

Department of Health & Human Services
Centers for Medicare & Medicaid Services
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DATE: April 4, 2024

TO: Pharmaceutical Manufacturers; All Part D Plan Sponsors

FROM: Vanessa S. Duran, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Medicare Part D Manufacturer Discount Program: 2025 Participant List;
Identification of Specified Manufacturers and Specified Small Manufacturers

This memorandum provides pharmaceutical manufacturers and Part D plan sponsors with important information about the Medicare Part D Manufacturer Discount Program (Discount Program) that begins on January 1, 2025. CMS is implementing the 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, through Health Plan Management System (HPMS) memoranda, CMS released the “Medicare Part D Manufacturer Discount Program Final Guidance” (Final Guidance)¹ and the “Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers” (Methodology).²

As stated in section 40 of the Final Guidance, beginning January 1, 2025, Part D coverage for applicable drugs is available only for applicable drugs for which the FDA-assigned labeler code is covered by a Discount Program agreement with CMS, as described in section 1860D-14C(b) of the Act. Under section 1860D-14C(b)(1)(C)(i) of the Act, manufacturers were required to enter into a Discount Program agreement no later than March 1, 2024 in order to participate in the Discount Program in 2025. All Discount Program agreements that will become effective in 2025 are now fully executed between the participating manufacturer and CMS.

As described in section 50.1 of the Final Guidance, the IRA provides for lower applicable discounts for certain manufacturers’ applicable drugs during a multi-year phase-in period which concludes by 2031. CMS has notified all participating manufacturers about their status as a specified manufacturer or specified small manufacturer under sections 1860D-14C(g)(4)(B)(ii) and 1860D-14C(g)(4)(C)(ii) of the Act, respectively, and the status of all labeler codes covered by their Discount Program agreement.

¹ <https://www.cms.gov/files/document/manufacture-discount-program-final-guidance.pdf-0>

² <https://www.cms.gov/files/document/manufacture-discount-program-specified-and-specified-small-manufacture-methodology.pdf-0>

CMS has posted a list of all participating labeler codes that will be covered under a Discount Program agreement beginning January 1, 2025. The list also identifies which labeler codes are eligible for the specified manufacturer or specified small manufacturer phased-in discounts that apply to applicable drugs marketed as of August 16, 2022. The participating labeler code list is based on the information currently in HPMS, and labeler codes may be added, removed, or transferred prior to January 1, 2025. CMS will issue updates to this list as applicable. To further assist Part D sponsors in accurately calculating applicable discounts, CMS will provide clarifying information later this spring related to identifying which specific National Drug Codes represent applicable drugs that were marketed as of August 16, 2022, and are eligible for the phase-ins.

The participating labeler code list is available in the “Downloads” section at the following location:

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

Consistent with section 50.2 of the Final Guidance and the Methodology, in making determinations about phase-in eligibility, CMS reviewed ownership data submitted and attested to by all participating manufacturers in HPMS and any supplemental information they provided, along with other CMS data, publicly available information, and information from other manufacturers identified as being in the same controlled group under section 52(a) or (b) of the Internal Revenue Code of 1986. The determinations are based upon the information available at the time of review and are contingent upon the accuracy of that information. A phase-in eligibility determination could change if CMS learns that the information relied on was not accurate, or as a result of certain ownership changes that occur during the phase-in period in accordance with sections 1860D-14C(g)(4)(B)(ii)(III) and 1860D-14C(g)(4)(C)(ii)(III) of the Act, or a recalculation by CMS under section 50.2.2 of the Final Guidance.

More information about the Discount Program, including the Final Guidance, is available at:

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

Questions about the Discount Program may be sent to

PartDManufacturerDiscountProgram@cms.hhs.gov.