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

Manufacturers create and package single-use, single-dose drugs.

Providers purchase drugs from distributors or directly from manufacturers.

Manufacturers report quarterly sales data to CMS to produce the ASP pricing files.

Providers administer drugs to Medicare patient(s).

Providers bill Medicare for drugs, using JW/JZ modifiers to report any/no discarded amounts.

Medicare Administrative Contractors (MAC) receive claims from providers.

MACs refer to the ASP pricing files or develop a payment limit for covered drugs not listed in the ASP drug pricing files.

MACs issue payments to the providers.

CMS calculates the manufacturers' refund due using claims data and the ASP payment limits.

CMS loads Discarded Drug Refund Reports into MPP.

Manufacturers view their reports and pay refunds due through MPP.

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.

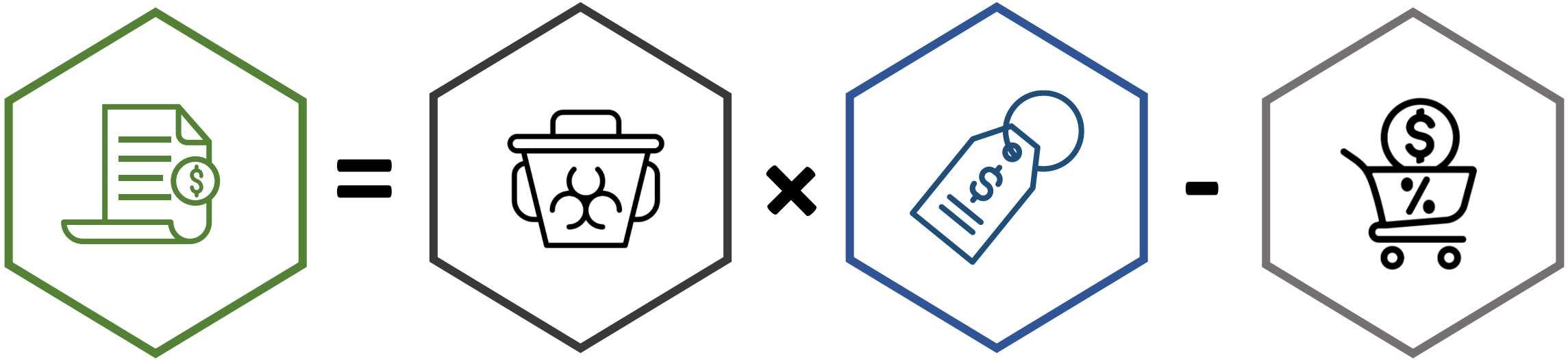
Applicable Percentages

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)

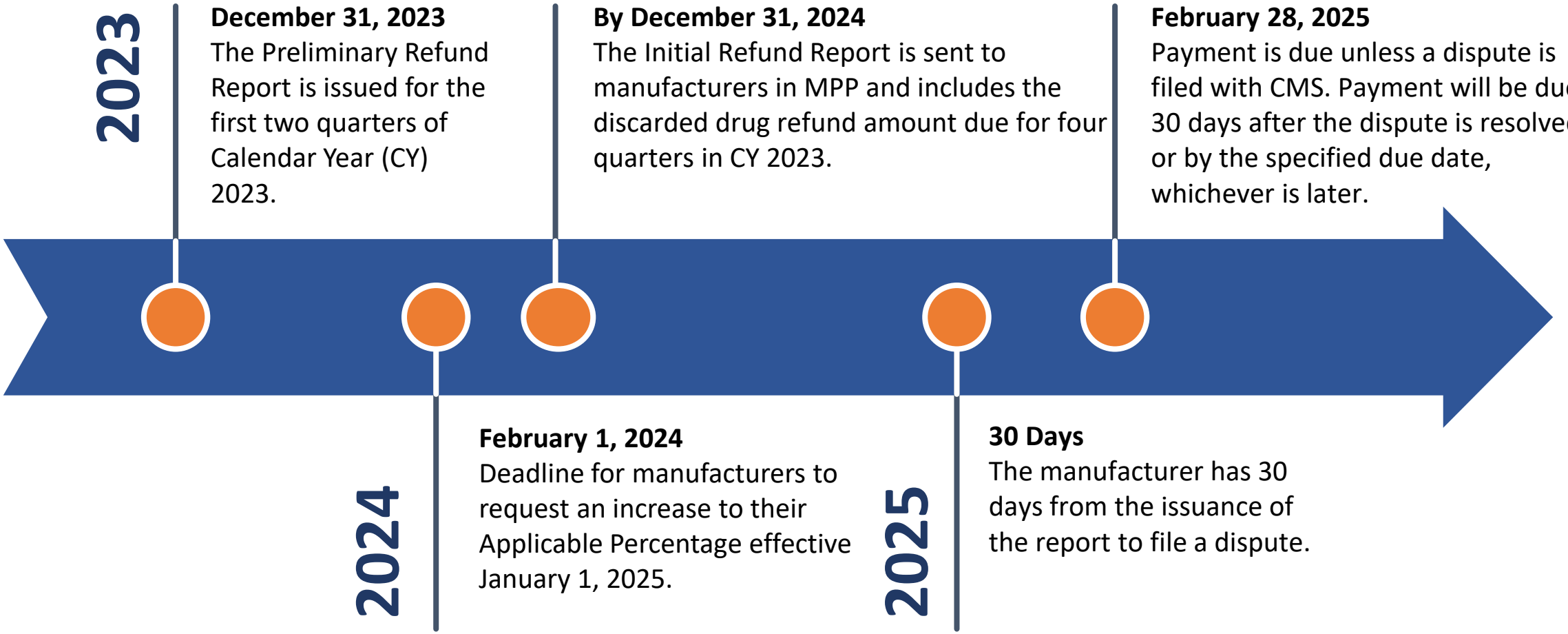
ASP Payment Limit

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
Total	*10,000*	*100%*	*$10,000.00*

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

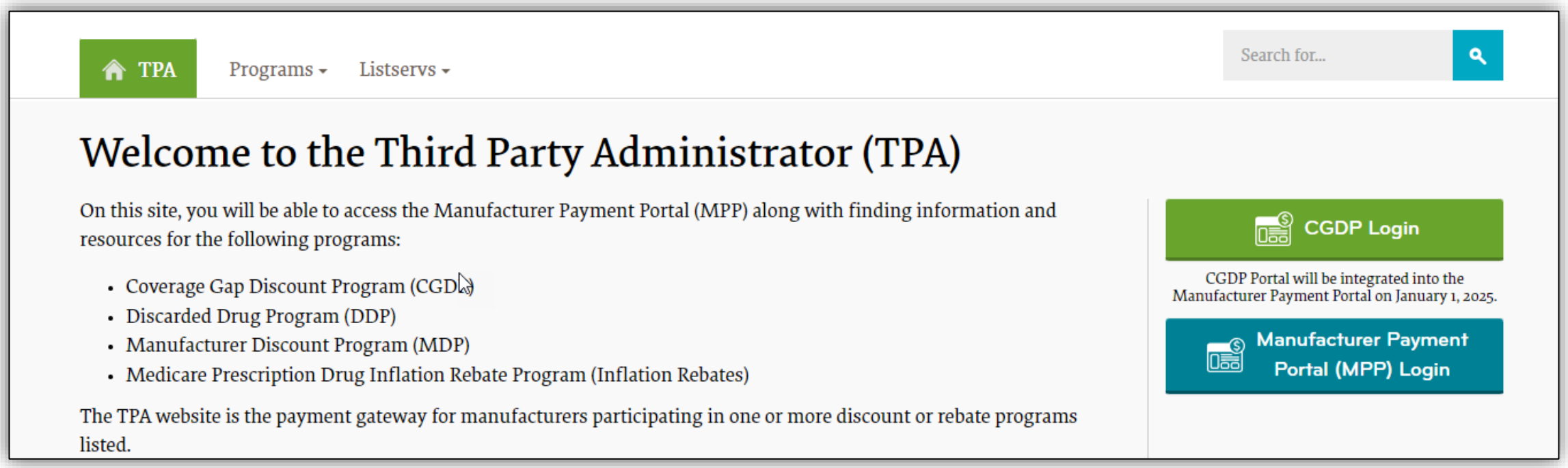
- TPA will use the Discarded Drug Program contact information collected in HPMS to assign manufacturer user access to the MPP.
- The Discarded Drug Program contact will be able to access reports and initiate payment for refunds due.
- The link to the new portal will be located on the home page of the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

Requesting a P Number

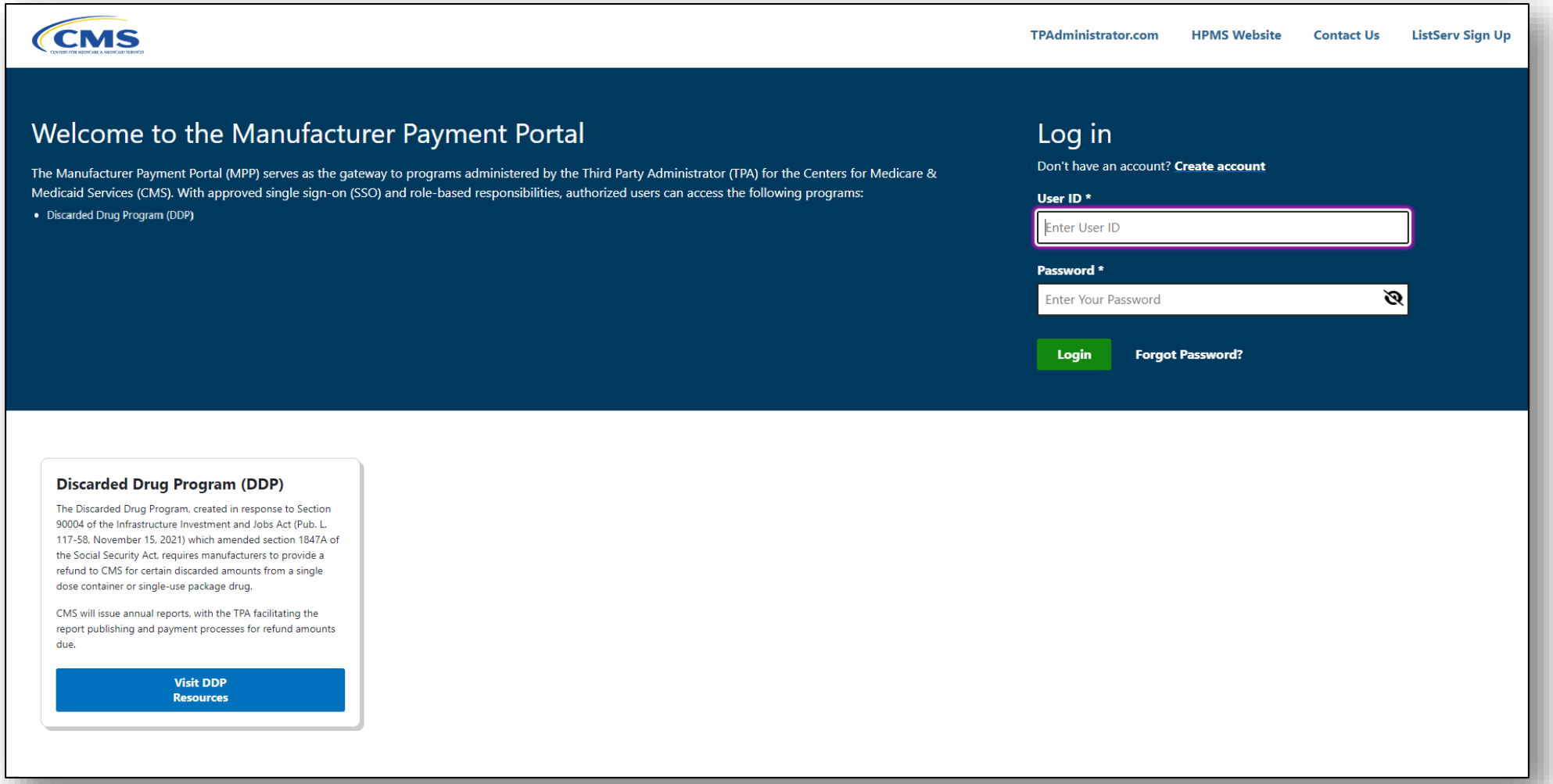
Email DiscardedDrugs@cms.hhs.gov

- 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”

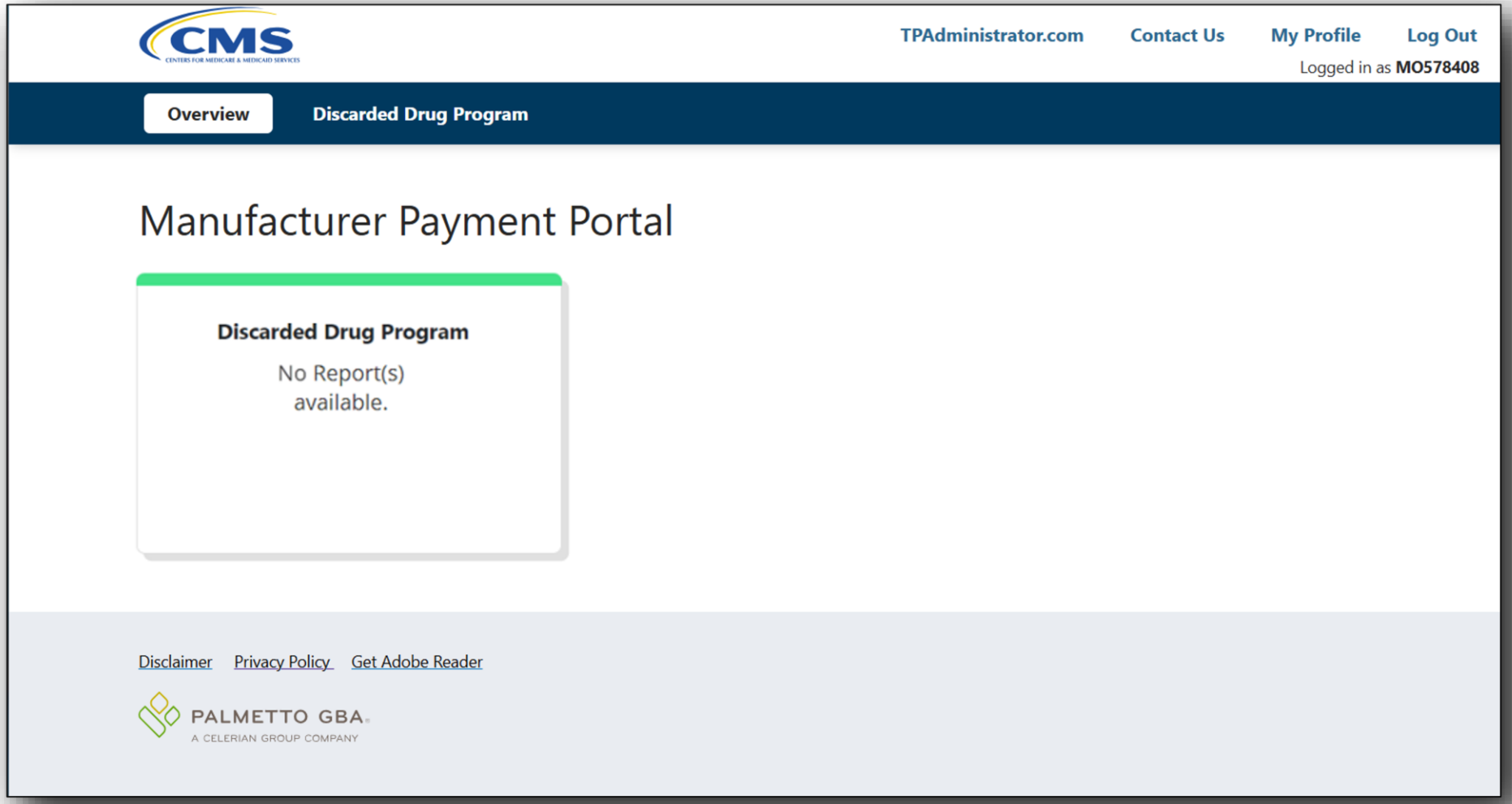
TPA Website


TPA
Programs
Listservs
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

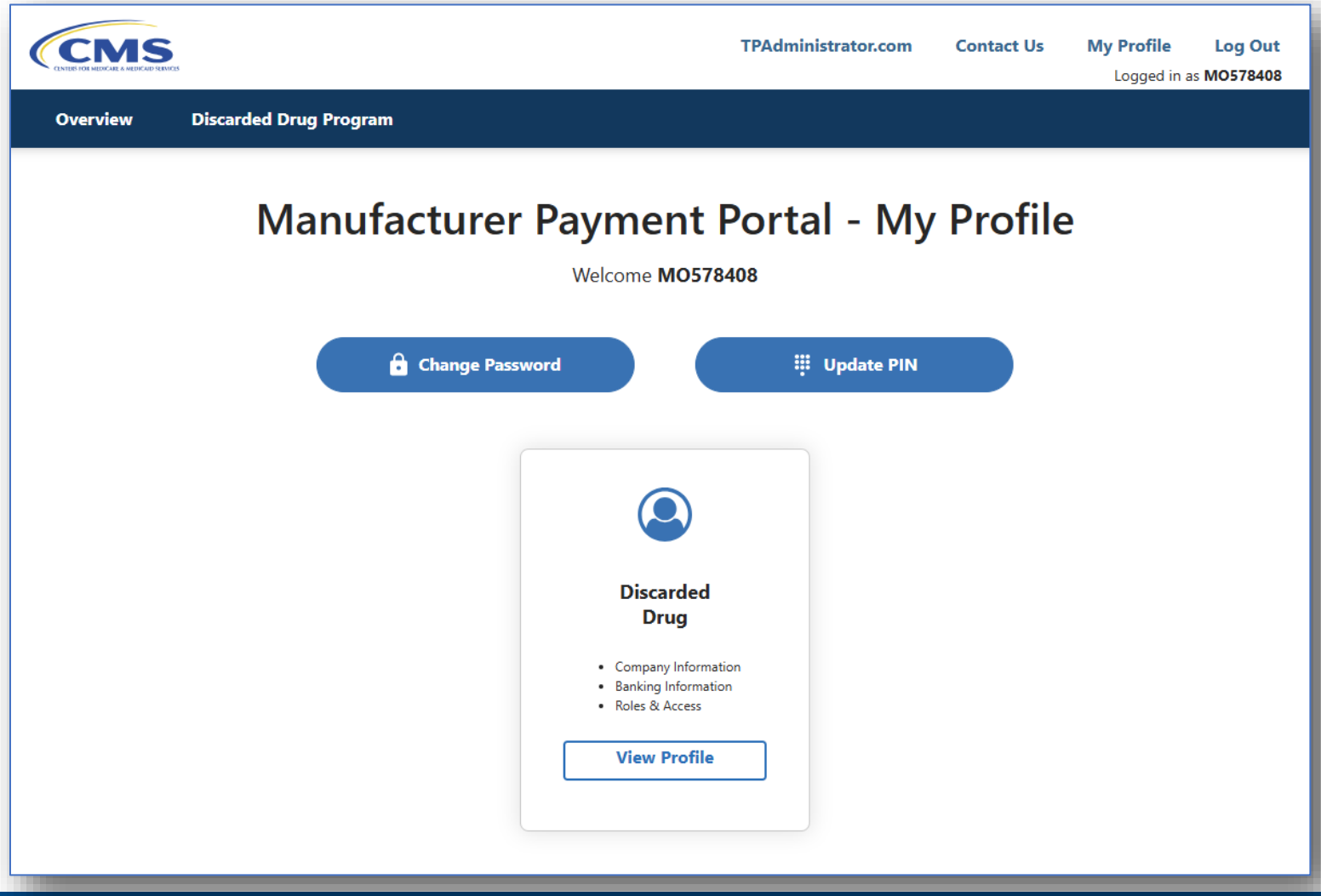
Accessing MPP



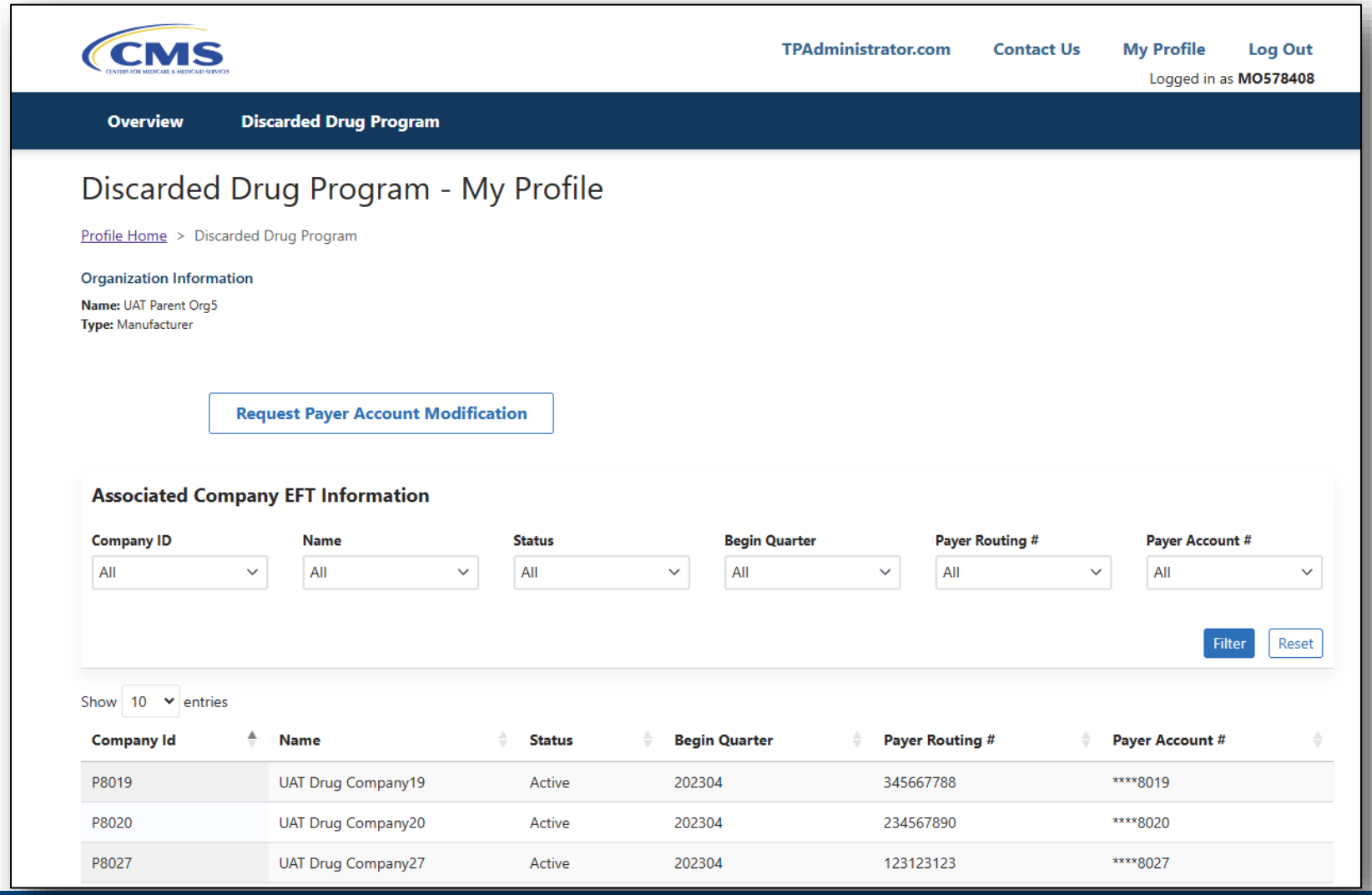
Landing Page - No Reports



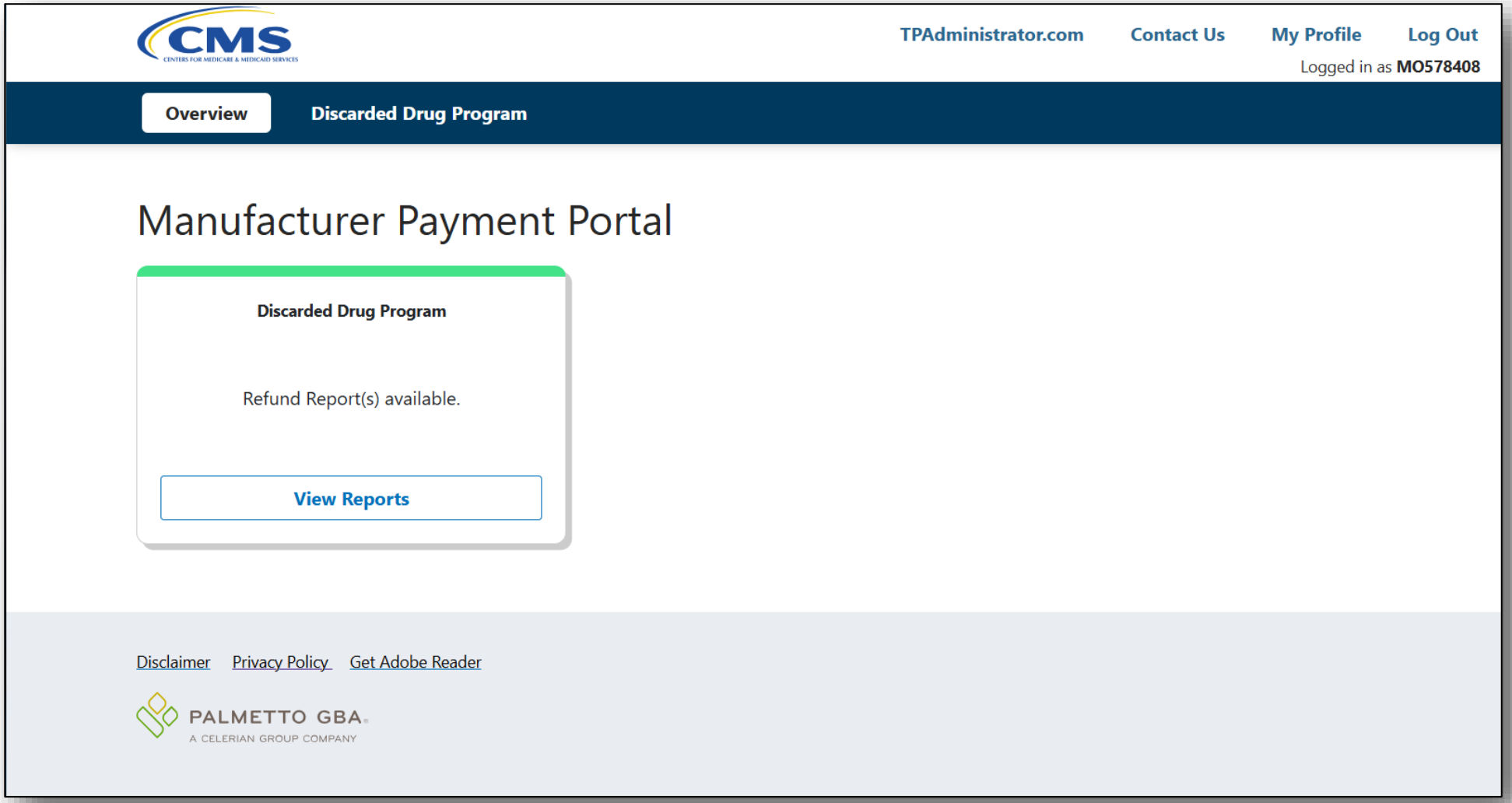
My Profile (1 of 2)



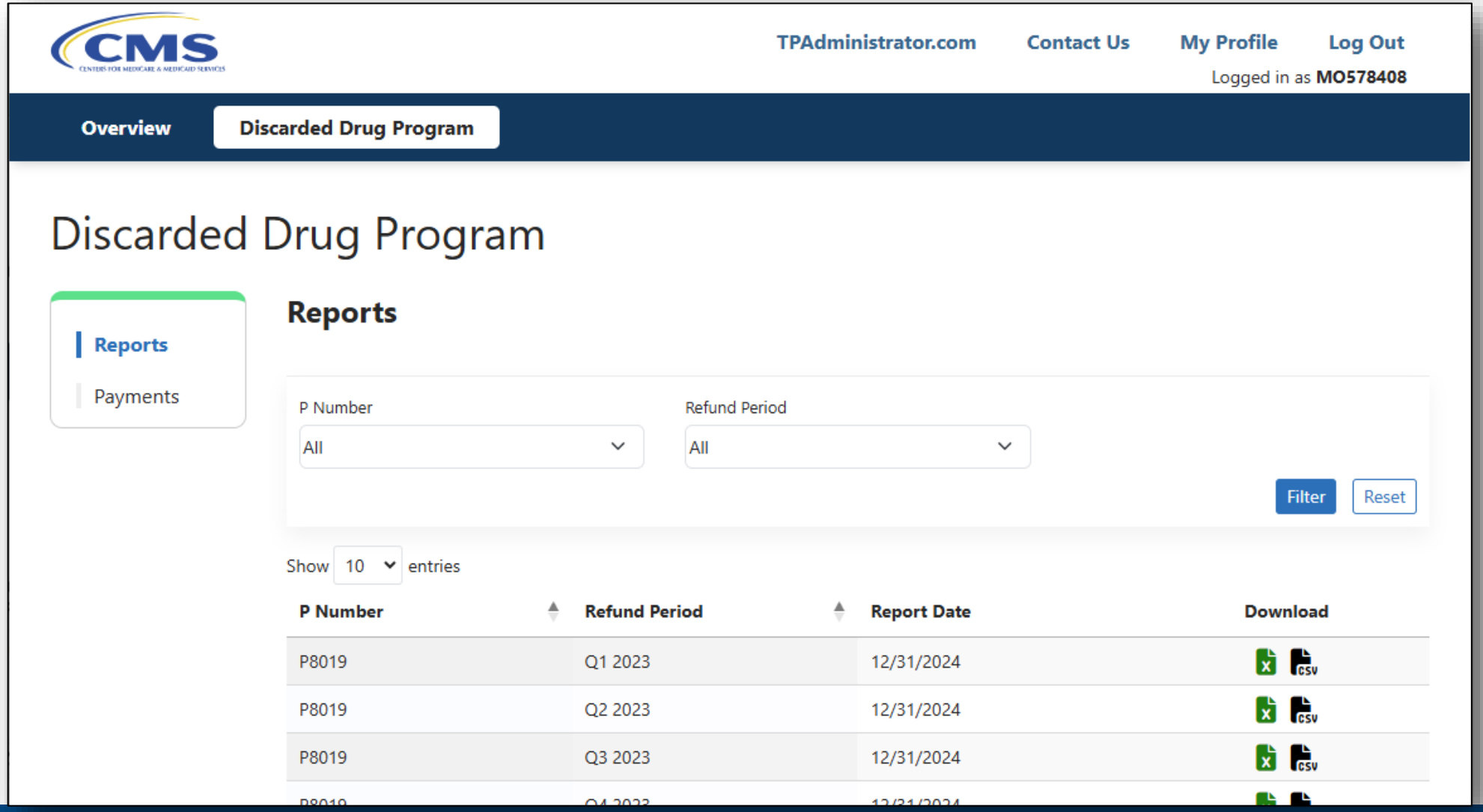
My Profile (2 of 2)



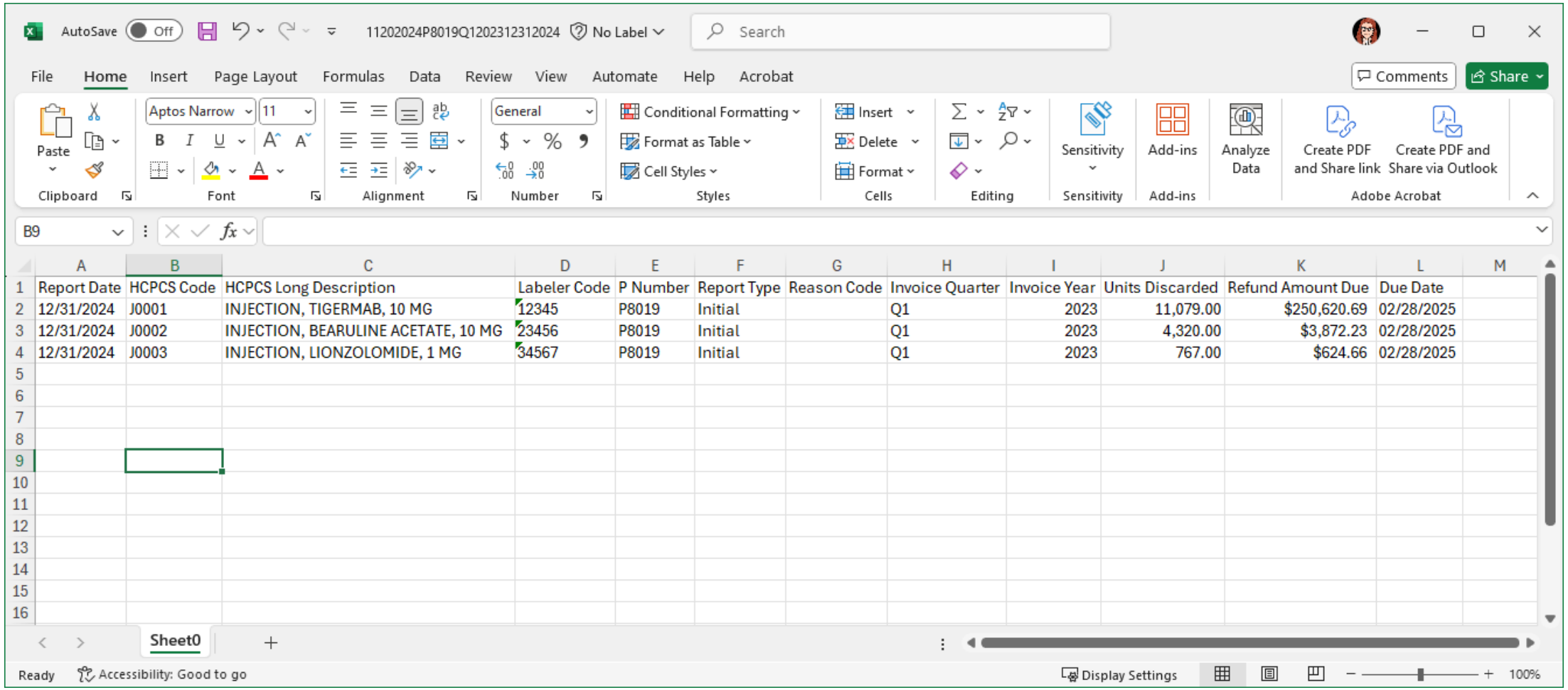
Landing Page - Reports Available



View Reports

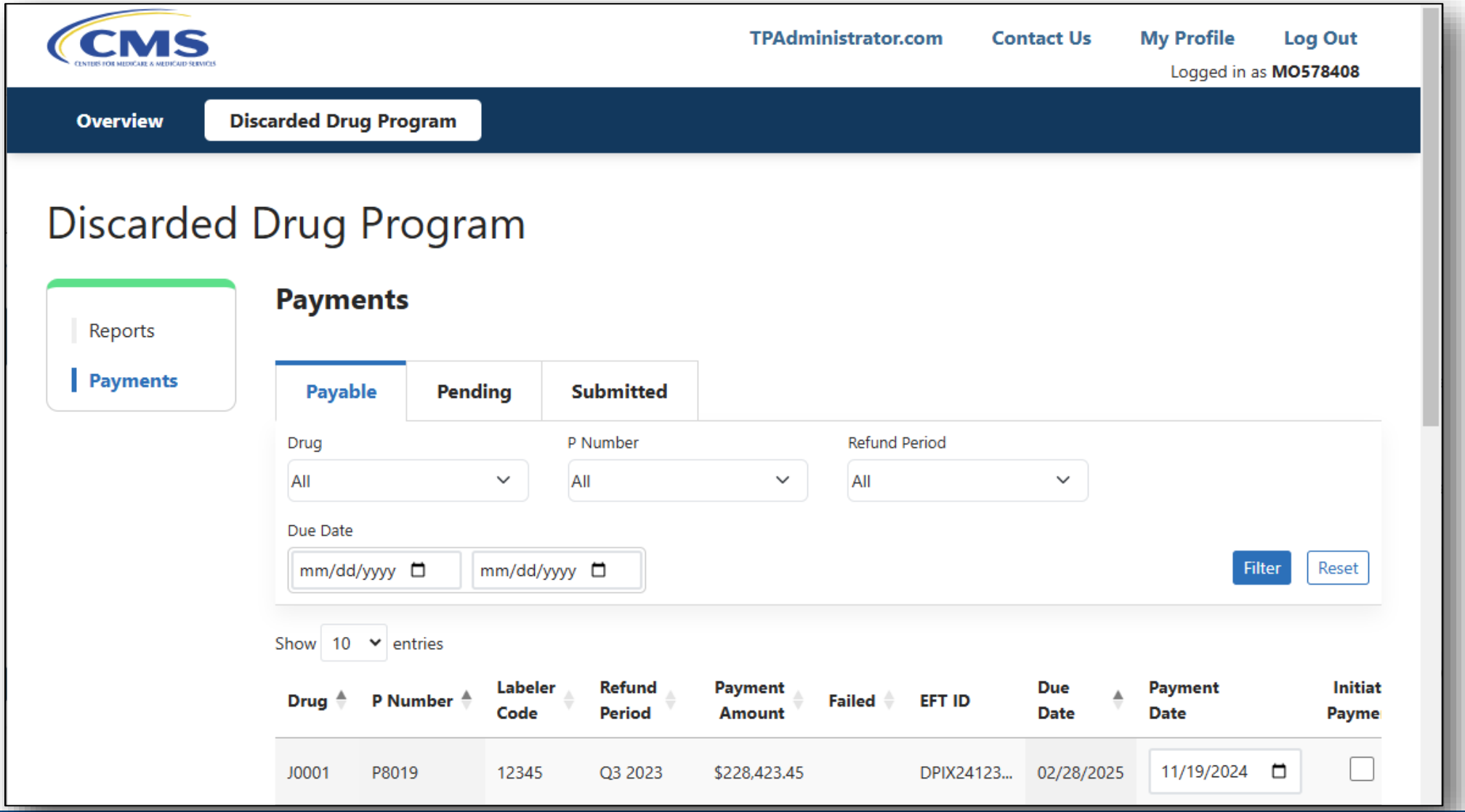


Reports

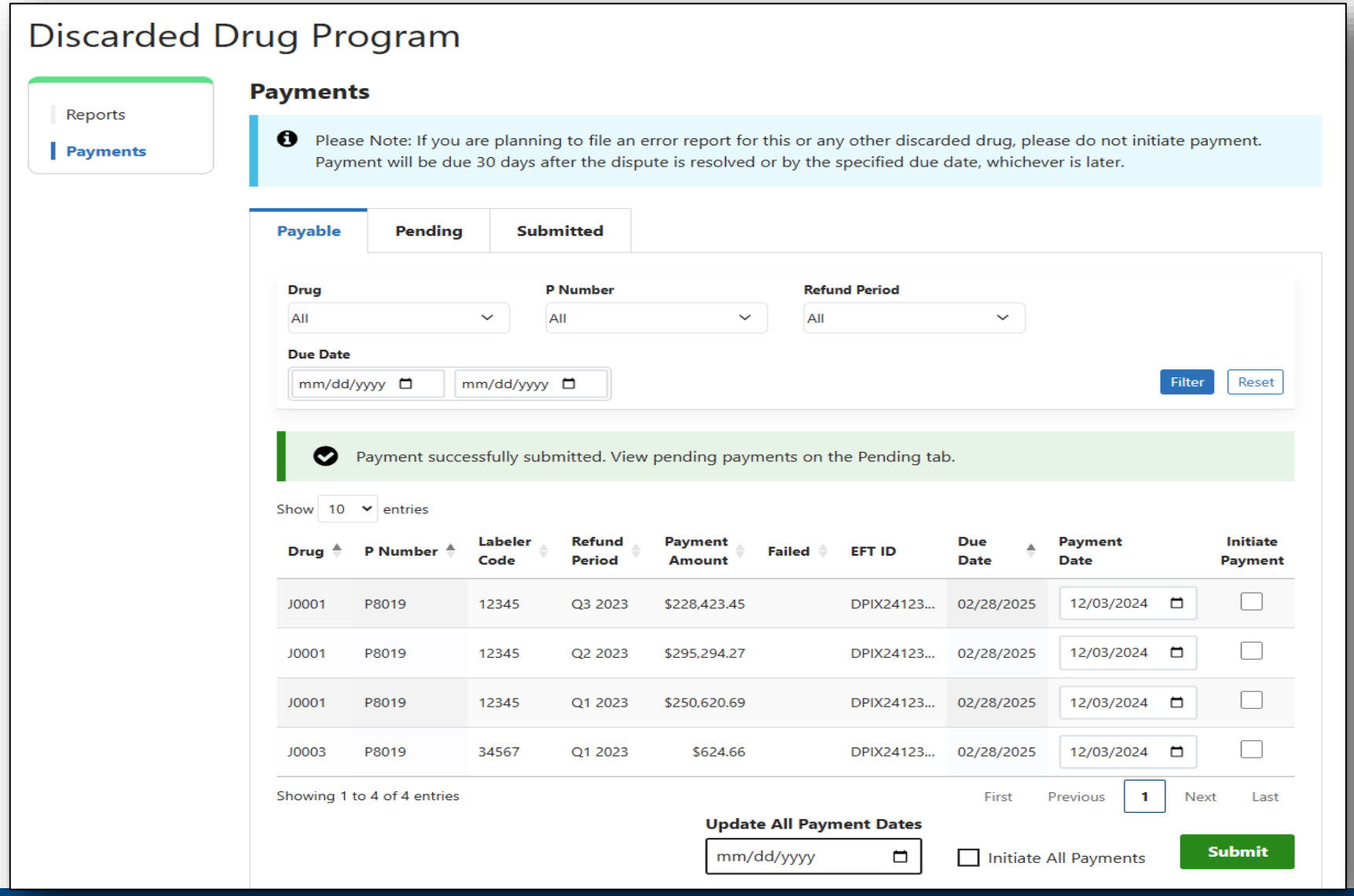


	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Report Date	HCPCS Code	HCPCS Long Description	Labeler Code	P Number	Report Type	Reason Code	Invoice Quarter	Invoice Year	Units Discarded	Refund Amount Due	Due Date	
2	12/31/2024	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q1	2023	11,079.00	$250,620.69	02/28/2025	
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	

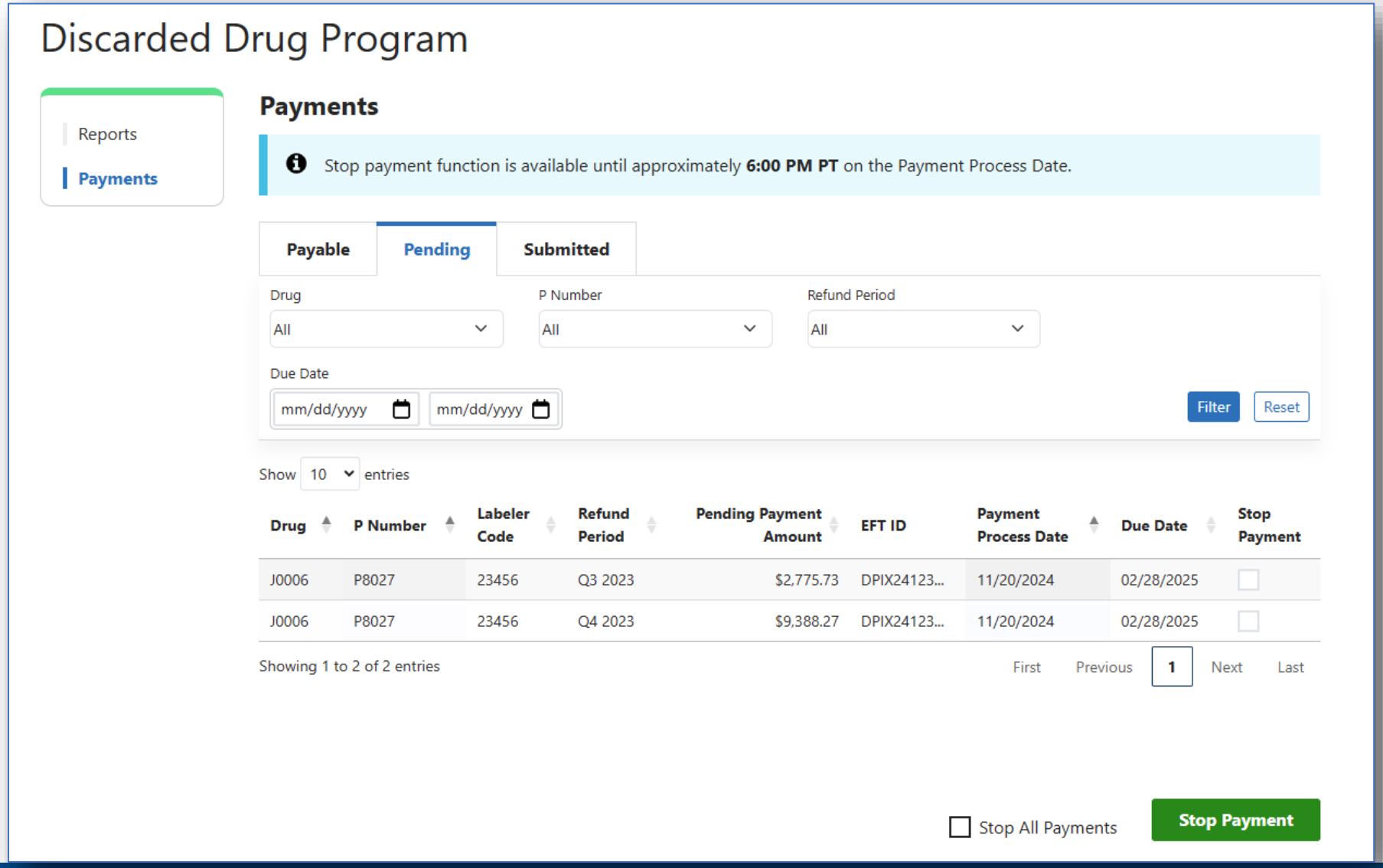
Payments


CMS
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
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
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

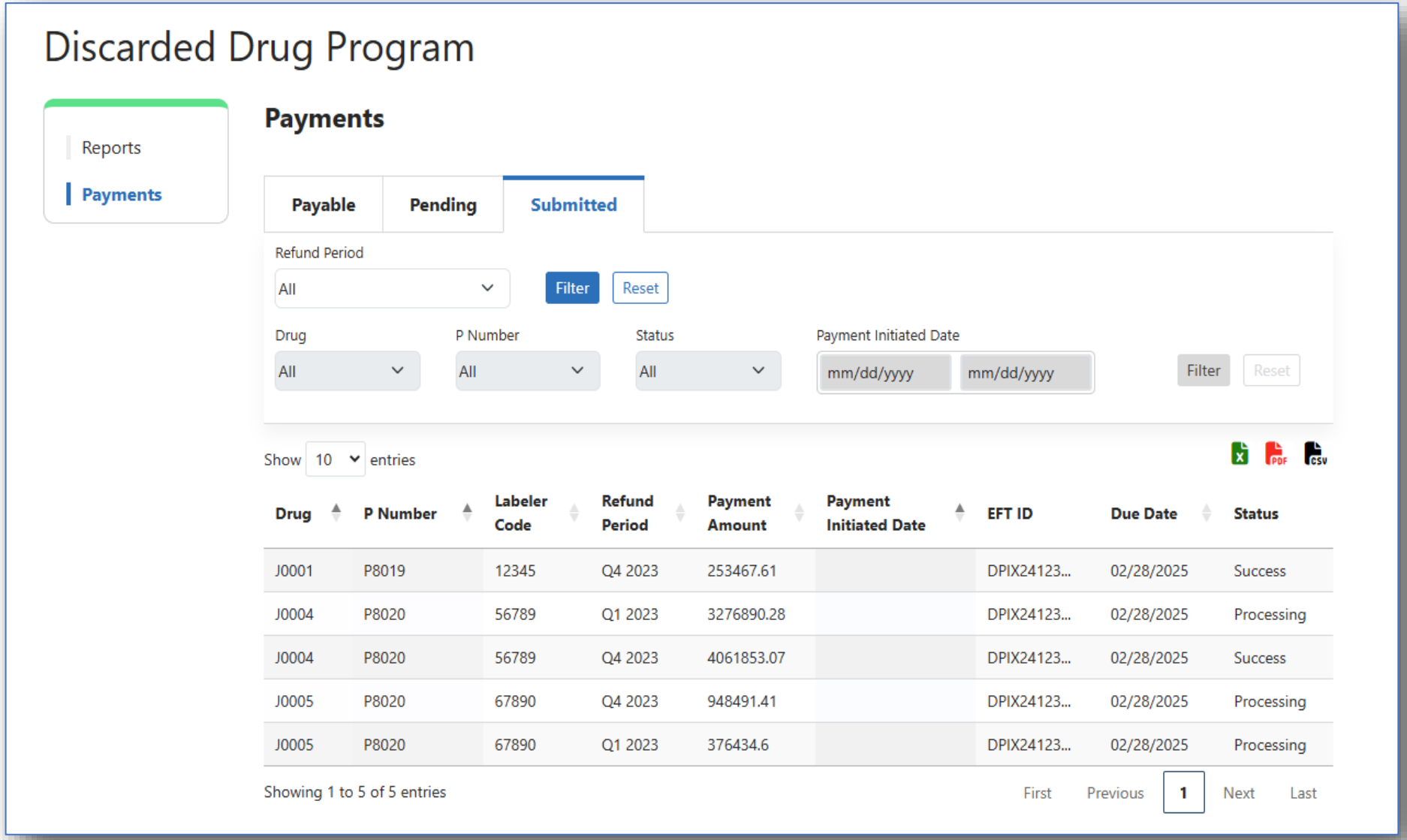
Payments Payable



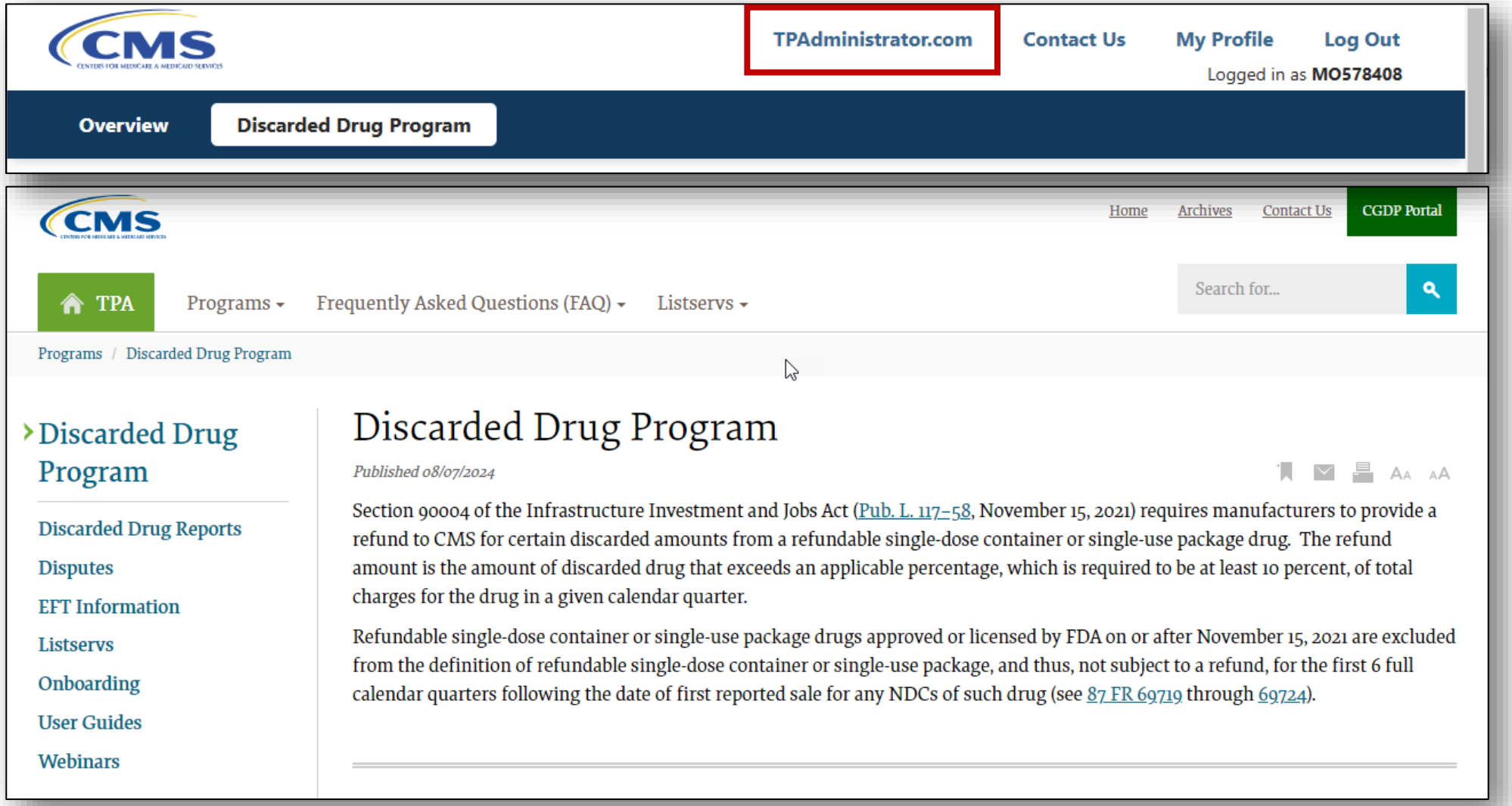
Payments Pending



Payments Submitted

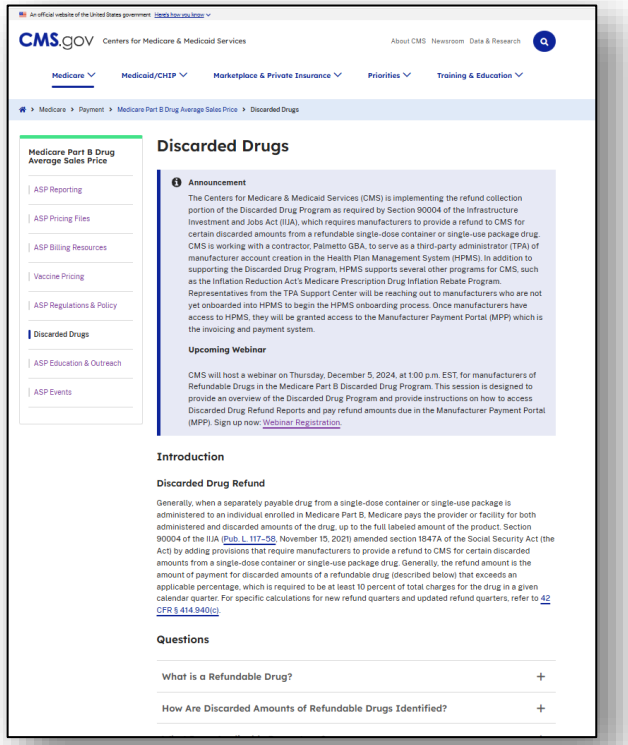


TPA Resources

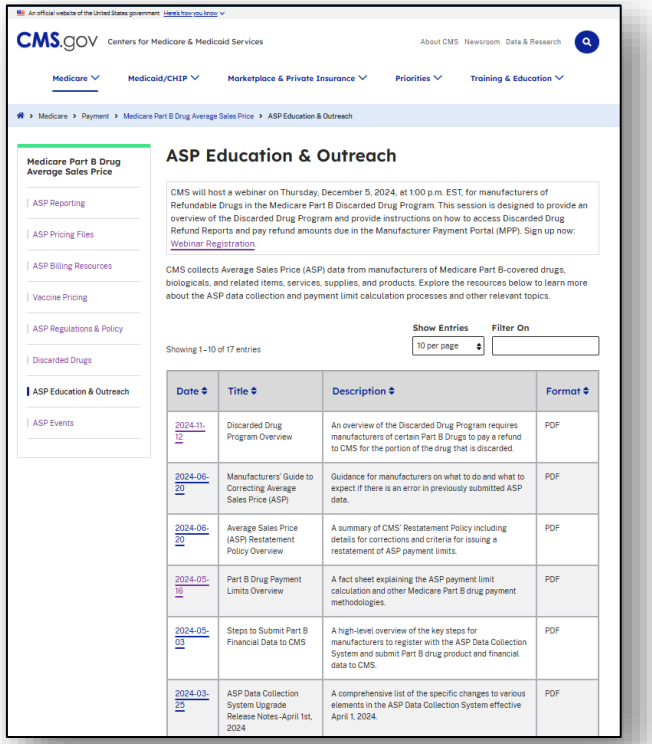


CMS ASP Website

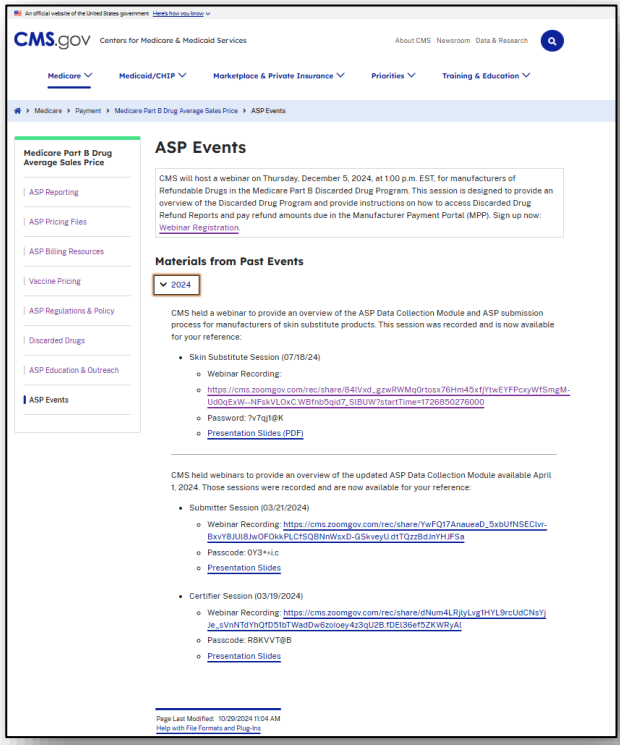
[Discarded Drugs Page](#)



[ASP Education & Outreach Page](#)



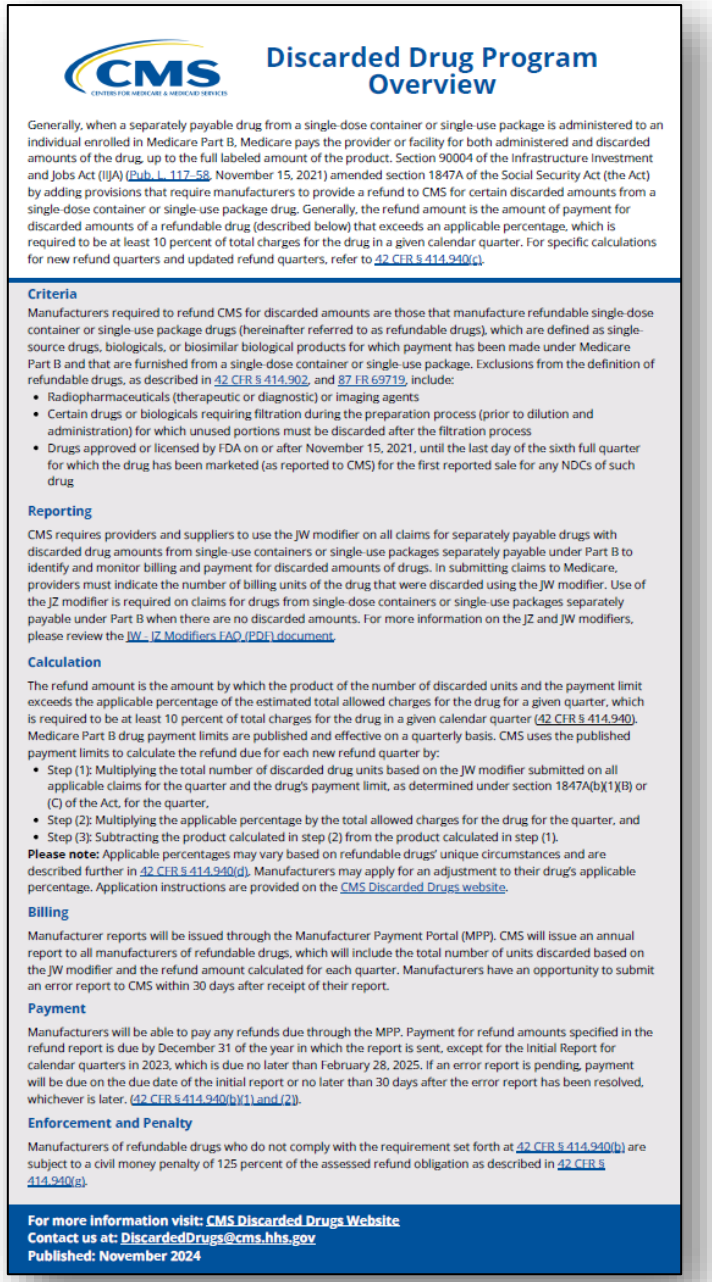
[ASP Events Page](#)



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



CMS

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)).

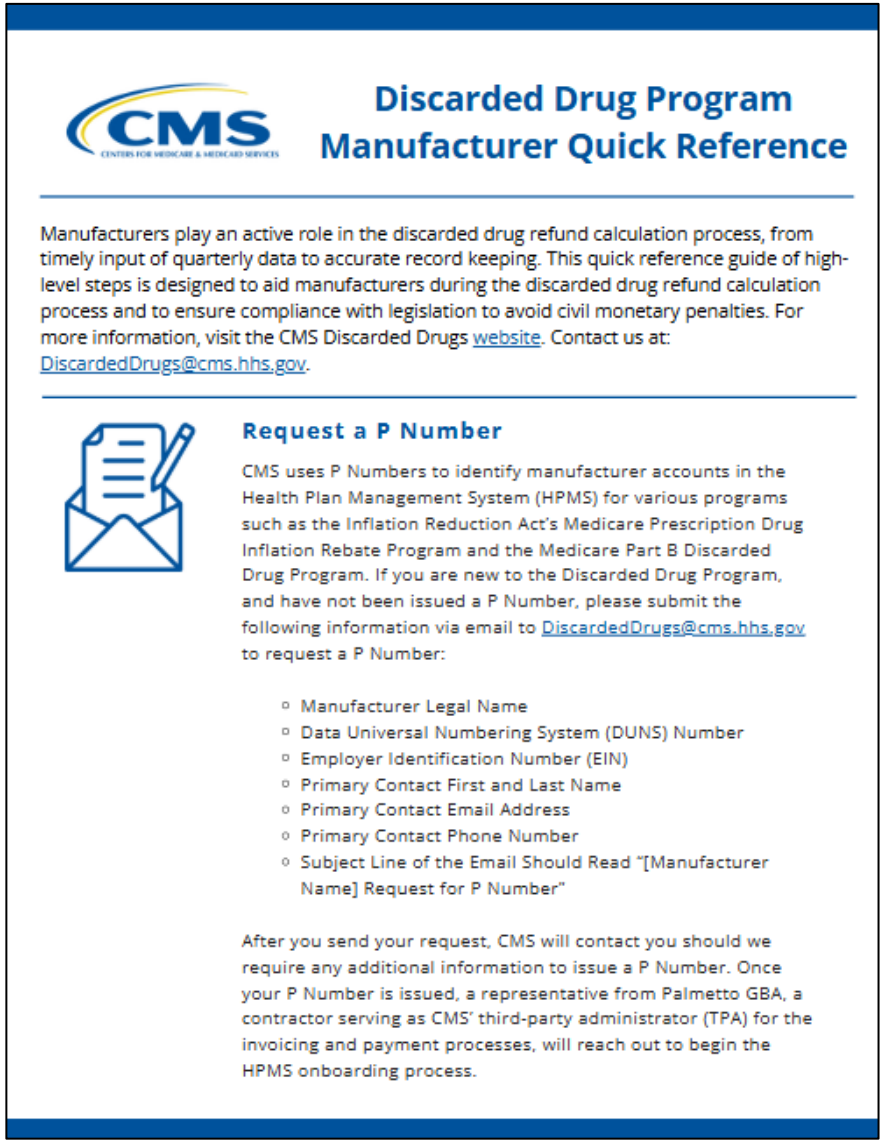
Enforcement and Penalty

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
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.

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.

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:

- 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
• The specific calculation element(s) that the manufacturer disputes • The proposed corrected calculation	• 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

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
  - 1-877-534-2772 (Option 1)

- **Feedback and Other Questions**
  - DiscardedDrugs@cms.hhs.gov