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

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

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

PART 1: NEGOTIATION DATA ELEMENTS ICR FORM

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

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

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

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

1191(c)(1) of the Act, the statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In accordance with section 40 of the 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 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter the "Primary Manufacturer").

Likewise, in accordance with section 40 of the 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]."

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

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

General Instructions

Overview

In accordance with section 50 of the 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

[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.

selected drug(s) from other parties, as applicable.

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

Submission Method

Primary Manufacturers will submit the information for Sections A through J via the CMS Health Plan Management System ("the CMS HPMS"), which can be accessed here: https://hpms.cms.gov/. Manufacturers of high-expenditure, single source drugs may register for access to the CMS HPMS, and are encouraged to do so before the questions for this ICR are available to access in the CMS HPMS. Instructions for manufacturers to gain access to HPMS can be found in the "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)" PDF.[3] Instructions for gaining signatory access to the CMS HPMS are also included in this PDF. Technical assistance will also be made available.

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

Submissions may be saved while work is in progress. Primary Manufacturers and interested parties may also wish to draft their submission outside of the 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

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

IRARebateandNegotiation@cms.hhs.gov.

- For Sections A through G of this form, the Primary Manufacturer must provide data **only with regard to the selected drug as identified** under section 1192 of the Act. If a Primary Manufacturer has more than one selected drug, the Primary Manufacturer is required to make a separate submission of the information required in Sections A through G of this ICR for each selected drug.
- All response fields are limited to a character count. The field and response format sections provide a character count and an estimated word count.
- Certification is required for submissions. Section H includes the Certification of Submission of Sections A through G for Primary Manufacturers. Section J includes the Certification of Submission of Section I for all respondents.
- For Sections A through G of this form, CMS will pre-populate or the Primary Manufacturer must submit, as indicated in the section, the applicable data for all dosage forms and strengths of the selected drug, including for dosage forms and strengths that were sold, labeled, or packaged by a Secondary Manufacturer.
- For non-monetary numeric amounts, include up to three decimal places.
- Response formats are indicated within any charts included in Sections A through G and Section I (e.g., # to indicate a numerical response is required).
- Primary Manufacturers must timely notify CMS if any of the information submitted changes after the initial submission of data, including as set forth in sections 40.2 and 50.1 of the 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.
- 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 FOIA Exemptions 3 and/or 4 (5 U.S.C. § 552(b)(3), (4)), [5] Primary Manufacturers are instructed to complete Question 27 regarding such applicable information provided in response to Sections A through G, and any interested party is instructed to complete Question 62 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 section 1194(e)(2) data submitted publicly, without sharing any personally identifiable information [6] (PII) or protected

[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 as non-proprietary because CMS understands these data are publicly available.

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

[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,

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 related to this ICR and the Medicare Drug Negotiation Program only.

Instructions for Reporting Monetary Amounts

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

facial photos, or work address; and, contextual information, such as a file for a specific health condition that contains a list of treated patients. See: https://www.hhs.gov/web/policies-and-standards/hhs-web-policies/privacy/index.html#what-is-pii.

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

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

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

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

(2) the GAAP Accounting Standard Certification (ASC) 830 for translating foreign currencies.

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

A. Selected Drug Information

Primary Manufacturer Response Required

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

(1) had Part D PDE utilization in the 12-month period beginning November 1, 2023 and ending October 31, 2024, or

(2) CMS believes are likely to have Part D PDE utilization in the future (for example, NDC-11s associated with recently approved NDAs / BLAs).

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

Definitions for Section A:

- Average Manufacturer Price (AMP) unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Drug sample: A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug (21 U.S.C. § 353(c)(1)).
- Labeler code: The first segment of the FDA-assigned NDC (21 C.F.R. § 207.33(b)(1)(i)). Each entity 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 are missing from the list (e.g., because they are new NDC-11s, discontinued NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug, provide the missing NDC-11 and corresponding Product Name and Labeler Code.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, provide the NCPDP Unit, Total NCPDP Units Per Package, AMP Unit and Total AMP Units Per Package.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, indicate whether:
  (1) any of the listed NDC-11s or additional NDC-11s are marketed and controlled solely by a manufacturer that is not the Primary Manufacturer or a Secondary Manufacturer,
  (2) any of the listed NDC-11s or additional NDC-11s are distributed by a private label distributor,
  (3) any of the listed NDC-11s or additional NDC-11s have been discontinued and the date of discontinuation [11], and
  (4) any of the listed NDC-11s or additional NDC-11s are a sample package, outer package, or inner package.
- If an NDC-11 is not controlled by a Primary or Secondary Manufacturer and the Primary Manufacturer is not able to determine the information for the NDC, select "Unknown" in response to whether the NDC-11 is "Marketed and Controlled Solely by a Manufacturer that is not the Primary or Secondary Manufacturer."

Product Name	**NDC-11 Numbers**	**Marketed and Controlled Solely by a Manufacturer that is not the Primary or Secondary Manufacturer**	**Discontinued** (Select if NDC-11 has been discontinued and provide date of discontinuation)	**Sample Package** (Select if NDC-11 is a sample package)	**Inner Package** (Select if NDC-11 is an 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, table, 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/Unknown*	*Text* *Date if Applicable*	*Text*	*Text*	*Text*	*Text*	*Text*	*#*	*Text*	*#*	*Numbers to be pre-populated by CMS*

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

B. Non-FAMP Data Collection

Primary Manufacturer Response Required

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

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

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

Definitions for Section B:

- Non-FAMP: Section 1194(c)(6) of the Act defines "average non-Federal average manufacturer price" as the average of the non-FAMP (as defined in 38 U.S.C. § 8126(h)(5)) for the four calendar quarters of the year involved.[12] For initial price applicability year 2027, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and 2024 (i.e., the calendar year prior to the statutorily-defined selected drug publication date, February 1, 2025). When there are less than 30 days of commercial sales data for all NDC-11s of the selected drug in calendar year 2021, the applicable year will be the first full calendar year following market entry of such drug. When there are at least 30 days of commercial sales data but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021, the Primary Manufacturer should submit 2021 data—to the extent that it exists—for all NDC-11s of the selected drug. For a given NDC-11 of such drug, when there are at least 30 days of commercial sales but less than a calendar quarter of data to calculate the non-FAMP in calendar year 2021 (or the first full year following market entry of such drug, when applicable) or 2024, the non-FAMP reported by the Primary Manufacturer to CMS should reflect the temporary non-FAMP predicated upon the first 30 days of commercial sales data. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2024 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.[13] 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).

Instructions for Section B:

Please follow the instructions below when completing the following tables.

[12] 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).

[13] See: https://www.va.gov/opal/docs/nac/fss/pl102585-2024-pbm-fcp-guidance-for-new-covered-drugs.pdf.

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

Table 1

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

Table 2

NDC-11	Calendar Quarter for 2024	Calendar Year	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
12345-6789-01	*QQ*	*YYYY*	*#*	*$*	*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

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

Definitions for Section C:

R&D costs mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications[14] of a drug falling into the five categories below, and excluding the

[14] For purposes of this ICR, CMS distinguishes between the use of the word "indication" and the term "FDA-approved indication" such that "FDA-approved indication" refers to the information included in drug labeling per 21 C.F.R. § 201.57(c)(2) or other applicable FDA regulation(s), and "indication" refers to the condition or disease state for which the selected drug is used. CMS will use "indication" for purposes of determining the initial offer, as

described in the final guidance.

following: (a) prior Federal financial support, (b) costs associated with applying for and receiving foreign approvals, and (c) costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

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

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

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

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

Instructions for Section C:

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

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

Question 1: Primary Manufacturer Acquisition Costs of the Selected Drug

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

Definitions for Question 1:

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

Instructions for Question 1:

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

RESPONSE FORMAT
Yes/No

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

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

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

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

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

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

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

described in more detail below.

Definitions for Question 2:

- Basic pre-clinical research costs are defined as all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses (defined below).
- For each FDA-approved indication of the selected drug, the basic pre-clinical research period is defined as the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the potential NDA(s) / BLA(s) or NDA(s) / BLA(s) of the selected drug (whichever is later) to the day before the last IND application for that FDA- approved indication of the selected drug went into effect.[15, 16] The basic pre-clinical research period may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. For example, if the selected drug had five IND applications that went into effect, use the date of the first IND application that went into effect as the end date for the 52-month period.[17]
- 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 biologics. 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

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

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

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

six years. See PhRMA, “Biopharmaceutical Research & Development: The Process Behind New Medicines,” 2015.

spending for indirect research.[18, 19] For example, if the *direct* pre-clinical research costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs for that period of time, then *indirect* costs should be allocated proportionally. Thus, for the selected drug, they should be 10 percent of the total spending on *indirect* pre-clinical research costs during that time period.

Instructions for Question 2a:

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

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

Instructions for Question 2b:

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

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

Instructions for Question 2c:

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

[18] 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.

[19] 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.

FIELD	RESPONSE FORMAT
Explanation of Basic Pre-Clinical Research for All-Approved Indications of the Selected Drug, Including Allocation and Apportionment Methods	*Text (30,000 character count limit, which is approximately 2,500 words)*

Question 3: Post-IND Costs for All FDA-Approved Indications of the Selected Drug
Please provide the following information on the direct costs incurred by the Primary Manufacturer beginning on the day the IND went into effect for the first FDA-approved indication for the selected drug through the date when the last FDA-required post-marketing trial was completed for the selected drug. The Primary Manufacturer must report the direct costs for all completed post-marketing trials for all FDA-approved indications of the selected drug. *Do not report costs for indications that are not FDA-approved indications for the selected drug.*

Definitions for Question 3:

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

Instructions for Question 3a:

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

acquisition and were incurred before the FDA approved the most recent FDA-

approved indication, those costs may be reported in the numerical response field. For example, if a Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug during the Phase I trial for the most recent FDA-approved indication, it may report the costs of the trials that followed the acquisition in the numerical response field.

- If the Primary Manufacturer acquired the right to hold the NDA(s) / BLA(s) of the selected drug after FDA-required post-marketing trials were completed or if no such post-marketing trials were completed for the selected drug, do not include any costs for these post-marketing trials in the numerical response field.
- If the selected drug received accelerated approval for any FDA-approved indication, include the direct costs for any completed post-approval confirmatory studies in the numerical response field. Direct costs for any post-approval confirmatory studies that have not been completed should be reported in Question 5.

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

Instructions for Question 3b:

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

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

Instructions for Question 3c:

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

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

Instructions for Question 3d:

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

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

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

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

Definitions for Question 4:

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

Instructions for Question 4a:

- In the numerical response field, only include costs that can be directly attributed to failed or abandoned product(s) with the same active moiety / active ingredient or mechanism of action *or* drugs in the same therapeutic class as the selected drug that did not receive FDA approval. Any non-monetary compensation for investigators and staff, patient recruitment, and per-patient costs included in the total amount should reflect the fair market value for such compensation at the time it was provided.
- Do not include acquisition costs for failed or abandoned products in the numerical response field. Such costs should be reported in Question 5.

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

Instructions for Question 4b:

- List all the applicable direct costs included in the numerical value given in Question 4a.

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 4c:

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

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

Question 5: Direct Costs of Other R&D for the Selected Drug Not Accounted for Above
The Primary Manufacturer must report the dollar amount of direct costs it attributes to R&D that was not accounted for in Questions 1 through 4.

Definition for Question 5:

- All other R&D direct costs are any other allowable costs that do not align with R&D definitions 1 through 4. For example, other R&D direct costs may include direct costs associated with conducting FDA-required postmarketing trials and other FDA post-marketing requirements and commitments that were not completed, Phase IV postmarketing studies for FDA-approved indications that were not required by FDA, post-IND costs for indications that did not receive FDA approval, acquisition costs for failed or abandoned products, and costs associated with generating real-world evidence that was submitted to FDA to support the safety or effectiveness of a selected drug or to support or satisfy a post-marketing requirement or commitment.

Instructions for Question 5a:

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

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

Instructions for Question 5b:

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

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

Instructions for Question 5c:

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

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

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

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

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

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

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

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

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

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

- In the numerical response field, report the global, total lifetime net revenue for the selected drug for the global, total lifetime net revenue period; do not make adjustments for inflation.

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

- In the free response field, explain how the final global, total lifetime net revenue was calculated, including any relevant currency conversions. Additionally, report the per calendar year revenue for the global, total lifetime net revenue and specify the calendar year date range(s) for the global, total lifetime net revenue period. Lastly, report the global, total lifetime net revenue for the selected drug for the global, total lifetime net revenue period after making adjustments for inflation and explain the methodology used to make such adjustments for inflation.

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

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

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

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

- In the numerical response field, report the U.S. lifetime net revenue for the selected drug for the U.S. lifetime net revenue period; do not make adjustments for inflation.

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

In the free response field, explain how the final amount was calculated. Additionally, report the per calendar year revenue for the U.S. lifetime net revenue and specify the calendar year date range(s) for the U.S. lifetime net revenue period. Lastly, report the U.S. lifetime net revenue for the selected drug for the U.S. lifetime net revenue period after making adjustments for inflation and explain the methodology used to make such adjustments for inflation.

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

Δ. Current Unit Costs of Production and Distribution

Primary Manufacturer Response Required

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

Definitions for Section D:

- In accordance with section 1191(c)(6) of the Act, the term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.
- Units must be reported in one of the three NCPDP Billing Unit Standard (BUS)[20]: 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:

[20] See: NCPDP BUS: https://standards.ncpdp.org/Billing-Unit- Request.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);
    - Average unit costs during the 12-month period ending December 31, 2024;
    - 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 are defined not to include:
    - R&D costs;
    - Marketing costs; and
    - Transfer prices.
- “Marketing costs” are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, and other paid promotion.
- “Transfer prices” are defined as prices charged for goods, services, or other intangible assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, “controlled group” of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of the Treasury regulations thereunder.

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

Follow the instructions below when answering Questions 7 and 8:

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

- Unit costs reported must represent the average per unit cost (1) within the time period

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

Question 7: Per Unit Production and Distribution Costs
Please complete the following table using additional rows as necessary for the 12-month period ending December 31, 2024.

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

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

Specifically, include any assumptions about costs including but not limited to:
- Allocated general and administrative overhead;
- Cost of capital;
- Labor compensation;
- Any included costs that were incurred outside of the U.S.;
- Allocated shared facility costs;
- Allocated shared transportation or other operational costs;
- Depreciation of facilities, equipment, or other assets involved in the production and distribution of the selected drug; and
- Number of units of drug samples and how their cost was determined.

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

E. Prior Federal Financial Support

Primary Manufacturer Response Required

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

Definitions for Section E:

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

Instructions for Section E:

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

- When completing this section:
    - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to direct costs for the basic pre-clinical research and clinical trials phase of research and development for FDA-approved indications of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to applicable Secondary Manufacturers of a selected drug). These direct costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of FDA-approved indications of the selected drug.
    - Include prior Federal financial support received for indirect costs of developing the selected drug. These indirect costs are operating costs such as administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.
        - To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research.[21, 22] 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

[21] 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.
[22] 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.

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

Question 9: Federal Funding Support Amount

Complete the table below. Do not make adjustments for inflation.

FIELD	RESPONSE FORMAT
Total Federal Financial Support	**$**

Question 10: Explanation of Calculation of Federal Financial Support

Disaggregate the total Federal financial support amount reported above by the amounts allocated to the sources in the list below. Please list amounts in order of highest to lowest. In addition, describe assumptions, methodological steps, and other information needed to calculate the estimates provided in Question 9. If you report a value for "other Federal financial support not

otherwise included elsewhere" in your response to this question, please list the source(s) of that Federal financial support. Please include the identification number for grants and comparable awards. In addition to reporting the total Federal financial support disaggregated amounts without making adjustments for inflation, also report each disaggregated amount adjusted for inflation, specify the year(s) in which the amounts were received, and explain the methodology used to adjust for inflation.

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

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

Question 11: Agreements Between Primary Manufacturer and Federal Government

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

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

Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
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 12 through 14.

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), as of February 1, 2025, both expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
  - All patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
  - All patent applications related to the selected drug that are pending issuance by the USPTO.
  - Patents and patent applications related to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;[23] 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 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).

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

- 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 and prohibitions on the approval of competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE); [24]
    - New Chemical Entity Exclusivity (NCE); [25]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP); [26]
    - New Clinical Investigation Exclusivity (NCI); [27]
    - Pediatric Exclusivity (PED); [28] and
    - Reference Product Exclusivity for Biological Products. [29]
- Active and pending FDA applications and approvals include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided.

Instructions for Section F:

- For Questions 12 through 14, the relevant time period for reporting begins on the later of the date that basic pre-clinical research began on the selected drug or the date the selected drug was acquired by the Primary Manufacturer and ends on the date the most recent NDA / BLA was approved for the selected drug.
- For Questions 12 through 14, include required data for the selected drug.

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

In the two tables below, please provide information about patents and patent applications related to the selected drug. Question 12A provides a table for reporting information about patents for the selected drug that have been granted by the USPTO. Question 12B provides a table for reporting information about patent applications related to the selected drug that are pending issuance by the USPTO.

Question 12A: Patents (Expired and Non-Expired)

In the table below, please list each patent that is related to the selected drug. For each patent (expired or unexpired) listed in the table 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 table. 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. A PDF file of the USPTO patent application may be uploaded but is not required for this question 12A. Add additional rows to your response to Question 12A as needed.

[24] Section 527 of the FD&C Act.
[25] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[26] Section 505E(a) of the FD&C Act.
[27] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[28] Section 505A(b) & (c) of the FD&C Act.
[29] Section 351(k)(7) of the PHS Act.

Patent Number	Date Filed	Patent Expiry Date	Patent Type	Is Patented Product Commercially Available	Never, Previously, or Currently Listed in FDA Orange Book/Purple Book	Patent Explanation	Patent Application
#	*MM/DD/YYYY*	*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; device patent; other (e.g., patent that claims other chemicals related to the active ingredient, design patent)*	*Yes/No*	*Never/ Previously / Currently*	*Text (3,600 character count limit, which is approximately 300 words*	*Optional. Upload corresponding patent application*

Question 12B: Patent Applications

In the table below, please list each patent application that is related to the selected drug. For each patent application listed in the table 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. Please upload a PDF file of the USPTO patent application. Do not include patent applications that were denied. Add additional rows to your response to Question 12B as needed.

Patent Number	Date Filed	Patent Type	Patent Explanation	Patent Application
#	*MM/ DD/ YY YY*	*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 13: 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. *Complete table for Question 13 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/YY YY*	*#*	*Text*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 14: All Active and Pending FDA Applications and Approvals

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

- Include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided. Leave approval date blank for

those applications not yet approved. *[Complete table for Question 14 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.

Application (NDA / BLA) Number	**Application Type (NDA; BLA)**	**Classification Code**[30]	**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)*

[30] 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 Questions 15 through 26 in this section is to collect the market data and revenue and sales volume data described in section 1194(e)(1)(E) of the Act.

Definitions for Section G:

- Wholesale Acquisition Cost (WAC) unit price: The manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-11 level.
- The three NCPDP BUS [31] are: each (EA), milliliter (ML), and gram (GM). For certain volume data of the selected drug, CMS is requesting units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS.
- Medicaid best price: The Medicaid best price is defined in 42 C.F.R. § 447.505. The Medicaid best price is reported at the NDC-9 level.
- AMP unit: The unit type used by the manufacturer to calculate AMP (42 C.F.R. § 447.504) and best price (42 C.F.R. § 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie. Such units are reported by the manufacturer on a monthly basis at the NDC-9 level.
- Federal supply schedule (FSS) price: The price offered by the VA in its FSS program, by delegated authority of the General Services Administration. [32] The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in 38 U.S.C. § 8126. The Big Four price is reported at the NDC-11 level. [33]
- Manufacturer U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The U.S. commercial average net unit price includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price excludes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance or free drug

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

[32] See: https://www.fss.va.gov/index.asp.

[33] 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.

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 U.S. commercial average net unit price includes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price—net of patient assistance includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price─ net of patient assistance program is reported at the NDC-11 level.
- Manufacturer U.S. commercial average net unit price─ best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The U.S. commercial average net unit price – best includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced- price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price – best excludes manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price – best is reported at the NDC-11 level.
- Manufacturer net Medicare Part D 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. This manufacturer net Medicare Part D average unit price would include specific data, including coverage gap discounts and other supply chain concessions (e.g., wholesale discounts) 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 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. This manufacturer net Medicare Part D average unit price – best would include specific data, including coverage gap discounts and other supply chain concessions (e.g. wholesale discounts) 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 15 through 26, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.
- For questions 15 through 26, 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 or 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.

Question 15: Wholesale Acquisition Cost Unit Price

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

- If the NDC-11 had multiple WACs for a given quarter, please calculate an average WAC per unit for the quarter using the following methodology. For each WAC per unit available in the quarter, please multiply the WAC per unit by the proportion of the total units sold in that quarter at that WAC out of total unit volume sold in the quarter. Then sum these values across all WACs available in the quarter to calculate the average WAC per unit for the quarter.
- Any deviation from the reported WAC unit price in the table below and the WAC unit price as reported in wholesale price guides or other publications of drug or biological price data must be explained in Question 16 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.
- Report all quarters for the three calendar years in 2022, 2023, and 2024. If the NDC-11 was marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed to any wholesaler or direct purchaser in a particular calendar quarter, please enter "0" in the total unit volume field and leave the WAC field blank and provide an explanation in the "Explanation of why WAC was not reported (if applicable)" field of why the NDC-11 had no WAC for that calendar quarter (e.g., the NDC-11 was first marketed in a later calendar quarter).

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

Question 16: Explanation of Information Reported in Question 15: 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 15 and those found in available drug databases (e.g., Medi-Span, First Databank, RED BOOK). Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

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

Question 17: Medicaid Best Price

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

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 19) Follow the instructions below when providing responses in the following table about the Medicaid best price of the selected drug:

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

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

Question 18: Explanation of Information Reported in Question 17: Medicaid Best Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 17. 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 19: Federal Supply Schedule (FSS) Price

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

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 21) Follow the instructions below when providing responses in the following table about FSS prices of the selected drug:

- The FSS price information must reflect what can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs. [34] 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.

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

- For each NDC-11, please include a row for each price period that occurred during the three years ending with the calendar year ending December 31, 2024, and fill out the requested information. If the NDC-11 did not have a FSS price during the three years ending with the calendar year ending December 31, 2024, please enter "0" in the total unit volume field and leave the "Federal Supply Schedule Price" field blank and provide an explanation in the "Explanation of why FSS price was not reported (if applicable)" field of why the NDC-11 had no FSS price for the three years ending with the calendar year ending December 31, 2024 (e.g., the NDC-11 was discontinued before the three year period began).

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 20: Explanation of Information Reported in Question 19: Federal Supply Schedule Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 19. 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 21: Big Four Price

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

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 23) Follow the instructions below when providing responses in the following table about the Big Four price of the selected drug:

- The Big Four price information must reflect the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs. [35] We note that the Big Four price information should be for the NDC-11 package (e.g.,

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

for a bottle of 30 tablets, please report the FSS price for the bottle).

- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). Total unit volume is the total number of units (i.e., EA, ML, or GM) for each NDC-11 indirectly (e.g., through a wholesaler) or directly sold to the Big Four federal agencies (Department of Veterans Affairs, Department of Defense, the Public Health Service, and the Coast Guard). Please do not include units associated with free samples in the reported total unit volume.
- For each NDC-11, please include a row for each price period that occurred during the three years ending with the calendar year ending December 31, 2024, and fill out the requested information. If the NDC-11 did not have a Big Four price during the three years ending with the calendar year ending December 31, 2024, please enter "0" in the total unit volume field and leave the "Big Four Price" field blank and provide an explanation in the "Explanation of why Big Four price was not reported (if applicable)" field of why the NDC-11 had no Big Four price for the three years ending with the calendar year ending December 31, 2024 (e.g., the NDC-11 was discontinued before the three year period began).
- Please complete Questions 19 and 20 for the FFS price of the selected drug and Questions 21 and 22 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 22: Explanation of Information Reported in Question 21: Big Four Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 21. 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 23: Manufacturer U.S. Commercial Average Net Unit Price

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

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

service, and

Medicaid managed care.

- For each NDC-11, please include a row for each quarter for the three years ending with the calendar year ending December 31, 2024, based on the Primary Manufacturer's responses in Section A. If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter "0" in the total unit volume field and leave the three price fields blank and provide an explanation in the "Explanation of why Manufacturer U.S. Commercial prices were not reported (if applicable)" field of why the NDC-11 had no Manufacturer U.S. commercial prices for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- The NDC-11 price reported in the "U.S. commercial average net unit price" field must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers.
- If the Primary Manufacturer or Secondary Manufacturer(s) provided manufacturer-run financial assistance such as coupons, co-payment assistance, or free drug products to patients, separately report the price net of such financial assistance to patients in the "U.S. commercial average net unit price─ net of patient assistance programs" field. If the Primary Manufacturer and Secondary Manufacturer(s) did not provide financial assistance to patients, please leave the "U.S. commercial average net unit price─ net of patient assistance programs" field blank.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to any commercial payer during the quarter in the "Manufacturer U.S. commercial average net unit price─ best" field.
- 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.
- Provide the total unit volume of the lowest price that the Primary Manufacturer and any Secondary Manufacturer(s) sold to any commercial payer during the quarter in the "Total unit volume for U.S. commercial average net unit price – best" field.

NDC-11	Quarter	Manufacturer U.S. Commercial Average Unit Net Price	Manufacturer U.S. Commercial Average Net Unit Price- Net of Patient Assistance Programs	Manufacturer U.S. Commercial Average Net Unit Price- Best	NCPDP Unit (EA, ML, GM)	Total Unit Volume	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	*QQYYYY*	*$*	*$*	*$*	*Text*	*#*	*#*	*Text (3,600 character count limit, which is approximately 300 words)*

Question 24: Explanation of Information Reported in Response to Question 23: Manufacturer U.S. Commercial Average Net Unit Price

Describe assumptions, methodological steps, and other information for the following topics related to Question 23:

- How sales to enrollees of group and individual commercial plans on- and off-Exchange were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-11s and calendar quarters.
- If applicable, how financial assistance, such as coupons or co-payment assistance, to patients was allocated across NDC-11s and calendar quarters.
- How information was used to calculate the "U.S. commercial average net unit price" , 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 25: Manufacturer Net Medicare Part D Average Unit Price

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

- Only include price and volume information of the selected drug for Part D plan sponsors.
- For each NDC-11, please include a row for each quarter for the three years ending with

the calendar year ending December 31, 2024, based on the Primary Manufacturer's responses in Section A. If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter "0" in the total unit volume field and leave the three price fields blank and provide an explanation in the "Explanation of why manufacturer net Medicare Part D Price was not reported (if applicable)" field of why the NDC-11 had no manufacturer net Medicare Part D price for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).

- The NDC-11 price reported in the manufacturer net Medicare Part D price must be net of discounts, including the applicable discount amount provided under the Medicare Coverage Gap Discount Program, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by Primary Manufacturer or any Secondary Manufacturer(s) to any purchasers.
- Provide the Medicare Coverage Gap Discount Program applicable discount amount paid by the Primary Manufacturer or any Secondary Manufacturer(s) during the quarter in the "Medicare Coverage Gap Discount Program" field.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to any Part D plan sponsor during the quarter in the "manufacturer net Medicare Part D average unit price ─ best" field.
- 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.
- Provide the total unit volume of the lowest price that the Primary Manufacturer and any Secondary Manufacturer(s) sold to any Part D plan sponsor during the quarter in the "Total unit volume for net Medicare Part D average unit price – best" field.

NDC-11	**Calendar Quarter**	**Manufacturer Net Medicare Part D Average Unit Price**	**Manufacturer Net Medicare Part D Average Unit Price - Best**	**Medicare Coverage Gap Discount Program Discount Amount Paid**	**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 26: Explanation of Information Reported in Response to Question 25: Manufacturer net Medicare Part D price

Describe assumptions, methodological steps, and other information for the following topics related to Question 25:

- How sales to Medicare Part D enrollees of Part D plan sponsors sales were determined.
- How discounts, including the applicable discount amount provided under the Medicare Coverage Gap Discount Program, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-11s and calendar quarters.
- If applicable, how financial assistance to patients were allocated across NDC-11s and calendar quarters.
- 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 27: 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.[36] For each section and/or question that a Primary Manufacturer believes contains information that should be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including Exemption 3 and/or 4 of the FOIA(5 U.S.C. § 552(b)(3), (4)),[37] list the applicable section letter and question number and provide a brief explanation regarding why the Primary Manufacturer believes the information should be withheld as proprietary information.

Section Letter and Question Number	Explanation
Text	*Text (60,000 character count limit, which is approximately 5,000 words)*

[36] 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 as non-proprietary because CMS understands these data are publicly available.

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

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

Required for Primary Manufacturers

Instruction for Section H:

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

Certification:

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

Yes [ ]
No [ ]

Contact Information to be entered:

Field	**Response**
Name of the Person Responsible for the Submission	*Text*
Signature	*Text*
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 pharmaceutical therapeutic alternative(s), respondents are not

required to include personally identifiable information [38] (PII) or protected health information [39] (PHI). CMS seeks to collect only the minimum necessary information related to the selected drug and its therapeutic alternatives for the purpose of implementing and operating the Negotiation Program. CMS will not retrieve evidence for manufacturer negotiations by personal identifier (PII or PHI). CMS will not, through this collection, create or maintain a system of records as understood by the Privacy Act of 1974 and accompanying Office of Management and Budget guidance.

Question 28: Respondent Information

Required: Individuals or organizations, including manufacturers, that wish to provide information in this Section I must provide the following information. [40]

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

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

[ ] Representative of a manufacturer of the selected drug

[ ] Representative of a manufacturer of a potential therapeutic alternative(s) to the selected drug

[ ] Representative of a manufacturer that does not manufacture the selected drug or 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 therapeutic alternative(s) or treating conditions pertinent to the selected drug

[38] 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.

[39] 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.

[40] 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.

or its 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)]

- Are you or your organization affiliated with the manufacturer of the selected drug or its therapeutic alternative(s)?[41]

General Instructions for Section I

- All questions are optional.
- Any interested party may answer Questions 29 through 60. Each interested party will be able to answer each of Questions 29 through 60 in Section I one time for each selected drug. You may answer some or all of the questions. If you do not wish to respond to a given question you may skip the question or enter "no response."
- Any respondent that answers any of Questions 29 through 60 should also review Questions 61 and 62 and respond as applicable.
- CMS has grouped Questions 29 through 60 in five categories of topics that are addressed by the set of questions. Specifically, these categories by question number are:
    - Questions 29-35: Manufacturer-Focused Input
    - Questions 36-42: Patient- or Caregiver-Focused Input
    - Questions 43-49: Clinical-Focused Input
    - Questions 50-56: Health Research-Focused Input
    - Questions 57-60: 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 29 through 60. These examples are intended as illustrative; a respondent is not limited to any category of questions based on the individual's or organization's insight and/or experience.
    - Manufacturer-Focused Input—for example, a Primary Manufacturer of a selected drug.
    - Patient or Caregiver-Focused Input—for example, an individual with experience taking the selected drug or a different medicine that may be used to treat the same condition or disease state (which is also called a potential therapeutic alternative(s) to the selected drug), a caregiver's experience caring for someone taking such

[41] 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.

drugs, patient organizations with insight into patients' lived experience of taking such drugs or living with a condition the drugs treat.
    - Clinical-Focused Input—for example, clinicians, pharmacists, hospitals, or other entities with clinical experience related to the selected drug, its therapeutic alternatives, or the condition(s) the drugs treat.
    - Health Research-Focused Input—for example, researchers, academic centers, patient groups, or other entities with evidence-based input regarding the selected drug or its therapeutic alternative(s).
    - Other Public Input—any other interested party that wishes to respond to the questions in section I.
- All declarative statements should be supported by evidence with a citation, unless you are sharing a personal experience with prescribing or taking the selected drug and/or its therapeutic alternative(s) or you are a caregiver describing the experience of the person taking the selected drug and/or its therapeutic alternative(s).
- 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.
- Please answer each question in narrative (text) form. Your responses will be limited to the character and citation maximums provided for each question.
    - Information provided in response to an individual question does not need to be duplicated across additional responses. CMS will review submissions holistically across the entire submission.
- Submissions for Section I may include but are not limited to published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports.
    - CMS prefers publicly available, peer reviewed literature rather than poster abstracts and non-peer reviewed literature. When providing non-peer reviewed literature, CMS must be provided sufficient information on these studies in order to assess their applicability to the Negotiation Program.
    - Please note that CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in section 50.2 of the 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 (e.g., [1], [2]) that corresponds to the number assigned to the citations provided for that same question.
    - Respondents are requested to provide citations in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g.,

a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/.

- CMS will review submitted studies that use cost-effectiveness measures or methods to determine if the study is relevant to the selected drug and/or its therapeutic alternative(s) and to determine if the cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than an individual who is younger, nondisabled, or not terminally ill. Respondents must indicate if their submission includes any cost-effectiveness measures or methods. Examples of cost-effectiveness measures or methods include but are not limited to quality-adjusted life-years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), Health Years in Total (HYT), and Generalized Risk-Adjusted Cost-Effectiveness (GRACE). CMS also requests that respondents provide a short description of any cost-effectiveness measures or methods included in the research submitted and the utility they believe the data provides in reviewing the selected drug without treating extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.
- As described in section 50.2 of the 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. [42] 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 will consider such separate evidence. In these cases, indicate clearly in the in-text citation if the evidence provided treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and clearly indicate what separate evidence CMS might consider.
- Submissions may include visual representations of the information, including tables, charts, and/or graphs. The information submitted in the space for visual representations should only include the table/chart/graph, and no additional text. CMS will not review any additional text included beyond the titles, labels, legends, and footnotes in the visual representation. PDF files will be accepted within specified file size limits for visual representations. List the question number that a submitted table/chart/graph corresponds to in the free text response provided with the question to submit tables/charts/graphs.
- Indicate in your response if a portion of a response applies to specific dosages, forms, strengths, and/or indications of a selected drug or its therapeutic alternative(s).
- CMS will only review the maximum number of citations or upload files permitted in the instructions for a particular question per each such question.

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

Definitions for Section I:

- Therapeutic Advance: CMS will determine the extent to which a selected drug represents a therapeutic advance as compared to its therapeutic alternative(s) by examining improvements in outcomes compared to its therapeutic alternative(s) and may consider the extent to which a selected drug represents a therapeutic advance by examining the extent to which the selected drug provides a substantial improvement in outcomes for an indication(s). CMS will consider the extent to which a selected drug represents a therapeutic advance at the time of submission of evidence related to 1194(e) factors through the Negotiation Data Elements and Drug Price Negotiation ICR.
- 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 will consider different therapeutic alternatives for each indication, as applicable. Therapeutic alternatives may be a brand name drug or biological product, generic drug, or biosimilar and may be on-label or off-label to treat a given indication. CMS will identify therapeutic alternatives within the same pharmacologic class as the selected drug based on properties such as chemical class, therapeutic class, or mechanism of action 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 such as cure, survival, progression-free survival, or improved morbidity could be considered when comparing the selected drug to its therapeutic alternative(s). Outcomes such as changes in symptoms or other factors that are of importance to patients and patient-reported outcomes may also be identified and considered in determining clinical benefit, if available. Additional outcomes such as changes to productivity, independence, and quality of life will also be considered to the extent that these outcomes correspond with a direct impact on individuals taking the drug, including patient-centered outcomes when available. The caregiver perspective will 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 including those that may experience disparities in access to care, health outcomes, or other factors when taking the selected drug that impact health equity.
- Health equity: The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography,

[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).

preferred language, or other factors that affect access to care and health outcomes.[44]

- 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.[45] Unmet medical need is determined at the time of submission of this information. Under section 1194(e)(2) of the Act, CMS will consider the extent to 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 nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia. 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, if appropriate, may also choose not to report on certain FDA-approved indications or off-label uses.
- Off-label Use: Off-label use means a use of a selected drug or therapeutic alternative that is not approved by the FDA but is included in nationally recognized, evidence-based guidelines and listed in CMS-recognized Part D compendia.

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

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

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

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

Questions 29 through 61: Optional for All Respondents

Questions 29 through 35: Manufacturer-Focused Questions

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

Instructions for Questions 29 through 35

[44] See: https://www.cms.gov/pillar/health-equity.

[45] 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.

Manufacturers are permitted to submit a dossier in Question 34. Dossier submission is optional. Such dossiers may be used to supplement responses provided in Questions 29 through 33 and 35. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 29 through 33 and 35, to the extent applicable.

Question 29: Potential therapeutic alternatives

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

Indication	**Therapeutic Alternative(s)**
List therapeutic alternatives for the indications	*Text* (6,000 character count limit, which is approximately 500 words)

Question 30: Use in treatment and clinical comparative effectiveness evidence

Question 30a: 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 29*) in the course of care for the indication(s) relative to the selected drug.

Field	**Response**
Response to Question 30a	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 30a	*Text* (Up to 50 citations)

Question 30b: For the indication(s) identified in the instructions and Question 29, identify relevant clinical outcome measures CMS should consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety). Provide supporting citations for identified clinical outcome measures.

Field	**Response**
Response to Question 30b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 30b	*Text* (Up to 50 citations)

Question 30c: 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. Provide supporting citations for relevant comparative evidence.

Field	Response
Response to Question 30c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 30c	*Text* (Up to 50 citations)

Question 31: Prevalence, utilization, and cost estimates

Question 31a: For the indication(s) of the selected drug, provide an estimate of its prevalence among the Medicare population. Provide citations and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 31a	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 31a	*Text* (Up to 50 citations)

Question 31b: 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. Provide citations and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 31b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 31b	*Text* (Up to 50 citations)

Question 31c: 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 therapeutic alternatives. Provide citations and/or brief methodology to support analyses.

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

Field	Response
Response to Question 31c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 31c	*Text* (Up to 50 citations)

Question 32: Therapeutic advance and unmet medical need

Question 32a: 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 therapeutic alternative(s). Provide supporting citations.

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

Question 32b: For the indication(s) of the selected drug, describe the extent to which the selected drug addresses an unmet medical need. Provide supporting citations.

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

Question 33: Specific populations and patient experience

Question 33a: For the indication(s) of the selected drug, identify any specific populations that are impacted by the selected drug and/or its therapeutic alternatives, and describe how they are impacted. Provide supporting citations.

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

Question 33b: For the indication(s) of the selected drug, identify evidence regarding patient experiences related to the indication(s), selected drug, and/or its therapeutic alternatives. This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the indication, treatment burden, burden of disease, or other patient experience data. Provide supporting citations.

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

Question 33c: For the indication(s) of the selected drug, identify any considerations related to access, social drivers of health and health-related social needs, health equity, and/or health disparities that are relevant to the indication, selected drug, and/or its therapeutic alternatives. Provide supporting citations.

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

Question 34: Dossier Submission

Manufacturers are permitted to submit a dossier in Question 34. Such dossiers may be used to supplement responses provided in questions 29 through 33, preferably formatted using an industry standard such as the most current AMCP Format (version 5.0) for Formulary Submissions. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 29 through 33, 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)

Question 35: Visual Representations to Support Responses to Questions 29 through 33
Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 29 through 33. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

Response	Indicate Question Each File Corresponds To
Text (Up to 10 PDF files)	*Text*

Questions 36 through 42: Patient-Focused Experience

CMS would like your input to better understand patients' and caregivers' experiences with [the

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

Question 36: Background

Question 36a: Have you or someone you provide care for ever taken [the selected drug]?

Field	**Response**
Response to Question 36a	*Check box: YES or NO*

Question 36a1: [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 36a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 36a2: [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 36a2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 36a3 [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 36a3	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 36a4: [If NO] What is your experience with this condition or conditions?

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

Question 37: Information on Your Condition(s) or Condition(s) of Someone You Care For

Question 37a: How do the condition(s) you listed in Question 36a1 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 37a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 37b: How has the condition(s) you listed in Question 36 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 37b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 37c: What is important to you or those you provide care for in managing the condition(s) you listed in Question 36?

- 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 37c	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 37d: What challenges do you, or someone you care for, face in managing this condition(s)?

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

Question 38: Information on the Current Medication to Treat Your Condition

Question 38a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Question 37?

Field	Response
Response to Question 38a	*YES or NO*

Question 38a1: [If YES] What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Question 36?

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

Field	Response
Response to Question 38a1	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 38a2: [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 36?

- 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 38a2	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 38a3: [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 36?

- 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 38a3	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 38a4: [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 38a4	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 39: Information on the Medication(s) Used in the Past to Treat Your Condition

Question 39a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Question 38?

Field	Response
Response to Question 39a	*YES or NO*

Question 39b1: [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 36?

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

Field	Response
Response to Question 39b1	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 39b2: [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 36?

- What other factors, if any, affected the choice of medication(s) used in the past to manage the condition(s) you listed in Question 36?
- 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 39b2	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 39b3: [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 36?

- 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 39b3	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 39b4: [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 36?

Field	Response
Response to Question 39b4	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 40: 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 40	*Text* (36,000 character count limit, which is approximately 3,000 words)
Citations	*Citations (50 limit)*

Question 41: Visual Representations to Support Responses to Questions 36 through 40
Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 36 through 40. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

Response	Indicate Question Each File Corresponds To
Text (Up to 10 PDF files)	*Text*

Question 42: Demographic Questions [Only when a respondent selects the "patient" or "caregiver" option in response to Question 28.]

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

Field	Response Options
Age	Select one: 18-24 years 25-34 years 35-44 years 45-64 years 65-84 years 85-99 years 100 years or older
Race/Ethnicity What is your race and/or ethnicity?	Select all that apply: American Indian or Alaska Native Asian Black or African American Hispanic or Latino Middle Eastern or North African Native Hawaiian or Pacific Islander White Other not listed
Regional Location	Select one: New England: CT, ME, MA, NH, RI, VT Middle Atlantic: NJ, NY, PA Midwest-East North Central: IN, IL, MI, OH, WI Midwest-West North Central: IA, KS, MN, MO, NE, ND, SD South-South Atlantic: DE, DC, FL, GA, MD, NC, SC, VA, WV

Field	Response Options
	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 43 through 49: Clinical-Focused Experience

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

Question 43: Background Questions

Question 43a: Are you a health care provider (i.e., a person who is trained and licensed to give health care[46])?

Field	Response
Response to Question 43a	*YES or NO*

Question 43a1: [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 43a1	*Text* (6,000 character count limit, which is approximately 500 words)

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

Question 43b: Do you have experience prescribing or managing the use of [the selected drug]?

Field	Response
Response to Question 43b	*YES or NO*

Question 43b1: [If YES] For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) have you prescribed or managed use of [the selected drug] that you would like to provide CMS information on? Check all that apply.

Field	Response
Response to Question 43b1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 43b2: [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 43b2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 44: Treatment-related Questions

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

Question 44b: 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 44b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 44b	*Text* (Up to 50 citations)

Question 44b1: What would you consider to be a meaningful improvement or treatment response for the outcomes listed in question 44b?

Field	Response
Response to Question 44b1	*Text* (12,000 character count limit, which is approximately 1,000 words)
Additional Materials for Question 44b1	*Text* (Up to 50 citations)

Question 44b2: Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?

Field	Response
Response to Question 44b2	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 44b2	*Text* (Up to 50 citations)

Question 44c: 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 include citations for nationally-recognized, evidence-based guidelines listed in CMS-recognized Part D compendia.

Field	Response
Response to Question 44c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 44c	*Text* (Up to 50 citations)

Question 45: Treatment-related Questions

Question 45a: 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 45a	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45a	*Text* (Up to 50 citations)

Question 45b: 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 45b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45b	*Text* (Up to 50 citations)

Question 45c: What medications would you consider to be therapeutic alternatives for [the selected drug] for treatment of the condition(s) treated with [the selected drug]?

Field	Response
Response to Question 45c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45c	*Text* (Up to 50 citations)

Question 45d: What considerations drive treatment selection among [the selected drug] and its therapeutic alternatives for the indication(s)?

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

Field	Response
Response to Question 45d	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45d	*Text* (Up to 50 citations)

Question 45e: Are there notable differences between how [the selected drug] or the therapeutic alternatives identified in Question 45c 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 45e	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45e	*Text* (Up to 50 citations)

Question 45f: How would you characterize the benefits and risks associated with [the selected drug]?

Field	Response
Response to Question 45f	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45f	*Text (Up to 50 citations)*

Question 45f1: What side effects or risks, common or serious, or other safety concerns would you take into consideration when selecting a treatment option from among [the selected drug] or its therapeutic alternatives for the condition(s) treated with [the selected drug]?

Field	Response
Response to Question 45f1	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45f1	*Text* (Up to 50 citations)

Question 45f2: In your opinion, how do the benefits and risks associated with [the selected drug] differ from the benefits and risks associated with its therapeutic alternatives for the indication(s)?

Field	Response
Response to Question 45f2	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45f2	*Text* (Up to 50 citations)

Question 45f3: What specific populations or patient subgroups may derive greater benefits or be at risk for greater harms by using [the selected drug] or any of its therapeutic alternatives for the indication(s)?

Field	Response
Response to Question 45f3	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45f3	*Text* (Up to 20 citations)

Question 45g: How would you assess whether a patient is tolerating and/or responding to [the selected drug] or any of its therapeutic alternatives when used for each indication(s)?

- When might you consider discontinuing a medication?
- When might you consider switching to a different medication?

- When might you consider adding another medication to the regimen?

Field	Response
Response to Question 45g	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 45g	*Text* (Up to 20 citations)

Question 46: Health Equity and Patient Experience

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

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

Question 47: Therapeutic Advance and Unmet Medical Need

Question 47a: For the condition(s) treated by [the selected drug], describe the extent to which [the selected drug] currently represents (or does not represent) a therapeutic advance as compared to its therapeutic alternative(s).

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

Question 47b: 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 47b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 47b	*Text* (Up to 50 citations)

Question 47c: 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 47c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 47c	*Text* (Up to 50 citations)

Question 48: What other information about [the selected drug], its therapeutic alternative(s), or the indication(s) do you think CMS should consider in its evaluation of [the selected drug]? Provide citations when applicable.

Field	Response
Response to Question 48	*Text* (36,000 character count limit, which is approximately 3,000 words)
Citations	*Citations (20 limit)*

Question 49: Visual Representations to Support Responses to Questions 43 through 48
Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 43 through 48. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

Response	Indicate Question Each File Corresponds To
Text (Up to 10 PDF files)	*Text*

Questions 50 through 56: Research-Focused Experience

CMS is collecting information to support its evaluation of [the selected drug] in the indication(s) it is used to treat relative to its therapeutic alternative(s). CMS is interested in obtaining input and evidence from individual researchers and research or advocacy organizations related to [the selected drug] and its potential therapeutic alternative(s), methodological approaches to evaluation of [the selected drug] consistent with statutory requirements, and publicly available evidence CMS should consider related to [selected drug] and the indication(s) it treats.

Question 50: 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 50	*YES or NO for each item 1-3 (listed above in question)*

Question 50a: 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 50a	*Text* (6,000 character count limit, which is approximately 500 words)

Question 51: Potential Therapeutic Alternatives

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

Field	Response
Response to Question 51	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 51	*Text* (Up to 50 citations)

Question 52: Comparative Clinical Evidence

Question 52a: What methodology, framework, or other analytic approach would you recommend CMS consider for use in its evaluation of the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting rationale and citations where applicable.

Field	Response
Response to Question 52a	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 52a	*Text* (Up to 50 citations)

Question 52b: What relevant clinical outcome measures should CMS consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of [the selected drug] and its potential therapeutic alternatives for the indication(s)? Provide supporting citations where applicable.

Field	Response
Response to Question 52b	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 52b	*Text* (Up to 50 citations)

Question 52c: 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. Provide supporting citations.

Field	Response
Response to Question 52c	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 52c	*Text* (Up to 50 citations)

Question 53: Specific Populations and Patient Experience

Question 53a: What evidence are you aware of regarding patient experiences related to use of [the selected drug], its potential therapeutic alternatives, and/or condition(s) treated by [the selected drug]? This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the condition(s), treatment burden, burden of disease, or other patient experience data. Provide supporting citations.

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

Question 53b: What specific populations or patient subgroups are impacted by [the selected drug] and/or its potential therapeutic alternatives for the condition(s) treated by [the selected drug]? How are these populations or subgroups impacted? Identify studies focused on the impact of [the selected drug] and its therapeutic alternatives on the specific populations. Provide supporting citations where applicable.

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

Question 53c: What considerations related to access, health equity, and/or health disparities are relevant to [the selected drug], its potential therapeutic alternatives, and/or or this condition(s) treated by [the selected drug]? Provide supporting citations where applicable.

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

Question 54: Prevalence, Utilization, and Cost Estimates

Question 54a: For each indication(s), provide an estimate of prevalence among the Medicare population. Provide citations and/or brief methodology to support the estimate.

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

Question 54b: For each indication(s), provide an estimate for Medicare utilization of [the selected drug] and/or its potential therapeutic alternatives. Estimates of Medicare utilization can include estimates of total number of patients treated, estimated share of [selected drug] prescriptions dispensed to patients for a given indication, or similar measures. Provide citations and/or a brief methodology to support the estimate.

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

Question 54c: For each indication(s), identify or provide evidence relevant to Medicare regarding relative health care resource utilization of patients who take [the selected drug] and its potential therapeutic alternatives. Relevant evidence of relative health care resource utilization may include but is not limited to: disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to [the selected drug] and any therapeutic alternatives. Provide citations and/or a brief methodology to support the assessments.

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

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

Question 55: What other information or evidence do you think CMS should consider in the evaluation of [the selected drug]? Provide citations when applicable.

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

Question 56: Visual Representations to Support Responses to Question 49 through 55
Provide up to 10 visual representations, if any, such as tables, charts, and/or graphs that support the responses to Questions 51 through 57. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

Response	**Indicate Question Each File Corresponds To**
Text (Up to 10 PDF files)	*Text*

Questions 57 through 60: Other Public Input

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

Question 57: 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 57	*Text* (6,000 character count limit, which is approximately 500 words)

Question 58: What is your experience with [the selected drug] or the condition(s) it treats?

Field	Response
Response to Question 58	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 59: What information or evidence do you think CMS should be aware of as it evaluates [the selected drug] for each indication(s)? Provide citations when applicable.

Field	Response
Response to Question 59	*Text* (36,000 character count limit, which is approximately 3,000 words)
Additional Materials for Question 59	*Citations (50 limit)*

Question 60: Visual Representations to Support Responses to Question 57 through 59
Provide up to 10 visual representations such as tables, charts, and/or graphs that support the responses to Questions 56 through 58. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

Response	Indicate Question Each File Corresponds To
Text (Up to 10 PDF files)	*Text*

<u>For Any Respondent that Responded to One or More Questions in Section I</u>

Question 61: Does any evidence submitted include a cost-effectiveness measure:

[ ] Yes
[ ] No
[ ] Don’t know

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

All question numbers listed with a checkbox to select.

For each question number selected, please select the applicable statement.
[ ] The evidence submitted includes QALYs or cost-effectiveness measures that treat extending

the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

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

Checkboxes will populate for each question selected.

Question 62: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld as Proprietary Information

For each question that a Respondent believes contains information that should be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA, list the applicable question number and provide a brief explanation regarding why the Respondent believes the information should be withheld as proprietary information. The Respondent should not include information that CMS specifies as proprietary in the section 40.2.1 of the final guidance.[47]

Section Letter and Question Number	Explanation
Text	*Text (60,000 character count limit, which is approximately 5,000 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.

Yes [ ]
No [ ]

Contact Information for respondent:

[47] 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 as non-proprietary because CMS understands these data are publicly available.

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, 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 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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

PART 2: DRUG PRICE NEGOTIATION PROCESS STATUTORY WRITTEN COUNTEROFFER ICR FORM

Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. In accordance with section 40 of the 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 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer").

In accordance with section 1191(b)(4) of the Act, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement (herein referred to as an "Agreement"), or, for initial price applicability year 2027, February 28, 2025. CMS intends to implement the offer and counteroffer process consistent with the statutory goal of negotiating to achieve agreement on "the lowest [MFP] for each selected drug," established in section 1194(b)(1) of the Act. In accordance with sections 1191(d)(5)(B) and 1194(b)(2)(B) of the Act, CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a selected drug for initial price applicability year 2027 no later than June 1, 2025. In accordance with section 1194(b)(2)(C) of the Act, 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"), including an Addendum populated with the proposal for the MFP. In accordance with section 1194(b)(2)(D) of the Act, CMS will provide a written response to the statutory written counteroffer. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later. Section 60.4 of the final guidance describes the remainder of the negotiation process in detail.

Every written offer and 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 as described in section 60.4 of the final guidance, 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 2027, 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 process if the Primary Manufacturer chooses to develop and submit a statutory written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2027.

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

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

Instructions for Completing the Statutory Written Counteroffer Form

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

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

- The Primary Manufacturer's statutory written 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 statutory written 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 statutory written counteroffer, or information that is otherwise available and considered by CMS. A Primary Manufacturer may also include in their statutory written counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) that supports the statutory written counteroffer proposal for the MFP and additional information it deems relevant, such as a request to include certain information from the statutory written counteroffer justification in CMS' public explanation of the MFP, and;
- A certification, including an attestation on the use of cost-effectiveness measures, by: (1) the chief executive officer (CEO), (2) the chief financial officer (CFO), (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Additional instructions for submitting the Statutory Written Counteroffer Form are as follows:

- If the Primary Manufacturer chooses to submit the Statutory Written Counteroffer Form, this form must be completed and submitted within the CMS HPMS within 30 days of receiving the written initial offer from CMS.
- Question 1 asks the Primary Manufacturer to input its statutory written 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 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 statutory written 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.
- 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 statutory written 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. 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. Respondents must indicate via the checkboxes in the form if their submission includes any cost-effectiveness measures or methods. Examples of cost-effectiveness measures or methods include but are not limited to Quality-Adjusted Life Years (QALYs), Equal Value of Life-Years Gained (evLYG), Equal Value Life-Year (evLY), Health Years in Total (HYT), and Generalized Risk-Adjusted Cost-Effectiveness (GRACE).
- If a Primary Manufacturer is the holder of the NDA(s)/BLA(s) for multiple selected drugs for an initial price applicability year, a separate form must be submitted for each selected drug for which the Primary Manufacturer chooses to submit a statutory written counteroffer.

Appendix. Statutory Written 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 2027. In accordance with section 1194(b)(2)(B) of the Act, CMS has provided the Primary Manufacturer of the selected drug named below with a written initial offer that contains CMS' proposal for the selected drug's maximum fair price (MFP), as defined in section 1191(c)(3), and a concise justification based on the factors described in section 1194(e). Submission of this form indicates that the Primary Manufacturer has not accepted CMS' written initial offer and is submitting a 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.

Counteroffer price Proposal for the MFP per 30-day equivalent supply of [selected drug name]
$

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)

Does the evidence submitted include a cost-effectiveness measure:
[ ] Yes
[ ] No
[ ] Don't know

If yes to the question above, please select the applicable statement.
[ ] The evidence submitted includes QALYs or cost-effectiveness measures that treat extending the life an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

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

Certification

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

Yes [ ] No [ ]

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1452 (Expires XX/XX/XXXX)**. This 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, 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 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027. 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