Discarded Drug Program Manufacturer Quick Reference

Manufacturers play an active role in the discarded drug refund calculation process, from timely input of quarterly data to accurate record keeping. This quick reference guide of high-level steps is designed to aid manufacturers during the discarded drug refund calculation process and to ensure compliance with legislation to avoid civil monetary penalties. For more information, visit the CMS Discarded Drugs website. Contact us at: DiscardedDrugs@cms.hhs.gov.

Request a P Number

CMS uses P Numbers to identify manufacturer accounts in the Health Plan Management System (HPMS) for various programs such as the Inflation Reduction Act's Medicare Prescription Drug Inflation Rebate Program and the Medicare Part B Discarded Drug Program. If you are new to the Discarded Drug Program, and have not been issued a P Number, please submit the following information via email to DiscardedDrugs@cms.hhs.gov to request a P Number:

- 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
- Subject Line of the Email Should Read "[Manufacturer Name] Request for P Number"

After you send your request, CMS will contact you should we require any additional information to issue a P Number. Once your P Number is issued, a representative from Palmetto GBA, a contractor serving as CMS' third-party administrator (TPA) for the invoicing and payment processes, will reach out to begin the HPMS onboarding process.

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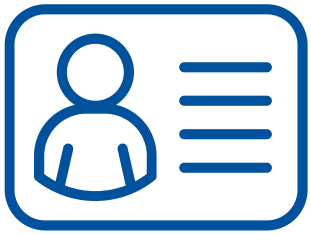

To Access the Manufacturer Payment Portal for the First Time, Update the HPMS Account

The Manufacturer Payment Portal (MPP) is the module used to manage Discarded Drug Refund Reports and pay refund amounts due. There are two actions manufacturers must complete in HPMS in order to gain access to the MPP: select the appropriate program designation and assign a Discarded Drug Program contact. These steps also apply to Part D manufacturers who now are a part of the Part B Discarded Drug Refund Program.

Select Program Type:

- Log in to HPMS and navigate to the **Drug Manufacturer Contract Management** module.
- Enter your P Number or select it from the drop down menu on the landing page.
- From the left-hand navigation, select **Manage Contract Data**.
- Under the manufacturer name, click the **Program Type** drop-down menu. Select either **Part B** (for manufacturers of only Part B drugs) or **Part D with Part B** (for manufacturers of both Part B and Part D drugs).
- Click **Save**.
- Once you click **Save**, the system updates the **Dashboard** page to show your selection.

Enter the Discarded Drug Program Contact Information:

- From the left-hand navigation select **Manage Contacts**.
- Select **Edit Contacts** button on the right side of the **Contacts** list.
- Enter the discarded drug contact's required information, all indicated with an asterisk.

Once these steps are complete, the TPA can create an account in the MPP. For technical assistance with HPMS, contact hpms@cms.hhs.gov.

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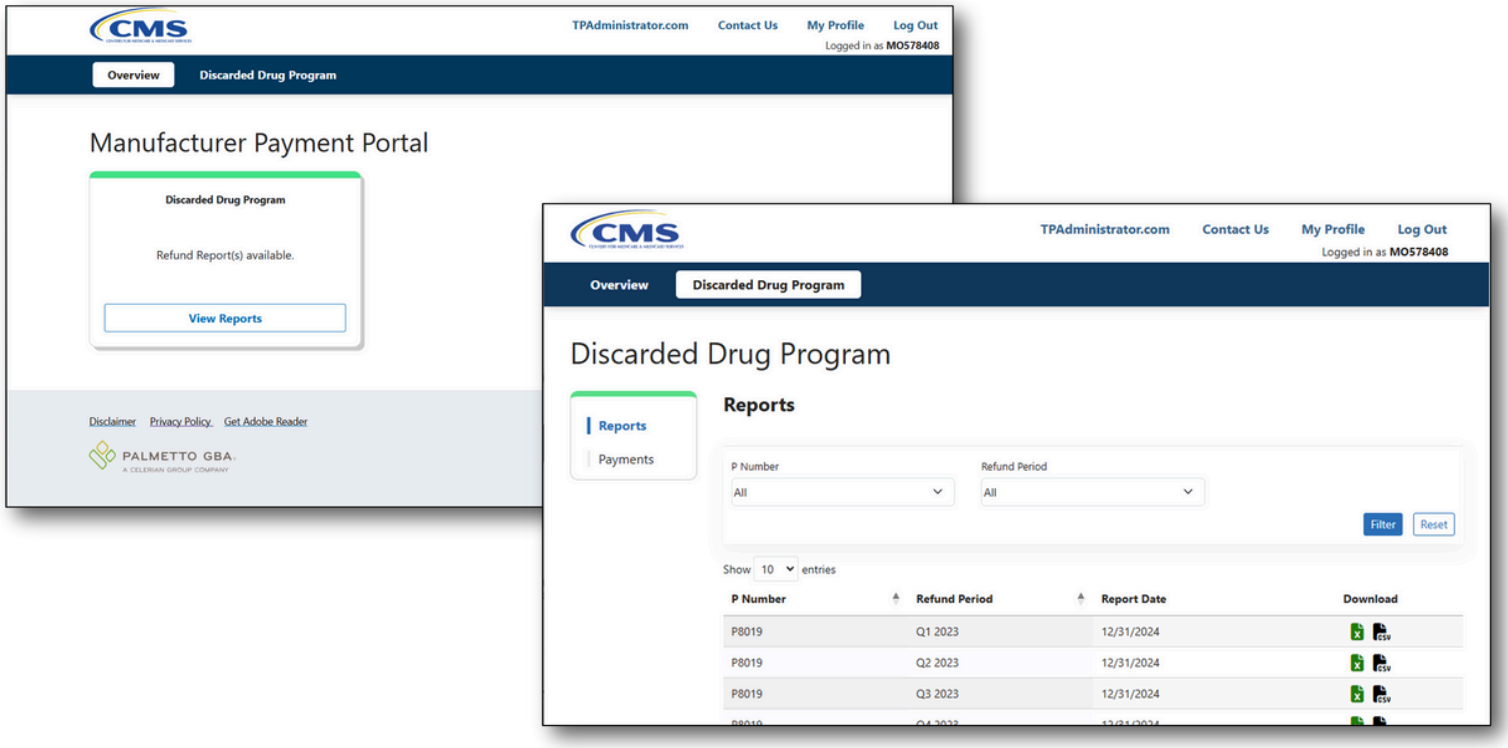
View Reports in MPP

Discarded Drug Refund Reports will be distributed annually to manufacturers via the MPP. These reports will include information on the total number of billing units of the refundable drug, if any, that were discarded in each calendar quarter and the refund amount due for each calendar quarter.

To view your report:

- From the TPA Website, click the **MPP Login**.
- Enter your Login credentials provided by TPA.
- Navigate to the **Discarded Drug Program** tile. If there are reports available, there will be a clickable box labeled **View Reports**.
- Click **View Reports**.
- On the **Reports** page, you can filter by **P Number** or **Refund Period** to find specific reports.
- Sort by columns in the table and download individual reports for additional details.

For technical assistance with MPP, contact tpaoperations@tpadministrator.com.



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Pay Refunds Due in MPP

Manufacturers pay their refunds due in MPP. Payment for refund amounts specified in the refund report is due by December 31 of the year in which the report is sent, except for the initial report for calendar quarters in 2023, which is due no later than February 28, 2025. If a dispute is pending, payment will be due on the due date of the initial report or no later than 30 days after the dispute has been resolved, whichever is later. (42 CFR § 414.940(b)(1) and (2)).

To pay refunds due:

- Log in to MPP.
- Navigate to **Discarded Drug Program**.
- Click **View Reports**.
- From the left navigation, click **Payments**.
- To initiate individual payments:
  - Click the **Initiate Payment** checkbox next to the line(s) you wish to pay.
  - Select the payment date, which defaults to today's date.
  - Click **Submit**.
- To initiate payment for all line items:
  - Check the box next to **Initiate All Payments** at the bottom right of the page.
  - Select the payment date, which defaults to today's date.
  - Click **Submit**.
- After clicking **Submit** with any of these options, the system will prompt you to enter your personal identification number (PIN) to complete the payment process.
- You can view all payments recently initiated on the **Payments Pending** tab, and all payments that have begun processing or have processed on the **Payments Submitted** tab.

For technical assistance with MPP, contact tpaoperations@tpadministrator.com.

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File an Error Report

Manufacturers of Part B drugs may submit one error report (also known as a dispute) for each drug to assert that there have been one or more errors in the refund report. Manufacturers have 30 days after receipt of their refund report(s) to submit an error report. To submit an error report, provide the following information in a written request to DiscardedDrugs@cms.hhs.gov within 30 days of receiving the refund report/invoices:

- Manufacturer name and address
- Name, telephone, and email address of one or more employees of the manufacturer
- For a mathematical calculation error, include:
  - The specific calculation element(s) that the manufacturer disputes
  - The proposed corrected calculation
- For any other asserted error, include:
  - An explanation of the nature of the error
  - How the error affects the refund calculation
  - An explanation of why the manufacturer believes that an error occurred
  - The proposed correction to the error
  - An explanation of why CMS should use the proposed corrected data

CMS will contact you should any additional information be required for your error report. If an error report is denied, payment will be due 30 days from the date of resolution or the original invoice due date, whichever is later. Have questions? Contact us at: DiscardedDrugs@cms.hhs.gov.

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