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DATE: September 4, 2024

TO: Drug Manufacturers

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SUBJECT: September 2024 Drug Manufacturer Module Enhancements

On September 13, 2024, CMS will release the following enhancements to the Drug Manufacturer Contract Management module in the Health Plan Management System (HPMS) to support implementation of the [Medicare Prescription Drug Inflation Rebate Program](#) and [Discarded Drug Refund Program](#) and other updates and improvements:

- CMS will begin issuing P numbers to manufacturers of drugs that are **only covered under Part B** and are **not** currently enrolled in HPMS for the Part D Manufacturer Discount Program (MDP). Instructions for requesting a Part B-only P number will be disseminated under separate cover.
 - Additional information on enrollment for the Medicare Prescription Drug Inflation Rebate Program will be available this fall.
 - Manufacturers of drugs that may be covered under Part D, but do not yet have a P number, should **not** use this process. Manufacturers that have not already entered into an MDP agreement and would like to participate beginning in 2026 cannot request a P number at this time. Instructions about this process will be issued at a later date.
- Manufacturers with an existing P number(s) will be required to indicate if their organization also manufactures drugs covered under Part B.
- Using the information supplied by manufacturers in this module, CMS will implement a new “program type” field to indicate whether manufacturer’s P number is for drugs covered under Part D only, drugs covered under Part D and drugs covered under Part B, or drugs covered under Part B only.

- CMS will implement the following changes to the Labeler Code Monthly Update Report for 2025:
 - Adding the labeler code termination date (to denote when a labeler code is no longer covered by a Manufacturer Discount Program agreement)
 - Adding the phase-in eligibility status
- The Primary Contact must have a U.S. phone number.
- Manufacturers will be required to enter the following P number-level contacts by **October 31, 2024**:
 - Compliance Contact
 - Discarded Drug Program Contact (only required for P numbers that manufacture Part B drugs)
 - Manufacturers will also have the *option* to enter Discarded Drug contacts at the labeler code-level.
- For the Medicare Inflation Rebate program, manufacturers will be required to enter the following P number-level contacts by **December 15, 2024**.
 - Inflation Rebate Administrator Contact
 - Inflation Rebate Payment Initiator Contact
 - Inflation Rebate Reports Contact
- Manufacturers will have the *option* to enter the following P number-level contacts:
 - Secondary Inflation Rebate Administrator Contact
 - Secondary Inflation Rebate Payment Initiator Contact
 - Secondary Inflation Rebate Reports Contact
- Manufacturers will also have the *option* to enter Inflation Rebate contacts at the labeler code-level.
 - **Additional information on this labeler code-level option and on the privileges of the required and optional Inflation Rebate contact roles for the Medicare Prescription Drug Inflation Rebate Program enrollment will be available this fall.**

CMS will be using the Third Party Administrator's (TPA's) Manufacturer Payment Portal (MPP) website that currently supports the Coverage Gap Discount Program (CGDP) to support the Medicare Prescription Drug Inflation Rebate Program (Inflation Rebate) and Discarded Drug program operations. Specifically, the TPA will use the Inflation Rebate and Discarded Drug contact information collected in HPMS to assign manufacturer user access to the MPP.

Labeler Code-Level Contacts

As described above, CMS will provide manufacturers with the ability to enter Inflation Rebate and Discarded Drug contacts at the P number-level (required) but will also give manufacturers the opportunity to enter contacts for these programs at the labeler code-level(s) (optional). Manufacturers will have the option to enter these contacts for one or more labeler codes under their P number if they want to limit end user access to Inflation Rebate and/or Discarded Drug data and invoices at the associated individual labeler code level.

If there is no need to limit access in the TPA's MPP system, the manufacturer will only enter the P number-level Inflation Rebate and Discarded Drug contacts. In this scenario, there would be no need to enter labeler code-level contact data.

However, if a P number has a business need to limit access in the MPP for either the Inflation Rebate or Discarded Drug program to one or more labeler codes, the manufacturer must complete the labeler code-level Inflation Rebate or Discarded Drug contacts **for only the impacted labeler codes**. For the non-impacted labeler codes, the TPA will use the P number-level contacts.

Example: Manufacturer A is responsible for P9999. P9999 has three labeler codes (00001, 00002, and 00003). Labeler codes 00001 and 00002 are affiliated with manufacturer A, but labeler code 00003 is affiliated with manufacturer B.

- If manufacturer B's agreement with manufacturer A permits access to the Inflation Rebate and/or Discarded Drug data for labeler code 00003, then manufacturer A will enter the Inflation Rebate and/or Discarded Drug contacts at the P number-level in HPMS. The TPA will apply Inflation Rebate and/or Discarded Drug MPP system access using the P number level contacts.
- If manufacturer B's agreement with manufacturer A does not permit access to the Inflation Rebate and/or Discarded Drug data for labeler code 00003, then manufacturer A must enter:
 - P number-level Inflation Rebate and/or Discarded Drug contacts; and
 - Labeler code-level Inflation Rebate and/or Discarded Drug contacts for labeler code 00003 only.
- The TPA will grant MPP system access for labeler codes 00001 and 00002 to the P number-level contacts and MPP system access for labeler code 00003 to the labeler code-level contacts.

Manufacturers must complete all new data entry and Compliance and Discarded Drug contact information in the Drug Manufacturer Contract Management module no later than **October 31, 2024**.

Regarding the new Medicare Prescription Drug Inflation Rebate Program, manufacturers must complete all new data entry in the Drug Manufacturer Contract Management module relevant to inflation rebate implementation no later than **December 15, 2024**. CMS will provide more information on Inflation Rebate HPMS contact roles and privileges and relation to MPP enrollment this fall.

Please contact Kristy Holtje at Kristy.Holtje@cms.hhs.gov for questions about this memo.