical response field.

FIELD	RESPONSE FORMAT
Basic Pre-Clinical Research Costs for All FDA-Approved Indications of the Selected Drug	\$

Instructions for Question 2b:

- List the direct research expenses and the indirect research expenses for the selected drug.

FIELD	RESPONSE FORMAT
List of the direct research expenses and indirect research expenses for the selected drug included in this section	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Instructions for Question 2c:

- Explain how the basic pre-clinical research costs were calculated, including the allocation and apportionment methods. This explanation should include the percentage of direct and indirect spending on the selected drug out of the total direct and indirect

¹⁷ Wouters OJ, McKee M, Luyten J., Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*. 2020;323(9):844–853. doi:10.1001/jama.2020.1166.

¹⁸ Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ, Stoddart GL., *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press, 2005, [https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition\(e43f24cd-099a-4d56-97e6-6524afaa37d1\)/export.html](https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html).

basic pre-clinical research costs for the Primary Manufacturer, an explanation of the values used in the direct and indirect cost calculation, and the length of the basic pre-clinical research period used.

FIELD	RESPONSE FORMAT
Explanation of Basic Pre-Clinical Research for All-Approved Indications of the Selected Drug, Including Allocation and Apportionment Methods	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Question 3: Post-IND Costs for All FDA-Approved Indications of the Selected Drug

Please provide the following information on the direct costs incurred by the Primary Manufacturer beginning on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug. The Primary Manufacturer must report the direct costs for all completed post-marketing trials for all FDA-approved indications of the selected drug. *Do not report costs for indications that are not FDA-approved indications for the selected drug.*

Definitions for Question 3:

- Post-IND costs are defined as all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication. Post-IND costs also include all direct costs associated with completed FDA-required, post-marketing trials that are conducted after the FDA has approved a product. Post-IND costs exclude FDA-required, post-marketing trials that were not completed.
- Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period. Direct post-IND costs also include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed FDA-required, post-marketing trial.
- The post-IND period begins on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug.

Instructions for Question 3a:

- The amount reported in the numerical response field must include all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication, as well as the direct costs for all completed, FDA-required post-marketing trials for all FDA-approved indications of the selected drug. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.
 - If the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug after all NDA(s) / BLA(s) were approved by the FDA for a selected drug, do not include any costs for these trials in the numerical response field.

- If the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug and there were additional post-IND costs that followed the acquisition and were incurred before the FDA approved the most recent FDA-approved indication, those costs may be reported in the numerical response field. For example, if a Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug during the Phase I trial for the most recent FDA-approved indication, it may report the costs of the trials that followed the acquisition in the numerical response field.
- If the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug after FDA-required post-marketing trials were completed or if no such post-marketing trials were completed for the selected drug, do not include any costs for these post-marketing trials in the numerical response field.
- If the selected drug received accelerated approval for any FDA-approved indication, include the direct costs for any completed post-approval confirmatory studies in the numerical response field. Direct costs for any post-approval confirmatory studies that have not been completed should be reported in Question 5.

FIELD	RESPONSE FORMAT
Post-IND Costs for Approved Indications of the Selected Drug	\$

Instructions for Question 3b:

- Respond “Yes” or “No” in the “FDA Expedited Program” field if the selected drug received fast track designation, breakthrough therapy designation, accelerated approval, or priority review designation for any of its FDA-approved indications. If “Yes,” indicate in the free response field the type of expedited program(s) and the FDA-approved indication(s) for which the designation was granted.

FIELD	RESPONSE FORMAT
FDA Expedited Program	<i>Yes/No</i>
If yes, indicate the expedited program(s) and FDA-approved indication(s)	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Instructions for Question 3c:

- List all the applicable direct costs included in the numerical value given in Question 3a.

FIELD	RESPONSE FORMAT
List of the direct costs included in this question	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Instructions for Question 3d:

- Explain how the post-IND costs for all FDA-approved indications numerical value were

calculated, including any conversions that were done. The Primary Manufacturer must identify the length of the post-IND period used in the calculations. Additionally, the Primary Manufacturer may include the post-IND cost associated with each FDA-approved indication or may break down those costs for each clinical trial phase.

FIELD	RESPONSE FORMAT
Explanation of Post-IND Costs for FDA-Approved Indications of the Selected Drug	<i>Text (30,000 character count limit, which is approximately 2,500 words)</i>

Question 4: Costs of Failed or Abandoned Products Related to the Selected Drug

The Primary Manufacturer may allocate a portion of the *direct* costs spent on basic pre-clinical research and clinical research for failed or abandoned products related to the selected drug.

Definitions for Question 4:

- Failed or abandoned product costs include a sum of the portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not receive FDA approval.
- Failed or abandoned product costs include a portion of direct *basic pre-clinical research* costs on drugs with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials.
 - Direct research expenses are costs that can specifically be attributed to the discovery and pre-clinical development of the drug.
 - Direct research expenses include personnel (compensation for investigators and staff) researching the drug, materials for conducting basic pre-clinical research, and in vivo and in vitro studies on the drug.
- Failed or abandoned products costs include a portion of direct *post-IND costs* for drugs in the same therapeutic class as the selected drug that did not receive FDA approval.
 - Direct post-IND costs are costs that can specifically be attributed to the dosing and clinical trials for the drug.
 - Direct post-IND costs include IRB review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting dosing and clinical trials for the drug.

Instructions for Question 4a:

- In the numerical response field, only include costs that can be directly attributed to failed or abandoned product(s) with the same active moiety / active ingredient or mechanism of action *or* drugs in the same therapeutic class as the selected drug that did not receive FDA approval. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.
- Do not include acquisition costs for failed or abandoned products in the numerical

response field. Such costs should be reported in Question 5.

FIELD	RESPONSE FORMAT
Costs of Allowable Abandoned or Failed Products Related to the Selected Drug	\$

Instructions for Question 4b:

- In the free response field, detail how these costs were determined, what portion of direct costs was included for basic pre-clinical research and post-IND costs, and how any allocation was done.

FIELD	RESPONSE FORMAT
Explanation of Costs on Allowable Abandoned or Failed Products Related to the Selected Drug, Including Allocation and Apportionment Methods	<i>Text (30,000 character count limit, which is approximately 2,500 words)</i>

Question 5: Direct Costs of Other R&D for the Selected Drug Not Accounted for Above

The Primary Manufacturer must report the dollar amount of direct costs it attributes to R&D that was not accounted for in Questions 1 through 4.

Definition for Question 5:

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1 through 4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required post-marketing trials that were not completed, Phase IV post-marketing studies for FDA-approved indications that were not required by FDA, post-IND costs for indications that did not receive FDA approval, and acquisition costs for failed or abandoned products.

Instructions for Question 5a:

- In the numerical response field, report the sum of all other R&D direct costs for the selected drug.

FIELD	RESPONSE FORMAT
Costs of Other R&D for the Selected Drug Not Accounted for Above	\$

Instructions for Question 5b:

- List each “other R&D direct cost” for the selected drug included in the numerical value in Question 5a.

FIELD	RESPONSE FORMAT
List of Other R&D Costs for the Selected Drug Not Accounted for Above	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Instructions for Question 5c:

- For each “other R&D direct cost” listed in Question 5b, explain how each was calculated.

FIELD	RESPONSE FORMAT
Explanation of Costs of Other R&D for the Selected Drug Not Accounted for Above, Including Allocation and Apportionment Methods	<i>Text (30,000 character count limit, which is approximately 2,500 words)</i>

Question 6: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

In order for CMS to consider the extent to which the Primary Manufacturer has recouped its research and development costs, the Primary Manufacturer must report the global, total lifetime net revenue for the selected drug from all countries, including the United States, in which the selected drug was sold on or after the date of approval as determined by each country’s drug regulatory agency. The Primary Manufacturer must also report the subset of U.S. lifetime net revenue for the selected drug sold to all U.S. entities following initial FDA approval. The Primary Manufacturer must provide the revenue for each calendar year of the total lifetime net revenue period. The definitions and instructions for this section are separated into two categories: (1) definitions and instructions for reporting global, including U.S., total lifetime net revenue for the selected drug and (2) definitions and instructions for reporting U.S. lifetime net revenue for the selected drug.

Definitions for Question 6: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer’s global and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.

Definitions for Question 6a: Global, including U.S., Total Lifetime Net Revenue for the Selected Drug:

- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in-kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- Global, total lifetime net revenue period is defined as the date the drug or biological

product was first sold anywhere globally through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.

- If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.
- Global, total lifetime net revenue for the selected drug must be in nominal USD.

Instructions for Question 6a: Global, including U.S., Total Lifetime Net Revenue for the Selected Drug:

- In the numerical response field, report the global, total lifetime net revenue for the selected drug for the global, total lifetime net revenue period.

FIELD	RESPONSE FORMAT
Global, Total Lifetime Net Revenue for the Selected Drug	\$

- In the free response field, explain how the final global, total lifetime net revenue was calculated, including any relevant currency conversions. Additionally, report the per calendar year revenue for the global, total lifetime net revenue and specify the calendar year date range(s) for the global, total lifetime net revenue period.

FIELD	RESPONSE FORMAT
Explanation of Global, Total Lifetime Net Revenue for the Selected Drug	<i>Text (60,000 character count limit, which is approximately 5,000 words)</i>

Definitions for Question 6b: U.S. Lifetime Net Revenue for the Selected Drug:

- U.S. lifetime net revenue for the selected drug is defined as the direct sales and payments from U.S. entities, minus the discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in-kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.
- U.S. lifetime net revenue period is defined as the date the drug or biological product was first sold in the U.S. through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- If U.S. lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available.
- U.S. lifetime net revenue for the selected drug must be in nominal USD.

Instructions for Question 6b: U.S. Lifetime Net Revenue for the Selected Drug:

- In the numerical response field, report the U.S. lifetime net revenue for the selected drug

for the U.S. lifetime net revenue period.

FIELD	RESPONSE FORMAT
U.S. Lifetime Net Revenue for the Selected Drug	\$

In the free response field, report the calendar year date ranges for the U.S. lifetime per calendar year net revenue period, and explain how the final amount was calculated.

FIELD	RESPONSE FORMAT
Explanation of U.S. Lifetime Net Revenue for the Selected Drug	<i>Text (30,000 character count limit, which is approximately 2,500 words)</i>

D. Current Unit Costs of Production and Distribution

Primary Manufacturer Response Required

Section D contains two questions on current unit costs of production and distribution for the selected drug. Question 7 is a table in which to report the average unit costs of production and distribution for each NDC-11 of the selected drug. Question 8 provides a free response field for explaining the methodology for calculating the amount reported in Question 7.

Definitions for Section D:

- In accordance with section 1191(c)(6) of the Act, the term “unit” means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three NCPDP (BUS)¹⁹: The three NCPDP BUS are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Costs of production are defined as all (direct and allocation of indirect) costs related to:
 - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
 - Formulation and preparation of the finished drug product;
 - Quality control and testing of the drug; and
 - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of distribution are defined as all (direct and allocation of indirect) costs related to:
 - Packaging and packaging materials;
 - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
 - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy,

¹⁹ See: <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>

- physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
 - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:
 - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
 - Average unit costs during the 12-month period ending October 31, 2024 (for selected drugs for initial price applicability year);
 - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
 - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
 - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
 - R&D costs;
 - Marketing costs; and
 - Transfer prices.
- “Marketing costs” are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion.
- “Transfer prices” are defined as prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, “controlled group” of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of Treasury regulations thereunder.

Instructions for Section D:

Follow the instructions below when answering Questions 7 and 8:

- Production and distribution unit costs must be reported separately for each NDC-11 of the selected drug, including any NDC-11 of the selected drug marketed by a Secondary Manufacturer.

- Unit costs reported must represent the average per unit cost (1) within the time period specified below, (2) across all package types, and (3) calculated according to the instructions and using the definitions specified below.
- Use the response field in Question 8 to explain any shared operating and other indirect costs that were included in the response to Question 7.
- Costs may be reported up to three decimal places (USD).

Question 7: Per Unit Production and Distribution Costs

Please complete the following table using additional rows as necessary for the 12-month period ending October 31, 2024.

NDC-11	Average Per Unit Production Cost	Average Per Unit Distribution Costs	NCPDP unit	Total Unit Volume	Costs are Not Available	Explanation of Why Costs are Not Available
12345-6789-01	\$XX.XX	\$XX.XX	Select one: <ul style="list-style-type: none"> • Gram (GM) • Milliliter (ML) • Each (EA) 	#	Select if applicable	Text (30,000 character count limit, which is approximately 2,500 words)

Question 8: Explanation of Calculation of Per Unit Production and Distribution Costs

Please describe the methodology used to calculate the average per unit costs of production and distribution reported in Question 7, including which indirect costs were included, specific allocation methodologies, assumptions, and whether such assumptions apply to all or a subset of the data reported.

Specifically, include any assumptions about costs including but not limited to:

- Allocated general and administrative overhead;
- Cost of capital;
- Labor compensation;
- Any included costs that were incurred outside of the U.S.;
- Allocated shared facility costs;
- Allocated shared transportation or other operational costs;
- Depreciation of facilities, equipment, or other assets involved in the production and distribution of the selected drug; and
- Number of units of drug samples and how their cost was determined.

FIELD	RESPONSE FORMAT
Explanation of Unit Production and Distribution Costs	Text (30,000 character count limit, which is approximately 2,500 words)

E. Prior Federal Financial Support

Primary Manufacturer Response Required

Section E focuses on capturing prior Federal financial support for novel therapeutic discovery and development with respect to the selected drug.

Definitions for Section E:

- “Federal financial support for novel therapeutic discovery and development” refers to tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- “*Prior* Federal financial support” refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for the selected drug.

Instructions for Section E:

Follow the instructions below when answering Questions 9, 10, and 11.

- When completing this section:
 - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to direct costs for the basic pre-clinical research and clinical trials phase of research and development for FDA-approved indications of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to applicable Secondary Manufacturers of a selected drug). These direct costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of FDA-approved indications of the selected drug.
 - Include prior Federal financial support received for indirect costs of developing the selected drug. These indirect costs are operating costs such as administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.
 - To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.^{20, 21} For example, if the *direct*

²⁰ Wouters OJ, McKee M, Luyten J., Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*. 2020;323(9):844–853. doi:10.1001/jama.2020.1166.

²¹ Drummond MF, Sculpher MJ, Torrance GW, O’Brien BJ, Stoddart GL., *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press, 2005, [https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition\(e43f24cd-099a-4d56-97e6-6524afaa37d1\)/export.html](https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html).

costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs must be allocated proportionally, thus for the selected drug they must be 10 percent of the total spending on *indirect* costs during that time period.

- For grants, Primary Manufacturers should use the indirect cost rate at the time of data submission to calculate the proportion of funds that should be allocated to indirect costs. This indirect cost rate could be the fixed rate, provisional/final rate, or predetermined rate.
 - For in-kind contributions and Cooperative Research and Development Agreements (CRADAs), if the dollar value of the in-kind contribution or CRADA is not readily ascertainable, the recipient should provide a reasonable estimate.
- If the Primary Manufacturer received prior Federal financial support for a failed or abandoned product with the same active moiety / active ingredient or mechanism of action as the selected drug that did not make it to clinical trials and/or drugs in the same therapeutic class as the selected drug that did not receive FDA approval, including indications for the selected drug that did not receive approval, the Primary Manufacturer should not include this amount in its answer for Question 9. Instead, the Primary Manufacturer must include this amount as a separate quantity when explaining prior Federal financial support in Question 10.
 - If the Primary Manufacturer shared the prior Federal financial support described in Questions 9 through 11 for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report support received only for costs the Primary Manufacturer incurred. Expenses should be allocated across entities based on each entity's respective stake in the selected drug's discovery and development. The allocation to the Primary Manufacturer should be reported as a dollar amount and the percentage of the total amount allocated to the Primary Manufacturer should be included in the free response field in Question 10. For example, if the Primary Manufacturer was allocated 80 percent of the prior Federal financial support for a period of the selected drug's development, the Primary Manufacturer would include 80 percent of that support in its total number for prior Federal financial support in Question 9. Then, it would note the source of the shared prior Federal financial support and that it received 80 percent of that support in Question 10. If the shared support came in the form of an agreement, the Primary Manufacturer would include this in the "Nature of Agreement" section of Question 11.

Question 9: Federal Funding Support Amount

Complete the table below.

FIELD	RESPONSE FORMAT
Total Federal Financial Support	\$

Question 10: Explanation of Calculation of Federal Financial Support

Disaggregate the total Federal financial support amount reported above by the amounts allocated to the sources in the list below. Please list amounts in order of highest to lowest. In addition, describe assumptions, methodological steps, and other information needed to calculate the estimates provided in Question 9. If you report a value for “other Federal financial support not otherwise included elsewhere” in your response to this question, please list the source(s) of that Federal financial support. Please include the identification number for grants and comparable awards.

- Tax credits (General, R&D)
- Orphan Drug Act and other specific tax credits
- National Institutes of Health (NIH) funding
- Department of Defense (DOD) Congressionally Directed Medical Research (CDMR) funding
- Biomedical Advanced Research and Development Authority (BARDA) funding
- Defense Advanced Research Projects Agency (DARPA) funding
- Federal financial support for failed or abandoned indications for the selected drug
- Federal financial support for failed or abandoned products related to the selected drug (as described in the definitions for this section)
- CRADA support
- In-kind contributions not included elsewhere
- Other Federal financial support not included elsewhere

FIELD	RESPONSE FORMAT
Federal Financial Support	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>

Question 11: Agreements Between Primary Manufacturer and Federal Government

List and describe each licensing agreement, pricing agreement, purchasing agreement, and other agreement in place between your company and any federal government agency related to the discovery, research, and/or development of the selected drug. Add additional rows to your response to Question 11 as needed.

- In the “Nature of Agreement” field, please provide details on the terms of the agreement, such as information on pricing, the nature and amount of goods/services agreed upon, an explanation of the allocation methodology to the selected drug, timelines to delivering goods/services, conditions on the agreement (exclusivity, sole supplier, etc.) and effective dates and expiration dates, if applicable. For example, this field could detail an agreement between the Primary Manufacturer and Federal Government where the Primary Manufacturer agrees to produce a certain quantity of a drug that is being developed and has not yet been approved or licensed, deliver it to the Federal Government within a specified timeline, and not contract with other state or local governmental entities or insurers while this agreement is in place.

Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
<i>Select the agreement option: licensing, pricing, purchasing, other, none</i>	<i>Text (1,200 character count limit, which is approximately 100 words)</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

F. Patents, Exclusivities, and Approvals

Primary Manufacturer Response Required

Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Follow the instructions below when answering Questions 12 through 15.

Definitions for Section F:

- CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
 - All patents issued by the United States Patent and Trademark Office (USPTO), as of February 1, 2025, both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
 - All patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
 - All patent applications related to the selected drug that are pending issuance by the USPTO.
 - Patents and patent applications related to the selected drug include but are not limited to any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;²² utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug; and design patents that, for example, claim a design on the packaging of the selected drug.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
 - Orphan Drug Exclusivity (ODE);²³

²² FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.

²³ Section 527 of the FD&C Act.

- New Chemical Entity Exclusivity (NCE);²⁴
- Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);²⁵
- New Clinical Investigation Exclusivity (NCI);²⁶
- Pediatric Exclusivity (PED);²⁷ and
- Reference Product Exclusivity for Biological Products.²⁸
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided.

Instructions for Section F:

- For Questions 12 through 15, the relevant time period for reporting begins on the later of the date that basic pre-clinical research began on the selected drug or the date the selected drug was acquired by the Primary Manufacturer and ends on the date the most recent NDA / BLA was approved for the selected drug.
- For Questions 12 through 15, include required data for the selected drug.

Question 12: Patents (Expired and Non-Expired) and Patent Applications

In the table below, please list each patent that is related to the selected drug, as well as each application for a patent related to the selected drug that is pending with the USPTO. Patents and patent applications related to the selected drug that should be listed below include but are not limited to utility patents that claim the drug product (formulation or composition), drug substance (active ingredient), metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug, as well as any design patents that, for example, claim a design on the packaging of the selected drug. Any patents or patent applications related to the selected drug where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency) must be listed below. Any patents that are or have been listed for the selected drug in the FDA Orange Book or Purple Book must be included in the table below. For each entry, indicate whether the patent claims the drug product, drug substance, and/or a method of use of the selected drug. For each patent (expired or unexpired) listed in the table below, please upload a PDF file of the USPTO patent application. Do not include patent applications which were denied. Add additional rows to your response to Question 12 as needed.

²⁴ Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.

²⁵ Section 505E(a) of the FD&C Act.

²⁶ Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.

²⁷ Section 505A(b) & (c) of the FD&C Act.

²⁸ Section 351(k)(7) of the PHS Act.

Patent Number	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Patent Application Pending	Patent Type	Listed in FDA Orange Book/Purple Book	Patent Application
#	MM/DD/YY YY	MM/DD/YYYY	Yes/No Flag	Yes/No Flag	Yes/No Flag	Yes/No Flag	Select patent types: Utility, Design	Yes/No Flag	Upload corresponding patent application.

Question 13: Explanation of Patents (Expired and Non-Expired) and Patent Applications

If applicable, please provide additional information about the patent applications reported in the table above and describe how they relate to the selected drug. This information can include further information on the purpose of the patent, for example, if the patent claims a specific indication(s) of the selected drug or a device used to administer the selected drug, or other information that will be helpful to understand how the patent contributes to the selected drug. As applicable, please also use this free response field to indicate which patents related to the selected drug are held by a federal agency and describe how they relate to the selected drug.

FIELD	RESPONSE FORMAT
<i>Explanation of patents</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 14: Exclusivity Periods

As applicable, please report all exclusivity periods under the FD&C Act or the PHS Act that are listed in the Orange Book or the Purple Book and are in effect or have expired for the selected drug. *Complete table for Question 14 by adding rows as needed.*

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA / BLA) Number	NDC-9s Covered by Exclusivity	Comments
<i>Select exclusivity type: Orphan Drug Exclusivity, New Chemical Entity Exclusivity, Generating Antibiotic Incentives Now Exclusivity for Qualified Infectious Disease Products, New Clinical Investigation Exclusivity, Pediatric Exclusivity, Reference Product Exclusivity for Biological Products</i>	<i>MM/DD/YYYY</i>	<i>#</i>	<i>Text</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 15: All Active and Pending FDA Applications and Approvals

List all active and pending FDA applications and approvals for the selected drug under section 505(c) of the FD&C Act or section 351(a) of the PHS Act.

- Include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided. Leave approval date blank for those applications not yet approved. *[Complete table for Question 15 by adding rows as needed using the indicated format]*
- Please submit any efficacy supplements that have been approved or are pending FDA approval but exclude manufacturing supplements.

Applica tion (NDA / BLA) Number	Applicatio n Type (NDA; BLA)	Classification Code ²⁹	Appro val Date	Indic at ion	Dos age For m and Str eng th	Sponso r	Applic ation Status	Comments
#	Select the application type: NDA, BLA	Select one or more of the following options: Options: Type 1 — New Molecular Entity, Type 2 — New Active Ingredient, Type 3 — New Dosage Form, Type 4 — New Combination, Type 5 — New Formulation or Other Differences (e.g., new indication, new applicant, new manufacturer) , Type 6 — New Indication or Claim, Same Applicant, Type 7 — Previously Marketed But Without an Approved NDA, Type 8 — Rx to OTC, Type 9 New Indication or Claim, Drug Not to be Marketed Under Type 9 NDA After Approval, Type 10 — New Indication or Claim, Drug to be Marketed Under Type 10 NDA After Approval	MM DD, YYYY	Text	Text	Text	Select one of the followi ng options : approv ed, tentativ ely approv ed, pending , withdra wn, or other	Text (3,600 character count limit, which is approximatel y 300 words)

G. Market Data and Revenue and Sales Volume Data

Primary Manufacturer Response Required

²⁹ These classification code options will only be available if the “NDA” application type is selected. If “BLA” is selected, this dropdown will be grayed out as BLAs do not use classification codes.

The purpose of Questions 16 through 28 in this section is to collect the market data and revenue and sales volume data described in section 1194(e)(1)(E) of the Act.

Definitions for Section G:

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.
- The three NCPDP BUS³⁰ are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505. The Medicaid best price is reported at the NDC-9 level.
- AMP unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration.³¹ The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level.³²
- Manufacturer U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The U.S. commercial average net unit price includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price excludes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary

³⁰ See: <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>.

³¹ See: <https://www.fss.va.gov/index.asp>.

³² The Big Four price is the maximum price a drug manufacturer is allowed to charge the Big Four federal agencies, which are the Department of Veterans Affairs, the Department of Defense, the Public Health Services, and the Coast Guard. See: <https://www.cbo.gov/publication/57007>.

Manufacturer(s). The U.S. commercial average net unit price is reported at the NDC-11 level.

- **Manufacturer U.S. commercial average net unit price— net of patient assistance program:** For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price includes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price—net of patient assistance includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price— net of patient assistance program is reported at the NDC-11 level.
- **Manufacturer U.S. commercial average net unit price— best:** For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The U.S. commercial average net unit price – best includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price – best excludes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price – best is reported at the NDC-11 level.
- **Manufacturer net Medicare Part D price:** For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the net Medicare Part D price as calculated by the Primary Manufacturer. This net Medicare Part D price would include specific data to which the manufacturer has access including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) not reflected in the sum of the plan-specific enrollment weighted amounts calculation, and utilization that may differ from the PDE data. The net Medicare Part D price is reported at the NDC-11 level.

Instructions for Section G:

- For Question 16 through 25, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.

Question 16: Wholesale Acquisition Cost Unit Price

Follow the instructions below when providing responses in the following table about the WAC unit price of the selected drug:

- If the NDC-11 had multiple WACs for a given quarter, please calculate an average WAC per unit for the quarter using the following methodology. For each WAC per unit

available in the quarter, please multiply the WAC per unit by the proportion of the total units sold in that quarter at that WAC out of total unit volume sold in the quarter. Then sum these values across all WACs available in the quarter to calculate the average WAC per unit for the quarter.

- Any deviation from the reported WAC unit price in the table below and the WAC unit price as reported in wholesale price guides or other publications of drug or biological price data must be explained in Question 17 so that CMS can understand the reasons for these differences.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). Total unit volume must be the total number of units sold to wholesalers and direct purchasers during the quarter. Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- CMS has pre-populated the rows for the NDC-11s and quarters for the three years ending with the calendar year ending December 31, 2024, based on the Primary Manufacturer's responses in Section A. If the NDC-11 was marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed to any wholesaler or direct purchaser in a particular calendar quarter, please enter "0" in the total unit volume field and leave the WAC field blank and provide an explanation in the "Explanation of why WAC was not reported (if applicable)" field of why the NDC-11 had no WAC for that calendar quarter (e.g., the NDC-11 was first marketed in a later calendar quarter).

NDC-11	Quarter	WAC	NCPDP Unit (EA, ML, GM)	Total Unit Volume	Explanation of why WAC was not reported (if applicable)
12345-6789-01	QQ/YYYY	\$	Text	#	Text (3,600 character count limit, which is approximately 300 words)

Question 17: Explanation of Information Reported in Question 16: Wholesale Acquisition Cost Unit Price

If applicable, describe assumptions, methodological steps, and other information necessary to explain the deviation between the WAC unit price provided in response to Question 16 and those found in available drug databases (e.g., Medi-Span, First Databank, RED BOOK). Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
Explanation of WAC unit price data	Text (12,000 character count limit, which is approximately 1,000 words)

Question 18: Medicaid Best Price

Was a Medicaid best price determination ever made for a calendar quarter for the selected drug during the most recent five years?

RESPONSE FORMAT
<i>Yes/No</i>

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 20) Follow the instructions below when providing responses in the following table about the Medicaid best price of the selected drug:

- The Medicaid best price information must reflect what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 C.F.R. § 447.505 – Determination of best price. The reported Medicaid best price in the table below must reflect any restatements that have been certified under the MDRP.
- Total unit volume for the quarter is the sum of monthly AMP units reported to the MDRP for the quarter.
- If a Medicaid best price determination was made during the calendar quarter for that NDC-9, please complete all requested fields. If the NDC-9 did not have a Medicaid best price determination in a particular calendar quarter, please enter “0” in the total unit volume field and leave the Medicaid best price field blank and provide an explanation in the “Explanation of why Medicaid best price was not reported (if applicable)” field of why the NDC-9 had no Medicaid best price determination for that calendar quarter (e.g., the NDC-9 was first marketed in a later quarter).

NDC-9	Quarter	Medicaid Best Price	AMP Unit (injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie)	Total Unit Volume	Explanation of why Medicaid Best Price was not reported (if applicable)
<i>12345-6789</i>	<i>QQYY YY</i>	<i>\$ (up to 6 decimal places)</i>	<i>Text</i>	<i>#</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 19: Explanation of Information Reported in Question 18: Medicaid Best Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 18. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
<i>Explanation of Medicaid Best Price data</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 20: Federal Supply Schedule (FSS) Price

Was a FSS price for the selected drug ever available during the most recent three years, ending with the calendar year ending December 31, 2024?

RESPONSE FORMAT
Yes/No

If FSS was not reported, provide an explanation of why.

FIELD	RESPONSE FORMAT
Explanation of why FSS was not reported	Text (6,000 character count limit, which is approximately 500 words)

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 22) Follow the instructions below when providing responses in the following table about FSS prices of the selected drug:

- The FSS price information must reflect what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.³³ We note that the FSS price information should be for the NDC-11 package (e.g., for a bottle of 30 tablets, please report the FSS price for the bottle).
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). Total unit volume is the total number of NCPDP units (i.e., EA, ML, or GM) for each NDC-11 sold indirectly (e.g., through a wholesaler) or directly to federal purchasers. Please do not include units associated with free samples in the reported total unit volume.
- For each NDC-11, please include a row for each price period that occurred during the three years ending with the calendar year ending December 31, 2024, and fill out the requested information. If the NDC-11 did not have a FSS price during the three years ending with the calendar year ending December 31, 2024, please enter “0” in the total unit volume field and leave the “Federal Supply Schedule Price” field blank and provide an explanation in the “Explanation of why FSS price was not reported (if applicable)” field of why the NDC-11 had no FSS price for the three years ending with the calendar year ending December 31, 2024 (e.g., the NDC-11 was discontinued before the three year period began).

³³ See: <https://www.va.gov/opal/nac/fss/pharmprices.asp>.

NDC-11	Price Start Date to End Date	Federal Supply Schedule Price	NCPDP unit (EA, ML, GM)	Total Unit Volume	Explanation of why FSS price was not reported (if applicable)
12345-6789-01	MMDDYY Y- MMDDYY Y	\$	Text	#	Text (3,600 character count limit, which is approximately 300 words)

Question 21: Explanation of Information Reported in Question 20: Federal Supply Schedule Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 20. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
<i>Explanation of Federal Supply Schedule price data</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 22: Big Four Price

Was a Big Four price ever available for the selected drug during the most recent three years ending with the calendar year ending December 31, 2024?

RESPONSE FORMAT
<i>Yes/No</i>

If the Big Four Price was not reported, provide an explanation of why.

FIELD	RESPONSE FORMAT
<i>Explanation of why Big Four price was not reported</i>	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 24) Follow the instructions below when providing responses in the following table about the Big Four price of the selected drug:

- The Big Four price information must reflect the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs.³⁴ We note that the Big Four price information should be for the NDC-11 package (e.g., for a bottle of 30 tablets, please report the FSS price for the bottle).
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). Total unit volume is the total number of units (i.e., EA, ML, or GM) for

³⁴ See: <https://www.va.gov/opal/nac/fss/pharmprices.asp>.

each NDC-11 indirectly (e.g., through a wholesaler) or directly sold to the Big Four federal agencies (Department of Veterans Affairs, Department of Defense, the Public Health Service, and the Coast Guard). Please do not include units associated with free samples in the reported total unit volume.

- For each NDC-11, please include a row for each price period that occurred during the three years ending with the calendar year ending December 31, 2024, and fill out the requested information. If the NDC-11 did not have a Big Four price during the three years ending with the calendar year ending December 31, 2024, please enter “0” in the total unit volume field and leave the “Big Four Price” field blank and provide an explanation in the “Explanation of why Big Four price was not reported (if applicable)” field of why the NDC-11 had no Big Four price for the three years ending with the calendar year ending December 31, 2024 (e.g., the NDC-11 was discontinued before the three year period began).
- Please complete Questions 20 and 21 for the FFS price of the selected drug and Questions 22 and 23 for the Big Four price of the selected drug even if the Primary Manufacturer or the Secondary Manufacturer is considered a “single pricer”.

NDC-11	Price Start Date to Price End Date	Big Four Price	NCPDP unit (EA, ML, GM)	Total Unit Volume	Explanation of why Big Four price was not reported (if applicable)
<i>12345-6789-01</i>	<i>MMDDYYYY-MMDDYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 23: Explanation of Information Reported in Question 22: Big Four Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 22. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
<i>Explanation of Big Four price data</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 24: Manufacturer U.S. Commercial Average Net Unit Price

Follow the instructions below when providing responses in the following table about the Manufacturer U.S. commercial average net unit price, including group and individual commercial plans on- and off-Exchange of the selected drug:

- Exclude price and volume information for the selected drug for Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care.

- If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter “0” in the total unit volume field and leave the three price fields blank and provide an explanation in the “Explanation of why Manufacturer U.S. Commercial prices were not reported (if applicable)” field of why the NDC-11 had no Manufacturer U.S. commercial prices for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). CMS has pre-populated the NCPDP BUS for each of the NDC-11s associated with the selected drug. Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- The NDC-11 price reported in the “U.S. commercial average net unit price” field must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers.
- If the Primary Manufacturer or Secondary Manufacturer(s) provided manufacturer-run financial assistance such as coupons, co-payment assistance, or free drug products to patients, separately report the price net of such financial assistance to patients in the “U.S. commercial average net unit price— net of patient assistance programs” field. If the Primary Manufacturer and Secondary Manufacturer(s) did not provide financial assistance to patients, please leave the “U.S. commercial average net unit price— net of patient assistance programs” field blank.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to any commercial payer during the quarter in the “Manufacturer U.S. commercial average net unit price— best” field.

NDC-11	Quarter	Manufacturer U.S. Commercial Average Unit Net Price	Manufacturer U.S. Commercial Average Net Unit Price- Net of Patient Assistance Programs	Manufacturer U.S. Commercial Average Net Unit Price- Best	NCPDP unit (EA, ML, GM)	Total Unit Volume	Explanation of why Manufacturer U.S. Commercial prices were not reported (if applicable)
<i>12345-6789-01</i>	<i>QYY YY Y</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>	<i>Text</i>	<i>#</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 25: Explanation of Information Reported in Response to Question 24: Manufacturer U.S. Commercial Average Net Unit Price

Describe assumptions, methodological steps, and other information for the following topics related to Question 24:

- How sales to enrollees of group and individual commercial plans on- and off-Exchange were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-11s and calendar quarters.
- If applicable, how financial assistance, such as coupons or co-payment assistance, to patients was allocated across NDC-11s and calendar quarters.
- How information was used to calculate the “U.S. commercial average net unit price” and the “U.S. commercial average net unit price— net of patient assistance programs” and to determine the “U.S. commercial average net unit price— best”.
- Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
<i>Explanation of manufacturer U.S. commercial average net unit price data</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 26: Manufacturer Net Medicare Part D Price

Follow the instructions below when providing responses in the following table about the manufacturer net Medicare Part D price of the selected drug.

- Only include price and volume information of the selected drug for Part D plan sponsors.
- If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter “0” in the total unit volume field and leave the three price fields blank and provide an explanation in the “Explanation of why manufacturer net Medicare Part D Price was not reported (if applicable)” field of why the NDC-11 had no manufacturer net Medicare Part D price for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). CMS has pre-populated the NCPDP BUS for each of the NDC-11s associated with the selected drug. Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- The NDC-11 price reported in the manufacturer net Medicare Part D price must be net of discounts, including the applicable discount amount provided under the Medicare Coverage Gap Discount Program, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by

Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers.

- Provide the Medicare Coverage Gap Discount Program applicable discount amount paid by the Primary Manufacturer or any Secondary Manufacturer(s) during the quarter in the “Medicare Coverage Gap Discount Program” field.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to any Part D plan sponsor during the quarter in the “manufacturer average net unit price to Part D plan sponsors— best” field.

NDC-11	Calendar Quarter	Manufacturer net Medicare Part D price	Manufacturer Average Net Unit Price to Part D Plan Sponsors-Best	Medicare Coverage Gap Discount Program discount amount paid	NCP DP unit (EA, ML, GM)	Total Unit Volume	Explanation of why manufacturer net Medicare Part D price was not reported (if applicable)
<i>12345-6789-01</i>	<i>QQYYY Y</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>	<i>Text</i>	<i>#</i>	<i>Text (3,600 character count limit, which is approximately 300 words)</i>

Question 27: Explanation of Information Reported in Response to Question 26: Manufacturer net Medicare Part D price

Describe assumptions, methodological steps, and other information for the following topics related to Question 26:

- How sales to Medicare Part D enrollees of Part D plan sponsors sales were determined.
- How discounts, including the applicable discount amount provided under the Medicare Coverage Gap Discount Program, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-11s and calendar quarters.
- If applicable, how financial assistance to patients were allocated across NDC-11s and calendar quarters.

FIELD	RESPONSE FORMAT
<i>Explanation of “manufacturer Net Medicare Part D price” data</i>	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>

Question 28: Primary Manufacturer Identification of Information Submitted in Sections A through G that the Primary Manufacturer Believes Should be Withheld Under FOIA

Section 1193(c) of the Act states that CMS must determine which information submitted to CMS by a manufacturer of a selected drug is proprietary information of that manufacturer. As described in section 40.2.1 of the draft guidance, CMS will treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer.³⁵ For each section and/or question that a Primary Manufacturer believes contains information that should be withheld by CMS under FOIA Exemptions 3 and/or 4 (5 U.S.C. § 552(b)(3), (4)),³⁶ list the applicable section letter and question number and provide a brief explanation regarding why the Primary Manufacturer believes the information should be withheld under FOIA.

Section Letter and Question Number	Explanation
<i>Text</i>	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

H. Certification of Submission of Sections A through G for Primary Manufacturers

Required for Primary Manufacturers

Instruction for Section H:

An individual eligible to certify this submission on behalf of the Primary Manufacturer must be one of the following: (1) the chief executive officer (CEO) of the Primary Manufacturer, (2) the chief financial officer (CFO) of the Primary Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO of the Primary Manufacturer, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Certification:

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare payment purposes, including determination of a maximum fair price, as defined in section 1191(c)(3) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has

³⁵ Specifically, as described in section 40.2.1 of the draft guidance, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

³⁶ See: <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.

changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes []

No []

Contact Information to be entered:

Field	Response
Name of the Person Responsible for the Submission	<i>Text</i>
Signature	<i>Text</i>
Date	<i>MMDDYYYY</i>

I. Evidence About Alternative Treatments

Optional for All Respondents, Including Primary Manufacturer

While CMS is seeking public input under section 1194(e)(2) of the Act to consider information on the selected drug and its pharmaceutical therapeutic alternative(s), please do not include personally identifiable information³⁷ (PII) or protected health information³⁸ (PHI). CMS seeks to collect only the minimum necessary information related to the selected drug and its therapeutic alternatives for the purpose of implementing and operating the Negotiation Program. CMS will not retrieve evidence for manufacturer negotiations by personal identifier (PII or PHI). CMS will not, through this collection, create or maintain a system of records as understood by the Privacy Act of 1974 and accompanying Office of Management and Budget guidance.

Question 29: Respondent Information

Required: Individuals or organizations, including manufacturers, that wish to provide information in this Section I must provide the following information.³⁹

³⁷ Personally identifiable information (PII) is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual. PII can include sensitive data, such as medical, financial, or legal information; "neutral" information such as name, facial photos, or work address; and, contextual information, such as a file for a specific health condition that contains a list of treated patients. See: <https://www.hhs.gov/web/policies-and-standards/hhs-web-policies/privacy/index.html#what-is-pii>.

³⁸ Protected health information (PHI) is individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. Individually identifiable information is information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition; the provisions of health care to the individual; or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. PII includes many common identifiers such as name, address, birth date, Social Security Number, etc. See <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>.

³⁹ This section will be included in the Primary Manufacturer's CMS HPMS negotiation module, and the Primary Manufacturer must submit any responses to the questions in this section there.

FIELD	RESPONSE FORMAT
Selected Drug	TEXT [Select from list]
Respondent Name	TEXT
Organization Name (if applicable)	TEXT
Respondent Email	TEXT

Select from the following: Which of the following best describes the person completing this form? *You may select more than one option.*

- ☐ Representative of a manufacturer of the selected drug
- ☐ Representative of a manufacturer of a potential therapeutic alternative(s) to the selected drug
- ☐ Representative of a manufacturer that does not manufacture the selected drug or its potential therapeutic alternative(s)
- ☐ Representative of a trade association
- ☐ Representative of a patient advocacy organization
- ☐ A health care provider who has experience prescribing, dispensing, or administering the selected drug or its therapeutic alternative(s) or treating conditions pertinent to the selected drug or its therapeutic alternative(s).
- ☐ A patient who has experience taking the selected drug or its therapeutic alternative(s)
- ☐ A caregiver for an individual who has experience taking the selected drug or its therapeutic alternative(s)
- ☐ Academic researcher or other subject matter expert on topics including but not limited to pharmaceutical policy, comparative effectiveness research, and/or clinical value assessment
- ☐ Other

If “Other” is selected, provide a brief description of the person completing this form: [Text (960 character count limit, which is approximately 80 words)]

- Are you or your organization affiliated with the manufacturer of the selected drug or its therapeutic alternative(s)?⁴⁰

General Instructions for Section I

- All questions are optional.
- Any interested party may answer Questions 30 through 64. Each interested party will be able to answer each of Questions 30 through 64 in Section I one time for each selected drug. You may answer some or all of the questions. If you do not wish to respond to a given question you may skip the question or enter “no response.”

⁴⁰ For the purpose of this ICR, an individual or organization is “affiliated with the manufacturer” if the individual or organization receives or has received funding from the manufacturer for research, speaking, or other engagements, and/or any other purpose related to the drug or its potential therapeutic alternative(s) or if the individual or organization has been asked by the manufacturer to respond to this ICR or to advise the manufacturer on the Negotiation Program, regardless of compensation.

- Any respondent that answers any of Questions 30 through 62 should also review Questions 63 and 64 and respond as applicable.
- CMS has grouped Questions 30 through 62 in five categories of topics that are addressed by the set of questions. Specifically, these categories by question number are:
 - Questions 30-37: Manufacturer-Focused Input
 - Questions 38-44: Patient- or Caregiver-Focused Input
 - Questions 45-51: Clinical-Focused Input
 - Questions 52-58: Health Research-Focused Input
 - Questions 59-62: Other Public Input
- CMS provides the following examples of individuals and organizations that may choose to address a category of questions based on personal and/or professional insight and expertise. ANY AND ALL INTERESTED PARTIES may respond to ANY AND ALL QUESTIONS 30 through 64. These examples are intended as illustrative; a respondent is not limited to any category of questions based on the individual's or organization's insight and/or experience.
 - [Manufacturer-Focused Input](#)—for example, a Primary Manufacturer of a selected drug.
 - [Patient or Caregiver-Focused Input](#)—for example, an individual with experience taking the selected drug or a different medicine that may be used to treat the same condition or disease state (which is also called a therapeutic alternative(s) to the selected drug), a caregiver's experience caring for someone taking such drugs, patient organizations with insight into patients' lived experience of taking such drugs or living with a condition the drugs treat.
 - [Clinical-Focused Input](#)—for example, clinicians, pharmacists, hospitals, or other entities with clinical experience related to the selected drug, its therapeutic alternatives, or the condition(s) the drugs treat.
 - [Health Research-Focused Input](#)—for example, researchers, academic centers, patient groups, or other entities with evidence-based input regarding the selected drug or its therapeutic alternative(s).
 - [Other Public Input](#)—any other interested party that wishes to respond to the questions in section I.
- All declarative statements should be supported by evidence with a citation, unless you are sharing a personal experience with prescribing or taking the selected drug and/or its therapeutic alternative(s) or you are a caregiver describing the experience of the person taking the selected drug and/or its therapeutic alternative(s).
- Please answer each question in narrative (text) form. Your responses will be limited to the character and citation maximums provided for each question.
 - Information provided in response to an individual question does not need to be duplicated across additional responses. CMS will review submissions holistically across the entire submission.
- Submissions for Section I may include but are not limited to published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports.
 - CMS prefers publicly available, peer reviewed literature rather than poster abstracts and non-peer reviewed literature. When providing non-peer reviewed literature, CMS must be provided sufficient information on these

- studies in order to assess their applicability to the Negotiation Program.
- Please note that CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in section 50.2 of the draft guidance.
 - Please provide citations to published material rather than copies of articles. The respondent is responsible for ensuring that their submission complies with applicable law, including but not limited to copyright law. If data are unpublished, clearly indicate this in the citation. For unpublished data without a citation, please summarize key findings as appropriate in your response.
 - When citing studies to support responses, briefly summarize the study context and relevant comparator or therapeutic alternative drug(s) studied, as applicable.
 - When information in the free text response is supported by a citation provided in response to that question, please label the end of the sentence in the free text response with a number (e.g., [1], [2]) that corresponds to the number assigned to the citations provided for that same question.
 - Respondents are requested to provide citations in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: <https://www.ncbi.nlm.nih.gov/books/NBK7256/>.
 - CMS will review submitted studies that use cost-effectiveness measures or methods to determine if the study is relevant to the selected drug and/or its therapeutic alternative(s) and to determine if the cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than an individual who is younger, nondisabled, or not terminally ill. Respondents must indicate if their submission includes any cost-effectiveness measures or methods. Examples of cost-effectiveness measures or methods include but are not limited to quality-adjusted life-years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), Health Years in Total (HYT), and Generalized Risk-Adjusted Cost-Effectiveness (GRACE). CMS also requests that respondents provide a short description of any cost-effectiveness measures or methods included in the research submitted and the utility they believe the data provides in reviewing the selected drug without treating extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.
 - As described in section 50.2 of the draft guidance, CMS will not use comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.⁴¹ Information submitted that treats extending the life of individuals in the listed populations as of lower value will not be used in the Negotiation Program. Moreover, in accordance with section 1182(e) of Title XI of the Social Security Act, CMS will not use QALYs. In instances where a study includes a measure that treats extending the life of individuals who are elderly, disabled, or

⁴¹ Section 1194(e)(2) of the Social Security Act.

terminally ill as of lower value but separates such a measure from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS will consider such separate evidence. In these cases, indicate clearly in the in-text citation if the evidence provided treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and clearly indicate what separate evidence CMS might consider.

- Submissions may include visual representations of the information, including tables, charts, and/or graphs. The information submitted in the space for visual representations should only include the table/chart/graph, and no additional text. CMS will not review any additional text included beyond the titles, labels, legends, and footnotes in the visual representation. PDF files will be accepted within specified file size limits for visual representations. List the question number that a submitted table/chart/graph corresponds to in the free text response provided with the question to submit tables/charts/graphs.
- Indicate in your response if a portion of a response applies to specific dosages, forms, strengths, and/or indications of a selected drug or its therapeutic alternative(s).
- CMS will only review the maximum number of citations or upload files permitted in the instructions for a particular question per each such question.

Definitions for Section I:

- **Therapeutic Advance:** A selected drug may be considered a therapeutic advance when evidence indicates that the selected drug represents a substantial improvement in outcomes compared to the selected drug's therapeutic alternative(s) for an indication(s). In cases where there is no therapeutic alternative, a selected drug may be considered a therapeutic advance when there is a substantial improvement in outcomes for the condition or disease state treated by the selected drug. CMS will consider the extent to which a selected drug represents a therapeutic advance.
- **Therapeutic Alternative:** A therapeutic alternative must be a pharmaceutical product that is clinically comparable to the selected drug (in other words, a different medicine that may be used to treat the same condition or disease state). CMS will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS will identify therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action as well as considering therapeutic alternatives in other drug classes. In cases where there are many potential therapeutic alternatives for a given indication of the selected drug, CMS may focus on a subset of therapeutic alternatives that are clinically comparable to the selected drug.
- **Outcomes:** Outcomes may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life. Outcomes such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients, and patient-reported outcomes will also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered, including patient-centered outcomes when available, to the extent that these outcomes

correspond with a direct impact on individuals taking the drug. The caregiver perspective will be considered when there is a direct impact on the individuals taking the selected drug or therapeutic alternative.

- Patient-centered outcome: An outcome that is important to patients' survival, functioning, or feelings as identified or affirmed by patients themselves, or judged to be in patients' best interest by providers and/or caregivers when patients cannot report for themselves.⁴²
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries including those that may experience disparities in access to care, health outcomes, or other factors when taking the selected drug that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.⁴³
- Unmet medical need: A drug or biological product may be considered to address an unmet medical need if the drug or biological product treats a disease or condition in cases where no other treatment options exist or existing treatments do not adequately address the disease or condition.⁴⁴ Unmet medical need is determined at the time of submission of this information. CMS will consider the extent to which a selected drug fills an unmet medical need.
- Indication: Indication refers to the condition or disease state that the selected drug treats. An indication may include any FDA-approved indication included on a drug label per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and off-label use(s) that are included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. For the purpose of this form, a respondent may combine FDA-approved indications (e.g., identical adult and pediatric indications) and off-label uses. The respondent, if appropriate, may also choose not to report on certain FDA-approved indications or off-label uses.
- Off-label Use: Off-label use means a use of a selected drug or therapeutic alternative that is not approved by the FDA but is included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.

FDA-Approved Indications and Off-label Uses for [the selected drug]

For reference by respondents to Section I, CMS is providing the FDA-approved indications for [the selected drug]. CMS notes that individuals may be prescribed [the selected drug] for conditions not listed as an FDA-approved indication (i.e., an off-label use). When responding to questions, please note which indications (including an FDA-approved indication or an off-label use) are relevant to your response or experience. If you are responding about more than one indication, please clearly note which indication your response refers to.

The selected drug is approved by the FDA for the following indications:

⁴² ISPOR Plenary, Patrick (2013) via FDA's "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders," June 2020. See: <https://www.fda.gov/media/139088/download>.

⁴³ See: <https://www.cms.gov/pillar/health-equity>.

⁴⁴ CMS will consider the nonbinding recommendations in the FDA "Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics" (May 2014) when considering if a drug addresses an unmet medical need for the purpose of the Negotiation Program.

- [List all FDA-approved indications (*populated by CMS*)]

Questions 30 through 63: Optional for All Respondents

Questions 30 through 37: Manufacturer-Focused Questions

CMS is collecting information to support its evaluation of [the selected drug (*all bracketed text is intended to be populated by CMS*)] for the indication(s) it is used to treat relative to its therapeutic alternative(s) for those indication(s). CMS is interested in obtaining input and evidence from manufacturers of selected drugs related to [the selected drug] and its potential therapeutic alternative(s), methodological approaches to evaluation of [the selected drug] consistent with statutory requirements, and publicly available evidence CMS should consider related to [selected drug] and the indication(s) it treats.

Instructions for Questions 30 through 37

Manufacturers are permitted to submit a dossier in Question 36. Such dossiers may be used to supplement responses provided in Questions 30 through 35 and 37. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 30 through 35 and 37, to the extent applicable.

Question 30: Off-label use

If applicable, describe off-label use(s) for [the selected drug] that CMS should consider. Include citations for the nationally recognized, evidence-based guidelines listed in CMS-recognized Part D compendia that discuss the off-label use(s) listed.

Field	Response
Response to Question 30	<i>Text</i> (18,000 character count limit, which is approximately 1,500 words)
Additional Materials for Question 30	<i>Text</i> (Up to 50 citations)

Question 31: Potential therapeutic alternatives

Provide a list of therapeutic alternatives CMS should consider for the indication(s) of [the selected drug].

Indication	Therapeutic Alternative(s)
List therapeutic alternatives for the indications (which includes off-label use(s) per the definition provided in the instructions)	<i>Text</i> (6,000 character count limit, which is approximately 500 words)

Question 32: Use in treatment and clinical comparative effectiveness evidence

Question 32a: Describe the selected drug's use in the course of care for its indication(s) (which includes off-label use(s) per the definition provided in the instructions) based on current clinical use, clinical practice guidelines, or other relevant clinical practice standards and provide all supporting citations. When relevant, please describe the use of each potential therapeutic alternative (identified in *Question 31*) in the course of care for the indication(s) relative to the selected drug.

Field	Response
Response to Question 32a	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 32a	<i>Text</i> (Up to 50 citations)

Question 32b: For the indication(s) identified in the instructions and Question 30, identify relevant clinical outcome measures CMS should consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety). Provide supporting citations for identified clinical outcome measures.

Field	Response
Response to Question 32b	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 32b	<i>Text</i> (Up to 50 citations)

Question 32c: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, identify any relevant evidence evaluating the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of the selected drug and potential therapeutic alternatives. Relevant comparative evidence may include but is not limited to: head-to-head randomized controlled trials, pragmatic clinical trials, network meta-analyses, observational studies, and real-world evidence. Provide supporting citations for relevant comparative evidence.

Field	Response
Response to Question 32c	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 32c	<i>Text</i> (Up to 50 citations)

Question 33: Prevalence, utilization, and cost estimates

Question 33a: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, provide an estimate of its prevalence among the Medicare population. Provide citations and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 33a	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 33a	<i>Text</i> (Up to 50 citations)

Question 33b: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, provide an estimate of Medicare utilization of the selected drug for that indication. Estimates of Medicare utilization can include estimates of total number of patients treated, estimates of share of selected drug prescriptions dispensed to patients with that indication, or similar measures. Provide citations and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 33b	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 33b	<i>Text</i> (Up to 50 citations)

Question 33c: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, identify or provide evidence relevant to Medicare regarding relative health care resource utilization associated with patients who take the selected drug and its potential therapeutic alternatives. Relevant evidence of relative health care resource utilization may include but is not limited to: disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to the selected drug and any therapeutic alternatives. Provide citations and/or brief methodology to support analyses.

Note, CMS will not use QALYs or any evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

Field	Response
Response to Question 33c	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 33c	<i>Text</i> (Up to 50 citations)

Question 34: Therapeutic advance and unmet medical need

Question 34a: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, describe the extent to which the selected drug currently represents a therapeutic advance as compared to its therapeutic alternative(s). Provide supporting citations.

Field	Response
Response to Question 34a	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 34a	<i>Text</i> (Up to 50 citations)

Question 34b: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, describe the extent to which the selected drug addresses an unmet medical need. Provide supporting citations.

Field	Response
Response to Question 34b	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 34b	<i>Text</i> (Up to 50 citations)

Question 35: Specific populations and patient experience

Question 35a: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, identify any specific populations that are impacted by the selected drug and/or its therapeutic alternatives, and describe how they are impacted. Provide supporting citations.

Field	Response
Response to Question 35a	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 35a	<i>Text</i> (Up to 50 citations)

Question 35b: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, identify evidence regarding patient experiences related to the indication(s), selected drug, and/or its therapeutic alternatives. This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the indication, treatment burden, burden of disease, or other patient experience data. Provide supporting citations.

Field	Response
Response to Question 35b	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 35b	<i>Text</i> (Up to 50 citations)

Question 35c: For the indication(s) (which include off-label use(s) per the definition provided in the instructions) of the selected drug, identify any considerations related to access, social drivers of health and health-related social needs, health equity, and/or health disparities that are relevant to the indication, selected drug, and/or its therapeutic alternatives. Provide supporting citations.

Field	Response
Response to Question 35c	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 35c	<i>Text</i> (Up to 50 citations)

Question 36: Dossier Submission

Manufacturers are permitted to submit a dossier in Question 36. Such dossiers may be used to supplement responses provided in questions 30 through 35, preferably formatted using an industry standard such as the most current AMCP Format (version 5.0) for Formulary Submissions. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 30 through 35, to the extent applicable.

While submitted dossiers may include a variety of economic information, CMS will not use QALYs or any evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

Response
<i>Text</i> (Up to 2 PDF files)

Question 37: Visual Representations to Support Responses to Questions 30 through 35

Provide visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 30 through 35. Indicate which question each file corresponds to.

Response	Indicate Question Each File Corresponds To
<i>Text</i> (Up to 10 PDF files)	<i>Text</i>

Questions 38 through 44: Patient-Focused Experience

CMS would like your input to better understand patients' and caregivers' experiences with [the selected drug]. In this section, CMS is interested in your experience with health condition(s) that [the selected drug] may be used to treat and other medications that may be used to manage those condition(s). Individual patients and caregivers, and organizations representing patients and/or caregivers are encouraged to answer the following.

Question 38: Background

Question 38a: Have you or someone you provide care for ever taken [the selected drug]?

Field	Response
Response to Question 38a	<i>Check box: YES or NO</i>

Question 38a1: [If YES] For which condition(s) (including FDA-approved indication(s) or off-label use as defined in the instructions) was [the selected drug] taken?

Field	Response
Response to Question 38a1	<i>Text</i> (6,000 character count limit, which is approximately 500 words)

Question 38a2: [If YES] When were you or someone you provide care for given a diagnosis related to this condition or conditions? You may write an approximate date, or if you never received a diagnosis write "N/A."

Field	Response
Response to Question 38a2	<i>Text</i> (6,000 character count limit, which is approximately 500 words)

Question 38a3 [If NO] What condition(s) (including FDA-approved indication(s) or off-label use as defined in the instructions) treated by [the selected drug] would you like to provide input on?

Field	Response
Response to Question 38a3	<i>Text</i> (36,000 character count limit, which is approximately

Field	Response
	3,000 words)

Question 38a4: [If NO] What is your experience with this condition or conditions?

Field	Response
Response to Question 38a4	Text (36,000 character count limit, which is approximately 3,000 words)

Question 39: Information on Your Condition(s) or Condition(s) of Someone You Care For

Question 39a: How do the condition(s) you listed in Question 39 impact your daily life and well-being or the daily life and well-being of someone you provide care for?

- For example,
 - What are your symptoms related to the condition(s) on a “good” or “bad” day?
 - How do these symptoms impact daily routines, work, family, and/or hobbies?
 - What other activities are impacted by your symptoms?

Field	Response
Response to Question 39a	Text (36,000 character count limit, which is approximately 3,000 words)

Question 39b: How has the condition(s) you listed in Question 38 changed or progressed over time?

- For example,
 - Have you, or someone you provide care for, experienced changes in severity of the condition(s)?
 - Have you, or someone you provide care for, experienced changes in how often you feel symptoms?

Field	Response
Response to Question 39b	Text (36,000 character count limit, which is approximately 3,000 words)

Question 39c: What is important to you or those you provide care for in managing the condition(s) you listed in Question 38?

- This may be how you feel or function in your daily life, how long you live, or other goals you have related to your medication(s) or condition(s).
- For example, this could mean fewer symptoms, better ability to complete daily tasks such as chores, fewer visits to your doctor or hospital, fewer side effects, lower health care costs, worrying less about your health, or other things.

Field	Response
Response to Question 39c	Text (36,000 character count limit, which is approximately 3,000 words)

Question 39d: What challenges do you, or someone you care for, face in managing this condition(s)?

Field	Response
Response to Question 39d	Text (36,000 character count limit, which is approximately 3,000 words)

Question 40: Information on the Current Medication to Treat Your Condition

Question 40a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Question 39?

Field	Response
Response to Question 40a	YES or NO

Question 40a1: [If YES] What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Question 38?

- If more than one medication is currently taken, please list medications in the order you started them.

Field	Response
Response to Question 40a1	Text (36,000 character count limit, which is approximately 3,000 words)

Question 40a2: [If YES] How did you or someone you care for decide to start taking the medication(s) currently used to manage the condition(s) you listed in Question 38?

- What factors, if any, affected the choice of medication(s) currently used to manage the condition(s) you have selected?
- For example, this could mean side effects, cost, interactions with other medication, whether your local pharmacy could get it, family influence, interference with your work or life, other health condition(s), or other things that influenced your choice.

Field	Response
Response to Question 40a2	Text (36,000 character count limit, which is approximately 3,000 words)

Question 40a3: [If YES] What has been your experience, or the experience of someone you provide care for, with the medication(s) currently used to manage the condition(s) you listed in Question 38?

- What are benefits of the medication(s)? What do you like about it?
- What are drawbacks of the medication(s)? What do you wish was different?
- How do the medication(s) impact daily life? Does the medication(s) make you feel better in your daily life?
- How easy or difficult is it to take the medication(s)? What is difficult about taking your medication(s)?

Field	Response
Response to Question 40a3	Text (36,000 character count limit, which is approximately 3,000 words)

Question 40a4: [If YES] How satisfied are you, or someone you care for, with the medication(s) you take

now to manage your condition(s)?

Field	Response
Response to Question 40a4	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 41: Information on the Medication(s) Used in the Past to Treat Your Condition

Question 41a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Question 39?

Field	Response
Response to Question 41a	<i>YES or NO</i>

Question 41b1: [If YES] What medication(s) have you, or someone you care for, taken in the past to manage the condition(s) you listed in Question 38?

- If possible, please indicate when past medication(s) were started and stopped to the best of your knowledge.

Field	Response
Response to Question 41b1	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 41b2: [If YES] How did you, or someone you care for, decide to start taking the medication(s) used in the past to manage the condition(s) you listed in Question 38?

- What other factors, if any, affected the choice of medication(s) used in the past to manage the condition(s) you listed in Question 38?
- For example, factors could include side effects, cost, interactions with other medication, whether your local pharmacy could get it, family influence, interference with your work or life, other health condition(s), or other things that influenced your choice.

Field	Response
Response to Question 41b2	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 41b3: [If YES] What was your experience, or the experience of someone you provide care for, with the medication(s) used in the past to manage the condition(s) you listed in Question 38?

- What are benefits of the medication(s)? What do you like about it?
- What are drawbacks of the medication(s)? What do you wish was different?
- How do the medication(s) impact daily life? Does the medication(s) make you feel better in your daily life?
- How easy or difficult is it to take the medication(s)? What is difficult about taking your medication(s)?

Field	Response
Response to Question 41b3	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 41b4: [If YES] Why did you, or someone you provide care for, stop taking the medication(s) used in the past to manage the condition(s) you listed in Question 38?

Field	Response
Response to Question 41b4	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 42: What other information about the condition(s) you have identified or the medication(s) used to manage these condition(s) do you think CMS should consider while evaluating [the selected drug]?

Field	Response
Response to Question 42	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Citations	<i>Citations</i> (50 limit)

Question 43: Visual Representations to Support Responses to Questions 38 through 42

Provide visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 38 through 42. Indicate which question each file corresponds to.

Response	Indicate Question Each File Corresponds To
<i>Text</i> (Up to 10 PDF files)	<i>Text</i>

Question 44: Demographic Questions [Only when a respondent selects the “patient” or “caregiver” option in response to Question 29.]

To put the above responses into context, CMS is interested in understanding the demographic information of the individual who has used the selected drug:

Field	Response Options
Age	Select one: 18 to 24 years 25-34 years 35-44 years 45-64 years 65-84 years 85-99 years 100 years or older
Race/Ethnicity What is your race and/or ethnicity?	Select all that apply: American Indian or Alaska Native Asian

Field	Response Options
	Black or African American Hispanic or Latino Middle Eastern or North African Native Hawaiian or Pacific Islander White Other not listed
Regional Location	Select one: New England (CT, ME, MA, NH, RI, VT) Middle Atlantic (NJ, NY, PA) Midwest-East North Central: IN, IL, MI, OH, WI Midwest-West North Central: IA, KS, MN, MO, NE, ND, SD South-South Atlantic: DE, DC, FL, GA, MD, NC, SC, VA, WV South-East South Central: AL, KY, MS, TN South-West South Central: AK, LA, OK, TX West-Mountain: AZ, CO, ID, NM, MT, UT, NV, WY West-Pacific: AK, CA, HI, OR, WA U.S. Territory: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands Other
Medicare Beneficiary	Select one: Yes No

Questions 45 through 51: Clinical-Focused Experience

CMS is collecting information to support its evaluation of [the selected drug] for the indication(s) it is used to treat relative to its therapeutic alternative(s) for those indication(s). CMS is interested in obtaining the perspectives of health care providers who have clinical experience with prescribing or managing use of [the selected drug] and/or its therapeutic alternative(s) for these indication(s).

Question 45: Background Questions

Question 45a: Are you a health care provider (i.e., a person who is trained and licensed to give health care⁴⁵)?

Field	Response
Response to Question 45a	<i>YES or NO</i>

Question 45a1: [If YES] What is your area of specialization? If you are currently practicing, provide a brief description of the type of practice and your practice site.

Field	Response
Response to Question 45a1	<i>Text (6,000 character count limit, which is approximately</i>

⁴⁵ Refer to the CMS Glossary for the term of “health care provider” available at: <https://www.cms.gov/glossary>.

Field	Response
	500 words)

Question 45b: Do you have experience prescribing or managing the use of [the selected drug]?

Field	Response
Response to Question 45b	<i>YES or NO</i>

Question 45b1: [If YES] For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) have you prescribed or managed use of [the selected drug] that you would like to provide CMS information on? Check all that apply.

Field	Response
Response to Question 45b1	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Question 45b2: [If NO] On which indication(s) (which includes off-label use(s) per the definition provided in the instructions) would you like to provide input?

Field	Response
Response to Question 45b2	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Question 46: Treatment-related Questions

Question 46a: What are goals of treatment for the condition(s) treated by [the selected drug]?

Field	Response
Response to Question 46a	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>

Question 46b: What outcomes do you use to assess improvement or treatment response for this indication(s)?

Field	Response
Response to Question 46b	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 46b	<i>Text (Up to 50 citations)</i>

Question 46b1: What would you consider to be a meaningful improvement or treatment response for the outcomes listed in question 46b?

Field	Response
Response to Question 46b1	<i>Text (12,000 character count limit, which is approximately 1,000 words)</i>
Additional Materials for Question 46b1	<i>Text (Up to 50 citations)</i>

Question 46b2: Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?

Field	Response
Response to Question 46b2	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 46b2	<i>Text (Up to 50 citations)</i>

Question 46c: Are there widely used evidence-based clinical practice guidelines for the condition(s) treated by [the selected drug]? If so, please cite these guidelines and explain how they are used to support clinical decision-making.

Field	Response
Response to Question 46c	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 46c	<i>Text (Up to 50 citations)</i>

Question 47: Treatment-related Questions

Question 47a: How does [the selected drug] fit into the current treatment paradigm for patients with the conditions(s) treated by [the selected drug]?

Field	Response
Response to Question 47a	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47a	<i>Text (Up to 50 citations)</i>

Question 47b: At what point in treatment might [the selected drug] be considered as a treatment option for patients with the condition(s) treated with [the selected drug]? What other treatments might be considered before [the selected drug] is considered a clinically appropriate treatment option, if any?

Field	Response
Response to Question 47b	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47b	<i>Text (Up to 50 citations)</i>

Question 47c: What medications would you consider to be therapeutic alternatives for [the selected drug] for treatment of the condition(s) treated with [the selected drug]?

Field	Response
Response to Question 47c	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>

Field	Response
Additional Materials for Question 47c	<i>Text (Up to 50 citations)</i>

Question 47d: What considerations drive treatment selection among [the selected drug] and its therapeutic alternatives for the indication(s)?

- For example, relative efficacy, safety profile, route of administration, patient characteristics, patient preferences, cost, formulary placement, etc.

Field	Response
Response to Question 47d	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47d	<i>Text (Up to 50 citations)</i>

Question 47e: Are there notable differences between how [the selected drug] or the therapeutic alternatives identified in Question 47c are prescribed or managed in your practice setting and how these drugs are used in broader clinical practice and/or treatment recommendations in current clinical guidelines for the condition(s) treated with [the selected drug]?

- Are there general debates or uncertainties related to selection or use of these drugs for the indication(s)?

Field	Response
Response to Question 47e	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47e	<i>Text (Up to 50 citations)</i>

Question 47f: How would you characterize the benefits and risks associated with [the selected drug]?

Field	Response
Response to Question 47f	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47f	<i>Text (Up to 50 citations)</i>

Question 47f1: What side effects or risks, common or serious, or other safety concerns would you take into consideration when selecting a treatment option from among [the selected drug] or its therapeutic alternatives for the condition(s) treated with [the selected drug]?

Field	Response
Response to Question 47f1	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47f1	<i>Text (Up to 50 citations)</i>

Question 47f2: In your opinion, how do the benefits and risks associated with [the selected drug] differ from the benefits and risks associated with its therapeutic alternatives for the indication(s)?

Field	Response
Response to Question 47f2	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47f2	<i>Text (Up to 50 citations)</i>

Question 47f3: What specific populations or patient subgroups may derive greater benefits or be at risk for greater harms by using [the selected drug] or any of its therapeutic alternatives for the indication(s)?

Field	Response
Response to Question 47f3	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47f3	<i>Text (Up to 20 citations)</i>

Question 47g: How would you assess whether a patient is tolerating and/or responding to [the selected drug] or any of its therapeutic alternatives when used for each indication(s)?

- When might you consider discontinuing a medication?
- When might you consider switching to a different medication?
- When might you consider adding another medication to the regimen?

Field	Response
Response to Question 47g	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 47g	<i>Text (Up to 20 citations)</i>

Question 48: Health Equity and Patient Experience

What health equity or access issues would you consider relevant to an evaluation of [the selected drug] and its therapeutic alternatives for the condition(s) treated by [the selected drug]?

Field	Response
Response to Question 48	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 48	<i>Text (Up to 50 citations)</i>

Question 49: Therapeutic Advance and Unmet Medical Need

Question 49a: For the condition(s) treated by [the selected drug], describe the extent to which [the selected drug] currently represents (or does not represent) a therapeutic advance as compared to its therapeutic alternative(s).

Field	Response
Response to Question 49a	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 49a	<i>Text (Up to 50 citations)</i>

Question 49b: For the condition(s) treated by [the selected drug], describe the extent to which [the selected drug] currently addresses (or does not address) an unmet medical need.

Field	Response
Response to Question 49b	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 49b	<i>Text (Up to 50 citations)</i>

Question 49c: What unmet medical needs do you believe persist among patients with the condition(s) treated by [the selected drug], if any?

Field	Response
Response to Question 49c	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 49c	<i>Text (Up to 50 citations)</i>

Question 50: What other information about [the selected drug], its therapeutic alternative(s), or the indication(s) do you think CMS should consider in its evaluation of [the selected drug]? Provide citations when applicable.

Field	Response
Response to Question 50	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Citations	<i>Citations (20 limit)</i>

Question 51: Visual Representations to Support Responses to Questions 45 through 50

Provide visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 45 through 50. Indicate which question each file corresponds to.

Response	Indicate Question Each File Corresponds To
<i>Text (Up to 10 PDF files)</i>	<i>Text</i>

Questions 52 through 61: Research-Focused Experience

CMS is collecting information to support its evaluation of [the selected drug] in the indication(s) it is used to treat relative to its therapeutic alternative(s). CMS is interested in obtaining input and evidence from individual researchers and research or advocacy organizations related to [the selected drug] and its potential

therapeutic alternative(s), methodological approaches to evaluation of [the selected drug] consistent with statutory requirements, and publicly available evidence CMS should consider related to [selected drug] and the indication(s) it treats.

Question 52: Background

Are you:

- (1) An individual or representative of an entity that has conducted research (including clinical trials or data analyses) related to use of [the selected drug] or its potential therapeutic alternative(s)?
- (2) Familiar with methods used to evaluate use of [the selected drug] or its potential therapeutic alternatives?
- (3) Aware of research-based evidence CMS should consider regarding [the selected drug], its potential therapeutic alternatives and/or the indication(s) it treats?

Field	Response
Response to Question 52	<i>YES or NO for each item 1-3 (listed above in question)</i>

Question 52a: On which indication(s) of [the selected drug] would you like to provide input?

Field	Response
Response to Question 52a	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

Question 53: Potential Therapeutic Alternatives

What medications would you consider to be therapeutic alternatives for [the selected drug] for each indication(s)? Provide supporting rationale and citations where applicable.

Field	Response
Response to Question 53	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 53	<i>Text (Up to 50 citations)</i>

Question 54: Comparative Clinical Evidence

Question 54a: What methodology, framework, or other analytic approach would you recommend CMS consider for use in its evaluation of the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting rationale and citations where applicable.

Field	Response
Response to Question 54a	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 54a	<i>Text (Up to 50 citations)</i>

Question 54b: What relevant clinical outcome measures should CMS consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting citations where applicable.

Field	Response
Response to Question 54b	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 54b	<i>Text (Up to 50 citations)</i>

Question 54c: What evidence related to the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Relevant comparative evidence may include but is not limited to: head-to-head randomized controlled trials, pragmatic clinical trials, network meta-analyses, observational studies, and real-world evidence. Provide supporting citations.

Field	Response
Response to Question 54c	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 54c	<i>Text (Up to 50 citations)</i>

Question 55: Specific Populations and Patient Experience

Question 55a: What evidence are you aware of regarding patient experiences related to use of [the selected drug], its potential therapeutic alternatives, and/or condition(s) treated by [the selected drug]? This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the condition(s), treatment burden, burden of disease, or other patient experience data. Provide supporting citations.

Field	Response
Response to Question 55a	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 55a	<i>Text (Up to 50 citations)</i>

Question 55b: What specific populations or patient subgroups are impacted by [the selected drug] and/or its potential therapeutic alternatives for the condition(s) treated by [the selected drug]? How are these populations or subgroups impacted? Identify studies focused on the impact of [the selected drug] and its therapeutic alternatives on the specific populations. Provide supporting citations where applicable.

Field	Response
Response to Question 55b	<i>Text (36,000 character count limit, which is approximately 3,000 words)</i>
Additional Materials for Question 55b	<i>Text (Up to 50 citations)</i>

Question 55c: What considerations related to access, health equity, and/or health disparities are relevant to [the selected drug], its potential therapeutic alternatives, and/or or this condition(s) treated by [the selected drug]? Provide supporting citations where applicable.

Field	Response
Response to Question 55c	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 55c	<i>Text</i> (Up to 50 citations)

Question 56: Prevalence, Utilization, and Cost Estimates

Question 56a: For each indication(s), provide an estimate of prevalence among the Medicare population. Provide citations and/or brief methodology to support the estimate.

Field	Response
Response to Question 56a	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 56a	<i>Text</i> (Up to 50 citations)

Question 56b: For each indication(s), provide an estimate for Medicare utilization of [the selected drug] and/or its potential therapeutic alternatives. Estimates of Medicare utilization can include estimates of total number of patients treated, estimated share of [selected drug] prescriptions dispensed to patients for a given indication, or similar measures. Provide citations and/or a brief methodology to support the estimate.

Field	Response
Response to Question 56b	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 56b	<i>Text</i> (Up to 50 citations)

Question 56c: For each indication(s), identify or provide evidence relevant to Medicare regarding relative health care resource utilization of patients who take [the selected drug] and its potential therapeutic alternatives. Relevant evidence of relative health care resource utilization may include but is not limited to: disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to [the selected drug] and any therapeutic alternatives. Provide citations and/or a brief methodology to support the assessments.

Note, CMS will not use QALYs or any evidence from comparative effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

Field	Response
Response to Question 56c	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Field	Response
Additional Materials for Question 56c	<i>Text</i> (Up to 50 citations)

Question 57: What other information or evidence do you think CMS should consider in the evaluation of [the selected drug]? Provide citations when applicable.

Field	Response
Response to Question 57	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 57	<i>Text</i> (Up to 50 citations)

Question 58: Visual Representations to Support Responses to Question 51 through 57

Provide visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 51 through 57. Indicate which question each file corresponds to.

Response	Indicate Question Each File Corresponds To
<i>Text</i> (Up to 10 PDF files)	<i>Text</i>

Questions 59 through 62: Other Public Input

CMS is collecting information to support its evaluation of [selected drug] relative to potential therapeutic alternatives. CMS is interested in obtaining any additional input that CMS should consider when evaluating [the selected drug].

Question 59: For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) would you like to provide input?

Field	Response
Response to Question 59	<i>Text</i> (6,000 character count limit, which is approximately 500 words)

Question 60: What is your experience with [the selected drug] or the condition(s) it treats?

Field	Response
Response to Question 60	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Question 61: What information or evidence do you think CMS should be aware of as it evaluates [the selected drug] for each indication(s)? Provide citations when applicable.

Field	Response
Response to Question 61	<i>Text</i> (36,000 character count limit, which is approximately 3,000 words)

Field	Response
Additional Materials for Question 61	<i>Citations (50 limit)</i>

Question 62: Visual Representations to Support Responses to Question 59 through 61

Provide visual representations such as tables, charts, and/or graphs that support the responses to Questions 58 through 60. Indicate which question each file corresponds to.

Response	Indicate Question Each File Corresponds To
<i>Text</i> (Up to 10 PDF files)	<i>Text</i>

For Any Respondent that Responded to One or More Questions in Section I

Question 63: Does any evidence submitted include a cost-effectiveness measure:

- ☐ Yes
☐ No
☐ Don't know

If yes, select which Questions included a cost-effectiveness measure in the evidence submitted.

All question numbers listed with a checkbox to select.

For each question number selected, please select the applicable statement.

☐ The evidence submitted includes QALYs or cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

☐ The evidence submitted DOES NOT include cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Checkboxes will populate for each question selected.

Question 64: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld Under FOIA

For each question that a Respondent believes contains information that should be withheld by CMS under FOIA Exemptions 3 and/or 4 (5 U.S.C. § 552(b)(3), (4))⁴⁶, list the applicable question number and provide a brief explanation regarding why the Respondent believes the information should be withheld under FOIA. The Respondent should not include information that CMS specifies as proprietary in the section 40.2.1 of the draft guidance.⁴⁷

⁴⁶ See: <https://www.justice.gov/oip/doj-guide-freedom-information-act-0>.

⁴⁷ Specifically, as described in section 40.2.1 of the draft guidance, CMS will treat research and development costs and recoupment,

Section Letter and Question Number	Explanation
<i>Text</i>	<i>Text (6,000 character count limit, which is approximately 500 words)</i>

J. Certification of Submission of Section I for All Respondents

Required for All Respondents of Section I

Certification:

I certify that all information and statements made in this submission are true and current to the best of my knowledge and belief and are made in good faith. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare payment purposes, including determination of a maximum fair price, as defined in section 1191(c)(3) of the Social Security Act.

Yes [☐]

No [☐]

Contact Information for respondent:

Field	Response
Name of the Person Responsible for the Submission	<i>Text</i>
Signature	<i>Text</i>
Date	<i>MMDDYYYY</i>

unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and applications and approvals under section 505(c) of the FD&C Act or section 351(a) of the PHS Act as non-proprietary because CMS understands these data are publicly available.

Paperwork Reduction Act Disclosure Statement:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1452 (Expires XX/XX/XXXX)**. This contains both a mandatory and voluntary information collection. The time required to complete this information collection is estimated to average 3 hours for individuals and 30 hours for organizations per response for the general public and 500 total hours for the manufacturers of selected drugs, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

******CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact Elisabeth Daniel (elisabeth.daniel@cms.hhs.gov).**

PART 2: DRUG PRICE NEGOTIATION PROCESS ICR FORM

Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with “the manufacturer” of the selected drug. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. In accordance with section 40 of the draft guidance, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be “the manufacturer” of the selected drug (hereinafter “Primary Manufacturer”).

In accordance with section 1191(b)(4) of the Act, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement (herein referred to as an “Agreement”), or, for initial price applicability year 2027, February 28, 2025. CMS intends to implement the offer and counteroffer process consistent with the statutory goal of negotiating to achieve agreement on “the lowest [MFP] for each selected drug,” established in section 1194(b)(1) of the Act. In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2027 no later than June 1, 2025.

After the written initial offer from CMS is sent to the Primary Manufacturer, the negotiation process may include the following steps, depending on when and whether agreement on the MFP is reached and an offer is accepted:

- (1) in accordance with section 1194(b)(2)(C) of the Act, an optional written counteroffer, including an Addendum populated with the counteroffer price as described in section 60.4.2 of Medicare Drug Price Negotiation Program: Draft Memorandum, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2027 (the “draft guidance”), from the Primary Manufacturer (if CMS’ written initial offer is not accepted by the Primary Manufacturer) that must be submitted no later than 30 days after the date of receipt of the written initial offer from CMS;
- (2) in accordance with section 1194(b)(2)(D) of the Act, a written response from CMS to the optional written manufacturer counteroffer, which CMS will provide within 30 days after receipt of the counteroffer or within 60 days of sharing the initial offer, whichever is later;
- (3) if the Primary Manufacturer’s written counteroffer is not accepted by CMS, up to three possible in-person, virtual, or hybrid (where a portion of attendees are in-person and a portion of attendees are virtual) negotiation meetings between the Primary Manufacturer and CMS; and
- (4) a final written offer, including an Addendum containing the final offer price as described in section 60.4.4 of the draft guidance, made by CMS to the Primary Manufacturer, if no agreement is reached before the end of the negotiation meetings.

Every offer and counteroffer described in described in section 1194(b)(2) of the Act will include an Addendum populated with the offered/counteroffered price. If an agreement is reached at any point during the negotiation process by the Primary Manufacturer accepting CMS’ written initial

offer or final offer (as described in section 60.4.4 of the draft guidance), CMS accepting the Primary Manufacturer's counteroffer, or an agreement being reached in association with the negotiation meetings, the Addendum to the Agreement, as described in section 40.3 of the draft guidance, will be executed by both parties and will constitute agreement on the MFP. Section 60.4.4 of the draft guidance describes how and when the Addendum will be created and signed. The MFP included in the executed Addendum will apply for the selected drug for initial price applicability year 2027 and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable.

This document describes the ICR that may occur during the negotiation process if the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2027.

The estimated burden of the ICR for a written counteroffer submission from a Primary Manufacturer of a selected drug and review of the written counteroffer submission by CMS staff is provided in the accompanying Supporting Statement. More information on the negotiation process can be found in the draft guidance.

Note: This ICR focuses on information required for the submission of written counteroffers during the drug price negotiation process for initial price applicability year 2027.

Instructions for Completing the Counteroffer Form

A Primary Manufacturer that seeks to submit a counteroffer for its selected drug must complete and submit the information requested in the Counteroffer Form in the CMS Health Plan Management System (CMS HPMS) in order for CMS to consider the Primary Manufacturer's counteroffer.

To complete the Counteroffer Form, the Primary Manufacturer must provide the following:

- The Primary Manufacturer's written counteroffer for the price per 30-day equivalent supply of the selected drug (as described in section 60.1 of the draft guidance);
- Subject to the 30,000 character count limit, which is approximately 2,500 words, a justification of the counteroffer based on the factors in section 1194(e) of the Act. The Primary Manufacturer's counteroffer justification should focus on the elements described in section 1194(e) of the Act and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer under section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS and better supports the Primary Manufacturer's counteroffer. These section 1194(e) data may be information already submitted to CMS by the Primary Manufacturer or other interested parties, information submitted as part of the counteroffer, or information that is otherwise available and considered by CMS. A Primary Manufacturer may also include in their counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in

section 1194(e)(2) that supports the counteroffer price and additional information they deem relevant, such as a request to include certain information from the counteroffer justification in CMS' public explanation of the MFP, and;

- A certification, including an attestation on the use of cost-effectiveness measures, by: (1) the chief executive officer (CEO), (2) the chief financial officer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Additional instructions for submitting the Counteroffer Form are as follows:

- If the Primary Manufacturer chooses to submit the Counteroffer Form, this form must be completed and submitted within the CMS HPMS within 30 days of receiving the written initial offer from CMS.
- Question 1 asks the Primary Manufacturer to input its counteroffer price for a 30-day equivalent supply of the selected drug. CMS will interpret this price as a single price per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight metric), and weighted across dosage forms and strengths, if applicable. The Primary Manufacturer may reference information provided by CMS during the negotiation process regarding the application of a single MFP across dosage forms and strengths of the selected drug to understand how the 30-day equivalent supply counteroffer price will convert into prices for each dosage form and strength of the selected drug.
- The Primary Manufacturer should answer Question 2 in narrative (text) form. Responses will be limited to the 30,000 character count limit, which is approximately 2,500 words, 10 visual representations of data, and a maximum of 50 citations. All response fields are limited to a character count. Response fields provide a maximum character count and corresponding estimated word count.
- Submissions may include but are not limited to published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports. CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in section 50.2 of the draft guidance.
- The Primary Manufacturer should provide citations to published material rather than copies of articles. The Primary Manufacturer is responsible for ensuring that its submission complies with applicable law, including but not limited to copyright law. If data are unpublished, clearly indicate this in the citation. For unpublished data without a citation, the Primary Manufacturer should summarize key findings as appropriate and upload any relevant visual representations as additional materials as described below.
- The Primary Manufacturer should provide citations in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: <https://www.ncbi.nlm.nih.gov/books/NBK7256/>

- When information in Question 2 is supported by a citation, the Primary Manufacturer should label the end of the sentence in the free text response with a number (e.g., [1], [2]) that corresponds to the number assigned to the provided citations.
- In addition to the counteroffer justification, the Primary Manufacturer may upload up to 10 charts, tables, or graphs as part of the ICR to support the justification. Data that are not in a visual form, such as a table or chart consisting only of text, will not be considered by CMS. PDF files will be accepted within specified file size limits for visual representations. The free text response should include clear numbers/references to the charts, tables, or graphs submitted. When information in Question 2 is supported by a chart, table, or graph, the Primary Manufacturer should label the end of the sentence in the free text response with a letter (e.g., [A], [B]) that corresponds to the letter assigned to the provided document.
- CMS will review submitted charts, tables, and graphs that use cost-effectiveness measures or methods to determine if the data are relevant to the selected drug and/or its therapeutic alternative(s) and to ensure any cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Respondents must indicate via the checkboxes in the form if their submission includes any cost-effectiveness measures or methods. Examples of cost-effectiveness measures or methods include but are not limited to Quality-Adjusted Life Years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), Health Years in Total (HYT), and Generalized Risk-Adjusted Cost-Effectiveness (GRACE).
- If a Primary Manufacturer is the holder of the NDA(s)/BLA(s) for multiple selected drugs for an initial price applicability year, a separate form must be submitted for each selected drug for which the Primary Manufacturer chooses to submit a counteroffer.

Appendix. Counteroffer ICR Form



Department of Health and Human Services Centers for Medicare & Medicaid Services

Counteroffer ICR Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act), for initial price applicability year 2027. In accordance with section 1194(b)(2)(B) of the Act, CMS has provided the Primary Manufacturer of the selected drug named below with a written initial offer that contains CMS' proposal for the selected drug's maximum fair price (MFP), as defined in section 1191(c)(3), and a concise justification based on the factors described in section 1194(e). Submission of this form indicates that the Primary Manufacturer has not accepted CMS' written initial offer and is submitting a written counteroffer in accordance with section 1194(b)(2)(C).

In order for CMS to consider the Primary Manufacturer's counteroffer, this form must be certified by (1) the chief executive officer (CEO) of the Primary Manufacturer, (2) the chief financial officer (CFO) of the Primary Manufacturer, (3) an individual other than a CEO or CFO of the Primary Manufacturer, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Question 1: Please provide the Primary Manufacturer's counteroffer price for the selected drug in the table below. CMS will interpret this price as a single price per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight metric), and weighted across dosage forms and strengths, if applicable. The Primary Manufacturer may use information previously shared by CMS on the application of a single MFP across dosage forms and strengths of the selected drug to understand how this counteroffer price will apply to the dosage forms and strengths as identified on the list of National Drug Codes (NDCs) of the selected drug maintained by CMS.

Counteroffer price per 30-day equivalent supply of [selected drug name]
--

\$

Question 2: Please provide a justification of the counteroffer price based on the factors in section 1194(e) of the Act. This counteroffer justification should also respond to the justification provided in CMS' written initial offer and provide the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the factors in section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS and better supports the Primary Manufacturer's counteroffer.

FIELD	RESPONSE FORMAT
Counteroffer Justification	Text (30,000 character count limit, which is approximately 2,500 words)

Additional Materials to Support the Justification	<i>Text</i> (Up to 50 citations) [file upload] (Up to 10 tables/charts/graphs)
---	---

Does the evidence submitted include a cost-effectiveness measure:

☐ Yes
☐ No
☐ Don't know

If yes to the question above, please select the applicable statement.

☐ The evidence submitted includes QALYs or cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

☐ The evidence submitted DOES NOT include cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including determination of an MFP, as defined in section 1191(c)(3) of the Act. I understand further that the proposed price submitted in this Counteroffer Form, if accepted by CMS, is intended to be the MFP as defined in section 1191(c)(3) of the Act for the selected drug for purposes of section 1193(a)(1) of the Act. I certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may give rise to liability, including under the False Claims Act.

Yes ☐ No ☐

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1452 (Expires XX/XX/XXXX)**. This is a required information collection to retain or obtain a benefit. Specifically, a Primary Manufacturer must submit the Drug Price Negotiation Information Collection Request- Counteroffer Form in order to submit a written counteroffer for a selected drug. The time required to complete this information collection is estimated to average 204.25 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.