

## Response to Public Comments Received – CMS-10846 (OMB 0938-NEW)

CMS received 2 comments on the Medicare Part D Manufacturer Discount Program (Discount Program) information collection request (ICR), which was posted in the Federal Register on February 7, 2023 for a 60-day public comment period (88 FR 7976). This document provides summaries of the comments received and CMS' responses.

Most of the comments received were policy-related and, therefore, outside the scope of this information collection. This includes comments related to interim payments by CMS to Part D sponsors to account for discounts provided at the point-of-sale (POS); payment reconciliation; financial protection for sponsors if a participating manufacturer fails to provide discounts under the terms of their Discount Program agreement; questions about data sources and methodology CMS will use to identify manufacturers eligible for phased-in discounts for specified manufacturers and specified small manufacturers; interpretation of statutory language related to identification; timing and format CMS will use to notify manufacturers of such identification; submission deadlines for providing required information; and dispute resolution processes.

On these and other policies related to the Discount Program, CMS refers commenters to program guidance, including the May 12, 2023 HPMS memorandum, *Medicare Part D Manufacturer Discount Program Draft Guidance and Request for Comment*<sup>1</sup> (draft guidance). CMS expects to issue final Discount Program guidance in late 2023 after consideration of all comments received.

We did not receive any comments pertaining to the burden estimates in this ICR. The remaining comments received are discussed below.

**Comment:** One commenter urged CMS to protect the confidentiality of proprietary information submitted in relation to this information collection and to outline CMS' approach for publicly sharing information regarding manufacturers identified as eligible for the phased-in discounts.

**Response:** CMS thanks the commenter for sharing their concerns. As noted in section A.10. of the supporting statement for this ICR, CMS will protect the confidentiality of information related to this ICR to the extent allowed by applicable laws and regulations. Manufacturers will be required to submit information through HPMS or through a similarly secure electronic portal maintained by the third party administrator (TPA). HPMS 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. The information being collected is necessary to create and execute Discount Program agreements, determine which drugs are applicable drugs and which manufacturers are eligible for phased-in discounts, and prepare invoices and facilitate payments under the program. As stated in section 50.1 of the draft guidance, prior to the start of the Discount Program, CMS intends to publish a list of manufacturers eligible for the phase-ins.

**Comment:** One commenter requested that CMS clarify which manufacturer within a controlled group should submit information for the MDP phase-in on behalf of a controlled group.

---

<sup>1</sup> <https://www.cms.gov/files/document/part-d-manufacturer-discount-program-draft-guidance-may-2023.pdf>

**Response:** CMS appreciates the opportunity to provide clarification. Sections 1860D-14C(g)(4)(B)(ii)(II)(bb) and 1860D-14C(g)(4)(C)(ii)(II)(bb) specify that the Discount Program agreement between CMS and a participating manufacturer require that the manufacturer provide and attest to information specified by CMS for purposes of determining which entities must be treated as one manufacturer. As such, each manufacturer (i.e., each P number) that enters into a Discount Program agreement with CMS is required to provide and attest to the required ownership information collected in HPMS, including information on other members of that manufacturer's controlled group, as applicable.

**Comment:** One commenter asked for information about the identification of manufacturers eligible for phased-in discounts, including the methodology CMS will use, the timelines, and the submission and notification process.

**Response:** We thank the commenter for their questions. While these questions are outside scope for this ICR, we direct the commenter to the draft guidance where this is discussed. As stated in section 50.1, CMS will use Medicare Parts B and D claims data and ownership information provided by manufacturers (see Appendix A of this ICR) to identify which manufacturers qualify for the phase-ins. CMS will consider all manufacturers who enter into a Discount Program agreement in time to participate in any year of the phase-in for such eligibility; manufacturers do not need to submit a separate application. CMS anticipates releasing additional details later this year regarding the methodology we will use to identify phase-in eligible manufacturers, the HPMS submission process, the process for notifying manufacturers about their eligibility, and other relevant information prior to releasing the updated HPMS Discount Program module in late 2023. For the first year of the Discount Program, CMS intends to provide manufacturers that submit and attest to the required ownership information by a certain date (to be announced later this year) with information regarding their eligibility for the phase-ins prior to the statutory deadline of March 1, 2024 to enter into a Discount Program agreement for 2025. To assist Part D sponsors in accurately calculating applicable discounts, CMS will publish a list of manufacturers eligible for the phase-ins prior to the start of the Discount Program.