



# Discarded Drug Program Webinar

December 5, 2024

# Welcome



Thank you for joining our **Discarded Drug Program** webinar.

- This session will be recorded and posted.
- Participants can submit questions via the Q&A feature.
- This is approximately a one-hour session with time for questions at the end.

# Agenda

Topic	Presenter
Introductory Remarks	Mark Bremer, CMS
Discarded Drug Program Overview	Katie Wilder, Contractor
Refund Calculations and Timeline	Katie Wilder, Contractor
Manufacturer Payment Portal Overview	TPA Representative, Contractor
Available Resources	Katie Wilder, Contractor
Q&A Session	Suzanne Bromley, Contractor
Closing Remarks	Mark Bremer, CMS

# Goals



- Provide an overview of the Discarded Drug Program
- Demonstrate how to:
  - Access Discarded Drug Refund Reports in the Manufacturer Payment Portal (MPP)
  - Pay any refund amounts due in MPP
- Answer your Discarded Drug Program questions

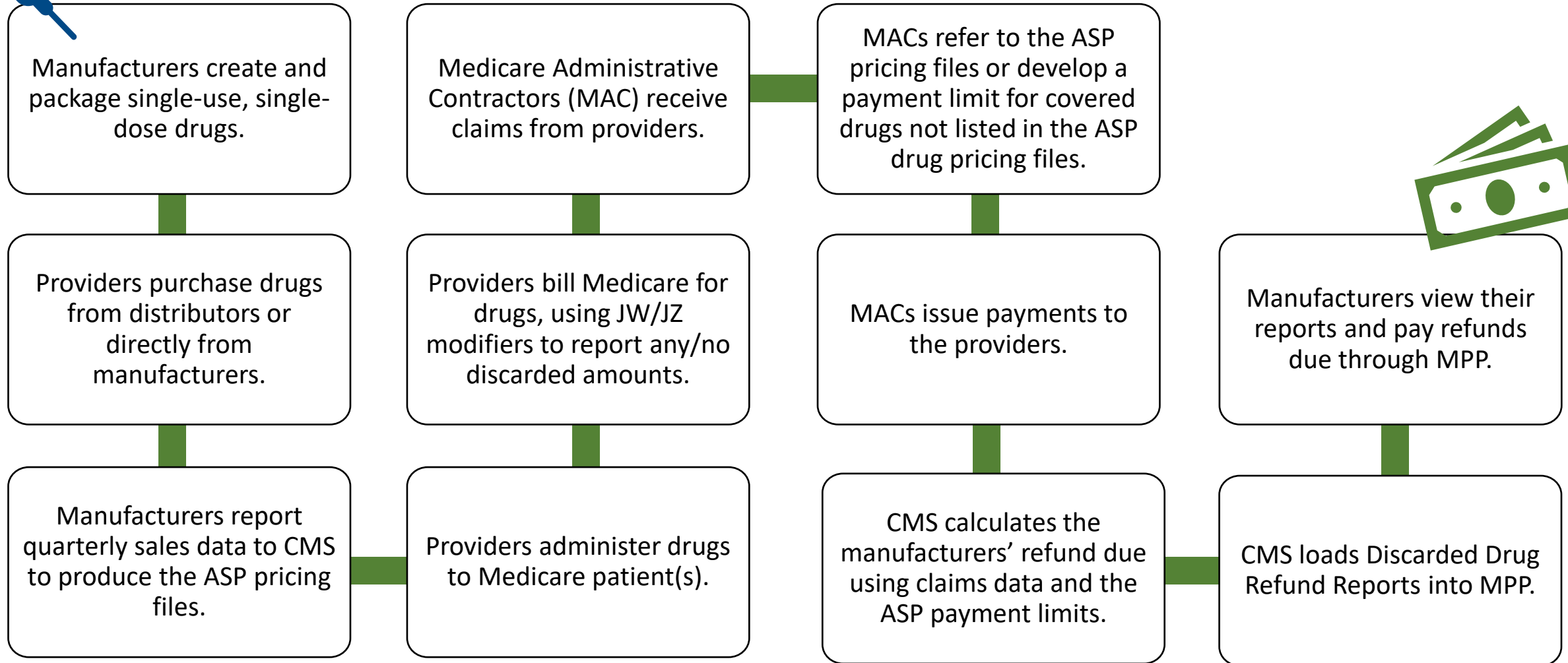
# Discarded Drug Program

Section 90004 of the Infrastructure Investment and Jobs Act (2021) requires manufacturers to provide a refund to CMS for the discarded amounts from drugs that meet certain criteria.

Manufacturers who fail to comply with the requirement under [42 CFR § 414.940\(b\)](#) will be subject to a Civil Monetary Penalty (CMP) equal to the sum of 125 percent of the assessed refund obligation.



# Discarded Drug Payment Lifecycle



# Definition of Refundable Drug



## Inclusion Criteria

- Single-source drug or biological, including biosimilars
- Must be furnished from a single-use package or single-dose container
- All national drug codes (NDCs) assigned to the drug's billing and payment code must be single-dose, as described in each product's labeling
- Payment is made under Medicare Part B



## Exclusion Criteria

- Radiopharmaceutical (therapeutic or diagnostic) or imaging agents
- Certain drugs or biologicals requiring filtration during preparation (prior to dilution and administration) for which unused portions must be discarded after the filtration process
- Drugs or biologicals approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first reported sale for any NDCs of such drug

# Tracking Discarded Drug Units

## History



- Effective **January 2017**, providers and suppliers are required to report the JW modifier on all claims that bill for drugs and biologicals separately payable under Medicare Part B with unused and/or discarded amounts.
- Starting in **July 2023**, the JZ modifier was added to track all such drugs with no discarded amounts.

## Definitions



- **Discarded amount:** Any amount of drug that is not a part of the dose and is not intended to have a therapeutic effect in the patient, up to the amount identified on the FDA-approved label.
- **JW Modifier:** Used on a Medicare Part B claim to denote the portion of the drug that was discarded.
- **JZ Modifier:** Used on a Medicare Part B claim to indicate no portion of the drug was discarded.



# Applicable Percentages

An applicable percentage is essentially the **discarded amount threshold** for a specific drug. The applicable percentage is used in the calculation of the refund amount due from manufacturers. It is required to be at least **10%**, but can be increased through notice-and-comment rulemaking for drugs with unique circumstances.



The following are increased applicable percentages for drugs with unique circumstances:

- **35%** - Drug reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics
- **90%** - Low volume dose drug contained within 0.1 mL or less
- **45%** - Low volume dose drug contained within 0.11 mL up to 0.4 mL
- **26%** - Designated orphan drugs under Section 526 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that are furnished to fewer than 100 unique beneficiaries per calendar year

# Calculation



**Manufacturer  
Refund Due**

=



**Total Number of  
Discarded Drug  
Units (JW units  
on claims data)**

×



**ASP Payment  
Limit**

-

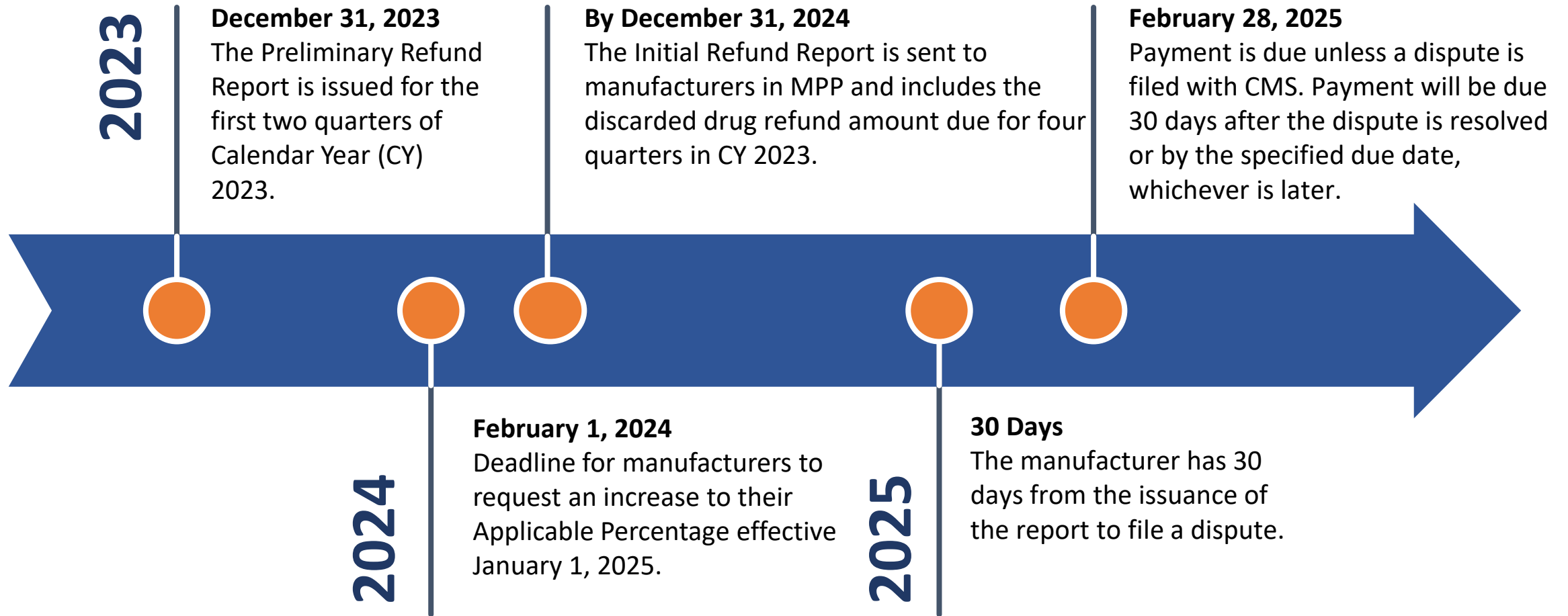


**Applicable  
Percentage  
Multiplied by  
Estimated Total  
Allowed Charges**

# Refund Calculation when Refundable Drugs have Multiple Manufacturers

Labeler Name	Billing Units Sold	Proportion of Units Sold	Refund Due Per Manufacturer
Labeler A	5,000	50%	\$5,000.00
Labeler B	1,500	15%	\$1,500.00
Labeler C	3,500	35%	\$3,500.00
<i>Total</i>	<i>10,000</i>	<i>100%</i>	<i>\$10,000.00</i>

# Initial Report Timeline



# Onboarding Process



## P Number Assignment

- A P Number is a unique identifier used in the Health Plan Management System (HPMS) to identify manufacturers and create accounts.
- Many manufacturers already have a P Number for participation in other programs, but some need a P Number issued for the Discarded Drug Program.
- Once a P Number is issued, a representative from the Third-Party Administrator (TPA) Support Center, Palmetto GBA, will contact the manufacturer.



## Health Plan Management System (HPMS) Account Creation

- Manufacturers must designate their Program Type (Part B or Part B and Part D) and provide contact information for a Discarded Drug Program Contact in HPMS.
- Manufacturers must ensure that the Discarded Drug Program Contact information in HPMS is accurate at all times.



## Manufacturer Payment Portal (MPP) Access

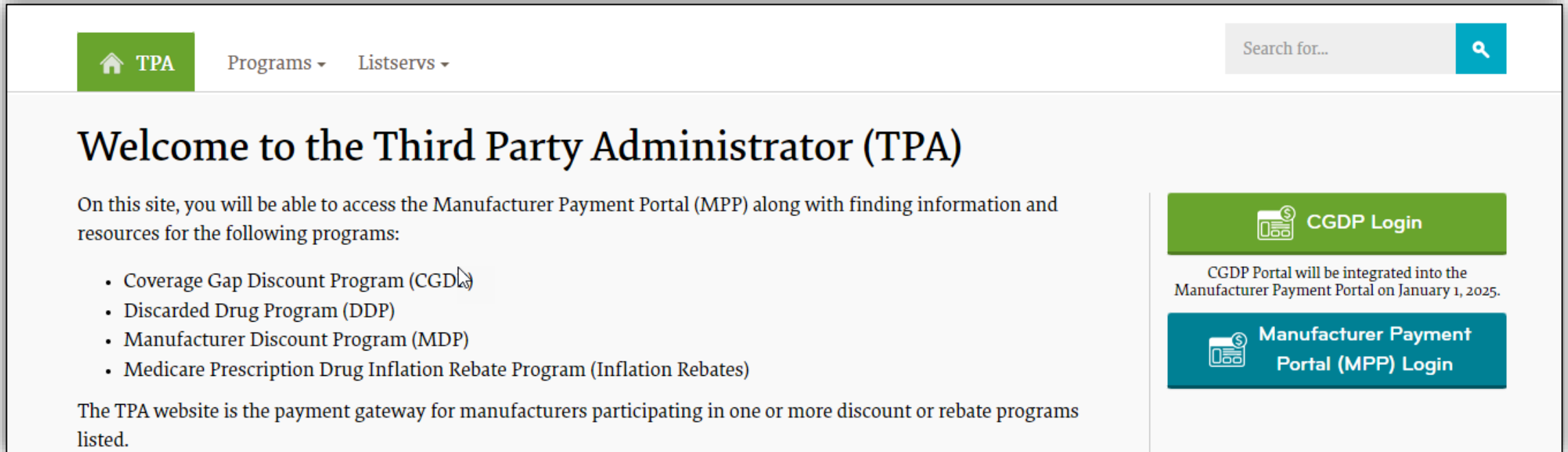
- TPA will use the Discarded Drug Program contact information collected in HPMS to assign manufacturer user access to the MPP.
- The Discarded Drug Program contact will be able to access reports and initiate payment for refunds due.
- The link to the new portal will be located on the home page of the TPA website ([www.tpadministrator.com](http://www.tpadministrator.com)).

# Requesting a P Number

Email [DiscardedDrugs@cms.hhs.gov](mailto:DiscardedDrugs@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
- Subject Line of the Email Should Read “[Manufacturer Name] Request for P Number”

# TPA Website



The screenshot shows the homepage of the TPA website. At the top left, there is a green navigation bar with a home icon and the text 'TPA'. To its right are two dropdown menus labeled 'Programs' and 'Listsers'. On the top right, there is a search bar with the placeholder text 'Search for...' and a magnifying glass icon. The main content area features a large heading 'Welcome to the Third Party Administrator (TPA)'. Below this heading is a paragraph explaining that users can access the Manufacturer Payment Portal (MPP) and find information and resources for several programs. A bulleted list follows, listing the Coverage Gap Discount Program (CGDP), Discarded Drug Program (DDP), Manufacturer Discount Program (MDP), and Medicare Prescription Drug Inflation Rebate Program (Inflation Rebates). Below the list is a paragraph stating that the TPA website is the payment gateway for manufacturers. On the right side of the page, there are two prominent buttons: a green one for 'CGDP Login' and a teal one for 'Manufacturer Payment Portal (MPP) Login'. Between these buttons is a notice stating that the CGDP Portal will be integrated into the MPP on January 1, 2025.

Home TPA Programs ▾ Listsers ▾


Search for... 🔍

## Welcome to the Third Party Administrator (TPA)


On this site, you will be able to access the Manufacturer Payment Portal (MPP) along with finding information and resources for the following programs:

- Coverage Gap Discount Program (CGDP)
- Discarded Drug Program (DDP)
- Manufacturer Discount Program (MDP)
- Medicare Prescription Drug Inflation Rebate Program (Inflation Rebates)

The TPA website is the payment gateway for manufacturers participating in one or more discount or rebate programs listed.

 **CGDP Login**

CGDP Portal will be integrated into the Manufacturer Payment Portal on January 1, 2025.

 **Manufacturer Payment Portal (MPP) Login**

# Accessing MPP

The screenshot shows the Manufacturer Payment Portal (MPP) login page. At the top left is the CMS logo (Centers for Medicare & Medicaid Services). At the top right are navigation links: TPAAdministrator.com, HPMS Website, Contact Us, and ListServ Sign Up. The main heading is "Welcome to the Manufacturer Payment Portal". Below this is a paragraph explaining the MPP's purpose and a bulleted list of programs, including the Discarded Drug Program (DDP). On the right side, there is a "Log in" section with a "Create account" link, input fields for "User ID" and "Password", and "Login" and "Forgot Password?" buttons. A callout box at the bottom left provides details about the DDP, including its legal basis and a "Visit DDP Resources" button.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

TPAAdministrator.com HPMS Website Contact Us ListServ Sign Up

## Welcome to the Manufacturer Payment Portal

The Manufacturer Payment Portal (MPP) serves as the gateway to programs administered by the Third Party Administrator (TPA) for the Centers for Medicare & Medicaid Services (CMS). With approved single sign-on (SSO) and role-based responsibilities, authorized users can access the following programs:


- Discarded Drug Program (DDP)

### Log in

Don't have an account? [Create account](#)

**User ID \***

**Password \***

[Login](#) [Forgot Password?](#)

#### Discarded Drug Program (DDP)

The Discarded Drug Program, created in response to Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021) which amended section 1847A of the Social Security Act, requires manufacturers to provide a refund to CMS for certain discarded amounts from a single dose container or single-use package drug.

CMS will issue annual reports, with the TPA facilitating the report publishing and payment processes for refund amounts due.

[Visit DDP Resources](#)



# Landing Page - No Reports

The screenshot displays the CMS TP Administrator interface. At the top left is the CMS logo (Centers for Medicare & Medicaid Services). The top right navigation bar includes links for TPAdministrator.com, Contact Us, My Profile, and Log Out, with a user login status of MO578408. A dark blue navigation bar contains two tabs: Overview (selected) and Discarded Drug Program. The main content area features the heading 'Manufacturer Payment Portal' and a central white box with a green border. This box contains the text 'Discarded Drug Program' and 'No Report(s) available.' Below the main content, a footer section includes links for Disclaimer, Privacy Policy, and Get Adobe Reader, along with the Palmetto GBA logo and the text 'A CELERIAN GROUP COMPANY'.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES


TPAdministrator.com   Contact Us   My Profile   Log Out  
Logged in as **MO578408**

Overview   Discarded Drug Program

## Manufacturer Payment Portal

**Discarded Drug Program**  
No Report(s)  
available.

[Disclaimer](#)   [Privacy Policy](#)   [Get Adobe Reader](#)

 **PALMETTO GBA**  
A CELERIAN GROUP COMPANY

# My Profile (1 of 2)

The screenshot shows the 'My Profile' page of the CMS (Centers for Medicare & Medicaid Services) Manufacturer Payment Portal. The page is titled 'Manufacturer Payment Portal - My Profile' and welcomes the user 'MO578408'. At the top, there is a navigation bar with the CMS logo, 'TPAdministrator.com', 'Contact Us', 'My Profile', and 'Log Out'. Below this, a dark blue header contains 'Overview' and 'Discarded Drug Program'. The main content area features two buttons: 'Change Password' and 'Update PIN'. A central card displays a user profile icon, the title 'Discarded Drug', and a list of profile details: 'Company Information', 'Banking Information', and 'Roles & Access'. A 'View Profile' button is located at the bottom of this card.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

TPAdministrator.com Contact Us My Profile Log Out  
Logged in as MO578408

Overview Discarded Drug Program

## Manufacturer Payment Portal - My Profile

Welcome MO578408


Change Password Update PIN

**Discarded Drug**

- Company Information
- Banking Information
- Roles & Access

View Profile

# My Profile (2 of 2)

TPAdministrator.com Contact Us My Profile Log Out  
Logged in as MO578408

Overview Discarded Drug Program

## Discarded Drug Program - My Profile

[Profile Home](#) > Discarded Drug Program

**Organization Information**

**Name:** UAT Parent Org5

**Type:** Manufacturer

[Request Payer Account Modification](#)

### Associated Company EFT Information

Company ID	Name	Status	Begin Quarter	Payer Routing #	Payer Account #
All	All	All	All	All	All

[Filter](#) [Reset](#)

Show 10 entries

Company Id	Name	Status	Begin Quarter	Payer Routing #	Payer Account #
P8019	UAT Drug Company19	Active	202304	345667788	****8019
P8020	UAT Drug Company20	Active	202304	234567890	****8020
P8027	UAT Drug Company27	Active	202304	123123123	****8027

# Landing Page - Reports Available

The screenshot displays the CMS TPA Administrator portal. At the top left is the CMS logo (Centers for Medicare & Medicaid Services). The top right navigation bar includes links for TPAAdministrator.com, Contact Us, My Profile, and Log Out, with a user login status of "Logged in as MO578408". A dark blue header bar contains two tabs: "Overview" (active) and "Discarded Drug Program". The main content area is titled "Manufacturer Payment Portal" and features a central white notification box with a green top border. The notification box contains the text "Discarded Drug Program", "Refund Report(s) available.", and a blue "View Reports" button. The footer area is light gray and contains links for Disclaimer, Privacy Policy, and Get Adobe Reader, along with the Palmetto GBA logo and the text "PALMETTO GBA. A CELERIAN GROUP COMPANY".

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

TPAdministrator.com   Contact Us   My Profile   Log Out  
Logged in as **MO578408**

**Overview**   Discarded Drug Program


## Manufacturer Payment Portal

**Discarded Drug Program**

Refund Report(s) available.

[View Reports](#)

[Disclaimer](#)   [Privacy Policy](#)   [Get Adobe Reader](#)

 **PALMETTO GBA.**  
A CELERIAN GROUP COMPANY

# View Reports

The screenshot shows the CMS (Centers for Medicare & Medicaid Services) website interface for the Discarded Drug Program. The top navigation bar includes the CMS logo, the URL TPAAdministrator.com, and links for Contact Us, My Profile, and Log Out. The user is logged in as MO578408. The main navigation bar has 'Overview' and 'Discarded Drug Program' tabs. The 'Discarded Drug Program' section is active, displaying a 'Reports' sidebar with 'Reports' and 'Payments' options. The main content area is titled 'Discarded Drug Program' and features a 'Reports' section with two dropdown menus for 'P Number' and 'Refund Period', both currently set to 'All'. There are 'Filter' and 'Reset' buttons. Below the filters, a 'Show 10 entries' dropdown is visible. A table displays the report data with columns for P Number, Refund Period, Report Date, and Download. The table contains four rows of data, with the first three rows fully visible.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

TPAdministrator.com   Contact Us   My Profile   Log Out  
Logged in as **MO578408**

Overview   **Discarded Drug Program**

## Discarded Drug Program

**Reports**

Reports  
Payments

P Number: All   Refund Period: All

Filter   Reset

Show 10 entries


P Number	Refund Period	Report Date	Download
P8019	Q1 2023	12/31/2024	
P8019	Q2 2023	12/31/2024	
P8019	Q3 2023	12/31/2024	
P8019	Q4 2023	12/31/2024	

# Reports

The screenshot displays the Microsoft Excel interface with a report table. The ribbon is set to 'Home', and the active cell is B9. The report table contains the following data:

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Report Date	HCPCS Code	HCPCS Long Description	Labeler Code	P Number	Report Type	Reason Code	Invoice Quarter	Invoice Year	Units Discarded	Refund Amount Due	Due Date	
2	12/31/2024	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q1	2023	11,079.00	\$250,620.69	02/28/2025	
3	12/31/2024	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Initial		Q1	2023	4,320.00	\$3,872.23	02/28/2025	
4	12/31/2024	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Initial		Q1	2023	767.00	\$624.66	02/28/2025	
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													
16													

# Payments

TPAdministrator.com Contact Us My Profile Log Out  
Logged in as MO578408

Overview Discarded Drug Program

## Discarded Drug Program

Reports  
Payments

### Payments

Payable Pending Submitted

Drug:

P Number:

Refund Period:

Due Date:

Filter Reset

Show  entries

Drug	P Number	Labeler Code	Refund Period	Payment Amount	Failed	EFT ID	Due Date	Payment Date	Initiat Payme
J0001	P8019	12345	Q3 2023	\$228,423.45		DPIX24123...	02/28/2025	11/19/2024 <input type="text"/>	<input type="checkbox"/>

# Payments Payable

## Discarded Drug Program

Reports

Payments

### Payments

**i** Please Note: If you are planning to file an error report for this or any other discarded drug, please do not initiate payment. Payment will be due 30 days after the dispute is resolved or by the specified due date, whichever is later.

Payable

Pending

Submitted

Drug

All

P Number

All

Refund Period

All

Due Date

mm/dd/yyyy

mm/dd/yyyy

Filter

Reset



Payment successfully submitted. View pending payments on the Pending tab.

Show 10 entries

Drug	P Number	Labeler Code	Refund Period	Payment Amount	Failed	EFT ID	Due Date	Payment Date	Initiate Payment
J0001	P8019	12345	Q3 2023	\$228,423.45		DPIX24123...	02/28/2025	12/03/2024	<input type="checkbox"/>
J0001	P8019	12345	Q2 2023	\$295,294.27		DPIX24123...	02/28/2025	12/03/2024	<input type="checkbox"/>
J0001	P8019	12345	Q1 2023	\$250,620.69		DPIX24123...	02/28/2025	12/03/2024	<input type="checkbox"/>
J0003	P8019	34567	Q1 2023	\$624.66		DPIX24123...	02/28/2025	12/03/2024	<input type="checkbox"/>

Showing 1 to 4 of 4 entries

First

Previous

1

Next

Last

Update All Payment Dates

mm/dd/yyyy

Initiate All Payments

Submit



# Payments Pending

## Discarded Drug Program

Reports

**Payments**

**Payments**

**i** Stop payment function is available until approximately **6:00 PM PT** on the Payment Process Date.

**Payable** **Pending** **Submitted**

Drug: All P Number: All Refund Period: All

Due Date: mm/dd/yyyy mm/dd/yyyy

**Filter** **Reset**

Show 10 entries

Drug	P Number	Labeler Code	Refund Period	Pending Payment Amount	EFT ID	Payment Process Date	Due Date	Stop Payment
J0006	P8027	23456	Q3 2023	\$2,775.73	DPIX24123...	11/20/2024	02/28/2025	<input type="checkbox"/>
J0006	P8027	23456	Q4 2023	\$9,388.27	DPIX24123...	11/20/2024	02/28/2025	<input type="checkbox"/>

Showing 1 to 2 of 2 entries

First Previous **1** Next Last

Stop All Payments **Stop Payment**

# Payments Submitted

## Discarded Drug Program

Reports

Payments

### Payments

Payable Pending Submitted

Refund Period

All

Filter

Reset

Drug

P Number

Status

Payment Initiated Date

All

All

All

mm/dd/yyyy

mm/dd/yyyy

Filter

Reset

Show 10 entries



Drug	P Number	Labeler Code	Refund Period	Payment Amount	Payment Initiated Date	EFT ID	Due Date	Status
J0001	P8019	12345	Q4 2023	253467.61		DPIX24123...	02/28/2025	Success
J0004	P8020	56789	Q1 2023	3276890.28		DPIX24123...	02/28/2025	Processing
J0004	P8020	56789	Q4 2023	4061853.07		DPIX24123...	02/28/2025	Success
J0005	P8020	67890	Q4 2023	948491.41		DPIX24123...	02/28/2025	Processing
J0005	P8020	67890	Q1 2023	376434.6		DPIX24123...	02/28/2025	Processing

Showing 1 to 5 of 5 entries

First Previous 1 Next Last

# TPA Resources

The screenshot displays the CMS TPA Administrator website. At the top left is the CMS logo. In the top right, there are links for 'TPAdministrator.com' (highlighted with a red box), 'Contact Us', 'My Profile', and 'Log Out'. Below these links, it says 'Logged in as MO578408'. A dark blue navigation bar contains 'Overview' and 'Discarded Drug Program'. The main content area features the CMS logo, navigation links for 'Home', 'Archives', 'Contact Us', and 'CGDP Portal', and a search bar. A secondary navigation bar includes 'TPA', 'Programs', 'Frequently Asked Questions (FAQ)', and 'Listsers'. The breadcrumb trail shows 'Programs / Discarded Drug Program'. The main heading is 'Discarded Drug Program', published on 08/07/2024. The text explains that Section 90004 of the Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for certain discarded amounts. It also notes that refundable single-dose container or single-use package drugs approved or licensed by FDA on or after November 15, 2021 are excluded from the definition of refundable single-dose container or single-use package, and thus, not subject to a refund, for the first 6 full calendar quarters following the date of first reported sale for any NDCs of such drug (see 87 FR 69719 through 69724). A left sidebar lists various resources: Discarded Drug Program, Discarded Drug Reports, Disputes, EFT Information, Listsers, Onboarding, User Guides, and Webinars.

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

**TPAdministrator.com**   [Contact Us](#)   [My Profile](#)   [Log Out](#)  
Logged in as **MO578408**

**Overview**   **Discarded Drug Program**

**CMS**  
CENTERS FOR MEDICARE & MEDICAID SERVICES

[Home](#)   [Archives](#)   [Contact Us](#)   **CGDP Portal**

[TPA](#)   [Programs](#) ▾   [Frequently Asked Questions \(FAQ\)](#) ▾   [Listsers](#) ▾   Search for...

[Programs](#) / [Discarded Drug Program](#)

## Discarded Drug Program

Published 08/07/2024

Section 90004 of the Infrastructure Investment and Jobs Act ([Pub. L. 117-58](#), November 15, 2021) requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

Refundable single-dose container or single-use package drugs approved or licensed by FDA on or after November 15, 2021 are excluded from the definition of refundable single-dose container or single-use package, and thus, not subject to a refund, for the first 6 full calendar quarters following the date of first reported sale for any NDCs of such drug (see [87 FR 69719](#) through [69724](#)).

**Discarded Drug Program**

- Discarded Drug Reports
- Disputes
- EFT Information
- Listsers
- Onboarding
- User Guides
- Webinars

# CMS ASP Website

## Discarded Drugs Page

The screenshot shows the CMS.gov website with the navigation menu set to Medicare > Payment > Medicare Part B Drug Average Sales Price > Discarded Drugs. The main content area is titled "Discarded Drugs" and features an "Announcement" section with a blue background. Below this is an "Upcoming Webinar" section and an "Introduction" section. A "Discarded Drug Refund" section follows, providing detailed information about the refund process. At the bottom, there are two expandable sections: "What is a Refundable Drug?" and "How Are Discarded Amounts of Refundable Drugs Identified?".

## ASP Education & Outreach Page

The screenshot shows the CMS.gov website with the navigation menu set to Medicare > Payment > Medicare Part B Drug Average Sales Price > ASP Education & Outreach. The main content area is titled "ASP Education & Outreach" and includes an "Announcement" section about a webinar on Thursday, December 5, 2024. Below this is a section stating that CMS collects ASP data from manufacturers. A table of "Show Entries" is displayed, showing 1-10 of 17 entries. The table has columns for Date, Title, Description, and Format.

Date	Title	Description	Format
2024-11-12	Discarded Drug Program Overview	An overview of the Discarded Drug Program requires manufacturers of certain Part B Drugs to pay a refund to CMS for the portion of the drug that is discarded.	PDF
2024-06-20	Manufacturers' Guide to Correcting Average Sales Price (ASP)	Guidance for manufacturers on what to do and what to expect if there is an error in previously submitted ASP data.	PDF
2024-06-20	Average Sales Price (ASP) Restatement Policy Overview	A summary of CMS' Restatement Policy including details for corrections and criteria for issuing a restatement of ASP payment limits.	PDF
2024-05-16	Part B Drug Payment Limits Overview	A fact sheet explaining the ASP payment limit calculation and other Medicare Part B drug payment methodologies.	PDF
2024-05-03	Steps to Submit Part B Financial Data to CMS	A high-level overview of the key steps for manufacturers to register with the ASP Data Collection System and submit Part B drug product and financial data to CMS.	PDF
2024-03-23	ASP Data Collection System Upgrade Release Notes- April 1st, 2024	A comprehensive list of the specific changes to various elements in the ASP Data Collection System effective April 1, 2024.	PDF

## ASP Events Page

The screenshot shows the CMS.gov website with the navigation menu set to Medicare > Payment > Medicare Part B Drug Average Sales Price > ASP Events. The main content area is titled "ASP Events" and includes an "Announcement" section about a webinar on Thursday, December 5, 2024. Below this is a "Materials from Past Events" section with a dropdown menu for the year 2024. The list includes "Skin Substitute Session (07/18/24)" and "Certifier Session (03/19/2024)".

# Program Overview

An overview of the Discarded Drug Program requires manufacturers of certain Part B Drugs to pay a refund to CMS for the portion of the drug that is discarded.

- Criteria
- Reporting
- Calculation
- Billing
- Payment
- Enforcement and Penalty



## Discarded Drug Program Overview

Generally, when a separately payable drug from a single-dose container or single-use package is administered to an individual enrolled in Medicare Part B, Medicare pays the provider or facility for both administered and discarded amounts of the drug, up to the full labeled amount of the product. Section 90004 of the Infrastructure Investment and Jobs Act (IIJA) ([Pub. L. 117-58](#), November 15, 2021) amended section 1847A of the Social Security Act (the Act) by adding provisions that require manufacturers to provide a refund to CMS for certain discarded amounts from a single-dose container or single-use package drug. Generally, the refund amount is the amount of payment for discarded amounts of a refundable drug (described below) that exceeds an applicable percentage, which is required to be at least 10 percent of total charges for the drug in a given calendar quarter. For specific calculations for new refund quarters and updated refund quarters, refer to [42 CFR § 414.940\(c\)](#).

### Criteria

Manufacturers required to refund CMS for discarded amounts are those that manufacture refundable single-dose container or single-use package drugs (hereinafter referred to as refundable drugs), which are defined as single-source drugs, biologicals, or biosimilar biological products for which payment has been made under Medicare Part B and that are furnished from a single-dose container or single-use package. Exclusions from the definition of refundable drugs, as described in [42 CFR § 414.902](#), and [87 FR 69719](#), include:

- Radiopharmaceuticals (therapeutic or diagnostic) or imaging agents
- Certain drugs or biologicals requiring filtration during the preparation process (prior to dilution and administration) for which unused portions must be discarded after the filtration process
- Drugs approved or licensed by FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first reported sale for any NDCs of such drug

### Reporting

CMS requires providers and suppliers to use the JW modifier on all claims for separately payable drugs with discarded drug amounts from single-use containers or single-use packages separately payable under Part B to identify and monitor billing and payment for discarded amounts of drugs. In submitting claims to Medicare, providers must indicate the number of billing units of the drug that were discarded using the JW modifier. Use of the JZ modifier is required on claims for drugs from single-dose containers or single-use packages separately payable under Part B when there are no discarded amounts. For more information on the JZ and JW modifiers, please review the [JW, JZ Modifiers FAQ \(PDF document\)](#).

### Calculation

The refund amount is the amount by which the product of the number of discarded units and the payment limit exceeds the applicable percentage of the estimated total allowed charges for the drug for a given quarter, which is required to be at least 10 percent of total charges for the drug in a given calendar quarter ([42 CFR § 414.940](#)). Medicare Part B drug payment limits are published and effective on a quarterly basis. CMS uses the published payment limits to calculate the refund due for each new refund quarter by:

- Step (1): Multiplying the total number of discarded drug units based on the JW modifier submitted on all applicable claims for the quarter and the drug's payment limit, as determined under section 1847A(b)(1)(B) or (C) of the Act, for the quarter.
- Step (2): Multiplying the applicable percentage by the total allowed charges for the drug for the quarter, and
- Step (3): Subtracting the product calculated in step (2) from the product calculated in step (1).

**Please note:** Applicable percentages may vary based on refundable drugs' unique circumstances and are described further in [42 CFR § 414.940\(d\)](#). Manufacturers may apply for an adjustment to their drug's applicable percentage. Application instructions are provided on the [CMS Discarded Drugs website](#).

### Billing

Manufacturer reports will be issued through the Manufacturer Payment Portal (MPP). CMS will issue an annual report to all manufacturers of refundable drugs, which will include the total number of units discarded based on the JW modifier and the refund amount calculated for each quarter. Manufacturers have an opportunity to submit an error report to CMS within 30 days after receipt of their report.

### Payment

Manufacturers will be able to pay any refunds due through the 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 an error report is pending, payment will be due on the due date of the initial report or no later than 30 days after the error report has been resolved, whichever is later. ([42 CFR § 414.940\(b\)\(1\)](#) and [\(2\)](#)).

### Enforcement and Penalty

Manufacturers of refundable drugs who do not comply with the requirement set forth at [42 CFR § 414.940\(b\)](#) are subject to a civil money penalty of 125 percent of the assessed refund obligation as described in [42 CFR § 414.940\(e\)](#).

For more information visit: [CMS Discarded Drugs Website](#)

Contact us at: [DiscardedDrugs@cms.hhs.gov](mailto:DiscardedDrugs@cms.hhs.gov)

Published: November 2024

# Checklist

- Instructions on how to complete key program tasks
- Support information



## 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](mailto: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](mailto: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.

# Error Reports

Manufacturers have 30 days after receipt of their refund report(s) to assert that there have been one or more errors in the report. To submit a dispute for each asserted error, provide the following information in a written request to [DiscardedDrugs@cms.hhs.gov](mailto:DiscardedDrugs@cms.hhs.gov):

- Manufacturer name and address
- Name, telephone, and email address of one or more employees of the manufacturer

For a Mathematical Calculation Error	For Any Other Asserted Error
<ul style="list-style-type: none"><li>• The specific calculation element(s) that the manufacturer disputes</li><li>• The proposed corrected calculation</li></ul>	<ul style="list-style-type: none"><li>• An explanation of the nature of the error</li><li>• How the error affects the refund calculation</li><li>• An explanation of why the manufacturer believes that an error occurred</li><li>• The proposed correction to the error</li><li>• An explanation of why CMS should use the proposed corrected data</li></ul>

# What's Next?

- ✓ Ensure you have a P Number
- ✓ Select your Program Designation (Part B or Part B and Part D) in HPMS
- ✓ Add your Program Contact Information in HPMS
- ✓ TPA will reach out in mid-December to enroll you into MPP
- ✓ Ensure you have access to MPP by logging in after enrollment
- ✓ Add EFT information before 11:59 p.m. on December 27, 2024
- ✓ Log in to MPP by December 31, 2024
- ✓ View and pay refund amounts due by February 28, 2025



# Q&A



# Closing Remarks

- [Discarded Drugs webpage](#)
- **Technical Support (TPA)**
  - [tpaoperations@tpadministrator.com](mailto:tpaoperations@tpadministrator.com)
  - 1-877-534-2772 (Option 1)
- **Feedback and Other Questions**
  - [DiscardedDrugs@cms.hhs.gov](mailto:DiscardedDrugs@cms.hhs.gov)

