Centers for Medicare & Medicaid Services Response to Public Comments Received for CMS-10858, OMB 0938-NEW

The Centers for Medicare & Medicaid Services (CMS) received six timely public submissions from pharmaceutical manufacturers, professional trade associations, and the general public on the Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act information collection request (ICR) (CMS-10858, OMB 0938-NEW) that was issued January 29, 2024 for a 60-day public comment period. CMS received one timely public submission from a member of the general public on the revised Rebate Reduction Requests under Sections 11101 and 11102 ICR, which was issued on June 3, 2024 for a 30-day comment period.

We note that some of the public comments received were outside the scope of the ICR. These out-of-scope public comments, which raised policy considerations rather than commenting on the proposed information collection, are not addressed in this summary and response. CMS appreciates commenters sharing their recommendations for inflation rebate reduction policies with CMS and may consider these comments for purposes of future rulemaking. In addition, certain out-of-scope comments raise policy issues that CMS addressed in the development of the Medicare Part B Drug Inflation Rebate Program Revised Guidance ("Part B revised guidance") and the Medicare Part D Drug Inflation Rebate Program Revised Guidance ("Part D revised guidance"), which were released on December 14, 2023. CMS refers commenters on this ICR to the comments and responses in these documents, which address, among other things, certain policies regarding rebate reduction amounts and how determinations for rebate reductions are made.

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. CMS did not receive any new, in-scope comments during the 30-day comment period.

In-Scope Comments Received During the 60-Day Comment Period

Burden to Report the Information Required and/or Requested

Comment: A few commenters stated that requiring manufacturers to submit a request to CMS to receive consideration for a rebate reduction is duplicative of the Food and Drug Administration's (FDA) existing processes for addressing drug shortages and increases administrative burden on manufacturers. A few manufacturers recommended CMS obtain the information needed to determine whether there is a severe supply chain disruption or likely shortage from FDA instead of creating a new reporting process to reduce duplication. A few commenters recommended CMS use FDA's drug shortages list for determining rebate reductions.

Response: CMS appreciates commenters sharing their concerns about the reporting requirements and recommendations regarding existing resources that CMS may use for determining rebate reductions.

The FDA Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) each maintain publicly available drug shortages lists via web pages for drugs and biological products within their respective jurisdictions.[1] CMS believes these FDA shortage lists can readily be used to determine whether a drug is currently in shortage. In accordance with sections 1847A(i)(3)(G)(i) and 1860D-14B(b)(1)(C)(i) of the Act, CMS will use the FDA drug shortage lists to determine whether to grant a rebate reduction for a Part B or Part D rebatable drug described as currently in shortage on an FDA shortage list during a calendar quarter or applicable period, respectively. As described in section 50.11 of the Medicare Part B Drug Inflation Rebate Revised Guidance and section 40.5.1 of the Medicare Part D Drug Inflation Rebate Revised Guidance, CMS will monitor the status of Part B and Part D rebatable drugs on an FDA shortage list, and manufacturers do not need to submit any information to CMS to be eligible for a reduction of the rebate amount for a Part B or Part D rebatable drug described as currently in shortage on an FDA shortage list.

However, the IRA instructs CMS to grant a rebate reduction or waiver in two additional cases: (1) when CMS determines there is a severe supply chain disruption for a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar during a calendar quarter or applicable period, respectively, and (2) when CMS determines that without such reduction or waiver, a generic Part D rebatable drug is likely to be in shortage during a subsequent applicable period. The statute does not instruct CMS to use FDA's drug shortages lists in making determinations regarding severe supply chain disruptions or likely shortages. As such, CMS considers severe supply chain disruptions and likely shortages to be generally distinct from current drug shortages identified on FDA's drug shortage lists for purposes of providing a rebate reduction for an eligible drug or biological product.

CMS understands that manufacturers must report to FDA certain information related to drug and biological product discontinuances and manufacturing interruptions under section 506C of the Federal Food, Drug and Cosmetic (FD&C) Act ("506C notification"). CMS understands that manufacturers are also encouraged to voluntarily notify FDA of other circumstances that are likely to lead to a meaningful disruption in supply of certain finished drugs or biological products although such notifications are not expressly required by section 506C of the FD&C Act. However, the criteria for determining whether a request qualifies for a rebate reduction differ from the requirements for submission of a 506C notification to FDA, and manufacturers requesting a rebate reduction may not have submitted a voluntary notification to FDA either. CMS believes that the information required in a 506C notification submitted to FDA would not be sufficient to make a rebate reduction determination because while 506C notifications must include information related to permanent discontinuances or manufacturing interruptions of a drug, they are not required to include information about other changes in production or distribution that may be relevant for CMS' determination of whether a severe supply chain disruption has occurred. In addition, 506C notifications and voluntary shortage notifications submitted to FDA by manufacturers are not made public so even if such notifications included

[1] See: CBER shortage list: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-shortages-anddiscontinuations; CDER shortage list: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

sufficient information for CMS to determine whether a severe supply chain disruption occurred, CMS would not have access in the ordinary course to the information in such notifications. For these reasons, CMS is requiring that a manufacturer submit a request containing specified information and supporting documentation (as described in Appendix A, B, C, and D, as applicable) to CMS to receive consideration for a rebate reduction when the manufacturer believes there is a severe supply chain disruption or likely shortage.

CMS appreciates commenters' feedback that it should partner with FDA to obtain the information CMS needs to review rebate reductions requests. As stated in the Medicare Part B Drug Inflation Rebate Revised Guidance and the Medicare Part D Drug Inflation Rebate Revised Guidance, CMS may consult with FDA for technical assistance in implementing the severe supply chain disruption and likely shortages provisions, as needed. However, for the reasons stated above, CMS maintains that there is a distinct informational need associated with severe supply chain disruptions and likely shortages and that manufacturers are well positioned to provide CMS with the information needed to review rebate reduction requests associated with severe supply chain disruptions and likely shortages.

Comment: One commenter questioned how CMS estimated that it will receive 10 rebate reduction requests and 10 rebate reduction extension requests per year as there are more than 10 drugs on FDA's shortages list and requested CMS clarify how it arrived at this estimate. This commenter also stated that a higher burden estimate may be appropriate in instances where there is a team of individuals completing a rebate reduction request form.

Response: CMS thanks the commenter for this feedback. CMS agrees with the commenter that the FDA drug shortages lists include more than 10 drugs. As previously mentioned, consistent with sections 1847A(i)(3)(G) and 1860D-14B(b)(1)(C) of the Act, CMS considers a severe supply chain disruption or likely shortage to be distinct from a current drug shortage (i.e., when a drug is described as currently in shortage on an FDA shortage list) for purposes of providing a rebate reduction. As instructed by statute, CMS will use the FDA drug shortage lists to determine whether to reduce the rebate amount for a Part B or Part D rebatable drug described as currently in shortage during a calendar quarter or applicable period, respectively. However, sections 1847A(i)(3)(G)(ii) and 1860D-14B(b)(1)(C)(ii) of the Act, which require CMS to reduce or waive rebates when there is a severe supply chain disruption, and section 1860D-14B(b)(1)(C)(iii) of the Act, which requires CMS to reduce or waive inflation rebates when there is a likely future shortage, do not instruct CMS to use FDA's drug shortages lists in making determinations regarding severe supply chain disruptions or likely shortages. As such, CMS does not believe the number of drugs described as currently in shortage on FDA's shortages lists is determinative of the number of severe supply chain disruption and likely to be in shortage rebate reduction requests CMS will receive.

In addition, the statute limits eligibility for a rebate reduction when there is a severe supply chain disruption to Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars and when there is a likely future shortage of certain generic Part D rebatable drugs. These narrow categories of drugs and biosimilars represent a small percentage of the drugs listed on the FDA's shortage lists. CMS underscores that multiple source or multi-source

generic drugs, which are the generic drugs most often in shortage,[2] are not Part B or Part D rebatable drugs and are not subject to Part B or Part D drug inflation rebates.

In arriving at its estimate of 10 rebate reduction requests and 10 rebate reduction extension requests per year, CMS based such estimate on the fact that there will be a limited number of Part B and Part D rebatable drugs that are eligible for a rebate reduction based on the criteria in statute and guidance. Based on a review of available information and technical assistance from FDA, CMS has not seen evidence to contradict the number of requests that CMS is estimating per year. In addition, allowing a single manufacturer to include multiple affected drugs on one form reduces the overall number of requests as compared to requiring a separate form for each drug.

CMS believes that 31 total burden hours per manufacturer is an appropriate estimate of burden to develop and submit one form. The estimated aggregate hours worked would be the same if there was one person working to complete the form or a team of individuals. For instance, if two individuals from the same labor category worked to develop and submit a form, the number of hours required per each individual would be half of what is listed in the table per individual, but the overall number of hours would stay the same and the total burden hours would not change. However, to acknowledge possible variability in the total burden estimate, CMS has provided a range, with a low estimate of 15.5 hours (reducing by half evenly for all labor categories) and a high estimate of 62 hours (doubling for all labor categories evenly), as further explained in the Supporting Statement. CMS also updated the burden estimate to use wage estimates from the Bureau of Labor Statistics' May 2023 National Industry-Specific Occupational Employment and Wage Estimates for Pharmaceutical and Medicine Manufacturing. These new wage estimates were used to update the estimates in section B, item 12, in the Supporting Statement accordingly.

Process and Format for Submitting Rebate Reduction Requests

Comment: One commenter stated that requiring manufacturers to send an email to receive a rebate reduction request form may delay the submission process and recommended CMS post the forms on the CMS website such that the manufacturer could submit the forms with its initial email to CMS.

Response: CMS appreciates the commenter sharing its concerns about access to the rebate reduction request forms and the recommendation to post the information collection forms online. CMS agrees that earlier access to the rebate reduction request forms may facilitate timely submission of rebate reduction requests. Upon completion of the Paperwork Reduction Act (PRA) process for this information collection, the rebate reduction request form templates (available as Appendix A, B, C, and D of this ICR) will be published on the Office of Management and Budget (OMB) website.[3] As such, manufacturers will be able to view the questions on the forms and evidentiary requirements in advance of submitting a rebate reduction request to CMS.

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[2] See: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us2023.

[3] Information Collection Review on RegInfo.gov. https://www.reginfo.gov/public/do/PRAMain.

CMS understands information included on the forms and the accompanying supporting documentation may contain information that manufacturers believe to be proprietary or trade secret, and manufacturers may have reservations about sharing such information by email. CMS also believes that instructing manufacturers to submit rebate reduction request forms and supporting documentation for multiple products via email may result in emails that exceed file size limits and create technical challenges that could delay the submission process. As such, as described in the Supporting Statement of this ICR, a manufacturer should first email IRARebateandNegotiation@cms.hhs.gov to indicate its intention to submit a request for a reduction in the rebate amount. CMS will then provide the manufacturer with the relevant request form(s) and access to a Box folder, or similar process approved by CMS, specific to the manufacturer's request that will allow for the manufacturer to submit materials relating to the rebate reduction request securely. CMS continues to evaluate options for manufacturer form submissions and may revise the submission method in the future.

Comment: A couple commenters stated that CMS' collection forms for severe supply chain disruptions and likely shortages do not address the relationship between Primary Manufacturers and Secondary Manufacturers or account for Secondary Manufacturers or co-manufacturers, in contrast to other CMS programs such as the Medicare Drug Price Negotiation Program which distinguish between these two entities. One commenter stated that this creates an inconsistency in CMS' implementation policies for drug payment programs under its jurisdiction and a data collection gap that may affect rebate reduction determinations. A couple commenters recommended CMS revise the ICR to account for information from both Primary Manufacturers and Secondary Manufacturers or co-manufacturers.

Response: CMS thanks the commenters for their feedback. CMS understands that contract manufacturers play a role in drug manufacturing and could be affected by a natural disaster or other unique or unexpected event that causes a severe supply chain disruption. As described in section 50.12 of the Medicare Part B Drug Inflation Rebate Revised Guidance and section 40.5.2 of the Medicare Part D Drug Inflation Rebate Revised Guidance, to receive a reduction in the rebate amount when there is a severe supply chain disruption, a manufacturer must demonstrate to CMS, among other things, that the disruption directly affects the manufacturer itself, a supplier of an ingredient or packaging, or a method of shipping or distribution that the manufacturer uses in a significant capacity to make or distribute the Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar. If a severe supply chain disruption occurs at a facility of a contract manufacturer and affects the manufacturer of the Part B biosimilar biological product or generic Part D rebatable drug or biosimilar, CMS would consider the effects of a severe supply chain disruption on a contract manufacturer in its evaluation of a severe supply chain disruption rebate reduction request. Similarly, issues at a facility of a contract manufacturer could also contribute to a likely future drug shortage. If a generic Part D rebatable drug is likely to be in shortage because of an issue at a facility of a contract manufacturer, CMS would consider that information in its evaluation of a likely to be in shortage rebate reduction request. To clarify that a manufacturer of a Part B rebatable biosimilar biological product or generic Part D rebatable drug or biosimilar may request a rebate reduction if the manufacturer believes there is a severe supply chain disruption at a contract facility, CMS

revised question 5 in the Severe Supply Chain Disruption Rebate Reduction Request Form (Appendix A) and question 6 in the Severe Supply Chain Disruption Rebate Reduction Extension Request Form (Appendix B), as well as the examples of evidence in the Likely to be in Shortage Rebate Reduction Request Form (Appendix C) and the Likely to be in Shortage Rebate Reduction Extension Request Form (Appendix D) to explicitly account for impact on contract manufacturers.

CMS disagrees with commenters that it should distinguish between primary manufacturers and secondary manufacturers to align the Medicare Prescription Drug Inflation Rebate Program with the Medicare Drug Price Negotiation Program. CMS adopted the designations of "Primary Manufacturer" and "Secondary Manufacturer" specifically for the purposes of the Medicare Drug Price Negotiation Program, as described in the Medicare Drug Price Negotiation Program: Revised Memorandum, Implementation of Sections 1191—1198 of the Social Security Act for Initial Price Applicability Year 2026, and does not believe these designations are relevant for the purpose of inflation rebate reductions. In the Medicare Part B and Part D Drug Inflation Rebate Programs, CMS has defined the term "manufacturer" for the purpose of determining manufacturer responsibility for paying an inflation rebate. As described in the Medicare Part B Drug Inflation Rebate Program Revised Guidance, CMS will use the same approach used to identify the manufacturer that is responsible for reporting Average Sales Price (ASP) data.[4] As described in the Medicare Part D Drug Inflation Rebate Program Revised Guidance, CMS will use the same approach used by the Medicaid Drug Rebate Program to identify the manufacturer responsible for a Part D drug inflation rebate amount owed.[5] The manufacturer responsible for submitting a rebate reduction request is the same manufacturer responsible for the rebate amount due.

[4] Section 1847A(c)(6)(A) of the Act defines "manufacturer" for purposes of Average Sales Price (ASP) reporting under Medicare Part B.

[5] Section 1927(k)(5) of the Act defines "manufacturer" for purposes of the Medicaid Drug Rebate Program.