

Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW)

Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (P.L. 117-169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (“the Negotiation Program”), codified in sections 1191 through 1198 of the Social Security Act (“the Act”). The Act establishes the Negotiation Program to negotiate a maximum fair price (“MFP”), defined at section 1191(c)(3) of the Act, for certain high expenditure, single source drugs covered under Medicare Part B and Part D (“selected drug”).¹ For the first year of the Negotiation Program, CMS will select ten Part D high expenditure, single source drugs for negotiation. The MFPs that are negotiated for these drugs will apply beginning in initial price applicability year 2026. The negotiation period for initial price applicability year 2026 begins October 1, 2023, or when the manufacturer of a selected drug enters into a Medicare Drug Price Negotiation Program Agreement with CMS, whichever is sooner. Section 1194(e) of the Act requires CMS to consider two sets of factors as the basis for determining the offer and counteroffer throughout the negotiation process: (1) certain data that must be submitted by the manufacturer of each drug selected for negotiation and (2) evidence about alternative treatments, as available, with respect to each selected drug and therapeutic alternatives for each selected drug.

In accordance with section 1193(a)(4) and section 1194(b)(2) of the Act, the manufacturer must submit, in a form and manner specified by CMS, information on the non-Federal average manufacturer price (“non-FAMP”) for the selected drug as defined in section 8126(h)(5) of title 38 of the U.S. Code 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 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 alternatives.

For the purposes of this Information Collection Request (ICR), a selected drug for initial price applicability year 2026 is defined as a drug included on the selected drug list published by CMS on September 1, 2023. 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. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with “the manufacturer” of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS intends to designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application (BLA(s)) for the selected drug to be “the manufacturer” of the selected drug (hereinafter “Primary Manufacturer”). Likewise, for initial price applicability year 2026, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or

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

BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a “Secondary Manufacturer.” Secondary Manufacturers would include any manufacturer of any authorized generics and any repacker or relabeler of the selected drug that meet these criteria.

CMS will collect certain data from the Primary Manufacturer, including information on non-FAMP and the data identified in section 1194(e)(1) of the Act, and will collect information on evidence about a selected drug and its therapeutic alternatives per section 1194(e)(2) of the Act from any interested party. This ICR Form serves as one of multiple ways that CMS intends to collect data per section 1194(e)(2) (see the supporting statement for further details).

Note: This ICR focuses on information required for selected drugs for initial price applicability year 2026.

General Instructions

The Primary Manufacturer of each selected drug must complete Sections A through I (“Selected Drug Information,” “Non-FAMP Data Collection,” “Research and Development Costs and Recoupment,” “Current Unit Costs of Production and Distribution,” “Prior Federal Financial Support,” “Patents, Exclusivities, and Approvals” “Market Data, Revenue, and Volume,” and “Certification of Submission”) for each of its selected drug(s). The Primary Manufacturer is responsible for aggregating and reporting all necessary data on its selected drug(s) from other parties, as applicable. Section H (“Evidence on Alternative Treatments”) collects available evidence on the selected drug and its therapeutic alternatives, as applicable. **Any interested party, including but not limited to patients and consumers, Part D plan sponsors and Medicare Advantage organizations, Primary Manufacturers, manufacturers of therapeutic alternatives 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 H.**

Primary Manufacturers will submit the information for Sections A through I via the Health Plan Management System (HPMS). Instructions for Primary Manufacturers to gain access HPMS to submit data related to sections A through I will be available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess>. Instructions for members of the public to gain access to HPMS to submit information related to sections H and J will be available at <https://hpms.cms.gov/app/ng/home/>.

- The instructions in this section apply to all sections A through I. If a term included in this ICR is also included and defined in the [Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments](#) (“the Negotiation Program: Initial Memorandum”), the term’s definition in this ICR is the same as in the Negotiation Program: Initial Memorandum.²

² Comments pertaining to the Negotiation Program: Initial Memorandum can be sent to IRAREbateandNegotiation@cms.hhs.gov with the following subject line “Medicare Drug Price Negotiation Program Guidance.” Comments received by April 14, 2023 will be considered.

- For Sections A through G of this form, the Primary Manufacturer must consider **only its selected drug(s) for negotiation** under section 1192 of the Act unless the specific instructions for a question state otherwise.
- Respond “Not applicable” to any question in Sections A to G that does not apply to the selected drug.
- Section I includes the Certification of Submission for all Primary Manufacturers. Section J includes the Certification of Submission for all respondents who are not Primary Manufacturers. Certification is required for all respondents.
- For Sections A through G of this form, the Primary Manufacturer must submit the applicable data for all dosage forms and strengths of a selected drug, including for dosage forms and strengths that were labeled or packaged by a Secondary Manufacturer.
- For the purposes of this form, “marketing” is defined as the introduction or delivery for introduction into interstate commerce of a drug product.
- For non-monetary numeric amounts, include up to three decimal places.
- Response formats are indicated within any charts included in sections A through H (e.g. # to indicate a numerical response is required).
- If the instruction for a particular response field indicates no explanation is necessary and no voluntary explanation is being provided, please include “not applicable (N/A)” in the free response field.
- CMS is soliciting comment on the inclusion of the 340B ceiling price (Questions 21 and 22) and 340 Prime Vendor Program (Questions 23 and 24) in Section G of this ICR form.

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 entity’s accounting policies and industry standards, when applicable. Describe the policies and methodologies used in the calculations in the free response field for the relevant question, as well as an explanation of the standard used.
- When calculating monetary values, assume at most an 8.1 percent annual cost of capital for purposes of applying an adjustment.³ If a Primary Manufacturer uses a cost of capital below 8.1 percent, that amount must be used.
- Monetary amounts must be reported in United States dollars (USD) and include two decimal places (i.e., dollars and cents).
- When converting another currency to USD, use the exchange rate applicable at the time the costs were incurred. The Internal Revenue Service (IRS) website lists government and external sources where historical exchange rates can be found to the day.⁴ If the exact date of a sale or conversion is not known, use the yearly average exchange rate for that currency for the year the costs were incurred.⁵ In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in this calculation.

³ Most studies on research and development costs apply a cost-of-capital adjustment to each company’s R&D spending to reflect the lag between investment and return on investment. The use of 8.1 percent is consistent with assumptions used by the Congressional Budget Office, see “Research and Development in the Pharmaceutical Industry,” CBO (April 2021), available at <https://www.cbo.gov/publication/57126>.

⁴ <https://www.irs.gov/individuals/international-taxpayers/foreign-currency-and-currency-exchange-rates>

⁵ <https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates>

- Do not count the same costs in multiple places, unless the additional specific instructions for that question instruct you to do so.
- Report nominal dollars at the time the costs were incurred. Do not make any adjustments for inflation. As applicable, in the free response field, report the cost per year and the inflation adjustment that is applicable for the Primary Manufacturer. CMS will make the relevant inflation adjustments, as necessary.

A. Selected Drug Information

Primary Manufacturer Response Required

Section A requires the Primary Manufacturer to list all 11-digit National Drug Codes (NDC-11s) of the selected drug, including any NDC-11s of the selected drug marketed by any Secondary Manufacturer(s).

Product Name	NDC-11 Numbers	Dosage Form (e.g. tablet)	Strength	Unit (e.g. mg)	Labeler Code
<i>Text</i>	<i>12345-6789-01</i>	<i>Text</i>	<i>#</i>	<i>Text</i>	<i>#</i>

B. Non-FAMP Data Collection.

Primary Manufacturer Response Required

For Section B, the Primary Manufacturer is required to report the non-Federal average manufacturer price (non-FAMP) for its selected drug(s) for calendar year 2021 (or, in the case that there is not an average non-FAMP available for such selected drug for calendar year 2021, for the first full year following the market entry for such drug).

CMS plans to use the reported NDC-11s and quarterly non-FAMP and total package unit volume in the table below to calculate the average non-FAMP for calendar year 2021 for initial price applicability year 2026.

Definitions for Section B:

- Non-FAMP price: Section 1194(c)(6) of the Act defines “average non-Federal average manufacturer price” as the average of the non-FAMP (as defined in section 8126(h)(5) of title 38 of the U.S. Code) for the four calendar quarters of the year involved.
- Non-FAMP unit: Non-FAMP unit is the package unit as described in section 8126(h)(6) of title 38 of the U. S. Code.

Instructions for Section B:

Please follow the instructions below when completing the following tables.

- Please complete the table immediately below about the non-FAMP for each calendar quarter of 2021 for the selected drug (or, in the case that there is not an average non-FAMP available for such drug for 2021, for calendar quarters for the first full year following the market entry for such drug).

- Please report the non-FAMP and total package unit volume for each NDC-11 of the selected drug. If an NDC-11 was not marketed, sold, or distributed in a particular calendar quarter, enter the NDC-11 and quarter but enter “0” in the total package unit volume field and leave the non-FAMP field blank.
- Non-FAMP and total package unit volume information must be provided by the Primary Manufacturer for its own NDC-11s and the NDC-11s of any Secondary Manufacturer(s).
- Any restatements of the non-FAMP for the four calendar quarters of 2021 made in any manufacturer non-FAMP submissions to the Department of Veterans’ Affairs must be reflected in the table below.
- Please indicate the total number of package units sold during the quarter and that are used in the calculation of the non-FAMP in the total package unit volume field.

NDC-11	Calendar Quarter	Total package unit volume	Non-FAMP
<i>Text</i>	<i>QYYYYY</i>	<i>#</i>	<i>\$</i>

If the reported non-FAMP is for a calendar year other than 2021, the market entry date must be provided in the free response field below. If necessary, describe assumptions, methodological steps, and other information needed to interpret reported non-FAMP prices. If no explanation is necessary, please include “not applicable (N/A)” in the free response field.

FIELD	RESPONSE FORMAT
Explanation of Non-FAMP Calculation	<i>Text (1,000-word limit)</i>

C. Research & Development Costs and Recoupment

Primary Manufacturer Response Required

Section C contains seven two-part questions: (1) dollar amounts for research and development (R&D) and recoupment costs, which must be reported in the numerical response field and (2) explanations of how those costs were calculated, where applicable, in the free response field.

Definitions for Section C:

CMS is considering R&D costs to mean a combination of costs incurred by the Primary Manufacturer for all FDA-approved indications of a drug falling into the following categories, and excluding total Federal financial support (see Question 10 in Section E), acquisition costs of the selected drug (as discussed in Section G), and costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals:

1. R&D: Basic Pre-Clinical Research Costs
2. R&D: Post-Investigational New Drug (IND) Application Costs
3. R&D: Completed U.S. Food and Drug Administration (FDA)-Required Phase IV Trials
4. R&D: Post-Marketing Trials
5. R&D: Abandoned and Failed Drug Costs
6. R&D: All Other R&D Costs

CMS is calculating recoupment of R&D costs using the global, total lifetime net revenue for the selected drug:

7. Recoupment: Global, Total Lifetime Net Revenue for the Selected Drug

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

CMS is only collecting costs on FDA-approved indications of the drug to the date the selected drug appeared on the selected drug list for a price applicability year, unless otherwise specified.

Instructions for Section C:

Follow these instructions for Questions 1 through 7 when reporting R&D costs:

- For each dollar amount listed below, the Primary Manufacturer must report one dollar amount in the numerical response field and a thorough explanation of the values, including any calculations or conversions and any assumptions made.
- All costs in this Section are for FDA-approved indications of the selected drug, unless otherwise specified. Do not report any costs for indications that are not labeled indications.
- All dollar figures submitted to CMS must be cash-outlay costs to the Primary Manufacturer. They must exclude any costs to entities that are not the Primary Manufacturer.
- Reported costs for Questions 1 through 6 must be mutually exclusive for each question; in other words, no costs must be counted in more than one section. Similarly, reported costs for Questions 1 through 6 must be collectively exhaustive for all R&D costs; in other words, all R&D costs that the Primary Manufacturer incurred for the selected drug must be accounted for in Questions 1 through 6.
- If the Primary Manufacturer received any federal funding, including tax credits, for any of the costs listed in Questions 1 through 6 below (e.g., Basic 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 federal funding in Questions 10, 11, and 12. Please reference Section E for instructions on reporting federal funding.
- If the Primary Manufacturer shared the expenses described in Questions 1 through 6 for any period of time or activity with any entity that is not the Primary Manufacturer, then the Primary Manufacturer must report only costs the Primary Manufacturer incurred. Report how shared expenses were allocated among the Primary Manufacturer and any other entity or entities in the free response field for the relevant question.
- Follow the instructions for Reporting Monetary Amounts, including those related to converting to USD if R&D costs occurred in other countries. While R&D may occur in other countries and those costs must be included and reported in USD, costs associated with receiving foreign approvals must not be included.
- Do not include acquisition costs in any numerical response field in this Section. That numerical value is being collected in Section G. The acquisition cost and timing for

the acquisition may be listed in the relevant free response field in this section along with any relevant explanation.

Question 1: Basic Pre-Clinical Research for All Approved Indications of the Selected Drug

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

Definitions for Question 1:

- Basic pre-clinical research is defined as all discovery and preclinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and is the sum of (1) direct research expenses and (2) a proportion of indirect research expenses.
- The basic pre-clinical research period is defined as the date of initial discovery⁶ *or* the date the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug (whichever is earlier) to the day before the last IND application for the selected drug went into effect.⁷ This may include both the initial research on the discovery of the selected drug and basic pre-clinical research related to new applications of the selected drug. If the length of the basic pre-clinical research period for the selected drug cannot be calculated, use 52 months ending the day before the first IND application went into effect. In other words, if the selected drug had five IND applications approved, use the date of the first IND application that went into effect as the end date for the 52-month period.⁸
- Direct research expenses are costs that can be specifically attributed to the discovery and preclinical development of the selected drug. Direct research expenses could include personnel (compensation for investigators and staff) researching the selected drug, materials for conducting basic preclinical research, and the costs of in vivo and in vitro studies on the selected drug before an IND application went into effect.
- Indirect research expenses and relevant general and administrative expenses are operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics. To calculate the proportion of indirect costs, the Primary Manufacturer must use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect

⁶ CMS acknowledges that the exact date of initial discovery might not be known, but manufacturers must use their best estimate.

⁷ For the purposes of identifying the date the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug, use the earliest date of acquisition for any NDA/BLA of the selected drug.

⁸ DiMasi, J, Hansen, R, Grabowski, H. The price of innovation: new estimates of drug development costs. Journal of Health Economics. <https://fds.duke.edu/db?attachment-25--1301-view-168>. CMS believes that 52 months represents a solid average across studies. For example, the Congressional Budget Office (CBO) estimated that the preclinical phase can take anywhere from 31 months to 84 months.

research.⁹ 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 ten percent of the total spending on *indirect* costs during that time period.

Instructions for Question 1:

- The amount reported for basic pre-clinical research in the numerical response field for Question 1 must be the sum of (1) direct research expenses and (2) a proportion of indirect research expenses.
 - If the Primary Manufacturer acquired the right to hold the most recent NDA/BLA of the selected drug after the last IND application submitted to the FDA went into effect, please include “\$0” for Question 1.
 - If there were basic pre-clinical research costs after the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug, the basic pre-clinical research costs must be reported in the numerical response field.
- In the free response field, list the direct research expenses and the indirect research expenses for the selected drug, the percentage of direct and indirect spending on the selected drug out of the total direct and indirect basic pre-clinical research costs, an explanation of the values used in the indirect cost calculation, and a list of the activities the Primary Manufacturer included in the direct research expenses and the indirect research expenses.
- In the free response field, identify the length of the basic pre-clinical research period, which runs from: the date of initial discovery *or* the date the Primary Manufacturer acquired the right to hold the first NDA/BLA of the selected drug, whichever is earlier, to the day before the last IND application for an FDA-approved indication of the selected drug went into effect.

FIELD	RESPONSE FORMAT
Basic Pre-Clinical Research Costs for All FDA-Approved Indications of the Selected Drug	\$
Explanation of Basic Pre-Clinical Research for All-Approved Indications of the Selected Drug, Including Allocation and Apportionment Methods	<i>Text (2500-word limit)</i>

Question 2: Post-IND Costs for All Approved Indications of the Selected Drug

Please provide the following information on the direct costs incurred by the Primary Manufacturer beginning on the day the IND went into effect for the first FDA-approved

⁹ 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; Drummond MF, Sculpher MJ, Torrance GW, O’Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, [https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition\(e43f24cd-099a-4d56-97e6-6524afaa37d1\)/export.html](https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html).

indication for the selected drug through the date the most recent NDA/BLA was approved for the selected drug. *Do not report costs for indications that are not labeled indications.*

Definitions for Question 2:

- Post-IND costs are defined as all costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication.
 - Direct post-IND costs are defined as Institutional Review Board (IRB) review and amendment costs, user fees, patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the dosing and Phase I, Phase II, and Phase III clinical trials during the post-IND period.
- The post-IND period is defined as the day the IND went into effect for the first FDA-approved indication for the selected drug through the date the most recent NDA/BLA was approved for the selected drug.

Instructions for Question 2:

- The amount reported in the numerical response field must include all direct costs associated with dosing and preparing the selected drug for clinical trials and the selected drug's Phase I, Phase II, and Phase III clinical trials for each FDA-approved indication.
 - If the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug after all NDA/BLAs were approved by the FDA for a selected drug, include \$0 in the numerical response field.
 - If the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug and there were additional post-IND costs that followed the acquisition and were incurred before the FDA approved the most recent FDA-approved indication, those costs may be reported in the numerical response field. For example, if a Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug during the Phase I trial for the most recent FDA-approved indication, it may report the costs of the trials that followed the acquisition in the numerical response field.
- The free response field must note if the selected drug received early approval (e.g., through the accelerated approval pathway) and the type of approval pathway. If the selected drug received early approval, include the cost for any accelerated approval confirmatory studies in the numerical response field.
- The free response field must list the applicable direct costs included and any calculations or conversions that were done.
- The free response field must identify the length of the post-IND period used in the calculations.
- The free response field may include the post-IND cost associated with each FDA-approved indication and may break down those costs down further for each clinical trial phase.
- Do not include the costs for any Phase IV trial or post-market trial for any of the approved indications, as those costs are collected in Questions 3 and 4.

FIELD	RESPONSE FORMAT
Post-IND Costs for Approved Indications of the Selected Drug	\$
Explanation of Post-IND Costs for Approved Indications of the Selected Drug, Including the Allocation and Apportionment Methods	<i>Text (2500-word limit)</i>

Question 3: Costs of all Completed, FDA-Required Phase IV Studies for the Selected Drug

The Primary Manufacturer shall report the direct costs for all completed, FDA-required Phase IV studies for all FDA-approved indications of the selected drug.

Definitions for Question 3:

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- Direct costs for completed Phase IV studies include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the completed Phase IV study.

Instructions for Question 3:

- In the numerical response field, report the direct costs for all completed, FDA-required Phase IV studies for all FDA-approved indications of the selected drug.
 - If the Primary Manufacturer acquired the right to hold the NDA/BLA(s) of the selected drug after FDA-required Phase IV studies were completed or if no Phase IV studies were completed for the selected drug, put \$0 in the numerical response field.
- In the free response field, include an explanation for how the numerical response was calculated and list what costs were included.
- Do not report costs for incomplete trials, as that must be reported in Question 5.

FIELD	RESPONSE FORMAT
Phase IV Studies Costs for the Selected Drug	\$
Explanation of Phase IV Studies Costs for the Selected Drug	<i>Text (2000-word limit)</i>

Question 4: Costs of All Post-Marketing Trials for the Selected Drug

Report the direct costs of all post-marketing trials for all FDA-approved indications of the selected drug.

Definitions for Question 4:

- Post-marketing trials are defined as studies conducted after the FDA has approved a product for marketing, including studies required of or agreed to by a manufacturer.
- The post-marketing trial costs must include the direct cost for FDA-required Phase IV trials that were not completed and the direct cost for post-marketing trials conducted for the purposes of marketing claims.

- Direct costs include patient recruitment, per-patient costs, research and data collection costs, personnel, and facility costs that are directly related to conducting the incomplete Phase IV trial or the post-marketing trial.

Instructions for Question 4:

- The numerical response may include direct costs for FDA-required Phase IV trials that were not completed and direct costs for post-marketing trials conducted for the purposes of marketing claims.
- The response for Question 4 must not include any costs included in Question 3.
- In the free response field, list what costs were included and how the amount reported was calculated.

FIELD	RESPONSE FORMAT
Costs of All Post-Marketing Trials for the Selected Drug	\$
Explanation of Costs of All Post-Marketing Trials for the Selected Drug	Text (1500-word limit)

Question 5: Costs of Failed or Abandoned Products Related to the Selected Drug

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

Definitions for Question 5:

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

Instructions for Question 5:

- In the numerical response field, only include costs that can be directly attributed to failed or abandoned product(s) with the same active moiety / active ingredient or mechanism of action *or* drugs in the same therapeutic class as the selected drug that did not achieve FDA approval.
- In the free response field, detail how these costs were determined, what portion of direct costs were included for basic pre-clinical research and clinical research costs, and how the allocation was done.

FIELD	RESPONSE FORMAT
Costs of Allowable Abandoned or Failed Products Related to the Selected Drug	\$
Explanation of Costs on Allowable Abandoned or Failed Products Related to the Selected Drug, Including the Allocation and Apportionment Methods	<i>Text (2500-word limit)</i>

Question 6: Costs of Other Research and Development for the Selected Drug Not Accounted for Above

The Primary Manufacturer must report the dollar amount of costs it attributes to research and development that were not accounted for in Questions 1 through 5 in the numerical response field with an explanation for the costs and how they were calculated in the free response field.

FIELD	RESPONSE FORMAT
Costs of Other Research and Development for the Selected Drug Not Accounted for Above	\$
Explanation of Costs of Other Research and Development for the Selected Drug Not Accounted for Above, Including the Allocation and Apportionment Methods	<i>Text (2500-word limit)</i>

Question 7: Global, Total Lifetime Manufacturer Net Revenue for the Selected Drug

In order for CMS to consider the extent to which the Primary Manufacturer has recouped its research and development costs, the Primary Manufacturer must report the global, total net revenue for the selected drug from all countries, including the U.S., in which the selected drug was sold on or after the date of approval as determined by each country's drug regulatory agency.

Definitions for Question 7:

- CMS will use the Primary Manufacturer's global, total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug.
- Global, total lifetime net revenue for the selected drug is defined as the direct sales and payments from all other entities, minus the discounts, chargebacks, rebates, cash

discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, other price concessions or similar benefits offered to any purchasers or any royalty payments or percentage payments in purchase contracts.

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

Instructions for Question 7:

- In the numerical response field, report the global, total lifetime net revenue for the selected drug for the global, total lifetime net revenue period.
- Global, total lifetime net revenue for the selected drug must be in nominal USD and reported from the date the drug or biologic was first sold anywhere globally to the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year.
- In the free response field, include any relevant currency conversions, report the date ranges for the global, total net revenue period, and explain how the final amount was calculated.

FIELD	RESPONSE FORMAT
Total Lifetime Net Revenue for the Selected Drug	\$
Explanation of Total Lifetime Net Revenue for the Selected Drug	<i>Text (2500-word limit)</i>

D. Current Unit Costs of Production and Distribution

Primary Manufacturer Response Required

Section D contains two questions on current unit costs of production and distribution for the selected drug. Question 8 is a table in which to report the average unit costs of production and distribution for all of the 9-digit National Drug Codes (NDC-9s) included in the selected drug. Question 9 provides a free response field for explaining the methodology for calculating the amount reported in Question 8.

Definitions for Section D:

- In accordance with section 1191(c)(6) of the Act, the term ‘unit’ means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

- Units must be reported in one of the three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)¹⁰: each (EA), milliliter (ML), or gram (GM). The unit reported must be specified for each of the NDC-9s included in the selected drug. Selections of EA, ML or GM must be made as follows:
 - “EA” is used when the product is dispensed in discrete units. These products are not measured by volume or weight. The Billing Unit of “EA” is also used to address exceptions where “GM” and “ML” are not applicable. Examples of products defined as “EA” include, but are not limited to:
 - Tablets;
 - Capsules;
 - Suppositories;
 - Transdermal patches;
 - Non-filled syringes;
 - Tapes;
 - Devices/Digital Therapies;
 - Blister packs;
 - Oral powder packets;
 - Powder filled vials for injection;
 - Kits; and
 - Unit-of-use packages of products other than injectables with a quantity less than one milliliter or gram must be billed as “one each,” for example, ointment in packets of less than 1 gram or eye drops in dropperettes that contain less than 1 mL.
 - “ML” is used when a product is measured by its liquid volume. Examples of products defined as “ML” include, but are not limited to:
 - Liquid non-injectable products of 1 mL or greater;
 - Liquid injectable products in vials/ampules/syringes;
 - Reconstitutable non-injectable products at the final volume after reconstitution except when they are in powder packets; and
 - Inhalers (when labeled as milliliters on the product).
 - “GM” is used when a product is measured by its weight. Examples of products defined as “GM” include, but are not limited to:
 - Creams (of 1 GM or greater);
 - Ointments (of 1 GM or greater); and
 - Inhalers (when labeled as GM on the product).¹¹
- 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;

¹⁰ <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>

¹¹ https://standards.ncdpd.org/Standards/media/pdf/BUS_fact_sheet.pdf. Permission is hereby granted to any organization to copy and distribute this material as long as this copyright statement is included, the contents are not changed, and the copies are not sold.

- 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;
 - 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, labelling, and shipping to any entity that acquires the drug from the Primary Manufacturer or any Secondary Manufacturer;
- Current unit costs of production and distribution of the selected drug are defined to include:
 - Units (and associated costs) marketed by the Primary Manufacturer and any Secondary Manufacturer(s);
 - Average unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year);
 - Only units (and associated costs) produced and distributed for U.S. sales; costs incurred outside of the U.S. are included, provided that they are incurred for the production or distribution of units produced and distributed for use in the U.S.;
 - Only costs incurred by the Primary Manufacturer and any Secondary Manufacturers; such costs may include payments to third parties (e.g., contractors) performing activities that qualify as production or distribution, as specified above; and
 - Allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-9 based on unit volume.
- Current unit costs of production and distribution of the selected drug are defined not to include:
 - R&D costs; and
 - Marketing costs.

Instructions for Section D:

Follow the instructions below when answering Questions 8 and 9:

- Production and distribution unit costs must be reported separately for NDC-9 included in the selected drug, including any NDC-9 of the selected drug marketed by a Secondary Manufacturer.
- Unit costs reported must represent the average per unit cost (1) within the time period specified below, (2) across all package types, and (3) calculated according to the instructions and using the definitions specified below.

- Use the response field in Question 9 to explain any shared operating and other indirect costs that were included in the response to Question 8.

Question 8: Per Unit Production and Distribution Costs

Please complete the following table using additional rows as necessary.

NDC-9	Average Per Unit Production Cost	Average Per Unit Distribution Costs	Indicate Unit Used	Total Unit Volume
12345-6789	\$XX.XX	\$XX.XX	<i>Select one:</i> • Gram (GM) • Milliliter (ML) • Each (EA)	#

Question 9: 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 8, including which indirect costs were included, specific allocation methodologies, assumptions, and whether such assumptions apply to all or a subset of the data reported.

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

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

FIELD	RESPONSE FORMAT
Explanation of Unit Production and Distribution Costs	<i>Text (2,500 word limit)</i>

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, and any other funds provided by the

federal government that support discovery, research, and/or development related to the selected drug.

- “Prior Federal financial support” refers to Federal financial support for novel therapeutic discovery and development (as defined above) issued during the time period from when initial research began (as defined above in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, to the day through the date the most recent NDA/BLA was approved for the selected drug.

Instructions for Section E:

Follow the instructions below when answering Questions 10, 11, and 12.

- When completing this section:
 - Include all prior Federal financial support provided by federal agencies or Federally supported grants or contracts that contributed to the basic pre-clinical research and clinical trials phase of research and development for the selected drug to the Primary Manufacturer only (do not include Federal financial support provided to applicable Secondary Manufacturers of a selected drug).
 - Include prior Federal financial support received for indirect costs of developing the selected drug, such as administrative overhead, staffing, facilities, technologies, or other purposes applying to the selected drug.
 - 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.¹² For example, if the *direct* costs spent on the selected drug were approximately ten 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 ten percent of the total spending on *indirect* costs during that time period.
 - If the Primary Manufacturer shared the prior Federal Financial support described in Questions 10 through 12 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 Question 11 or 12, if applicable.

Question 10: Support Amount by Type of Support

Complete the table below.

¹² 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; Drummond MF, Sculpher MJ, Torrance GW, O’Brien BJ, Stoddart GL. *Methods for the Economic Evaluation of Health Care Programme*. 3rd ed. Oxford, UK: Oxford University Press; 2005, [https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition\(e43f24cd-099a-4d56-97e6-6524afaa37d1\)/export.html](https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html).

Type of Federal Financial Support	Amount
Tax credits (General, R&D)	\$
Orphan Drug Act and Other Specific Tax Credits	\$
Direct Federal Financial Support of Development	\$
NIH Grants	\$
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	\$
Other Federal Financial Support Not Included Elsewhere	\$
TOTAL FEDERAL FINANCIAL SUPPORT	\$

Question 11: Explanation of Calculation of Federal Financial Support

Describe assumptions, methodological steps, and other information needed to calculate the estimates provided in Question 10.

- If you reported a value in “Other Federal Financial Support Not Otherwise Included Elsewhere” in your response to Question 10, please list the source(s) of that Federal financial support.

Type of Federal Financial Support	Identification Number for Grants and Comparable Awards	RESPONSE FORMAT
Tax credits (General, R&D)	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
Orphan Drug Act and Other Specific Tax Credits	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
Direct Federal Financial Support of Development	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
NIH Grants	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
Department of Defense (DOD) Congressionally Directed Medical Research (CDMR) Funding	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
Biomedical Advanced Research and Development Authority (BARDA) Funding	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>

Type of Federal Financial Support	Identification Number for Grants and Comparable Awards	RESPONSE FORMAT
Defense Advanced Research Projects Agency (DARPA) Funding	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>
Other Federal Financial Support Not Included Elsewhere	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>

Question 12: 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 prior Federal financial support. Add additional rows to your response to Question 12 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, 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, deliver it to the Federal Government within a specified timeline, and not contract with other state or local governmental entities or insurers while this agreement is in place.

Type of Agreement	Federal Agency(ies) Participating in Agreement	Nature of Agreement
<i>Drop down menu of agreement options: licensing, pricing, purchasing, other</i>	<i>Text (100-word limit)</i>	<i>Text (1,000-word limit)</i>

F. Patents, Exclusivities, and Approvals

Primary Manufacturer Response Required

Section F focuses on capturing data on the selected drug related to pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act. Follow the instructions below when answering Questions 13 through 16.

Definitions for Section F:

- CMS considers patents relevant to this data to include:
 - all pending and approved patent applications, including expired and non-expired approved patents, submitted, sponsored, licensed, and/or acquired by the Primary Manufacturer relating to the selected drug as of September 1, 2023;

- patents linked to the selected drug where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product); and
- all patent applications, pending and approved, for which a claim of patent infringement could reasonably be, or has been, asserted against a person engaged in the unlicensed manufacture, use, or sale of the selected drug in any form.
- A pending patent application is any provisional or nonprovisional patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has not been issued.
- An approved patent application is any patent application submitted to the United States Patent and Trademark Office for which a patent number(s) has been issued.
- An expired patent is any patent application approved by the United States Patent and Trademark Office for which a patent number(s) was issued and that has now expired.
- Exclusivity periods recognized by FDA refer to certain delays and prohibitions on the approval of competitor drugs that attach upon approval of a drug. An NDA or BLA holder is eligible for exclusivity if statutory requirements are met.¹³ Exclusivities include:
 - Orphan Drug Exclusivity (ODE);¹⁴
 - New Chemical Entity Exclusivity (NCE);¹⁵
 - Generating Antibiotic Incentives Now (GAIN) Exclusivity for Qualified Infectious Disease Products (QIDP);¹⁶
 - New Clinical Investigation Exclusivity (NCI);¹⁷
 - Pediatric Exclusivity (PED);¹⁸ and
 - Reference Product Exclusivity for Biological Products.¹⁹
- Active and pending FDA applications and approvals includes:
 - all applications for approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or sections 351(a) of the Public Health Service Act, including those not yet decided; and
 - all applications for which the Primary Manufacturer is directly or indirectly involved in the production, preparation, propagation, compounding, conversion, processing, packaging, repackaging, labeling, relabeling, or distribution (not just those applications the Primary Manufacturer has submitted or sponsored).

Instructions for Section F:

- For Questions 13 through 16, the relevant time period for reporting begins on the earlier of the date that basic pre-clinical research began on the selected drug or the date the selected drug was acquired by the Primary Manufacturer and ends on the date the most recent NDA/BLA was approved for the selected drug.

¹³ <https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity>

¹⁴ 21 C.F.R. 316.31, 316.34

¹⁵ 21 C.F.R. 314.108

¹⁶ Section 505E of the Federal Food, Drug, and Cosmetic Act

¹⁷ 21 C.F.R. 314.108

¹⁸ Section 505A of the Federal Food, Drug, and Cosmetic Act

¹⁹ Section 351(a) of the PHS Act

- For Questions 13 through 16, include required data for the selected drug.

Question 13: Pending and Approved Patent Applications (Expired and Non-Expired)

For each patent application for the selected drug, indicate whether the patent covers the drug product, drug substance, and/or a method of use of the selected drug. Please upload a PDF file of the patent application for each pending and approved (including expired and non-expired) patent listed in the table below. Do not include patent applications which were denied. Add additional rows to your response to Question 13 as needed.

Patent Number	Date Filed	Patent Expiry Date	Drug Product Patent	Drug Substance Patent	Drug Method of Use Patent	Status	Patent Type	Listed in FDA Orange Book/Purple Book	Patent Application
#	MM DD, YY YY	MM DD, YYYY	Yes/No Flag	Yes/No Flag	Yes/No Flag	Pending, Approved or Expired	Drop down menu of patent types. Options: Utility, Design	Yes/No Flag	Upload button (one per row) where the patent application can be uploaded

Question 14: Explanation of Approved Patent Applications (Expired and Non-Expired)

If applicable, please provide additional information about the patents reported above and how they relate to the selected drug. This information can include further information on the purpose of the patent (such as if it is for a drug compound, formulation, method of using the drug, method of manufacturing the drug, etc.), if it is to cover specific indications, or other information that will be helpful to understand how the patent contributes to the selected drug. Please also use this space to describe any patents included in the table above that are not listed in the FDA Orange Book or Purple Book but relate to the selected drug, as applicable.

FIELD	RESPONSE FORMAT
<i>Explanation of patents</i>	<i>Text (1,000-word limit)</i>

Question 15: FDA Regulatory Exclusivity Periods

Report all FDA regulatory exclusivity periods in effect for the selected drug. *Complete table for Question 15 by adding rows as needed.*

Type of Exclusivity	Exclusivity Expiration Date	New Drug Application Number or Biological License Application Number	NDC-9s Covered by Exclusivity	Comments
Drop down menu of exclusivity types. Options: Orphan Drug Exclusivity, New Chemical Entity Exclusivity, GAIN Exclusivity for Qualified Infectious Disease Products, New Clinical Investigation Exclusivity, Pediatric Exclusivity, Reference Product Exclusivity for Biological Products	MM DD, YYYY	#	Text	Text (300-word limit)

Question 16: 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 Federal Food, Drug, and Cosmetic Act and 351(a) of the Public Health Service Act.

- Include all applications for approval under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act, including those not yet decided. Leave approval date blank for those applications not yet decided. *[Complete table for Question 16 by adding rows as needed using the indicated format]*

Applicat ion Number	Application Type (NDA; BLA)	Submissio n Number	Classificatio n Code ²⁰	Appro val Date	Indicat ion	Dosage Form and Strength	Sponso r	Applic ation Status (Active /Pendi ng)	Comm ents
#	<i>Drop down menu of application types. Options: NDA, BLA</i>	#	Drop down menu of classification types. With checkboxes, not radio buttons. Multiple types can be selected. 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	<i>MM DD, YYYY</i>	<i>Text</i>	<i>Text</i>	<i>Text</i>	<i>Text</i>	<i>Text (300- word limit)</i>

²⁰ 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.

Applicat ion Number	Application Type (NDA; BLA)	Submissio n Number	Classificatio n Code ²⁰	Appro val Date	Indicat ion	Dosage Form and Strength	Sponso r	Applic ation Status (Active /Pendi ng)	Comm ents
			Applicant, Type 7 — Previously Marketed But Without an Approved NDA, Type 8 — Rx to OTC, Type 9 — New Indication or Claim, Drug Not to be Marketed Under Type 9 NDA After Approval, Type 10 — New Indication or Claim, Drug to be Marketed Under Type 10 NDA After Approval						

G. Market Data, Revenue, and Sales Volume Data

Primary Manufacturer Response Required

The purpose of questions 17 through 38 in this section is to collect the market data and revenue and sales volume data described in section 1194(e)(1)(E) of the Act.

Definitions for Section G:

- Wholesale acquisition cost (WAC) unit price: The manufacturer's list price for the drug or biological 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 pricing data (as defined in section 1847A(c)(6)(B) of the Act). The WAC unit price is reported at the NDC-9 level.

- National Council of Prescription Drug Programs Billing Unit Standards: The three National Council for Prescription Drug Programs (NCPDP) Billing Unit Standards (BUS)²¹ 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 that also uses the NCPDP BUS.
- 340B ceiling price: The 340B ceiling price is defined in section 340B(a)(1) of the PHS Act and in 42 CFR §10.3 and §10.10(a). The 340B ceiling price is reported at the NDC-11 level.
- Medicaid best price: The Medicaid best price is defined in 42 CFR §447.505(a). The Medicaid best price is reported at the NDC-9 level.
- Average manufacturer price (AMP) unit: The type of unit used to report AMP (42 CFR §447.504) and best price (42 CFR §447.505) to Medicaid: injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie.
- 340B prime vendor program (PVP) price: The price offered under the 340B PVP established by section 340B(a)(8) of the PHS Act. The 340B PVP price is reported at the NDC-11 level.
- Federal supply schedule (FSS) price: The price offered by the Department of Veterans Affairs (VA) in its FSS program, by delegated authority of the General Services Administration.²² The FSS price is reported at the NDC-11 level.
- Big Four price: The Big Four price is described in section 8126 of title 38, U. S. C. The Big Four price is reported at the NDC-11 level.
- U.S. commercial average net unit price: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for group or individual commercial plans on- and off-Exchange, excluding Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid Managed Care. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price is reported at the NDC-9 level.
- U.S. commercial average net unit price— without patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the U.S. commercial average net unit price net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The U.S. commercial average net unit price— without patient assistance program is reported at the NDC-9 level.

²¹ <https://standards.ncdpd.org/Billing-Unit-Request.aspx#:~:text=Billing%20Unit%20Requests,grams%22%20or%20%22milliliters.%22>

²² <https://www.fss.va.gov/index.asp>

- U.S. commercial average net unit price— best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest U.S. commercial average net unit price offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any commercial payer in the U.S. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The U.S. commercial average net unit price— best is reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the average net unit price of the selected drug for Part D plan sponsors. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors is reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors— without patient assistance program: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the manufacturer average net unit price to Part D Plan sponsors net of coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). The manufacturer average net unit price to Part D Plan sponsors— without patient assistance program is reported at the NDC-9 level.
- Manufacturer average net unit price to Part D Plan sponsors— best: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the lowest manufacturer average net unit price to Part D Plan sponsors offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any Part D plan sponsor. The average net unit price must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers. The manufacturer average net unit price to Part D Plan sponsors— best is reported at the NDC-9 level.
- Covered entity: Covered entity is defined in 42 CFR §10.3.
- Acquisition: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer's purchase of the rights to hold previously approved or future NDA(s)/BLA(s) of the selected drug from another manufacturer.
- Gross revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, the Primary Manufacturer and all Secondary Manufacturer(s) total sales to all purchasers in the U.S. Gross revenue is reported at the NDC-9 level.
- Net revenue: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, gross revenue minus 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, or other price concessions or similar benefits offered to any purchasers in the U.S. Net revenue is reported at the NDC-9 level.

- Net revenue— without patient assistance programs: For the sole purpose of data collection under section 1194(e)(1)(E) of the Act, net revenue further net coupons and co-payment assistance to patients offered by the Primary Manufacturer and any Secondary Manufacturer(s). Net revenue— without patient assistance programs is reported at the NDC-9 level.
- Quarterly total U.S. unit volume: The total number of units (using NCPDP BUS) of the selected drug sold to any purchaser during the quarter. Quarterly total U.S. unit volume is reported at the NDC-9 level.

Instructions for Section G:

- For the purpose of answering Questions 17 through 38, please also follow the instructions specific to each question.
- Use the list of definitions in the ‘Definitions for Section G. Market Data, Revenue, and Volume’ section to answer the questions.
- For Question 19 through 38, information for the Primary Manufacturer and any Secondary Manufacturer(s) must be reported.
- For Questions 18, 20, 26, 28, 30, 36, please include not applicable (N/A) in the free response field if no explanation is necessary,

Question 17: Primary Manufacturer Acquisition Costs of the Selected Drug

Did the Primary Manufacturer acquire the rights to hold previously approved or future NDA/BLA(s) of the selected drug from another manufacturer?

RESPONSE FORMAT

<i>Yes/No</i>

(If response is ‘Yes’, please fill out the following table. If response is ‘No’, please skip to Question 19) Follow the instructions below when providing responses in the following table about the Primary Manufacturer’s acquisition costs of the selected drug:

- Please report the total costs of the acquisition(s) of the NDA/BLA(s) of the selected drug in the total acquisition costs field. Include costs of previously approved or future NDA/BLA(s) of other drugs and biological products if these other drugs and biological products were part of the same acquisition as the previously approved or future NDA/BLA(s) of the selected drug.
- Please provide a proportional allocation of the total acquisition costs reported in the total acquisition costs field for the selected drug in the total acquisition costs— selected drug field in situations where the total acquisition costs of the approved or future NDA/BLA(s) of the selected drug included costs other than for acquisition of the selected drug. If this situation is not relevant, please leave the total acquisition costs— selected drug field blank.

Total Acquisition Costs	Total Acquisition Costs- Selected Drug
\$	\$

Question 18: Explanation of Allocation of Total Acquisition Costs for the Selected Drug

If relevant, please describe the methodology used to allocate the total acquisition costs for the selected drug in the total acquisition costs— selected drug field of Question 17.

FIELD	RESPONSE FORMAT
<i>Explanation of allocation of total acquisition costs for the selected drug</i>	<i>Text (1,000-word limit)</i>

Question 19: Wholesale Acquisition Cost Unit Price

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

- Any deviation from the reported WAC unit price in the table below and the WAC unit price as reported in wholesale price guides or other publications of drug or biological price data must be explained in Question 20 so that CMS can understand the reasons for these differences.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-9s associated with the selected drug. 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.
- Include a row for each NDC-9 and each quarter during the most recent five years if the NDC-9 was marketed, sold, or distributed at any time during the most recent five years and complete all fields. If the NDC-9 was not marketed, sold, or distributed to any wholesaler or direct purchaser in a particular quarter, please still include a row for this particular quarter, and enter the NDC-9, quarter, and unit type information, but enter “0” in the total unit volume field and leave the WAC field blank.

NDC-9	Quarter	WAC	Unit type (e.g., each, ML, GM)	Total Unit Volume
<i>12345-6789</i>	<i>QQYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

Question 20: Explanation of Information Reported in Question 19: 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 19 and those found in available drug databases (e.g., Medi-Span, First Databank, RED BOOK).

FIELD	RESPONSE FORMAT
<i>Explanation of WAC unit price data</i>	<i>Text (1,000-word limit)</i>

Question 21: 340B Ceiling Price (Comment Solicitation)

As noted in the General Instructions Section of this Information Collection Request form, CMS is soliciting comment on the inclusion of 340B ceiling price.

Was a 340B ceiling price ever available for the selected drug during the most recent five years?

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

If response is Yes, please fill out the following table. If response is No, please skip to Question 23) Follow the instructions below when providing responses in the following table about the 340B ceiling prices of the selected drug:

- The 340B ceiling price information must reflect what is published in the Health Services Resource Administration's (HRSA) 340B Office of Pharmacy Affairs Information System Pricing Component.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-11s associated with the selected drug. Total unit volume is the number of units sold to 340B covered entities during the quarter. Please do not include units associated with free samples in the reported total unit volume.
- Include a row for each NDC-11 and each quarter during the most recent 5 years if a 340B ceiling price existed at any time during the most recent five years and complete all fields. If the NDC-11 did not have a 340B ceiling price in a particular quarter, please still include a row for this particular quarter and enter NDC-11, quarter, and unit type information, but enter "0" in the total unit volume field, and leave the 340B ceiling price field blank.

NDC-11	Quarter	340B ceiling Price	Unit Type	Total Unit Volume
<i>12345-6789</i>	<i>QQYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

Question 22: Explanation of Information Reported in Question 21: 340B Ceiling Price

Describe assumptions, methodological steps, and other information used to determine the total number of units sold to 340B covered entities in the quarter provided in response to Question 21.

FIELD	RESPONSE FORMAT
<i>Explanation of 340B ceiling price data</i>	<i>Text (1,000-word limit)</i>

Question 23: 340B Prime Vendor Program Price (Comment Solicitation)

As noted in the General Instructions Section of this Information Collection Request form, CMS is soliciting comment on the inclusion of 340B Prime Vendor Program price.

Was a 340B Prime Vendor Program price ever available for the selected drug during the most recent five years?

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

(If response is Yes, please fill out the following table. If response is No, please skip to Question 25) Follow the instructions below when providing responses in the following table about the 340B Prime Vendor Program prices for the selected drug:

- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-11s associated with the selected drug. Total unit volume is the number of units sold to 340B covered entities during the quarter. Please do not include units associated with free samples in the reported total unit volume.
- Include a row for each NDC-11 and each quarter during the most recent 5 years if a 340B Prime Vendor Program price existed at any time for that NDC-11 during the most recent five years and complete all fields. If the NDC-11 did not have a 340B Prime Vendor Program price in a particular quarter, please still include a row for this particular quarter, but enter “0” in the total unit volume field, and leave the 340B Prime Vendor Program price field blank.

NDC-11	Quarter	340B Prime Vendor Program Price	Unit Type (e.g., each, ML, GM)	Total Unit Volume
<i>12345-6789</i>	<i>QQYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

Question 24: Explanation of Information Reported in Question 23: 340B Prime Vendor Program Price

Describe assumptions, methodological steps, and other information used to estimate the 340B Prime Vendor Program Price and to determine the total number of units sold to 340B covered entities in each quarter provided in response to Question 23.

FIELD	RESPONSE FORMAT
<i>Explanation of 340B Prime Vendor Program price data</i>	<i>Text (1,000-word limit)</i>

Question 25: Medicaid Best Price

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

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

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 27) Follow the instructions below when providing responses in the following table about the Medicaid best price of the selected drug:

- The Medicaid best price information must reflect what was submitted to Medicaid under the Medicaid Drug Rebate Program (MDRP) in accordance with the Medicaid National Drug Rebate Agreement and as described in section 42 CFR 447.505 – Determination of best price. The reported Best Price in the table below must reflect any restatements that have been certified under the MDRP.
- Please report price information using the same average manufacturer price (AMP) unit type used to report AMP and Medicaid best price to Medicaid (i.e., injectable anti-hemophilic factor, capsule, suppository, gram, milliliter, tablet, transdermal patch, each, millicurie, microcurie). Total unit volume is the sum of monthly AMP units reported to the MDRP for the quarter.
- Include a row for each NDC-9 and each quarter during the most recent 5 years if a Medicaid best price determination was made at any time during the most recent five years for that NDC-9 and complete all fields. If the NDC-9 did not have a Medicaid best price determination in a particular quarter, please still include a row for this particular quarter and enter NDC-9, quarter, and unit type information, but enter “0” in the total unit volume field, and leave the Medicaid best price field blank.

NDC-9	Quarter	Medicaid Best Price	Unit Type	Total Unit Volume
<i>12345-6789</i>	<i>QQYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

Question 26: Explanation of Information Reported in Question 25: Medicaid Best Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 25.

FIELD	RESPONSE FORMAT
<i>Explanation of Medicaid Best Price data</i>	<i>Text (1,000-word limit)</i>

Question 27: Federal Supply Schedule Price

Was a Federal Supply Schedule (FSS) price for the selected drug ever available during the most recent five years?

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

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 29) Follow the instructions below when providing responses in the following table about FSS prices of the selected drug:

- The FSS price information must reflect what can be found online in the Pharmaceutical pricing data for all VA National Acquisition Center programs.²³
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-11s associated with the selected drug. Total unit volume is the total number of units (i.e., EA, ML, or GM) for each NDC-11 sold to direct federal purchasers. Please do not include units associated with free samples in the reported total unit volume.
- Include a row for each NDC-11 and price period that occurred during the most recent five years.

NDC-11	Price Start Date to End Date	Federal Supply Schedule Service Price	Unit Type (e.g., each, ML, GM)	Total Unit Volume
<i>12345-6789-00</i>	<i>MMDDYYYY-MMDDYYYY</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

Question 28: Explanation of Information Reported in Question 27: Federal Supply Schedule Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 27.

FIELD	RESPONSE FORMAT
<i>Explanation of federal supply schedule price data</i>	<i>Text (1,000-word limit)</i>

Question 29: Big Four Price

Was a Big Four price ever available for the selected drug during the most recent five years?

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

(If response is Yes, please fill out the following tables. If response is No, please skip to Question 31) Follow the instructions below when providing responses in the following table about the Big Four price of the selected drug:

²³ <https://www.va.gov/opal/nac/fss/pharmprices.asp>.

- 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.²⁴
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-11s associated with the selected drug. Total unit volume is the total number of units (i.e., EA, ML, or GM) for each NDC-11 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.
- Include a row for each NDC-11 and price period that occurred during the most recent five years.

NDC-11	Price Start Date to Price End Date	Big Four Price	Unit Type (e.g., each, ML, GM)	Total Unit Volume
12345-6789-00	MMDDYYYY-MMDDYYYY	\$	Text	#

Question 30: Explanation of Information Reported in Question 29: Big Four Price

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 29.

FIELD	RESPONSE FORMAT
Explanation of Big Four price data	Text (1,000-word limit)

Question 31: U.S. Commercial Average Net Unit Price

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

- Exclude price and volume information for the selected drug for Medicare fee-for-service (Parts A and B), Medicare Advantage, Medicare Part D, Medicaid fee-for-service, and Medicaid Managed Care.
- Include a row for each NDC-9 and each quarter during the most recent five years if the NDC-9 was ever marketed, sold, or distributed at any time during the most recent five years and complete all fields. If the NDC-9 was not marketed, sold, or distributed in a particular quarter, please still add include a row for this particular quarter, and enter the NDC-9, quarter, and unit type information, but enter “0” in the total unit volume field and leave the three price fields blank.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-9s associated

²⁴ <https://www.va.gov/opal/nac/fss/pharmprices.asp>.

with the selected drug. Please do not include units associated with free samples in the calculated prices or reported total unit volume.

- The NDC-9 price reported in the U.S. commercial average net unit price field must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers.
- If the Primary Manufacturer or Secondary Manufacturer(s) provided coupons or co-payment assistance to patients, separately report the price net of coupons and co-payment assistance to patients in the U.S. commercial average net unit price— without patient assistance programs field. If the Primary Manufacturer and Secondary Manufacturer(s) did not provide coupons or co-payments assistance to patients, please leave the U.S. commercial average net unit price— without patient assistance programs field blank.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to any commercial payer during the quarter in the U.S. commercial average net unit price— best field.

NDC-9	Quarter	U.S. Commercial Average Net Unit Price	U.S. Commercial Average Net Unit Price- Without Patient Assistance Programs	U.S. Commercial Average Net Unit Price- Best	Unit type (e.g., each, ML, GM)	Total Unit Volume
<i>12345-6789</i>	<i>QQYYY</i> <i>Y</i>	\$	\$	\$	#	#

Question 32: Explanation of Information Reported in Response to Question 31: U.S. Commercial Average Net Unit Price

Describe assumptions, methodological steps, and other information for the following topics related to Question 31:

- How sales to enrollees of group and individual commercial plans on- and off-Exchange were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-9s and quarters.
- If applicable, how coupons and co-payment assistance to patients were allocated across NDC-9s and quarters.
- How all of this information was used to calculate the U.S. commercial average net unit price and U.S. commercial average net unit price— without patient assistance programs and determine the U.S. commercial average net unit price— best.

FIELD	RESPONSE FORMAT
<i>Explanation of U.S. commercial average net unit price data</i>	<i>Text (1,000-word limit)</i>

Question 33: Manufacturer Average Net Unit Price to Part D Plan Sponsors

Follow the instructions below when providing responses in the following table about the manufacturer average net unit price to Part D plan sponsors of the selected drug.

- Only include price and volume information of the selected drug for Part D plan sponsors.
- Include a row for each NDC-9 and each quarter during the most recent five years if the NDC-9 was marketed, sold, or distributed at any time during the most recent five years and complete all fields. If the NDC-9 was not marketed, sold, or distributed in a particular quarter, please still add a row for this particular quarter, and enter the NDC-9, quarter, and unit type information, but enter “0” in the total unit volume field and leave the three price fields blank.
- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-9s associated with the selected drug. Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- The NDC-9 price reported in the manufacturer average net unit price to Part D plan sponsors field must be net of discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered by the Primary Manufacturer and any Secondary Manufacturer(s) to any purchasers.
- If the Primary Manufacturer or Secondary Manufacturer(s) provided coupons or co-payment assistance to patients, separately report the price net of coupons and co-payment assistance to patients in the manufacturer average net unit price to Part D plan sponsors—without patient assistance programs field. If the Primary Manufacturer and Secondary Manufacturer(s) did not provide coupons or co-payment assistance to patients, please leave the manufacturer average net unit price to Part D plan sponsors—without patient assistance programs field blank.
- Provide the lowest price that the Primary Manufacturer or any Secondary Manufacturer(s) made available to a Part D plan sponsor during the quarter in the manufacturer average net unit price to Part D plan sponsors—best field.

NDC-9	Quarter	Manufacturer Average Net Unit Price to Part D Plan Sponsors	Manufacturer Average Net Unit Price to Part D Plan Sponsors- Without Patient Assistance Programs	Manufacturer Average Net Unit Price to Part D Plan Sponsors- Best	Unit Type (e.g., each, ML, GM)	Total Unit Volume
<i>12345-6789</i>	<i>QQYYYY</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>	<i>Text</i>	<i>#</i>

**Question 34: Explanation of Information Reported in Response to Question 33:
Manufacturer Average Net Unit Price to Part D Plan Sponsors**

Describe assumptions, methodological steps, and other information for the following topics related to Question 33:

- How sales to Medicare Part D enrollees of Part D plan sponsors sales were determined.
- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-9s and quarters.
- If applicable, how coupons and co-payment assistance to patients were allocated across NDC-9s and quarters.
- How all of this information was used to calculate the manufacturer average net unit price to Part D sponsors and manufacturer average net unit price to Part D plan sponsors—without patient assistance programs and to determine the manufacturer average net unit price to Part D plan sponsors— best.

FIELD	RESPONSE FORMAT
<i>Explanation of manufacturer average net unit price to Part D plan sponsors data</i>	<i>Text (1,000-word limit)</i>

Question 35: Quarterly Total U.S. Gross and Net Revenue

Report quarterly total U.S. gross and net revenue for the selected drug, separately by NDC-9 and quarter. Follow the instructions below when providing responses in the following table:

- Gross revenue must reflect sales by the Primary Manufacturer and all Secondary Manufacturer(s) to all purchasers in the U.S. for the NDC-9 in the quarter and be reported in the gross revenue field.
- To calculate net revenue for each NDC-9 and quarter reported, in the net revenue field, subtract 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, or other price concessions or similar benefits offered to any purchasers in the United States.

- If the Primary Manufacturer and Secondary Manufacturer(s) provided coupons or co-payment assistance to patients, separately report the net revenue further net of coupons and co-payment assistance to patients in the net revenue— without patient assistance programs field. If the Primary Manufacturer and Secondary Manufacturer(s) did not provide coupons or co-payments assistance to patients, please leave the net revenue— without patient assistance programs field blank.
- Include a row for each NDC-9 and each quarter during the most recent five years if the NDC-9 was marketed, sold, or distributed at any time during the most recent five years and complete all fields. If the NDC-9 was not marketed, sold, or distributed in a particular quarter, please still add a row for this particular quarter, and enter the NDC-9 and quarter, but leave the three revenue fields blank.

NDC-9	Quarter	Gross Revenue	Net Revenue	Net Revenue-Without Patient Assistance Programs
<i>Text</i>	<i>QQYYYY</i>	<i>\$</i>	<i>\$</i>	<i>\$</i>

Question 36: Explanation of Quarterly Total U.S. Gross and Net Revenue from Question 35

Describe assumptions, methodological steps, and other information for the following topics related to Question 35.

- How discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to any purchasers were allocated across NDC-9s and quarters.
- If applicable, how coupons and co-payment assistance to patients were allocated across NDC-9s and quarters.

FIELD	RESPONSE FORMAT
<i>Explanation of Quarterly Total U.S. Gross and Net Revenue</i>	<i>Text (1,000-word limit)</i>

Question 37: Quarterly Total U.S. Unit Volume

Report quarterly total U.S. unit volume for the selected drug, separately for each NDC-9 and quarter.

Instructions for Question 37:

- Report total U.S. unit volume to any purchaser for the selected drug.

- Units must be reported in one of the three NCPDP BUS: each (EA), milliliter (ML), or gram (GM). The unit type reported must be specified for each of the NDC-9s associated with the selected drug. Please do not include units associated with free samples in the calculated prices or reported total unit volume.
- Include a row for each NDC-9 and each quarter during the most recent five years if the NDC-9 was marketed, sold, or distributed at any time during the most recent five years and complete all fields. If the NDC-9 was not marketed, sold, or distributed in a particular quarter, please still add a row for this particular quarter, and enter the NDC-9, quarter, and unit type information, but enter “0” in the total unit volume field.

NDC-9	Quarter	Unit Type (e.g., each ML, GM)	Total Unit Volume
12345-6789	QQYYYY	Text	Text

Question 38: Explanation of Quarterly Total U.S. Unit Volume from Question 37

If applicable, describe other information you feel is necessary to interpret reported information in response to Question 37.

FIELD	RESPONSE FORMAT
<i>Explanation of quarterly total U.S. unit volume</i>	Text (1,000-word limit)

H. Evidence About Alternative Treatments

Optional for All Respondents, Including Primary Manufacturer

CMS collects your email and name so the Health Plan Management System (HPMS) can provide you a secure, custom link for submission of information and evidence.

While CMS is seeking public input under section 1194(e)(2) of the Act to consider information on the selected drug and its therapeutic alternative(s), please limit your response and do not include personally identifiable information²⁵ (PII) or protected health information²⁶ (PHI). CMS intends to collect only the minimum necessary information related to the selected drug and its therapeutic alternative(s) for the purpose of implementing and operating the Negotiation Program, and will not retrieve evidence for manufacturer negotiations by personal identifier (PII or PHI). CMS does not, through this collection, intend to create or maintain a system of records

²⁵ Personally 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>

²⁶ Protected health information 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. See <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>

as understood by the Privacy Act of 1974 and accompanying Office of Management and Budget guidance.

Question 39: Respondent Information

Required: Individuals or organizations, including Secondary Manufacturers, that wish to provide information in this Section H must provide the following information.²⁷

FIELD	RESPONSE FORMAT
Selected Drug	<i>TEXT</i>
Respondent Name	<i>TEXT</i>
Organization Name	<i>TEXT</i>
Respondent Email	<i>TEXT</i>

Optional: Check the relevant box: Which of the following best describes the person completing this form?

- ☐ Representative of a manufacturer that does not manufacture the selected drug
- ☐ Representative of a Secondary Manufacturer of the selected drug
- ☐ Representative of a trade association or patient advocacy organization
- ☐ A health care provider who has experience prescribing, dispensing, or administering this drug
- ☐ A patient who has experience taking this drug
- ☐ Other

Instructions for Questions 40 through 43:

Please follow the instructions below when answering these questions.

- The following questions are optional. You may answer some or all of the questions. Enter “No response” if you do not wish to respond to a given question.
- Please answer each question in narrative (text) form. Your responses will be limited to the word and citation maximums provided for each question.
- 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 is unpublished, clearly indicate this in the citation.
- Do NOT include as evidence comparative clinical effectiveness research 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 these populations as of lower value, for example certain uses of quality-adjusted life-years (QALYs) when

²⁷ This section will be included in the Primary Manufacturer’s HPMS negotiation module, and the Primary Manufacturer must submit any responses to the questions in this section there.

associated with life extension, will not be used. In instances where a study uses a metric such as QALYs in a life-extension context but has clearly separated this use of QALYs from other evidence in the report (e.g., clinical effectiveness, risks, harms, etc.) that is relevant to the factors listed in section 1194(e)(2) of the Act, CMS will consider such separate evidence. In these cases, indicate clearly in the in-text citation if the evidence provided treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill and clearly indicate what separate evidence CMS might consider.

- All declarative statements must 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).
- When citing studies to support responses, briefly summarize the study context and relevant comparator or therapeutic alternative drug(s) studied, as applicable.
- 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 is unpublished, clearly indicate this in the citation.
- When citing studies to support responses, briefly summarize the study context and relevant comparator or therapeutic alternative drug(s) studied, as applicable.
- 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).

Question 40: Prescribing Information

Instructions for Question 40:

- Specify which therapeutic alternative(s) and indications you are referencing when discussing FDA prescribing information.

Questions to Respond to for Question 40:

- What prescribing information has been approved by the FDA for the selected drug and for therapeutic alternative(s) to the selected drug?
- Please provide information about how the selected drug and its therapeutic alternative(s) are used in the course of care for the condition or disease treated by each indication.

FIELD	RESPONSE FORMAT
Response to Question 40	<i>Text (1,000-word limit)</i>
Additional Materials for Question 40	• <i>Text</i> • <i>Links or up to 20 attachments to FDA-approved labels or other materials</i>

Does any evidence provided treat 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? Yes [] No []

Question 41: Therapeutic Impact and Comparative Effectiveness

Instructions for Question 41:

- Specify the therapeutic alternative and indication of the selected drug that you are discussing.
- When discussing the therapeutic impact of the selected drug, indicate outcome(s) used, the indication(s) to which the evidence applies, and the therapeutic alternative(s) to which the evidence applies.

Questions to Respond to for Question 41:

- Please provide information on the therapeutic impact of the selected drug compared to existing therapeutic alternatives. What is known about the comparative effectiveness of the selected drug and its therapeutic alternative(s)? Please discuss for each indication of the selected drug, as applicable. Consider discussing health outcomes, surrogate endpoints, intermediate outcomes, patient-reported outcomes, and patient experience.
- To what extent does the selected drug represent a therapeutic advance as compared to existing therapeutic alternatives? Please discuss for each indication of the selected drug, as applicable.
- Please describe any differences in the safety profile of the selected drug and its therapeutic alternative(s) for each indication, as applicable.
- Please provide current costs of such existing therapeutic alternatives (if known).

FIELD	RESPONSE FORMAT
Response to Question 41	<i>Text</i> (3,000-word limit)
Additional Materials for Question 41	<i>Text</i> (Up to 50 citations)

Does any evidence provided treat 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? Yes [] No []

Question 42: Comparative Effectiveness on Specific Populations

Instructions for Question 42:

- Specify which specific population and which indication of the selected drug you are discussing.

Questions to Respond to for Question 42:

- What is known about the comparative effectiveness of the selected drug and therapeutic alternatives to the selected drug with respect to specific populations, such as individuals with disabilities, the elderly, the terminally ill, and children?
- Are there other specific populations not noted in the question above that use the selected drug that could be considered?
- As applicable, for other specific populations that use the selected drug, what is known about comparative effectiveness of the selected drug and its therapeutic alternative(s)?

- In addition to comparative effectiveness, please discuss any differences in the safety profile of the selected drug compared to its therapeutic alternative(s) for each applicable specific population.

Field	Response
Response to Question 42	<i>Free Response Field</i> (3,000-word limit)
Additional Materials for Question 42	<i>Free Response Field</i> (Up to 50 citations)

Does any evidence provided treat 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? Yes [] No []

Question 43: Addressing Unmet Medical Needs

Definitions for Question 43:

- Unmet medical need: A drug or biologic that treats a disease or condition in cases where very limited or no other treatment options exist is considered to meet an unmet medical need.

Instructions for Question 43:

- Specify the therapeutic alternative and indication of the selected drug that you are discussing.
- When discussing the therapeutic impact of the selected drug, indicate outcome(s) used, the indication(s) to which the evidence applies, and the therapeutic alternative(s) to which the evidence applies.

Questions to Respond to for Question 43:

- To what extent do the selected drug and therapeutic alternative(s) to the selected drug address an unmet medical need?

FIELD	RESPONSE FORMAT
Response to Question 43	<i>Text</i> (1,000-word limit)
Additional Materials for Question 43	<i>Text</i> (Up to 50 citations)

Does any evidence provided treat 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? Yes [] No []

I. Certification of Submission for Primary Manufacturers

Required for Primary Manufacturers

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after

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

Yes []

No []

Contact Information

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

J. Certification of Submission for Respondents Who Are Not Primary Manufacturers

Required for All Respondents Who Are Not Primary Manufacturers

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

Yes []

No []

Contact Information

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

Field	Response
Date	<i>MMDDYYYY</i>

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