Centers for Medicare & Medicaid Services Response to Public Comments Received for CMS-10849, OMB 0938-1452

The Centers for Medicare & Medicaid Services (CMS) received 15 timely public submissions from consumer and patient advocacy organizations, professional trade associations, pharmaceutical manufacturers, health plans, data vendors, and the general public on the Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452) that was issued July 2, 2024 for a 60day public comment period.

We note that some of the public comments were outside the scope of the ICR. 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responses to the summary of the timely public submissions CMS received on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (the "draft guidance") which was released on May 3, 2024 and open for comment until July 2, 2024. CMS refers commenters to the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (the "final 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); the process for identifying a qualifying single source drug for initial price applicability year 2027; 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; reporting of updates to the data elements; and the process for establishing the maximum fair price (MFP), including the stakeholder engagement process (e.g., the patient-focused listening sessions and CMS-manufacturer meetings) and the information subject to confidentiality requirements.

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]

Negotiation Data Elements

Burden to Report the Information Required and/or Requested

Comment: Some commenters requested that CMS reduce the burden of submission requirements. These commenters noted that CMS is requesting a large volume of data and/or

1 References to section lettering reflects the 60-day notice, which remains the same in the 30-day notice. References to the question numbering in the summary of a public comment reflects the numbering in the 60-day notice; however, responses incorporate revisions to question numbers in 30-day notice.

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, data from a Secondary Manufacturer) or may not be able to produce in the manner and timeframe requested. A few commenters stated the data collection requirements fail the Paperwork Reduction Act standards to be the "least burdensome necessary" and 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.

Some commenters stated that CMS underestimates the burden of these submission requirements. One commenter suggested the burden estimate is not sufficient to account for the time to determine and coordinate responses that capture information related to a Secondary Manufacturer. A couple of these commenters suggested reduction in burden could be accomplished by removing reporting requirements that are duplicative with existing reporting requirements of other federal agencies or information that is publicly available. While most of these comments focused on the burden for the Negotiation Data Elements data submission, one commenter also stated they believed the estimated burden for a Primary Manufacturer to submit a counteroffer was too low. The same commenter noted that CMS' estimated cost to review section 1194(e) data and to modify the CMS HPMS system exceeded the cost estimate for Primary Manufacturers to complete the data submission. Three commenters provided specific estimates for burden. One commenter provided an estimate of over 7,700 staff hours to comply with the data submission requirements of this ICR for Primary Manufacturers. Another commenter estimated staff hours for a Primary Manufacturer would likely exceed 1,000 hours to prepare the data submission and respond to data elements for this ICR. A third commenter estimated at least 1,000-2,000 staff hours of a Primary Manufacturer specifically for the Negotiation Data Elements data submission.

Response: CMS appreciates commenters sharing their concerns about the reporting requirements. To address commenters' concerns regarding the necessity of certain specific requests for information, in revisions provided with the 60-day package, CMS reduced the number of years of data requested for certain collection items from five to three years (e.g., Wholesale Acquisition Cost, Medicaid best price) and CMS improved the precision of the information requested to improve clarity of the request and in turn reduce time spent to understand the request (e.g., Section F patents information); however, CMS also added additional opportunities for Primary Manufacturers and the public to submit certain information (e.g., Section I). In this proposed 30-day package, CMS further revised Section F to clarify the specific information requested in the tables in Questions 12A and 12B to reduce time spent to understand the request and to make reporting of the information more efficient. CMS incorporated technical revisions to Section I questions based on comments received to the 60-day package in order to reduce time spent to understand the request. Additionally, CMS has considered the feedback shared regarding actual time to respond to the initial price applicability year 2026 version of this ICR. In response to public feedback regarding completing the data collection, CMS revised the burden estimate upward in this proposed 30-day package. Specifically, CMS increased the base estimate for a Primary Manufacturer to submit section

1194(e) data on one selected drug to 1,000 hours. CMS is also revising the cost range estimates for Primary Manufacturers to 500 hours per selected drug as a low estimate and 2,000 hours per selected drug as a high estimate in this proposed 30-day package. CMS is maintaining its burden estimates for the general public to complete the section 1194(e)(2) data submission and for Primary Manufacturers to develop and submit a statutory written counteroffer as nearly all comments on burden were regarding the Negotiation Data Elements submission by Primary Manufacturers and no commenters offered specific burden estimates for the public section 1194(e)(2) submission or statutory written counteroffer submission.

CMS recognizes that similar comments were provided in relation to the ICR for initial price applicability year 2026 stating 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. However, CMS maintains, consistent with the response provided to similar comments received for the ICR for initial price applicability year 2026, that CMS may not be able to ensure that such data are complete or up-todate when they are publicly available, and, 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.

Comment: A couple of commenters stated that lack of instructions for certain pieces of complex data requested means that Primary Manufacturers may interpret questions differently and, therefore, use different assumptions in their responses, which impacts response burden. These commenters specifically expressed concern about the lack of instructions for data requests for cost of capital and lifetime net revenue. Additionally, a few commenters recommended that CMS allow Primary Manufacturers to use reasonable assumptions regarding submission of data as described in section 1194(e)(1) of the Social Security Act (the "Act") or the ability to report a range of estimates of monetary amounts in lieu of one exact figure.

Response: CMS thanks the commenters for their feedback. As outlined in the Supporting Statement and stated in response to similar comments received in response to the 60-day proposed Negotiation Data Elements ICR for initial price applicability year 2026, 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)).

CMS is generally not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with the submission of each data element required based on section 1194(e)(1) of the Act but rather CMS has identified specific data elements for which the Primary Manufacturer is required to report any assumptions it used (e.g., Questions 1 through 6 for research and development costs, Question 8 for per unit production and distribution costs,

Question 10 for Federal financial support, Question 24 for Manufacturer U.S. Commercial price, and Question 26 for Manufacturer net Medicare Part D price). Additionally, CMS is not requesting a range of pricing data because CMS believes this is inconsistent with how such data is otherwise reported to federal and state entities. 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 A of the final guidance. For example, CMS provides instructions to calculate "cost of capital" within the Instructions for Reporting Monetary Amounts and to calculate "lifetime net revenue" within the definitions for Questions 6a and 6b. Costs should be determined using the methodologies described in this ICR and consistent with generally accepted accounting principles, where applicable. CMS has considered industry standards, when CMS is aware of such standards, in defining the metrics included in this information collection. 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: Some commenters stated that information about how CMS will weigh and use the information provided by respondents in response to this ICR is helpful to respondents in determining what information the respondent should provide to CMS and impacts the level of burden on a respondent in preparing responses. One commenter stated that the higher number of questions in Section I appears to assign more weight to CMS' use of Section I information compared to the remainder of the data elements. One commenter requested that CMS share certain data with manufacturers in advance of the selected drug publication date, such as Medicare expenditure data and the methodology used to weigh the various factors in developing the initial offer for MFP to assist respondents in preparing responses to the collection, and which therapeutic alternatives will be considered by CMS.

Response: CMS thanks the commenters for their feedback. CMS refers commenters to section 50 of the final guidance for a discussion of how CMS will use the negotiation factors to determine initial offers. The final guidance has been published prior to the publication of this ICR. CMS declines to provide specific data regarding therapeutic alternatives or expenditure information as part of this data collection and notes that certain pieces of the information the commenter described are publicly available (e.g., the Medicare Part D Drug Spending Dashboard, available at: https://data.cms.gov/tools/medicare-part-d-drug-spending-dashboard).

Comment: A couple of commenters suggested that CMS improve data automation, for example, by use of intelligent data sources extracting from documents or direct integration with available databases. One commenter requested CMS improve the user experience within the CMS HPMS, particularly for manufacturers to submit large volumes of data and review the data prior to certification. This commenter suggested use of an upload template in lieu of manual entry.

Response: CMS thanks the commenters for their suggestions. CMS plans to implement a design alternative for Sections A, B, D, and G to reduce the Primary Manufacturer burden of manually inputting each specified data element required in these sections for initial price applicability year 2027. CMS will provide manufacturers with a new file import option for certain data-intensive questions in Sections A, B, D, F, and G to reduce Primary Manufacturer burden. Direct data entry

will remain available for these questions. Upon import, HPMS will populate the data entry form fields, after which manufacturers will use the existing save/complete functionality to save and validate the imported data. CMS expects that these changes would reduce manufacturer burden and has included this impact within the burden estimate for this information collection.

Comment: A few commenters shared concerns with CMS about the volume of data that was required to be submitted within the 28 days between the statutory deadlines for CMS to publish the list of selected drugs for initial price applicability year 2027 and for a manufacturer that signs an agreement to participate in the Negotiation Program to submit the data.

Response: CMS thanks the commenters for their feedback. CMS understands commenters' concerns about the volume of data that must be submitted within a short timeframe for a manufacturer that participates in the Negotiation Program. However, as the commenters note, the deadlines for both CMS and manufacturers are established by statute.

Comment: A couple of commenters stated that CMS should consider the increased burden of responding to Section I for patients navigating challenges including language barriers, visual impairments, lack of Internet access and other issues.

Response: CMS appreciates this feedback. In response to public feedback received about the process used to access the questions, the structural presentation of the questions within the CMS webpage, and the readability of the questions, CMS made significant revisions to the organization of the questions and the text used for the question prompts for the collection of information for initial price applicability year 2027. For example, CMS grouped questions together that more closely align to a respondent's areas of expertise and for easier navigation by respondents. CMS also sought input from the CMS Office of Minority Health and the CMS Office of Strategic Operations and Regulatory Affairs for expertise regarding the complexity of information requested whilst ensuring that the ICR meets the requirements of the PRA. CMS will take the suggestions regarding translations and alternative collection methods into consideration for future initial price applicability years. Notably, CMS provides comprehensive oral interpretation services of written materials and notices through the tollfree hotlines for Medicare and the Health Insurance Marketplace®. As explained in more detail in response to comments received on section 60.4 of the final guidance, CMS is dedicated to making its electronic information technologies accessible to people with disabilities. CMS is subject to, and strives to exceed, the requirements of Section 508 of the Rehabilitation Act (29 U.S.C. 794d).[2]

Deadline to Submit Information and Engagement with Interested Parties

Comment: A few commenters requested that CMS increase the time provided for respondents to answer the questions included in Section I either by moving up the submission opening date or extending the submission closing date. A couple of commenters suggested separating the public submission of information from the manufacturer submission since the statute provides a deadline only for the manufacturer-required data. One commenter requested a 60-day submission

2 See: https://www.cms.gov/about-cms/web-policies-important-links/accessibility-compliance.

period for the public to respond to Section I. A couple of commenters raised concerns about how the submission time and burden may negatively impact the volume of responses provided by patients and caregivers; for example, smaller organizations and under-resourced communities may not have sufficient resources to respond within 30 days. Finally, one commenter requested that respondents be permitted to supplement data submissions beyond the dates of public listening sessions.

Response: CMS appreciates the time and resources likely to be spent by interested parties to identify and compile the relevant information and draft the responses necessary to respond to this ICR. As described in the final guidance, CMS will use information submitted by the Primary Manufacturer and other interested parties when developing the initial offer for a selected drug. Due to the statutorily defined negotiation period timing, particularly the time necessary for CMS to develop an initial offer, it is not feasible to extend the timeframe for Section I submission.

In addition, as described in section 60.4, of the final guidance, CMS intends to host up to 15 patient-focused roundtable events, which will be open to the public, including patients, patient advocacy organizations, and caregivers, and will allow for discussion among speakers, 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. CMS will also host one town hall meeting, focused on clinical considerations related to the selected drugs. These events will be held in Spring 2025. Additional information about these events will be shared in the future. Primary Manufacturers may also submit additional information with their statutory written counteroffers.

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

Comment: A few commenters expressed support for the inclusion of Questions 28 and 64 of the 60-day ICR permitting the respondent to identify information that the respondent believes should be protected from public disclosure based on the Freedom of Information Act (FOIA). Another commenter suggested CMS explain its plan to ensure its use of confidential information will comply with section 1193(c) of the Act. A couple of commenters suggested that CMS provide manufacturers with notice of potential disclosure and the opportunity to object to such disclosure. One commenter requested CMS revise Questions 28 and 64 to clarify that CMS is also bound by the FOIA-related regulations at 45 CFR Part 5, including requirements regarding permitting submitters to self-designate information as confidential. Finally, one commenter requested the removal of character limits for Question 28 and 64 explanations so that entities are not limited in describing the confidential or proprietary information submitted.

Response: CMS thanks the commenters for their feedback. CMS refers interested parties to section 40.2.1 of the final guidance regarding the policy for handling of confidential information under the Negotiation Program. As described in the final guidance, the confidentiality policy is consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 of the FOIA. Question 27 (previously Question 28) and Question 62 (previously Question 64) were included in the ICR for initial price applicability year 2027 to

provide a mechanism to collect a submitter's self-designation of information as confidential and/or proprietary consistent with existing federal requirements for protecting proprietary information, including Exemptions 3 and/or 4 the FOIA. CMS has revised the text of these questions for clarity regarding application of section 40.2.1 of the final guidance.

CMS has increased the character limits from 6,000 characters (approximately 500 words) to 60,000 characters (approximately 5,000 words) included for Questions 27 and 62 as requested in comments because CMS recognizes that more space may be needed to fully describe any relevant information in the response. We do not expect the full character limit will typically be used by respondents.

Comment: A couple of commenters requested that CMS provide additional information about the security of and safeguards around the data submitted.

Response: CMS thanks the commenters for their feedback. As explained in the response to this ICR for initial price applicability year 2026, the CMS HPMS adheres to Department of Health and Human Services (HHS)/CMS policies, procedures, controls, and standards for information security and privacy. Among other safeguards, the CMS HPMS requires a CMS-issued user ID and password, with multi-factor authentication. The CMS HPMS adheres to CMS Information Security Incident Handling Procedures. 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. For further information, CMS refers interested parties to section 40.2.1 of the final guidance and CMS responses to related comments received about section 40.2.1 of the final guidance.

Process of and Formats for Submitting the Information

Comment: A few commenters provided suggestions on ways to make the information collection process more user-friendly for patients, caregivers, and other interested parties. Suggestions included using a separate, more easily navigable portal (i.e., not the CMS HPMS) for public submissions; establishing a process separate from the ICR process for public submissions; providing a glossary of terms or using technology to provide definitions when a respondent hovers their mouse over a defined term; establishing a process by which a respondent can provide input in a way that is most suited to their needs; and leveraging best practices for patient engagement established by groups such as the National Pharmaceutical Council and the Professional Society for Health Economics and Outcomes Research (ISPOR). One commenter referenced the "publicly available web link" mentioned in section 50 of the initial price applicability year 2027 draft guidance and requested the link be available as soon as possible. A couple of commenters requested CMS ensure the technology is accessible to individuals with disabilities and ensure that familiarity with technology or survey formats does not impede contributions unnecessarily.

Response: CMS thanks the commenters for their comments. Consistent with the submission process for initial price applicability year 2026, CMS will use a web-based application for initial price applicability year 2027 to maintain standardization of submissions and minimize the risk of

incomplete submissions. Further, CMS web-based platforms and the CMS HPMS adhere to all applicable policies, procedures, controls, and standards required by HHS and CMS information security and privacy programs.

Specifically, the submission platform for public submissions will remain a publicly-accessible web application that is accessible from the CMS.gov and the CMS HPMS landing page (www.https://hpms.cms.gov). The questions for initial price applicability year 2027 will be open to view and respond to via this web application once the submission period for the data elements opens.

As already stated in these responses to public comments, CMS is dedicated to making its electronic information technologies accessible to people with disabilities, including through compliance with section 508 of the Rehabilitation Act.

Comment: To ensure robust responses and responses that represent Medicare beneficiaries, a few commenters suggested that CMS conduct targeted outreach to Medicare beneficiaries that have experience with the selected drug and/or its therapeutic alternative(s). One of these commenters specifically recommended that CMS conduct outreach to underrepresented groups. A couple of commenters also suggested that CMS develop user-friendly materials such as print or video instructions to aid respondents in answering the ICR questions and clarifying what type of information CMS seeks.

Response: CMS thanks the commenters for their feedback. CMS agrees with commenters that increased participation generally and among underrepresented populations and people with Medicare specifically would help ensure diverse perspectives are communicated and heard. CMS will conduct outreach to patient advocacy organizations, disease groups, and other consumer associations regarding public engagement opportunities, including the section 1194(e)(2) data submission. Additionally, CMS is working with the CMS Office of Minority Health for initial price applicability year 2027 to help increase participation among underrepresented populations. CMS will consider developing plain language materials and other preparation materials to aid with the public data submission.

Negotiation Data Elements Form

General Instructions and Instructions for Reporting Monetary Amounts

Comment: One commenter requested CMS clarify whether certain data elements pertaining to manufacturers and Medicare (e.g., manufacturer commercial net price, Medicare Part D average net unit price) include data from United States (U.S.) territories.

Response: CMS thanks the commenter for their suggestions. CMS has revised the Instructions for Reporting Monetary amounts to specify that the geographic area for data on U.S. commercial markets, Medicare markets, and Medicaid markets are defined by the definition of the "United States" in 42 C.F.R § 400.200, unless the geographic area is specified in the authority for the underlying data source (e.g., Federal Supply Schedule (FSS) and Big Four prices).

Comment: A few commenters expressed concerns with the limitation of characters. A couple of these commenters requested that CMS expand or remove the limitations in order to permit the respondent to fully address the question. A few commenters requested that CMS maintain wordbased limits instead of character-limits because the commenter stated that word limits are more user friendly and intuitive for tracking submission length. One commenter noted that CMS reduced word limits for certain questions in the ICR for initial price applicability year 2027 compared to the ICR for initial price applicability year 2026 (e.g., Section C). One commenter suggested increasing the word count on Question 31 of the 60-day ICR and allowing manufacturers to submit a rationale for therapeutic alternatives listed.

Response: CMS thanks commenters for their suggestions. In the 60-day proposed revisions to update this ICR form from the ICR for initial price applicability year 2026, CMS revised word limits to character limits to align with the standard formatting used for counting in the CMS HPMS. Therefore, this approach may be familiar to manufacturers that use the CMS HPMS in connection to other CMS programs, such as the Manufacturer Discount Program. CMS believes that generally available typing programs provide word and character counts to the user.

Additionally, in the 60-day update to this ICR form, CMS revised the character limits for questions where CMS revised the formatting of a question from the ICR for initial price applicability year 2026 to break out a single question that included many subparts into multiple separate questions for the 60-day proposed initial price applicability year 2027 version. CMS revised character limits downward when one question became multiple questions, but CMS did not reduce the overall limit (e.g., Section C). CMS also added opportunities for respondents to explain the information submitted (e.g., Section G).

In the 30-day revised version of this ICR for initial price applicability year 2027, CMS revised character limits to correspond with the proposed revisions to collection of patent information in Section F and in response to comments pertaining to Questions 27 and 62 (Questions 28 and 64 in the 60-day ICR). Additionally, CMS revised the character limits in Section C, Question 2c upwards to provide consistent limits across the multiple questions separated in the 60-day version of this ICR and to maintain a higher character limit for each of these question subparts. Otherwise, CMS is maintaining the text and citations limits in the 30-day version. Please see section 60.4 of the final guidance, which describes additional opportunities for information sharing.

Comment: One commenter expressed concern with the cost of capital methodology. Specifically, the commenter stated that the cap specified of 8.1 percent is arbitrary and uninformed. The commenter noted that the cap does not adequately consider a manufacturer's capital costs and penalizes a manufacturer because the cap does not appear to allow for adjustments due to future interest or inflation rate changes. The commenter suggested that CMS remove the cap or, at a minimum, permit manufacturers to adjust the cap based on interest and inflation rate levels for a given year. Finally, the commenter requested clarification regarding whether CMS will apply an inflation adjustment on its own and, if so, at what level of inflation.

Response: CMS thanks the commenter for their feedback. CMS maintains the instruction regarding the cost of capital adjustment in the 30-day proposed materials. CMS continues to rely on the value provided by the Congressional Budget Office as referenced in the ICR.[3]

Based on the commenter request for clarification of the instruction regarding the application of inflation adjustment, CMS has revised the general instruction about inflation adjustment in the "Instructions for Reporting Monetary Amounts" to specify that a Primary Manufacturer should not adjust for inflation unless specifically included in an instruction for a question within the ICR. CMS has removed the language in this instruction that CMS will make the relevant trending adjustment, as appropriate. Additionally, CMS has modified instructions for Questions 6a, 6b, 9 and 10. Specifically, CMS requests that the Primary Manufacturer include adjustments for inflation for U.S. and global, total lifetime net revenue (Question 6) and Federal financial support (Question 10) and explain the methodology used to make such adjustments for inflation. CMS believes these are the data elements where an inflation adjustment is appropriate.

Comment: One commenter asked if the monetary reporting instructions apply to Section I.

Response: The Instructions for Reporting Monetary Amounts apply to all sections of the ICR. However, the instructions include specific steps when certain actions are applicable only. For example, when reporting a monetary amount, the respondent should provide the amount in U.S. dollars and include two decimal places unless otherwise specified in Sections D or G. CMS has revised the General Instructions for Section I to clarify that the Additional Instructions and the Instructions for Reporting Monetary Amounts apply to Section I. These instructions pertain to original data provided by respondents and are not appliable to citations that a respondent may provide with existing published data.

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

Comment: A couple of commenters asserted that the revised format of the ICR for initial price applicability year 2027 increases reporting burden beyond that of the ICR for the initial price applicability year 2026, due to the addition of new questions and word limits with respect to R&D costs. To address this increased reporting burden, one commenter suggested CMS combine Question 2b, which instructs the Primary Manufacturer to list the direct and indirect research expenses for the selected drug, with Question 2c, which instructs the Primary Manufacturer to explain the values used in the direct and indirect cost calculation. One commenter asserted that gathering data in the five R&D cost categories will require extensive effort from manufacturers, that historic data may not be accessible at all, and that allocating costs at the level of granularity required may not be feasible, as costs may be shared across a disease area or across multiple projects. A couple of commenters recommended alternative approaches for CMS collection of R&D costs and recoupment, for example, allowing Primary Manufacturers to attest that R&D costs have been recouped or streamlining R&D cost reporting to two categories (e.g., R&D costs before and after FDA approval). One commenter stated CMS should not require Primary

3 See "Research and Development in the Pharmaceutical Industry," CBO (April 2021), available at https://www.cbo.gov/publication/57126.

Manufacturers to deduct prior Federal financial support from the final calculated amounts in Questions 2 through 5, which they assert is burdensome, inconsistent with U.S. Generally Accepted Accounting Principles (GAAP), and duplicative of another CMS reporting requirement. One commenter suggested that to reduce reporting burden, CMS should either allow all relevant pre-clinical expenses to be reported, regardless of whether those expenses are tied to an FDA-approved indication, or CMS should explicitly acknowledge that pre-clinical research costs are presumed to be for an FDA-approved indication, as the FDA-approved label is not known until the end of the R&D cycle.

Response: CMS appreciates commenters' feedback but disagrees that the revisions to the R&D data submission requirements for purposes of initial price applicability year 2027 increase manufacturer burden compared to initial price applicability year 2026. In response to lessons learned to date from implementing the Negotiation Program for initial price applicability year 2026, including Primary Manufacturer data submission, CMS revised the ICR for initial price applicability year 2027 to improve the precision of the information requested to reduce the burden encountered by Primary Manufacturers having to supplement and correct their initial submissions and to promote consistency across submissions. For example, in the ICR for initial price applicability year 2027, CMS separated instructions and questions for each R&D cost category such that the numerical response is a distinct question from the free text response. To ensure Primary Manufacturers provide a response for each component of a question, CMS further separated some of these free text response fields into individual questions (for example, Questions 2b and 2c). CMS understands commenters' concerns about reporting burden and revised Question 2c to reduce duplication with information requested in Question 2b. CMS also revised character count limits for individual questions to better reflect the estimated amount of information CMS believes is necessary to provide a sufficient answer, including by increasing the character count limit in Question 2c in response to commenters' concerns.

CMS generally expects a Primary Manufacturer to be able to report R&D costs incurred for a drug to which they hold the rights. CMS understands that Primary Manufacturers may not be able to access certain historical R&D data, particularly in cases where the selected drug was acquired from another manufacturer and thus specifies in the instructions in Questions 2 and 3 for reporting basic pre-clinical research costs and post-investigational New Drug Application (post-IND costs), respectively, that Primary Manufacturers are not required to report such costs for the time period prior to their acquisition of the drug. CMS acknowledges that certain R&D cost reporting requirements, such as requiring Primary Manufacturers to report R&D costs at the product-specific level or instructing these manufacturers to subtract prior Federal financial support from R&D costs, may be inconsistent with U.S. GAAP standards or Primary Manufacturer's existing accounting practices. However, section 1194(e)(1) of the Act requires that the Primary Manufacturer reports R&D costs "for the drug" and inclusion of prior Federal financial support in the R&D cost amounts would result in an inflated figure that does not accurately reflect the Primary Manufacturer's research expenses. Finally, 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) of the Act. Lastly, consistent with the definition of pre-clinical basic research costs and instructions for reporting such costs, basic pre-clinical research costs should reflect the total R&D expenses incurred by the Primary Manufacturer for all FDA-approved indications for the selected drug related to basic pre-clinical research and must not include expenses associated with ongoing basic pre-clinical research or expenses associated with basic pre-clinical research for indications that have not received FDA approval.

Section D: Current Unit Costs of Production and Distribution

Comment: One commenter recommended that CMS change the reporting period for the average unit cost during the 12-month period ending October 31, 2024 (for selected drugs for initial price applicability year), to a reporting period that is quarterly to align with SEC reporting periods. The commenter stated that manufacturers would need to implement additional controls to assess the completeness and accuracy of production and distribution cost data on an off-cycle basis as the one proposed. The commenter recommended that CMS request production and distribution data as of the close of a company's most recent fiscal year to align with the company's external financial reporting or alternatively that CMS align its request date to a quarter close, e.g., September 30, 2024 or December 31, 2024.

Response: CMS thanks the commenter for providing feedback on the average unit cost (for production and distribution) during the 12-month period ending date found in Section D. In response to these comments received during the 60-day public comment period for this ICR and the draft guidance, CMS revised the date of October 31, 2024 to be December 31, 2024 to better align with the dates that Primary Manufacturers use for providing similar data to other entities.

Section E: Prior Federal Financial Support

Comment: One commenter recommended that CMS reduce reporting burden by allowing manufacturers to submit a single number for prior Federal financial support along with an explanation detailing the support included in the amount. This commenter also recommended CMS streamline reporting of prior Federal Financial support by leveraging data available from other sources, such as data directly available through government grant programs that provide financial support to drug manufacturers.

Response: CMS thanks the commenter for their feedback. Primary Manufacturers must 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 is 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 available through other sources, such as the agencies that administer government grant programs that provide financial support to drug manufacturers and publicly available documents, section 1194(e)(1) of the Act requires that manufacturers submit

information about prior Federal financial support to CMS. Furthermore, CMS may not be able to ensure that such data are complete or up to date. CMS believes that the Primary Manufacturer is best positioned to provide the requested data.

Section F: Patents, Exclusivities, and Approvals

Comment: One commenter stated the request for patent information related to the selected drug is overbroad and ambiguous. A couple of commenters opposed the 300-word limit on the explanation of patents in Question 13 of the 60-day ICR, which is a significant decrease from the ICR for initial price applicability year 2026 according to one of these commenters. One commenter suggested CMS remove Questions 12 and 14 of the 60-day ICR on expired patents and regulatory exclusivities, which they assert is overly burdensome, particularly given CMS' definition of a qualifying single source drug. This commenter also questioned the utility of such information to negotiation.

Response: CMS appreciates these commenters sharing their concerns. In response to comments received during the 60-day public comment period for this ICR for initial price applicability year 2027 and the draft Negotiation Guidance for initial price applicability year 2027, as well as based on lessons learned from Primary Manufacturer data submissions for initial price applicability year 2026, CMS has removed the Question 13 included in the 30-day notice and revised Question 12 to streamline the patent reporting requirements while also providing Primary Manufacturers with additional opportunity to describe the patents relevant to the selected drug. Specifically, CMS has separated Question 12 into two Questions 12A and 12B and has provided a 3,600 character count limit per patent and patent application explanation, replacing the 3,600character count limit on the explanation of all patents and patent applications in Question 13 in the ICR for initial price applicability year 2026. CMS has also made optional the requirement that a manufacturer upload the USPTO application for patents that have been granted, such that submission of this information is mandatory only for patent applications that are pending with USPTO. Finally, as explained in the final guidance for initial price applicability year 2027, CMS has revised the definition of patents to clarify and provide examples of the patents and patent applications CMS considers to be relevant for purposes of this data submission.

Section G: Market Data and Revenue and Sales Volume Data

Comment: A couple of commenters recommended that CMS change the timeline to report metrics using the most recent three years ending with the fourth quarter of 2024 rather than most recent five years in Question 18 (Medicaid Best Price) of the 60-day ICR. One of the commenters stated that a three-year timeline aligns with the timelines specified in other parts / questions of Section G (Wholesale Acquisition Cost Unit Price, Federal Supply Schedule Price, and Big Four Price) and, therefore, makes the most sense in terms of consistency and simplicity.

Response: CMS thanks the commenters for providing feedback on the timeline referenced in Question 17 (Medicaid Best Price, previously Question 18). CMS revised Question 17 to request the Medicaid best price for the most recent three years as opposed to five years. CMS also

revised Question 23 (Manufacturer U.S. Commercial Average Net Unit Price, previously Question 24) and Question 25 (Manufacturer Net Medicare Part D Price, previously Question 26) to reflect data submission is for a three-year timeframe ending with the calendar year ending December 31, 2024.

Comment: One commenter stated that in Question 24 of the 60-day ICR the total unit volume for "U.S. commercial average net unit price" and the "Manufacturer U.S. commercial average net unit price-best" does not accurately represent market dynamics because the commenter stated that the two price points may be offered on different sets of unit volume. The commenter stated that a limited set of customers may receive the manufacturer U.S. commercial average net unit price-best, which in turn means a total of limited units. The commenter recommended that CMS exclude the commercial-best price for the MFP determination or, at a minimum, CMS should separate the total unit volumes between the Manufacturer U.S. commercial average net unit price and the Manufacturer U.S. commercial average net unit price – best.

Response: CMS thanks the commenters for providing feedback on the units requested in Question 23 (Manufacturer U.S. Commercial Average Net Unit Price, previously Question 24). CMS revised the data requested in Question 23 to add a column requesting "Total Unit Volume for U.S. Commercial Average Net Unit Price - Best" and in Question 25 to add a column requesting "Total Unit Volume for Net Medicare Part D Average Unit Price – Best" in order to differentiate the total unit volumes of the "Manufacturer U.S. Commercial Average Net Unit Price – Best" and "Manufacturer Net Medicare Part D Average Unit Price – Best" from the total unit volumes.

Comment: One commenter supported CMS' proposed collection of the "U.S. commercial average net unit price" and its distinction from the "U.S. commercial average net unit price–net of patient assistance program." One commenter urged CMS to remove Question 26 (Manufacturer Net Medicare Part D Price) of the 60-day ICR and Question 27 (Explanation of Information Reported in Response to Question 26: Manufacturer net Medicare Part D price) of the 60-day ICR. The commenter noted that CMS removed Net Medicare Part D Price from the required data for initial price applicability year 2026 and they are opposed to CMS' reintroduction of the element for initial price applicability year 2027. The commenter stated that these data elements are not contemplated as information for submission in the statute and would impose a significant organizational burden on manufacturers, as they do not align with existing reporting requirements or accounting procedures.

Response: CMS thanks the commenter for the feedback. As stated in CMS' response to similar public comments provided on the initial price applicability year 2027 draft guidance about the inclusion of the metric "manufacturer net Medicare Part D average unit price", by requiring Primary Manufacturers to submit the manufacturer net Medicare Part D average unit price as part of their section 1194(e)(1) data submissions, CMS could consider this metric in the development of the initial offer. Additionally, CMS believes that the Primary Manufacturer has access to the specific data required to calculate this and the related data elements included in this information collection. CMS has provided defined these terms to clarify which specific data should be included in this set of metrics.

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

Comment: A couple of commenters expressed concern around the certification language requiring data submitters to affirm the data is complete and accurate when word limits, preexisting data retention policies, or the requirement to submit data on behalf of a Secondary Manufacturer may prevent a data submitter from having access to all relevant records and therefore being able to share all information. One commenter requested that CMS remove both the requirement to timely notify CMS of changed information and the liability clause. One commenter suggested CMS include language that states that a manufacturer will have made reasonable assumptions in responding to the data elements due to differences in ICR and manufacturer and industry accounting practices and based on the manufacturer's interpretation of the ICR requirements.

Response: CMS thanks commenters for their feedback. CMS maintains the language in Section H. Consistent with the CMS response to similar public comments received in response to the ICR for initial price applicability year 2026, CMS reiterates that CMS will rely on this data from the negotiation data elements in Sections A through G to develop its initial offer of the MFP. 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.

Section I: Evidence about Alternative Treatments

Comment: Some commenters expressed support for the revisions to questions directed at patients and caregivers. One commenter cautioned CMS against oversimplifying patient experience. One commenter requested that CMS publish the types of respondents that answer Section I and that CMS stratify the respondents across types. One commenter requested that CMS monitor responses to Section I to determine if the questions provided are precise enough to request the necessary information.

Response: CMS thanks commenters for their feedback. CMS will consider sharing the respondent types as part of the materials published with the MFP explanation. More information on the MFP explanation is available in section 60.6.1 of the final guidance.

Comment: One commenter expressed concern that the request to identify a respondent's relationship with a manufacturer may chill manufacturers' ability to support outreach to patient and caregiver populations to provide responses to Section I. Another commenter suggested that CMS clarify that a respondent's affiliation with a manufacturer will not detract from CMS' review of patient-centered information.

Response: CMS thanks the commenters for their feedback. CMS will review all submitted information. CMS believes information regarding relationships with manufacturers is important to promote transparency in the negotiation process. CMS refers interested parties to section 60.4.2 of the final guidance regarding how CMS uses information provided in response to

Section I in the development of CMS' initial offer and concise justification within the Negotiation Program.

Comment: One commenter stated that CMS does not require a conflict-of-interest (COI) disclosure from entities such as pharmacy benefit managers (PBMs) or payers that may profit from high drug prices but not support continued development of new medicines for patients.

Response: CMS is aware of potential COIs across industry entities such as health insurance plans and PBMs. CMS will review all submitted information. CMS refers interested parties to section 60.4.2 of the final guidance regarding how CMS uses information provided in response to Section I for the Negotiation Program.

Comment: A couple of commenters requested that CMS test the questions through a pilot. One of these commenters also shared concerns about whether the collection resulted in standardized collection methods and data, citing FDA's processes as a model that CMS can adopt to increase methodological rigor and move toward a more "representative sample" of responses from interested parties.

Response: CMS thanks the commenters for their feedback and declines to accept the request to test the questions through a pilot. CMS has consulted with the FDA regarding FDA processes to gather public information. CMS has revised questions in Section I based on public feedback received in response to the Negotiation Data Elements ICR for initial price applicability year 2026 and initial and revised guidance for initial price applicability year 2026. CMS will consider this feedback in the future as well. Any interested party may respond to the ICR. CMS has revised questions in Section I for initial price applicability year 2027 to be grouped by categories that may be appropriate to a particular interested party based on that individual's or organization's insight and/or experience (e.g., patient-focused, clinical-focused, manufacturerfocused) in order to improve the ease with which an interested party may navigate the questions and, in turn, potentially increase the volume of responses to CMS.

Comment: One commenter suggested that data may not be available to respond to the questions for rare diseases.

Response: CMS thanks the commenter for their feedback. To capture information that may not directly fit under a specific question regarding data and other research, CMS has also included questions in Section I that provide open-ended opportunities for any interested party to provide any information that the respondent thinks CMS should be aware of as CMS evaluates a selected drug for each indication(s) (see e.g., Question 59).

Comment: A couple of commenters supported CMS' revision of Section I to group questions based on expertise.

Response: CMS thanks these commenters for their input.

Comment: One commenter supported the use of logic within Section I to present a follow-up question as appropriate based on the respondent's answer to the preceding question (e.g., if the

response to Question 40 of the 60-day ICR is Yes, Questions 40a1 through 4 will be populated for the respondent).

Response: CMS appreciates this commenter's feedback.

Comment: One commenter noted that manufacturers may have limited evidence of off-label use due to limitations on studying and promoting off-label use and suggested that CMS reconsider whether to request off-label use information from manufacturers.

Response: CMS appreciates this commenter's input and has removed the question regarding offlabel use from the manufacturer-focused section of this ICR. CMS does request information on off-label use in various questions included in the research-focused section, the patient and caregiver-focused section, and the clinical-focused section.

Comment: A couple of commenters supported CMS' confirmation that CMS would not use cost-effectiveness measures that 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, including Quality-Adjusted Life-Years (QALYs). One commenter recommended that any time that any question in which the respondent could respond with evidence generated via a QALY or other similar cost-effectiveness measures should contain a reminder that respondents should not submit such evidence as CMS will not consider it or use it in its decision-making.

Response: CMS appreciates these commenters' support. CMS notes that the General Instructions for Section I include information on CMS' approach to cost-effectiveness measures and directions for respondents to 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 within the cited research CMS might consider.

Comment: A couple of commenters supported CMS' decision to allow manufacturers to submit a dossier for the selected drug through this ICR. One commenter requested that CMS clarify dossier submission is optional. One commenter stated that CMS' request for an outline of relevant dossier information increases manufacturer burden and requested that CMS clarify whether CMS will review visuals (tables, charts, etc.) in question responses or only if included in a dossier. One commenter suggested CMS provide guidelines on the format and content of the dossier through a template or additional guidance.

Response: CMS thanks commenters for their feedback. CMS provided additional clarification in the instructions for Questions 29-35 to clarify that dossier submission is optional. CMS also notes that the request for an outline of relevant information included in a submitted dossier is also optional and may not be applicable in all cases. Regarding the comment on whether CMS will review visuals submitted in response to ICR questions or only those included in a dossier, CMS notes that Question 35 provides manufacturers with an opportunity to submit additional visuals to support responses to Questions 29-33, which have response fields that are text-only. CMS will review material submitted in Question 35 as well as information provided via a

dossier, if submitted. Finally, CMS notes that Question 34 indicates that CMS prefers dossiers to adhere to an industry-standard format, such as the most current AMCP Format (version 5.0) for Formulary Submissions and will not be issuing additional instruction on dossier formatting or content for initial price applicability year 2027.

Comment: One commenter asked CMS to limit the number of questions requesting protected health information (PHI), stating that requests to provide PHI could deter patients and caregivers from responding.

Response: CMS appreciates this commenter's feedback and directs the commenter to the optional Section I where CMS states that respondents are not required to include personally identifiable information (PII) or PHI. CMS also notes that CMS seeks to collect only the minimum necessary information related to the selected drug and its therapeutic alternatives for the purpose of implementing and operating the Negotiation Program.

Comment: One commenter requested that CMS allow manufacturers to submit an executive summary of the information provided through the ICR.

Response: CMS has standardized this information collection request to the extent practicable and included the opportunity for manufacturers to optionally submit a dossier. CMS believes this is sufficient for collecting the information necessary for the Negotiation Program.

Comment: A few commenters suggested that CMS requesting more identifying information from individuals responding to the clinical-focused questions to better understand the respondent's clinical experience, stating that this would aid CMS in determining if it is appropriate to include responses in the selected drug's evaluation. Examples of additional information to collect include: years of experience, number of patients treated, specialized training in the disease area where the selected drug is indicated, percent of patients treated taking the selected drug, and practice zip code.

Response: CMS appreciates these commenters' suggestion to gather additional information on respondents answering the clinical-focused questions. CMS does not intend to request additional information on such respondents beyond the background information requested in Question 43. CMS does not believe the examples of additional information suggested by commenters would necessarily allow for CMS to determine relative expertise across respondents.

Comment: A few commenters recommended that CMS allow patients and caregivers to optionally provide additional demographic and socioeconomic data, including but not limited to gender identity, rurality, education level, socioeconomic status, and preferred language. One of these commenters also suggested that CMS expand the race and ethnicity categories to align with standards used by the Office of Management and Budget (OMB).

Response: CMS intends to request the minimum necessary demographic information from patient and caregiver respondents to balance the benefit of receiving this information for use in the Negotiation Program with respondent burden. The race and ethnicity information requested in Question 42 is formatted to conform with the OMB minimum standard for 2024, specifically

the categories listed in Figure 3 on page 22194 of the Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity.[4] CMS also notes that all questions in Section I are optional unless otherwise noted, including the question on demographic information, as indicated in the General Instructions for Section I.

Comment: One commenter expressed concern about how CMS is considering metrics related to equity because CMS grouped research-related questions together, including questions seeking input on research metrics and methodologies. The commenter was also concerned that CMS' willingness to review cost-effectiveness measures to determine whether those measures discriminate against someone "who is elderly, disabled, or terminally ill" could result in CMS considering metrics that undervalue communities of color.

Response: CMS thanks this commenter for their input. CMS notes that all questions in Section I are open to all respondents. That is, questions grouped as research-focused input are open to any respondent interested in providing input on those questions. CMS also reiterates in the General Instructions for Section I, and as described in section 50.2 of the final guidance, CMS will not use comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Information submitted that treats extending the life of individuals in the listed populations as of lower value will not be used in the Negotiation Program. Moreover, in accordance with section 1182(e) of Title XI of the Social Security Act and other applicable law, including section 504 of the Rehabilitation Act, CMS will not use QALYs. In keeping with the CMS Pillar related to health equity[5], CMS understands that certain measures and studies may undervalue communities of color or other underrepresented groups and is committed to reviewing measures and studies through a health equity lens to mitigate unintended consequences of using such measures and studies in the Negotiation Program.

Comment: One commenter indicated that some questions (e.g., Questions 33A, 33B, 56A, 56B as numbered in the 60-day ICR) seek information that CMS should be able to access.

Response: CMS thanks the commenter for their feedback. The questions cited as examples of information that CMS should have access to include estimates of Medicare prevalence and utilization for indications of the selected drug. While CMS has access to Prescription Drug Event (PDE) data and beneficiary counts, PDE data do not include information on diagnosis or indication. CMS is requesting that respondents who are aware of studies related to the use of a selected drug within the Medicare population provide this information, if applicable.

Comment: A few commenters noted that some questions are included in certain respondent-type groupings within Section I but not other question groupings for additional respondent-types. For

4 See: https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf.
5 Information about the CMS Pillars is available at: https://www.cms.gov/about-cms/what-we-do/cms-strategicplan.

example, a request to suggest therapeutic alternatives is not included in the patient-focused experience section but is included in others.

Response: CMS thanks the commenters for their feedback. CMS appreciates that respondents may want to submit information on questions that are not included in the group of questions that matches their self-identified "role." As such, CMS notes that all questions in Section I are open to all respondents, regardless of the role they select. For example, respondents wishing to provide information on health disparities and social determinants of health may, for example, answer Question 46 regardless of whether the respondent has clinical-focused experience. CMS' intent in grouping the questions by respondent type was to simplify the ICR form and indicate which sets of questions relate to specific topic areas. This does not preclude any respondent from answering any question in Section I.

Comment: A couple of commenters requested additional information on the submission of visuals via PDF files, such as in Question 37 of the 60-day ICR. One commenter requested that CMS provide instructions on how to create these visuals.

Response: CMS thanks the commenters for their feedback. Questions 35 (previously Question 27), 41, 49, 56, and 60 allow respondents to submit up to 10 visuals supporting a response in the related group of questions. CMS allows for up to 10 PDF files within the HPMS file size limit to be submitted containing up to 10 visuals. CMS understands that a single PDF may contain more than one visual, but regardless of how many visuals are in each PDF file, respondents are still limited to 10 total visuals for each of these questions. Because these visuals may vary in type and content, CMS is not able to provide additional instructions to respondents on creating the visuals beyond what is included in the General Instructions for Section I, however, CMS revised the instructions for these questions to provide additional clarification.

Comment: A few commenters provided specific suggestions or requests for clarification on Questions 29-37 of the 60-day ICR, related to manufacturer-focused experience. These included: a request for CMS to clarify whether manufacturers should submit patient reported outcome (PRO) data in Question 30 or in Question 33; a request for manufacturers to be able to provide input via Question 29 on drugs that they believe are not appropriate therapeutic alternatives and why; and a suggestion for Question 32 to explicitly request data on relative improvement over existing therapies, specific metrics used to define "therapeutic advance," and patient experience data demonstrating that unmet medical needs are based on outcomes that matter to the patient population.

Response: CMS appreciates these suggestions. CMS notes that Questions 30-33 of the 30-day ICR all provide both a free text response field and submission of up to 50 citations. As such, manufacturers may submit PRO data via text response or citation in response to any question for which that data is applicable. Manufacturers may also submit information on therapeutic alternatives in a similar manner in the applicable questions, including information on drugs that a manufacturer believes should not be considered a therapeutic alternative.

For Question 32 regarding the extent to which a drug represents a therapeutic advance and/or fills an unmet medical need, CMS has defined these terms in this ICR in alignment with the final guidance and declines to add further detail. CMS notes that Question 33 specifically requests information on patient preferences and priorities and welcomes such information in this ICR.

Comment: A few commenters provided specific suggestions or requests for clarification on Questions 38-44, as numbered in the 60-day ICR, related to patient-focused experience.

For Question 38, this included a suggestion to allow respondents to elaborate on why the selected drug was chosen over another option initially, including the role of health care providers in that decision; a suggestion to add a question about whether there are any symptoms that impact the patient's daily life but are not adequately addressed by their current treatment; and a request for clarification in Question 38a2 on what information CMS is seeking, including whether this question is looking to establish the time of diagnosis from the patient's perspective.

One commenter provided a recommendation to solicit additional information in Question 39 on the impact on emotional and mental health when managing chronic conditions. A commenter suggested expanding Question 40 to explore access barriers more thoroughly and to include other types of pharmacies, such as home delivery services; and a commenter recommended that CMS expand the list of examples in Q40a2, to include insurance coverage, physician recommendations based on clinical guidelines, and physician recommendations based on clinical experience.

A commenter suggested collecting information in Question 41 about difficulties accessing past treatments due to prior authorization or step therapy protocols, including how these access challenges (prior authorizations, step therapy) were communicated and managed by health care providers. Similarly, a commenter suggested adding questions about medication cost, medication availability, and patient support resources. One commenter suggested providing clarification on the type of additional information that'd be most useful in Question 42.

Finally, a commenter requested that CMS allow submission of citations in Question 43; and one commenter requested that CMS solicit patient information that reflects the whole patient, including quality of life impacts not quantified in clinical studies, and other information that is important to patients.

Response: CMS thanks the commenters for their suggestions. Regarding Question 38a2 of the 60-day ICR, as noted in the question, CMS is interested in understanding whether the respondent has been diagnosed with a condition for which the selected drug is indicated and how long the patient has lived with the diagnosis. Regarding the ability to submit citations, CMS notes that respondents answering questions in the patient-focused experience section may submit citations in Question 40 and may submit PDF files of visuals in Question 41.

Regarding the suggestion for Question 38 of the 60-day ICR to allow respondents to elaborate on why the selected drug was chosen over another option initially, CMS directs the commenter to Question 38a2 and 39b2 of the 30-day ICR, which includes this request for both current and past medications taken. CMS has also added the examples suggested by the commenter including, but not limited to mail-order pharmacy access to Questions 38a2 and 39b2 of the 30-day ICR.

CMS added a prompt to Questions 38a3 and 39b3 of the 30-day ICR to gather information on whether taking the selected drug has impacted the patient's emotional or mental well-being. Finally, Question 42 of the 60-day ICR (i.e., Question 40 of the 30-day ICR) is intended to be an open-ended opportunity for the respondent to provide any additional information that they wish CMS to consider, and therefore CMS declines to make changes to this question. CMS also believes that taken cumulatively, the responses to this ICR and the patient-focused roundtables described in the Final Guidance will provide a "whole patient" perspective, to the extent possible.

Comment: A couple of commenters provided specific suggestions and clarifications on Questions 45-51 of the 60-day ICR, related to clinical-focused experience. Suggestions for Question 46 included: specifying whether treatment goals are remission, symptom management, or quality of life improvement; clarifying the type of outcomes CMS is referring to as well as a suggestion to ask respondents to specify a threshold for meaningful change for those outcomes; recommending that CMS provide examples of subpopulations that may experience different outcomes, such as those based on age, comorbidities, or genetic factors; asking respondents to provide citations for Question 46b and for CMS to request how much weight the respondent gives guidelines in treatment decisions and which specific guidelines they use; and requesting respondents explain in Question 46c how evidence-based clinical practice guidelines are applied in practice, particularly when there is divergence from standard recommendations or when guidelines lag behind current practice, including examples.

For Question 47, a commenter suggested including considerations of health disparities, genetic factors, and comorbidities when discussing patient subpopulations. One commenter recommended prompting respondents to provide scenarios or otherwise elaborate on situations when the selected drug is used, or not, including factors such as efficacy, safety, administration route, patient characteristics, and cost.

Response: CMS appreciates the commenter's suggestions. CMS added examples of treatment goals (e.g., remission, symptom management, quality of life improvement, or cure); and examples of types of outcomes (e.g., clinical, functional, or patient-reported) to Question 44 of the 30-day ICR (which corresponds to Question 46 of the 60-day ICR). CMS maintained the language in Questions 44 and 45 in the 30-day ICR (which correspond to Questions 46 and 47 of the 60-day ICR) around patient subpopulations rather than specifying types of subpopulations as the response can vary based on the condition or indication being discussed. CMS notes that Question 44b of the 30-day ICR includes the ability to provide citations.

CMS believes responses to Questions 46 and 47 of the 60-day ICR (which correspond to Questions 44 and 45 of the 30-day ICR) will provide sufficient information regarding the application of clinical guidelines in real world scenarios. As noted previously, any respondent, including patients, may answer any question regardless of their self-identified role. As such, CMS declines to reframe Question 45 in the 30-day ICR.

Comment: One commenter provided specific suggestions and clarifications on Questions 52-58, of the 60-day ICR related to research-focused experience. These included a suggestion to include

patient-reported, clinical, and safety outcomes in Question 54b; and a recommendation to collect evidence related to patient priorities and preferences, including how patients perceive the benefits and drawbacks of the selected drug compared to its therapeutic alternatives.

Response: CMS thanks the commenter for their feedback. As mentioned previously, CMS appreciates that respondents may want to submit information on questions that are not included in the group of questions that matches their self-identified "role." As such, CMS notes that all questions in Section I are open to all respondents, regardless of the role they select.

Comment: One commenter suggested that CMS state clearly and often that respondents are not required to answer all questions. The commenter also requested that CMS use common language to help mitigate barriers to understanding the questions in Section I.

Response: CMS appreciates this input. CMS believes that it is clear in the General Instructions for Section I that all questions are optional. CMS has also sought to use clear, concise language throughout Section I, particularly in questions grouped under Patient- and Caregiver-Focused Input, to enhance readability and understanding for respondents.

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

Comment: One commenter stated that the Section J may discourage submissions about patients that are concerned about sharing PII and PHI or for other privacy concerns.

Response: CMS thanks the commenter for their feedback. Respondents are not required to include PHI or PII in their Section I submissions. Further, CMS will not retrieve evidence for manufacturer negotiations by personal identifier (PII or PHI). As explained in further detail in section 60.3.3 of the final guidance, CMS will collectively consider the qualitative information provided by the public in response to questions about section 1194(e)(2) factors. Additionally, CMS will not, through this collection, create or maintain a system of records as understood by the Privacy Act of 1974 and accompanying Office of Management and Budget guidance. As previously stated in this document, section 40.2.1 of the final guidance includes additional information regarding the confidentiality and security of information shared with CMS related to the Negotiation Program and the CMS HPMS adheres to HHS/CMS policies, procedures, controls, and standards for information security and privacy.