Drug Price Negotiation for Initial Price Applicability Year 20XX
under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)
Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452)

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program ("the Negotiation Program"), codified in sections 1191 through 1198 of the Social Security Act ("the Act"). The Act establishes the Negotiation Program to negotiate a maximum fair price (MFP), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs payable under Medicare Part B and/or covered under Medicare Part D (each a "selected drug").[1] As discussed in proposed 42 CFR 429.101, for initial price applicability year 2029 and each initial price applicability year thereafter, CMS will select up to 20 high expenditure, single source drugs payable under Part B and/or covered under Part D for negotiation. For each such initial price applicability year, CMS will also renegotiate MFPs for drugs selected for renegotiation (if any), in accordance with section 1194(f)(4) of the Act. Any MFPs that are renegotiated for these drugs will apply beginning with the initial price applicability year for which the drug was selected for renegotiation (see proposed 42 CFR 429.610). For a drug selected for negotiation and with respect to that specific selected drug, the negotiation period for the initial price applicability year begins February 28 of the calendar year of the selected drug publication date for such initial price applicability year, or when the Primary Manufacturer of such selected drug enters into a Medicare Drug Price Negotiation Program Agreement with CMS for such selected drug, whichever is sooner. For a drug selected for renegotiation and with respect to that specific selected drug, the renegotiation period for the initial price applicability year begins February 28 of the calendar year of the selected drug publication date for such initial price applicability year.

This ICR Form includes three parts: Part 1—Negotiation Data Elements ICR Form, Part 2—Temporary Floor for Small Biotech Drugs ICR Form, and Part 3—Counteroffer ICR Form.

PART 1: NEGOTIATION DATA ELEMENTS ICR FORM

In accordance with sections 1194(e) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.500(a)(2), 429.505(a), and 429.620(c), CMS considers two sets of factors as the basis for determining initial offer(s) and counteroffer(s) throughout the negotiation process and renegotiation process: (1) certain data that must be submitted by the manufacturer of each drug (as described in section 1194(e)(1)) of the Act); and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternative(s) for each selected drug (as described in section 1194(e)(2) of the Act).

[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.

In accordance with section 1193(a)(4) and section 1194(b)(2)(A) of the Act and proposed 42 CFR 429.405(a) and 429.615(b)(1)(ii), the manufacturer must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price ("non-FAMP") as defined in 38 U.S.C. 8126(h)(5) for the selected drug and information that CMS requires to carry out the negotiation process, including the factors outlined in section 1194(e)(1) of the Act, which, in conjunction with the available evidence on the factors outlined in section 1194(e)(2), will serve as the basis for determining initial offers and counteroffers. In addition, manufacturers and the public may submit information on the factors outlined in section 1194(e)(2) of the Act, which describe evidence about the selected drug and its therapeutic alternative(s). In accordance with section 1194(f)(4)(B) of the Act and proposed 42 CFR 429.615(b), CMS will apply a similar approach regarding data collection once a drug is selected for renegotiation of the MFP, if any drugs are selected for renegotiation.

For the purposes of this ICR, references to a selected drug subject to the data collections in this form include drugs selected for negotiation and renegotiation on the selected drug list published by CMS by the selected drug publication date for the initial price applicability year for which this ICR is submitted.

In section 1191(c)(1) of the Act, the statute adopts the definition of a manufacturer established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate, or renegotiate, as applicable, an MFP with "the manufacturer" of the selected drug. In accordance with proposed 42 CFR 429.20, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug, 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 proposed 42 CFR 429.20, CMS will refer to any manufacturer of a drug product included in the selected drug, that is not the Primary Manufacturer for the selected drug, and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug; or (2) markets the selected drug in accordance with an agreement with the Primary Manufacturer but is not listed on an NDA or BLA of the selected drug as a "Secondary Manufacturer[2]."

In accordance with proposed 42 CFR 429.100(d), 429.405(a), 429.505(b)(1), and 429.615(b)(1), CMS will collect certain data from the Primary Manufacturer,

[2] As specified in proposed 42 CFR 429.20, 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.

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 in accordance with proposed 42 CFR 429.505(d)(1) and 429.615(b)(3). This ICR Form serves as one of multiple ways that CMS will collect data described in section 1194(e)(2) (see the Supporting Statement for further details). Submission of the information collected in this ICR Form is due by 11:59 PM PT on March 1 of the year of the selected drug publication date for the initial price applicability year for which this ICR is submitted (consistent with proposed 42 CFR 429.100(d), 429.405, 429.505, and 429.615(b)).

Note: This ICR focuses on information required and optional for selected drugs for negotiation and renegotiation for initial price applicability year 20XX.

General Instructions

Overview

In accordance with proposed 42 CFR 429.100(d), 429.405(a), 429.505(b)(1), and 429.615(b)(1), the Primary Manufacturer of each selected drug must complete Sections A through H for each of its selected drug(s), which are specifically:

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

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

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

Submission Method

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

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

All respondents who are not Primary Manufacturers will use a separate web application to access the questions in Sections I and J. This application will be accessible from an entry point on CMS.gov, as well as on the CMS HPMS landing page, which is publicly accessible at https://hpms.cms.gov. Additional instructions to access this public web application will be available on CMS.gov.

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

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

Additional Instructions

- The instructions in this section apply to all Sections A through J. If a term included in this ICR is also included and defined in proposed 42 CFR 429.20, the term's definition in this ICR is the same as in proposed 42 CFR 429.20. Questions about proposed title 42, part 429 of the CFR, including questions about terms defined in this ICR, should be sent to IRARebateandNegotiation@cms.hhs.gov.
- For Sections A through G of this form, the Primary Manufacturer must provide data **only with regard to the selected drug as identified** under section 1192 of the Act. If a Primary Manufacturer has more than one selected drug, the Primary Manufacturer is required to make a separate submission of the information required in Sections A through G of this ICR for each selected drug.
- All response fields are limited to a character count. The field and response format sections provide a character count and an estimated word count. Total character counts include all characters within the response, including spaces between words.
- Certification is required for submissions. Section H includes the Certification of Submission of Sections A through G for Primary Manufacturers. Section J includes the Certification of Submission of Section I for All Respondents.
- For Sections A through G of this form, the Primary Manufacturer must submit, as indicated in the section, the applicable data for all dosage forms and strengths of the selected drug, including for dosage forms and strengths that were manufactured, marketed,

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

controlled, or sold by a Secondary Manufacturer.

- Technical assistance will be available in a CMS HPMS Negotiation Data Elements ICR Form User Guide, including additional instructions on submitting data for applicable sections via a template upload.
- For non-monetary numeric amounts, include up to three decimal places.
- Response formats are indicated within any charts included in Sections A through G and Section I (e.g., # to indicate a numerical response is required).
- Primary Manufacturers must timely notify CMS, after the initial submission of data in this ICR Form, if any of the information submitted changes, as set forth in proposed 42 CFR 429.100(e), 429.405(b), 429.505(c), and 429.615(b)(2). Please timely notify CMS via the IRA Mailbox at IRARebateandNegotiation@cms.hhs.gov if any such changes are applicable to the selected drug.
    - If a Primary Manufacturer of a drug selected for renegotiation has updates to the Primary Manufacturer's prior full submission(s) of section 1194(e)(1) data, the Primary Manufacturer should notify CMS of these updates separately from this ICR Form in accordance with section 50.1 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, the final guidance for initial price applicability year 2028, and proposed 42 CFR 429.100(e), 429.405(b), 429.505(c), and 429.615(b)(2), as applicable.
- Throughout this form, references to "the most recent full submission" in instructions specific to submissions for a drug selected for renegotiation refer to the Primary Manufacturer's most recent submission of the Negotiation Data Elements Form for the selected drug and do not include any submissions of updates or corrections to information submitted in the Negotiation Data Elements Form, as set forth in proposed 42 CFR 429.100(e), 429.405(b), 429.505(c), and 429.615(b)(2), or submissions through the Identification and Selection of Renegotiation-Eligible Drugs ICR Form.
- 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 proposed 42 CFR 429.300, CMS will treat certain data elements submitted by a Primary Manufacturer of a selected drug in accordance with section 1194(e)(1) and section 1194(e)(2) of the Act as proprietary if the information constitutes confidential commercial or financial information of the Primary Manufacturer or a Secondary Manufacturer.[4] In order to identify information within a response that a respondent believes should be withheld by CMS under the Freedom of Information Act (FOIA) Exemptions 3 and/or 4 (5 U.S.C. 552(b)(3), (4)),[5] Primary Manufacturers are instructed to complete

[4] Specifically, as described in proposed 42 CFR 429.300(c), CMS will treat non-FAMP and associated non-FAMP data collection, research and development costs of the Primary Manufacturer for the selected drug, current unit costs of production and distribution of the selected drug, data on pending patent applications for the selected drug, and market data and revenue and sales volume for the selected drug in the United States as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary.

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

Question 26 regarding such applicable information provided in response to Sections A through G, and any interested party is instructed to complete Question 57 regarding such applicable information provided in Section I. Proposed 42 C.F.R. 429.300(d) and 429.705 discuss the situations in which CMS may share submitted data related to the section 1194(e)(2) factors publicly, without sharing any personally identifiable information[6] (PII) or protected health information[7] (PHI), proprietary information, or information that is protected from disclosure under other applicable law. CMS will not include Questions 29 and 62, and any responses submitted to CMS for Question 29 and 62, within the evidence published alongside the explanation of the MFP (as set forth in proposed 42 CFR 429.705(b)). For example, this means that when publishing the explanation of MFP, CMS will not publish a Primary Manufacturer's identification of which data should be withheld in response to Question 29, but CMS still retains the authority to determine whether such data may be published in accordance with CMS' confidentiality policy as set forth in proposed 42 CFR 429.300.

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

Instructions for Reporting Monetary Amounts

- When calculating and reporting monetary values, the information must be determined using the methodologies described throughout the document and consistent with the Generally Accepted Accounting Principles (GAAP), when applicable. Describe the policies and methodologies used in the calculations in the free response field for the relevant question, as well as the standard used if it is inconsistent with GAAP.
- When calculating and reporting monetary values, do not adjust for cost of capital.
- Monetary amounts must be reported in United States dollars (USD) and include two decimal places (i.e., dollars and cents), unless otherwise specified in Section D or Section G. Use the free response field of an applicable question, when it is available, to clarify any rounding limitations or alternative rounding standard relied on.
- The geographic area for data on United States (U.S.) Commercial markets, Medicare markets, and Medicaid markets is based on the definition of the United States in 42 CFR 400.200, unless the geographic area is specified in the authority for the data source (e.g., for

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

[7] Protected health information (PHI), consistent with proposed 42 CFR 429.20, has the as the meaning set forth at 45 CFR 160.103. For example, PHI includes 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.

Federal Supply Schedule[8] (FSS) pricing and sales to specified Federal agencies ("Big Four price") described in 38 U.S.C. 8126 [9]).

- When converting another currency to USD, use the exchange rate in effect on the date the cost was incurred. If that rate is unavailable, use the monthly or annual average exchange rate for the year in which the cost was incurred.
    - All new conversions should follow the principles of the GAAP Accounting Standard Certification (ASC) 830, the U.S. accounting standard for translating foreign currency values.
    - If a currency conversion was completed prior to this instruction using a different method, and recalculating using ASC 830 would impose a significant burden, CMS will accept the previously calculated value without requiring recalculation. In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in the calculation.
- Do not report the same costs in multiple places unless the additional specific instructions for that question instruct you to do so.
- Do not include any costs that are unallowable under an applicable law or costs that are otherwise expressly excluded from this ICR.
- Do not make any adjustments for inflation to any dollar amounts reported unless the additional specific instructions for that question instruct you to do so. When reporting an inflation adjusted value, inflation adjustments should be made to the most recent full calendar year preceding the calendar year in which this ICR is due by using the annual percentage increase of the consumer price index for all urban consumers (CPI-U)[10] for such preceding calendar year (e.g. 2026 for initial price applicability year 2029).

A. Selected Drug Information

Primary Manufacturer Response Required

In Section A, for each drug selected for negotiation and renegotiation for initial price applicability year 20XX, CMS will populate the CMS HPMS with the list of the 11-digit National Drug Codes (NDC-11s) associated with the NDA(s) / BLA(s) of the selected drug that is identified by CMS as the baseline list of NDC-11s in accordance with proposed 42 CFR 429.100(c)(1).

- **For Primary Manufacturers of drugs selected for renegotiation only:** The baseline list of NDC-11s for drugs selected for renegotiation will reflect updates provided by Primary Manufacturers in accordance with section 40.2 of the revised guidance for initial price

[8] The most recently published pharmaceutical price for the selected drug as included in the Federal Supply Schedule as managed by the Department of Veterans Affairs per 48 CFR part 38. See: https://department.va.gov/administrations-and-offices/acquisition-logistics-and-construction/freedom-of-information-act-requests/#toc_Historical_VA_Pharmaceutical_Prices.

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

[10] The "CPI-U" means, consistent with proposed 42 CFR 429.20, the consumer price index for all urban consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/cpi/data.htm).

applicability year 2026, the final guidance for initial price applicability year 2027, the final guidance for initial price applicability year 2028, and proposed 42 CFR 429.100(e).

CMS includes in Section A, the NDC-11s of the selected drug that:

(1) are associated with Healthcare Common Procedure Coding System (HCPCS) codes that appear on NDC-HCPCS code crosswalks published by CMS[11] for the most recent quarter in the 12-month period beginning November 1 of the two calendar years prior to the selected drug publication date for the initial price applicability year and ending October 31 from the calendar year prior to the selected drug publication date for the initial price applicability year, or

(2) had Part D PDE utilization in the 12-month period beginning November 1 of the two calendar years prior to the selected drug publication date for the initial price applicability year and ending October 31 from the calendar year prior to the selected drug publication date for the initial price applicability year, or

(3) any additional NDC-11s CMS identifies that are associated with the NDA(s) / BLA(s) of the selected drugs as found in recent updates of the NDC Structured Product Labeling (SPL) Data Elements file (NSDE) file or the NDC Directory (including its NDC Excluded Drugs Database file).

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.

If a Primary Manufacturer believes that an NDC-11 that has been populated by CMS within Section A of the CMS HPMS should not be populated, or an error has occurred, they can submit an email to IRARebateandNegotiation@cms.hhs.gov.[12]

Definitions for Section A:

- Average Manufacturer Price (AMP) unit: The unit type, as reported monthly by the manufacturer, used by the manufacturer to calculate AMP (42 CFR 447.504) and best price (42 CFR 447.505) for purposes of the Medicaid Drug Rebate Program (MDRP): injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, or microcurie.
- Drug sample: A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug (Section 503(c)(1) of the Federal Food, Drug, and Cosmetics Act).
- Private label distributor, consistent with proposed 42 CFR 429.20, has the meaning set

[11] See: https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.

[12] Separately, and as specified in the "Additional Instructions" within this ICR Form, *after* the initial submission of data in this ICR Form, Primary Manufacturers must timely notify CMS, if any of the information submitted changes, as set forth in proposed 42 CFR 429.305(c).

forth in 21 CFR 207.1.

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

Instructions for Section A:

- Review the list of NDC-11s populated by CMS, and if any NDC-11s associated with the NDA(s) / BLA(s) of the selected drug that are covered under Part D and/or payable under Part B are missing from the list (e.g., because they are new NDC-11s, discontinued NDC-11s), including any missing NDC-11s of a Secondary Manufacturer of the selected drug, provide the missing NDC-11 and corresponding Product Name.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, provide the NCPDP Unit, Total NCPDP Units Per Package, and the AMP Unit and Total AMP Units Per Package.
- For each of the listed NDC-11s or any additional NDC-11s added by the Primary Manufacturer, indicate whether:
    - any of the listed NDC-11s or additional NDC-11s are not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer,
    - any of the listed NDC-11s or additional NDC-11s are distributed by or under the name of a private label distributor,
    - any of the listed NDC-11s or additional NDC-11s have been discontinued and the date of discontinuation[13], and
    - any of the listed NDC-11s or additional NDC-11s are a sample package, outer package, or inner package. If the NDC-11 is neither an inner package nor an outer package, select "No" in response to both the inner package and the outer package data fields. "Yes" may not be selected for both an inner and outer package because an NDC-11 cannot be categorized as *both* an inner and an outer package.
- If an NDC-11 is not manufactured, marketed, controlled, or sold by the Primary Manufacturer or a Secondary Manufacturer, select "Yes" in response to the field labeled "Not Manufactured, Marketed, or Sold by the Primary Manufacturer or a Secondary Manufacturer." Otherwise, select the "No" response option.
    - **If "Yes" is selected in response to whether the NDC-11 is "Neither Marketed nor Controlled by the Primary Manufacturer or a Secondary Manufacturer," the Primary Manufacturer should not provide information about this NDC-11 in the remainder of the data fields within Section A or within any other section in this ICR Form.**

Product Name	**NDC-11 Numbers**	**Not Manufactured, Marketed, or Sold by the Primary**	**Discontinued** (Select if NDC-11 has been discontinued and provide date of	**Sample Package** (Select if NDC-11 is a	**Inner Package** (Select if NDC-11 is an inner	**Outer Package** (Select if NDC-11 is an outer	**Private Label** (Select if NDC-11 is a	**NCPDP Unit** (EA, mL, GM)	**Total NCPDP Units per Package**	**AMP Unit** (Injectable anti-hemophiliac factor,	**Total AMP Units per Packa**

[13] Please provide the date of discontinuation that was reported to FDA pursuant to 21 CFR 314.81(b)(3)(iii) and (iv).

		Manufacturer or a Secondary Manufacturer	discontinuation)	sample package)	package)	package)	private label)			capsule, suppository, gram, milliliter, tablet, transdermal patch, EC, millicurie, microcurie)	**ge**
Text to be pre-populated by CMS	*Numbers to be pre-populated by CMS*	*Yes/No*	*Yes/No* *Date if Applicable*	*Yes/No*	*Yes/No*	*Yes/No*	*Yes/No*	*EA, mL, GM*	*#*	*Text*	*#*

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

Primary Manufacturers must provide the information, as directed in Sections B through G of this ICR Form, about all NDC-11s marked as "discontinued," a "sample package," an "inner package," an "outer package," and a "private label," in Section A.

B. Non-FAMP Data Collection

Primary Manufacturer Response Required

For Section B, for Primary Manufacturers of drugs selected for negotiation: the Primary Manufacturer is required to report the non-FAMP for its selected drug for the four quarters of calendar years 2021 (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, the Primary Manufacturer is required to report average non-FAMP for the first full calendar year following the market entry for such drug), as well as the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted .

CMS plans to use the reported NDC-11s, quarterly non-FAMP, and total NDC-11 package volume in the data fields below to calculate the average non-FAMP for calendar year 2021 (or for the first full calendar year following the market entry of the selected drug) and the calendar year prior to the selected drug publication date for a drug selected for negotiation for the initial price applicability year for which this ICR is submitted (for additional information regarding the collection of non-FAMP for negotiation refer to proposed 42 CFR 429.405).

For Section B, for Primary Manufacturers of drugs selected for renegotiation that were selected originally for negotiation for initial price applicability year 2026 or 2027 and have not previously been renegotiated in initial price applicability year 2028 or thereafter only: the Primary Manufacturer is required to report the non-FAMP for all NDC-11s included in Section A that are payable under Part B, but not covered under Part D, and for which the Primary Manufacturer did not originally report non-FAMP for these NDC-11s payable under Part B for the initial price applicability year for which the selected drug was first selected for negotiation. If there is no non-FAMP to report in response to Section B, select "Not Applicable". For additional information regarding the collection of non-FAMP for renegotiation refer to proposed 42 CFR 429.615(b)(1)(ii).

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.[14] Specifically, for drugs selected for negotiation, these are the quarters of 2021 (or of the first full calendar year following marketing entry of the drug) and the calendar year prior to the statutorily-defined selected drug publication date for a specific initial price applicability year. For drugs selected for renegotiation that were selected originally for initial price applicability year 2026 and 2027 and have not previously been selected for renegotiation in initial price applicability year 2028 or thereafter, these are the quarters for the same calendar years for which non-FAMP data was reported in the Primary Manufacturer's data submission for the negotiation period in which the selected drug's MFP was negotiated. 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 an applicable year, 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 of such year. The temporary non-FAMP should be calculated following the same methodology used to calculate the temporary non-FAMP amount used to determine the Temporary Federal Ceiling Price, as described in the Department of Veterans Affairs (VA) 2025 Updated Guidance for Calculation of Federal Ceiling Prices (FCPs) for New Drugs subject to Public Law 102-585.[15] Any restatements of the non-FAMP made in any manufacturer non-FAMP submissions to the VA must be reflected in the non-FAMP submitted to CMS.
- Non-FAMP package: Non-FAMP package is the package unit as described in 38 U.S.C. 8126(h)(6) and represents the NDC-11 package (e.g., for an NDC-11 that represents a bottle of 30 tablets, the non-FAMP package would be the bottle; for an NDC-11 that represents a single dose vial containing 25 mg/mL, the non-FAMP package would be the vial).

Instructions for Section B:

[14] 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).

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

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

- Please complete the data fields immediately below:
    - 2021 **or** First Other Full Year of Market Entry after 2021: please fill in the information for non-FAMP for each calendar quarter of 2021 for the selected drug if at least one NDC-11 of the selected drug has an average non-FAMP available for at least one quarter in 2021 (***or***, in the case that there is not an average non-FAMP available for any NDC-11 of such drug for 2021, please fill in the information for the applicable calendar quarters for the first full year following the market entry for such drug).
        - If the first full year following the market entry happens to be the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted then please proceed to fill in the data for the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted only.
    - The calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted: please fill in the information for non-FAMP for the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted, as applicable.
- Please note that when filling in the data, there may be a different number of NDC-11s with available data in 2021 (or first other full year of market entry) versus the calendar year prior to the selected drug publication date for a drug selected for negotiation (or renegotiation, as applicable) for the initial price applicability year for which this ICR is submitted. As an example, if any NDC-11s of the selected drug have non-FAMP data in at least one quarter of 2021, all associated NDC-11s should be reported for the four quarters of 2021 (in that scenario, if there is no data for all quarters in 2021 for a given NDC-11, please do not enter any data in the data fields for "2021 or First Other Full Year of Market Entry After 2021" for that NDC-11 and provide an explanation of why there is no data). Additionally, all NDC-11s for the four quarters of the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted, even if an NDC-11 was available in the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted but not available during any quarter of 2021, should be reported.
- Please report the non-FAMP and total non-FAMP package volume for each NDC-11 of the selected drug. Primary Manufacturers are responsible for reporting the calendar year as either calendar year 2021 or the calendar year of first year post market entry.
    - If an NDC-11 was not marketed, sold, or distributed in a particular calendar quarter, including for any NDC-11s that are marked as "discontinued," a "sample package," an "inner package," an "outer

package," and a "private label" in Section A, enter "0" in the total NDC-11 package volume field and leave the non-FAMP field blank. In these situations, please provide an explanation in the "Explanation of why non-FAMP was not reported (if applicable)" field of why the NDC-11 had no non-FAMP for that calendar quarter (e.g., first marketed in a later calendar quarter; discontinued prior to 2021; sample).

- Non-FAMP and total non-FAMP package volume information must be provided by the Primary Manufacturer for its own NDC-11s and the NDC-11s of the selected drug manufactured, marketed, controlled, or sold by 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 the calendar year prior to the selected drug publication date for a drug selected for negotiation (or renegotiation, as applicable) for the initial price applicability year for which this ICR is submitted made in any manufacturer non-FAMP submissions to the VA must be reflected in the data fields below.
- Please indicate the total number of NDC-11 packages sold during the quarter and that are used in the calculation of the non-FAMP in the total non-FAMP package volume field.

2021 or First Other Full Year of Market Entry after 2021

NDC-11	Calendar Quarters of 2021 or First Calendar Year Post Market Entry (e.g., Calendar Quarters in one of 2022, 2023, 2024, 2025 [20XX])	Calendar Year	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
12345-6789-01	*QQ*	*Select One: 2021, 2022, 2023,*	*#*	*$*	*Text (12,000 character count limit, which is approximately 1,000 words)*

NDC-11	Calendar Quarters of 2021 or First Calendar Year Post Market Entry (e.g., Calendar Quarters in one of 2022, 2023, 2024, 2025 [20XX])	Calendar Year	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
		2024, 2025, [20XX]			

Note: If the Primary Manufacturer indicates that the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted is the "First Other Full Year of Market Entry after 2021," then the CMS HPMS will only display the data fields for the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted for completion.

202XX

NDC-11	Calendar Quarter for 20XX	Total Non-FAMP Package Volume	Non-FAMP	Explanation of why non-FAMP was not Reported (if applicable)
12345-6789-01	*QQ*	*#*	*$*	*Text (12,000 character count limit, which is approximately 1,000 words)*

[ ] For a drug selected for renegotiation for which there is no non-FAMP to report in response to Section B: Not Applicable.

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

Primary Manufacturer Response Required

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

Definitions for Section C:

- R&D costs is defined as a combination of costs incurred by the Primary Manufacturer for a drug falling into two categories: (1) Costs Related to the Selected Drug, Including Basic Pre-Clinical Research of the Selected Drug, Post-Investigational New Drug (IND) Costs of the Selected Drug, and Other Allowable Costs; and (2) Costs for Failed and Abandoned Products Related to the Selected Drug.
- Basic pre-clinical research costs are defined as the sum of (1) direct research expenses; and (2) the appropriate proportion of indirect research expenses (defined below).
    - Direct basic pre-clinical research costs are costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug. Direct research expenses could include personnel (monetary and non-monetary compensation for investigators and staff) researching the selected drug, materials for conducting basic pre-clinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
    - Indirect basic pre-clinical research costs and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biological products.
- Post-IND costs are defined as direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials. Post-IND costs also include direct costs associated with completed FDA-required, postmarketing trials that are conducted after the FDA has approved a product.
    - Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel (compensation for investigators and staff) researching the selected drug, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials. Direct post-IND costs also include personnel, patient recruitment, and per-patient costs, research and data collection costs, and facility costs that are directly related to conducting the completed FDA-required, postmarketing trial.
        - Personnel, patient recruitment, and per-patient costs include monetary and non-monetary compensation. Any non-monetary compensation for investigators and staff included in the total amount should reflect the fair market value for such compensation at the time it was provided.
- Other allowable costs for costs related to the selected drug are defined as direct

costs associated with conducting FDA-required postmarketing trials and other FDA post-marketing requirements and commitments that were not completed, Phase IV postmarketing studies, direct post-IND costs (following the definitions and instructions for calculating direct post-IND costs above), direct costs associated with researching and utilizing devices for the selected drug, direct costs to support or satisfy a postmarketing requirement or commitment, and direct costs for patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting Phase IV and postmarketing trials.

- Failed or abandoned product costs are defined as the sum of (1) direct *basic pre-clinical research* costs on drugs with the same mechanism of action as the selected drug that did not make it to clinical trials; and (2) direct *post-IND costs* for drugs with the same mechanism of action as the selected drug that did not receive FDA approval.

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

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

The associated time periods for these terms are included below.

<u>Instructions for Questions 1 through 3:</u>

- For each dollar amount listed below and for the applicable time periods specified, the Primary Manufacturer must report one dollar amount in the numerical response field. For the dollar amount provided, the Primary Manufacturer must provide an explanation of the value(s), including any calculations or conversions and any assumptions made in the free response field.
  - All dollar figures submitted to CMS must be cash-outlay costs to the Primary Manufacturer. They must exclude any costs to entities that are not the Primary Manufacturer.

- **For Primary Manufacturers of drugs selected for negotiation:**
    - In Questions 1 and 2, report R&D costs through December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) for a drug selected for negotiation for the initial price applicability year for which this ICR is submitted.
    - In Question 3, report the global and U.S. net revenue for the selected drug from the date the drug or biological product was first sold globally[16] through December 31 of the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted.
        - If the drug was acquired by the Primary Manufacturer after the selected drug was first sold globally, start the period from the first month of the first full quarter the selected drug was owned by the Primary Manufacturer.
- **For Primary Manufacturers of all drugs selected for renegotiation:**
    - In Questions 1 and 2, report R&D costs that were incurred: (1) **after** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data through December 31 of the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted; and (2), for Primary Manufacturers of drugs selected for renegotiation for a drug that was selected for negotiation for initial price applicability year 2026 or 2027 and the selected drug has not been selected for renegotiation in initial price applicability year 2028 or thereafter**, on or before** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data that meet the definition of R&D costs specified in this ICR *and* the Primary Manufacturer has not previously reported the same data in any prior full submission of data related to the section 1194(e)(1) factors from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later, through December 31 of the calendar year prior to the selected drug.[17]
    - In Question 3, report the global and U.S. net revenue from the last date for which data was reported for global and U.S. net revenue in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data through December 31 the calendar year prior to the selected drug publication date for the initial price applicability year for which this ICR is submitted.
    - If there are no costs to report in response to Questions 1, 2 and/or 3, select "Not Applicable" for each relevant question.
- For Questions 1 through 3, if R&D costs and/or net revenue for the selected drug

[16] For purposes of this instruction, global revenue is inclusive of U.S. revenue.

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

are not available for the exact dates specified above in these instructions, the R&D costs and/or net revenue may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in the free response field for each question.

- If the Primary Manufacturer received any prior Federal financial support, as defined in Section E in this ICR, for any of the costs listed in Questions 1 through 2 below (e.g., basic pre-clinical research, clinical trials, etc.), deduct such funding from the final calculated numerical amount before answering the relevant question and note that deduction in the applicable free response field. CMS will be collecting additional information on prior Federal financial support in Questions 6, 7, and 8. Please reference Section E for instructions on reporting prior Federal financial support.
    - Do not include prior Federal financial support and costs associated with applying for and receiving foreign approvals in Section E.
- If the Primary Manufacturer shared the expenses described in Questions 1 through 2 (after any acquisition of the selected drug, if relevant) for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report only costs the Primary Manufacturer incurred. Report how shared expenses were allocated among the Primary Manufacturer and any other entity or entities in the free response field for the relevant question.
- Follow the instructions for Reporting Monetary Amounts, including those related to converting to USD if R&D costs occurred in other countries. While R&D may occur in other countries and those costs may be included and reported in USD, costs associated with applying for and receiving foreign approvals must not be included.
- Acquisition costs are not allowable in Section C.

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

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

<u>Instructions for Question 1a:</u>

- In the numerical response field for "Cost Related to the Selected Drug," report the sum of the (1) direct and the proportion of indirect costs for basic pre-clinical research for the selected drug; (2) direct post-IND costs; and (3) direct costs for other allowable costs.
    - To calculate the proportion of pre-clinical indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is

used to estimate the proportional spending for indirect research.[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.

- In the response field for "Cost Related to the Selected Drug Adjusted for Inflation," report the cost included for the "Cost Related to the Selected Drug" data field adjusted for inflation.

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

Instructions for Question 1b:

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

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

Instructions for Question 1c:

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

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

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

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

Instructions for Question 2a:

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

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

Instructions for Question 2b:

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

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

Instructions for Question 2c:

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

any allocation was done.
- Explain any methodology relevant to the cost included in the response to Question 2a adjusted for inflation in the free response.

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

[ ] (For a drug selected for renegotiation only) If there are no costs to report, select: Not Applicable.

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

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

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

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

[ ] (For a drug selected for renegotiation only) If there is no revenue to report, select: Not Applicable.

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

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

[ ] (For a drug selected for renegotiation only) If there is no revenue to report, select: Not Applicable.

Instructions for Question 3c:

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

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

[ ] (For a drug selected for renegotiation only) If there is no revenue to report, select: Not Applicable.

Instructions for Question 3d:

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

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

[ ] (For a drug selected for renegotiation only) If there is no revenue to report, select: Not Applicable.

D. Current Unit Costs of Production and Distribution

Primary Manufacturer Response Required

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

Definitions for Section D:

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

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

uses the NCPDP BUS.

- Costs of production are defined as all (direct and allocation of indirect) costs related to:
    - Purchase of raw ingredients, including intermediates, active pharmaceutical ingredients, excipients, and other bulk chemicals;
    - Formulation and preparation of the finished drug product;
    - Quality control and testing of the drug; and
    - Operating costs for personnel, facilities, transportation, importation (if any), and other expenses related to the preparation of the finished drug product for the selected drug.
- Costs of distribution are defined as all (direct and allocation of indirect) costs related to:
    - Packaging and packaging materials;
    - Labeling (e.g., the mechanical aspects of printing and affixing the approved label);
    - Shipping to any entity (e.g., distributor, wholesaler, retail or specialty pharmacy, physician office or hospital, etc.) that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer; and
    - Operating costs for facilities, transportation, and other expenses related to packaging, labeling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer.
- Current unit costs of production and distribution of the selected drug are defined to include:
    - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
    - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
    - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third-party vendors (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
    - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume.
- Current unit costs of production and distribution of the selected drug do not include:
    - R&D costs;
    - Marketing costs; and
    - Transfer prices.
- “Marketing costs” are defined as expenditures incurred in the introduction or delivery for introduction into interstate commerce of a drug product, specifically including media advertisements, direct-to-consumer promotional incentives including patient assistance programs, promotion of the drug to health professionals, including providing free products to health professionals or patients, and other paid promotion.
- “Transfer prices” are defined as prices charged for goods, services, or other intangible

assets in transactions between two members of the same controlled group of the Primary Manufacturer or any Secondary Manufacturer, including sales of a drug product, provision of services (e.g., contract manufacturing), or transfer of intellectual property. For the purposes of the definition of transfer prices, "controlled group" of the Primary Manufacturer or any Secondary Manufacturer refers to all entities that were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code and the Department of the Treasury regulations thereunder.

Instructions for Section D:

Follow the instructions below when answering Questions 4 and 5:

- Production and distribution unit costs must be reported separately for each NDC-11 of the selected drug, including any NDC-11 of the selected drug manufactured, marketed, controlled, or sold by a Secondary Manufacturer.
- Unit costs reported must represent the average per unit cost (1) within the time period specified below, (2) across all package types, and (3) calculated according to the instructions and using the definitions specified below.
- Use the response field in Question 5 to explain any shared operating and other indirect costs that were included in the response to Question 4.
- Costs may be reported up to three decimal places (USD).

Question 4: Per Unit Production and Distribution Costs

- Please complete the following data fields using additional rows as necessary for the 12-month period ending December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted.

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

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

Question 5: Explanation of Calculation of Per Unit Production and Distribution Costs

Please describe the methodology used to calculate the average per unit costs of production and distribution reported in Question 4, including which indirect costs were included,

specific allocation methodologies, assumptions, and whether such assumptions apply to all or a subset of the data reported.

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

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

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

E. Prior Federal Financial Support

Primary Manufacturer Response Required

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

Definitions for Section E:

- "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.
- Prior Federal financial support includes the manufacturer's reasonable estimate of the dollar value of in-kind contributions and Cooperative Research and Development Agreements (CRADAs) that do not have a readily ascertainable value.
- Direct prior federal financial support costs are costs that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of the selected drug.

Instructions for Section E:

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

- The applicable time period is as follows:
  - **For Primary Manufacturers of drugs selected for negotiation:**
    - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to any of the costs described in response to Question 1 of this ICR Form of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to Secondary

Manufacturers of a selected drug) that was received during the time period from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later, through December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted.

- **For Primary Manufacturers of drugs selected for renegotiation:**
  - Include all prior Federal financial support provided by U.S. federal agencies or Federally-supported grants or contracts that contributed to any of the costs described in response to Question 1 of this ICR Form of the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to Secondary Manufacturers of a selected drug) that was received during the time period from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data through December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted.
  - As described in Section C, **for Primary Manufacturers of drugs selected for renegotiation for a drug that was selected originally for negotiation for initial price applicability year 2026 or 2027, and the selected drug has not previously been selected for renegotiation in initial price applicability year 2028 or thereafter,** if the Primary Manufacturer incurred R&D costs **on or before** the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data that meet the definition of R&D costs specified in this ICR, the Primary Manufacturer has not previously reported the same data in any prior full submission of data related to the section 1194(e)(1) factors, *and* the Primary Manufacturer is reporting such R&D costs under Section C, include all applicable prior Federal financial support from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later, through December 31 of the calendar year prior to the selected drug publication date of the initial price applicability year for which this ICR is submitted.[21]
  - If there are no costs to report in response to Questions 6, 7 and/or 8, select "Not Applicable" for each relevant question.
- For Question 6, if prior Federal financial support for the selected drug is not available for the exact dates specified above in these instructions, the prior Federal financial support may be reported through the most recent quarter for which such data are available. The Primary Manufacturer should specify the time period used in Question 7.
- Include prior Federal financial support received for indirect costs of developing the selected

[21] For initial price applicability year 2026 and initial price applicability year 2027, CMS did not permit R&D costs to be reported for indications that had not yet received FDA approval at the time of ICR submission; however, CMS, consistent with the definitions in this ICR, now permits reporting of such R&D costs related to the selected drug. Therefore, if such R&D costs were reported under Section C, this Section E requires a Primary Manufacturer to report prior Federal financial support associated with such R&D costs that may have occurred on or before the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of data related to the section 1194(e)(1) factors for the negotiation period in which the selected drug's MFP was negotiated that a Primary Manufacturer has not reported for the selected drug previously.

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.[22, 23] For example, if the *direct* costs spent on the selected drug were approximately 10 percent of a Primary Manufacturer's total *direct* basic pre-clinical research costs, then *indirect* costs must be allocated proportionally, thus for the selected drug they must be 10 percent of the total spending on *indirect* costs during that time period.
    - For grants, Primary Manufacturers should use the indirect cost rate at the time of data submission to calculate the proportion of funds that should be allocated to indirect costs. This indirect cost rate could be the fixed rate, provisional/final rate, or predetermined rate.
    - For in-kind contributions and CRADAs, if the dollar value of the in-kind contribution or CRADA is not readily ascertainable, the recipient should provide a reasonable estimate.
- If the Primary Manufacturer shared the prior Federal financial support described in Questions 6 through 8 for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report support received only for costs the Primary Manufacturer incurred. Expenses should be allocated across entities based on each entity's respective stake in the selected drug's discovery and development. The allocation to the Primary Manufacturer should be reported as a dollar amount and the percentage of the total amount allocated to the Primary Manufacturer should be included in the free response field in Question 8. For example, if the Primary Manufacturer was allocated 80 percent of the prior Federal financial support for a period of the selected drug's development, the Primary Manufacturer would include 80 percent of that support in its total number for prior Federal financial support in Question 6. Then, it would note the source of the shared prior Federal financial support and that it received 80 percent of that support in Question 7. If the shared support came in the form of an agreement, the Primary Manufacturer would include this in the "Nature of Agreement" section of Question 8.

Question 6: Federal Funding Support Amount

Instructions for Question 6:

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

[22] 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.
[23] 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.

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

Question 7: Explanation of Calculation of Federal Financial Support

Instructions for Question 7a:

- In the free response field, disaggregate the total Federal financial support amount reported above by the amounts allocated to the sources in the list below. Please list amounts in order of highest to lowest.
  - In addition, describe assumptions, methodological steps, and other information needed to calculate the estimates provided in Question 6.
  - If you report a value for "other Federal financial support not otherwise included elsewhere" in your response to this question, please list the source(s) of that Federal financial support.
  - Please include the identification number for grants and comparable awards.

List of sources for Question 7a

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

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

Instructions for Question 7b:

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

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

Question 8: Agreements Between Primary Manufacturer and Federal Government

List and describe each licensing agreement, pricing agreement, purchasing agreement, and other agreement in place between your company and any federal government agency related to the discovery, research, and/or development of the selected drug. Add additional rows to your response to Question 8 as needed.

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

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

F. Patents, Exclusivities, and Approvals

Primary Manufacturer Response Required

Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Service (PHS) Act. Follow the instructions below when answering Questions 9 through 11.

Definitions for Section F:

- Patents Exclusivities and Approvals. CMS considers relevant patents, both expired and unexpired, and relevant patent applications to include:
  - All patents issued by the United States Patent and Trademark Office (USPTO), both

expired and unexpired, for which a claim of patent infringement could reasonably be, or has been, asserted against a person or manufacturer engaged in the unlicensed manufacture, use, or sale of the selected drug in any form or any person or manufacturer seeking FDA approval of a product that references the selected drug.
    - All patents relevant to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency).
    - All patent applications related to the selected drug that are pending issuance by the USPTO.
- Patents and patent applications relevant to the selected drug include, but are not limited to, any patents that are, have been, or may be listed for the selected drug in the FDA Orange Book or Purple Book;[24] patents that claim the composition of matter (e.g., active ingredient, including its chemical or biological structure), drug product (e.g., the final product taken by or administered to a patient), drug substance (e.g., 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).
- Relevant patents and patent applications do not include patent applications that were denied by the USPTO.
- Exclusivity periods under the FD&C Act or the PHS Act refer to certain delays on the submission or approval of applications for competitor drug products. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met. Exclusivities include:
    - Orphan Drug Exclusivity (ODE);[25]
    - New Chemical Entity Exclusivity (NCE);[26]
    - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);[27]
    - New Clinical Investigation Exclusivity (NCI);[28]
    - Pediatric Exclusivity (PED);[29] and
    - Reference Product Exclusivity for Biological Products.[30]
- 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

[24] FDA serves a ministerial role with regard to the listing of patent information in the Orange Book and Purple Book.
[25] Section 527 of the FD&C Act.
[26] Section 505(c)(3)(E)(ii) and Section 505(j)(5)(F)(ii) of the FD&C Act.
[27] Section 505E(a) of the FD&C Act.
[28] Section 505(c)(3)(E)(iii) & (iv) and Section 505(j)(5)(F)(iii) & (iv) of the FD&C Act.
[29] Section 505A(b) & (c) of the FD&C Act.
[30] Section 351(k)(7) of the PHS Act.

not yet decided.

Instructions for Section F:

- For Questions 9 through 11, the relevant time period for reporting is:
  - **For Primary Manufacturers of drugs selected for negotiation:**
    - Consistent with the definitions above, include patents, approvals and exclusivities issued or filed (and related items) as of December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted.
  - **For Primary Manufacturers of drugs selected for renegotiation:**
    - Include any patents, approvals and exclusivities not previously reported to CMS in any prior full submission of section 1194(e)(1) data issued or filed as of December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted; and
    - Include any patents, approvals, and exclusivities issued or filed that were previously reported to CMS in any prior full submission of section 1194(e)(1) data where there has been a change since the most recent full submission as of December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted. If there are no data to report in response to Questions 9, 10 and/or 11, select "Not applicable" for each relevant question.

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

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

For drugs selected for renegotiation, do not report relevant patents included in prior full submission(s) of data reported by the Primary Manufacturer related to the section 1194(e)(1) factors unless a change occurred following the most recent full submission and prior to December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted. Information may include, for example, a new patent issued after the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated, and any patent where there has been a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated (e.g., patent was removed from the

Orange Book).

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

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

*If no expiration date is available, enter 12/31/9999.

Question 9B: Patent Applications

In the data fields below, please list each patent application that is relevant to the selected drug for

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

For drugs selected for renegotiation, do not report relevant patent applications included in prior full submission(s) of data reported by the Primary Manufacturer related to the section 1194(e)(1) factors unless a change has occurred following the most recent full submission of section 1194(e)(1) data and prior to December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted. Information may include, for example, a new application or applications that have experienced a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data.

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

Patent Number	**Date Filed**	**Patent Type**	**Patent Explanation, or Explanation of What Changed Since Last Submission**	**Patent Application**
Text	*MM/ DD/ YY YY (not applicable if patent pending)*	*Select patent type (allow more than one to be selected): composition of matter patent; 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.*

[ ] (For a drug selected for renegotiation only) Not Applicable.

Question 10: Exclusivity Periods

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

For drugs selected for renegotiation, do not report exclusivity periods listed in prior full submission(s) of data reported by the Primary Manufacturer related to the section 1194(e)(1) factors unless a change has occurred following the most recent full submission of section 1194(e)(1) data and prior to December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted. Information may include, for example, a new exclusivity since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data.

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

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

[ ] (For a drug selected for renegotiation only) Not Applicable.

*If no expiration date is available, enter 12/31/9999.

Question 11: All Active and Pending FDA Applications and Approvals

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

- Include all applications for approval under section 505(c) of the FD&C Act or section 351(a) of the PHS Act, including those not yet decided. Leave approval date blank for those applications not yet approved. *[Complete the data fields for Question 11 by adding rows as needed using the indicated format]*
  - Please submit any efficacy supplements that have been approved or are pending FDA approval but exclude manufacturing supplements.

For drugs selected for renegotiation, do not report active or pending FDA applications listed in prior full submission(s) of data reported by the Primary Manufacturer related to the section 1194(e)(1)

factors unless a change has occurred following the most recent full submission of section 1194(e)(1) data and prior to December 31 of the calendar year prior to the selected drug publication date (as defined in proposed 42 CFR 429.20) of the initial price applicability year for which this ICR is submitted. Information may include, for example, a new application or applications that have experienced a change since the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of section 1194(e)(1) data.

Application (NDA / BLA) Number	**Application Type (NDA; BLA)**	**Classification Code[31]**	**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	*MM DD, YYYY (an approval date entry is not required if patent pending)*	*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)*

[31] 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.

Application (NDA / BLA) Number	Application Type (NDA; BLA)	Classification Code	Approval Date	Indication	Dosage Form and Strength	Sponsor	Application Status	Comments
		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						

[ ] (For a drug selected for renegotiation only) Not Applicable.

Question 12: Predicted Loss of Exclusivity

Provide and explain the Primary Manufacturer's best estimate for loss of exclusivity (earliest expected date on which a generic drug or biosimilar of the selected drug[32] would be allowed to enter the market) for the selected drug. The Primary Manufacturer may choose to include the following information in providing a "best estimate" and explaining such estimate: how specific patents reported in response to Question 9A and/or exclusivities reported in response to Question 10 may protect the selected drug for a given length of time for different strengths, formulations, and indications, the role of any legal decisions or settlement agreements with the manufacturer(s) of or other applicable third-party, that may impact when generic drug(s) or biosimilar(s) of the selected drug are or may be coming to market, or references to public documents (e.g., a Form 10K filing pursuant to section 13 or 15(d) of the Securities and Exchange Act of 1934) or public statements where the Primary Manufacturer has provided commentary on the expected loss of exclusivity of the selected drug.

FIELD	RESPONSE FORMAT
Predicted loss of exclusivity	*Text (6,000 characters which is 500 words)*

G. Market Data and Revenue and Sales Volume Data

Primary Manufacturer Response Required

The purpose of Section G is to collect the market data and revenue and sales volume data described in section 1194(e)(1)(E) of the Act.

[32] Refer to proposed 42 CFR 429.20 for definitions of "generic drug" and "biosimilar".

Definitions for Section G:

- The three NCPDP BUS[33] are: each (EA), milliliter (mL), and gram (GM). For certain volume data of the selected drug, CMS requests units be reported using the NCPDP BUS for all but Medicaid best price to facilitate comparison with the amounts in the quantity dispensed field found in PDE data, which also uses the NCPDP BUS. If an NCPDP BUS of EA is used, one EA must represent a single individual dosage form or dispensable unit (e.g., one tablet, capsule, vial, syringe, inhaler, or patch) and should match what is reported in Section A.
- 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 using NCPDP BUS.
- Average sales price (ASP): The manufacturer's average sales price is defined in 42 CFR 414.902.
- ASP Unit: The unit type used by the manufacturer to report ASP as specified in 42 CFR 414.802.
- Medicaid best price: The Medicaid best price is defined in 42 CFR 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 CFR 447.504) and best price (42 CFR 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 most recently published pharmaceutical price for the selected drug as included in the Federal Supply Schedule as managed by the Department of Veterans Affairs per 48 CFR part 38.[34] The FSS price is reported at the NDC-11 package level.
- Big Four price: The Big Four price is described in 38 U.S.C. 8126.[35] The Big Four price is reported at the NDC-11 package level.
- Manufacturer U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug to commercial health insurance plans, including small group and individual plans on- and off-Exchange and large group plans, excluding Original Medicare (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care. The following items should be deducted from gross revenue in your calculation: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or

[33] See: https://standards.ncpdp.org/Billing-Unit-Request.aspx

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

[35] 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.

other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer. The following items should not be deducted from gross revenue in your calculations: payments to wholesalers, group purchasing organizations (GPOs), pharmacies, or other purchasers and manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price is reported at the NDC-11 level using NCPDP BUS.

- Manufacturer U.S. commercial average net unit price– net of patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer U.S. commercial average net unit price– net of patient assistance program is the manufacturer U.S. commercial average net unit price, with the additional following items deducted: manufacturer-run patient assistance programs that provide financial assistance such as coupons, co-payment assistance, or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price– net of patient assistance program is reported at the NDC-11 level using NCPDP BUS.
- Manufacturer U.S. commercial average net unit price– best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer U.S. commercial average net unit price– best is the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The following items should be deducted from gross revenue in your calculations: discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any commercial payer. The following items should not be deducted from the gross revenue in your calculations: payments to wholesalers, GPOs, pharmacies, or other purchasers and 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 using NCPDP BUS.
- Manufacturer net Medicare Part D average unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price as calculated by the Primary Manufacturer. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year date specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price is reported at the NDC-11 level using NCPDP BUS.

- Manufacturer net Medicare Part D average unit price – best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer net Medicare Part D average unit price – best is the lowest manufacturer net Medicare Part D average unit price offered by the Primary Manufacturer or any Secondary Manufacturer(s) to any Part D plan sponsors in the U.S. The following items should be deducted from gross revenue in your calculation: coverage gap discounts for calendar years prior to the calendar year specified in the applicable information collection and discounts under the Manufacturer Discount Program for the same calendar year as specified in the applicable information collection, and other supply chain concessions (e.g., wholesale discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in kind, free or reduced-price services, grants, or other price concessions) of the Primary Manufacturer or any Secondary Manufacturer(s) not reflected in the sum of the plan-specific enrollment weighted amounts calculation and utilization, that may differ from the PDE data. The manufacturer net Medicare Part D average unit price – best is reported at the NDC-11 level using NCPDP BUS.
- Maximum fair price (MFP): The maximum fair price (MFP) has the meaning set forth in section 1191(c)(3) of the Act. The MFP should be reported in 30-day equivalent supply.

Instructions for Section G:

- For Question 13 through 28, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.
- For Questions 13 through 28, for the sole purpose of data collection under section 1194(e)(1)(E) of the Act, as applicable, the total unit volume must be reported at the NDC-9 or NDC-11 level and reflect the NCPDP BUS and the AMP unit. The total unit volume must include the total unit volume sold by the Primary Manufacturer and any Secondary Manufacturer(s) in the U.S. for the data reported.
- If an NCPDP BUS of EA is used, one EA must represent a single individual dosage form or dispensable unit (e.g., one tablet, capsule, vial, syringe, inhaler, or patch) and should match what is reported in Section A.
- Include NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued.
- For each section, detail in the free response an explanation of the unit used (e.g., unit is one syringe in a four-pack of syringes).

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

- **For drugs selected for negotiation**, a row for each applicable calendar quarter for three years of data ending December 31 of the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted.
- **For drugs selected for renegotiation**, a row for each applicable calendar quarter, beginning with the calendar quarter after the last calendar quarter of data that was submitted to CMS in the most recent full section 1194(e)(1) submission and ending December 31 of the calendar year prior to the selected

drug publication date (defined at proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted. If the period beginning with the calendar quarter after the last calendar quarter of data that was submitted to CMS in the most recent full submission of section 1194(e)(1) data and ending December 31 of the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted is longer than three years, the reporting period is the three calendar years ending with December 31 of the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted.

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

Question 13: Wholesale Acquisition Cost Unit Price

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

- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (mL), or gram (GM). Total unit volume must be the total number of units sold to wholesalers and direct purchasers during the quarter. Please do not include units associated with free samples in the calculated prices or reported total unit volume. If an NCPDP BUS of EA is used, one EA must represent a single individual dosage form or dispensable unit (e.g., one tablet, capsule, vial, syringe, inhaler, or patch) and should match what is reported in Section A.
- If the NDC-11 had multiple WACs for a given quarter, please calculate an average WAC per unit for the quarter using the following methodology. For each WAC per unit available in the quarter, please multiply the WAC per unit by the proportion of the total units sold in that quarter at that WAC out of total unit volume sold in the quarter. Then sum these values across all WACs available in the quarter to calculate the average WAC per unit for the quarter.
- Any deviation from the reported WAC unit price in the data fields below and the WAC unit price as reported in wholesale price guides or other publications of drug or biological price data must be explained in Question 14 so that CMS can understand the reasons for these differences.
- If the NDC-11 was marketed, sold, or distributed at any time during the quarter (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), please complete all requested fields. If the NDC-11 was not marketed, sold, or distributed to any wholesaler or direct purchaser in a particular calendar quarter, please enter "0" in the total unit volume field and provide an explanation in the "Explanation of Unit and 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).

- In the "Explanation of Unit and Explanation of Why WAC Was Not Reported" field, for each NDC-11 provide a written explanation of the specific unit provided for this submission (e.g., the unit EA refers to a single capsule in a bottle of 30).

NDC-11	Quarter	WAC	NCPDP Unit (EA, mL, GM)	Total Unit Volume	Explanation of Unit and 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 14: Explanation of Information Reported in Question 13: 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 13 and those found in available drug databases (e.g., Medi-Span, First Databank, RED BOOK). Additionally, if the WAC unit price has changed between December 31 of the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) of the initial price applicability year for which the drug is selected for negotiation (or renegotiation, as applicable) and for which this ICR is submitted and January 31 of the calendar year this ICR form is submitted, provide the updated WAC unit price. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

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

Question 15: Average Sales Price (ASP)

Has ASP ever been reported for a calendar quarter for the selected drug during the applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

(If response is Yes, please fill out the following data fields. If response is No, please skip to Question 17) Follow the instructions below when providing responses in the following table about each ASP unit of the selected drug:

- Report the ASP, the ASP Unit, and Total Units Sold for the last two sales quarters in the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) of the initial price applicability year for which the drug is selected for negotiation (or renegotiation, as applicable) and for which this ICR is submitted.
- The information provided in the data fields must reflect the same data that was

submitted to CMS consistent with 42 CFR 414.800 *et seq.* (subpart J – Submission of Manufacturer's Average Sales Price Data), including, for example, the ASP Unit(s) reported in accordance with 42 CFR 414.802.

- ASP Unit refers to the ASP Unit type used by the manufacturer to report ASP as specified in 42 CFR 414.802 (e.g. EA, mL, IU).
- If an ASP is reported and "0" is entered for Total Units Sold, explain why "0" units are reported.
- If the NDC-11 was marketed, sold, or distributed at any time during a quarter (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), please complete all requested fields.
- If the NDC-11 was not marketed, sold, or distributed to any wholesaler or direct purchaser in a particular calendar quarter, please enter "0" in the total unit volume field and provide an explanation in the "Explanation of why ASP was not reported (if applicable)" field of why the NDC-11 had no ASP for that calendar quarter (e.g., the NDC-11 was first marketed in a later calendar quarter)
- If ASP was not reported for a specific NDC-11 for a specific quarter, select the checkbox for "Not Applicable" for the NDC-11 and enter an explanation in the "Explanation of Unit and Explanation of why ASP was not reported (if applicable)" field.
- If an ASP reported is negative, provide an explanation in the "Explanation of Unit and Explanation of why ASP was not reported (if applicable)" field of why the ASP is negative.
- In the "Explanation of Unit and Explanation of Why ASP Was Not Reported" field, for each NDC-11 provide a written explanation of the specific unit provided for this submission (e.g., the unit EA refers to a single capsule in a bottle of 30).

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

* Data field is not populated if "Not Applicable" is selected for the "Sales Quarter" for an NDC-11.

Question 16: Explanation of Information Reported in Question 15: ASP

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

response to Question 15. Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

FIELD	RESPONSE FORMAT
Explanation of ASP 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 applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

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

- The Medicaid best price information must reflect what was submitted to Medicaid under the MDRP in accordance with the Medicaid National Drug Rebate Agreement and as described in 42 CFR 447.505 – Determination of best price. The reported Medicaid best price in the data fields below must reflect any restatements that have been certified under the MDRP.
- Total unit volume for the quarter is the sum of monthly AMP units reported to the MDRP for the quarter.
- If a Medicaid best price determination was made during the calendar quarter for that NDC-9 (including corresponding NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), please complete all requested fields. If the NDC-9 did not have a Medicaid best price determination in a particular calendar quarter, please enter "0" in the total unit volume field and provide an explanation in the "Explanation of why Medicaid best price was not reported (if applicable)" field of why the NDC-9 had no Medicaid best price determination for that calendar quarter (e.g., the NDC-9 was first marketed in a later quarter).

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

Question 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 applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

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

- The FSS price information must reflect the published pharmaceutical price(s) for the selected drug as included in the Federal Supply Schedule as managed by the Department of Veterans Affairs per 48 CFR part 38, which can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs, and inclusive of the Industrial Funding Fee (IFF).[36] 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).
- Total unit volume is the total number of units for each NDC-11 sold indirectly (e.g., through a wholesaler) or directly to federal purchasers. Please do not include units

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

associated with free samples in the reported total unit volume.

- For each NDC-11, please include a row for each price period that occurred during an applicable calendar quarter specified in the instructions above, and fill out the requested information.
  - If the NDC-11 did not have a FSS price during an applicable calendar quarter specified in the instructions above, please enter "0" in the total unit volume field. Also provide an explanation in the "Explanation of why FSS price was not reported (if applicable)" field of why the NDC-11 had no FSS price during an applicable calendar quarter specified in the instructions above (e.g., the NDC-11 was discontinued before the period for the requested data began).
- If an NDC-11 had a FSS price for a reported price period but no units were sold, please enter "0" in the Total Unit Volume Field and provide the FSS in the "Explanation of why FSS price was not reported (if applicable)" field.
- Please complete Questions 19 and 20 for the FSS 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 price."

NDC-11	**Price Start Date to End Date**	**Federal Supply Schedule Price**	**Package Description**	**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 applicable time period specified in the instructions above?

RESPONSE FORMAT
Yes/No

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

- The Big Four price information must reflect the information that can be found online in the pharmaceutical pricing data for all VA National Acquisition Center programs, and inclusive of the Industrial Funding Fee (IFF).[37] We note that the Big Four price information should be for the NDC-11 package (e.g., for a bottle of 30 tablets, please report the Big Four price for the bottle).
- Total unit volume is the total number of units for each NDC-11 indirectly (e.g., through a wholesaler) or directly sold to the Big Four federal agencies (Department of Veterans Affairs, Department of Defense, the Public Health Service, and the Coast Guard). Please do not include units associated with free samples in the reported total unit volume.
- For each NDC-11, please include a row for each price period that occurred during an applicable calendar quarter specified in the instructions above (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued), and fill out the requested information. If the NDC-11 did not have a Big Four price during an applicable calendar quarter specified in the instructions above, please enter "0" in the total unit volume field and provide an explanation in the "Explanation of why Big Four price was not reported (if applicable)" field of why the NDC-11 had no Big Four price during an applicable calendar quarter specified in the instructions above (e.g., the NDC-11 was discontinued before the period for the requested data began).
- Please complete Questions 19 and 20 for the FFS FSS 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 price."

NDC-11	Price Start Date to Price End Date	Big Four Price	Package Description	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.

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

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 date fields about the Manufacturer U.S. commercial average net unit price:

- For each NDC-11, please include a row for each quarter during the applicable time period specified in the instructions above, based on the Primary Manufacturer's responses in Section A (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued).
  - If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields.
  - If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter "0" in the total unit volume field provide an explanation in the "Explanation of why Manufacturer U.S. Commercial prices were not reported (if applicable)" field of why the NDC-11 had no Manufacturer U.S. commercial prices for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- Exclude price and volume information for the selected drug for the following plans: Original Medicare (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid managed care.
- If the Primary Manufacturer and Secondary Manufacturer(s) did not provide financial assistance to patients, please leave the "U.S. commercial average net unit price─ net of patient assistance programs" field blank. Use "$0" as the price for a unit provided by the manufacturer at no charge to the patient.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (mL), or gram (GM). Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- In the "Explanation of Units and Why Manufacturer U.S. Commercial Prices Were Not Reported (if applicable" field, for each NDC-11 provide a written explanation of the specific unit provided for this submission (e.g., the unit EA refers to a single capsule in a bottle of 30).

NDC-11	Quarter	Manufacturer U.S. Commercial Average Unit Net Price	Manufacturer U.S. Commercial Average Net Unit Price- Net of Patient Assistance Programs	Manufacturer U.S. Commercia l Average Net Unit Price-Best	NCPDP Unit (EA, mL, GM)	Total Unit Volume	Total Unit Volume for U.S. Commercial Average Net Unit Price - Best	Explanation of Units and 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 private health insurance plans, including small group and individual plans on- and off-Exchange and large group plans were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any commercial payer were allocated across NDC-11s and calendar quarters.
- If applicable, how financial assistance, such as coupons or co-payment assistance, to patients was allocated across NDC-11s and calendar quarters.
- How information was used to calculate the "U.S. commercial average net unit price" the "U.S. commercial average net unit price─ net of patient assistance programs," and the "U.S. commercial average net unit price─ best".
- Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

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

Question 25: Manufacturer Net Medicare Part D Average Unit Price

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

- For each NDC-11, please include a row for each quarter during the applicable time period specified in the instructions above, based on the Primary Manufacturer's responses in Section A (including NDC-11s that were marked in Section A as sample packages, inner packages, outer packages and NDC-11s that are discontinued).
  - If the NDC-11 was ever marketed, sold, or distributed at any time during the quarter, please complete all requested fields.
  - If the NDC-11 was not marketed, sold, or distributed in a particular quarter, please enter "0" in the total unit volume field and provide an explanation in the "Explanation of why manufacturer net Medicare Part D Price was not reported (if applicable)" field of why the NDC-11 had no manufacturer net Medicare Part D price for that calendar quarter (e.g., the NDC-11 was first marketed in a later quarter).
- Only include price and volume information of the selected drug for Part D plan sponsors.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (mL), or gram (GM). Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- In the "Explanation of Unit and Explanation of Why Manufacturer Net Medicare Part D Average Unit Price Was Not Reported" field, for each NDC-11 provide a written explanation of the specific unit provided for this submission (e.g., the unit EA refers to a single capsule in a bottle of 30).

NDC-11	**Calendar Quarter**	**Manufacturer Net Medicare Part D Average Unit Price**	**Manufacturer Net Medicare Part D Average Unit Price - Best**	**Medicare Manufacturer Discount Program or Coverage Gap Discount Program Amount Paid (Per NCPDP Unit)**	**NCPDP Unit (EA, mL, GM)**	**Total Unit Volume**	**Total Unit Volume for Net Medicare Part D Average Unit Price - Best**	**Explanation of Units and Why Manufacturer Net Medicare Part D Average Unit Price Was Not Reported (if applicable)**
12345-6789-01	*QQYYY*	*$*	*$*	*$*	*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 Coverage Gap Discount Program or Medicare Manufacturer Discount Program, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any commercial payer were allocated across NDC-11s and calendar quarters.
- If applicable, how unit price was separated for enrollee and/or plan type.
- How information was used to calculate the "Manufacturer Net Medicare Part D Average Unit Price" and the "Manufacturer Net Medicare Part D Average Unit Price – best."
- Please indicate not applicable (N/A) in the free response field if no explanation is necessary.

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

Question 27: Payer Mix of Prescriptions for the Selected Drug

Question 27a: Payer Mix by Unit Volume of Prescriptions for the Selected Drug
Estimate the percentage of total units dispensed for all indications for the Selected Drug that were paid for by each payer type for the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) for the initial price applicability year for which this ICR is submitted.

PAYER TYPE(S)	**PERCENT OF UNITS DISPENSED PAID FOR BY PAYER TYPE**
Select Option (Original Medicare (Parts A and B), Medicare Advantage, Medicaid fee-for-service, Medicaid managed care, Commercial (Private health insurance plans, including small group and individual plans on- and off-Exchange and large group plans, excluding Original Medicare (Parts A and B), Other 3rd Party Payer, Manufacturer-run patient assistance programs that provide financial assistance such as coupons or free drug products to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s)), Cash, Other)	#

Question 27b: Payer Mix by Unit Volume of Prescriptions for the Selected Drug by Indication (OPTIONAL)

Estimate the percentage of prescriptions within each indication that were paid for by each payer type for the same time period as Question 27A.

INDICATION(S)	**PAYER TYPE(S)**	**PERCENT OF UNITS DISPENSED PAID FOR BY INDICATION AND PAYER TYPE**
List each indication (repeat an indication, as needed, for each payer type); add additional rows until estimates are provided for each indication.	*Select Option (Original Medicare, Medicare Advantage, Medicaid managed care, Medicaid fee-for-service, Commercial, Other 3rd Party, Cash, Other)*	#

Question 27c: Explanation of Payer Mix by Unit Volume of Prescriptions for the Selected Drug

Describe assumptions, methodological steps, and other information relied on to provide the responses to Questions 27a and 27b. If other was selected above, please explain what that refers to.

FIELD	**RESPONSE FORMAT**
Explanation	*Text (12,000 character count limit, which is approximately 1,000 words)*

Question 28: Maximum Fair Price

For drugs selected for renegotiation only, report the single agreed upon MFP for the 30-day equivalent supply of the selected drug. The single agreed upon MFP must reflect the information that can be found online in the most recent published file, Selected Drug List and Negotiated Prices, also known as Maximum Fair Prices in Statute, and inclusive of any annual inflation adjustments.

FIELD	**RESPONSE FORMAT**
MFP as a 30-Day Equivalent Supply for the Selected Drug	*$*

Question 29: Primary Manufacturer Identification of Information Submitted in Sections A through G that the Primary Manufacturer Believes Should be Withheld as Proprietary Information[38]

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 proposed 42 CFR 429.300, 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 confidential if CMS deems the information is proprietary including trade secrets and confidential commercial or financial information.[39]

In addition to the information CMS already designates as proprietary consistent with 42 CFR 429.300: For information submitted that the Primary Manufacturer believes should *also* be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including under Exemption 3 and/or 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(3), (4)),[40] follow the instructions below to identify this information for CMS. This identification of information by the Primary Manufacturer will be used during CMS' process to determine which information submitted by a manufacturer is proprietary and which information may be disclosed in the public explanation of the MFP consistent with proposed 42 CFR 429.300.

- In the "Location" data field, identify the location of the information the Primary Manufacturer believes should be withheld in Sections A through G by either:
    - Using [brackets] at the start and end of any full sentence(s) within a free response field(s) that contains information the Primary Manufacturer believes should be withheld. Also use [brackets] at the start and end of any data provided, if permitted in the data entry field (for example, because the field is a text field), to identify information the Primary Manufacturer believes should be withheld.
        - Label the end of each bracketed sentence with a number in sequential order and use the same number originally assigned to a bracket throughout Sections A through G each time the same justification will be used in response to Question 29 as the reason the manufacturer believes the information should be withheld (e.g., {1}, {2}). To differentiate references in response to Question 29 from citations, use different symbols for numbering (for example, a {curly brace} for Question 26 and (parenthesis) for citations).
    - For a data response field where brackets cannot be entered (for example, the field

[38] Primary Manufacturer's response to Question 29 will not be included in the MFP Explanations (which are described in proposed 42 CFR 429.705(b)).

[39] Specifically, as described in proposed 42 CFR 429.300, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that are publicly available as non-proprietary because CMS understands these data are publicly available.

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

requires a numerical response) (in other words, a "non-bracketed location"), listing the specific location of the information by identifying the Section letter, Question number, data entry field, and/or line number to specifically identify the starting and ending point, of information the Primary Manufacturer believes should be withheld.

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

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

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

An individual eligible to certify this submission on behalf of the Primary Manufacturer must be one of the following: (1) the chief executive officer (CEO) of the Primary Manufacturer; (2) the chief financial officer (CFO) of the Primary Manufacturer; (3) an individual with equivalent authority to a CEO or CFO of the Primary Manufacturer; or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Required for Primary Manufacturers:

Certification:

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

otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act and/or in the form of civil monetary penalties pursuant to section 1197(c) of the Act.

Checkbox for certification [ ]

Contact Information to be entered:

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

I. Evidence About Alternative Treatments

Optional for All Respondents, Including Primary Manufacturer

While CMS is seeking public input under section 1194(e)(2) of the Act to consider information on the selected drug and its potential therapeutic alternative(s), respondents are not required to include personally identifiable information[41] (PII), protected health information[42] (PHI) or proprietary information that includes confidential or trade-secret information. CMS seeks to collect only the minimum necessary information related to the selected drug and its potential therapeutic alternatives for the purpose of implementing and operating the Negotiation Program. CMS will not retrieve evidence for manufacturer negotiations by personal identifier (PII or PHI). CMS will not, through this collection, create or maintain a system of records as understood by the Privacy Act of 1974 and accompanying Office of Management and Budget guidance. Section I is applicable to drugs selected for negotiation and drugs selected for renegotiation.

For Primary Manufacturers of drugs selected for renegotiation that choose to respond to Section I, the applicable time period to provide the requested responses is from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's most recent full submission of data related to section 1194(e)(2) factors to CMS for the negotiation period in which

[41] 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.

[42] Protected health information (PHI), consistent with proposed 42 CFR 429.20, is individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. Individually identifiable information is information, including demographic data, that relates to the individual's past, present, or future physical or mental health or condition; the provisions of health care to the individual; or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. PII includes many common identifiers such as name, address, birth date, Social Security Number, etc. See https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html.

the selected drug's MFP was negotiated through December 31 of the calendar year prior to the selected drug publication date (defined at proposed 42 CFR 429.20) of the initial price applicability year for which the drug is selected for negotiation (or renegotiation, as applicable) and for which this ICR is submitted.

Question 30: Respondent Information

Required: Individuals or organizations, including manufacturers, that wish to provide information in this Section I must provide the following information.[43]

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

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

[ ] Representative of a manufacturer of the selected drug [this category is pre-selected for a Primary Manufacturer when submitting information about its selected drug]

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

[ ] Representative of a manufacturer that does not manufacture the selected drug or a potential therapeutic alternative(s)

[ ] Representative of a trade association

[ ] Representative of a patient advocacy organization

[ ] A health care provider who has experience prescribing, dispensing, or administering the selected drug or its potential therapeutic alternative(s) or treating conditions pertinent to the selected drug or its potential therapeutic alternative(s)

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

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

[ ] Academic researcher or other subject matter expert on topics including but not limited to pharmaceutical policy, comparative effectiveness research, and/or clinical value assessment

[ ] Other

[43] 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.

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

- [For all options (except this question does not populate for a Primary Manufacturer when submitting about its selected drug)] Are you or your organization affiliated with the manufacturer of the selected drug or its potential therapeutic alternative(s)?[44]

General Instructions for Section I

- All questions are optional.
- Any interested party may answer Questions 30 through 61. Each interested party will be able to answer each of Questions 30 through 61 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 30 through 60 should also review Question 61 and respond as applicable.
- CMS has grouped Questions 31 through 58 in five categories of topics that are addressed by the set of questions. Specifically, these categories by question number are:
    - Questions 31-37: Patient- or Caregiver-Focused Input
    - Questions 38-43: Manufacturer-Focused Input
    - Questions 44-49: Clinical-Focused Input
    - Questions 50-56: Health Research-Focused Input
    - Questions 57-59: 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 31 through 59. These examples are intended as illustrative; a respondent is not limited to any category of questions based on the individual's or organization's insight and/or experience.
    - Patient or Caregiver-Focused Input—for example, an individual with experience taking the selected drug or a different medicine that may be used to treat the same condition or disease state (which is also called a potential therapeutic alternative(s) to the selected drug), a caregiver's experience caring for someone taking such drugs, patient organizations with insight into patients' lived experience of taking such drugs or living with a condition the drugs treat.
    - Manufacturer-Focused Input—for example, a Primary Manufacturer of a selected drug.
    - Clinical-Focused Input—for example, clinicians, pharmacists, hospitals, or other entities with clinical experience related to the selected drug, its therapeutic alternatives, or the condition(s) the drugs treat.
    - Health Research-Focused Input—for example, researchers, academic centers, patient

[44] 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.

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, along with citations for any responses in Section I and visual representations.
- The Additional Instructions and the Instructions for Reporting Monetary Amounts included in this ICR apply to Section I. These instructions are for respondents providing original data but are not applicable when a respondent provides citations for existing published data.
- If known to you, indicate in your response if a portion of a response applies to specific dosages, forms, strengths, and/or indications of a selected drug or its therapeutic alternative(s).
- Please answer each question in narrative (text) form. Your responses will be limited to the character count maximum specified for a specific question. The total character count includes all characters, such as spaces between words and symbols.
- **Information provided in response to an individual question does not need to be duplicated across additional responses. CMS will review submissions holistically across the entire submission.**
- All declarative statements should be supported by evidence with a citation, unless you are sharing a personal experience with prescribing or taking the selected drug and/or its therapeutic alternative(s) or you are a caregiver describing the experience of the person taking the selected drug and/or its therapeutic alternative(s).
- Submissions for Section I may include but are not limited to published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports.
    - CMS prefers publicly available, peer reviewed literature rather than poster abstracts and non-peer reviewed literature. When providing non-peer reviewed literature, CMS must be provided sufficient information on these studies in order to assess their applicability to the Negotiation Program. Information should, at a minimum, include methods, data sources, and limitations for unpublished evidence.
    - Please note that CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in proposed 42 CFR 429.505(e).
    - Please provide citations to published material rather than copies of articles. The respondent is responsible for ensuring that their submission complies with applicable law, including but not limited to copyright law. If data are unpublished, clearly indicate this in the citation. For unpublished data without a citation, please summarize key findings as appropriate in your response.
- When citing studies to support responses, briefly summarize the study context and relevant comparator or therapeutic alternative drug(s) studied, as applicable.
    - When information in the free text response is supported by a citation provided in response to that question, please label the end of the sentence in the free text response with a number in the order the citation first appears (e.g., [1], [2]) and submit the citations in the same order in response to Question 61. Use the number originally assigned to for the same source citation each time the citation is used throughout Section I.

    - In response to Question 61, respondents are requested to provide the list of all citations. Additional instructions are included with Question 61 to link and format citations.
- CMS will review submitted studies that use cost-effectiveness measures or methods to determine if the study is relevant to the selected drug and/or its therapeutic alternative(s) and to determine if the cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than an individual who is younger, nondisabled, or not terminally ill.
- As described in proposed 42 CFR 429.505(d), 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.[45] 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 quality-adjusted life-years (QALYs). In instances where a study includes a measure that treats extending the life of individuals who are elderly, disabled, or terminally ill as of lower value but separates such a measure from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS may consider such separate evidence.
- Submissions may include visual representations of the information, including tables, charts, and/or graphs. The information submitted in the space for visual representations in Question 60 should only include the table/chart/graph, and no additional text. CMS will not review any additional text included beyond the titles, labels, legends, and footnotes in the visual representation. PDF files will be accepted within specified file size limits for visual representations. List the question number that a submitted table/chart/graph corresponds to in the free text response provided with the question to submit tables/charts/graphs.
    - To upload a PDF file, it must first be converted to a Zip file. Multiple PDF files must be uploaded together in one Zip file.
- CMS will only review the maximum number of citations or upload files permitted in the instructions.

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

- Therapeutic Advance: Consistent with proposed 42 CFR 429.20, a demonstrated improvement in one or more outcomes or other clinical considerations for an identified condition of a selected drug as compared to its therapeutic alternative(s). For purposes of the Negotiation Program, anytime CMS considers therapeutic advance, CMS would consider the extent to which the drug represents a therapeutic advance at the time of consideration based on all available information at such time of consideration.
- Therapeutic Alternative: Consistent with proposed 42 CFR 429.20, a pharmaceutical product or group of pharmaceutical products other than the selected drug that may be used to treat the same condition or disease state as the selected drug.
- Outcomes: Consistent with proposed 42 CFR 429.20, the impact of an intervention,

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

which may be clinical or related to the functioning, symptoms, quality of life, or other aspects of a patient's life.

- 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.[46]
- Specific populations: Specific populations include individuals with disabilities, the elderly, individuals who are terminally ill, children, and other patient populations among Medicare beneficiaries.
- Unmet medical need: Consistent with proposed 42 CFR 429.20, 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.[47] For purposes of the Negotiation Program, anytime CMS considers an unmet medical need, CMS would consider the extent to which the drug addresses an unmet medical need at the time of consideration based on all available information at such time of consideration.
- 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 CFR 201.57(c)(2) or other applicable FDA regulation(s) and off-label use(s) that are included in evidence-based clinical practice guidelines and the off-label use is a medically-accepted indication covered under Part D and/or payable under Part B, taking into consideration the major drug compendia, authoritative medical literature, and/or accepted standards of medical practice. For the purpose of an ICR submission, a respondent may combine FDA-approved indications (e.g., identical adult and pediatric indications) and off-label use(s). The respondent may also choose not to report on certain FDA-approved indications or off-label uses.
- Off-label Use: Consistent with proposed 42 CFR 429.20, off-label use means use for a condition for a selected drug or therapeutic alternative that is not an FDA-approved indication but is included in evidence-based clinical practice guidelines and is a medically accepted indication payable under Part B or covered under Part D or both, taking into consideration the major drug compendia, authoritative medical literature, accepted standards of medical practice, or some combination thereof.

<u>FDA-Approved Indications and Off-label Uses for the selected drug</u>

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.

[46] 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).

[47] 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.

The selected drug is approved by the FDA for the following indications: [CMS to provide a prepopulated list of all FDA-approved indications that will be accessible to respondents]

Questions 31 through 60: Optional for All Respondents

Questions 31 through 37: Patient-Focused Experience

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

Question 31: Background

Question 31a: Have you or someone you provide care for ever taken the selected drug?

Field	Response
Response to Question 31a	*Check box: YES or NO*

If you answer yes, review Questions 31a1 and 31a2. If you answer no, skip to Questions 31a3 and 31a4.

Question 31a1: [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 31a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 31a2: [If YES] How long have you or someone you provide care for lived with this condition or conditions?

Field	Response
Response to Question 31a2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 31a3 [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 31a3	*Text* (6,000 character count limit, which is approximately 500 words)

Question 31a4: [If NO] What is your experience with this condition or conditions?

- Please include how long you or someone you provide care for have lived with the condition or conditions, if applicable.

Field	***Response***
Response to Question 31a4	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 32: Information on Your Condition(s) or Condition(s) of Someone You Care For

Question 32a: How do the condition(s) you listed in Question 31a1 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 32a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 32b: What is important to you or those you provide care for in managing the condition(s) you listed in Question 31?

- 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). These may be short- or long-term considerations.
- 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 32b	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 32c: What challenges do you, or someone you care for, face in managing this condition(s)?

Field	**Response**
Response to Question 32c	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 33: Information on the Current Medication to Treat Your Condition

Question 33a: Are you, or someone you care for, currently taking medication(s) to manage the condition(s) you listed in Question 31?

Field	Response
Response to Question 33a	*YES or NO*

If you answer yes, review Questions 33a2 through 33a4. If you answer no, skip to Question 34.

Question 33a1: [If YES] What medication(s) are you, or someone you provide care for, currently taking to manage the condition(s) you listed in Question 31?

- If more than one medication is currently taken, please list medications in the order you started them.
- If possible, please indicate how long you have taken your current medication(s), to the best of your knowledge.

Field	Response
Response to Question 33a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 33a2: [If YES] What factors, if any, affected the choice of medication(s) you or someone you care for are currently using to manage the condition(s) you listed in Question 31?

- 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 33a2	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 33a3: [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 31?

- 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 33a3	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 33a4: [If YES] How satisfied are you, or someone you care for, with the medication(s) you are currently taking to manage your condition(s)?

Field	Response
Response to Question 33a4	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 34: Information on the Medication(s) Used in the Past to Treat Your Condition

Question 34a: Have you, or someone you care for, taken other medication(s) in the past to manage the condition(s) you listed in Question 31?

Field	Response
Response to Question 34a	*YES or NO*

If you answer yes, review Question 34b1 through 34b4. If you answer no, skip to Question 35.

Question 34b1: [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 31?

- If possible, please indicate how long past medication(s) were taken to the best of your knowledge.

Field	Response
Response to Question 34b1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 34b2: [If YES]
What factors, if any, affected the choice of medication(s) used in the past to manage the condition(s) you listed in Question 31?

- 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 34b2	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 34b3: [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 31?

- 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 34b3	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 34b4: [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 31?

Field	Response
Response to Question 34b4	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 35: Medical Needs Related to Condition(s)

What are important medical needs related to condition(s) you listed in Question 28, and to what extent are these needs being addressed, or not addressed, by existing treatment options for this condition(s)?

- What medical needs were you hoping treatments for this condition(s) would address?
- Do certain medication(s) or treatment(s) address those needs to a greater or lesser extent than others?

Field	Response
Response to Question 35	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 36: 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 36	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 37: Demographic Questions [Only when a respondent selects the "patient" or "caregiver" option in response to Question 30.]

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

Field	Response Options
Age	Select one: Under 18 years 18-24 years 25-34 years 35-44 years 45-64 years 65-84 years 85-99 years 100 years or older
Regional Location	Select one: New England: CT, ME, MA, NH, RI, VT Middle Atlantic: NJ, NY, PA Midwest-East North Central: IN, IL, MI, OH, WI Midwest-West North Central: IA, KS, MN, MO, NE, ND, SD South-South Atlantic: DE, DC, FL, GA, MD, NC, SC, VA, WV South-East South Central: AL, KY, MS, TN South-West South Central: AR, LA, OK, TX West-Mountain: AZ, CO, ID, NM, MT, UT, NV, WY West-Pacific: AK, CA, HI, OR, WA U.S. Territory: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands Other
Medicare Beneficiary	Select one: Yes No

Questions 38 through 43: Manufacturer-Focused Questions

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

Instructions for Questions 38 through 43

Manufacturers are permitted to submit a dossier in Question 43. Dossier submission is optional. Such dossiers may be used to supplement responses provided in Questions 38 through 43. CMS requests that manufacturers submitting a dossier also submit an outline of the location of information related to Questions 38 through 43, to the extent applicable.

Question 38: Potential therapeutic alternatives

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

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

Question 39: Use in treatment and clinical comparative effectiveness evidence

Question 39a: 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 38*), if any, in the course of care for the indication(s) relative to the selected drug.

Field	Response
Response to Question 39a	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 39b: For the indication(s) identified in the instructions and Question 38, identify relevant clinical outcome measures CMS should consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety). Include references to any supporting citations listed in Question 60 for identified clinical outcome measures.

Field	Response
Response to Question 39b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 39c: For the indication(s) of the selected drug, identify any relevant

evidence evaluating the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of the selected drug and potential therapeutic alternatives. Relevant comparative evidence may include but is not limited to: head-to-head randomized controlled trials, pragmatic clinical trials, network meta-analyses, observational studies, and real-world evidence. Include references to any supporting citations listed in Question 60 for relevant comparative evidence.

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

Question 40: Prevalence, utilization, and cost estimates

Question 40a: For the indication(s) of the selected drug, provide an estimate of its prevalence among the Medicare population. Include references to any citations listed in Question 56 and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 40a	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 40b: For the indication(s) of the selected drug, provide an estimate of Medicare utilization of the selected drug for that indication. Estimates of Medicare utilization can include estimates of total number of patients treated, estimates of share of selected drug prescriptions dispensed to patients with that indication, or similar measures. Include references to any citations listed in Question 60 and/or brief methodology to support the estimate(s).

Field	Response
Response to Question 40b	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 40c: 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: patterns of use, disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to the selected drug and any potential therapeutic alternatives. Include references to any citations listed in Question 61 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 40c	*Text* (18,000 character count limit, which is approximately 1,500 words)

Question 41: Therapeutic advance and unmet medical need

Question 41a: For the indication(s) of the selected drug, describe the extent to which the selected drug currently represents a therapeutic advance as compared to its potential therapeutic alternative(s) taking into consideration differences in outcomes and costs. Reference any supporting citations listed in Question 61.

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

Question 41b: For the indication(s) of the selected drug, describe any unmet medical need(s) and the extent to which the selected drug and its potential therapeutic alternative(s) address such need(s).

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

Question 42: Specific populations and patient experience

Question 42a: For the indication(s) of the selected drug, identify any specific populations (e.g., elderly, individuals with disabilities, the terminally ill, children, and other patient populations) that are impacted by the selected drug and/or its potential therapeutic alternative(s), and describe how they are impacted. Include any supporting citations listed in Question 61.

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

Question 42b: For the indication(s) of the selected drug, identify evidence regarding patient experiences related to the indication(s), selected drug, and/or its potential therapeutic alternative(s). This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the indication, treatment burden, burden of disease, or other patient experience data. Reference any supporting citations listed in Question 61.

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

Question 43: Dossier Submission

Manufacturers are permitted to submit a dossier in Question 43. Such dossiers may be used to supplement responses provided in questions 38 through 42, preferably formatted using an industry standard such as the most current AMCP Format for Formulary Submissions. Manufacturers submitting a dossier may highlight and/or submit **an outline indicating the location of information within the drug dossier** that the manufacturer suggests is related to Questions 38 through 42, 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.

CMS notes that citations included in a dossier submission are not subject to the 250-citation limit specified in Question 61, however, like any content included in a dossier submission, these citations will be considered supplemental in nature. Citations submitted in Question 61 should directly support the written responses to Questions 38 through 42.

Response
Text (Up to 2 PDF files in a Zip file, one of these files may include an outline of the location of the information in the drug dossier related to Questions 38 through 42, as applicable)

Questions 44 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 potential therapeutic alternative(s) for those indication(s). CMS is interested in obtaining the perspectives of health care providers who have clinical experience with prescribing or managing use of the selected drug and/or its potential therapeutic alternative(s) for these indication(s).

Question 44: Background Questions

Question 44a: Are you a health care provider (i.e., a person who is trained and licensed to give health care[48])?

Field	Response
Response to Question 44a	*YES or NO*

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

If you answer yes, review Questions 44a1. If you answer no, skip to Question 44.

Question 44a1: [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 44a1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 44b: Do you have experience prescribing or managing the use of the selected drug?

Field	Response
Response to Question 44b	*YES or NO*

If you answer yes, review Question 44b1. If you answer no, skip to Question 44b2.

Question 44b1: [If YES] For which indication(s) (which includes off-label use(s) per the definition provided in the instructions) have you prescribed or managed use of the selected drug that you would like to provide CMS information on?

Field	Response
Response to Question 44b1	*Text* (6,000 character count limit, which is approximately 500 words)

Question 44b2: [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 44b2	*Text* (6,000 character count limit, which is approximately 500 words)

Question 45: Treatment-related Questions

Question 45a: 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 45a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 45b: 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 45b	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 45b1: What would you consider to be a meaningful improvement or treatment response for the outcomes listed in Question 45b?

- Is there a widely-accepted minimum clinically important difference for these outcomes?

Field	**Response**
Response to Question 45b1	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 45b2: Would you assess improvement or treatment response differently in certain patient subpopulations? If so, which subpopulations and why?

Field	**Response**
Response to Question 45b2	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 45c: Are there widely used evidence-based clinical practice guidelines for the condition(s) treated by the selected drug? If so, please cite these guidelines and explain how they are used to support clinical decision-making. For off-label use, please also reference any citations listed in Question 61 for major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.

Field	**Response**
Response to Question 45c	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46: Additional Treatment-related Questions

Question 46a: 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 46a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46b: 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 46b	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46c: What medications would you consider to be potential therapeutic alternatives for the selected drug for treatment of the condition(s) treated with the selected drug? For the list of potential therapeutic alternatives and indications, provide a brief explanation of the reason for the identification of the potential therapeutic alternative(s) of the selected drug and any indication(s). Reference any citations listed in Question 61 where applicable.

Field	**Response**
Response to Question 46c	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46d: What considerations drive treatment selection among the selected drug and its potential therapeutic alternative(s) for the indication(s)?

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

Field	**Response**
Response to Question 46d	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46e: Are there notable differences between how the selected drug or the potential therapeutic alternative(s) identified in Question 46c 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 46e	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46f: How would you characterize the benefits and risks associated with the selected drug?

Field	**Response**
Response to Question 46f	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46f1: In your opinion, how do the benefits and risks associated with the selected drug differ from the benefits and risks associated with its potential therapeutic alternative(s) for the indication(s)?

Field	Response
Response to Question 46f1	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46f2: What specific populations or patient subgroups may derive greater benefits or be at risk for greater harms by using the selected drug or any of its potential therapeutic alternative(s) for the indication(s)?

Field	Response
Response to Question 46f2	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 46g: How would you assess whether a patient is tolerating and/or responding to the selected drug or any of its potential therapeutic alternative(s) when used for each indication(s)?

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

Field	Response
Response to Question 46g	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 47: Access and Patient Experience

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

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

Question 48: Therapeutic Advance and Unmet Medical Need

Question 48a: For the condition(s) treated by the selected drug, describe the extent to which the selected drug currently represents (or does not represent) a therapeutic advance as compared to its potential therapeutic alternative(s) taking into consideration differences in outcomes and costs.

Field	Response

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

Question 48b: For the indication(s) of the selected drug, describe any unmet medical need(s) and the extent to which the selected drug and its potential therapeutic alternatives address such need(s).

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

Question 49: What other information about the selected drug, its potential therapeutic alternative(s), or the indication(s) do you think CMS should consider in its evaluation of the selected drug? Reference any citations listed in Question 61 when applicable.

Field	**Response**
Response to Question 49	*Text* (12,000 character count limit, which is approximately 1,000 words)

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

Question 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 potential therapeutic alternatives for the selected drug for each indication(s)? For the list of potential therapeutic alternative(s) and indications, provide a brief explanation of the reason for the identification of the potential therapeutic alternative(s) of the selected drug and any indication(s). Reference any citations listed in Question 61 where applicable.

Field	Response
Response to Question 51	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 52: Comparative Clinical Evidence

Question 52a: What relevant clinical outcome measures should CMS consider in its evaluation of clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of the selected drug and its potential therapeutic alternative(s) for the indication(s)? Reference any supporting citations listed in Question 61 where applicable.

Field	Response
Response to Question 52a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 52b: For the indication(s) of the selected drug, identify any relevant evidence evaluating the clinical comparative effectiveness (e.g., clinical efficacy, real-world effectiveness, or safety) of the selected drug and potential therapeutic alternative(s). Relevant comparative evidence may include but is not limited to: head-to-head randomized controlled trials, pragmatic clinical trials, network meta-analyses, observational studies, and real-world evidence. Reference any supporting citations listed in Question 61.

Field	Response
Response to Question 52b	*Text* (36,000 character count limit, which is approximately 3,000 words)

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 alternative(s), and/or condition(s) treated by the selected drug? This may include but is not limited to evidence regarding patient priorities and preferences related to treatment of the condition(s), treatment burden, burden of disease, or other patient experience data. Reference any supporting citations listed in Question 61.

Field	Response
Response to Question 53a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 53b: What specific populations or patient subgroups are impacted by the selected drug and/or its potential therapeutic alternative(s) for the condition(s) treated by the selected drug? How are these populations or subgroups impacted? Identify studies focused on the impact of the selected drug and its potential therapeutic alternative(s) on the specific populations. Reference any supporting citations listed in Question 61 where applicable.

Field	Response
Response to Question 53b	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 53c: What considerations related to health insurance coverage or access to the selected drug, its potential therapeutic alternative(s), and/or or this condition(s) treated by the selected drug? Reference any supporting citations listed in Question 61 where applicable.

Field	Response
Response to Question 53c	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 54: Prevalence, Utilization, and Cost Estimates

Question 54a: For each indication(s), provide an estimate of prevalence among the Medicare population. Reference any citations listed in Question 61 and/or provide a brief methodology to support the estimate.

Field	Response
Response to Question 54a	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 54b: For each indication(s), provide an estimate for Medicare utilization of the selected drug and/or its potential therapeutic alternative(s). Estimates of Medicare

utilization can include estimates of total number of patients treated, estimated share of [selected drug] prescriptions dispensed, furnished, or administered to patients for a given indication, or similar measures. Reference any citations listed in Question 61 and/or provide a brief methodology to support the estimate.

Field	Response
Response to Question 54b	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 54c: 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: patterns of use, disease burden or cost-of-illness analyses, cost-effectiveness or cost-utility analyses, and/or other analyses of health care resource utilization relevant to the selected drug and any potential therapeutic alternatives. Include references to any citations listed in Question 61 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 54c	*Text* (12,000 character count limit, which is approximately 1,000 words)

Question 55: Therapeutic advance and unmet medical need

Question 55a: For the indication(s) of the selected drug, describe the extent to which the selected drug currently represents a therapeutic advance as compared to its potential therapeutic alternative(s) taking into consideration differences in outcomes and costs. Reference any supporting citations listed in Question 61.

Field	Response
Response to Question 55a	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 55b: For the indication(s) of the selected drug, describe any unmet medical need(s) and the extent to which the selected drug and its potential therapeutic alternative(s) address such need(s).

Field	Response
Response to Question 55b	*Text* (36,000 character count limit, which is approximately 3,000 words)

Question 56: What other information or evidence do you think CMS should consider in the evaluation of the selected drug? Reference any citations listed in Question 61 when applicable.

Field	Response
Response to Question 56	*Text* (12,000 character count limit, which is approximately 1,000 words)

Questions 57 through 59: Other Public Input

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

Question 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* (12,000 character count limit, which is approximately 1,000 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)? Reference any citations listed in Question 61 when applicable.

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

Questions 60 and 61: Visual Information and Citations

Question 60: Visual Representations to Support Responses in Section I
Provide up to 20 visual representations such as tables, charts, and/or graphs that support the responses in Section I. Indicate which question each file corresponds to. Regardless of the number of PDF files uploaded in the single Zip file, respondents may not submit more than 20 total visuals (e.g., tables, charts, and/or graphs).

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

Question 61: Citations to Support Responses in Section I
Provide up to 250 citations that support the responses provided in Section I. Citations should be labeled with a number corresponding to the number used by the respondent to reference the source in-text throughout Section I. Citations should be listed in the order the citation is first used within Section I. For example, the citation #1 included on the citation list, can be referenced in-text as such (1). CMS notes that the 250-citation limit applies across the submission, including any citations in the additional attachments for visual representations. If there are citations relevant to the visual representations, include them in this citation list.

Provide each citation in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/. When available, please include a Pub Med ID (https://pubmed.ncbi.nlm.nih.gov/) or, if the Pub Med ID is not available, include the Digital Object Identifier (DOI) (https://www.doi.org/). Additionally, please provide a hyperlink to the source, if possible.

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

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

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

Numbered List	Full Citation	PubMed ID, if available [if no PubMed,	Hyperlink, if available

		provide DOI]	
1	Surname First-and-Middle-Initials, Surname First-and-Middle Initials. Article Title. Journal Title. Date of Publication; Volume (Issue): Pagination.	123456789	www.pubmed.com/example

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

Question 62: Identification of Information Submitted in Section I that the Respondent Believes Should be Withheld as Proprietary Information[49]

In addition to the information CMS already designates as proprietary consistent with proposed 42 CFR 429.300: [50] For each question that a respondent to Section I believes contains information that should be withheld by CMS consistent with existing federal requirements for protecting proprietary information, including under Exemptions 3 and/or 4 of the FOIA, follow the instructions below to identify this information for CMS. This identification of information by a respondent to Section I will be used during CMS' process to determine which information submitted is proprietary and which information may be disclosed in the public explanation of the MFP consistent with proposed 42 CFR 429.300.

- Using [brackets] at the start and end of any full sentence(s) within a free response field(s) that contains information the respondent believes should be withheld. Also use [brackets] at the start and end of any data provided, if permitted in the data entry field (for example, because the field is a text field), to identify information the respondent believes should be withheld.
    - Label the end of each bracketed sentence with a number in sequential order and use the same number originally assigned to a bracket throughout Section I each time the same justification will be used in response to Question 61 as the reason the respondent believes the information should be withheld (e.g., {1}, {2}). To differentiate references in response to Question 61 from citations, use different symbols for numbering (for example, a {curly brace} for Question 61 and (parenthesis) for citations).
- In the "Location" data field, identify the location of the information the respondent believes should be withheld in Section I by either:
    - For a data response field where brackets cannot be entered (for example, a visual representation) (in other words, a "non-bracketed location"), listing the specific

[49] A respondent's response to Question 62 will not be included in the MFP Explanations (which is described in proposed 42 CFR 429.705(b)). For clarity, this means that CMS will not publish that a Primary Manufacturer identified certain data should be withheld in response to Question 62 in publishing the explanation of the MFP, but CMS still retains the authority to determine whether such data may be published in accordance with its confidentiality policy as set forth in proposed 42 CFR 429.300.

[50] Specifically, as described in proposed 42 CFR 429.300, CMS will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary. CMS will treat the data on prior Federal financial support and approved patent applications, exclusivities, and approved applications under section 505(c) of the FD&C Act or section 351(a) of the PHS Act that is publicly available as non-proprietary.

location of the information by identifying the Question number, data entry field, and/or line number to specifically identify the starting and ending point, of information the respondent believes should be withheld.

- In the "Justification" data field, provide a brief explanation regarding why respondent believes the information should be withheld as proprietary information.
  - For a bracketed item, provide the Justification for each separate number used within Section I (e.g., {1}, {2}). Do not repeat the same Justification.
    - If a Primary Manufacturer provides a Section I submission and includes a response to Question 62, restart numbering at {1} in Section I.
  - For a non-bracketed location, if the Justification is the same Justification as a bracketed item, the respondent should use the number assigned to the bracketed item with the corresponding justification as the response to the "Justification" data field. For example, if a non-bracketed item's Justification is the same as the Justification for bracketed item {1}, the respondent should enter "{1}" in the Justification response field for that non-bracketed item.

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

J. Certification of Submission of Section I for All Respondents

Required for All Respondents of Section I

Certification:

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

Checkbox to indicate yes [ ]

Contact Information for respondent:

Field	**Response**
Name of the Person Responsible for the Submission	*Text*

Field	Response
Signature	*Text*
Date	*MMDDYYYY*

Paperwork Reduction Act Disclosure Statement:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1452 (Expires XX/XX/XXXX)**. This information collection is both a mandatory and voluntary information collection and this information will be used to implement Sections 11001 and 11002 of the Inflation Reduction Act. The time required to complete this information collection is estimated to average 3 hours for individuals and 30 hours for organizations per response for the general public and 1,000 total hours per response for the manufacturers of selected drugs for negotiation and 750 hours for manufacturers of selected drugs for renegotiation, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. This information collection is both mandatory and voluntary (sections 1193(a)(4) and 1194(e)(1) and (2) of the Social Security Act) and will be carried out consistent with the confidentiality requirements specified at section 1193(c) of the Social Security Act and proposed 42 CFR 429.300. 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: TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS ICR FORM

In accordance with section 1194(d) of the Act and proposed 42 CFR 429.440, in the case of a selected drug that is a qualifying single source drug described in section 1192(d)(2) of the Act and, with respect to a drug selected for negotiation, is a drug selected for negotiation for initial price applicability year 2029 or 2030, or, with respect to a drug selected for renegotiation, is a drug selected for renegotiation for initial price applicability year 2029 or 2030, for which the Primary Manufacturer submits information in accordance with proposed 42 CFR 429.440(b)(1), and CMS determines that such drug meets the requirements of proposed 42 CFR 429.440(b)(2), CMS will not offer or accept an MFP that is below the temporary floor for small biotech drugs (the "Temporary Floor for Small Biotech Drugs"). The Temporary Floor for Small Biotech Drugs will be established at 66 percent of the average non-FAMP price for such drug for 2021, increased by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U)[51] from September 2021 to September of the year prior to the selected drug publication date with respect to the initial price applicability year. If a selected drug does not have an average non-FAMP for 2021, the average non-FAMP for the first full year following the market entry for the selected drug will be used, increased by the percentage increase in the CPI-U from December of the first full year following the market entry to September of the year prior to the selected drug publication date.

CMS needs to collect information to accurately identify, at the request of the Primary Manufacturer, whether a given selected drug is eligible for the Temporary Floor for Small Biotech Drugs.

For initial price applicability year 2029 and 2030, section 1194(d) of the Act requires CMS to evaluate whether a selected drug meets the criteria in section 1192(d) of the Act to qualify as a "small biotech" drug and be eligible for the Temporary Floor for Small Biotech Drugs. CMS will make separate determinations with respect to the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track") and the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"). For initial price applicability year 2029 and 2030, a selected drug that meets either the Part D or Part B criteria will qualify as a small biotech drug and be eligible for the Temporary Floor for Small Biotech Drugs.

For purposes of determining if the selected drug is a "small biotech" drug for purposes of determining if the selected drug is eligible for the Temporary Floor for Small Biotech Drugs, in accordance with proposed 42 CFR 429.440, CMS needs to collect information to accurately identify the "Part D 2021 Manufacturer" and/or the "Part B 2021 Manufacturer", as applicable, as defined in proposed 42 CFR 429.440(a). The Part D 2021 Manufacturer is the entity that either had a Medicare Coverage Gap Discount Program (CGDP) Agreement under section 1860D-14A of the Act in effect for the qualifying single source drug on December 31, 2021 or had an arrangement whereby the manufacturer's labeler codes were listed on another manufacturer's Medicare CGDP Agreement, consistent with section 1860D-14A of the Act, in effect on December 31, 2021. The

[51] The "CPI-U" means the Consumer Price Index for All Urban Consumers (United States city average) as published by the Bureau of Labor Statistics (https://www.bls.gov/cpi/data.htm).

Part B 2021 Manufacturer is the NDA holder or the BLA holder for the qualifying single source drug on December 31, 2021. In addition, the aggregation rule at section 1192(d)(2)(B)(i) of the Act requires that CMS treat as a single manufacturer all corporations or partnerships, sole proprietorships, and other entities that, on December 31, 2021, were treated as a single employer (i.e., part of the same controlled group) under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 (IRC) with the Part D 2021 Manufacturer or Part B 2021 Manufacturer. The Part D 2021 Manufacturer and its controlled group, as defined in proposed 42 CFR 429.440(a), comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part D 2021 Manufacturer. CMS also collects information regarding the unique identifier assigned by CMS (P Number) and labeler code(s) for these entities. The Part B 2021 Manufacturer and its controlled group, as defined in proposed 42 CFR 429.440(a) comprises all persons that, as of December 31, 2021, were treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 with the Part B 2021 Manufacturer. CMS also collects information regarding the NDA(s) and/or BLA(s) for qualifying single source drugs held by the Part B 2021 Manufacturer and the Part B 2021 Manufacturer's controlled group on December 31, 2021. Additionally, the limitation at section 1192(d)(2)(B)(ii) of the Act states that a qualifying single source drug does not meet the requirements of section 1192(d) if the manufacturer of such drug is acquired after 2021 by another entity that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(C)(ii) of the Act[52], and therefore such drug would not be eligible for the Temporary Floor for Small Biotech Drugs under section 1194(d) of the Act.

A determination by CMS that a given selected drug qualifies as a small biotech drug and is therefore eligible for the Temporary Floor for Small Biotech Drugs for an initial price applicability year is not based on whether or not CMS previously determined that a selected drug was eligible for the Small Biotech Exception in initial price applicability years 2026, 2027, and/or 2028.

Instructions:

- A Primary Manufacturer must complete and submit the information requested on this form in order for the drug to be considered to be a small biotech drug and eligible for the Temporary Floor for Small Biotech Drugs for initial price applicability year 2029 or 2030. For a selected drug covered under Part D to be considered under the Part D Track, a Primary Manufacturer should complete Section A, Section B, and Section D; for a selected drug payable under Part B to be considered under the Part B Track, a Primary Manufacturer should complete Section A, Section C, and Section D; to be considered under both the Part D Track and Part B Track, a Primary Manufacturer should complete Section A, Section B, Section C, and Section D.
- If the Primary Manufacturer holding the NDA(s) / BLA(s) for the drug was acquired by another entity after December 31, 2021, the Primary Manufacturer must provide information regarding that acquiring entity for CMS to assess whether the acquisition triggers the limitation at section 1192(d)(2)(B)(ii) of the Act.

[52] *See* 42 CFR 423.2716, 423.2720, and 423.2724.

- Primary Manufacturers may submit a request for the Temporary Floor for Small Biotech Drugs for an initial price applicability year via the CMS Health Plan Management System (the "CMS HPMS").
- A request for the Temporary Floor for Small Biotech Drugs that is incomplete or not timely submitted via the CMS HPMS in accordance with these instructions and applicable regulations will not be accepted.
- All submissions require certification. The certification of the ICR should be executed by (1) the chief executive officer (CEO) of the Primary Manufacturer; (2) the chief financial officer (CFO) of the Primary Manufacturer; (3) an individual with equivalent authority to a CEO or CFO of the Primary Manufacturer; or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).
- To complete this form, the Primary Manufacturer must provide the following:
  - Disclosure of whether the Primary Manufacturer was acquired by another entity after 2021, and if so, identifying information about the acquiring entity as of the date of submission, including the acquiring entity's name, EIN(s), and mailing address, as well as any P number(s) of the acquiring entity;
  - Under the Part D track:
    - Identifying information as of December 31, 2021 for the entity that had a Medicare CGDP Agreement for the selected drug covered under Part D in effect on December 31, 2021, and for all members of that entity's controlled group as of December 31, 2021 that had a Medicare CGDP Agreement in effect on December 31, 2021; and/or
  - Under the Part B track:

    Identifying information as of December 31, 2021 for the entity that held the NDA(s) / BLA(s) for the selected drug payable under Part B as of December 31, 2021, and all NDA(s) and/or BLA(s) held by that entity and its controlled group as of December 31, 2021.

A. Primary Manufacturer Information

Section A contains one question regarding the acquisition of the Primary Manufacturer.

Question 1: Acquisition of the Primary Manufacturer

Question 1a: Was the Primary Manufacturer acquired after December 31, 2021? Note: This question is about the acquisition of the Primary Manufacturer and is **not** about the acquisition of the selected drug.

Yes / No

Note: If the answer to question 1a is 'Yes,' answer Question 1b. If the answer to Question 1a is 'No,' skip Question 1b and proceed to Section B (if applying for the Part D Track) or Section C (if

applying for the Part B Track).

Instructions for Question 1b: If you answered "Yes" to Question 1a above, please provide the following information about the entity that acquired the Primary Manufacturer.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn

B. Part D Track: Information for Selected Drugs Covered Under Part D

If requesting the Temporary Floor for Small Biotech Drugs for a selected drug covered under Part D, **please complete Section B of this ICR in its entirety**. Otherwise, please skip to the Part B Track in Section C.

Section B contains two questions for the Part D Track for a selected drug that is covered under Part D. One question asks about the entity that had a Coverage Gap Discount Program Agreement in effect for the selected drug as of December 31, 2021 ("Part D 2021 Manufacturer"). The other question collects information about the members of that entity's controlled group (if any) as of December 31, 2021 that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021.

Question 2: Part D 2021 Manufacturer Coverage Gap Discount Program Agreement Information

Question 2a: On December 31, 2021, did the Primary Manufacturer have a Coverage Gap Discount Program Agreement in effect for the selected drug?[53]

Yes / No

Note: If the answer to Question 2a is 'No,' answer Question 2b and skip Question 2c. If the answer to Question 2a is 'Yes,' skip Question 2b and answer Question 2c.

Question 2b: Please provide the following information as of December 31, 2021 about the entity that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021, for the selected drug.

[53] A manufacturer that participated in the Coverage Gap Discount Program (CGDP) in 2021 by means of an arrangement whereby its labeler codes were listed on another manufacturer's CGDP Agreement would be considered to have had an agreement in effect during 2021.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number), if any	nnnnn
Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	nnnnn

Instructions for Question 2c: Please provide the following information as of December 31, 2021 about the Primary Manufacturer.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number), if any	nnnnn
Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	nnnnn

Question 3: Part D 2021 Manufacturer Controlled Group Information

Question 3a: Did the entity that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021 for the selected drug (i.e., either the Primary Manufacturer or the entity identified in Question 2b, as applicable) have other members in its controlled group as of December 31, 2021 that had a Medicare Coverage Gap Discount Program Agreement in effect on December 31, 2021? For the purposes of this information collection request, "controlled group" means all corporations or partnerships, sole proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

Yes / No

Note: If the answer to Question 3a is 'Yes,' answer Question 3b. If the answer to Question 3a is 'No,' skip Question 3b and proceed to Section C (if applying for the Part B Track) or certification to complete the Part D Track.

Question 3b: If yes, provide the following information as of December 31, 2021, for **each such** member of the controlled group of the entity that had the Coverage Gap Discount Program Agreement in effect on December 31, 2021, for the selected drug.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn
Labeler Code(s) owned by this entity that are associated with this entity's unique identifier (P number), if any	nnnnn
Labeler Code(s) owned by this entity that are associated with unique identifier(s) (P number(s)) owned by other entities, if any	nnnnn

Add a separate entry with the six data elements for each member of the entity's controlled group that had a Coverage Gap Discount Program Agreement in effect on December 31, 2021.

C. Part B Track: Information for Selected Drugs Payable Under Part B

If requesting the Temporary Floor for Small Biotech Drugs for a selected drug payable under Part B, **please complete Section C of this ICR in its entirety**. Otherwise, please skip to Section D.

Section C contains two questions that pertain to information required to make a determination under the Part B Track for a selected drug that is payable under Part B. Section C contains one question about the entity that held the NDA(s) or BLA(s) for the selected drug as of December 31, 2021 ("Part B 2021 Manufacturer"). CMS will populate information regarding the NDA(s) or BLA(s) that comprise the selected drug as of the selected drug publication date. The other question collects information about the members of that entity's controlled group (if any) as of December 31, 2021.

Question 4: 2021 NDA/BLA Holder Information

Question 4a: On December 31, 2021, did the Primary Manufacturer hold the NDA(s) / BLA(s) for the selected drug?

Yes / No

Note: If the answer to Question 4a is 'Yes,' skip to Question 4di and Question 4dii. If the answer to Question 4a is 'No,' answer Question 4b and Question 4c, and skip Questions 4di and 4dii.

Question 4b: Please provide the following information as of December 31, 2021 about the entity that held the NDA(s) or BLA(s) on December 31, 2021, for the selected drug.

Field	Response
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn

Mailing Address	Text
Unique Identifier Assigned by CMS (P number), if any	Pnnnn

Question 4c: Please list the NDA(s) and/or BLA(s) that were held as of December 31, 2021 by the entity that held the NDA(s) or BLA(s) on December 31, 2021 for the selected drug (i.e., the entity identified in Question 4b). This list should include the NDA(s) and/or BLA(s) for the selected drug, as well as all NDA(s) and/or BLA(s) for drugs and biological products other than the selected drug.

Application Number (123456)	**Application Type (NDA; BLA)**	**Approval Date**	**NDA/BLA Holder**
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text

Add a separate row for each additional NDA / BLA.

Question 4di: Please review the list of NDA(s) and/or BLA(s) of the selected drug that are held by the Primary Manufacturer as of the selected drug publication date. Use the check box to indicate whether the NDA or BLA was held by the Primary Manufacturer on December 31, 2021. Add a separate row for any additional NDA(s) and/or BLA(s) of the selected drug held by the Primary Manufacturer on December 31, 2021 that were not prepopulated by CMS.

Application Number (123456)	**Application Type (NDA; BLA)**	**Approval Date**	**NDA/BLA Holder**	**Check Box if NDA/BLA was held on December 31, 2021**
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text	[ ]

Add a separate row for each additional NDA / BLA that is not pre-populated by CMS.

Question 4dii: Please list all NDA(s) and/or BLA(s) for drugs and biological products other than the selected drug held by the Primary Manufacturer as of December 31, 2021.

Application Number (123456)	**Application Type (NDA; BLA)**	**Approval Date**	**NDA/BLA Holder**
Nnnnnn	Select NDA or BLA	MM/DD/YYYY	Text

Add a separate row for each additional NDA / BLA.

Question 5: Part B 2021 Manufacturer Controlled Group Information

Question 5a: Did the entity that held the NDA(s) or BLA(s) on December 31, 2021 for the selected drug (i.e., either the Primary Manufacturer or the entity identified in Question 4b, as applicable) have other members in its controlled group as of December 31, 2021? For this information collection request, "controlled group" means all corporations or partnerships, sole proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986.

Yes / No

Note: If the answer to Question 5a is 'Yes,' answer Question 5b. If the answer to Question 5a is 'No,' skip to certification.

Question 5b: If yes, provide the following information as of December 31, 2021, for **each such** member of the controlled group of the entity.

Field	**Response**
Entity Name	Text
Employer Identification Number(s) (EIN(s))	nn-nnnnnnn
Mailing Address	Text
NDA(s) and/or BLA(s) the entity held as of December 31, 2021	nnnnn

Add an additional row for each NDA and BLA the entity held as of December 31, 2021.

Add a separate entry with the four data elements for each member of the entity's controlled group.

D. 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 to determine whether the selected drug of the Primary Manufacturer qualifies for the Temporary Floor for Small Biotech Drugs, as described in proposed 42 CFR 429.440. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed or is otherwise inaccurate. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act and/or in the form of civil monetary penalties pursuant to section 1197(d) of the Act.

Check box for certification: [ ]

Contact Information

Field	Response
Name of the Person Responsible for the Submission	(information is prepopulated by CMS based on the CMS HPMS user information)
Signature	Text
Date	Date

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 is a required information collection to retain or obtain a benefit. Specifically, a manufacturer must submit the ICR in order for its selected drug to be considered for the Temporary Floor for Small Biotech Drugs. The time required to complete this information collection is estimated to average 9.75 hours per response for Primary Manufacturer to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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

PART 3: DRUG PRICE NEGOTIATION AND RENEGOTIATION PROCESS COUNTEROFFER ICR FORM

Section 1193(a)(1) of the Social Security Act ("the Act") establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of manufacturer established in section 1847A(c)(6)(A) of the Act. In accordance with proposed 42 CFR 429.20, to the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of an initial price applicability year, 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, for a drug selected for negotiation and with respect to that specific selected drug, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Negotiation Program Agreement, or, February 28th of the calendar year of the selected drug publication date for the initial price applicability year that the drug is selected for negotiation. For a drug selected for renegotiation and with respect to that specific selected drug, the renegotiation period for the initial price applicability year begins February 28 of the calendar year of the selected drug publication date for such initial price applicability year. CMS intends to implement the offer and counteroffer process consistent with the statutory goal of negotiating to achieve agreement on "the lowest [MFP] for each selected drug," established in section 1194(b)(1) of the Act. In accordance with sections 1194(b)(2)(B) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.520(a) and 429.620(f), CMS will make a written initial offer to the Primary Manufacturer with the proposal for the MFP for a drug selected for negotiation or renegotiation for an initial price applicability year no later than June 1 of the calendar year of the selected drug publication date for the initial price applicability year that the drug is selected for negotiation or renegotiation. In accordance with sections 1194(b)(2)(C) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.525(a) and 429.620(g), the Primary Manufacturer will respond to CMS' written initial offer no later than 30 days after the date of receipt of the written initial offer from CMS. If the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer will submit a written counteroffer (referred to herein as the "statutory written counteroffer" for the negotiation process and the "renegotiation written counteroffer" for the renegotiation process, collectively referred to herein as the "Counteroffer"), including an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP for the drug selected for negotiation or renegotiation. In accordance with sections 1194(b)(2)(D) and 1194(f)(4)(B) of the Act and proposed 42 CFR 429.525(c) and 429.620(g), CMS will provide a written response to the statutory written counteroffer and the renegotiation written counteroffer, respectively. CMS will provide this response within 30 days of receipt or within 60 days of sharing the written initial offer, whichever is later. If CMS rejects the Primary Manufacturer's Counteroffer, CMS and Primary Manufacturers can choose to initiate additional, written offers and counteroffers via the additional price exchange module in the CMS HPMS. Proposed 42 CFR 429.530, 429.535, 429.620(h), and 429.620(i) describes the remainder of the negotiation process and renegotiation process in greater detail.

Every written offer and counteroffer, including a Counteroffer, will include an Addendum to the Negotiation Program Agreement populated with the proposal for the MFP. If an agreement on the MFP is reached at any point during the negotiation process described at 42 CFR subpart F or the renegotiation process described at 42 CFR subpart G, the Addendum to the Negotiation Program Agreement, as proposed in 42 CFR 429.200(e), will be executed by both parties and will constitute agreement on the MFP. The MFP included in the executed Addendum to the Negotiation Program Agreement will apply for the selected drug for an initial price applicability year, subject to the conditions and timing described in proposed 42 CFR 429.130 and 429.135 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 proposed 42 CFR 429.705 and 429.620(k) for information on how the MFP will be updated for subsequent years in the price applicability period.

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

The estimated burden of the ICR for a Counteroffer submission from a Primary Manufacturer of a selected drug and review of the Counteroffer submission by CMS staff is provided in the accompanying Supporting Statement. More information on the negotiation process can be found in 42 CFR subpart F and more information on the renegotiation process can be found in proposed 42 CFR subpart G.

Note: This ICR focuses on information required for the submission of Counteroffers during the negotiation and renegotiation process for initial price applicability year 20XX.

Instructions for Completing the Counteroffer ICR Form

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

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

- The Primary Manufacturer's Counteroffer proposal for the MFP per 30-day equivalent supply of the selected drug (as described in proposed 42 CFR 429.525(b));
- Subject to the 30,000 character count limit, which is approximately 2,500 words, a justification of the Counteroffer based on the factors listed in section 1194(e) of the Act. The Primary Manufacturer's Counteroffer justification should focus on the elements described in section 1194(e) of the Act and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer under section 1194(e)(1) or (e)(2) of the Act, or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the

written initial offer made by CMS and better supports the Primary Manufacturer's Counteroffer. The data related to the section 1194(e) factors may be information already submitted to CMS by the Primary Manufacturer or other interested parties, information submitted as part of the Counteroffer, or information that is otherwise available and considered by CMS. A Primary Manufacturer may include in their Counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) of the Act that supports the Counteroffer proposal for the MFP and additional information it deems relevant, such as a request to include certain information from the Counteroffer justification in CMS' public explanation of the MFP, and;

- A certification by: (1) the chief executive officer (CEO); (2) the chief financial officer (CFO); (3) an individual with equivalent authority to a CEO or CFO of the Primary Manufacturer; or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Additional instructions for submitting the Counteroffer ICR Form are as follows:

- If the Primary Manufacturer chooses to submit the Counteroffer ICR Form, this form must be completed and submitted within the CMS HPMS within 30 days of receiving the written initial offer from CMS.
- Question 1 asks the Primary Manufacturer to enter its Counteroffer proposal for the MFP for a 30-day equivalent supply of the selected drug. CMS will interpret this proposal as a single price per 30-day equivalent supply (rather than per unit – such as tablet, capsule, injection – or per volume or weight-based metric), weighted across dosage forms and strengths, if applicable. The Primary Manufacturer may reference information provided by CMS during the negotiation or renegotiation process regarding the application of a single MFP across dosage forms and strengths of the selected drug to understand how the 30-day equivalent supply Counteroffer proposal for the MFP will convert into prices for each dosage form and strength of the selected drug.
- The Primary Manufacturer should answer Question 2 in narrative (text) form. Responses will be limited to the 30,000 character count limit, which is approximately 2,500 words, 10 visual representations of data, and a maximum of 50 citations. All response fields are limited to a character count. Response fields provide a maximum character count and corresponding estimated word count. Total character counts include all characters within the response, including spaces between words.
- Submissions may include but are not limited to published or unpublished material such as peer-reviewed articles, whitepapers, case studies, and government reports.
    - CMS prefers publicly available, peer reviewed literature rather than poster abstracts and non-peer reviewed literature. When providing non-peer reviewed literature, CMS must be provided sufficient information on these studies in order to assess their applicability to the Negotiation Program. Information should, at a minimum, include methods, data sources, and limitations for unpublished evidence.

- Please note that CMS reserves the right to review submitted materials for relevance and in accordance with the standards outlined in proposed 42 CFR 429.505(e).
- 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 in your response and upload any relevant visual representations 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]) and submit the citations in the same order in response to Question 3. In response to Question 3, respondents are requested to provide the list of all citations. Additional instructions are included with Question 3 to link and format citations.
- CMS will review submitted studies that use cost-effectiveness measures or methods to determine if the study is relevant to the selected drug and/or its therapeutic alternative(s) and to determine if the cost-effectiveness measure used does not value extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than an individual who is younger, nondisabled, or not terminally ill.
- As described in 42 CFR 429.505(e), 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. Information submitted that treats extending the life of individuals in the listed populations as of lower value will not be used in the Negotiation Program. Moreover, in accordance with section 1182(e) of Title XI of the Social Security Act and other applicable law, including section 504 of the Rehabilitation Act, CMS will not use QALYs. In instances where a study includes a measure that treats extending the life of individuals who are elderly, disabled, or terminally ill as of lower value but separates such a measure from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS may consider such separate evidence.
- In addition to the Counteroffer justification, the Primary Manufacturer may upload up to 10 visual representations of information, including charts, tables, and/or graphs, as part of the ICR to support the justification. The information submitted in the space for visual representations in Question 4 should only include the table, chart, or graph with 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. PDF files must be uploaded together in a Zip file. The free text response should include clear numbers/references to the charts,

tables, or graphs submitted. When information in Question 2 is supported by a chart, table, or graph, the Primary Manufacturer should label the end of the sentence in the free text response with a letter (e.g., [A], [B]) that corresponds to the letter assigned to the provided document.

- CMS will only review the maximum number of citations or upload files permitted in the instructions.
- If a Primary Manufacturer is the holder of the NDA(s) / BLA(s) for multiple selected drugs for an initial price applicability year, a separate form must be submitted for each selected drug for which the Primary Manufacturer chooses to submit a Counteroffer.

Appendix: Counteroffer ICR Form

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Statutory Written Counteroffer
ICR Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). In accordance with section 1194(b)(2)(B) of the Act, CMS has provided the Primary Manufacturer of the selected drug named above with a written initial offer that contains CMS' proposal for the selected drug's maximum fair price (MFP), as defined in section 1191(c)(3) of the Act, and a concise justification based on the factors described in section 1194(e) of the Act. 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) of the Act and proposed 42 CFR 429.525(a).

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 with equivalent authority to a CEO or CFO of the Primary Manufacturer; or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Question 1: Proposal for the MFP per 30-day equivalent supply
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-based metric), weighted across all dosage forms and strengths of the selected drug, 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 will apply to the dosage forms and strengths as identified on the list of National Drug Codes (NDCs) of the selected drug maintained by CMS.

Proposal for the MFP per 30-day equivalent supply
$

Question 2: Statutory Written Counteroffer Justification
Please provide a justification of the statutory written counteroffer proposal for the MFP based on the factors listed 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 listed 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)

Question 3: Citations to Support the Justification
Provide up to 50 citations that support the justification provided in response to Question 2. Citations should be labeled with a number corresponding to the number used by the respondent to reference the source in-text throughout the response to Question 2. Citations should be listed in the order the citation is first used within the response to Question 2. For example, the citation #1 included on the citation list, can be referenced in-text as such [1].

Provide each citation in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/. When available, please include a Pub Med ID (https://pubmed.ncbi.nlm.nih.gov/) or, if the Pub Med ID is not available, include the Digital Object Identifier (DOI) (https://www.doi.org/). Additionally, please provide a hyperlink to the source, if possible.

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

FIELDS	RESPONSE FORMAT
• *Numbered List* • *Full Citation* • *PubMed ID, if available* • *If the PubMed ID is not available, the Digital Object Identifier (DOI), if available* • *Hyperlink, if available*	*Text* (Up to 50 citations within a PDF file in one Zip file)

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

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

Question 4: Visual Representations to Support the Justification
Provide up to 10 visual representations such as tables, charts, and/or graphs that support the justification provided in response to Question 2. Regardless of the number of PDF files uploaded in the

single Zip file, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

FIELD	RESPONSE
Visual Representations to Support the Justification	*Text* (Up to 10 PDF files in a single Zip file)

Certification

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including determination of an MFP, as defined in section 1191(c)(3) of the Act. I understand further that the proposed price submitted in this Statutory Written Counteroffer ICR Form, if accepted by CMS, is intended to be the MFP as defined in section 1191(c)(3) of the Act for the selected drug for purposes of section 1193(a)(1) of the Act. I certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may give rise to liability, including under the False Claims Act and/or in the form of civil monetary penalties pursuant to section 1197(c) of the Act.

Yes [ ] No [ ]

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1452 (Expires XX/XX/XXXX)**. This information collection includes the form a Primary Manufacturer must submit in order to submit a statutory written counteroffer for a selected drug, and this information will be used to implement Sections 11001 and 11002 of the Inflation Reduction Act. The time required to complete this information collection is estimated to average 204.25 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and to review and complete the information collection. This information collection is required to retain or obtain a benefit (section 1194(b)(2)(C) of the Social Security Act) and will be carried out consistent with the confidentiality requirements specified at section 1193(c) of the Social Security Act and in proposed 42 C.F.R. 429.300. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Renegotiation Written Counteroffer ICR Form

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-

169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (the Act). In accordance with section 1194(f)(4)(B) of the Act and proposed 42 CFR 429.620(f), CMS has provided the Primary Manufacturer of the selected drug named above with a written initial offer that contains CMS' proposal for the selected drug's maximum fair price (MFP), as defined in section 1191(c)(3) of the Act, and a concise justification based on the factors described in section 1194(e). Submission of this form indicates that the Primary Manufacturer has not accepted CMS' written initial offer and is submitting a renegotiation written counteroffer.

In order for CMS to consider the Primary Manufacturer's renegotiation written counteroffer, this form must be certified by (1) the chief executive officer (CEO) of the Primary Manufacturer; (2) the chief financial officer (CFO) of the Primary Manufacturer; (3) an individual with equivalent authority to a CEO or CFO of the Primary Manufacturer; or (4) an individual that has been granted delegation of signature authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

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

Proposal for the MFP per 30-day equivalent supply
$

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

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

Question 3: Additional Materials to Support the Justification
Provide up to 50 citations that support the justification provided in response to Question 2. Citations should be labeled with a number corresponding to the number used by the respondent to reference the source in-text throughout the response to Question 2. Citations should be listed in the order the citation

is first used within the response to Question 2. For example, the citation #1 included on the citation list, can be referenced in-text as such [1].

Provide each citation in the National Library of Medicine (NLM) style format appropriate for the source of information (e.g., a journal article). Information on how to format citations is available for free through the NLM at: https://www.ncbi.nlm.nih.gov/books/NBK7256/. When available, please include a Pub Med ID (https://pubmed.ncbi.nlm.nih.gov/) or, if the Pub Med ID is not available, include the Digital Object Identifier (DOI) (https://www.doi.org/). Additionally, please provide a hyperlink to the source, if possible.

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

FIELDS	RESPONSE FORMAT
• *Numbered List* • *Full Citation* • *PubMed ID, if available* • *If the PubMed ID is not available, the Digital Object Identifier (DOI), if available* • *Hyperlink, if available*	*Text* (Up to 50 citations within a PDF file in one Zip file)

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

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

Question 4: Visual Representations to Support the Justification
Provide up to 10 visual representations such as tables, charts, and/or graphs that support the justification provided in response to Question 2. Regardless of the number of PDF files uploaded in the single Zip file, respondents may not submit more than 10 total visuals (e.g., tables, charts, and/or graphs).

FIELD	RESPONSE
Visual Representations to Support the Justification	*Text* (Up to 10 PDF files in a single Zip file)

Certification
I hereby certify, to the best of my knowledge, that the information being sent to CMS in this

submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS for Medicare reimbursement purposes, including determination of an MFP, as defined in section 1191(c)(3) of the Act. I understand further that the proposed price submitted in this Renegotiation Written Counteroffer ICR Form, if accepted by CMS, is intended to be the MFP as defined in section 1191(c)(3) of the Act for the selected drug for purposes of section 1193(a)(2) 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 and/or in the form of civil monetary penalties pursuant to section 1197(c) of the Act.

Yes [ ] No [ ]

PRA Disclosure Statement

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