Centers for Medicare & Medicaid Services Response to Public Comments Received for CMS-10847, OMB 0938-NEW

The Centers for Medicare & Medicaid Services (CMS) received 24 timely public submissions from consumer and patient advocacy organizations, professional trade associations, pharmaceutical manufacturers, health plans, data vendors, and the general public on the Negotiations Data Elements Information Collection Request (CMS-10847, OMB 0938-NEW) that was issued March 21, 2023 for a 60-day public comment period. We note that some of the public comments were outside the scope of the information collection request (ICR). These out-of-scope public comments are not addressed in this summary and response. However, responses to many of these out-of-scope comments may be found in CMS responses to the summary of the more than 7,500 timely public submissions CMS received on 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 "initial memorandum") which was released on March 15, 2023 and open for comment until April 14, 2023. CMS refers commenters to the Medicare Drug Price Negotiation Program: Revised Memorandum, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2026 (the "revised guidance") for these responses, which address, among other things, definitions of terms contained in this ICR (e.g., qualifying single source drug, Primary Manufacturer, prior Federal funding, unit costs of production and distribution, Research & Development (R&D) costs and recoupment); issuance of certain policies for the Medicare Drug Negotiation Program (the "Negotiation Program") as final, i.e., section 30 of the initial memorandum and revised guidance; the process for identifying a qualifying single source drug for initial price applicability year 2026; manufacturer review of evidence submitted to CMS; the methodology for weighting of negotiation factors and examples of how factors will be used for adjustments to an offer and/or counteroffer; and the process for establishing the maximum fair price (MFP), including the stakeholder engagement process and the information subject to confidentiality requirements.

This ICR (CMS-1047, OMB 0938-NEW) is being published for a 30-day public comment period.

Summaries of the public comments that are within the scope of this ICR and responses to those public comments are set forth in this document under the appropriate heading.[1]

Burden to Report the Information Required and/or Requested

Comment: Many commenters stated that CMS' submission requirements are burdensome. These commenters noted that CMS is requesting a large volume of data and/or level of detail to which the Primary Manufacturer may not have access (e.g., due to the drug being acquired from another manufacturer, historical data being hard to access) or may not be able to produce in the manner and timeframe requested. A few commenters stated that CMS underestimates the burden of these submission requirements, which these commenters believed would take longer than the estimated 500 hours. A few commenters recommended that CMS reduce the number of questions

[1] References to section and question numbers reflect the lettering and numbering in the 30-day notice.

and/or data elements required to be submitted or allow Primary Manufacturers to use reasonable assumptions regarding submission of data as describe in section 1194(e)(1) of the Social Security Act (the "Act").

Response: CMS appreciates commenters sharing their concerns about the reporting requirements. CMS believes that 500 hours per manufacturer is an appropriate estimate of burden. However, to acknowledge possible variability, CMS has provided a range for the burden estimate, with a low estimate of 250 hours and a high estimate of 1,000 hours, as further explained in the Supporting Statement. To address commenters' concerns regarding the large total number of questions and regarding the necessity of certain specific requests for information, CMS revised questions in this ICR resulting in a net reduction of the total number of questions. CMS eliminated the requests for certain information (e.g., section G requests for 340B ceiling price, 340B prime vendor program price, and manufacturer average net unit price) and reduced the granularity required for certain information (e.g., section C requests on R&D costs and recoupment); however, CMS also provided additional opportunities for Primary Manufacturers and the public to submit certain information (e.g., section I options to submit visual representations of information and an optional question on patient/caregiver experiences). Therefore, CMS believes that the burden range remains appropriate for this ICR.

CMS understands commenters' concerns about the volume of data that must be submitted within a 30-day timeframe for a manufacturer that participates in the Negotiation Program. However, section 1194(e)(1) of the Act requires the submission of these specific data elements from participating manufacturers in order to inform CMS' calculation of the MFP, and the statute requires that these data be submitted by October 2, 2023. As outlined in the Supporting Statement, CMS believes Primary Manufacturers have experience providing similar data and information to other federal and state entities. For example, Primary Manufacturers currently collect and report information related to manufacturer financials (e.g., 10-K filings with the Securities and Exchange Commission (SEC)) and sales and pricing data (e.g., Average Manufacturer Price to CMS as part of participation in the Medicaid Drug Rebate Program (MDRP)).

To address concerns about Primary Manufacturers not having access to certain data due to, for example, the rights to the selected drug being acquired from another entity, CMS has revised instructions throughout the ICR so that Primary Manufacturers will not report information on R&D costs (other than acquisition costs), patents, or prior Federal financial support for periods prior to their acquisition of the selected drug.

CMS also understands that allowing manufacturers to submit information based on their own reasonable assumptions may reduce reporting burden. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. Data submitted in response to this ICR by Primary Manufacturers and the public must be based on consistent definitions and scope, as reflected in the revised instructions of this ICR and Appendix C of the revised guidance. Costs should be determined using the methodologies described in this ICR and consistent with generally accepted accounting principles, where applicable. CMS expects that

Primary Manufacturers will submit data that are complete and accurate, and that their submissions will be prepared in good faith and after reasonable efforts, consistent with the certification they submit.

Comment: A few commenters stated that CMS' submission requirements are duplicative of existing reporting requirements of other federal agencies or information that is publicly available, for example, 340B ceiling price, Medicaid best price, and patent information.

Response: CMS thanks commenters for their feedback. CMS understands that some manufacturer-specific data described in sections 1193(a)(4) and 1194(e)(1) of the Act may already be collected from manufacturers by CMS or other federal agencies. For example, for purposes of calculating the federal ceiling price, drug manufacturers report the quarterly and annual non-Federal Average Manufacturer Price on an annual basis to the Department of Veterans Affairs (VA). The Federal Supply Schedule and the Big Four are prices negotiated by the VA and available publicly. In addition, some of the requested data may be publicly available, although CMS may not be able to ensure that such data are complete or up-to-date. As noted elsewhere, CMS has removed or revised certain requests for information from the draft ICR to reduce burden. Ultimately, CMS believes that the Primary Manufacturer is best positioned to provide the requested data and the statute provides that manufacturers participating in the Negotiation Program will submit the requested data.

Deadline to Submit Information and Engagement with Interested Parties

Comment: Some commenters requested an extension of the October 2, 2023, submission deadline for initial price applicability year 2026 (such as a 60- or 90-day period for data submission), while some other commenters requested the ability to submit data on a rolling basis as such data became relevant for a particular step of the negotiation process and/or the option to supplement data submissions after October 2, 2023. Some commenters requested an extended submission period for only the information requested in response to section I of this ICR (information in section 1194(e)(2) of the Act), including a 60-day submission period and/or an extension of the deadline for the public only. A few commenters requested that CMS supplement the ICR submission via the CMS Health Plan Management System (CMS HPMS) with other avenues for information sharing, including townhalls, particularly for information to be submitted by the public and described in section 1194(e)(2) of the Act.

Some commenters suggested that in order for them to meet the October 2, 2023, data submission deadline, CMS must revise the number and content of the questions.

Finally, some commenters linked their concerns regarding the ability to timely submit complete information with their concerns about the imposition of civil monetary penalties and excise tax liability for any failure to submit complete data.

Response: CMS appreciates commenter's concerns regarding the October 2, 2023, deadline. Sections 1194(b)(2)(A) and 1191(d)(5)(A) of the Act, which together require that the manufacturer-specific data described in sections 1193(a)(4)(A) and 1194(e)(1) of the Act be submitted to CMS by October 2, 2023, for initial price applicability year 2026. Further, due to the statutorily defined negotiation period timing, it is not feasible to extend the timeframe for the

submission of sections 1194(e)(1) and 1194(e)(2) information. As described in the revised guidance, CMS will use information submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected drug. Sections 40.2 and 50.1 of the revised guidance and the definitions set forth in Appendix C of the revised guidance provide a manufacturer participating in the Negotiation Program sufficient notice of requirements that govern the submission of information in response to this ICR. As discussed in the revised guidance, CMS revised Appendix C in response to comments received on the initial memorandum. CMS is also revising some instructions and questions in this ICR in response to comments received.

In addition, as described in section 60.4 of the revised guidance, CMS will also host patient-focused meetings that will be open to the public, including patients, beneficiaries, caregivers, patient/public advocacy organizations, and other interested parties to share patient-focused input on therapeutic alternatives and other information regarding selected drugs related to the factors in section 1194(e)(2) of the Act. These patient-focused meetings will occur later in Fall 2023 after the section 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback. Primary manufacturers may also submit additional information with their counteroffers.

CMS appreciates the time and resources required by interested parties to identify and compile the relevant information and draft the responses necessary to respond to this ICR. To streamline the additional time and processes necessary for interested parties to compile and draft responses to this ICR, CMS used terms and data standards that are in line with industry and/or government standards to the extent possible within the statutory requirements for the Negotiation Program. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted.

Confidentiality of Information Submitted Under This ICR and Its Storage by CMS

Comment: A few commenters suggested CMS allow manufacturers to designate which data are confidential and proprietary and not subject to public disclosure, such as by indicating with a checkbox. One commenter stated that CMS could not prevent a manufacturer from choosing what information to share publicly.

Response: Information that is deemed proprietary shall only be used by CMS or disclosed to and used by the Comptroller General of the United States for purposes of carrying out the Negotiation Program. Proprietary information, including trade secrets and confidential commercial or financial information, will also be protected from disclosure if the proprietary information meets the requirements set forth under Exemptions 3 and/or Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. § 552(b)(3), (4))[2] (see section 40.2.1 of the revised guidance and the Supporting Statement for additional information regarding disclosures of information).

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

Comment: A few commenters raised concerns about the security of data received by CMS in response to this ICR. A couple of commenters suggested limiting access to the information to personnel who needed such access for the course of their work and had a legitimate need. Another commenter suggested that CMS require personnel accessing the information a nondisclosure agreement that includes clear consequences for a violation. Another commenter suggested limiting access to only personnel who need to use it for the Negotiation Program and to use the MDRP as an example.

Response: CMS HPMS adheres to Department of Health and Human Services (HHS)/CMS policies, procedures, controls, and standards for information security and privacy. CMS HPMS requires a CMS-issued user ID and password, with multi-factor sign on. CMS HPMS adheres to CMS Information Security Incident Handling Procedures.

This ICR clarifies that CMS staff and contractors are subject to all applicable policies, procedures, controls, and standards required of HHS/CMS information security and privacy programs and nondisclosure requirements. Further, the revised guidance clarified that CMS employees that leave CMS are informed of nondisclosure requirements prior to departure.

Comment: One commenter expressed concern about the security of email in the event CMS uses email as a backup to CMS HPMS or in the course of business of review and analysis of the information submitted via this ICR. The commenter suggested that proper storage and access controls must be used for these mechanisms

Response: CMS will provide technical assistance to manufacturers and other interested parties submitting information in response to this ICR. CMS does not anticipate needing to use email as a back-up as CMS HPMS is already used by CMS for certain other Medicare data submissions and is regularly monitored by CMS; however, in the event information must be shared via email, CMS will provide submission instructions consistent with CMS controls, including password protection and encryption.

Process of and Formats for Submitting the Information

Comment: A few commenters requested that CMS accept responses to this ICR, particularly for public submissions in response to section I of this ICR, via another mechanism, such as regulations.gov or a designated mailbox, either in addition to or in lieu of submitting through CMS HPMS. One commenter reported being concerned that CMS HPMS allows only one individual per manufacturer to access and submit data via CMS HPMS.

Response: CMS thanks commenters for expressing their concerns regarding submission of data in response to questions in section I of this ICR through CMS HPMS. CMS is revising this ICR to clarify that the submission platform that will be used by interested parties other than Primary Manufacturers is a user-friendly, publicly-accessible web application that does not require creation of an account in CMS HPMS. This application will be accessible from an entry point on CMS.gov, as well as on the publicly-accessible CMS HPMS landing page at https://hpms.cms.gov. Individuals will need to submit an email and respond to an email confirmation message from CMS prior to accessing and answering questions contained in section

I. Additional instructions for respondents to access this public web application will be forthcoming from CMS and made available on CMS.gov.

CMS is using a web-based application for initial price applicability year 2026 in order to: (1) to standardize the system used with other components of the Negotiation Program and (2) to create a user interface that minimizes the risk of incomplete submissions. CMS web-based platforms and CMS HPMS have the additional benefit of adhering to all applicable policies, procedures, controls, and standards required by HHS and CMS information security and privacy programs.

Per CMS' Instructions to Drug Manufacturers released May 4, 2023 (available in the Downloads section of https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess), CMS will not limit the number of users per manufacturer who are permitted access to CMS HPMS.

Comment: Many commenters requested revisions to instructions for data formats (e.g., text only required) and word limits. For example, many commenters requested that no word limits be placed on free response text fields, while other commenters suggested that a higher word limit be permitted, particularly for information submitted in response to section 1194(e)(1) of the Act. Additionally, some commenters requested that types of information be permitted other than numerical and word formats, including charts and tables. Finally, a few commenters requested revisions to the number of citations permitted in response to section 1194(e)(2) data in section I; for example, including no limit or raising the limit to 200 citations.

Response: CMS thanks commenters for their suggestions. After consideration of the comments, CMS updated this ICR to permit submission of visual representations of information by adding an option to upload up to 10 tables, charts, and/or graphs for each of questions 28 through 30 in section I.

Otherwise, CMS is maintaining the text and citations limits. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted. Please see section 60.4 of the revised guidance, which describes additional opportunities for information sharing.

Section B: Non-FAMP Data Collection

Comment: Some commenters requested removal of information pertaining to non-Federal average manufacturer price (non-FAMP) because manufacturers already submit FAMP data to the VA. A couple of commenters suggested that manufacturers attest to the use of the VA data for the Negotiation Program but are not required to separately submit. Some commenters also suggested revisions to the definition of non-FAMP, for example, by revising the year from fiscal to calendar and permitting restatements.

Response: Manufacturers are required to submit the data in section 1193(a)(4)(A) of the Act to CMS. The data are needed to calculate the ceiling for the MFP. CMS directs commenters to responses to comments received on Appendix C of the revised guidance.

Comment: A few commenters requested clarification on the format for reporting units since non-FAMP units may vary from prescription drug event (PDE) units. A few commenters also suggested revisions to the format of units reported, including that manufacturers should report the unit measurement in the non-FAMP explanatory field in section B.

Response: CMS revised the instructions and structure of section B to add a unit type field in the table that will assist CMS in translating package unit to the National Council for Prescription Drug Programs (NCPDP) unit, which is used for PDE reporting, in the event that a manufacturer needs to report non-NCPDP units. CMS also directs commenters to section 60.2.3 of the revised guidance, which clarifies that NCPDP units will be used when averaging non-FAMP across NDC-11s.

Section C: Research and Development (R&D) Costs and Recoupment

Comment: Some commenters stated that CMS' R&D data submission requirements go beyond statute and/or are unnecessary for CMS to determine recoupment. These commenters expressed concern that reporting R&D expenditures by the six categories proposed by CMS is burdensome and/or inconsistent with how industry typically tracks and reports this information. A few commenters also stated that it may be difficult for manufacturers to obtain older R&D financial data and expressed concern that CMS would penalize manufacturers for previous pricing practices and data collection that occurred before the Inflation Reduction Act (IRA) went into effect. Some commenters recommended alternative approaches for CMS collection of R&D costs and recoupment, for example, that CMS allow manufacturers to report one number for R&D costs, reduce the number of categories for R&D reporting, apply a forward-looking framework and tie reporting to a cutoff in the future, allow reasonable assumptions, and/or permit manufacturers to attest that R&D costs have been recouped.

Response: CMS appreciates commenters' feedback but disagrees that the R&D data submission requirements go beyond what is permitted by statute. Nonetheless, after consideration of the comments, CMS revised section C of this ICR, as well as Appendix C of the revised guidance, to consolidate questions, instructions, and definitions across several R&D categories and to require reporting of acquisition costs as part of R&D rather than market data. The revised R&D categories are as follows: (1) Acquisition Costs, (2) Basic Pre-Clinical Research Costs, (3) Post-Investigational New Drug (IND) Application Costs (includes costs for completed, Food and Drug Administration (FDA)-required post-marketing trials, which were previously in their own category), (4) Abandoned and Failed Drug Costs, and (5) All Other R&D Direct Costs (includes costs associated with post-marketing trials that were not completed or were conducted for the purposes of marketing claims; this was previously its own category).

CMS also revised the instructions in question 2 for reporting basic pre-clinical research costs to clarify that the relevant time period for reporting such costs begins on the later of the date of initial discovery or the date the Primary Manufacturer acquired the right to hold the New Drug Application (NDA)(s) / Biologic License Application (BLA)(s) of the selected drug. This revision is intended to respond to commenters' concerns that manufacturers may not be able to access certain R&D data, particularly in cases where the selected drug was acquired from

another manufacturer. CMS generally expects a manufacturer to be able to report R&D costs incurred for a drug to which they hold the rights.

While CMS understands that allowing manufacturers to attest to R&D costs may reduce reporting burden, section 1194(e)(1) of the Act requires the Primary Manufacturer to submit data on the R&D costs incurred by the manufacturer for the selected drug and the extent to which the manufacturer has recouped R&D costs. CMS believes that submission of an attestation alone would not be consistent with the statutory requirement that the manufacturer submit information described in section 1194(e)(1). CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted. As stated in both this ICR and Appendix C of the revised guidance, costs should be determined using the methodologies described in this ICR and when applicable, consistent with generally accepted accounting principles.

Comment: Some commenters expressed concern with CMS' approach to limit reporting of R&D costs to those related to FDA-approved indications, but requiring submission of global, total lifetime net revenue.

Response: CMS appreciates commenters sharing these concerns. CMS understands that R&D occurs globally and as stated in the instructions for section C of this ICR, the Primary Manufacturer must report R&D costs incurred in other countries that are related to the FDA-approved indication of a selected drug, excluding costs of foreign regulatory approvals. To clarify that CMS will consider both a Primary Manufacturer's global and also U.S. revenue when considering whether R&D costs have been recouped, CMS revised this ICR to move the reporting of U.S. revenue from section G (Market data and revenue and sales volume data) to the R&D section and specifically to the revised category "Global and U.S. total lifetime manufacturer net revenue for the drug." Further, to align reporting of U.S. revenue with global total lifetime net revenue, CMS revised this ICR to (1) eliminate reporting of quarterly U.S. gross revenue and (2) replace reporting of quarterly U.S. net revenue for the selected drug with U.S. lifetime net revenue for the selected drug.

Section D: Current Unit Costs of Production and Distribution

Comment: Some commenters noted that manufacturers do not calculate costs of production at the NDC-9 level, adding that the use of NDC-9 for production and distribution costs does not match the use of NDC-11 in section B of this ICR. Additionally, one commenter wrote that CMS —not manufacturers—should perform any crosswalk from NDC-11 to NDC-9. A few commenters recommended CMS provide discretion to manufacturers to describe production and distribution costs in a narrative explanation.

Response: CMS appreciates the feedback from commenters. After consideration of these comments, CMS revised this ICR to clarify that manufacturers should report costs of production and distribution at the NDC-11 level.

Comment: One commenter expressed concern that manufacturers will need to use reasonable assumptions to submit unit costs of production and distribution at the product level, otherwise they would face the threat of fines or False Claims Act liability.

Response: CMS appreciates the commenter's concern and notes that CMS revised this ICR, as well as Appendix C of the revised guidance, to clarify that costs should be determined using the methodologies described in this ICR and consistent with generally accepted accounting principles, as applicable, and should not include any costs that are unallowable under applicable law or costs that are expressly excluded from this ICR and Appendix C of the revised guidance. CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the Act or otherwise use reasonable assumptions. Data submitted in response to this ICR by Primary Manufacturers and the public must be based on consistent definitions and scope, as reflected in the revised instructions of this ICR and Appendix C of the revised guidance.

Comment: One comment suggested CMS allow manufacturers to determine the most appropriate 12-month period for reporting costs, noting that manufacturers are unlikely to track information as CMS proposed for selected drugs for initial price applicability year (i.e., during the 12-month period ending May 31, 2023).

Response: CMS appreciates the suggestion and notes that it chose this time period to align with the statute for initial price applicability year 2026. For example, sections 1191(d)(3)(B) and 1192(d)(1)(A) of the Act require that CMS identify negotiation-eligible drugs for initial price applicability year using total expenditure data during the period beginning on June 1, 2022, and ending on May 31, 2023.

Section E: Prior Federal Financial Support

Comment: A few commenters noted that R&D costs in this ICR are limited to those related to FDA-approved indications of the selected drug, but that the definition for prior Federal financial support is broader. These commenters asked that CMS be consistent and consider only prior Federal financial support directly related to labeled indications of the selected drug.

Response: CMS reaffirms that its definition of prior Federal financial support only includes funds provided by the Federal government that support discovery, research, and/or development *related to the selected drug*. CMS revised this section of the ICR to clarify that the scope of this data collection is on FDA-approved indications of the selected drug, thereby aligning with the R&D section (section C). Like the R&D section, the prior Federal financial support section directs that Primary Manufacturers submit funds related to FDA-approved indications of the selected drug from when initial research began or the selected drug was acquired, whichever is later, through the date of the latest NDA / BLA approval. Primary Manufacturers should not submit funding data that is not related to the selected drug.

Comment: A couple of commenters requested that CMS clarify that prior Federal financial support should only be reported for the period starting from when the Primary Manufacturer acquired the drug.

Response: CMS revised this ICR to confirm that if the Primary Manufacturer acquired the selected drug, it only needs to report prior Federal financial support from the date of acquisition through the date of the latest NDA / BLA approval. If the Primary Manufacturer did not acquire the drug, it should report prior Federal financial support from the beginning of initial research through the date of the latest NDA / BLA approval. Overall, the time period for reporting costs is from when initial research began or when the selected drug was acquired, whichever is later, through the date of the latest NDA / BLA approval.

Comment: One commenter noted that the time horizon between the initial start of research through the date of the latest NDA / BLA approval may be very long and requested that CMS establish a look back period for prior Federal financial support that is limited to 10 years back from the latest NDA / BLA approval.

Response: To ensure consistency across all sections of this ICR in terms of timing for data reporting, CMS is not defining a lookback period based on a preset number of years and instead will require data submission from when initial research began or when the drug was acquired through the latest NDA / BLA approval date. CMS believes that using this time horizon for all relevant elements of this data collection will provide the most complete picture of the selected drug and better inform negotiations than a defined lookback period.

Comment: One commenter stated that including procurement and contract funds in prior Federal financial support is inconsistent with the concept of Federal financial support and asked that CMS remove any commercial contracts or agreements between the Primary Manufacturer and the government from its data collection.

Response: CMS clarified in this ICR that a Primary Manufacturer should include only contracts and agreements with the Federal government that are related to the discovery, research, and/or development of the selected drug.

Comment: A few commenters suggested that Primary Manufacturers should have to submit only one number for prior Federal financial support and an explanation of these funds and should not have to disaggregate funds into specific categories. Commenters stated that having to break up prior Federal financial support into categories imposed an unnecessary reporting burden and found the reporting format overly prescriptive. Commenters also suggested that disaggregating data for prior Federal financial support went beyond the statute because the statute refers to prior Federal financial support as one-line item.

Response: CMS disagrees that requiring disaggregated data for prior Federal financial support goes beyond the statute. CMS made minor revisions to this ICR so that Primary Manufacturers report one total number for prior Federal financial support and then disaggregate this number into amounts by source in a subsequent question. The Primary Manufacturer will be required to describe the various sources these funds derived from when explaining this one number so that CMS can have a more complete understanding of federal support to inform negotiations. Although some of this information may be publicly available, CMS may not be able to ensure that such data are complete or up-to-date. CMS believes that the Primary Manufacturer would be best positioned to provide the requested data.

Section F: Patents, Exclusivities, and Approvals

Comment: Some commenters expressed concern that complying with CMS' reporting requirements would be burdensome or challenging for manufacturers, for example, because Primary Manufacturers may not have insight into patents that are not their own or may not have older applications available in electronic format to submit to CMS. Some commenters recommended that to reduce burden, CMS should use publicly available resources such as the FDA's Orange Book or Purple Book to procure patent information.

Response: CMS thanks commenters for sharing their concerns. While CMS understands that certain patent information is collected by other agencies and is publicly available in the FDA Orange and Purple Books, section 1194(e)(1) of the Act requires that manufacturers submit patent information to CMS. Although some of the requested data may be publicly available, CMS may not be able to ensure that such data are complete or up-to-date. Further, other information required by section 1194(e)(1) of the Act—for example, information about pending patents or FDA applications under review—may not be publicly available. As such, CMS believes that the Primary Manufacturer would be best positioned to provide the requested data. To address concerns about Primary Manufacturers not having insight into patents that are not their own, CMS revised the instructions in section F of this ICR so that the relevant time period for reporting patent information begins on the later of the date that basic pre-clinical research began on the selected drug or the date the selected drug was acquired by the Primary Manufacturer. CMS expects that the Primary Manufacturer generally would be able to provide patent information for selected drugs to which they hold the rights.

Comment: One commenter stated while question 14 asks Primary Manufacturers to list each period of regulatory exclusivity under the Federal Food, Drug, & Cosmetic Act (FD&C Act) or the Public Health Service Act (PHS Act) and the corresponding expiration date, for licensure of biological products specifically, FDA does not consider every licensure to be a "first licensure" qualifying for its own 12-year exclusivity period. The commenter further noted that FDA does not routinely publish determinations about reference product exclusivity or its expiration dates in the Purple Book and thus recommended that CMS acknowledge that in some cases, there may be uncertainty as to whether a biological product has received 12-year reference product exclusivity.

Response: CMS appreciates this feedback and in response to this comment has revised question 14 to note that CMS understands that FDA has not made a determination of first licensure for each 351(a) biological product included in the Purple Book. However, the absence of a date of first licensure in the Purple Book does not mean that a biological product on the list is not, or was not, eligible for reference product exclusivity. CMS expects that the Primary Manufacturer will report any periods of reference product exclusivity for the selected drug to the extent the determination of exclusivity is listed in the Purple Book.

Comment: Some commenters expressed concerns with CMS' patent reporting instructions and/or definitions and recommended that CMS modify or clarify the scope of patent information that must be submitted. For example, a few commenters requested that CMS provide additional information about which patents would be considered "related to" or "linked to" the selected

drug. One commenter recommended that CMS clarify and revise certain questions and definitions related to submission of FDA applications and approvals to CMS.

Response: CMS appreciates commenters' suggestions and revised questions 12 and 13 and their instructions to provide additional information about the types of patents and patent applications considered to be "related to" the selected drug. For example, question 12 specifies that patents related to the selected drug include, but are not limited to, utility patents that claim the drug product, drug substance, metabolites or intermediaries of a selected drug, method(s) of using the drug, or method(s) of manufacturing the drug, as well as any design patents that, for example, claim a design on the packaging of the selected drug. Any patents that are or have been listed for the selected drug in the FDA Orange Book or Purple Book must be reported. CMS also revised question 15 to remove reporting of the application submission number and clarify that efficacy supplements must be submitted but manufacturing supplements should not be submitted.

Section G: Market Data and Revenue and Sales Volume Data

Comment: Some commenters expressed concern that submissions are duplicative and overly burdensome. For example, volume is captured in multiple questions.

Response: CMS thanks commenters for their concern. To reduce burden, CMS revised this ICR, as well as Appendix C of the revised guidance, to remove the collection of 340B ceiling price, 340B prime vendor program price, and manufacturer average net unit price. For metrics where unit volume has been requested, it is necessary to appropriately weight across the entire selected drug.

Comment: Some commenters recommended streamlining requirements such that CMS would use prices already reported to CMS and other federal agencies, including non-FAMP, Medicaid best price, average manufacturer price, Federal supply schedule price, and Big Four price, and not require separate reporting to CMS for purposes of the Negotiation Program.

Response: CMS appreciates commenters' recommendation and notes that CMS revised this ICR, as well as Appendix C of the revised guidance, to remove the collection of 340B ceiling price, 340B prime vendor program price, and manufacturer average net unit price. CMS removed these metrics because it will not consider them for the purposes of developing the initial offer. CMS maintains collection of non-FAMP, Medicaid best price, Federal supply schedule price, and Big Four price because they reflect the price of drugs procured by other entities and will be considered, in part, as the basis for offers and counteroffers. For example, as described in the revised guidance (section 60.3.2), CMS will use the Federal supply schedule price or Big Four price if the selected drug has no therapeutic alternative, if the prices of the therapeutic alternatives identified are above the statutory ceiling for the MFP, or if there is a single therapeutic alternative with a price above the statutory ceiling for the MFP. Additionally, while CMS understands commenters' concerns about submitting data that is already available, the statute requires manufacturers to submit the data described in section 1194(e)(1)(E) of the Act. Additionally, although some of the requested data may be publicly available, CMS may not be able to ensure that such data are complete or up-to-date. CMS believes that the Primary Manufacturer would be best positioned to provide the requested data.

Comment: Many commenters expressed concern that CMS is overreaching and should collect only what is required for negotiation of MFP. Some commenters also reported concern that some metrics are out of scope for Medicare. Specifically, these commenters cited the following metrics as concerning: 340B ceiling price, 340B prime vendor program price, Medicaid best price, Federal supply schedule price, Big Four price, and acquisition costs.

Response: CMS appreciates commenters' concern about collecting specific metrics. CMS revised this ICR, as well as Appendix C of the revised guidance, to remove collection of 340B ceiling price, 340B prime vendor program, and manufacturer average net unit price. CMS removed these metrics because it will not consider them for the purposes of developing the initial offer. CMS believes certain metrics are in scope of the Negotiation Programs because they reflect the price of drugs procured by other entities and will be considered, in part, as the basis for offers and counteroffers. Further, it is informative to collect a range of prices for the selected drug to inform negotiations, including Medicaid best price, Federal supply schedule price, Big Four price, and acquisition costs. For example, as described in the revised guidance (section 60.3.2), CMS will use the Federal supply schedule price or Big Four price if the selected drug has no therapeutic alternative, if the prices of the therapeutic alternatives identified are above the statutory ceiling for the MFP, or if there is a single therapeutic alternative with a price above the statutory ceiling for the MFP.

Comment: One commenter expressed concern that the industry uses NDC-11 for Wholesale Acquisition Cost (WAC) data and that CMS did not provide instruction on how to average WAC data to get to NDC-9.

Response: CMS appreciates this feedback and revised this ICR to request WAC at the NDC-11 level instead of the NDC-9 level. Additionally, CMS revised certain other pricing metrics (e.g., U.S. commercial average net unit price) in section G of this ICR to request data at the NDC-11 level instead of the NDC-9 level.

Comment: Some commenters reported concern that CMS created various new metrics that are not clearly defined, noting that these new metrics will create burden for manufacturers to calculate. Metrics they cited include "U.S. commercial net unit price" and "manufacturer average net unit price to Part D plan sponsors."

Response: CMS appreciates commenters' concerns regarding these metrics. In response to comments, CMS removed the metric "manufacturer average net unit price to Part D plan sponsors" from the ICR and from Appendix C of the revised guidance. Additionally, CMS clarified that patient assistance programs—one aspect of the metric "U.S. commercial net unit price"—refers to manufacturer-run patient assistance programs that provide financial assistance programs such as coupons and co-payment assistance or free drug products to patients.

Comment: One commenter requested CMS remove data submission for "manufacturer average net unit price to Part D plan sponsors – without patient assistance programs" because, per the HHS Office of Inspector General, manufacturers may not offer co-payment assistance to Part D beneficiaries.

Response: CMS removed the collection of the metric "manufacturer average net unit price to Part D plan sponsors" from the ICR.

Comment: One commenter requested CMS clarify whether manufacturers should report: (1) all units subject to 340B ceiling price under the 340B program (whether they are sold for ceiling price or for a lower price) or (2) only units actually sold at 340B ceiling prices.

Response: CMS thanks the commenter for this request. CMS removed the collection of 340B ceiling prices and 340B prime vendor program prices from the ICR.

Comment: One commenter asked whether, if a manufacturer updates and recertifies its Medicaid best price for a particular quarter after it submits its manufacturer-specific data, it is expected to update data previously submitted to CMS.

Response: CMS thanks the commenter for the question. CMS expects Primary Manufacturers to notify CMS if any information submitted in the ICR has changed.

Section H: Certification of Submission of Sections A through G for Primary Manufacturers

Comment: A couple of commenters stated that the statute does not require interested parties submitting data to complete a certification.

Response: CMS believes that a certification is required for program integrity purposes to provide assurance that data are complete and accurate.

Comment: One commenter stated that the statute does not require a data submitter be held liable under the False Claims Act and recommended that CMS remove this liability.

Response: CMS will rely on this data to develop its initial offer of the MFP and to finalize an MFP with the Primary Manufacturer. Complete and accurate data is required to ensure CMS has a full understanding of the selected drug's profile, its therapeutic alternatives, and the Primary Manufacturer's investment in the drug when negotiating an MFP. Furthermore, this certification language is in line with other ICRs related to the Negotiation Program and CMS does not believe the language should be different for this ICR.

Comment: A few commenters expressed concern around the certification language requiring data submitters to affirm the data is complete and accurate when word limits and preexisting data retention policies may prevent a data submitter from having access to all relevant records and therefore being able to share all information. Commenters suggested CMS only require a certification that the information is accurate.

Response: CMS expects data submitters to submit complete and accurate information within the confines of the limits provided in this ICR.

Comment: A couple of commenters suggested CMS remove the certification requirement of timely notification of changes to prevent unnecessary burden and unintended noncompliance.

Response: CMS believes that this certification requirement is necessary for the Negotiation Program as it ensures the MFP is negotiated based on the most current data. Without this language in the certification, CMS' ability to properly consider the factors described in section 1194(e)(1) of the Act could be compromised. Furthermore, this certification language is in alignment with other information collection requests related to the Negotiation Program and CMS does not believe the language should be different for this ICR.

Comment: A few commenters recommended that CMS revise the certification in this ICR so that it replicates the certification of manufacturers when submitting Medicare Part B Average Sales Price (ASP) data to CMS, which requires only that information was submitted in "good faith" and reflects the data submitter's best "knowledge and belief."

Response: The ASP data collection is a quarterly collection that allows restatements of financial data. The data collection described in this ICR is a one-time data collection where statutory requirements related to negotiation factors as well as deadlines and time constraints require agreement to an MFP based on certain factors and within a tight timeline with minimal margin for changing course based on a discovery of incomplete or inaccurate information. Therefore, this certification language reflects CMS' intent to collect complete and accurate information for negotiation. Furthermore, this language aligns with other information collection requests related to the Negotiation Program and CMS does not believe the language should be different for this ICR.

Section I: Evidence about Alternative Treatments

Comment: Many commenters requested CMS clarify evidence requirements for the submission of the information requested to address the factors described in section 1194(e)(2) of the Act and to revise the permissible types of evidence permitted under section I of this ICR to, for example, limit to U.S.-based studies; include feedback from stakeholder engagement sessions, white papers, non-head-to-head trials, patient surveys, and experiences from patient data registries; and limit evidence to licensed comparators only.

Response: CMS expects a wide range of data to be appropriately submitted for section I of this ICR and does not seek to limit the types of data submitted based on format. CMS revised section I instructions to clarify these parameters.

CMS will review submissions in alignment with sections 50 and 60 of the revised guidance. CMS also notes that section 60.4 of the revised guidance clarified that CMS will host patient-focused listening sessions that will be open to the public, including patients, beneficiaries, caregivers, patient/public advocacy organizations, and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) information regarding selected drugs. These patient-focused listening sessions will occur in Fall 2023 after the 1194(e) data submission, which will give patients and other interested parties additional time to prepare their feedback.

Comment: Some commenters requested clarification regarding the definition of unmet medical need. A few commenters expressed concerns that unmet medical need will be determined for the drug and not for each indication of the drug.

Response: CMS added the definition of unmet medical need and the clarification that unmet medical need will be considered for each indication of a selected drug to the instructions for question 30 in section I of this ICR.

Comment: Some commenters suggested that a check-off indicator box to indicate that a quality-adjusted life year (QALY) is included in submitted evidence is not sufficient and that CMS should implement additional levels of review to ensure QALYs are not considered in negotiation. One commenter expressed concern that requiring commenters to indicate whether a study includes QALYs or similar measures may be confusing and may cause an interested party to hesitate to submit otherwise useful information.

Response: CMS revised the instructions for section I of this ICR to reflect the revised guidance relating to QALYs and cost-effectiveness measures.

CMS revised questions 27 through 30 to require respondents to identify whether cost-effectiveness measures are used in the submitted evidence and, if so, whether the measure used in submitted evidence treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. This revision is intended to add clarity for respondents.

Comment: Some commenters requested CMS consider a variety of factors to determine selection of therapeutic alternatives, including considering additional value metrics; considering only on-label uses, while others requested off-label use; considering caregiver perspectives; considering sub-populations; considering personal experiences; and considering socioeconomic factors. One commenter thanked CMS for considering specific populations.

Response: After considering the comments received, CMS added definitions of "outcomes" and "patient-centered outcome" for question 28 and clarified in the instructions for questions 28 and 30 in section I of this ICR that CMS will consider outcomes such as independence, productivity, and quality of life, as well as the caregiver perspective, when such outcomes and perspectives are directly related to the person with experience taking the selected drug or its potential therapeutic alternative(s). CMS also added definitions of "specific populations" and "health equity" to this ICR and Appendix C of the revised guidance and clarified in the instructions for question 29 in section I of this ICR that respondents should include information or experiences related to health equity and specific populations that may be underserved or underrepresented. Finally, CMS added a definition of "therapeutic alternative" to Appendix C of the revised guidance that applies for question 28.

Sections J: Certification of Submission of Section I for All Respondents

Comment: One commenter suggested that CMS add guardrails to the certification for respondents who are not Primary Manufacturers to ensure the source is truly patient-focused and/or from the public and does not represent the views of other interested parties.

Response: CMS affirms that its existing certification language is structured to ensure that the respondent is submitting information reflecting evidence that is accurate based on the respondent's information, knowledge, and/or experience.

Comment: A few commenters stated that CMS did not provide a definition or guidance on what constitutes a complete submission.

Response: CMS thanks commenters for this feedback. A complete submission is a full submission that reflects the standards described in this ICR and Appendix C of the revised guidance and is within the respondent's information, knowledge, and/or experience.

Comment: A few commenters expressed concern that the certification language may not be appropriate for non-manufacturer respondents and may chill data submissions as it implies potential liability. Commenters recommended that if a certification is used, it should be limited to a narrower set of respondents. One commenter recommended that CMS work with patient groups to develop certification language that will not deter submissions.

Response: CMS thanks commenters for this feedback. CMS revised the certification language for submissions received for any respondent in response to section I questions to maintain that the certification is based on true and current statements, made to the best of the submitter's knowledge and belief, and made in good faith. CMS revised the structure of the ICR so that a separate certification is required for submission of each of section 1194(e)(1) (ICR sections A through G) and section 1194(e)(2) of the Act (ICR section I) question responses. Accurate and complete submission is critical for the drug price negotiation process as the data submitted is what will be used to inform CMS' initial offer of the MFP and negotiations with the Primary Manufacturer. Without a certification, CMS risks the MFP being based on incomplete, inaccurate, and/or outdated information.

Comment: A couple of commenters requested that CMS monitor submissions of evidence under section 1194(e)(2) of the Act to determine whether, and the extent to which, a certification may create a barrier for certain stakeholders. This comment was alongside a comment that the certification requirement may create a barrier for external stakeholders and another comment saying that CMS should not require patient groups, patients, and caregivers responding in an individual capacity to sign a certification.

Response: CMS thanks commenters for this feedback. As mentioned in the comment and response directly above, CMS revised the certification language for submissions received for any respondent in response to section I questions to maintain that the certification is based on true and current statements, made to the best of the submitter's knowledge and belief, and made in good faith. CMS believes that this revised certification will be less onerous and provide less of a barrier for interested parties responding in an individual capacity.