



Discarded Drug Program Webinar

August 2026

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 1-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	Jacquelyn Cunningham, 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
 - Calculation of refund amounts due
- 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

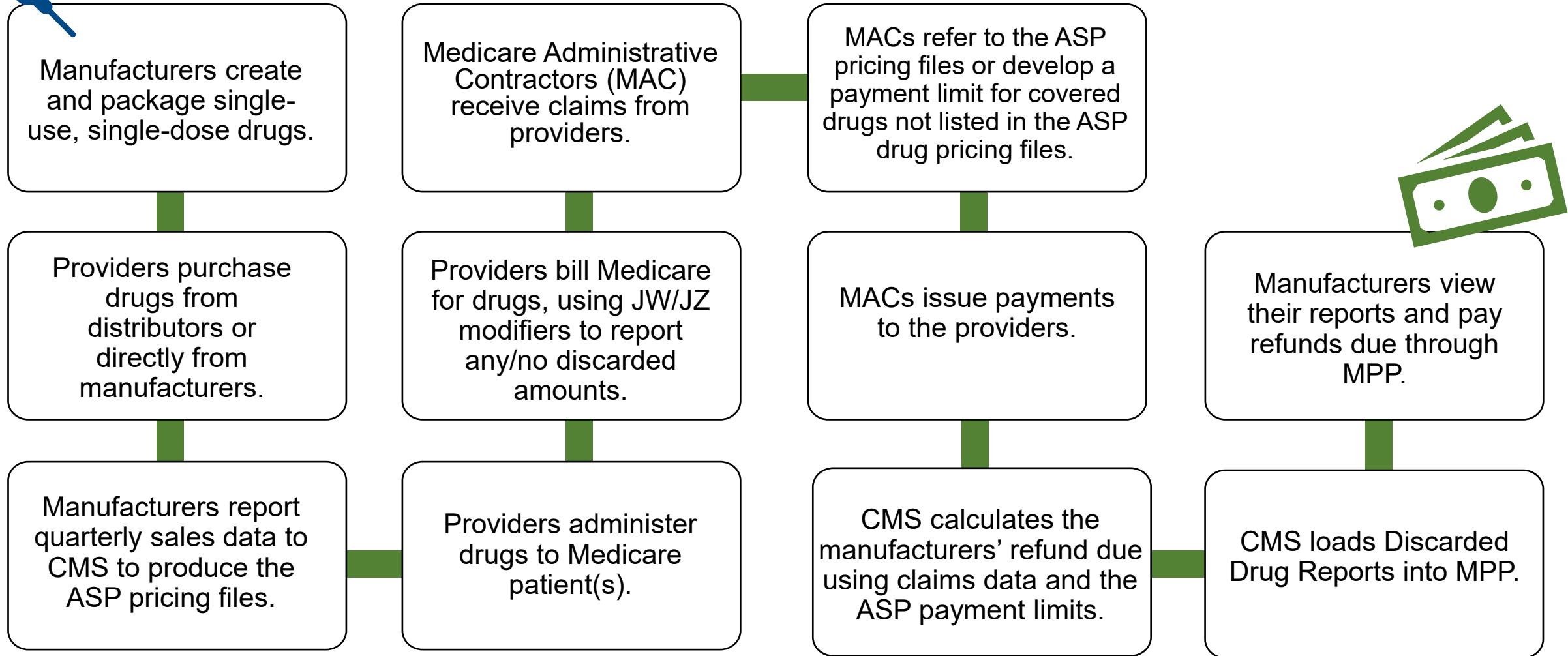
Discarded Drug Program

Manufacturers are required to provide a refund to be deposited into the Supplementary Medical Insurance (SMI) Trust Fund for the discarded amounts from drugs that meet certain criteria as stated in [42 CFR § 414.940](#).

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 product, 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

- Radiopharmaceuticals (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 approved or licensed by the Food and Drug Administration (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
- A drug approved or licensed by FDA on or after November 15, 2021 and for which the date the drug was first marketed (as reported to CMS) does not adequately approximate the date of first payment under Part B due to an applicable national coverage determination, until the last day of the sixth full quarter for which the drug has been covered and paid under Medicare Part B for the first NDC assigned to the billing and payment code 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

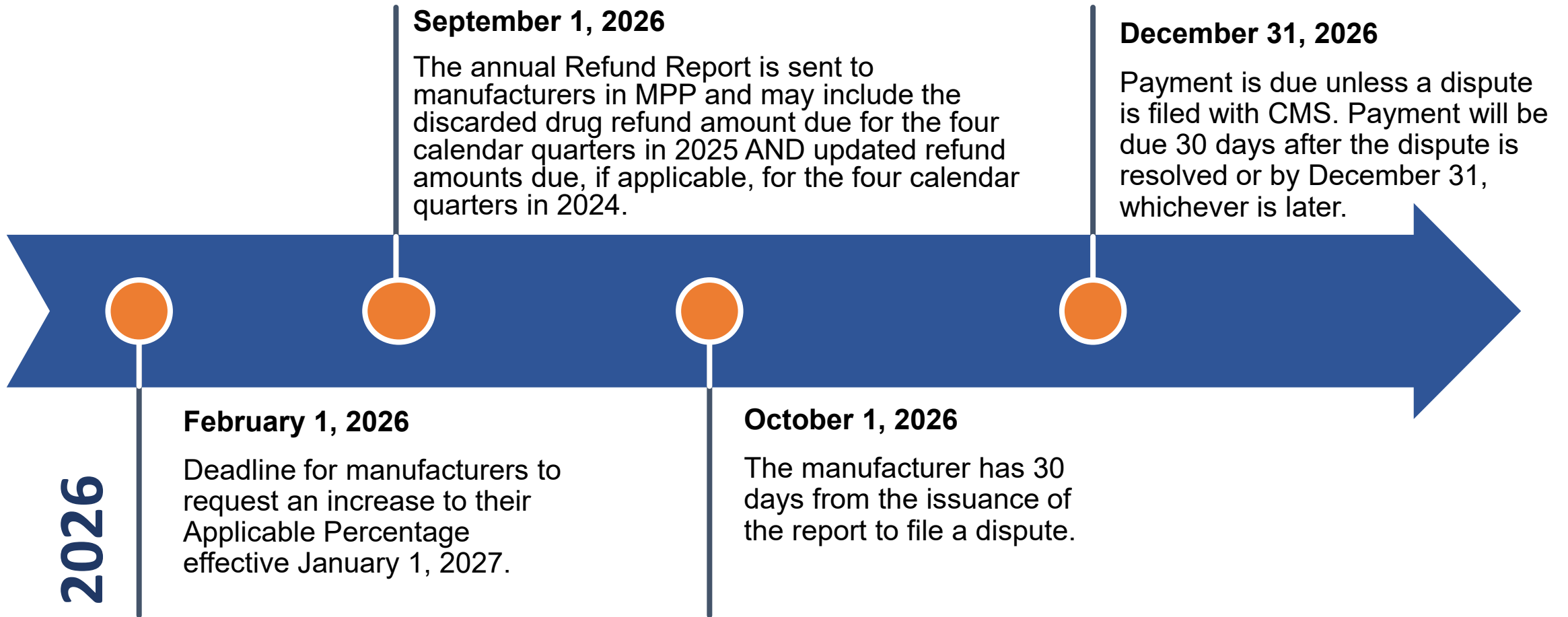
An applicable percentage is essentially the **discarded amount threshold** for a specific drug. The applicable percentage is used in the calculation of the refund amount due from manufacturers. It is required to be at least **10%** but can be increased through notice-and-comment rulemaking for drugs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



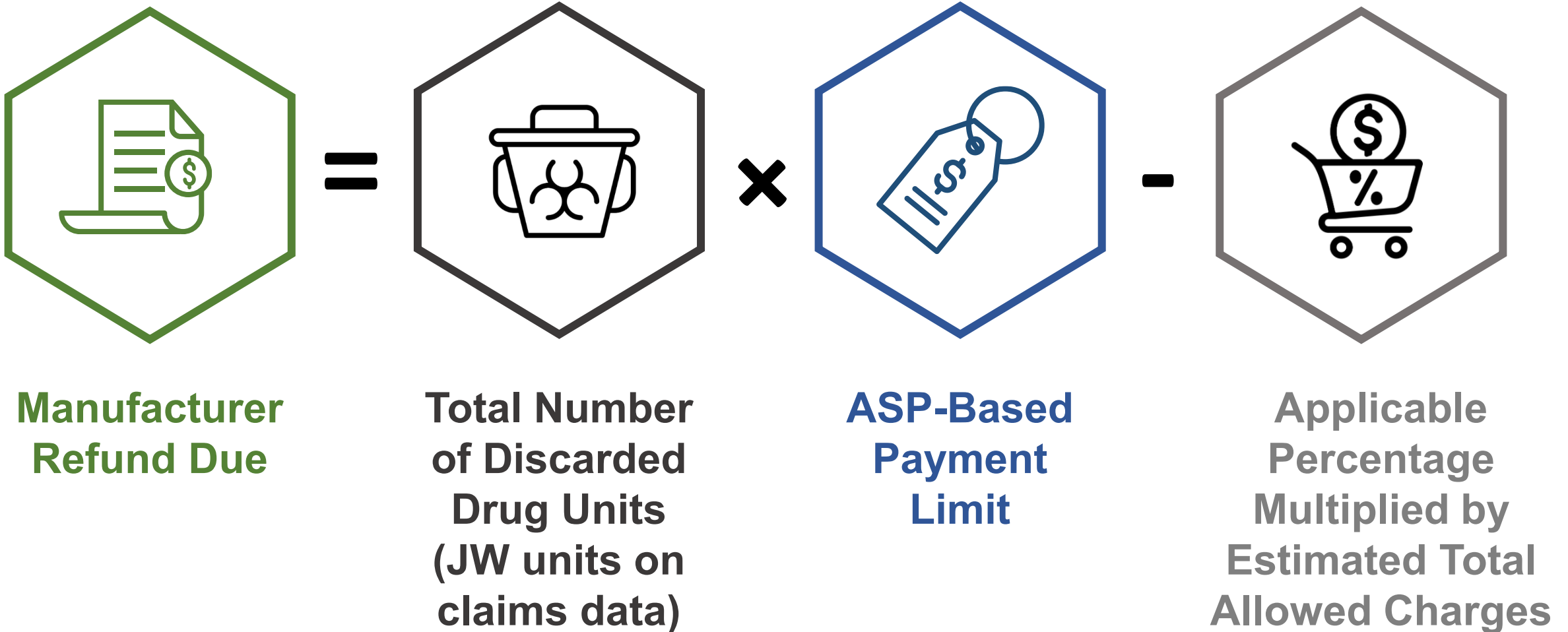
The following are increased applicable percentages for drugs with unique circumstances:

- **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

Report Timeline



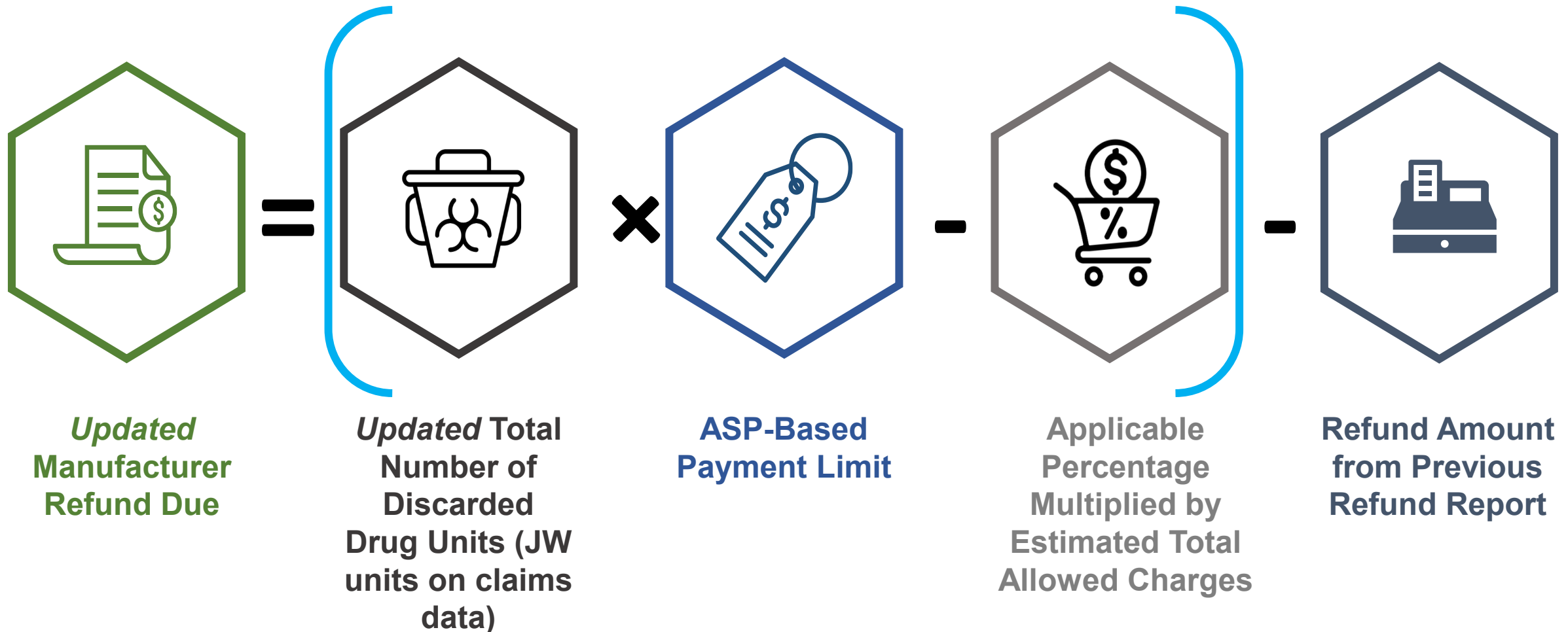
New Refund Quarter Calculation



Refund Calculation When Refundable Drugs Have Multiple Manufacturers

Labeler Name	Billing Units Sold	Proportion of Units Sold	Refund Due Per Manufacturer
Labeler A	3,750	50%	\$3,750.00
Labeler B	1,125	15%	\$1,125.00
Labeler C	2,625	35%	\$2,625.00
<i>Total</i>	<i>7,500</i>	<i>100%</i>	<i>\$7,500.00</i>

Updated Refund Quarter Calculation



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



TPAdministrator.comHPMS WebsiteContact UsListserv 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:

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

Log in

User ID *

Enter User ID

Password *

Enter Your Password

LoginForgot Password?

Coverage Gap Discount Program (CGDP)

The CGDP, created as part of the Affordable Care Act (ACA) in 2010, makes Drug Manufacturer discounts available at point-of-sale (POS) for applicable Part D drugs for Medicare beneficiaries in the coverage gap.

These discounts are provided by Part D Sponsors and discounted payments are due between the Drug Manufacturers and Part D Sponsors with a quarterly invoice process, facilitated by the TPA.

Visit CGDP Resources

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

Manufacturer Discount Program (MDP)

The MDP, created as part of the Inflation Reduction Act (IRA) of 2022, requires drug manufacturers to pay discounts on certain brand-name drugs, biologics, and biosimilars in the initial coverage and catastrophic phase of the Medicare prescription drug benefit.

Starting in 2025, the MDP will replace the existing CGDP, with the TPA facilitating the invoice process for manufacturer discount amounts due between Drug Manufacturers and Part D Sponsors.

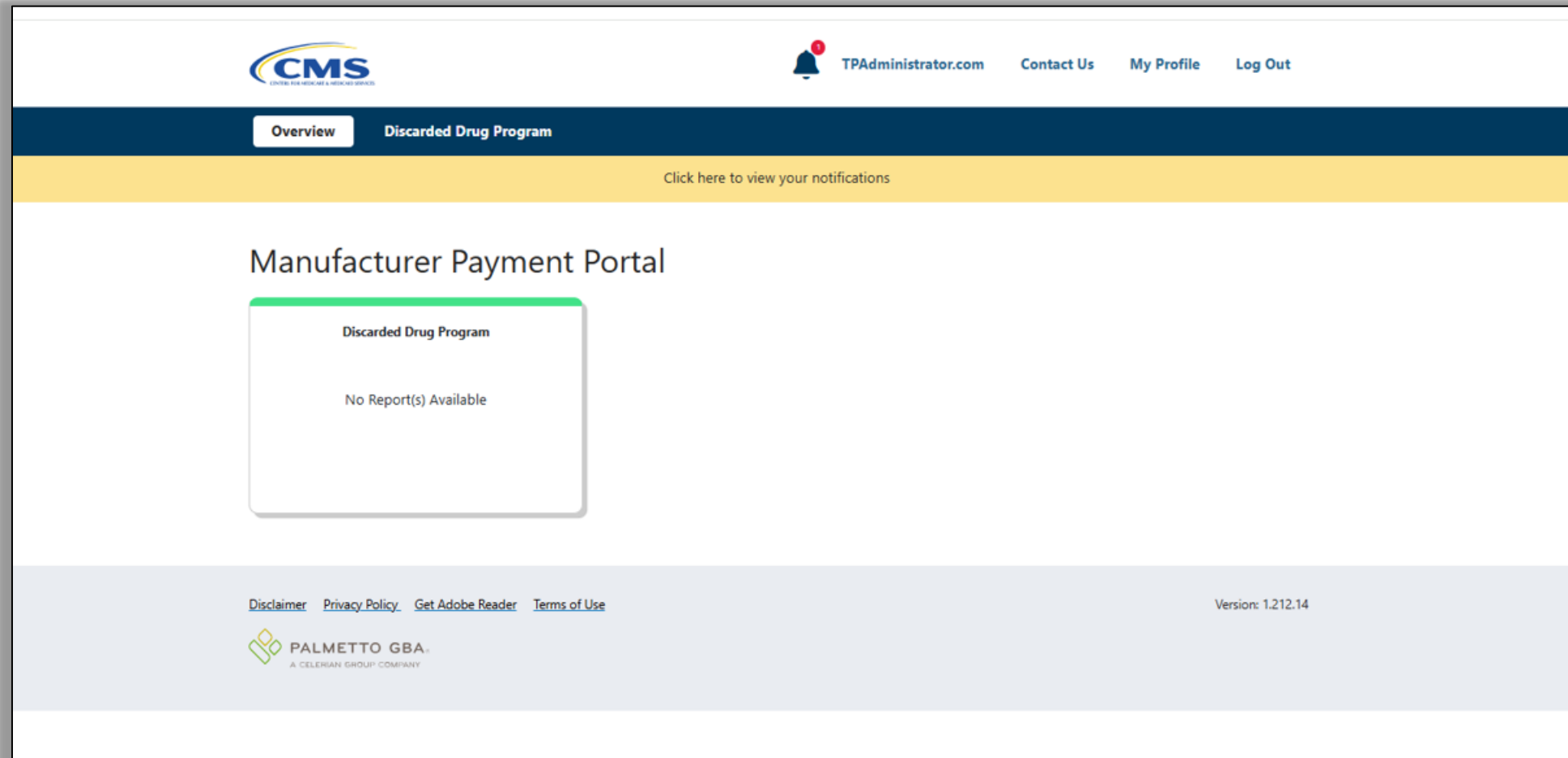
Visit MDP Resources

Medicare Prescription Drug Inflation Rebate Program (Inflation Rebates)

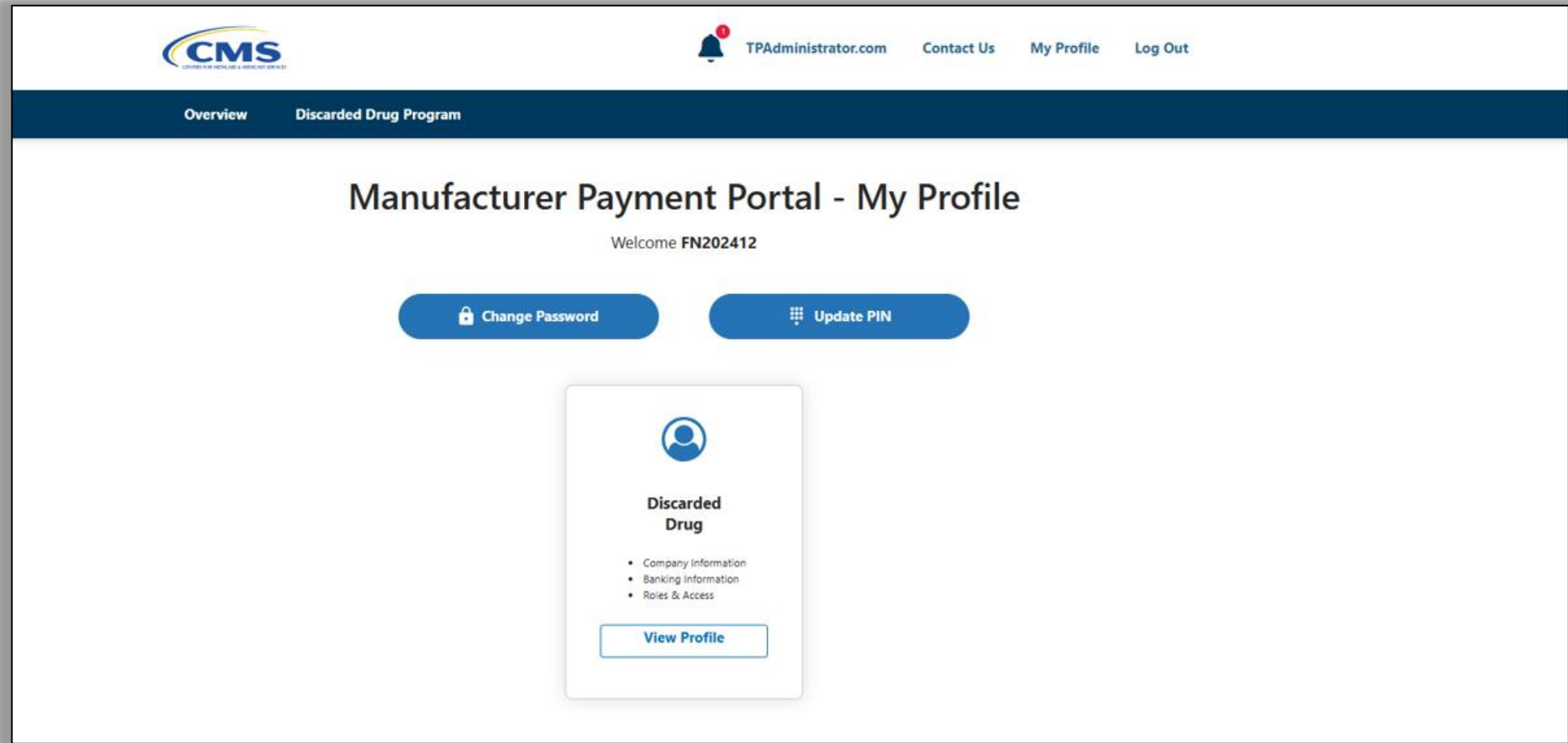
The Medicare Prescription Drug Inflation Rebate Program, created as part of the Inflation Reduction Act (IRA) in 2022, established Medicare Part B prescription drug inflation rebates for single-source drugs and biologics with prices increasing faster than the rate of inflation and established Part D prescription drug inflation rebates for certain drugs and biologics with prices increasing faster than the rate of inflation.

Visit Inflation Rebates Resources

Landing Page - No Reports



My Profile (1 of 2)



My Profile (2 of 2)



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Discarded Drug Program - My Profile

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Organization Information
Name: pagenation
Type: Manufacturer

Request Payer Account Modification

Associated Company EFT Information

Company ID

All

Name

All

Status

All

Payer Routing #

All

Payer Account #

All

Filter

Reset

Show 10 entries

Company Id	Name	Status	Payer Routing #	Payer Account #
P8017	Pageone	Active	123456789	*****6789
P8018	pagetwo	Active	123456789	*****6789
P8023	pagethree	Active	123456789	*****6789
P8024	pagefour	Active	123456789	*****6789

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Request Payer Account Modification



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Discarded Drug Program Payer Electronic Funds Transfer (EFT) Online Form

As the Third-Party Administrator (TPA) Support Center for the Discarded Drug Program (DDP) under contract with the Centers for Medicare & Medicaid Services (CMS), Palmetto GBA, LLC (Palmetto GBA) will facilitate EFT in the form of an Automatic Clearing House (ACH) transaction for the participating manufacturers to issue payments authorized in the Palmetto GBA Manufacturer Payment Portal (MPP).

Palmetto GBA has partnered with JP Morgan to originate and settle these transactions on behalf of payors. On behalf of the Payor, by completion and submission of this signed authorization, the signatory is authorizing Palmetto to provide instructions to JP Morgan to initiate debit entries to the bank account provided above and if necessary to electronically credit the account to correct erroneous transactions. Additionally, by signing, the signatory affirms this form provides company ID 1571062326 to the ACH debit filter of the bank account below to prevent unauthorized ACH returns. This authorization will remain in full force and effect until Palmetto GBA receives written notification that the Payor or business wishes to revoke the authorization. Notification must be given in such time and such manner as to afford Palmetto GBA a reasonable opportunity to act on it. The signatory of this authorization certifies that all information provided above is accurate and complete and that they are authorized to sign on behalf of the Payor.

Company Information

Name of Organization*:

Address Line #1*:

Address Line #2:

City*:

State*:

Zip Code*:

P Number(s) *:

Taxpayer Identification Name / Employer Identification Number *:

Taxpayer Identification Number / Employer Identification Number*:

EFT Type: ACH

Bank Account Type*

Form Completed By

Name*:

Email*:

Phone*:

Authorized Signer Information

Name*:

Email*:

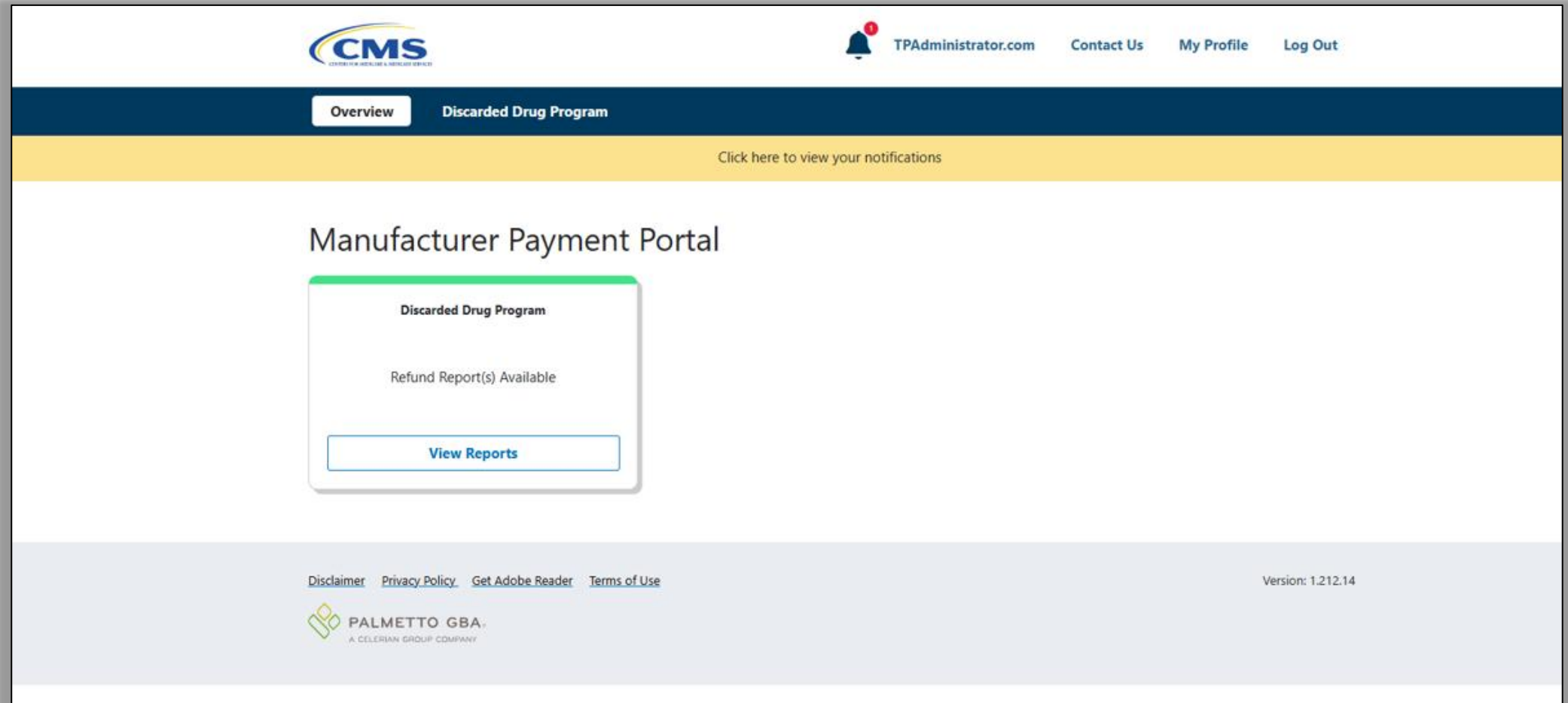
Phone*:

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PALMETTO GBA.
A CELEBRITY GROUP COMPANY

Landing Page - Reports Available



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Reports

P Number

Report Date

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Show

10

 entries

Select	P Number	Report Date
☐	P1910 	11/05/2025
☐	P1910	09/01/2025
☐	P1910	09/01/2026

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Version: 1.264.0

Reports

Report Date														
	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Report Date	CS Code	HCPCS Long Description	Labeler Code	P Number	Report Type	Reason Code	Invoice Quarter	Invoice Year	Units Discarded	Refund Amount Due	Adjusted Refund Amount Due	Comments	Due Date
2	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Updated		Q1	2023	10,986.00	(\$2,333.92)	\$0.00	Applied \$2,333.92 credit to J0001 Q2 2024	12/31/2025
3	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q1	2024	12,599.50	\$306,998.27	\$306,998.27		12/31/2025
4	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Updated		Q2	2023	12,113.40	(\$7,414.14)	\$0.00	Applied \$7,414.14 credit to J0001 Q2 2024	12/31/2025
5	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q2	2024	11,399.80	\$268,167.91	\$250,593.47		12/31/2025
6	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Updated		Q3	2023	9,871.60	(\$4,511.36)	\$0.00	Applied \$4,511.36 credit to J0001 Q2 2024	12/31/2025
7	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q3	2024	13,257.40	\$332,597.03	\$332,597.03	Received \$2,333.92 credit from J0001 Q1 2023; Received \$7,414.14 credit from J0001 Q2 2023; Received \$4,511.36 credit from J0001 Q3 2023; Received \$3,315.02 credit from J0001 Q4 2023	12/31/2025
8	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Updated		Q4	2023	10,436.00	(\$3,315.02)	\$0.00	Applied \$3,315.02 credit to J0001 Q2 2024	12/31/2025
9	09/01/2025	J0001	INJECTION, TIGERMAB, 10 MG	12345	P8019	Initial		Q4	2024	13,036.00	\$320,869.25	\$320,869.25		12/31/2025
10	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Updated		Q1	2023	4,320.00	\$0.00	\$0.00		12/31/2025
11	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Initial		Q1	2024	760.00	\$0.00	\$0.00		12/31/2025
12	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Updated		Q2	2023	4,220.00	\$0.00	\$0.00		12/31/2025
13	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Initial		Q2	2024	210.00	\$0.00	\$0.00		12/31/2025
14	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Updated		Q3	2023	200.00	\$0.00	\$0.00		12/31/2025
15	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Initial		Q3	2024	20.00	\$0.00	\$0.00		12/31/2025
16	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Updated		Q4	2023	480.00	\$0.00	\$0.00		12/31/2025
17	09/01/2025	J0002	INJECTION, BEARULINE ACETATE, 10 MG	23456	P8019	Initial		Q4	2024	80.00	\$0.00	\$0.00		12/31/2025
18	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Updated		Q1	2023	767.00	\$0.00	\$0.00		12/31/2025
19	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Initial		Q1	2024	648.00	\$0.00	\$0.00		12/31/2025
20	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Updated		Q2	2023	489.00	\$0.00	\$0.00		12/31/2025
21	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Initial		Q2	2024	1,025.00	\$883.91	\$883.91		12/31/2025
22	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Updated		Q3	2023	525.00	\$0.00	\$0.00		12/31/2025
23	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Initial		Q3	2024	871.00	\$0.00	\$0.00		12/31/2025
24	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Updated		Q4	2023	0.00	\$0.00	\$0.00		12/31/2025
25	09/01/2025	J0003	INJECTION, LIONZOLOMIDE, 1 MG	34567	P8019	Initial		Q4	2024	1,335.00	\$3,171.39	\$3,171.39		12/31/2025
26											Total Amount Due	\$1,215,113.32		
27														

Payments



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Discarded Drug Program

Discarded Drug Program

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Payments

ⓘ 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

Show 10 entries

Drug	P Number	Labeler Code	Refund Period	Payment Amount	Failed	EFT ID	Due Date	Payment Date	Initiate Payment
J2796	P1910 <i>ⓘ</i>	55513	Q4 2024	\$2,768,809.64		DPID25110...	12/31/2025	07/21/2026	☐
J2802	P1910	55513	Q1 2024	\$5,396.72		DPUX26090...	12/31/2026	07/21/2026	☐
J2802	P1910	55513	Q2 2024	\$10,428.54		DPUX26090...	12/31/2026	07/21/2026	☐
J2802	P1910	55513	Q3 2024	\$28,752.15		DPUX26090...	12/31/2026	07/21/2026	☐
J2802	P1910	55513	Q4 2024	\$35,044.84		DPUX26090...	12/31/2026	07/21/2026	☐
J2802	P1910	55513	Q1 2025	\$2,789,296.14		DPUX26090...	12/31/2026	07/21/2026	☐

Payments Payable

Discarded Drug Program

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Payments

Payments



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	☐
J0001	P8019	12345	Q2 2023	\$295,294.27		DPIX24123...	02/28/2025	12/03/2024	☐
J0001	P8019	12345	Q1 2023	\$250,620.69		DPIX24123...	02/28/2025	12/03/2024	☐
J0003	P8019	34567	Q1 2023	\$624.66		DPIX24123...	02/28/2025	12/03/2024	☐

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Update All Payment Dates

mm/dd/yyyy



☐ Initiate All Payments

Submit

Payments Pending

Discarded Drug Program

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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	☐
J0006	P8027	23456	Q4 2023	\$9,388.27	DPIX24123...	11/20/2024	02/28/2025	☐

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☐ Stop All Payments

Stop Payment

Payments Submitted

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Reset

Drug

All

P Number

All

Status

All

Payment Initiated Date

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

J2796

P1910

55513

Q3 2024

\$3,078,307.10

12/16/2025

DPID25110...

12/31/2025

Success

Showing 1 to 1 of 1 entries

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TPA Resources

The screenshot displays the CMS TPA Administrator website. At the top, the CMS logo is on the left, and navigation links for 'TPAdministrator.com', 'Contact Us', 'My Profile', and 'Log Out' are on the right. Below this is a dark blue header with 'Overview' and 'Discarded Drug Program' tabs. The main content area features the CMS logo, a search bar, and a navigation menu with 'TPA', 'Programs', 'Frequently Asked Questions (FAQ)', and 'Listservs'. A breadcrumb trail shows 'Programs / Discarded Drug Program'. On the left, a sidebar lists links: 'Discarded Drug Program', 'Discarded Drug Reports', 'Disputes', 'EFT Information', 'Listservs', 'Onboarding', 'User Guides', and 'Webinars'. The main article is titled 'Discarded Drug Program' with a publication date of '08/07/2024'. The text explains that 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. It also states 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).

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Overview Discarded Drug Program

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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](#)).

CMS ASP Website

[Discarded Drugs page](#)

Medicare

Medicaid/CHIP

Marketplace & Private Insurance

Initiatives

Training & Education

Medicare > Payment > Medicare Part B Drug Average Sales Price > Discarded Drugs

Medicare Part B Drug Average Sales Price

ASP Reporting

ASP Pricing Files

ASP Billing Resources

Vaccine Pricing

ASP Regulations & Policy

Discarded Drugs

ASP Education & Outreach

ASP Events

Discarded Drugs

Announcement

CMS sent Discarded Drug Refund Reports for CY 2023 "updated quarters" and CY 2024 "new refund quarters" (as defined at [42 CFR 7.414.902](#)) in September of 2025. These funds were deposited into the Supplementary Medical Insurance (SMI) Trust Fund, as required by law. The total refunds owed for updated calendar quarters in 2023 and new calendar quarters in 2024 exceed **\$173 million**. The billing and payment codes for which a manufacturer (or manufacturers) paid a refund, and the amount of refund paid, are listed in the [Previous Years' Discarded Drug Refund Information - CY 2023 Updated Refund Quarters and CY 2024 New Refund Quarters](#).

The process for issuing Discarded Drug Refund Reports for the four "new refund quarters" of CY 2023 and the four "updated refund quarters" of CY 2024 has begun, and we intend to send this report in September 2026. CMS is working with a contractor, Palmetto GBA, to serve as a Third-Party Administrator (TPA) for issuing the Discarded Drug Refund Reports and facilitating refund payment. To access the [Manufacturer Payment Portal \(MPP\)](#), manufacturers must provide contact information in the Health Plan Management System (HPMS). Representatives from the TPA Support Center, or CMS, may reach out to manufacturers who are not yet onboarded to HPMS to begin the HPMS onboarding process.

Introduction

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 labeled amount of the product. Section 1847A(h) of the Social Security Act (the Act) requires manufacturers to pay a refund to CMS (to be deposited into the Federal Supplementary Medical Insurance Trust Fund) for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as a refundable drug). Generally, the refund amount is the amount of discarded drug that exceeds an applicable percentage (required to be at least 10 percent) of total charges for the drug in a given calendar quarter.

Questions

What is a Refundable Drug?

+

How Are Discarded Amounts of Refundable Drugs Identified?

+

What Is an Applicable Percentage?

+

Can a Manufacturer Request an Increased Applicable Percentage for a Refundable Drug?

+

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Medicare Part B Drug Average Sales Price

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ASP Education & Outreach

CMS collects Average Sales Price (ASP) data from manufacturers of Medicare Part B-covered drugs, biologics, and related items, services, supplies, and products. Explore the resources below to learn more about the ASP data collection and payment limit calculation processes and other relevant topics.

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Filter On

Date	Title	Description	Format
2026-07-09	ASP Data Collection System Submitter User Guide	Step-by-step instructions on how to submit Medicare Part B drug product and financial data to CMS in the ASP Data Collection System	PDF
2026-07-09	ASP Data Collection System Certifier User Guide	Step-by-step instructions on how to certify submitted Medicare Part B drug product and financial data in the ASP Data Collection System	PDF
2026-06-26	ASP Data Collection System Registration Guide	A guide to help users prepare for the first time they log in to the newly updated ASP Data Collection System	PDF
2026-06-26	Frequently Asked Questions (FAQs): Bona Fide Service Fee Certification and Average Sales Price Reasonable Assumptions	A document used to provide answers to Frequently Asked Questions (FAQs) from interested parties about requirements for the BFSF certification and ASP reasonable assumptions	PDF
2026-04-02	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
2026-04-02	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

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Medicare Part B Drug Average Sales Price

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Announcement

CMS will host a webinar on August 11, 2026, at 1:00 p.m. EST for manufacturers of Refundable Drugs in the Medicare Part B Discarded Drug Program. This session provides an overview of the Discarded Drug Program and the [Manufacturer Payment Portal \(MPP\)](#). We will provide information on the calculations for new and updated refund quarters, as well as instructions for accessing Discarded Drug Refund Reports and paying refund amounts due in the [MPP](#).

Sign up now: [Tuesday, August 11, 2026, 1:00 p.m. EST](#)

Post Events

Webinar Name	Date	Description	Links
Discarded Drug Webinar	08/07/2025	Provides an overview of the second program year of Discarded Drug Refund Program and the Manufacturer Payment Portal for manufacturers of refundable drugs	Webinar Recording Passcode: G8@kek*5 Presentation Slides (PDF)
Discarded Drug Webinar	12/05/2024	Provides an overview of the Discarded Drug Refund Program and the Manufacturer Payment Portal for manufacturers of refundable drugs	Webinar Recording Passcode: 8H1V9485 Presentation Slides (PDF)
Skin Substitute Products: Entering Data in the ASP Data Collection System	07/18/2024	Provides an overview of the ASP Data Collection Module and ASP submission process for manufacturers of skin substitute products	Webinar Recording Password: 7 v7q18K Presentation Slides (PDF)

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\(g\)](#).

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 the issuance 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?

- ✓ Verify system access.
- ✓ Add or update Electronic Funds Transfer (EFT) information now.
- ✓ View reports on or after September 1, 2026.
- ✓ Pay refund amounts due by December 31, 2026.

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

