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 on the Small Biotech Exception and Biosimilar Delay Information Collection Request for Initial Price Applicability Year 2027 (CMS-10844, OMB 0938-1443) issued May 3, 2024. These submissions by a professional trade association and two pharmaceutical manufacturers 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. CMS refers those who submitted out-of-scope comments, including with respect to, for example, whether CMS will provide information about potential qualifying single source drugs before publication of the selected drug list for initial price applicability year 2027, eligibility for the Small Biotech Exception (SBE) and the Biosimilar Delay, including Additional Delay Requests, and other policies related to the SBE and Biosimilar Delay or other aspects of the Medicare Drug Price Negotiation Program, to the statute and program guidance, including 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 (hereinafter, the "final guidance").[1]

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

Request for a Small Biotech Exception

Comment: One commenter requested that CMS set forth and solicit input on the SBE methodology for all years of the program. Additionally, this commenter requested CMS to consider uniformity and predictability in the implementation of the SBE and requested clarification as to whether CMS uses non-publicly available data, beyond the prescription drug event (PDE) data addressed in the ICR and related to the draft of the final guidance policies, to inform an SBE determination. Additionally, this commenter requested robust public comment opportunities for stakeholder engagement related to the SBE.

Response: CMS thanks the commenter for their recommendations. CMS is declining to adopt the request to set forth and solicit comment on a single SBE methodology for all program years. This ICR implements the SBE methodology for only initial price applicability year 2027. We refer readers to the final guidance, in which we set forth the initial price applicability year 2027 methodology. While CMS aims for consistency across program years, as appropriate, CMS has provided for an SBE methodology only for a single initial price applicability year because of statutory differences in program requirements across years.

CMS appreciates stakeholder engagement regarding the SBE, including through the public comment periods on the ICR and the guidance documents for initial price applicability years 2026 and 2027, and anticipates similar engagement prospectively for initial price applicability year 2028.

[1] Available at:https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

In response to the request for clarification on how data collected through this ICR will be used with other data to make an SBE determination, CMS refers readers to section 30.2.1 of the final guidance for discussion on the criteria and data used by CMS to consider an SBE request and make a determination of an SBE.

Comment: One commenter requested CMS to provide a definition for the term "acquired" as it is used under section 1192(d)(2)(B)(ii) of the Act. This commenter suggested that an acquisition should be defined as the transfer of substantially all assets of the manufacturer. Additionally, this commenter requested that CMS clarify at which point in time the agency will determine if the acquiring manufacturer, for purposes of section 1192(d)(2)(B)(ii) of the Act, is a specified manufacturer [under the Medicare Part D Manufacturer Discount Program ("Manufacturer Discount Program"] for purposes of the SBE.

Response: CMS declines to adopt the commenter's suggested definition for the term "acquired" as used under section 1192(d)(2)(B)(ii) of the Act. For purposes of the SBE, acquired has a meaning consistent with that of other aspects of the Medicare program.

As specified in section 30.2.1 of the final guidance, for purposes of the limitation at section 1192(d)(2)(B)(ii) of the Act, CMS will use the determinations of the Manufacturer Discount Program upon receipt of an SBE request. CMS will consider an acquiring entity to have met the Manufacturer Discount Program definition of specified manufacturer for purposes of this limitation if the acquiring entity is identified by CMS under the Manufacturer Discount Program as either a specified manufacturer under 1860D-14C(g)(4)(B)(ii) of the Act or a specified small manufacturer under 1860D-14C(g)(4)(C)(ii) of the Act. For an acquisition to be relevant to the limitation, and therefore to potentially preclude a drug from being considered a qualifying single source drug that could be eligible for an SBE, the transaction must occur after 2021 and must involve the acquisition of the Submitting Manufacturer after the Submitting Manufacturer became the NDA / BLA holder. As stated in section 30.2.1 of the final guidance, for more information about identifying specified manufacturers and specified small manufacturers, refer to program guidance for the Manufacturer Discount Program.[2]

Request for a Biosimilar Delay

Comment: A couple of commenters requested CMS consider additional criteria to determine if there is a high likelihood that a Biosimilar will be licensed and marketed before February 1, 2027. These commenters suggested that to support these additional criteria, CMS include additional questions in the ICR to request the submission of decisions by the United States Patent and Trademark Office (USPTO) Patent Trial and Appeal Board (PTAB), and/or an attestation from the Biosimilar Manufacturer that no valid patents would be infringed upon once the Biosimilar is launched. Additionally, one commenter requested that CMS permit Biosimilar Manufacturers to provide an open-ended written narrative or submit additional information

[2] See section 50.1 of the Manufacturer Discount Program Final Guidance, and see also, the November 17, 2023 HPMS memorandum titled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers".

related to the high likelihood determination which the Biosimilar Manufacturer believes supports the determination.

Response: CMS thanks commenters for their recommendations. CMS directs readers to the comment summary and related responses in the final guidance and section 30.3.1.2 for policies regarding high likelihood determinations. In summary, CMS revised the factors that CMS will use to determine if "patents related to the Reference Drug are unlikely to prevent a Biosimilar from being marketed" in section 30.3.1.2 of the final guidance to include language that CMS will consider the latest PTAB decisions, in addition to court decisions, that establish the invalidity, unenforceability, or non-infringement of any potentially applicable unexpired patent relating to the reference product included in the Reference Drug that the patent holder asserted was applicable to the Biosimilar to determine whether patents related to the Reference Drug are unlikely to prevent the Biosimilar from being marketed.

We anticipate documentation uploaded by a Biosimilar Manufacturer in Section 3 of the Biosimilar Delay ICR Form will include information about PTAB decisions (and court decisions), as applicable. CMS declines to add attestations, open-ended free text or allow unrestricted uploads of additional documentation to this ICR. CMS believes the information specified in section 30.3.1.2 of the final guidance is sufficient for the Biosimilar Manufacturer to provide clear and convincing evidence that the Biosimilar will be marketed. CMS may request additional information and documents from a Biosimilar Manufacturer that submits an Initial Delay Request for initial price applicability year 2027 as specified in section 1192(f)(1)(B)(ii)(II) of the Act.

Comment: One commenter requested that CMS include an additional option under Question 9 on licensure that permits the Biosimilar Manufacturer to select that the Biosimilar Manufacturer intends to submit a BLA to the Food and Drug Administration (FDA) by February 1, 2027, given that February 1, 2027 is two years after when the Reference Drug would have been selected absent a successful Initial Delay Request.

Response: CMS thanks the commenter for the suggestion. CMS declines to include this option in Question 9 because the statute at section 1192(f)(3) of the Act requires that an application for licensure under section 351(k) of the Public Health Service Act for the Biosimilar has been accepted for review or approved by the FDA as a requirement for CMS to approve an Initial Delay Request. In section 30.3.1.2 of the final guidance, CMS has chosen the latest deadline (January 15, 2025) for such submissions that provides sufficient time for CMS to review the information and make determinations on negotiation eligibility prior to publication of the selected drug list for initial price applicability year 2027, which must be no later than February 1, 2025.

Comment: One commenter requested that CMS include questions in the ICR pertaining to Additional Delay Requests to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year as stated in section 1192(f)(1)(B)(i)(II) of the Act to allow manufacturers to plan for such future delay requests. This commenter suggested that the additional questions capture the information relevant to criteria

suggested by the commentator for CMS review of an Additional Delay Request when the BLA for the Biosimilar was pending FDA review during the first year of the Initial Delay Request. The commenter suggested the following as non-exhaustive examples: an FDA approval letter, an FDA Complete Response letter, if the Biosimilar Manufacturer has since resubmitted the BLA, and materials related to marketing plans in the second applicable initial price applicability year, such as the Biosimilar Manufacturer's investor disclosures.

Response: CMS thanks the commenter for the recommendation. CMS requested public comment regarding the criteria for determining Additional Delay Requests in the draft version of the final guidance. CMS directs commenters to the comment summary and related responses in the final guidance for initial price applicability year 2027. There were no approved Initial Delay Requests for initial price applicability year 2026 so there are not any Additional Delay Requests for CMS to consider for initial price applicability year 2027. In summary, CMS in the final guidance declines to include questions for Additional Delay Requests in the ICR for initial price applicability year 2027; however, CMS will consider these suggestions in CMS' policy development for this issue in future guidance or rulemaking and ICR(s).