

Department of Health & Human Services
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: November 17, 2023

TO: Pharmaceutical Manufacturers

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SUBJECT: Instructions for Submitting Required Ownership Information for the Medicare Part D Manufacturer Discount Program; Opportunity to Receive Preliminary Information About Status as a Specified Manufacturer and Specified Small Manufacturer

Beginning January 1, 2025, CMS is implementing the Medicare Part D Manufacturer Discount Program (Discount Program), codified in sections 1860D-14C and 1860D-43 of the Social Security Act (the Act), under the program instruction authority in section 11201(f) of the Inflation Reduction Act of 2022 (P.L. 117-169) (IRA). On November 17, 2023, CMS issued the Medicare Part D Manufacturer Discount Program Final Guidance.¹

As described in section 50.1 of the final guidance, section 1860D-14C(g)(4) of the Act specifies that manufacturers meeting the statutory criteria for specified manufacturers and specified small manufacturers are subject to a multi-year phase-in period during which they pay a lower percentage discount on certain applicable drugs dispensed to applicable beneficiaries. In accordance with the Part D Manufacturer Discount Program Information Collection Request (ICR)² (CMS-10846, OMB control no. 0938-1451) approved through September 30, 2025, and section 50.2 of the final guidance, CMS must collect certain information from participating manufacturers in order to correctly identify specified manufacturers and specified small manufacturers.

On November 17, 2023, CMS released the Ownership Information functionality within the Manufacturer Discount Program module in the Health Plan Management System (HPMS) for the purpose of collecting this information, which is required of all manufacturers in order to execute a Discount Program agreement with CMS. As discussed in section 50.2.1 of the final guidance, for the first year of the Discount Program, CMS will provide manufacturers that submit and attest to all required ownership information, prior to executing a Discount Program agreement, with

¹ See HPMS memorandum entitled “Medicare Part D Manufacturer Discount Program Final Guidance” issued November 17, 2023.

² https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003 (Select “all” to see full details.)

preliminary, non-binding information regarding their eligibility for discount phase-in as a specified manufacturer or specified small manufacturer. Manufacturers interested in receiving this preliminary information must submit and attest to the required ownership information in HPMS by 11:59 p.m. PST on **December 8, 2023**.

While the ownership information must be submitted and attested to by all manufacturers that participate in the Discount Program, the early submission is only required for those manufacturers that want to receive preliminary, non-binding eligibility information prior to executing a Discount Program agreement. The deadline for all participating manufacturers to provide and attest to the required ownership information is 11:59 p.m. PST on **March 1, 2024**.

Manufacturers will be able to revise the ownership information submission, even after they have completed the attestation (e.g., to correct an error). Any edits made to the submission after the attestation will require a new attestation. CMS will use the most current information submitted and attested to by the deadline. Manufacturers that submit and attest to the required information by December 8, 2023, will receive the preliminary, non-binding information regarding the eligibility for specified manufacturer and specified small manufacturer phase-ins by January 31, 2024.

HPMS Access

In order to access HPMS, the manufacturer must have a contract “P” number. All manufacturers that have a Coverage Gap Discount Program agreement will retain their existing P numbers. Instructions on how to request a P number are available in the Downloads section on CMS’ webpage: [Part D Information for Pharmaceutical Manufacturers](#). Access to the Ownership Information functionality in the Manufacturer Discount Program module will be granted automatically to active manufacturer users in HPMS. Instructions for requesting HPMS access and creating a user ID are available in the May 4, 2023 HPMS memo entitled “[Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System \(HPMS\)](#).” On average, HPMS user ID requests require 3-5 days to complete.

Prior to using the Manufacturer Discount Program module, manufacturers should ensure that they have established the appropriate individuals with HPMS electronic signature access. Only signatory drug manufacturer users may complete required attestations and signatures in the module. Instructions for requesting electronic signature access and restrictions regarding individuals eligible for signature access are included in the May 4, 2023 HPMS memo entitled “[Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System \(HPMS\)](#).” Within the module’s documentation section, in the HPMS Manufacturer Discount Program Module User Guide, manufacturers can review additional instructions, including how to navigate the Discount Program module; how to enter, edit, and save required manufacturer data in the module; and how to attest to and submit the required data to CMS.

Ownership Data Submission Module – Clarifications

The questions in the Ownership Data submission module contemplate that the submitting manufacturer (the entity to which the P number is assigned) is the signatory manufacturer on the agreement and that the agreement covers all labeler codes of the submitting manufacturer, or the

submitting manufacturer and other members of the same controlled group, and no labeler codes of manufacturers that are not members of the same controlled group. However, because CMS does not prohibit a participating manufacturer under the Coverage Gap Discount Program, and does not at this time prohibit a participating manufacturer under the Manufacturer Discount Program, from covering by its agreement labeler code(s) of another manufacturer, submitting manufacturers in certain circumstances may need to provide clarifying information to CMS. We've outlined expectations for the ownership information submission for various circumstances below.

The "submitting manufacturer" refers to the manufacturer to which the P number is assigned, and the labeler codes that include that manufacturer's applicable drugs and any labeler codes of other controlled group members that are covered under the submitting manufacturer's P number.

1. The submitting manufacturer should indicate "Yes" for Question 1 in the following scenarios:
 - a. The submitting manufacturer's labeler code(s) was covered in 2021 by a different manufacturer's Coverage Gap Discount Program agreement, but the submitting manufacturer subsequently obtained its own P number.
 - b. The submitting manufacturer is a parent organization and its 2021 Coverage Gap Discount Program agreement only covered labeler codes of manufacturers within its controlled group and continues to do so.
2. The submitting manufacturer should contact CMS at PartDManufacturerDiscountProgram@cms.hhs.gov for further instructions in the following scenarios:
 - a. The submitting manufacturer's 2021 Coverage Gap Discount Program agreement covered the submitting manufacturer's labeler code(s) and labeler code(s) of other manufacturer(s) that are not part of the same controlled group.
 - b. The submitting manufacturer does not have any labeler code(s) and the submitting manufacturer's 2021 Coverage Gap Discount Program agreement exclusively covered labeler code(s) of other manufacturers that are not part of the same controlled group as the submitting manufacturer.

Questions about this memorandum or the Discount Program may be submitted to PartDManufacturerDiscountProgram@cms.hhs.gov.

For technical assistance with HPMS, contact the HPMS Help Desk at either hpms@cms.hhs.gov or 1-800-220-2028.