



CENTER FOR MEDICARE

August 17, 2026

Warning Letter- Manufacturer Discount Program - Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturers

Contract ID: P1383

Manufacturer Name: kaleo, Inc.

David Smiy
Primary Contact
10900 Nuckols Road
Suite 200
Glen Allen, Virginia 23060

VIA EMAIL: david.smiy@kaleo.com

RE: Manufacturer Discount Program - Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number Contract ID: P1383

Dear David Smiy:

The Centers for Medicare & Medicaid Services (CMS) is issuing this notice of determination to impose a civil money penalty to kaleo, Inc., P1383. Pursuant to section 1860D-14C(e) of the Social Security Act (the Act) and section 120 of the Medicare Part D Manufacturer Discount Program Final Guidance (Final Guidance)¹, CMS is providing notice of a civil money penalty (CMP) assessment in the amount of \$1,719.28.

Basis for the Civil Money Penalty

CMS is imposing a CMP of \$1,719.28 on kaleo, Inc., P1383 based on a report provided by the Third Party Administrator (TPA) for the Medicare Part D Manufacturer Discount Program (MDP). The information which the TPA provided indicates that your organization failed to pay Part D sponsors for applicable discounts within 38 calendar days from receipt of the 2026 first quarter invoice. This is a violation of section 1860D-14C(b)(3) of the Act, section 80.2.3 of the Final Guidance, and section II(b) of the Medicare Part D Manufacturer Discount Program Agreement (Discount Agreement).

Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

- 96 Part D Sponsors: \$6,877.10
 - List of Impacted Sponsors See Attachment 3

The CMP that your company owes is equal to:

- The 25% late payment penalty; \$1,719.28

You **must** contact the TPA, 1-877-534-2772, to pay any invoiced amounts your company has failed to pay to Part D sponsors.

You **must** pay the 25% late payment penalty via Pay.gov. Please see the required payment method below under Method to Submit CMP Payments.

The determination by CMS to impose a CMP will become final and due no later than sixty (60) calendar days from the date on this letter, October 16, 2026, if you do not request a hearing to appeal in the manner and time frame described below under Right to Request a Hearing.

Please note that any further failures by kaleo, Inc. to comply with these or any other CMS requirements may subject your organization to termination as set forth in section 1860D-14C(b)(4)(B)(i) of the Act, section 80.1.3.1 of the Final Guidance, and section VII(b) of the Discount Agreement.

Method to Submit CMP Payments

CMP payments must be made using Pay.gov (Instructions on Attachment 1). Pay.gov provides a free service to entities that make online payments to a federal government agency. The Pay.gov Collection Service collects and processes the Internet-authorized deductions from a checking or savings account via Automated Clearing House (ACH) debit entries processed at the Federal Reserve Bank of Cleveland (FRB-C). Your Pay.gov payment transaction will not require a Username and Password.

Companies sometimes have blocks on their bank accounts that will only allow designating transactions to be processed. It may be necessary to provide your banking institute with the following two pieces of information to unblock the bank account:

- **Originating Depository Financial Institution (ODFI):** FRB-C is the payment processor for ACH payments made through Pay.gov and will appear as the ACH ODFI. FRB-C processes Pay.gov ACH transactions under the American Bankers Association (ABA) routing numbers 041036046 and 042736141.
- **Company ID:** Every ACH batch contains a company ID number in accordance with the National Automated Clearing House Association (NACHA) requirements. CMS' company ID number for Pay.gov payments is 7505008032.

For Pay.gov technical issues contact Pay.gov Customer Service at (800) 624-1373 or (216) 579-2112, Monday-Friday from 7:00 a.m. to 7:00 p.m. Eastern Time.

You will find it helpful to have the following information available to complete your payment:

- P# (P#####)
- MDP CMP determination letter from CMS (MDP ONLY)
- Bank account and routing numbers
- Point of contact regarding the payment

Right to Request a Hearing

Your organization may request a hearing before an Administrative Law Judge of the Department of Health and Human Services, Departmental Appeals Board (DAB), Civil Remedies Division (CRD), to appeal CMS' determination to impose a civil money penalty in accordance with section IV(a) of the Discount Agreement. Procedures governing this process are set out in section 120.2 of the Final Guidance and codified at 42 CFR Part 423, Subpart T.

You must:

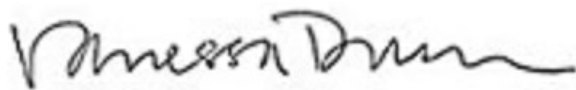
- **File your hearing request electronically** using the DAB's Electronic Filing System (DAB E-File) at <https://dab.efile.hhs.gov> **no later than sixty (60) days from the date on this letter;** October 16, 2026 (Instructions on Attachment 2) and
- **E-Mail a copy of your hearing request to CMS** at, PartDManufacturerDiscountProgram@cms.hhs.gov
- **If you do not file electronically, mail a copy of your hearing request to,**

Craig Miner, Director, Division of Part D Policy
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mailstop: C1-26-16
Baltimore, MD 21244

If you've filed for bankruptcy or are involved in a bankruptcy proceeding, Medicare financial obligations will be handled in accordance with the applicable bankruptcy process. If you haven't already notified CMS, please inform us promptly of this bankruptcy so we can coordinate the Department of Justice to ensure your case is managed properly. When notifying us of the bankruptcy, include the name under which it was filed, the docket number, and the district where it was filed. If you dispute this determination, please follow the appropriate appeals process described in Attachment 2: Right to Request a Hearing.

Acknowledgement of this letter is required. Please reply to PartDManufacturerDiscountProgram@cms.hhs.gov. If you have any questions about this notice, please contact PartDManufacturerDiscountProgram@cms.hhs.gov.

Sincerely,



Vanessa Duran, Director
Medicare Drug Benefit and C & D Data Group
Center for Medicare

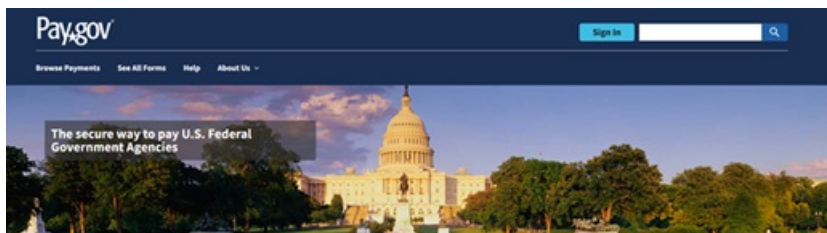
CC via email:

PartDManufacturerDiscountProgram@cms.hhs.gov, MDBG, MPPG, OC, OGC

Attachment 1

Step 1

Access Pay.gov at <https://www.pay.gov>



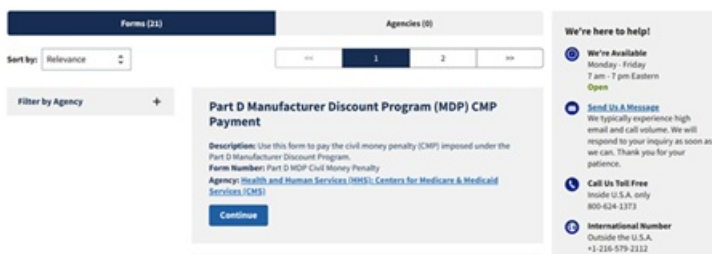
Step 2

- In the Search by keyword... box, Type: *Part D Manufacturer Discount Program (MDP) CMP Payment (not case sensitive)*
- then click on Search icon



Step 3

- On the Part D Manufacturer Discount Program (MDP) CMP Payment tile, click on **Continue**.
NOTE: Do Not Use for CGDP CMPs. (Only MDP)



Step 4

- You may select Preview Form, Cancel (to delete all information and return to Pay.gov home page), or Continue to the Form.
- Use this form to pay the civil money penalty (CMP) imposed under the Part D Manufacturer Discount Program only.
- If you don't have an existing account, you will have the option to create an account on the sign-in page. To continue as a guest user, click on 'Continue to the Form' to initiate payment.
- Click on Continue to the Form to initiate payment. Have available your MDP CMP Determination letter from CMS.

Part D Manufacturer Discount Program (MDP) CMP Payment

1 Before You Begin 2 Complete Agency Form 3 Enter Payment Info 4 Review & Submit 5 Confirmation

About this form
Use this form to pay the civil money penalty (CMP) imposed under the Part D Manufacturer Discount Program.

Accepted Payment Methods:

- Bank account (ACH)

With an account you can:

- See the payments you made since you created an account.
- Store payment information so you don't have to re-enter it.
- Copy a form you already submitted the next time you need to make a payment.

To take advantage of these benefits, you can [Sign In](#). If you don't have an existing account, you will have the option to create an account on the sign-in page. To continue as a guest user, click the 'Continue to the Form' button.

[Preview Form](#) [Cancel](#) [Continue to the Form](#)

Step 5

Complete the required fields on the Medicare Part D Manufacturer Discount Civil Money Penalty Payment form,

- **Part D Discount Program:** Manufacturer Discount Program (MDP) only
- **Manufacturer P Number:** (P####) must be a P followed by 4-digits
- **Manufacturer Name:** manufacturer's complete name
- **Point of Contact Name:** first and last name of person authorized to make the payment
- **Point of Contact Phone:** (*****) US 10-digit phone number, dashes will auto populate
- **Point of Contact Email:** email address
- **Date of CMP Determination Letter:** (MM/DD/YEAR) type or select the date from the CMP Determination Letter received from CMS
- **Invoice Quarter subject to the CMP:** (Q1, Q2, Q3, Q4) use the drop-down arrow to select the calendar quarter the invoice payment was late or unpaid
- **Year:** use the drop-down arrow to select the calendar year the invoice payment was late or unpaid
- **Payment Amount:** the twenty-five percent penalty calculation amount indicated on the MDP CMP Determination letter from CMS. You must contact the TPA, 1-877-534-2772, to pay any invoiced amounts your company has failed to pay to Part D sponsors.
- Click on View PDF to review or Click on Continue

Medicare Part D Manufacturer Discount Program Civil Money Penalty Payment

Part D Discount Program *

Manufacturer P Number *

Manufacturer Name *

Point of Contact Name *

Point of Contact Phone *

Point of Contact Email *

Date of Civil Money Penalty (CMP) Determination Letter *

MM/DD/YYYY

Invoice Quarter Subject to the CMP *

Year *

Payment Amount *

[Continue](#) [View PDF](#)

NOTE: You will immediately receive a message if any of the required information is missing on the payment form. Fill in the missing information and then click on Continue or View PDF.

Step 6

Have your banking information available to enter the required payment information.

Part D Manufacturer Discount Program (MDP) CMP Payment

Before You Begin Complete Agency Form Enter Payment Info Review & Submit Confirmation

Please provide the payment information below. Required fields are marked with an *

* Payment Amount
\$75,000,000.00

* Payment Date (month/year)
10/26/2025

☐ Current government agency ☐ Existing government agency

* Account Holder Name
Teste

* Select Account Type
Select

☐ Business Checking ☐ Business Savings ☐ Personal Checking ☐ Personal Savings

* Routing Number
000000000

* Account Number
000000000000000000

* Confirm Account Number
000000000000000000

[Previous](#) [Return to Form](#) [Cancel](#) [Review and Submit Payment](#)

Enter or review,

- **Payment Amount:** the payment amount entered on the previous page auto populates. Click on Previous or Return to Form at the bottom of the screen to correct the payment amount.
 - **Payment Date:** automatically populates the next available date the Federal Reserve Bank of Cleveland (FRB-C) will initiate the payment transaction.
 - **Account Holder Name:** name as it appears on the manufacturer's official bank account
 - **Select Account Type:** (Business Checking, Business Savings, Personal Checking, or Personal Savings) use the drop-down arrow to select account type
 - **Routing Number:** bank routing number
 - **Account Number:** bank account number
 - **Confirm Account Number:** re-type the bank account number
- Select one:
- Previous - to return to Payment Information page
 - Return to Form – to return to initial MDP CMP form
 - Cancel – to delete/cancel all information entered on the MDP CMP Payment form and return to Pay.gov home page or
 - Review and Submit Payment

Step 7

Part D Manufacturer Discount Program (MDP) CMP Payment

Before You Begin Complete Agency Form Enter Payment Info Review & Submit Confirmation

Please review the payment information below. Required fields are marked with an *

Payment Information

Payment Type: Bank account (ACH)
Payment Amount: \$99,999,999.99
Payment Date: 10/26/2025

Account Information

Account Holder Name: teste
Routing Number: 042000424
Account Number: *****0424

* Email Address:

* Confirm Email Address:

CC:

You may enter multiple email addresses in this field. Separate email addresses with a comma.

Authorization and Disclosure Statement

Authorization and Disclosure—Consumers and Businesses
The debit transaction(s) to which you are agreeing are handled on behalf of Federal agencies by "Pay.gov," which consists of services offered by the U.S. Treasury Department's Bureau of the Fiscal Service. As used in this document, "we" or "us" refers to the Bureau of the Fiscal Service and its assets and contractors operating Pay.gov.
[Printable version](#)

☐ I agree to the Pay.gov authorization and disclosure statement

[Previous](#) [Return to Form](#) [Cancel](#) [Submit Payment](#)

- Review the Payment Information and Account Information
- **Email Address:** Enter the email address to receive the payment confirmation
- **Confirm Email Address:** re-type the email address

- **CC:** please send a carbon copy to: PartDManufacturerDiscountProgram@cms.hhs.gov
- Read and/or print the Authorization and Disclosure. If you agree, Click the box, I agree to the Pay.gov authorization and disclosure statement
- Select one:
 - Submit Payment- to submit your payment
 - Cancel- to delete and cancel all information entered on the MDP CMP Payment form and return to Pay.gov home page
 - Return To Form- to return to the MDP CMP Payment form
 - Previous- to return to the Payment Information page

Step 8

- Read the payment confirmation.

Attachment 2

Right to a Hearing Before an Administrative Law Judge

Your organization may request a hearing before an Administrative Law Judge of the Department of Health and Human Services, Departmental Appeals Board (DAB), Civil Remedies Division (CRD), to appeal CMS' determination imposing a civil money penalty in accordance with Section IV(a) of the Manufacturer Discount Program agreement. Procedures governing this process are set out in section 1860D-14C(e) of the Social Security Act and section 120 of the Revised Medicare Part D Manufacturer Discount Program Final Guidance.

Content of the Hearing Request:

Your hearing request must identify specific issues and the findings of fact and conclusions of law with which you disagree and must specify the basis for each contention that a CMS finding of fact or conclusion of law is incorrect. 42 C.F.R. § 423.1020(b).

Registering for DAB E-File:

To file your request for hearing, you need to first create a **DAB E-File User Account**:

1. Go to <https://dab.efile.hhs.gov/>.
2. Click Register on the banner at the top of the screen.
3. Enter the requested information on the Register New Account form.
4. Select Register Account at the bottom of the form to submit. If you have more than one representative, each representative must register separately to use DAB-File on your behalf.

You will receive an e-mail confirming your registration and will be able to log into your DAB E-File account. Your confirmation e-mail and all future case-related notifications will be sent from the e-mail address: notifications@dab.efile.hhs.gov.

File Your Request for Hearing

1. After creating your DAB E-File account and logging in, navigate to the **Cases Before DAB**

- Administrative Law Judges** tile.
2. Select the **Manage Civil Remedies Division Cases** link and enter the requested information on the **File New Appeal** page.
 - In the **Documents** section you must upload:
 - Your request for hearing; and
 - A copy of the underlying notice letter from CMS (e.g., the CMS notice accompanying this instruction), which sets forth the CMS action being appealed

All documents, including your request for hearing, are deemed filed on the day they are uploaded to DAB E-File on or before 11:59 P.M. ET. By filing your request for hearing through DAB E-File, you consent to accept service of all case-related documents (including documents filed by CMS or issued by the Administrative Law Judge), electronically. Correspondingly, CMS is also deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found by clicking the **E-Filing Instructions** link on the **Manage Civil Remedies Division Cases** page.

If You Cannot File Electronically

If you are unable to file electronically, you may request a waiver from the electronic filing requirement. To do so, mail your request explaining why you cannot file electronically, along with your written request for hearing **no later than sixty (60) days after receiving this letter** to:

Department of Health and Human Services
Departmental Appeals Board, MS 6132
Director, Civil Remedies Division
330 Independence Avenue, S.W.
Cohen Building – Room G-644
Washington, D.C. 20201

For technical issues with DAB E-File, contact DAB E-File System Support at dabctacttechnicalsupport@hhs.gov.

If you need additional information, contact the DAB Civil Remedies Division at (202) 565-9462.

¹ Available at: <https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf>