

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

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TO: Pharmaceutical Manufacturers; All Part D Plan Sponsors

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SUBJECT: Medicare Part D Manufacturer Discount Program: Important Updates and Upcoming Deadlines

The Inflation Reduction Act of 2022, Public L. 117-169 (IRA), established the Medicare Part D Manufacturer Discount Program (Discount Program) that begins on January 1, 2025. This memorandum contains important updates and information for manufacturers and Part D sponsors.

Participating Labeler Code List and Phase-In National Drug Code (NDC) List

On April 4, 2024, CMS released an initial list of all participating labeler codes that will be covered under a Discount Program agreement beginning January 1, 2025 (“participating labeler code list”), as well as an accompanying HPMS memorandum titled “Medicare Part D Manufacturer Discount Program: 2025 Participant List; Identification of Specified Manufacturers and Specified Small Manufacturers”. On May 9, 2024, CMS released an initial list of 9-digit National Drug Codes (NDC-9s) (“NDC list”) eligible for Discount Program phase-ins.

Today, we are releasing updated versions of the 2025 participating labeler code list and NDC list. The updated lists are presented in the final file formats that will be used for the monthly lists beginning with January 2025. Included with each list is a README file that defines the fields included in the respective file. As with the initial participating labeler code and NDC lists, the updated lists are based on the information currently in HPMS. Labeler codes may still be added, removed, or transferred prior to release of the January 2025 monthly labeler code and NDC lists.

CMS will release the January 2025 monthly participating labeler code list and NDC list in mid-December 2024. To ensure inclusion in those files, **manufacturers must submit any remaining labeler code changes (add, delete, or transfer) no later than November 1, 2024**. Manufacturers that submit requests for labeler code changes after November 1, 2024 should not expect those changes to be reflected in the January 2025 files.

Updated Discount Program FAQs

On April 19, 2024, CMS released FAQs related to the Discount Program. Since that time, we have

continued to receive technical questions from manufacturers, Part D sponsors, and other interested parties regarding the policies and methodologies described in the Medicare Part D Manufacturer Discount Program Final Guidance and the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers, both of which were released on November 17, 2023. The attached document contains updated and expanded FAQs to provide additional clarifications related to those questions.

All of the documents referenced in this memorandum are available in the Downloads section on the Part D Information for Pharmaceutical Manufacturers page:

<https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers>

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