Centers for Medicare and Medicaid Services Response to Public Comments Received for CMS-10844, OMB 0938-1443

The Centers for Medicare and Medicaid Services (CMS) received three public submissions commenting on the Negotiation Program Drug Selection for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (CMS-10844, OMB 0938-1443) (hereinafter, the Drug Selection ICR) issued May 13, 2025. These submissions by two pharmaceutical manufacturers and one anonymous commenter included some comments that were outside the scope of the information collection request (ICR). These out-of-scope public comments are not addressed in this summary and response document. CMS refers those who submitted out-of-scope comments, including with respect to, for example, defined terms, the identification criteria for renegotiation-eligible drugs, the selection criteria for renegotiation-eligible drugs, the factors that contribute to an initial offer by CMS of a maximum fair price (MFP), and the process of renegotiating an MFP for drugs selected for renegotiation, to the Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026, 2027 and 2028 (hereinafter, the "final guidance").

Summaries of the public comments that are within the scope of the Drug Selection ICR and CMS' responses to those public comments are set forth in this document under the appropriate heading.

Request for a Small Biotech Exception

Comment: One commenter asked CMS to maintain consistency between the information requested for a small biotech exception for a drug covered under Part D and for drugs payable under Part B and only require that manufacturers submit the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) for which they are seeking a request for a small biotech exception.

Response: As described in section 30.2.1 of the final guidance, to determine whether a qualifying single source drug meets the requirements for the exception for small biotech drugs (the "Small Biotech Exception" (SBE)), CMS will make separate determinations with respect to the Part B criteria pursuant to section 1192(d)(2)(A)(ii) of the Act (the "Part B Track"), and the Part D criteria pursuant to section 1192(d)(2)(A)(i) of the Act (the "Part D Track").

In applying the Part D track, the statute requires CMS to consider Total Expenditures under Part D for all covered Part D drugs during 2021, Total Expenditures under Part D for the qualifying single source drug during 2021, and Total Expenditures under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a Medicare Coverage Gap Discount Program (CGDP) Agreement in effect on December 31, 2021. In order to calculate Total Expenditures under Part D for the qualifying single source drug during 2021, CMS needs to collect the NDA(s)/BLA(s) for the qualifying single source drug that the manufacturer that seeks the SBE for its qualifying single source drug(s) (the "Submitting Manufacturer") would like to be considered for an SBE. In order to calculate Total Expenditures

under Part D during 2021 for all covered Part D drugs for which the Part D 2021 Manufacturer and its controlled group had a CGDP Agreement in effect on December 31, 2021, CMS needs to collect information about (1) the entity that had a CGDP Agreement in effect on December 31, 2021 for the qualifying single source drug for which the Submitting Manufacturer seeks the SBE (i.e., the Part D 2021 Manufacturer); and (2) identifying information and labeler codes owned by any other entities in the Part D 2021 Manufacturer's controlled group as of December 31, 2021 that had a CGDP Agreement in effect on December 31, 2021.

In applying the Part B Track, the statute requires CMS to consider Total Expenditures under Part B during 2021 for all qualifying single source drugs, Total Expenditures under Part B during 2021 for the qualifying single source drug, and Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group. As in applying the Part D Track of the SBE, in order to calculate Total Expenditures under Part B during 2021 for the qualifying single source drug, CMS needs to collect the NDA(s)/BLA(s) for the qualifying single source drug that the Submitting Manufacturer would like to be considered for an SBE. However, because the Part B Track of the SBE, unlike the Part D Track, requires consideration of Total Expenditures under Part B in 2021 for all qualifying single source drugs of the Part B 2021 Manufacturer and its controlled group, the agency needs to collect all NDA(s)/BLA(s) held by the Part B 2021 Manufacturer and its controlled group as of December 31, 2021.

Comment: One commenter stated that they believe that the agency's revised burden estimate for submission of an SBE for initial price applicability year 2028 underestimates the burden associated with the submission of an SBE for initial price applicability year 2028.

Response: CMS thanks this commenter for their thoughts on the burden estimate. In revising the format of the burden estimate to provide the low, base, and high estimates for initial price applicability year 2028, CMS modeled the burden estimates on the type of SBE requests that CMS estimates to be the most common type of request for initial price applicability year 2028. CMS estimates that the Part B Track will have a slightly higher burden than the Part D Track. CMS' initial price applicability year 2028 burden estimate ranges were informed by the initial price applicability year 2027 burden estimate ranges (which only included SBE eligibility for drugs covered under Part D), the agency's assessment of the relative burden associated with SBE submissions anticipated for initial price applicability year 2028 (i.e., including the Part B Track only and Part B and Part D Track submissions), and the agency's assessment of the volume of information provided with actual applications submitted for the SBE for initial price applicability year 2027. Based on its review of initial price applicability year 2027 SBE submissions, CMS found that the initial price applicability year 2027 burden estimates tended to overestimate the burden associated with such submissions. Nonetheless, CMS recognizes that the initial price applicability year 2027 submissions may not reflect all Part D Track SBE submissions and does not account for all tracks, which is why CMS revised the burden estimate to include a range of estimates. CMS believes the high estimate is sufficient to capture the variety of larger burden estimates that may apply to situations in which a Submitting Manufacturer is making an SBE request for both the Part D Track and the Part B Track, or making an SBE request wherein CMS

is requesting additional information, such as those in which the Submitting Manufacturer was acquired after December 31, 2021.

Request for a Biosimilar Delay

Comment: One commenter suggested that CMS grant manufacturers of a biosimilar a "meaningful opportunity" to request a biosimilar delay, which included the commenter suggesting that CMS use the most recently available information to make a determination of the high likelihood that a biosimilar will be marketed within the requisite time period.

Response: CMS thanks the commenter for their feedback. Consistent with final guidance and CMS' responses to similar comments received on the draft guidance regarding the timing for submission of a request for a biosimilar delay, CMS reiterates that the Drug Selection ICR deadline is based upon the statute and operational constraints related to the drug selection process. CMS already includes an additional date for updating CMS on the status of the Biosimilar application for licensure in instances where updates since the submission of the request for the biosimilar delay may satisfy the eligibility criteria.

Finally, for the clear and convincing evidence required for the high likelihood determination specified in section 1192(f)(3)(B) of the Act (where CMS will review Biosimilar Delay Requests to determine whether there is a high likelihood that the Biosimilar will be licensed and marketed before the High Likelihood Deadline, which is February 1, 2028 for drugs selected for initial price applicability year 2028), CMS directs the commenter to section 30.3.1.3 of the final guidance where CMS added revisions to two items related to patents to address certain concerns about timing by: (1) extending the date by which there must be no unexpired patents relating to the reference product included in the Reference Drug that are applicable to the Biosimilar (from none at the filing of the request for the biosimilar delay to none by the High Likelihood Deadline), and (2) permitting the Biosimilar Manufacturer to be involved in pending patent litigation so long as neither a court nor the United States Patent and Trademark Office (USPTO)'s Patent Trial and Appeal Board (PTAB) has adversely ruled against the Biosimilar Manufacturer's legal patent assertion(s) pertaining to an unexpired patent or patent(s) relating to the reference product included in the Reference Drug applicable to the Biosimilar *and* the Biosimilar Manufacturer has specified a launch date for the Biosimilar that is a calendar date before the requisite deadline.

Identification and Selection of a Renegotiation-Eligible Drug

Comment: One commenter disagreed with CMS' instructions that Primary Manufacturers "should not report any data or costs that were previously reported to CMS under a previous data submission" and "should only include data not previously reported to CMS" because the commenter said a Primary Manufacturer should be able to provide any information that the Primary Manufacturer believes may be influential to CMS' identification and selection of a renegotiation-eligible drug. The commenter stated, as an example of previously-submitted data that should be included, previously reported data that may have been undervalued by the Primary Manufacturer in the Primary Manufacturer's original data submission to CMS.

Response: CMS thanks the commenter for this feedback. The Drug Selection ICR is an

opportunity for a Primary Manufacturer to share information with CMS that will be used by CMS to identify and select renegotiation-eligible drugs based on a new indication or a material change in a section 1194(e) factor. (The Drug Selection ICR does not collect information for drugs with a monopoly status change, as these drugs are automatically eligible, and must be selected, for renegotiation.) Therefore, the information collected in the Drug Selection ICR should be distinct from the information that was previously reported to CMS for the prior negotiation period. To ensure that the Drug Selection ICR is appropriately streamlined and targeted to reduce manufacturer burden, CMS will not repeat the collection of information provided previously.

Additionally, CMS reminds Primary Manufacturers of the ongoing obligation to provide CMS with updates to the originally submitted section 1194(e)(1) data. In accordance with section 50.1 of the revised guidance for initial price applicability year 2026, the final guidance for initial price applicability year 2027, and the final guidance for initial price applicability year 2028, the Primary Manufacturer should notify CMS of these updates separately from the Drug Selection ICR. CMS may consider updates to the Primary Manufacturer's original data submission to inform renegotiation eligibility and selection and to inform renegotiation if the drug is selected for renegotiation.

Otherwise, consistent with sections 130.1.3 and 130.1.4 of the final guidance (to determine if there is a new indication or a material change in a section 1194(e) factor to identify and select renegotiation-eligible drugs), CMS is requesting information on the applicable data elements from the last date for which the Primary Manufacturer reported data in the Primary Manufacturer's original full submission of section 1194(e)(1) data for the negotiation period in which the selected drug's MFP was negotiated through September 30, 2025 (with only a few exceptions related to, for example, the expansion of reportable research and development (R&D) costs for initial price applicability year 2028 that permits Primary Manufacturers to report certain information that predates the original full submission of section 1194(e)(1) data because it was not previously reportable).

Comment: One commenter disagreed with CMS' instructions to adjust certain values for inflation because the commenter stated that the values are not traditionally adjusted for inflation. The commenter also stated that CMS' methodology for inflation adjustment is not consistent with U.S. Generally Accepted Accounting Principles (GAAP) standards for inflation adjustment.

Response: CMS thanks the commenter for their feedback. CMS no longer includes any requests to adjust values for the cost of capital because CMS does not believe this is consistent with industry standards or GAAP. CMS has revised the instruction for inflation adjustment to specify that, for a question where CMS requests the Primary Manufacturer to adjust for inflation, the Primary Manufacturer use the annual percentage increase of the consumer price index for all urban consumers (CPI-U) for 2025. CMS disagrees with the commenter that inflation adjustment is not appropriate. However, CMS requests both the nominal and adjusted values because CMS recognizes that due to the varied development histories of the selected drugs, the relevant inputs for each selected drug may have occurred at different points in time.

Comment: One commenter suggested the 300-word limit for Question 9, related to the Explanation of Patents (Expired and Non-Expired) and Patent Applications, was insufficient to capture the long and complex process of discovery and development of new medicines. This commenter also raised concerns that the information requested in response to the question was too broad and ambiguous.

Response: CMS thanks the commenter for this feedback. CMS clarifies that the approximately 300-word limit (or 3,600-character limit) is for each patent listed by the Primary Manufacturer in Questions 9A, 9B, 10 and 11. As for the commenter's suggestion that CMS' request for information is too broad and ambiguous, CMS provides instructions to include a narrow response that is not intended to capture the entire history of the discovery and development of the drug. For example, for Question 9A, CMS requests the Primary Manufacturer explain for new patents or patents with changes since the previous negotiation, as applicable to a particular listing in the table, the patented invention, the manner and process of making or using the invention, the patent's relation to the other patents, and the reason a patent was removed from the Orange Book (if applicable). Further, to the degree the commenter feels the word limit in Question 9, specifically, is insufficient for the answer the commenter wishes to provide, CMS notes that the explanation fields for Questions 10 and 11 are open fields for which the Primary Manufacturer may choose to provide additional information.

Comment: One commenter suggested that CMS should either separate total unit volumes between the collection of the "manufacturer U.S. commercial average net unit price" and the "manufacturer U.S. commercial average net unit price— best," or remove these elements from the ICR because this commenter suggested that the two price points are offered with different sets of volumes. Specifically, this commenter contends that "manufacturer U.S. commercial average net unit price— best" is offered to a limited set of customers but, this commenter suggests, CMS may erroneously interpret the data to correlate the price with a total commercial unit volume.

Response: CMS thanks the commenter for raising these concerns. CMS directs the commenter to Appendix A of the final guidance where CMS has included technical corrections to "manufacturer U.S. commercial average net unit price" to clarify the items that should or should not be deducted from the price. CMS declines to revise these data elements in the Drug Selection ICR. CMS believes that the Primary Manufacturer has access to the specific data required to calculate these data elements and CMS provides terms and instructions to clarify which specific data should be included in this set of metrics. In addition, Question 13 asks the Primary Manufacturer to describe the assumptions, methodological steps, and other information used by the Primary Manufacturer to calculate the "manufacturer U.S. commercial average net unit price," and the related prices requested in Question 12, where the Primary Manufacturer could include the information raised by the commenter regarding prices available to different sets of customers.

Comment: One commenter suggested the 3,000-word count was insufficient to provide the information requested in Questions 14 and 15 for all potential indications of a selected drug with

sufficient detail and evidence. This commenter also requested CMS allow the submission of supporting exhibits (i.e., charts, graphs, etc.).

Response: CMS thanks the commenter for their concerns. As stated in the instructions for Questions 14 and 15, because the information requested in the Drug Selection ICR is only about "new information or evidence" since the date of the initial agreed-upon maximum fair price (MFP) for the selected drug, CMS maintains that that the 36,000-character count (approximately 3,000-word count) is sufficient. CMS has added the opportunity to submit up to five visual representations (which may include charts and graphs) with Questions 14 and 15 to provide new evidence or data. CMS also added the opportunity to provide citations of new evidence with Question 15 to be consistent with Question 14.