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

The Centers for Medicare and Medicaid Services (CMS) received six public submissions from consumer and patient advocacy organizations, professional trade associations, and pharmaceutical manufacturers on the Small Biotech Exception Information Collection Request (CMS-10844, OMB 0938-NEW) issued January 24, 2023. 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. CMS refers those who submitted out-of-scope comments, including with respect to, for example, the timing and format for CMS to notify Submitting Manufacturers of its determination regarding their request, whether CMS will publish a list of qualifying single source drugs that were named in successful Small Biotech Exception requests, eligibility for the Small Biotech Exception, and other policies related to the Small Biotech Exception or other aspects of the Medicare Drug Price Negotiation Program, to the statute and program guidance, including the Initial Negotiation Program Guidance.[1] CMS plans to provide further information regarding the deadline for submission of Small Biotech Exception requests for initial price applicability year 2026, the timing and format for CMS to notify Submitting Manufacturers of its determination regarding their request, and the timing and format for CMS to publish the list of qualifying single source drugs that were named in successful Small Biotech Exception requests after approval of this ICR.

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.

Comments on Scope of Information Collected

Comment: Two commenters recommended that CMS change the language on the Small Biotech Exception Information Collection Request Form to require a Submitting Manufacturer to report information for only the members of its controlled group that had a Coverage Gap Discount Program agreement in effect on December 31, 2021, (1) because members of the controlled group that did not have a Coverage Gap Discount Program agreement in effect on December 31, 2021, would not impact CMS' determination of whether the qualifying single source drug meets the Small Biotech Exception and (2) in order to align with the language in the Medicare Part D Manufacturer Discount Program ICR.

Response: CMS agrees with commenters and has revised the Small Biotech Exception Information Collection Request Form and supporting statement accordingly.

Comment: One commenter requested that CMS clarify which 11-digit National Drug Codes (NDC-11s) a manufacturer should submit as part of the Small Biotech Exception Information Collection Request Form.

[1] 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 ("Initial Negotiation Program Guidance" – see https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf).

Response: CMS appreciates the opportunity to provide clarification. CMS has revised the Small Biotech Exception Information Collection Request Form and supporting statement to clarify that a manufacturer should submit all NDC-11s for the qualifying single source drug (as defined in section 30.1 of the Initial Negotiation Program Guidance) for which the manufacturer seeks the Small Biotech Exception. CMS is requiring this information to be submitted, along with the active ingredient / active moiety and New Drug Application(s) (NDAs) or Biologics License Applications (BLAs) for the qualifying single source drug, to allow CMS to timely and accurately identify and aggregate the appropriate expenditures under Part D to determine whether the qualifying single source drug qualifies for the Small Biotech Exception.

Process of Submitting the Information to Request the Small Biotech Exception

Comment: Two commenters requested that CMS revise the language used in the certification of the Small Biotech Exception Information Collection Request Form. Specifically, these commenters requested that CMS narrow the scope of the certification by removing language stating that CMS will rely upon the information submitted for Medicare reimbursement purposes.

Response: CMS thanks the commenters for their recommendations. CMS is declining to adopt these changes, however, in order to ensure manufacturers are fully cognizant that their submissions are material to payment under federal health care programs. No changes were made to the certification in response to these comments.

Comment: Three commenters requested that CMS accept responses to this information collection request by e-mail or mail, either in addition to or in lieu of submitting through the Health Plan Management System (HPMS).

Response: CMS thanks the commenters for expressing their concern on this point. CMS is requiring manufacturers to submit Small Biotech Exception requests for initial price applicability year 2026 through HPMS (unless the completion of such tool is delayed, in which case CMS will accept responses by e-mail) for two primary reasons: (1) to standardize the system used with other components of the Medicare Drug Price Negotiation Program and (2) to create a user interface that minimizes the risk of incomplete submissions. HPMS has the additional benefit of adhering to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services and CMS information security and privacy programs. CMS will provide documentation on navigating HPMS to submit a Small Biotech Exception request and will provide technical assistance requested at hpms@cms.hhs.gov. CMS has updated the cost to the Federal Government of this information collection in the supporting statement to reflect burden associated with providing technical assistance. CMS had previously indicated it would accept submissions for the Small Biotech Exception for initial price applicability year 2026 only by mail in the case that the HPMS tool is not completed in time. CMS has revised the supporting statement to reflect that CMS will now, in the case that the HPMS tool is not completed in time, accept Small Biotech Exception requests via e-mail only, and not by mail. Upon further review, CMS believes that using e-mail as a backup for submissions will be more

efficient and less burdensome than a non-electronic submission method. CMS believes this change is a beneficial alignment with the goal of using information technology.

Comment: Two commenters requested clarity on how CMS will maintain the confidentiality of manufacturer-submitted information.

Response: CMS thanks the commenters for expressing their concern on this point. CMS will protect the confidentiality of manufacturers by requiring that manufacturers submit their data for the Small Biotech Exception through HPMS, which already collects sensitive information and adheres to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services and CMS information security and privacy programs. In the event that the HPMS tool is delayed and CMS accepts responses through e-mail, CMS will provide Submitting Manufacturers with instructions on how to submit their responses in a manner consistent with CMS' controls (e.g., password protecting and encrypting information) and will continue to adhere to all applicable policies, procedures, controls, and standards required by the Department of Health and Human Services and CMS information security and privacy programs.

Comment: Two commenters requested that CMS extend flexibility to manufacturers submitting a Small Biotech Exception request for initial price applicability year 2026, including accepting requests after the deadline or that include incomplete information.

Response: CMS thanks the commenters for expressing these concerns. As noted above, CMS plans to provide technical assistance (at hpms@cms.hhs.gov) related to the Small Biotech Exception request and to allow sufficient time for manufacturers to submit a request for initial price applicability year 2026 after this information collection request is approved. Due to statutory deadlines for initial price applicability year 2026, however, CMS will not accept Small Biotech Exception requests that are incomplete or not submitted timely.