## Medicare Part D Manufacturer Discount Program: Instructions for Participation

As explained in section 40 of the *Medicare Part D Manufacturer Discount Program Final Guidance* (Final Guidance), <sup>1</sup> effective January 1, 2025, Part D coverage for applicable drugs—that

is, brand name drugs and biological products—is available only for applicable drugs covered by a Medicare Part D Manufacturer Discount Program (Discount Program) agreement with CMS. These instructions provide details for pharmaceutical manufacturers that <u>do not</u> currently participate in the Discount Program under their own contract "P" number on the process to enter into a Discount Program agreement, including requesting a P number, securing Health Plan Management System (HPMS) access, submitting required ownership information, and signing the Discount Program and Third Party Administrator (TPA) Agreements. As per section 80.1.2 of the Final Guidance, manufacturers with an existing Discount Program agreement do not need to renew their agreement to continue to participate in the program.

# Request a P Number

Manufacturers of brand name drugs that want to participate in Part D must obtain a Part D contract P number to initiate the contracting process. Manufacturers that do not currently have a Part D P number should email the following information to <a href="mailto:PartDManufacturerDiscountProgram@cms.hhs.gov">PartDManufacturerDiscountProgram@cms.hhs.gov</a> with the subject line "[manufacturer name] Request for P Number":

- Program type: either Part D or Part D with Part B,
- Manufacturer name,
- DUNs number, and
- Primary contact first and last name, email, and phone number.

Manufacturers with Part B-only P numbers that are seeking a Part D P number in order to participate in the Discount Program should email <a href="https://example.com/HPMSConsultantAccess@cms.hhs.gov">HPMSConsultantAccess@cms.hhs.gov</a> to request that their Part B-only P number be converted to a Part D with Part B P number.

### **Obtain HPMS User and Signatory Access**

Manufacturers must use HPMS to complete all subsequent steps for executing a Discount Program agreement. For instructions on how to obtain HPMS user and signatory access, see the May 4, 2023 memorandum entitled *Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)*.<sup>2</sup>

### **Provide and Attest to Ownership Data**

As described in section 50.2 of the Final Guidance, CMS will analyze a manufacturer's ownership data alongside other information to determine a participating manufacturer's Discount Program discount phase-in eligibility.<sup>3</sup> Accordingly, manufacturers must enter ownership data in the

<sup>&</sup>lt;sup>1</sup> https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf

<sup>&</sup>lt;sup>2</sup> https://www.cms.gov/files/document/instructions-requesting-drug-manufacturer-access-hpms.pdf

<sup>&</sup>lt;sup>3</sup> Also see the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified

Manufacturer Discount Program module in HPMS prior to signing a Discount Program agreement.

Manufacturers must enter required contract and contact data in the Drug Manufacturer Contract Management module before submitting required ownership data in the Manufacturer Discount Program module. A red exclamation point will display on the Ownership Data page in the Manufacturer Discount Program module if required information is missing in the Drug Manufacturer Contract Management module.

# **Review and Sign Manufacturer Agreements**

As described in sections 80.1, 80.3, and 80.4 of the Final Guidance, in order to participate in the Discount Program, manufacturers must review and sign the Discount Program and TPA agreements in HPMS. The agreements may be previewed on the Part D Information for Pharmaceutical Manufacturers page.<sup>4</sup> in the Downloads section.

Beginning January 1, 2026, Discount Program agreement effective dates will always be the first day of a calendar quarter. In order for an agreement to be effective on the first day of the next calendar quarter, manufacturers must sign the agreement no later than the last day of the first month of a calendar quarter. If a manufacturer enters into the agreement after the last day of the first month of a particular calendar quarter, the initial term will begin on the first day of the second calendar quarter after the calendar quarter in which the manufacturer signed the agreement.

Agreement Effective	Manufacturer Signature	Manufacturer Signature
Date	Window Begins	Window Ends
January 1	August 1	October 31
April 1	November 1	January 31
July 1	February 1	April 30
October 1	May 1	July 31

#### **Additional Information**

Manufacturers should refer to the Final Guidance and the Part D Information for Pharmaceutical Manufacturers webpage for other important Discount Program information not contained within this memorandum.

For questions related to the Manufacturer Discount Program, contact PartDManufacturerDiscountProgram@cms.hhs.gov.

For questions related to HPMS user access, including signatory access, contact <u>HPMSConsultantAccess@cms.hhs.gov</u>.

Manufacturers and Specified Small Manufacturers for more information:

 $<sup>\</sup>underline{\text{https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf-0}.$ 

<sup>&</sup>lt;sup>4</sup> https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers