



MEDICARE DRUG REBATE AND NEGOTIATIONS GROUP

DATE: November 21, 2024

TO: Drug Manufacturers

FROM: Christina Ritter, Director
Medicare Drug Rebate and Negotiations Group

SUBJECT: Action Needed: Medicare Prescription Drug Inflation Rebate Program Onboarding

Dear Drug Manufacturers:

In August 2022, the Inflation Reduction Act (IRA) of 2022 (P.L. 117-169) was signed into law. Among many other provisions, this landmark law requires drug companies that raise the prices of certain drugs faster than the rate of inflation to pay Medicare a rebate. To implement the Medicare Prescription Drug Inflation Rebate Program (“Inflation Rebates”) for drugs covered under Part B and Part D, the Centers for Medicare & Medicaid Services (CMS) intends to utilize an online Manufacturer Payment Portal (MPP).

If you are in receipt of this memo and are not your company’s contact for the Medicare Prescription Drug Inflation Rebate Program, please forward as appropriate.

In an effort to reduce the burden on end users, CMS is building the MPP—enhancing and expanding the current Coverage Gap Discount Program (CGDP) Portal—to serve as a centralized location for authorized manufacturer points of contact to view information (including invoices and reports), and to take actions (e.g., make payments) for Inflation Rebates and other CMS programs (e.g., Manufacturer Discount Program (MDP)). Program-specific guidance for each program housed in the new MPP will be provided as the program goes live.

The purpose of this memo is to provide program-specific guidance for Inflation Rebates. Starting now, manufacturers of drugs covered under Part B and/or Part D should begin the process of gaining access to the MPP for Inflation Rebates. This memo details the steps that manufacturers must take to gain access to this portal and their action timeline. CMS intends to use the CMS Health Plan Management System (“the CMS HPMS”) Drug Manufacturer Contract Management Module to manage access to the MPP. Therefore, as a first step, manufacturers should complete the following items (unless indicated as optional) in the CMS HPMS by **January 15, 2025**, in order to gain timely access to the Inflation Rebates information in the MPP. More information on the timing and process for the MPP enrollment for Inflation Rebates will be made available to those contacts registered in the CMS HPMS in the coming months.

- **Manufacturers of drugs covered under Part B only**
 - Request a P Number if the manufacturer is not already affiliated with a P Number (e.g., if a manufacturer already requested a P Number for the Discarded Drug Program, they should use this P Number for Inflation Rebates)

- **Manufacturers of drugs covered under Part B and Part D**
 - Indicate if an existing P Number for Part D is affiliated with a manufacturer of drug(s) covered under Part B

- **All manufacturers**
 - Enter Primary Inflation Rebate contacts at the P Number level
 - Optionally enter Secondary Inflation Rebate contacts at the P Number level
 - Submit requests to add, terminate, or transfer labeler codes in CMS HPMS, as needed
 - If the manufacturer chooses to receive invoices at the labeler code level, enter Primary and Secondary (optional) Inflation Rebate contacts at the labeler code level

Key Activities for Manufacturer Access to the MPP for the Medicare Prescription Drug Inflation Rebate Program in the CMS HPMS

In this section, CMS answers key questions around establishing Inflation Rebate contacts in the CMS HPMS for manufacturers to access Inflation Rebate information in the MPP.

How to Request a P Number and Gain Access to the CMS HPMS – for Manufacturers of Drugs Covered Under Part B Only:

To request a P Number, manufacturers should email the following information to IRAREbateandNegotiation@cms.hhs.gov:

- Manufacturer Legal Name
- Data Universal Numbering System (DUNS) Number
- Employer Identification Number (EIN)
- Primary Contact First and Last Name
- Primary Contact Email Address
- Primary Contact Phone Number

The subject line of the email should read “[Manufacturer Name] Request for P Number.” Once CMS receives the request and establishes the P Number in the CMS HPMS, the manufacturer’s Primary Contact will receive an email containing the pending P Number with further instructions for obtaining access to the CMS HPMS.

Please note if a manufacturer has already requested a P Number for the Discarded Drug Program, they should use this same P Number for Inflation Rebates, so they do not need to request a new P Number.

How to Indicate the Manufacturer(s) Affiliated with an Existing P Number also Manufacture Drugs Covered Under Part B – for Manufacturers of Drugs Covered under Part B and Part D:

Manufacturers of drugs covered under Part D that already have an assigned P Number in the CMS HPMS can indicate that an existing P Number for Part D also applies to drugs covered under Part B by taking the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Contract Data’ page
4. Change the ‘Program Type’ field to ‘Part D with Part B’ if the company also manufactures drugs covered under Part B

Note that CMS is not currently processing requests for new P Numbers for manufacturers of drugs covered under Part D that wish to participate in the MDP. CMS will release instructions at a later date regarding how manufacturers of drugs covered under Part D can request a P Number to participate in MDP for 2026.

How to Enter Inflation Rebate Points of Contact at the P Number-Level – for All Manufacturers:

To obtain access to Inflation Rebates information in the MPP once it goes live, an individual needs to be listed as an Inflation Rebates contact in the CMS HPMS. There are three (3) manufacturer contact types for Inflation Rebates, each of which may be assigned up to two (2) manufacturer *or* contractor contacts. Additionally, at least one contact *must* be assigned to a manufacturer and must have a valid manufacturer email address. A user with CMS HPMS access is able to assign any user, regardless of whether or not they have CMS HPMS access, as a contact for Inflation Rebates. Please note that only individuals listed as one of these contacts in the CMS HPMS will have access to Inflation Rebates information in the MPP. CMS strongly recommends that a manufacturer lists different individuals for each of the Inflation Rebate contact types.

1. For Inflation Rebates, manufacturers should enter the following P Number-level contacts by **January 15, 2025:**
 - **Primary Inflation Rebate Administrator Contact:** Individuals listed as Inflation Rebate Administrator Contacts will be able to view all invoices, view reports, modify banking information, and initiate payments
 - **Primary Inflation Rebate Payment Initiator Contact:** Individuals listed as Inflation Rebate Payment Initiators will be able to view all invoices, view reports, and initiate payments
 - **Primary Inflation Rebate Reports Contact:** Individuals listed as Inflation Rebate Reports Contacts will be able to view all invoices and reports

2. Manufacturers also have the *option* to enter the following P Number-level contacts:
 - **Secondary Inflation Rebate Administrator Contact:** This user has the same permissions as the Primary Inflation Rebate Administrator Contact
 - **Secondary Inflation Rebate Payment Initiator Contact:** This user has the same permissions as the Primary Inflation Rebate Payment Initiator Contact
 - **Secondary Inflation Rebate Reports Contact:** This user has the same permissions as the Primary Inflation Rebate Reports Contact

How to Manage Labeler Codes Affiliated with a P Number on CMS HPMS:

In the CMS HPMS, all manufacturers have the ability to add, terminate, or transfer labeler codes. The below instructions are also in the user manuals in the CMS HPMS module.

To add a labeler code to a P Number, please take the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Labeler Codes’ page
4. Select the Add Labeler button above the Approved Labeler Codes table, and then select Add New. The Add Labeler Request pop-up window displays
5. Enter the labeler code, firm name, and reason for request
6. Select submit once all required fields are entered

To terminate a labeler code from a P Number, please take the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Labeler Codes’ page
4. In the Approved Labeler Codes table, select the trash can icon in the actions column in the row of the labeler code. The Terminate Labeler Request pop-up window displays.
5. Enter the reason for the request
6. Review the attestation text and select the checkbox to attest
7. Select submit once all required fields are entered

To delete a labeler code via a transfer (i.e., transfer an existing labeler code to a different P Number), please take the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Labeler Codes’ page

4. In the Approved Labeler Codes table, select the Transfer icon in the Actions column in the row of the labeler code. The Delete Labeler via Transfer Request pop-up window displays
5. Enter the target P Number that the labeler code will be transferred to in the Transfer Note field or provide other identifying information about the entity
6. Enter the reason for request
7. Select submit once all required fields are entered

To add a labeler code via a transfer (i.e., add a labeler code from another P Number), please take the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Labeler Codes’ page
4. Select the Add Labeler button above the Approved Labeler Codes table, and then select Add via Transfer. The Add via Transfer Labeler Request pop-up window displays
5. Select the Labeler Code drop-down list and select a labeler that the source contract previously submitted in a Delete via Transfer request
6. Update the firm name, if applicable
7. Enter the source P Number that the labeler code will be transferred from in the Transfer Note field or provide other identifying information about the entity
8. Enter the reason for request
9. Select submit once all required fields are entered

How to Enter Inflation Rebate Points of Contact at the Labeler Code-Level – for Manufacturers that Would Like the Option to Limit End User Access to Inflation Rebate Data and Invoices in the MPP

In the CMS HPMS, all manufacturers will have the ability to add one or more labeler codes to their P Number and CMS will give manufacturers the opportunity to optionally enter contacts at the *labeler code level* for the Medicare Prescription Drug Inflation Rebate Program.

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 data and invoices at the associated individual labeler code level. For example, if a manufacturer has an agreement with the owner of a P Number to manage the Manufacturer Discount Program for its labeler code, but they want to handle Inflation Rebates invoices themselves, they may want to separate their labeler code from the P Number for purposes of Inflation Rebates and provide contacts at the labeler code level.

If a manufacturer would like to separate their labeler code from their P Number, they must enter Inflation Rebate contacts at the labeler code level, otherwise, the Inflation Rebate contacts defaults to the P Number-level in the MPP.

To enter Inflation Rebate contacts at the labeler code level, please take the following steps:

1. Log in to the CMS HPMS and navigate to the ‘Drug Manufacturer Contract Management Module’
2. Select a P Number from the drop-down list
3. Use the left sidebar to navigate to the ‘Manage Contact Data’ page
4. Scroll to the bottom of the page to the ‘Manage Contact Data – Labeler Code Level Contacts’
5. Select a labeler code from the drop-down list
6. Select ‘Edit Contacts’ in the ‘Manage Contact Data – Labeler Code Level Contacts’ section
7. Enter contact information for each Primary Inflation Rebate contact type. Please note that if you enter one Primary Inflation Rebate contact, you will need to enter the other two contact types as well
8. A user may enter optional contact information for the Secondary Inflation Rebate contacts

For more information on gaining access to the CMS HPMS and entering Inflation Rebate contacts, please refer to the *September 4, 2024* and *September 13, 2024* HPMS memos, posted to CMS.gov at: <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly>.

If you have CMS HPMS access questions, please email the CMS HPMS Help Desk at HPMS@cms.hhs.gov.

Please direct any questions regarding Medicare Prescription Drug Inflation Rebate Program Manufacturer Onboarding to IRAREbateandNegotiation@cms.hhs.gov.

We appreciate your attention to this effort.