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

The Centers for Medicare & Medicaid Services (CMS) received 16 timely public submissions from patient organizations, professional trade associations, pharmaceutical manufacturers, research organizations, and the general public on the Drug Price Negotiation Process Information Collection Request (CMS-10849, OMB 0938-NEW) that was issued April 18, 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. Rather, many of the issues raised in these out-of-scope comments are found in CMS' responses to the more than 7,500 timely public submissions CMS received in response to 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")[1], which was released on March 15, 2023 and open for comment until April 14, 2023. CMS refers commenters to the Medicare Drug Price Negotiation Revised Guidance (the "revised guidance")[2], which was released on June 30, 2023, for these responses, which address, among other things, the definition of qualifying single source drugs; the drug selection process; orphan drugs; Primary and Secondary Manufacturers; opportunities to submit section 1194(e) data; corrective action process; confidentiality and data use; data security; transparency; the initial offer and factors considered; 30-day equivalent supply calculation; methodology for applying the MFP across dosage forms and strengths; CMS' response to Primary Manufacturer counteroffers; negotiation meetings; public explanation of the MFP; formulary placement and utilization management; engagement with interested parties; statutory and agency authority; and broader comments on the structure and impacts of the Medicare Drug Price Negotiation Program.

This ICR (CMS-10849, 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.

General

Comment: A few commenters expressed concern that they do not have sufficient information on various elements of the negotiation process to be able to offer comments on the counteroffer process. One commenter stated that they find it difficult to respond to the counteroffer process when they do not know what the initial offer, justification, and agreement will look like.

Response: CMS understands commenters' concerns regarding being able to fully comment on this ICR. Since the 60-day comment period for this ICR closed, CMS has issued the revised guidance, the Negotiation Data Elements ICR for a 30-day comment period, and the Medicare

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.
[2] https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation.

Drug Price Negotiation Program Agreement.[3] These documents will provide a fuller picture of the negotiation process. Interested parties may submit additional comments on this ICR during the 30-day comment period.

Data Security for Confidential, Proprietary, and Sensitive Information

Comment: One commenter recommended that CMS consider the safeguards already present under the Medicaid Drug Rebate Program (MDRP) when determining how to secure proprietary and sensitive data shared for the counteroffer process.

Response: The MDRP requires users to create their own user ID that cannot be shared and is verified for identity. MDRP users must also use multi-factor authentication and apply for role-based access. Like MDRP, the CMS HPMS employs many protocols and procedures for ensuring appropriate user access to specific sections of the CMS HPMS. An individual must apply for and obtain a CMS-issued user account and password in order to access the CMS HPMS. In addition to the CMS-issued user ID and password, internal CMS staff must use a Personal Identity Verification (PIV) card when accessing the website on the CMS network, while all users accessing the system from outside of the CMS network must use multi-factor authentication. The CMS HPMS further employs role-based access, ensuring that each user is granted access only to those functions required by their position. Each manufacturer is limited to the data associated with its assigned pending contract "P" number(s), and each manufacturer user can only perform the functions in the modules that have been approved and assigned, such as only certain manufacturer users can obtain signatory access to the modules. In addition to the current numerous privacy and security protections safeguarding sensitive product and pricing data submitted by manufacturers in the CMS HPMS, CMS is further restricting internal access to the manufacturer modules to critical, specific personnel for troubleshooting and ensuring technical support, and restricting internal access to the submitted data to a limited set of users directly relevant to the drug price negotiation process. Any system outside of HPMS used to store or analyze any submitted manufacturer data will be required to adhere to all applicable policies, procedures, controls, and standards required by the HHS/CMS information security and privacy programs to ensure the confidentiality of the manufacturer information and protect the integrity of the government information systems.

Comment: One commenter asked CMS to specify how it will protect information that will be submitted through Box. The commenter requested information on how information will be kept confidential in Box and protected from misuse by Box staff.

Response: CMS clarifies that Box is mentioned in this ICR as a back-up option to the CMS HPMS for data submission. 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 Box as a back-up as CMS has determined that the CMS HPMS infrastructure and design should be able to accommodate the business and technical needs of the Drug Price Negotiation functionality. However, in the event that information needs to be shared via Box, CMS will provide submission instructions consistent with CMS controls, including password protection and encryption, and will ensure this process adheres to all applicable policies,

[3] https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

procedures, controls, and standards required by the HHS/CMS information security and privacy programs to ensure the confidentiality, integrity, and availability of manufacturer information and government information systems.

Comment: A few commenters asked that CMS ensure it has adequate agreements with contractors and others that will have access to data submitted by manufacturers to properly safeguard proprietary data.

Response: 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.

Burden Estimate for Primary Manufacturers to Develop and Submit a Counteroffer

Comment: Some commenters indicated that CMS' burden estimate for manufacturers to develop and submit a counteroffer was significantly underestimated and requested that CMS recalculate this amount. Commenters noted that manufacturers will need to review CMS' initial offer and justification in addition to developing and submitting their counteroffer, which will require more time and money than currently estimated. A few commenters also noted that the burden estimate created concern about the comprehensiveness of CMS' initial offer justification. A few commenters also noted that CMS' burden estimate to review and make a decision on manufacturer counteroffers was significantly higher than the burden estimate for manufacturers to develop and submit a counteroffer.

Response: CMS thanks commenters for this feedback. In response to these comments and the added burden due to policy updates in the revised guidance that provide CMS will aim to share section 1194(e)(2) data submitted by other interested parties with the Primary Manufacturer of a selected drug when feasible, CMS revised the burden estimate for the counteroffer development and submission by increasing the expected time burden from 79 hours per selected drug to 204 hours per selected drug. CMS notes that that CMS' burden estimate to support the counteroffer process estimates 2,273 hours for all selected drugs where a counteroffer is submitted. Of these total hours, 233 are allocated to building the CMS HPMS module for the counteroffer data submission. After removing these hours for the technical build, CMS estimates it will spend 204 hours on the counteroffer process per selected drug. Revisions to this ICR increase the Primary Manufacturer burden estimate to reflect CMS' belief, after reviewing these comments, and further consideration of the negotiation offer process, that the burden estimate in the initial ICR was understated. CMS also updated the burden estimate to use wage estimates from the Bureau of Labor Statistics' May 2022 National Industry-Specific Occupational Employment and Wage Estimates for the Pharmaceutical and Medicine Manufacturing industry. Cost estimates were also updated accordingly in section B, item 12, in the Supporting Statement.

Comment: One commenter noted that it is difficult to provide informed comments on the burden associated with this ICR because interested parties do not know what CMS will provide in its initial offer justification.

Response: CMS thanks the commenter for this note and points the commenter to sections 60.3 and 60.4 of the revised guidance, which detail how the initial offer will be formulated and what information will be shared in the initial justification.

Counteroffer Form, Justification, and Word Limits

Comment: One commenter expressed concern that the Counteroffer Form does not provide meaningful insight into how CMS will evaluate drugs or the factors it will consider during the drug price negotiation process.

Response: CMS thanks the commenter for this comment. Sections 60.3 and 60.4 of the revised guidance detail how CMS will evaluate selected drugs for purposes of developing an initial offer and the factors it will consider during the negotiation process.

Comment: One commenter suggested CMS allow manufacturers to submit any information relevant to the negotiation process as part of the counteroffer and not be restricted to just section 1194(e) information. The commenter also suggested CMS should consider all information submitted when evaluating the manufacturer's counteroffer. One commenter also expressed concern that off-label use of a selected drug for certain conditions may not be considered in the initial offer and recommended manufacturers be able to submit information on unmet needs, and other relevant information, in the counteroffer process.

Response: CMS clarifies that Primary Manufacturers are not restricted in the type of information they can submit, but CMS will focus on section 1194(e) elements when considering the counteroffer. As described in section 60.4.2 of the revised guidance, the Primary Manufacturer's counteroffer justification should focus on the elements described in section 1194(e) and indicate the reasons the Primary Manufacturer believes that the information submitted by the Primary Manufacturer on the factors described in section 1194(e)(1) or (e)(2) of the Social Security Act (the "Act"), or other available data related to the selected drug and its therapeutic alternatives as described in section 1194(e)(2) of the Act, does not support the written initial offer made by CMS. Primary Manufacturers may also include in their counteroffer justification new information regarding the selected drug and its therapeutic alternative(s) as described in section 1194(e)(2) that supports the counteroffer.

Comment: One commenter noted that the ICR does not contemplate a manufacturer response to feedback from other interested parties on a selected drug. The commenter asked if manufacturers would be able to review data submissions from other parties and if manufacturers could incorporate this information into their counteroffer justification.

Response: As discussed in the revised guidance, CMS will share section 1194(e)(2) data submissions from other interested parties with the Primary Manufacturer of the selected drug when feasible. These data will be appropriately redacted and will not include proprietary information, protected health information (PHI) / personally identifiable information (PII), or information that is protected from disclosure under other applicable law. Primary Manufacturers may include and/or respond to information from section 1194(e)(2) submissions from other interested parties, as available, in their counteroffer justifications.

Comment: One commenter suggested CMS structure the Counteroffer Form to promote transparent exchange and evaluation of evidence on the value and benefit of selected drugs.

Response: CMS thanks the commenter for this suggestion. The counteroffer justification, with a now increased word limit of 2,500 words and the ability to submit additional materials to support the justification (i.e., up to 50 citations and up to 10 tables/charts/graphs), should be used to provide evidence on the selected drug's value and clinical benefit.

Comment: Many commenters requested that CMS either increase or eliminate the 1,500-word limit for counteroffer justifications. Commenters stated that they found the word limit arbitrary, and that the word limit is insufficient to explain a manufacturer's rationale for the counteroffer and would result in manufacturers omitting key information. Commenters also stated that the complexity and amount of information available around a selected drug makes it challenging to provide a meaningful justification in 1,500 words. One commenter suggested that CMS eliminate the word limit for initial price applicability year 2026 and identify a limit for future years if necessary.

Response: CMS thanks commenters for this suggestion. In response to these comments, CMS revised this ICR to increase the counteroffer justification word limit from 1,500 words to 2,500 words and has additionally provided for the submission of visual representations of information (see the comment and response directly below). CMS believes that this increased word limit will be sufficient for Primary Manufacturers to share key information in support of their counteroffer as it can be supplemented by these visual representations of information.

Prior to the initial offer and possible counteroffer, Primary Manufacturers would have had the opportunity to submit longer written submissions about the section 1194(e) factors in the data submission due on October 2, 2023 and meet with CMS to provide context for their submissions. These Fall 2023 activities will provide foundational information about the selected drug prior to CMS' initial offer and allow Primary Manufacturers to focus on presenting the key, compelling information to support their counteroffer in the counteroffer justification.

CMS declines to eliminate the word limit for the counteroffer justification as a word limit is needed due to statutory time constraints in the negotiation process. Pursuant to sections 1191(b)(4)(B) and 1191(d)(2)(B) of the Act, the statutory deadline for the conclusion of negotiations is August 1, 2024 for initial price applicability year 2026. As discussed in the revised guidance, following CMS' initial offer and any Primary Manufacturer counteroffer, the negotiation process may include up to three post-counteroffer negotiation meetings and a final offer, as applicable. To allow sufficient time for these processes, CMS must be judicious about the amount of information Primary Manufacturers may submit in the Counteroffer Form. CMS believes that the revisions discussed above provide an appropriate balance between affording Primary Manufacturers the opportunity to share relevant information and ensuring that the negotiation process can be completed within the statutory time limits.

Comment: Some commenters recommended that the Counteroffer Form should allow manufacturers to upload studies, charts and tables, key information sources, and supplemental information to support the counteroffer.

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 alongside the counteroffer justification. CMS will not consider information uploaded as part of this submission that is not a visual representation of data, i.e., a table or chart consisting only of text.

30-Day Equivalent Supply Methodology

Comment: One commenter expressed that interested parties could not contribute meaningful feedback to this ICR without additional information on how CMS will apply a single MFP across diverse indications with variable unmet needs and varying alternative treatment options.

Response: CMS points the commenter to section 60.5 of the revised guidance, which was published after this ICR's 60-day comment period closed, for additional information on the 30-day equivalent supply methodology.

Comment: One commenter noted that manufacturers may be unwilling or unable to calculate the 30-day equivalent supply price for a counteroffer as it ties the price to a possible length of therapy as opposed to a specific dosage form and strength. The commenter suggested that CMS' initial offer include a price sheet that lists the offered MFP for all, or the highest volume, NDC-11s for the selected drug. The commenter further stated that the Counteroffer Form should include a similar price sheet where the manufacturer may input the expected MFP for each NDC-11.

Response: CMS thanks the commenter for this suggestion. CMS will use the single 30-day equivalent supply approach described in the revised guidance when negotiating the MFP. As described in section 60.1 of the revised guidance, during the negotiation period, CMS will share with the Primary Manufacturer the inputs for the methodology CMS will use to translate the MFP across dosage forms and strengths of the selected drug. This information will be shared so that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process (i.e., any offer or counteroffer that identifies a single price would be clearly translatable to per unit prices at the dosage form and strength level). As discussed in section 40.5 and 60.4.1 of the revised guidance, CMS will provide a Primary Manufacturer with information on the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug in advance of the initial offer. Aligned with this information, CMS will provide MFPs applied at the NDC-9 level as an attachment to CMS' initial offer to promote a common understanding of how the single MFP would translate to each NDC-9 of the selected drug. Primary Manufacturers may use this information when developing a counteroffer to understand how the counteroffer price per 30-day equivalent supply will convert into prices by NDC-9. CMS reaffirms that for the counteroffer, the Primary Manufacturer is expected to submit a counteroffer to the 30-day equivalent supply MFP proposed by CMS in its initial offer. CMS will not consider alternative MFP methodologies for each NDC-9 or NDC-11 that are inconsistent with the 30-day equivalent supply approach described in revised guidance.

Comment: A few commenters requested that CMS share the MFP for each NDC-9 of the selected drug in the initial offer. These commenters also asked that CMS provide the total units dispensed for each NDC-9 of the selected drug in the 2022 Part D Prescription Drug Event (PDE) data and a tool or spreadsheet detailing CMS' methodology for applying the 30-day equivalent supply MFP across different dosage forms and strengths.

Response: CMS thanks commenters for these requests. As discussed in the comment and response directly above, CMS will share information on the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug in advance of the initial offer. As described in section 60.1 of the revised guidance, CMS will share inputs on the 30-day equivalent supply methodology so that the Primary Manufacturer will have visibility into the implied unit prices based on the MFP for each dosage form and strength throughout the negotiation process. Therefore, CMS' initial offer will include, in addition to the initial offer MFP, an attachment with the MFPs applied across the NDC-9s of the selected drug. CMS declines to share PDE unit data for each NDC-9 of a selected drug.

Comment: One commenter asked that CMS include a field in the Counteroffer Form where a manufacturer can include its methodology for calculating the 30-day equivalent supply MFP in case the methodology is different from CMS' approach.

Response: CMS declines to include a field in the Counteroffer Form where a Primary Manufacturer may include its methodology for calculating the 30-day equivalent supply. CMS will employ the methodology described in Section 60.5 of the revised guidance to develop its initial offer for the 30-day equivalent supply MFP. As discussed in section 60.4.1 of the revised guidance, as feasible, CMS will provide information on the calculation of the statutorily-determined ceiling and the computation of how CMS will apply a single MFP across dosage forms and strengths of the selected drug to the Primary Manufacturer within 60 days of the Primary Manufacturer's submission of data that complies with the requirements described in section 50.1 of the revised guidance. As described in section 40.5 of the revised guidance, a Primary Manufacturer may submit a suggestion of error regarding the ceiling calculation or computation of how CMS will apply a single MFP across dosage forms and strengths.

Public Explanation of MFP

Comment: One commenter suggested CMS include a field in the Counteroffer Form for the manufacturer to request that certain information shared in the Counteroffer Form be included in the public explanation of the MFP. The commenter also suggested CMS provide an explanation in the revised guidance or updated Counteroffer Form if CMS plans to implement an alternative form or process for this purpose.

Response: Primary Manufacturers may request that certain information be included in the public explanation of the MFP in any data submission and may utilize the free text response on the Counteroffer Form for this purpose for the counteroffer process. CMS will consider a Primary Manufacturer's request but cannot guarantee the requested details will be included in the public explanation of the MFP. As described in the revised guidance, CMS will publish redacted

information regarding the section 1194(e) data received, exchange of offers and counteroffers, and the negotiation meetings, if applicable, in the public explanation of the MFP.

Certification of Submission and Signatures

Comment: One commenter suggested including fields on the Counteroffer Form for the Primary Manufacturer and CMS to sign and countersign if the counteroffer price is accepted.

Response: CMS declines to add signature fields to the Counteroffer Form for the acceptance of the counteroffer price, as any agreed-upon MFP will be effectuated via an Addendum to the Medicare Drug Price Negotiation Program Agreement (herein referred to as an "Agreement"), as described in section 40.3 of the revised guidance, which CMS and the Primary Manufacturer would need to sign and execute. A template of the Agreement and Addendum was released for manufacturer and other interested party review on CMS' website on July 3, 2023.[4] Concurrent with the Primary Manufacturer's submission of a written counteroffer, the Primary Manufacturer will populate an Addendum in the CMS HPMS containing the price identified in the counteroffer and sign the Addendum; if CMS wishes to accept the counteroffer, it will countersign the Addendum in the CMS HPMS. CMS will determine that negotiations have concluded upon execution by both parties of the Addendum setting forth the agreed-upon MFP.

Comment: A few commenters suggested CMS remove from the certification the requirement for "completeness," or to define what constitutes a complete submission. One commenter suggested CMS remove the liability clause. A few commenters suggested CMS also remove the requirement of timely notification of changed information. A few commenters suggested CMS adopt a "good faith" approach to the certification, as done for Average Sales Price (ASP) submissions.

Response: CMS affirms that its existing certification language is structured to ensure that the Primary Manufacturer is submitting information that is complete and accurate based on the respondent's information, knowledge, and/or experience. This certification is necessary to ensure the Primary Manufacturer's counteroffer and the information about the selected drug's profile and therapeutic alternatives that supports the counteroffer allow for a full understanding of the basis for the counteroffer within the confines of the limits provided in the ICR. A complete submission is a full submission that reflects the standards described in this ICR and the revised guidance and is within the respondent's information, knowledge, and/or experience.

CMS believes that the timely notification of changed information requirement in the certification is necessary for the Medicare Drug Price 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 information described in the counteroffer justification could be compromised.

The ASP data collection is a quarterly collection that allows restatements of financial data. The Counteroffer Form described in this ICR is a one-time information collection subject to statutory

[4] https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

deadlines 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. CMS has revised the certification language in this ICR to align with the certification language used in other information collection requests related to the Negotiation Program.