Drug Price Negotiation for Initial Price Applicability Year 2028 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 payable under Medicare Part B and/or covered under Medicare Part D (each a "selected drug").[1] As discussed in section 20 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028 ("the Medicare Drug Price Negotiation Program Final Guidance" or "final guidance"), for initial price applicability year 2028, CMS will select up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. For initial price applicability year 2028, CMS will also renegotiate MFPs for drugs selected for renegotiation (if any), in accordance with section 1194(f)(4) of the Act. Any MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2028. The negotiation period for initial price applicability year 2028 begins February 28, 2026, 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—Counteroffer ICR Form.

PART 1: NEGOTIATION DATA ELEMENTS ICR FORM

Section 1194(e) of the Act and sections 50 and 130.4 of the final guidance require CMS to consider two sets of factors as the basis for determining initial offer(s) and counteroffer(s) throughout the negotiation process and renegotiation process in accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and sections 60 and 130.4 of the final guidance, which includes renegotiation of any selected drug: (1) certain data that must be submitted by the manufacturer of each drug (as described 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 (as described 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 sections 50 and 130.3.2 of the final guidance, the manufacturer must submit, in a

[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.

form and manner specified by CMS, information on the non-Federal average manufacturer price ("non-FAMP") as defined in 38 U.S.C. § 8126(h)(5) for the selected drug 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 initial 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). In accordance with section 1194(f)(4)(B) of the Act and section 130.3 of the final guidance, CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation.

For the purposes of this ICR, references to a selected drug subject to the data collections in this form include drugs included on the selected drug list published by CMS by February 1, 2026 and any selected drugs from initial price applicability years 2026 or 2027 that are selected for renegotiation pursuant to section 1194(f)(3) of the Act. In section 1191(c)(1) of the Act, the statute adopts the definition of a 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 final 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 2028, 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 final 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 Manufacturer[2]."

In accordance with sections 50 and 130.3.2 of the final guidance, 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

[2] As specified in section 40 of the final 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.

multiple ways that CMS will collect data described in 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 PT on March 1, 2026.

Note: This ICR focuses on information required and optional for selected drugs for negotiation and renegotiation for initial price applicability year 2028.

General Instructions

Overview

In accordance with sections 50 and 130.3.2 of the final 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.

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 the CMS HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the CMS Health Plan Management System (HPMS) for the Medicare Drug Price Negotiation Program"

PDF.[3] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF. Technical assistance will also be made available.

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. 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 web application 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 ICR is also included and defined in final guidance, the term's definition in this ICR is the same as in the final guidance. Questions about the final 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. Total character counts include all characters within the response, including spaces between words.
- 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, 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.
- Technical assistance will be available in a CMS HPMS Negotiation Data Elements ICR Form User Guide, including additional instructions on submitting data for applicable sections via a template upload.

[3] https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-cms-health-plan-management-system-cms-hpms-medicare.pdf.

- 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, after the initial submission of data in this ICR Form, if any of the information submitted changes, as set forth in sections 40.2, 50.1, and 130.3 of the final guidance. Please timely notify CMS via the IRA Mailbox at IRARebateandNegotiation@cms.hhs.gov if any such changes are applicable to the selected drug.
    - If a Primary Manufacturer of a drug selected for renegotiation has updates to the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated, the Primary Manufacturer should notify CMS of these updates separately from this ICR Form in accordance with section 50.1 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, and the final guidance for initial price applicability year 2028.
- 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 final 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 the Freedom of Information Act (FOIA) Exemptions 3 and/or 4 (5 U.S.C. § 552(b)(3), (4)),[5] Primary Manufacturers are instructed to complete Question 26 regarding such applicable information provided in response to Sections A through G, and any interested party is instructed to complete Question 57 regarding such applicable information provided in Section I. Sections 40.2.1, 60.4, and 60.6 of the final guidance discuss the situations in which CMS may share submitted section 1194(e)(2) data submitted publicly, without sharing any personally

[4] Specifically, as described in section 40.2.1 of the final 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 approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary because CMS understands these data are publicly available.

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

identifiable information[6] (PII) or protected health information[7] (PHI), proprietary information, or information that is protected from disclosure under other applicable law.
- Definitions included in this ICR are intended for purposes only related to this ICR and the Medicare Drug Price Negotiation Program.

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 and reporting monetary values, do not adjust for cost of capital.
- 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.
- The geographic area for data on United States (U.S.) Commercial markets, Medicare markets, and Medicaid markets is based on the definition of the United States in 42 C.F.R § 400.200, unless the geographic area is specified in the authority for the data source (e.g., Federal Supply Schedule[8] (FSS) and "Big Four Agency" price[9] ("Big Four price")).
- When converting another currency to USD, use the exchange rate in effect on the date the cost was incurred. If that rate is unavailable, use the monthly or annual average exchange rate for the year in which the cost was incurred.
    - All new conversions should follow the principles of the GAAP Accounting Standard Certification (ASC) 830, the U.S. accounting standard for translating foreign currency values.
    - If a currency conversion was completed prior to this instruction using a different method, and recalculating using ASC 830 would impose a

[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] The price offered by the VA in its FSS program, by delegated authority of the General Services Administration. See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-of-information-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

[9] The Big Four price is described in section 8126 of title 38 of the U.S. Code.

significant burden, CMS will accept the previously calculated value without requiring recalculation. In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in the calculation.

- 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 unless the additional specific instructions for that question instruct you to do so. When reporting an inflation adjusted value, inflation adjustments should be made to 2025 by using the annual percentage increase of the consumer price index for all urban consumers (CPI-U)[10] for 2025.

A. Selected Drug Information

Primary Manufacturer Response Required

In Section A, for each selected drug for negotiation and renegotiation for initial price applicability year 2028, 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 final guidance, meaning those NDC-11s of the selected drug that:

(1) are associated with Healthcare Common Procedure Coding System (HCPCS) codes that had Part B claims with utilization in the 12-month period beginning November 1, 2024 and ending October 31, 2025, or
(2) had Part D PDE utilization in the 12-month period beginning November 1, 2024 and ending October 31, 2025, or
(3) any additional NDC-11s CMS identifies that are associated with the NDA(s) / BLA(s) of the selected drugs as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file).

Pursuant to section 30.4 of the final guidance, CMS will not include in this list any NDC-11s for which CMS has evidence suggesting a lack of coverage under Part D and Part B (e.g., NDC-11s for which there are no PDE records with a coverage status code of "C" and which are not associated with any HCPCS codes).

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.

[10] The "CPI-U" means the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/cpi/data.htm).

If a Primary Manufacturer believes that an NDC-11 that has been populated by CMS within Section A of the CMS HPMS should not be populated, or an error has occurred, they can submit an email to IRARebateandNegotiation@cms.hhs.gov..[11]

For Section A, for Primary Manufacturers of drugs selected for renegotiation only: The list of NDC-11s for drugs selected for renegotiation should reflect updates provided by Primary Manufacturers for drugs covered under Part D in accordance with sections 40.2 and 50.1 of the final guidance. As applicable to the data populated in the CMS HPMS, please follow the instructions in Section A.

Definitions for Section A:

- Average Manufacturer Price (AMP) unit: The unit type, as reported monthly by the manufacturer, 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, or microcurie.
- 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 (Section 503(c)(1) of the Federal Food, Drug, and Cosmetics Act).
- Labeler code: The first segment of the U.S. Food and Drug Administration (FDA)-assigned NDC (21 C.F.R. § 207.33(b)(1)(i)). Each person who engages in manufacturing, repacking, relabeling, or private label distribution of a drug subject to listing under 21 C.F.R. Part 207 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: The total number of AMP units per NDC-11 package size.
- Total National Council for Prescription Drug Programs (NCPDP) Units per Package: 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 that are covered under Part D and/or payable under Part B 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, and the AMP Unit and Total AMP Units Per Package.

[11] Separately, and as specified in the "Additional Instructions" within this ICR Form, *after* the initial submission of data in this ICR Form, Primary Manufacturers must timely notify CMS, if any of the information submitted changes, as set forth in sections 40.2, 50.1 and 130.3 of the final guidance.

- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, indicate whether:
    - any of the listed NDC-11s or additional NDC-11s are neither marketed nor controlled by the Primary Manufacturer or a Secondary Manufacturer,
    - any of the listed NDC-11s or additional NDC-11s are distributed by or under the name of a private label distributor,
    - any of the listed NDC-11s or additional NDC-11s have been discontinued and the date of discontinuation[12], and
    - any of the listed NDC-11s or additional NDC-11s are a sample package, outer package, or inner package. If the NDC-11 is neither an inner package nor an outer package, select "No" in response to both the inner package and the outer package data fields.
- If an NDC-11 is neither marketed nor controlled by the Primary Manufacturer or a Secondary Manufacturer, select "Yes" in response to the field labeled "Neither Marketed nor Controlled by the Primary Manufacturer or a Secondary Manufacturer." Otherwise, select the "No" response option.
    - **If "Yes" is selected in response to whether the NDC-11 is "Neither Marketed nor Controlled by the Primary Manufacturer or a Secondary Manufacturer," the Primary Manufacturer should not provide information about this NDC-11 in the remainder of the data fields within Section A or within any other section in this ICR Form.**

Product Name	**NDC-11 Numbers**	**Neither Marketed nor Controlled by the Primary or a 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 inner package)	**Outer Package** (Select if NDC-11 is an outer 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-hemophiliac factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, EC, millicurie, microcurie)	**Total AMP Units per Package**	**Labeler Code**
Text to be pre-populated by CMS	*Numbers to be pre-populated by CMS*	*Yes/No*	*Yes/No* *Date if Applicable*	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*	*EA, mL, GM*	*#*	*Text*	*#*	*Numbers to be pre-populated by CMS*

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

Primary Manufacturers must provide the information, as directed in Sections B through G of this

[12] Please provide the date of discontinuation that was reported to FDA pursuant to 21 C.F.R. §§ 314.81(b)(3)(iii) and (iv).

ICR Form, about all NDC-11s marked as "discontinued," a "sample package," an "inner package," an "outer package," and a "private label," in Section A.

B. Non-FAMP Data Collection

Primary Manufacturer Response Required

For Section B, for Primary Manufacturers of drugs selected for negotiation: the Primary Manufacturer is required to report the non-FAMP for its selected drug 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 2025 (i.e., the calendar year prior to the selected drug publication date, February 1, 2026).

CMS plans to use the reported NDC-11s, quarterly non-FAMP, and total NDC-11 package volume in the data fields 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 2025 for initial price applicability year 2028.

For Section B, for Primary Manufacturers of drugs selected for renegotiation: the Primary Manufacturer is required to report the non-FAMP for NDC-11s payable under Part B, if applicable, for its selected drug that are included in Section A.

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.[13] For initial price applicability year 2028, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2025 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2026). 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

[13] 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).

the first full year following market entry of such drug, when applicable) or 2025, 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) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.[14] 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 bottle of 30 tablets, the non-FAMP package would be the bottle; for an NDC-11 that represents a single dose vial containing 25 mg/mL, the non-FAMP package would be the vial).

Instructions for Section B:

Please follow the instructions below when completing the data fields below.

- Please complete the data fields immediately below:
  - 2021 **or** First Other Full Year of Market Entry after 2021: please fill in the information for non-FAMP for each calendar quarter of 2021 for the selected drug if at least one NDC-11 of the selected drug has an average non-FAMP available for at least one quarter in 2021 (***or***, in the case that there is not an average non-FAMP available for any NDC-11 of 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 2025, then please proceed to fill in the data for 2025 only.
  - 2025: please fill in the information for non-FAMP for calendar year 2025.
- Please note that when filling in the data, there may be a different number of NDC-11s with available data in 2021 (or first other full year of market entry) versus 2025. As an example, if any NDC-11s of the selected drug have non-FAMP data in at least one quarter of 2021, all associated NDC-11s should be reported for the four quarters of 2021 (in that scenario, if there is no data for all quarters in 2021 for a given NDC-11, please do not enter any data in the data fields for "2021 or First Other Full Year of Market Entry After 2021" for that NDC-11 and provide an explanation of why there is no data). Additionally, all NDC-11s for the four quarters of 2025, even if an NDC-11 was available in 2025 but not available during any quarter of 2021, should be reported.
- Please report the non-FAMP and total non-FAMP package volume for each NDC-11 of the selected drug. Primary Manufacturers are responsible for

[14] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2025-pbm-fcp-guidance-for-new-covered-drugs.pdf. Archived Dear Manufacturer Letters from the VA are available at: https://www.va.gov/opal/nac/fss/publicLaw.asp.

reporting the calendar year 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, including for any NDC-11s that are marked as "discontinued," a "sample package," an "inner package," an "outer package," and a "private label" in Section A, 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; discontinued prior to 2021; sample).
- 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 2025 made in any manufacturer non-FAMP submissions to the VA must be reflected in the data fields 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.

2021 or First Other Full Year of Market Entry after 2021

NDC-11	Calendar Quarters of 2021 or First Calendar Year Post Market Entry (e.g., Calendar Quarters in 2022, 2023, or 2024)	Calendar Year	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
12345-6789-01	*QQ*	*Select One: 2021, 2022, 2023, 2024*	*#*	*$*	*Text (12,000 character count limit, which is approximately 1,000 words)*

Note: If the Primary Manufacturer indicates that 2025 is the "First Other Full Year of Market Entry after 2021," then the CMS HPMS will only display the data fields for 2025 for completion.

2025

NDC-11	Calendar Quarter for 2025	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
12345-6789-01	*QQ*	*#*	*$*	*Text (12,000 character count limit, which is approximately 1,000 words)*

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

Primary Manufacturer Response Required

This section contains three data questions related to global research and development (R&D) costs incurred by the Primary Manufacturer related to the selected drug and the Primary Manufacturer's global and U.S. net revenue for the selected drug for CMS' consideration of the extent to which R&D costs have been recouped by the Primary Manufacturer related to the selected drug.

Definitions for Section C:

- R&D costs is defined as a combination of costs incurred by the Primary Manufacturer for a drug falling into two categories: (1) Costs Related to the Selected Drug, Including Basic Pre-Clinical Research of the Selected Drug, Post-Investigational New Drug (IND) Costs of the Selected Drug, and Other Allowable Costs and (2) Costs for Failed and Abandoned Products Related to the Selected Drug.
- Basic pre-clinical research costs are defined as the sum of (1) direct research expenses; and (2) the appropriate proportion of indirect research expenses (defined below).
    - 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 (monetary and non-monetary 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 biological products.
- Post-IND costs are defined as 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. Post-IND costs also include direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA

has approved a product.
    - 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 (compensation for investigators and staff) researching the selected drug, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials. Direct post-IND costs also include personnel, patient recruitment, and per-patient costs, research and data collection costs, and facility costs that are directly related to conducting the completed FDA-required, postmarketing trial.
        - Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation. 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.
- Other allowable costs for costs related to the selected drug are defined as direct costs associated with conducting FDA-required postmarketing trials and other FDA post-marketing requirements and commitments that were not completed, Phase IV postmarketing studies , direct post-IND costs (following the definitions and instructions for calculating direct post-IND costs above), direct costs associated with researching and utilizing devices for the selected drug, direct costs to support or satisfy a postmarketing requirement or commitment, and direct costs for patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting Phase IV and postmarketing trials.
- Failed or abandoned product costs are defined as the sum of (1) direct *basic pre-clinical research* costs on drugs with the same mechanism of action as the selected drug that did not make it to clinical trials and (2) direct *post-IND costs* for drugs with the same mechanism of action as the selected drug that did not receive FDA approval.

CMS is including both the Primary Manufacturer's global and U.S. net revenue for the selected drug in its consideration of the extent to which the Primary Manufacturer has recouped R&D costs.

- Recoupment: Global and U.S. Net Revenue for the Selected Drug.
    - Global 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.
    - U.S. 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.

The associated time periods for these terms are included below.

Instructions for Questions 1 through 3:

- For each dollar amount listed below and for the applicable time periods specified, the Primary Manufacturer must report one dollar amount in the numerical response field. For the dollar amount provided, the Primary Manufacturer must provide an explanation of the value(s), including any calculations or conversions and any assumptions made in the free response field.
  - 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.
- **For Primary Manufacturers of drugs selected for negotiation:**
  - In Questions 1 and 2, report R&D costs through December 31, 2025.
  - In Question 3, report the global and U.S. net revenue for the selected drug from the date the drug or biological product was first sold globally through December 31, 2025.
    - If the drug was acquired by the Primary Manufacturer after the selected drug was first sold globally, start the period from the first month of the first full quarter the selected drug was owned by the Primary Manufacturer.
- **For Primary Manufacturers of drugs selected for renegotiation:**
  - In Questions 1 and 2, report R&D costs that were incurred: (1) **after** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through December 31, 2025; and (2) **on or before** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated that meet the definition of R&D costs specified in this ICR/Appendix A of the final guidance for initial price applicability year 2028 *and* the Primary Manufacturer has not previously reported the same data in the Primary Manufacturer's original full submission of section 1194(e)(1) data starting from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later.[15]
  - In Question 3, report the global and U.S. net revenue from the last date for

[15] For initial price applicability year 2026 and initial price applicability year 2027, CMS did not permit costs to be reported for indications that had not yet received FDA approval at the time of ICR submission; however, CMS will permit reporting of such R&D costs related to the selected drug for initial price applicability year 2028. Therefore, this Section C also permits the Primary Manufacturer to report R&D costs that may have occurred on or before the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated that a Primary Manufacturer has not reported as an R&D cost for the selected drug previously.

which data was reported for global and U.S. net revenue in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through December 31, 2025.

- For Questions 1 through 3, if R&D costs and/or net revenue for the selected drug are not available for the exact dates specified above in these instructions, the R&D costs and/or net revenue may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in the free response field for each question.
- If the Primary Manufacturer received any prior Federal financial support, as defined in Section E in this ICR, for any of the costs listed in Questions 1 through 2 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 6, 7, and 8. Please reference Section E for instructions on reporting prior Federal financial support.
  - Do not include prior Federal financial support and costs associated with applying for and receiving foreign approvals in Section E.
- If the Primary Manufacturer shared the expenses described in Questions 1 through 2 (after any acquisition of the selected drug, if relevant) 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 may be included and reported in USD, costs associated with applying for and receiving foreign approvals must not be included.
- Acquisition costs are not allowable in Section C.

Question 1: Costs Related to the Selected Drug, Including Basic Pre-Clinical Research Costs of the Selected Drug, Post-IND Costs of the Selected Drug, and Other Allowable Costs

Provide the following information about R&D costs (for the time periods as specified in the instructions above) incurred by the Primary Manufacturer for the selected drug related to basic pre-clinical research, post-IND costs for the selected drug, and other allowable costs.

Instructions for Question 1a:

- In the numerical response field for "Cost Related to the Selected Drug," report the sum of the (1) direct and the proportion of indirect costs for basic pre-clinical research for the selected drug; (2) direct post-IND costs; and (3) direct costs for

other allowable costs.
    - To calculate the proportion of pre-clinical 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.[16, 17] 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.
- In the response field for "Cost Related to the Selected Drug Adjusted for Inflation," report the cost included for the "Cost Related to the Selected Drug" data field adjusted for inflation.

Costs Related to the Selected Drug	**Costs Related to the Selected Drug Adjusted for Inflation**
$	*$*

Instructions for Question 1b:

- List the direct and indirect costs for the selected drug that were included in the reported amount in Question 1a.

FIELD	**RESPONSE FORMAT**
List of the direct and indirect costs for the selected drug included in Question 1a	*Text (6,000 character count limit, which is approximately 500 words)*

Instructions for Question 1c:

- Explain how the numerical value reported in Question 1a was calculated, including the allocation and apportionment methods.
- **For Primary Manufacturers of drugs selected for renegotiation:** this explanation should include whether any of the reported costs are costs incurred on or before the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e) data and the total costs for this period of data.
- Explain any methodology relevant to the cost included in response to Question 1a

[16] 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.

[17] 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.

adjusted for inflation in the free response.

FIELD	RESPONSE FORMAT
Explanation of Costs Related to the Selected Drug, Including Allocation and Apportionment Methods, and an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 2: Costs of Failed or Abandoned Products Related to the Selected Drug

The Primary Manufacturer may report *direct* costs spent on basic pre-clinical research and clinical research for failed or abandoned products that are related to the selected drug (for the time periods as specified in the instructions above).

Instructions for Question 2a:

- In the numerical response field for "Costs of Allowable Failed or Abandoned Products Related to the Selected Drug," only include basic pre-clinical research and post-IND costs that can be directly attributed to failed or abandoned product(s) with the same mechanism of action as the selected drug that did not receive FDA approval.
- In the response field for "Cost Allowable Failed or Abandoned Products Related to the Selected Drug Adjusted for Inflation," report the cost included for the "Costs of Allowable Failed or Abandoned Products Related to the Selected Drug" data field adjusted for inflation.

Costs of Allowable Failed or Abandoned Products Related to the Selected Drug	Costs of Allowable Failed or Abandoned Products Related to the Selected Drug Adjusted for Inflation
$	*$*

Instructions for Question 2b:

- List all the applicable direct costs included in the numerical value given in Question 2a.

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

Instructions for Question 2c:

- In the free response field, detail how these costs were determined, what portion of direct costs was included for basic pre-clinical research and direct post-IND costs, and how any allocation was done.
- Explain any methodology relevant to the cost included in the response to Question 2a adjusted for inflation in the free response.

FIELD	RESPONSE FORMAT
Explanation of Costs on Allowable Failed or Abandoned Products Related to the Selected Drug, Including Allocation and Apportionment Methods, and an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 3: Global and U.S. Net Revenue for the Selected Drug

CMS will use both the Primary Manufacturer's global and U.S. net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug (for the time periods as specified in the instructions above).

Instructions for Question 3a:

- In the numerical response field for "Global Net Revenue for the Selected Drug" in Question 3a, report the global net revenue.
- In the numerical response field for "Global Net Revenue for the Selected Drug Adjusted for Inflation" in Question 3a, report the global net revenue reported adjusted for inflation.

Global Net Revenue for the Selected Drug	Global Net Revenue for the Selected Drug Adjusted for Inflation
$	*$*

Instructions for Question 3b:

- In the free response field, explain how the global, net revenue was calculated, including any relevant currency conversions.
- Explain any methodology relevant to the net revenue included in the response to Question 3a adjusted for inflation in the free response.

FIELD	RESPONSE FORMAT
Explanation of Global Net Revenue for the Selected Drug and an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

Instructions for Question 3c:

- In the numerical response field for "U.S. Net Revenue for the Selected Drug" in Question 3c, report the U.S. net revenue.
- In the numerical response field for "U.S. Net Revenue for the Selected Drug Adjusted for Inflation" in Question 3c, report the U.S. net revenue reported adjusted for inflation.

U.S. Net Revenue for the Selected Drug	U.S. Net Revenue for the Selected Drug Adjusted for Inflation
$	*$*

Instructions for Question 3d:

- In the free response field, explain how the U.S. net revenue was calculated.
- Explain any methodology relevant to the net revenue included in the response to Question 3c adjusted for inflation in the free response.

FIELD	RESPONSE FORMAT
Explanation of U.S. Net Revenue for the Selected Drug and an Explanation of the Methodology for the Inflation Adjustment	*Text (30,000 character count limit, which is approximately 2,500 words)*

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 (for the time period as specified in the instructions below). Question 4 includes data fields in which to report the average unit costs of production and distribution for each NDC-11 of the selected drug. Question 5 provides a free response field for explaining the methodology for calculating the amount reported in Question 4.

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 (e.g., capsule or tablet, milligram of molecules, grams, international units) of the drug or biological product that is dispensed, furnished, or administered.
- Units must be reported in one of the three NCPDP Billing Unit Standard (BUS).[18] 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:

[18] See: https://standards.ncpdp.org/Billing-UnitRequest.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22.

    - Packaging and packaging materials;
    - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
    - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
    - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- 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);
    - 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-party vendors (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 do not 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, including providing free products to health professionals or patients, 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 the Treasury regulations thereunder.

<u>Instructions for Section D:</u>

Follow the instructions below when answering Questions 4 and 5:

- 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 5 to explain any shared operating and other indirect costs that were included in the response to Question 4.
- Costs may be reported up to three decimal places (USD).

Question 4: Per Unit Production and Distribution Costs

Please complete the following data fields using additional rows as necessary for the following periods:

- **for drugs selected for negotiation,** the 12-month period ending December 31, 2025, and
- **for drugs selected for renegotiation,** the 12-month period ending December 31, 2025.

Include NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued.

NDC-11	Average Per Unit Production Cost	Average Per Unit Distribution Costs	NCPDP Unit (EA, mL, GM)	Total Unit Volume	Costs are Not Available	Explanation of Why Costs are Not Available
12345-6789-01	*$XX.XXX*	*$XX.XXX*	*Text*	*#*	*Select if applicable*	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 5: 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 4, 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 other assumptions about costs, if applicable, 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 includes the manufacturer's reasonable estimate of the dollar value of in-kind contributions and Cooperative Research and Development Agreements (CRADAs) that do not have a readily ascertainable value.
- Direct prior federal financial support costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of the selected drug.

Instructions for Section E:

Follow the instructions below when answering Questions 6, 7, and 8.

- The applicable time period is as follows:
  - **For Primary Manufacturers of drugs selected for negotiation:**
    - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to any of the costs described in response to Question 1 of this ICR Form of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to Secondary Manufacturers of a selected drug) that was received during the time period from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later, through December 31, 2025.
  - **For Primary Manufacturers of drugs selected for renegotiation:**
    - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to any of the costs described in response to Question 1 of this ICR Form of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to Secondary Manufacturers of a selected drug) that was received during the time period from the

last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through December 31, 2025.

- As described in Section C, if the Primary Manufacturer incurred R&D costs **on or before** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated that meet the definition of R&D costs specified in this ICR/Appendix A of the final guidance for initial price applicability year 2028 *and* the Primary Manufacturer has not previously reported the same data in the Primary Manufacturer's original full submission of section 1194(e)(1) data, include all applicable prior Federal financial support from when initial research began or when the drug was acquired by the Primary Manufacturer, whichever is later, through December 31, 2025.[19]

- For Question 6, if prior Federal financial support for the selected drug is not available for the exact dates specified above in these instructions, the prior Federal financial support may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in Question 7.
- 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 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.

[19] For initial price applicability year 2026 and initial price applicability year 2027, CMS did not permit costs to be reported for indications that had not yet received FDA approval at the time of ICR submission; however, CMS will permit reporting of such prior Federal financial support related to the selected drug for initial price applicability year 2028. Therefore, this Section E also permits a Primary Manufacturer to report support that may have occurred on or before the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated that a Primary Manufacturer has not reported for the selected drug previously.

[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.

- For in-kind contributions and 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 shared the prior Federal financial support described in Questions 6 through 8 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 8. 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 6. Then, it would note the source of the shared prior Federal financial support and that it received 80 percent of that support in Question 7. 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 8.

Question 6: Federal Funding Support Amount

Instructions for Question 6:

- In the numerical response field for "total Federal financial support," report the total Federal financial support.
- In the numerical response field for "total Federal financial support adjusted for inflation," report the total Federal financial support reported adjusted for inflation.

Total Federal Financial Support	**Total Federal Financial Support Adjusted for Inflation**
$	*$*

Question 7: Explanation of Calculation of Federal Financial Support

Instructions for Question 7a:

- In the free response field, 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 6.
  - 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.

List of sources for Question 7a

- 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
- CRADA support
- In-kind contributions not included elsewhere
- Other Federal financial support not included elsewhere

FIELD	RESPONSE FORMAT
Explanation of Federal Financial Support, including disaggregated amounts as applicable	*Text (36,000 character count limit, which is approximately 3,000 words)*

Instructions for Question 7b:

- Explain any methodology relevant to the total Federal financial support adjusted for inflation included in the response to Question 6 in the free response.
- Report each total Federal financial support disaggregated amount adjusted for inflation, and explain the methodology used to adjust for inflation.

FIELD	RESPONSE FORMAT
Explanation of methodology used to adjust for inflation	*Text (6,000 character count limit, which is approximately 500 words)*

Question 8: 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 8 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**
Select the agreement option: licensing, pricing, purchasing, other, none	*Text (1,200 character count limit, which is approximately 100 words)*	*Text (12,000 character count limit, which is approximately 1,000 words)*

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 9 through 11.

Definitions for Section F:

- Patents Exclusivities and Approvals. 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) 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 relevant 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 relevant 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] patents that claim the drug product (e.g., the final product taken by or administered to a patient), drug substance (active ingredient) or other chemicals related to the active ingredient of a selected drug (e.g., crystalline forms, polymorphs, salts, metabolites or intermediates); patents that claim a formulation of the drug; method-of-use patents (e.g., patents that claim an indication or use of the drug for treating a particular disease); process patents (e.g., patents that claim technologies and method(s) of

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

manufacturing the drug); device patents (e.g., patents that claim the device used to administer the selected drug); and design patents (e.g., patents that claim a design on the packaging of the selected drug).

- Relevant patents and patent applications do not include patent applications that were denied by the USPTO.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays on the submission or approval of applications for competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[23]
    - 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 9 through 11, the relevant time period for reporting is:
    - **For Primary Manufacturers of drugs selected for negotiation:**
        - The time period 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 December 31, 2025.
    - **For Primary Manufacturers of drugs selected for renegotiation:**
        - for a drug that was originally selected for negotiation for initial price applicability year 2026, include (1) patents, approvals and exclusivities issued or filed (and related items) after September 1, 2023 through December 31, 2025 and (2) patents and exclusivities (and related items) issued or filed on or before September 1, 2023 for which there has been a change after September 1, 2023 through December 31, 2025, if requested below; and
        - for a drug that was originally selected for negotiation for initial price applicability year 2027, include (1) patents, approvals and exclusivities issued or filed (and related items) after February 1, 2025 through December 31, 2025 and (2) patents and exclusivities (and related items) issued or filed on or before September 1, 2023 for which there has been a change after February 1, 2025 through September 30, 2025, if requested below.

[23] Section 527 of the FD&C Act.
[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.

Question 9A: Patents (Expired and Non-Expired)

In the data fields below, please list each patent that is relevant to the selected drug for the applicable time period specified in the instructions. For each patent (expired or unexpired) listed in the data fields below, in the patent explanation field, please provide a clear and concise written description of the patented invention and, if relevant, of the manner and process of making and using the invention, as well as how a patent relates to any other patents listed in the data fields. For example, if a listed patent is a parent or child of another patent, include the patent number and how the two patents relate to each other. If the patent was previously listed in the FDA Orange Book or Purple Book but is no longer listed, please explain why.

For drugs selected for renegotiation, do not report relevant patents included in the Primary Manufacturer's original full submission of section 1194(e)(1) data where no change has occurred. Information may include, for example, a new patent issued after the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated, and any patent where there has been a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated (e.g., patent was removed from the Orange Book).

A Zip file of the PDF file(s) of the USPTO patent application(s) may be uploaded but is not required for this question 9A. Add additional rows to your response to Question 9A as needed.

Patent Number	**Date Filed**	**Patent Expiry Date**	**Patent Type**	**Never, Previously, or Currently Listed in FDA Orange Book/Purple Book**	**Patent Explanation or Explanation of What Changed Since Last Submission**	**Patent Application**
#	*MM/ DD/ YYYY (not applicable it patent expired)*	*MM/ DD/YYYY*	*Select patent type (allow more than one to be selected): drug product patent; drug substance patent; formulation patent; process patent; method-of-use patent;*	*Never/ Previously / Currently*	*Text (3,600 character count limit, which is approximately 300 words*	*Optional. Upload corresponding patent application*

Patent Number	Date Filed	Patent Expiry Date	Patent Type	Never, Previously, or Currently Listed in FDA Orange Book/Purple Book	Patent Explanation or Explanation of What Changed Since Last Submission	Patent Application
			device patent; other (e.g., patent that claims other chemicals related to the active ingredient, design patent)			

Question 9B: Patent Applications

In the data fields below, please list each patent application that is relevant to the selected drug for the applicable time period specified in the instructions. For each patent application listed in the data fields below, in the patent explanation field, please provide a clear and concise written description of the invention and, if relevant, of the manner and process of making and using the invention, as well as how a patent application relates to any other patents. Do not include patent applications that were denied.

For drugs selected for renegotiation, do not report relevant patent applications included in the Primary Manufacturer's original full submission of section 1194(e)(1) data where no change has occurred. Information may include, for example, a new application or applications that have experienced a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated).

Please upload a Zip file of a PDF file of the USPTO patent application(s). Add additional rows to your response to Question 9B as needed.

Patent Number	Date Filed	Patent Type	Patent Explanation, or Explanation of What Changed Since Last Submission	Patent Application
#	*MM/ DD/ YY YY (not applicable if patent pending)*	*Select patent type (allow more than one to be selected): drug product patent; drug substance patent; formulation patent; process patent; method-of-use patent; device patent; other (e.g., patent that claims other chemicals related to the active ingredient, design patent)*	*Text (3,600 character count limit, which is approximately 300 words)*	*Upload corresponding patent application.*

Question 10: Exclusivity Periods

As applicable, please report all exclusivity periods under the FD&C Act or the PHS Act that are listed or were listed in the Orange Book or the Purple Book and are in effect or have expired for the selected drug for the applicable time period specified in the instructions.

For drugs selected for renegotiation, do not report exclusivity periods listed in the Primary Manufacturer's original full submission of section 1194(e)(1) data where no change has occurred. Information may include, for example, a new exclusivity since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated.

Complete the data fields for Question 10 by adding rows as needed.

Type of Exclusivity	Exclusivity Expiration Date	Application (NDA / BLA) Number	NDC-9s Covered by Exclusivity	Comments
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	*MM/DD/YYYY*	*#*	*Text*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 11: 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 for the time period specified in the instructions.

- 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 the data fields for Question 11 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.

For drugs selected for renegotiation, do not report active or pending FDA applications listed in the Primary Manufacturer's original full submission of section 1194(e)(1) data where no change has occurred. Information may include, for example, a new application or applications that have experienced a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Classification Code[29]	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application 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 following ng options: approved, tentatively approved, pending, withdrawn, or other*	*Text (3,600 character count limit, which is approximately 300 words)*

[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.

G. Market Data and Revenue and Sales Volume Data

Primary Manufacturer Response Required

The purpose of Section G 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 BUS[30] are: each (EA), milliliter (mL), and gram (GM). For certain volume data of the selected drug, CMS requests 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.
- Average sales price (ASP): The manufacturer's average sales price is defined in 42 C.F.R. § 414.902.
- ASP Unit: The unit type used by the manufacturer to report ASP as specified in 42 C.F.R. § 414.802.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.[32] The Big Four price is reported at the NDC-11 level.
- 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 private health insurance plans, including small group and individual plans on- and off-Exchange and large group plans, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed

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

[31] See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-ofinformation-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

[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.

care. The following items should be deducted from gross revenue in your calculation: 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 commercial payer in the U.S. The following items should not be deducted from gross revenue in your calculations: 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 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 manufacturer U.S. commercial average net unit price─ net of patient assistance program is the manufacturer U.S. commercial average net unit price, with the additional following items deducted: 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 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 manufacturer U.S. commercial average net unit price─ best is 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 following items should be deducted from gross revenue in your calculations: 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 or any Secondary Manufacturer(s) to any purchasers. The following items should not be deducted from the gross revenue in your calculations: 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 average unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price as calculated by the Primary Manufacturer. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year date specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale 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) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net

Medicare Part D average unit price is reported at the NDC-11 level.

- Manufacturer net Medicare Part D average unit price – best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price – best is the lowest manufacturer net Medicare Part D average unit price offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any Part D plan sponsors in the U.S. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale 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) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price – best is reported at the NDC-11 level.

Instructions for Section G:

- For Question 12 through 25, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.
- For Questions 12 through 25, for the sole purpose of data collection under section 1194(e)(1)(E) of the Act, as applicable, the total unit volume must be reported at the NDC-9 or NDC-11 level and reflect the NCPDP BUS and the AMP unit. The total unit volume must include the total unit volume sold by the Primary Manufacturer and any Secondary Manufacturer(s) in the U.S. for the data reported.
- Include NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued.

Follow the specific instructions for each question below. The applicable reporting time periods are as follows (except unless otherwise instructed for a specific question):

- **for drugs selected for negotiation for initial price applicability year 2028**, the calendar years 2023, 2024, and 2025 through the calendar quarter ending with December 31, 2025,
- **for a drug that was selected for negotiation for initial price applicability year 2026 and has been selected for renegotiation for initial price applicability year 2028**, calendar years 2024 and 2025 through the calendar quarter ending with December 31, 2025, and
- **for a drug that was selected for negotiation for initial price applicability year 2027 and has been selected for renegotiation for initial price applicability year 2028**, calendar year 2025 through the calendar quarter ending with December 31, 2025.

If the required data for the selected drug is not available for the exact dates specified above in these instructions, the Primary Manufacturer should report the date through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in the question's free response field.

Question 12: Wholesale Acquisition Cost Unit Price

Follow the instructions below when providing responses in the following data fields 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 data fields 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 13 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.
- If the NDC-11 was marketed, sold, or distributed at any time during the quarter (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), 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 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 13: Explanation of Information Reported in Question 12: 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 12 and those found in available drug databases (e.g., Medi-Span, First Databank, RED BOOK). Additionally, if the WAC unit price has changed between December 31, 2025, and the date of the submission of this ICR form, provide the updated WAC unit price. 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 14: Average Sales Price (ASP)

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

- Report the ASP, the ASP Unit, and Total Units Sold for the last two sales quarters in calendar year 2025 ending with December 31, 2025.
- The information provided in the data fields must reflect the same data that was submitted to CMS consistent with 42 C.F.R. § 414.800 *et seq.*(subpart J – Submission of Manufacturer's Average Sales Price Data), including, for example, the ASP Unit(s) reported in accordance with 42 C. F.R § 414.802.
- ASP Unit refers to the ASP Unit type used by the manufacturer to report ASP as specified in 42 C.F.R. § 414.802 (e.g. EA, mL, IU).
- If an ASP is reported and "0" is entered for Total Units Sold, explain why "0" units are reported.
- If the NDC-11 was marketed, sold, or distributed at any time during a quarter (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), 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 provide an explanation in the "Explanation of why ASP was not reported (if applicable)" field of why the NDC-11 had no ASP for that calendar quarter (e.g., the NDC-11 was first marketed in a later calendar quarter).
- If an ASP reported is negative, provide an explanation in the "Explanation of why ASP was not reported (if applicable)" field of why the ASP is negative.

NDC-11	Sales Quarter	ASP	ASP Unit (the same ASP unit as reported in the ASP Data Collection System)	Total Units Sold	Explanation of why ASP was not Reported (if applicable)
12345-6789-01	*QQ/YYYY*	*$*	*Text*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 15: Explanation of Information Reported in Question 14: ASP

If applicable, describe other information you feel is necessary to interpret reported information in

response to Question 14. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

Question 16: Medicaid Best Price

Was a Medicaid best price determination ever made for a calendar quarter for the selected drug during the applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following data fields. If response is No, please skip to Question 18) Follow the instructions below when providing responses in the following data fields 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 42 C.F.R. § 447.505 – Determination of best price. The reported Medicaid best price in the data fields 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 (including corresponding NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), 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 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)**
12345-6789	*QQYYYY*	*$ (up to 6 decimal places)*	*Text*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 17: Explanation of Information Reported in Question 16: Medicaid Best Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 16. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

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

Question 18: Federal Supply Schedule (FSS) Price

Was a FSS price for the selected drug ever available during the applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following data fields. If response is No, please skip to Question 20) Follow the instructions below when providing responses in the following data fields 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 an applicable calendar quarter specified in the instructions above, and fill out the requested information.
    - If the NDC-11 did not have a FSS price during an applicable calendar quarter specified in the instructions above, please enter "0" in the total unit volume field. Also 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 during an applicable calendar quarter specified in the instructions above (e.g., the NDC-11 was discontinued before the period for the requested data began).
- If an NDC-11 had a FSS price for a reported price period but no units were sold, please enter "0" in the Total Unit Volume Field and provide the FSS in the "Explanation of why

[33] See: https://www.va.gov/opal/nac/fss/pharmprices.asp.

FSS price was not reported (if applicable)" field.

- Please complete Questions 18 and 19 for the FSS price of the selected drug and Questions 20 and 21 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 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	*MMDDYYYY-MMDDYYYY*	*$*	*Text*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 19: Explanation of Information Reported in Question 18: Federal Supply Schedule 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
Explanation of Federal Supply Schedule price data	*Text (12,000 character count limit, which is approximately 1,000 words)*

Question 20: Big Four Price

Was a Big Four price ever available for the selected drug during the applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following data fields. If response is No, please skip to Question 22) Follow the instructions below when providing responses in the following data fields 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 Big Four price for the bottle).
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or

[34] See: https://www.va.gov/opal/nac/fss/pharmprices.asp.

gram (GM). Total unit volume is the total number of units (i.e., EA, ML, or GM) for 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 an applicable calendar quarter specified in the instructions above (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), and fill out the requested information. If the NDC-11 did not have a Big Four price during an applicable calendar quarter specified in the instructions above, please enter "0" in the total unit volume field 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 during an applicable calendar quarter specified in the instructions above (e.g., the NDC-11 was discontinued before the period for the requested data began).
- Please complete Questions 18 and 19 for the FFS FSS price of the selected drug and Questions 20 and 21 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)
12345-6789-01	*MMDDYYYY-MMDDYYYY*	*$*	*Text*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 21: Explanation of Information Reported in Question 20: Big Four 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
Explanation of Big Four price data	*Text (12,000 character count limit, which is approximately 1,000 words)*

Question 22: Manufacturer U.S. Commercial Average Net Unit Price

Follow the instructions below when providing responses in the following date fields about the Manufacturer U.S. commercial average net unit price:

- For each NDC-11, please include a row for each quarter during the applicable time period specified in the instructions above, based on the Primary Manufacturer's responses in

Section A (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued).
    - 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 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).
- Exclude price and volume information for the selected drug for any entity not included in Medicaid best price (e.g. Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care).
- 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. Use "$0" as the price for a unit provided by the manufacturer at no charge to the patient.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (mL), or gram (GM). Please do not include units associated with free samples in the calculated prices or reported total unit volume.

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. Commercia l Average Net Unit Price-Best**	**NCPDP Unit (EA, mL, GM)**	**Total Unit Volume**	**Total Unit Volume for U.S. Commercial Average Net Unit Price - Best**	**Explanation of why Manufacturer U.S. Commercial prices were not Reported (if applicable)**
12345-6789-01	*QQYYY*	*$*	*$*	*$*	*Text*	*#*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 23: Explanation of Information Reported in Response to Question 22: Manufacturer U.S. Commercial Average Net Unit Price

Describe assumptions, methodological steps, and other information for the following topics related to Question 22:

- How sales to enrollees of private health insurance plans, including small group and individual plans on- and off-Exchange and large group plans 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 commercial payer 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" the "U.S. commercial average net unit price─ net of patient assistance programs," and 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
Explanation of manufacturer U.S. commercial average net unit price data	*Text (12,000 character count limit, which is approximately 1,000 words)*

Question 24: Manufacturer Net Medicare Part D Average Unit Price

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

- For each NDC-11, please include a row for each quarter during the applicable time period specified in the instructions above, based on the Primary Manufacturer's responses in Section A (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued).
    - 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 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).
- Only include price and volume information of the selected drug for Part D plan sponsors.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (mL), or gram (GM). Please do not include units associated with free samples in the calculated prices or reported total unit volume.

NDC-11	Calendar Quarter	Manufacturer Net Medicare Part D Average Unit Price	Manufacturer Net Medicare Part D Average Unit Price - Best	Medicare Discount Program Amount Paid (Per NCPDP Unit)	NCPDP Unit (EA, mL, GM)	Total Unit Volume	Total Unit Volume for Net Medicare Part D Average Unit Price - Best	Explanation of why manufacturer net Medicare Part D price was not Reported (if applicable)
12345-6789-01	*QQYYYY*	*$*	*$*	*$*	*Text*	*#*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 25: Explanation of Information Reported in Response to Question 24: Manufacturer net Medicare Part D price

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

- 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 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 commercial payer were allocated across NDC-11s and calendar quarters.
- If applicable, how unit price was separated for enrollee and/or plan type.
- How information was used to calculate the "Manufacturer Net Medicare Part D Average Unit Price" and the "Manufacturer Net Medicare Part D Average Unit Price – best."
- Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
Explanation of "manufacturer Net Medicare Part D price" data	*Text (12,000 character count limit, which is approximately 1,000 words)*

Question 26: Primary Manufacturer Identification of Information Submitted in Sections A through G that the Primary Manufacturer Believes Should be Withheld as Proprietary Information

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 final 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]

In addition to the information CMS already designates as proprietary consistent with section 40.2.1 of the final guidance: For information submitted that the Primary Manufacturer believes should *also* be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including under Exemption 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4)),[36] follow the instructions below to identify this information for CMS. This identification of information by the Primary Manufacturer will be used during CMS' process to determine which information submitted by a manufacturer is proprietary and which information may be disclosed in the public explanation of the MFP consistent with section 60.6.1 of the final guidance.

- In the "Location" data field, identify the location of the information the Primary Manufacturer believes should be withheld in Sections A through G by either:
    - Using [brackets] at the start and end of any full sentence(s) within a free response field(s) that contains information the Primary Manufacturer believes should be withheld. Also use [brackets] at the start and end of any data provided, if permitted in the data entry field (for example, because the field is a text field), to identify information the Primary Manufacturer believes should be withheld.
        - Label the end of each bracketed sentence with a number in sequential order and use the same number originally assigned to a bracket throughout Sections A through G each time the same justification will be used in response to Question 26 as the reason the manufacturer believes the information should be withheld (e.g., {1}, {2}). To differentiate references in response to Question 26 from citations, use different symbols for numbering (for example, a {curly brace} for Question 26 and (parenthesis) for citations).
    - For a data response field where brackets cannot be entered (for example, the field requires a numerical response) (in other words, a "non-bracketed location"), listing the specific location of the information by identifying the Section letter, Question

[35] Specifically, as described in section 40.2.1 of the final 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 approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary because CMS understands these data are publicly available.

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

number, data entry field, and/or line number to specifically identify the starting and ending point, of information the Primary Manufacturer believes should be withheld.

- In the "Justification" data field, provide a brief explanation regarding why the Primary Manufacturer believes the information should be withheld as proprietary information.
    - For a bracketed item, provide the Justification for each separate number used within Sections A through G (e.g., {1}, {2}). Do not repeat the same Justification.
    - For a non-bracketed location, if the Justification is the same Justification as a bracketed item, the Primary Manufacturer should use the number assigned to the bracketed item with the corresponding justification as the response to the "Justification" data field. For example, if a non-bracketed item's Justification is the same as the Justification for bracketed item {1}, the Primary Manufacturer should enter "{1}" in the Justification response field for that non-bracketed item.

LOCATION (List the Bracket Number (E.g. {1}, {2}) or Question/Section/Data Entry Field/Line Number))	**JUSTIFICATION**
List of Bracket Locations, in Order of First Appearance (E.g. {1}, {2}); Add a row for each additional item	*Text (each item 2,400 character count limit, which is approximately 200 words)*
List of Non-Bracketed Locations, Identified by the Section, Question, Data Entry Field and/or Line Number; Add a row for each additional item	*Text (each item 2,400 character count limit, which is approximately 200 words)*

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

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).

Required for Primary Manufacturers:

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 changed or is otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability,

including under the False Claims Act and/or in the form of civil monetary penalties pursuant to section 1197(c) of the Act.

Checkbox for certification [ ]

Contact Information to be entered:

Field	Response
Name of the Person Responsible for the Submission	*Text*
Signature	*Text (Electronic Dated Signature)*
Date	*MMDDYYYY*

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 potential therapeutic alternative(s), respondents are not required to include personally identifiable information[37] (PII), protected health information[38] (PHI) or proprietary information that includes confidential or trade-secret information. CMS seeks to collect only the minimum necessary information related to the selected drug and its potential 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. Section I is applicable to drugs selected for negotiation and drugs selected for renegotiation.

For Primary Manufacturers of drugs selected for renegotiation that choose to respond to Section I, the applicable time period to provide the requested responses is from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(2) data to CMS for the negotiation period in which the selected drug's MFP was negotiated through December 31, 2025.

[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.https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

Question 27: Respondent Information

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

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 if applicable.*

[ ] Representative of a manufacturer of the selected drug [this category is pre-selected for a Primary Manufacturer when submitting information about its 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 a 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 potential therapeutic alternative(s) or treating conditions pertinent to the selected drug or its potential therapeutic alternative(s)

[ ] A patient who has experience taking the selected drug or a potential therapeutic alternative(s)

[ ] A caregiver for an individual who has experience taking the selected drug or a potential 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)]

- [For all options (except this question does not populate for a Primary Manufacturer

[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.

when submitting about its selected drug)] Are you or your organization affiliated with the manufacturer of the selected drug or its potential therapeutic alternative(s)?[40]

General Instructions for Section I

- All questions are optional.
- Any interested party may answer Questions 27 through 57. Each interested party will be able to answer each of Questions 27 through 57 in Section I one time for each selected drug. Instructions and questions in this section include the language "selected drug" in [brackets] to indicate that the information displayed will be used for each of the selected drugs.
- 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."
- Any respondent that answers any of Questions 27 through 56 should also review Question 57 and respond as applicable.
- CMS has grouped Questions 28 through 54 in five categories of topics that are addressed by the set of questions. Specifically, these categories by question number are:
    - Questions 28-33: Patient- or Caregiver-Focused Input
    - Questions 34-39: Manufacturer-Focused Input
    - Questions 40-45: Clinical-Focused Input
    - Questions 46-51: Health Research-Focused Input
    - Questions 52-54: 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 28 through 56. 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.
    - 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 potential 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.
    - Manufacturer-Focused Input—for example, a Primary Manufacturer of a selected drug.
    - 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).

[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.

    - Other Public Input—any other interested party that wishes to respond to the questions in Section I, along with citations for any responses in Section I and visual representations.
- The Additional Instructions and the Instructions for Reporting Monetary Amounts included in this ICR apply to Section I. These instructions are for respondents providing original data but are not applicable when a respondent provides citations for existing published data.
- If known to you, 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).
- Please answer each question in narrative (text) form. Your responses will be limited to the character count maximum specified for a specific question. The total character count includes all characters, such as spaces between words and symbols.
    - **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.**
- 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).
- 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. Information should, at a minimum, include methods, data sources, and limitations for unpublished evidence.
    - 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 final 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 in the order the citation first appears (e.g., [1], [2]) and submit the citations in the same order in response to Question 56. Use the number originally assigned to for the same source citation each time the citation is used throughout Section I.
    - In response to Question 56, respondents are requested to provide the list of all citations. Additional instructions are included with Question 56 to link and format

citations.

- 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.
- As described in section 50.2 of the final 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 and other applicable law, including section 504 of the Rehabilitation 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 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 may consider such separate evidence.
- Submissions may include visual representations of the information, including tables, charts, and/or graphs. The information submitted in the space for visual representations in Question 55 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.
    - To upload a PDF file, it must first be converted to a Zip file. Multiple PDF files must be uploaded together in one Zip file.
- CMS will only review the maximum number of citations or upload files permitted in the instructions.

<u>Definitions for Section I:</u>

- Therapeutic Advance: CMS intends to examine improvements in outcomes to determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) (e.g., selected drug is curative versus a therapeutic alternative that delays progression) and will consider the costs of the selected drug and its therapeutic alternative(s). CMS may consider the magnitude of differences in outcomes of interest conferred by the selected drug compared to the selected drug's therapeutic alternative(s) for an indication(s) [42] when determining the extent to which a selected drug represents a therapeutic advance. For purposes of the Negotiation Program, anytime CMS considers

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

[42] For purposes of the final guidance and 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.

therapeutic advance, CMS will consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.

- Therapeutic Alternative: A therapeutic alternative must be a pharmaceutical product or group of pharmaceutical products that is clinically comparable to the selected drug (in other words, a medicine other than the selected drug that may be used to treat the same condition or disease state). CMS intends to 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 intends to 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 and then also consider therapeutic alternatives in different pharmacologic 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 of interest to CMS may include direct clinical outcomes (e.g., cure, mortality) and/or validated or reasonably likely surrogate endpoints (e.g., serum hemoglobin A1c). In determining outcomes of interest, CMS will consider patient-reported outcomes and outcomes of importance to patients, if available. CMS may also consider additional outcomes and contextual factors, such as health-related quality of life or patient/caregiver preferences regarding treatment, to the extent these outcomes and factors correspond with benefits or harms to individuals taking the selected drug or therapeutic alternatives. The caregiver perspective may be considered to the extent it reflects directly upon the experience or relevant outcomes of the patient taking the selected drug.
- 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.[43]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries.
- Unmet medical need: A circumstance in which the relevant disease or condition is one for which no other treatment options exist, or existing treatments do not adequately address the disease or condition.[44] For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS will consider the extent to which the drug represents an unmet medical need at the time of consideration based on all available information at such time of consideration. Under section 1194(e)(2) of the Act, CMS will consider the extent to

[43] A patient-centered outcome is defined as: 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. (Source: https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary).

[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.

which a selected drug and its therapeutic alternatives address 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 in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s) and off-label use(s) that are included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D and/or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. For the purpose of an ICR submission, a respondent may combine FDA-approved indications (e.g., identical adult and pediatric indications) and off-label use(s). The respondent 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 evidence-based clinical practice guidelines and the off-label use is a medically-accepted use covered under Part D or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

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: [CMS to provide a prepopulated list of all FDA-approved indications that will be accessible to respondents]

Questions 28 through 57: Optional for All Respondents

Questions 28 through 33: 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 [the selected drug], the 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 28: Background

Question 28a: Have you or someone you provide care for ever taken [the selected drug]?

Field	Response
Response to Question 28a	*Check box: YES or NO*

If you answer yes, review Questions 28a1 and 28a2. If you answer no, skip to Questions 28a3 and 28a4.

Question 28a1: [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 28a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 28a2: [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 28a2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 28a3 [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 28a3	*Text* (6,000 character count limit, which is approximately 500 words)

Question 28a4: [If NO] What is your experience with this condition or conditions?

Field	***Response***
Response to Question 2a4	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 29: Information on Your Condition(s) or Condition(s) of Someone You Care For

Question 29a: How do the condition(s) you listed in Question 28a1 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 29a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 29b: How has the condition(s) you listed in Question 28 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 29b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 29c: What is important to you or those you provide care for in managing the condition(s) you listed in Question 28?

- 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 29c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 29d: What challenges do you, or someone you care for, face in managing this condition(s)?

Field	Response
Response to Question 29d	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 30: Information on the Current Medication to Treat Your Condition

Question 30a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Question 28?

Field	Response
Response to Question 30a	*YES or NO*

If you answer yes, review Questions 30a2 through 30a4. If you answer no, skip to Question 31.

Question 30a1: [If YES] What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Question 28?

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

Field	Response
Response to Question 30a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 30a2: [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 28?

- 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 or mail-order pharmacy could provide it, family influence, interference with your work or life, other health condition(s), whether the medication was covered by your insurance, whether your medical provider recommended the medication based on clinical guidelines or clinical experience, or other things that influenced your choice.

Field	Response
Response to Question 30a2	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 30a3: [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 28?

- 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)?
- Has taking this medication impacted your emotional or mental well-being? How?

Field	Response
Response to Question 30a3	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 30a4: [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 30a4	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 31: Information on the Medication(s) Used in the Past to Treat Your Condition

Question 31a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Question 28?

Field	Response
Response to Question 31a	*YES or NO*

If you answer yes, review Question 31b1 through 31b4. If you answer no, skip to Question 32.

Question 31b1: [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 28?

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

Field	Response
Response to Question 31b1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 31b2: [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 28?

- What other factors, if any, affected the choice of medication(s) used in the past to manage the condition(s) you listed in Question 28?
- For example, factors could include side effects, cost, interactions with other medication, whether your local pharmacy or mail order pharmacy could provide it, family influence, interference with your work or life, other health condition(s), whether the medication was covered by your insurance, whether your medical provider recommended the medication based on clinical guidelines or clinical experience, or other things that influenced your choice.

Field	Response
Response to Question 31b2	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 31b3: [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 28?

- 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)?
- Has taking this medication impacted your emotional or mental well-being? How?

Field	Response
Response to Question 31b3	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 31b4: [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 28?

Field	Response
Response to Question 31b4	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 32: 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 32	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 33: Demographic Questions [Only when a respondent selects the "patient" or "caregiver" option in response to Question 27.]

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: Under 18 years 18-24 years 25-34 years 35-44 years 45-64 years 65-84 years 85-99 years 100 years or older
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

Field	Response Options
	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: AR, 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 34 through 39: Manufacturer-Focused Questions

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 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 34 through 39

Manufacturers are permitted to submit a dossier in Question 39. Dossier submission is optional. Such dossiers may be used to supplement responses provided in Questions 34 through 38. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 34 through 38, to the extent applicable.

Question 34: Potential therapeutic alternatives

Provide a list of potential therapeutic alternatives CMS should consider for the indication(s) of [the selected drug]. For the list of potential therapeutic alternatives and indications, provide a brief explanation of the reason for the identification of the therapeutic alternative(s) of the selected drug and any indication(s).

Field	Response
List the potential therapeutic alternatives of the selected drug, along with which indication(s) of the selected drug the respondent would like CMS to consider for each of the potential	*Text* (12,000 character count limit, which is approximately 1,000 words)

Field	Response
therapeutic alternatives listed	

Question 35: Use in treatment and clinical comparative effectiveness evidence

Question 35a: Describe the selected drug's use in the course of care for its indication(s) 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 34*) in the course of care for the indication(s) relative to the selected drug.

Field	Response
Response to Question 35a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 35b: For the indication(s) identified in the instructions and Question 34, identify relevant clinical outcome measures CMS should consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety). Include references to any supporting citations listed in Question 56 for identified clinical outcome measures.

Field	Response
Response to Question 35b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 35c: For the indication(s) 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. Include references to any supporting citations listed in Question 56 for relevant comparative evidence.

Field	Response
Response to Question 35c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 36: Prevalence, utilization, and cost estimates

Question 36a: For the indication(s) of the selected drug, provide an estimate of its prevalence among the Medicare population. Include references to any citations listed in Question 56 and/or brief methodology to support the estimate(s).

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

Question 36b: For the indication(s) 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. Include references to any citations listed in Question 56 and/or brief methodology to support the estimate(s).

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

Question 36c: For the indication(s) 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 potential therapeutic alternatives. Include references to any citations listed in Question 56 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 36c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 37: Therapeutic advance and unmet medical need

Question 37a: For the indication(s) of the selected drug, describe the extent to which the selected drug currently represents a therapeutic advance as compared to its potential therapeutic alternative(s).

Field	Response
Response to Question 37a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 37b: For the indication(s) of the selected drug, describe the extent the selected drug and its potential therapeutic alternative(s) address an unmet medical

need.

Field	Response
Response to Question 37b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 38: Specific populations and patient experience

Question 38a: For the indication(s) of the selected drug, identify any specific populations that are impacted by the selected drug and/or its potential therapeutic alternative(s), and describe how they are impacted. Include any supporting citations listed in Question 56.

Field	Response
Response to Question 38a	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 38b: For the indication(s) of the selected drug, identify evidence regarding patient experiences related to the indication(s), selected drug, and/or its potential therapeutic alternative(s). 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. Reference any supporting citations listed in Question 56.

Field	Response
Response to Question 38b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 39: Dossier Submission

Manufacturers are permitted to submit a dossier in Question 39. Such dossiers may be used to supplement responses provided in questions 34 through 38, 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 within the drug dossier** that the manufacturer suggests is related to Questions 34 through 38, 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
Text (Up to 2 PDF files in a Zip file, one of these files should include an outline of the location of the information in the drug dossier related to Questions 34 through 38, as applicable)

Questions 40 through 45: 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 potential 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 potential therapeutic alternative(s) for these indication(s).

Question 40: Background Questions

Question 40a: Are you a health care provider (i.e., a person who is trained and licensed to give health care[45])?

Field	Response
Response to Question 40a	*YES or NO*

If you answer yes, review Questions 40a1. If you answer no, skip to Question 40.

Question 40a1: [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 40a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 40b: Do you have experience prescribing or managing the use of [the selected drug]?

Field	Response
Response to Question 40b	*YES or NO*

If you answer yes, review Question 40b1. If you answer no, skip to Question 40b2.

Question 40b1: [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?

Field	Response
Response to Question 40b1	*Text* (6,000 character count limit, which is approximately 500 words)

[45] Refer to the CMS Glossary for the term of "health care provider" available at: https://www.cms.gov/glossary.

Question 40b2: [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 40b2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 41: Treatment-related Questions

Question 41a: What are goals of treatment for the condition(s) treated by [the selected drug]?

- Examples of treatment goals may include but are not limited to disease remission, symptom management, quality of life improvement, or cure.

Field	Response
Response to Question 41a	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 41b: What outcomes do you use to assess improvement or treatment response for this indication(s)?

- Please provide specific clinical, functional, or patient-reported outcomes.

Field	Response
Response to Question 41b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 41b1: What would you consider to be a meaningful improvement or treatment response for the outcomes listed in Question 41b?

Field	Response
Response to Question 41b1	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 41b2: Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?

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

Question 41c: 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. For off-label use, please also reference any citations listed in Question 56 for major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.

Field	Response
Response to Question 41c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 42: Additional Treatment-related Questions

Question 42a: 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 42a	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42b: 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 42b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42c: What medications would you consider to be potential therapeutic alternatives for [the selected drug] for treatment of the condition(s) treated with [the selected drug]? For the list of potential therapeutic alternatives and indications, provide a brief explanation of the reason for the identification of the potential therapeutic alternative(s) of the selected drug and any indication(s). Reference any citations listed in Question 56 where applicable.

Field	Response
Response to Question 42c	*Text* (12,500 character count limit, which is approximately 1,000 words)

Question 42d: What considerations drive treatment selection among [the selected drug] and its potential therapeutic alternative(s) 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 42d	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42e: Are there notable differences between how [the selected drug] or the potential therapeutic alternative(s) identified in Question 42c 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]?

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

Field	Response
Response to Question 42e	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42f: How would you characterize the benefits and risks associated with [the selected drug]?

Field	Response
Response to Question 42f	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42f1: 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 potential therapeutic alternative(s) for the condition(s) treated with [the selected drug]?

Field	Response
Response to Question 42f1	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42f2: In your opinion, how do the benefits and risks associated with [the selected drug] differ from the benefits and risks associated with its potential therapeutic alternative(s) for the indication(s)?

Field	Response
Response to Question 42f2	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42f3: 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 potential therapeutic alternative(s) for the indication(s)?

Field	Response
Response to Question 42f3	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 42g: How would you assess whether a patient is tolerating and/or responding to [the selected drug] or any of its potential therapeutic alternative(s) 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 42g	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 43: Access and Patient Experience

What health insurance coverage or access issues do patients experience when trying to obtain [the selected drug] and its potential therapeutic alternative(s) for the condition(s) treated by [the selected drug]?

Field	Response
Response to Question 43	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 44: Therapeutic Advance and Unmet Medical Need

Question 44a: 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 potential therapeutic alternative(s).

Field	Response
Response to Question 44a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 44b: 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 44b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 44c: 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 44c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 45: What other information about [the selected drug], its potential therapeutic alternative(s), or the indication(s) do you think CMS should consider in its evaluation of [the selected drug]? Reference any citations listed in Question 56 when applicable.

Field	Response
Response to Question 45	*Text* (36,000 character count limit, which is approximately 3,000 words)

Questions 46 through 51: 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 potential 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 46: 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 46	*YES or NO for each item 1-3 (listed above in question)*

Question 46a: On which indication(s) (which includes off-label use(s) per the definition provided in the instructions) of [the selected drug] would you like to provide input?

Field	Response
Response to Question 46a	*Text* (6,000 character count limit, which is approximately 500 words)

Question 47: Potential Therapeutic Alternatives

What medications would you consider to be potential therapeutic alternatives for [the selected drug] for each indication(s)? For the list of potential therapeutic alternative(s) and indications, provide a brief explanation of the reason for the identification of the potential therapeutic alternative(s) of the selected drug and any indication(s). Reference any citations listed in Question 56 where applicable.

Field	Response
Response to Question 47	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 48: Comparative Clinical Evidence

Question 48a: 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 reference any citations listed in Question 56 where applicable.

Field	Response
Response to Question 48a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 48b: 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 alternative(s) for the indication(s)? Reference any supporting citations listed in Question 56 where applicable.

Field	Response
Response to Question 48b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 48c: For the indication(s) 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 alternative(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. Reference any supporting citations listed in Question 56.

Field	Response
Response to Question 48c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 49: Specific Populations and Patient Experience

Question 49a: What evidence are you aware of regarding patient experiences related to use of [the selected drug], its potential therapeutic alternative(s), 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. Reference any supporting citations listed in Question 56.

Field	Response
Response to Question 49a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 49b: What specific populations or patient subgroups are impacted by [the selected drug] and/or its potential therapeutic alternative(s) 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 potential therapeutic alternative(s) on the specific populations. Reference any supporting citations listed in Question 56 where applicable.

Field	Response
Response to Question 49b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 49c: What considerations related to health insurance coverage or access to [the selected drug], its potential therapeutic alternative(s), and/or or this condition(s) treated by [the selected drug]? Reference any supporting citations listed in Question 56 where applicable.

Field	Response
Response to Question 49c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 50: Prevalence, Utilization, and Cost Estimates

Question 50a: For each indication(s), provide an estimate of prevalence among the Medicare population. Reference any citations listed in Question 56 and/or provide a brief methodology to support the estimate.

Field	Response
Response to Question 50a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 50b: For each indication(s), provide an estimate for Medicare utilization of [the selected drug] and/or its potential therapeutic alternative(s). Estimates of Medicare utilization can include estimates of total number of patients treated, estimated share of [selected drug] prescriptions dispensed, furnished, or administered to patients for a given indication, or similar measures. Reference any citations listed in Question 56 and/or provide a brief methodology to support the estimate.

Field	Response
Response to Question 50b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 50c: 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 alternative(s). 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 potential therapeutic alternative(s). Reference any citations listed in Question 56 and/or provide 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 50c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 51: What other information or evidence do you think CMS should consider in the evaluation of [the selected drug]? Reference any citations listed in Question 56 when applicable.

Field	Response
Response to Question 51	*Text* (36,000 character count limit, which is approximately 3,000 words)

Questions 52 through 54: Other Public Input

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

Question 52: 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 52	*Text* (6,000 character count limit, which is approximately 500 words)

Question 53: What is your experience with [the selected drug] or the condition(s) it treats?

Field	Response
Response to Question 53	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 54: What information or evidence do you think CMS should be aware of as it evaluates [the selected drug] for each indication(s)? Reference any citations listed in Question 56 when applicable.

Field	Response
Response to Question 54	*Text* (36,000 character count limit, which is approximately 3,000 words)

Questions 55 and 56: Visual Information and Citations

Question 55: Visual Representations to Support Responses in Section I
Provide up to 20 visual representations such as tables, charts, and/or graphs that support the responses in Section I. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded in the single Zip file, respondents may not submit more than 20 total visuals (e.g., tables, charts, and/or graphs).

RESPONSE	FIELD
Text (Up to 20 PDF files in a single Zip file)	*Indicate Question Each File Corresponds To By Selecting the Applicable Question From a List*

Question 56: Citations to Support Responses in Section I
Provide up to 250 citations that support the responses provided in Section I. Citations should be labeled with a number corresponding to the number used by the respondent to reference the source in-text throughout Section I. Citations should be listed in the order the citation is first used within Section I. For example, the citation #1 included on the citation list, can be referenced in-text as such (1).

Provide each citation 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 available,

please include a Pub Med ID (https://pubmed.ncbi.nlm.nih.gov/) or, if the Pub Med ID is not available, include the Digital Object Identifier (DOI) (https://www.doi.org/). Additionally, please provide a hyperlink to the source, if possible.

Respondents must upload a single PDF document of the list of citations in a Zip file. To create the PDF document, respondents may use an Excel file that includes the information specified in the data fields below for each citation listed by the respondent.

RESPONSE	FIELDS
Text (Up to 250 citations within a PDF file in one Zip file)	• *Numbered List* • *Full Citation* • *PubMed ID, if available* • *If the PubMed ID is not available, the Digital Object Identifier (DOI), if available* • *Hyperlink, if available*

An example of how a respondent may format the response fields within an Excel file is also included below for reference.

Numbered List	Full Citation	PubMed ID, if available [if no PubMed, provide DOI]	Hyperlink, if available
1	Surname First-and-Middle-Initials, Surname First-and-Middle Initials. Article Title. Journal Title. Date of Publication; Volume (Issue): Pagination.	123456789	www.pubmed.com/example

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

Question 57: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld as Proprietary Information

In addition to the information CMS already designates as proprietary consistent with section 40.2.1 of the final guidance:[46] For each question that a respondent to Section I believes contains information that should be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including under Exemptions 3 and/or 4 of the FOIA, follow the instructions to below to identify this information for CMS. This identification of information by a

[46] Specifically, as described in section 40.2.1 of the final 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 approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that is publicly available as non-proprietary.

respondent to Section I will be used during CMS' process to determine which information submitted is proprietary and which information may be disclosed in the public explanation of the MFP consistent with section 60.6.1 of the final guidance.

- Using [brackets] at the start and end of any full sentence(s) within a free response field(s) that contains information the respondent believes should be withheld. Also use [brackets] at the start and end of any data provided, if permitted in the data entry field (for example, because the field is a text field), to identify information the respondent believes should be withheld.
    - Label the end of each bracketed sentence with a number in sequential order and use the same number originally assigned to a bracket throughout Section I each time the same justification will be used in response to Question 57 as the reason the respondent believes the information should be withheld (e.g., {1}, {2}). To differentiate references in response to Question 57 from citations, use different symbols for numbering (for example, a {curly brace} for Question 57 and (parenthesis) for citations).
- In the "Location" data field, identify the location of the information the respondent believes should be withheld in Section I by either:
    - For a data response field where brackets cannot be entered (for example, a visual representation) (in other words, a "non-bracketed location"), listing the specific location of the information by identifying the Question number, data entry field, and/or line number to specifically identify the starting and ending point, of information the respondent believes should be withheld.
- In the "Justification" data field, provide a brief explanation regarding why respondent believes the information should be withheld as proprietary information.
    - For a bracketed item, provide the Justification for each separate number used within Section I (e.g., {1}, {2}). Do not repeat the same Justification.
        - If a Primary Manufacturer provides a Section I submission and includes a response to Question 57, restart numbering at {1} in Section I.
    - For a non-bracketed location, if the Justification is the same Justification as a bracketed item, the respondent should use the number assigned to the bracketed item with the corresponding justification as the response to the "Justification" data field. For example, if a non-bracketed item's Justification is the same as the Justification for bracketed item {1}, the respondent should enter "{1}" in the Justification response field for that non-bracketed item.

LOCATION (List the Bracket Number (E.g. {1}, {2}) or Question/Data Entry Field/Line Number))	**JUSTIFICATION**
List of Bracket Locations, in Order of First Appearance (E.g. {1}, {2}); Add a row for each additional item	*Text* (2,400 character count limit, which is approximately 200 words)
List of Non-Bracketed Locations, Identified by the, Question, Data Entry Field and/or Line Number; Add a row for each additional item	*Text (each item 2,400 character count limit, which is approximately 200 words)*

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.

Checkbox to indicate yes [ ]

Contact Information for respondent:

Field	Response
Name of the Person Responsible for the Submission	*Text*
Signature	*Text*
Date	*MMDDYYYY*

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 information collection is both a mandatory and voluntary information collection and this information will be used to implement Sections 11001 and 11002 of the Inflation Reduction Act. 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 1,000 total hours per response for the manufacturers of selected drugs for negotiation and 750 hours for manufacturers of selected drugs for renegotiation, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. This information collection is both mandatory and voluntary (sections 1193(a)(4) and 1194(e)(1) and (2) of the Social Security Act) and will be carried out consistent with the confidentiality requirements specified at section 1193(c) of the Social Security Act and section 40.2.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028. 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 AND RENEGOTIATION PROCESS COUNTEROFFER ICR FORM

Section 1193(a)(1) of the Social Security Act ("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 final 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 2028, 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 2028, February 28, 2026. 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 1194(b)(2)(B) and 1194(f)(4)(B) of the Act and sections 60.4 and 130.4.3 of the final guidance, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug or the proposal for the renegotiated MFP for a selected drug for initial price applicability year 2028 no later than June 1, 2026. In accordance with sections 1194(b)(2)(C) and 1194(f)(4)(B) of the Act and sections 60.4 and 130.4.3 of the final guidance, the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit a written counteroffer (referred to herein as the "statutory written counteroffer" for the negotiation process and the "renegotiation written counteroffer" for the renegotiation process, collectively referred to herein as the "Counteroffer), including an Addendum populated with the proposal for the MFP. In accordance with sections 1194(b)(2)(D) and 1194(f)(4)(B) of the Act and sections 60.4 and 130.4.3 of the final guidance, CMS will provide a written response to the statutory written counteroffer and the renegotiation written counteroffer, respectively. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later. If CMS rejects the Primary Manufacturer's Counteroffer, CMS and Primary Manufacturers can choose to initiate additional, written offers and counteroffers via the additional price exchange module in the CMS HPMS. Sections 60.4 and 130.4.3 of the final guidance describes the remainder of the negotiation process and renegotiation process in greater detail, respectively.

Every written offer and counteroffer, including a Counteroffer, will include an Addendum populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process or the renegotiation process in accordance with sections 60.4 and 130.4 of the final guidance, respectively, the Addendum to the Agreement, as described in section 40.3 of the final guidance, will be executed by both parties and will constitute agreement on the MFP. The MFP included in the executed Addendum will apply for the selected drug for initial

price applicability year 2028, subject to the conditions and timing described in section 70 of the final guidance and will be updated according to section 1195(b)(1)(A) of the Act for subsequent years in the price applicability period, as applicable. Refer to section 60.6 of the final guidance for information on how the MFP will be updated for subsequent years in the price applicability period.

This document describes the ICR that may occur during the negotiation and renegotiation process if the Primary Manufacturer chooses to develop and submit a Counteroffer to CMS' written initial offer during the negotiation or renegotiation process for initial price applicability year 2028.

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

Note: This ICR focuses on information required for the submission of Counteroffers during the negotiation and renegotiation process for initial price applicability year 2028.

Instructions for Completing the Counteroffer ICR Form

A Primary Manufacturer that seeks to submit a Counteroffer for its selected drug must complete and submit the information requested in the Statutory Written Counteroffer ICR Form or the Renegotiation Written Counteroffer ICR Form, as applicable, in the CMS Health Plan Management System (CMS HPMS) in order for CMS to consider the Primary Manufacturer's Counteroffer.

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

- The Primary Manufacturer's Counteroffer proposal for the MFP per 30-day equivalent supply of the selected drug (as described in section 60.1 of the final 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 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 proposal for the MFP and additional information it deems relevant, such as a request to include certain information from the Counteroffer justification in CMS' public

explanation of the MFP, and;

- A certification 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 ICR Form are as follows:

- If the Primary Manufacturer chooses to submit the Counteroffer ICR 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 enter its Counteroffer proposal for the MFP for a 30-day equivalent supply of the selected drug. CMS will interpret this proposal 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 or renegotiation 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 proposal for the MFP 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. Total character counts include all characters within the response, including spaces between words.
- 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 final 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 visual representations of information, including charts, tables, and/or graphs, as part of the ICR to support the justification. The information submitted in the space for visual representations should only include the table, chart, or graph, with no additional text beyond the titles, labels, legends, and footnotes in the visual representation. If the Primary Manufacturer provides additional text, such as extensive narrative descriptions embedded within a visual representation, CMS will not review such additional text. PDF files will be accepted within specified file size limits for visual representations. PDF files must be uploaded together in a Zip file. 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 visual representations 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.
- 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

Statutory Written 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 2028. In accordance with section 1194(b)(2)(B) of the Act, CMS has provided the Primary Manufacturer of the selected drug named above 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 statutory written counteroffer in accordance with section 1194(b)(2)(C).

In order for CMS to consider the Primary Manufacturer's statutory written 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 statutory written counteroffer proposal for the MFP for the selected drug in the table below. CMS will interpret this proposal 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 statutory written counteroffer proposal for the MFP 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.

Proposal for the MFP per 30-day equivalent supply
$

Question 2: Please provide a justification of the statutory written counteroffer proposal for the MFP based on the factors in section 1194(e) of the Act. This statutory written 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 statutory written counteroffer.

FIELD	RESPONSE FORMAT
Statutory Written Counteroffer Justification	*Text* (30,000 character count limit, which is approximately 2,500 words)
Additional Materials to Support the Justification	*Text* (Up to 50 citations) [file upload] (Up to 10 tables/charts/graphs)

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 Statutory Written Counteroffer ICR 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 information collection includes the form a Primary Manufacturer must submit in order to submit a statutory written counteroffer for a selected drug, and this information will be used to implement Sections 11001 and 11002 of the Inflation Reduction Act. 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 to review and complete the information collection. This information collection is required to retain or obtain a benefit (section 1194(b)(2)(C) of the Social Security Act) and will be carried out consistent with the confidentiality requirements specified at section 1193(c) of the Social Security Act and section 40.2.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028. 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

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Renegotiation Written 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 2028. In accordance with section 1194(f)(4)(B) of the Act and section 130.4.3 of the final guidance, CMS has provided the Primary Manufacturer of the selected drug named above 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 renegotiation written counteroffer.

In order for CMS to consider the Primary Manufacturer's renegotiation written 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 renegotiation written counteroffer proposal for the MFP for the selected drug in the table below. CMS will interpret this proposal 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 renegotiation written counteroffer proposal for the MFP 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.

Proposal for the MFP per 30-day equivalent supply
$

Question 2: Please provide a justification of the renegotiation written counteroffer proposal for the MFP based on the factors in section 1194(e) of the Act. This renegotiation written 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 renegotiation written counteroffer.

FIELD	RESPONSE FORMAT
Renegotiation Written Counteroffer Justification	*Text* (30,000 character count limit, which is approximately 2,500 words)
Additional Materials to Support the Justification	*Text* (Up to 50 citations) [file upload] (Up to 10 tables/charts/graphs)

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 Renegotiation Written Counteroffer ICR 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 information collection includes the form a Primary Manufacturer must submit in order to submit a renegotiation written counteroffer for a selected drug, and this information will be used to implement Sections 11001 and 11002 of the Inflation Reduction Act. 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 to review and complete the information collection. This information collection is required to retain or obtain a benefit (section 1194(b)(2)(C) of the Social Security Act) and will be carried out consistent with the confidentiality requirements specified at section 1193(c) of the Social Security Act and section 40.2.1 of the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027, and 2028. 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