

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland



CENTER FOR MEDICARE

September 15, 2025

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

Contract ID: P1444

Manufacturer Name: Scilex Pharmaceuticals, Inc.

Michele Pericci
Primary Contact
960 San Antonio Road
Palo Alto, California 94303

VIA EMAIL: mpericci@scilexholding.com

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number Contract ID: P1444

Dear Michele Pericci:

The Centers for Medicare & Medicaid Services (CMS) is issuing this notice of determination to impose a civil money penalty to Scilex Pharmaceuticals, Inc., P1444. Pursuant to 42 CFR §423.2340, CMS is providing notice of a civil money penalty (CMP) assessment in the amount of \$5,229.75.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$5,229.75 on Scilex Pharmaceuticals, Inc., P1444 based on a report provided by the Third Party Administrator (TPA) for the Coverage Gap Discount Program. The information which the TPA provided indicates that your organization failed to pay specified Part D sponsors for applicable discounts within 38 calendar days from receipt of the 2025 first quarter invoice. This is a violation of 42 CFR §423.2315(b)(3) and Section II(b) of the Medicare Coverage Gap Discount Program Agreement (Discount Agreement).

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

- 31 Part D Sponsors: \$20,919.00
 - List of Impacted Sponsors, see Attachment 3

The CMP that your company owes is equal to:

- Any invoiced amounts your company has failed to pay to Part D sponsors; \$20,919.00
- Plus the 25% late payment penalty; \$5,229.75

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 November 14, 2025 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 Scilex Pharmaceuticals, Inc. to comply with these or any other CMS requirements may subject your organization to termination as described in 42 CFR §423.2345 and section VIII 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 7505008012.

For Pay.gov technical issues contact Pay.gov Customer Service at (800) 624-1373 or (216) 579-2112, Monday-Friday from 6:00 A.M. to 7:00 P.M. Eastern Time.

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

- P# (P####)
- CMP payment demand letter from CMS
- Bank account and routing numbers
- Point of contact regarding the payment
- Business mailing address

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) to appeal CMS' determination to impose a civil money penalty in accordance with Section IV(b) of the Discount Agreement. Procedures governing this process are set out in 42 C.F.R. § 423.2340.

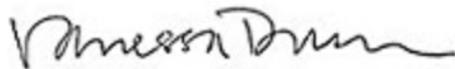
You must:

- file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at <https://dab.efile.hhs.gov> no later than sixty (60) days after receiving this letter; November 14, 2025 (Instructions on Attachment 2); and
- email a copy of your hearing request to CMS:

Centers for Medicare & Medicaid Services, Craig Miner, Deputy Director, Division of Part D Policy at CGDPandManufacturers@cms.hhs.gov.

Acknowledgement of this letter is required, please reply to CGDPandManufacturers@cms.hhs.gov. If you have any questions about this notice, please contact Sonia Eaddy, sonia.eaddy@cms.hhs.gov.

Sincerely,



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

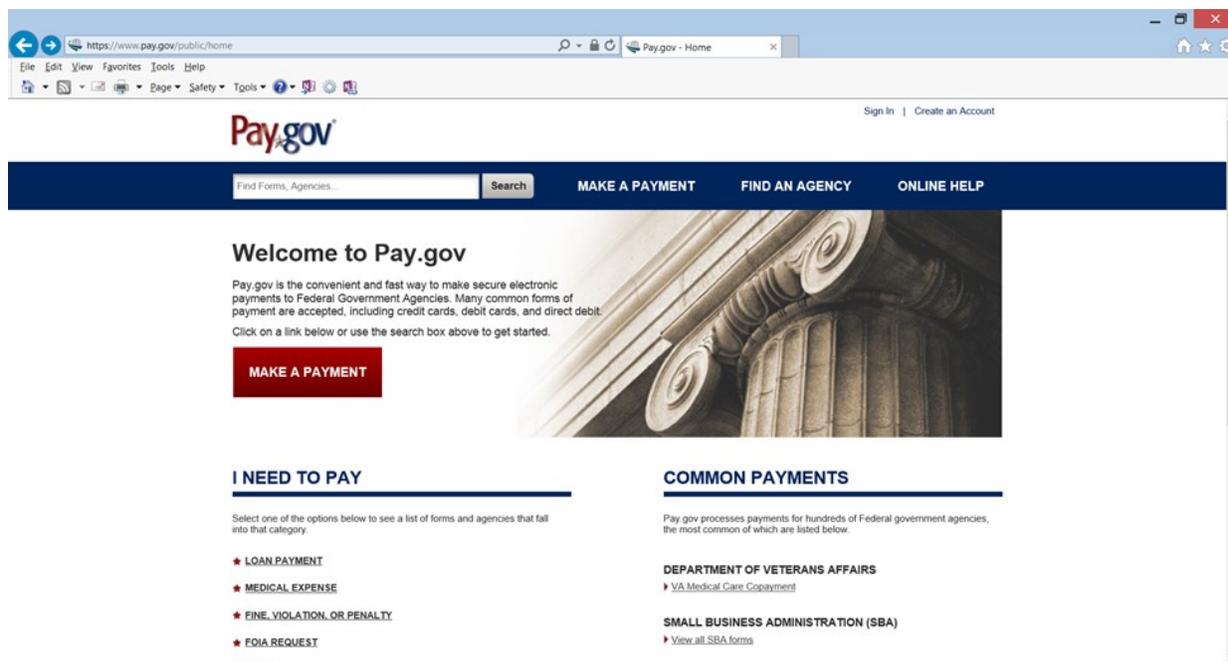
CC via email:

CGDPandManufacturers@cms.hhs.gov

Attachment 1

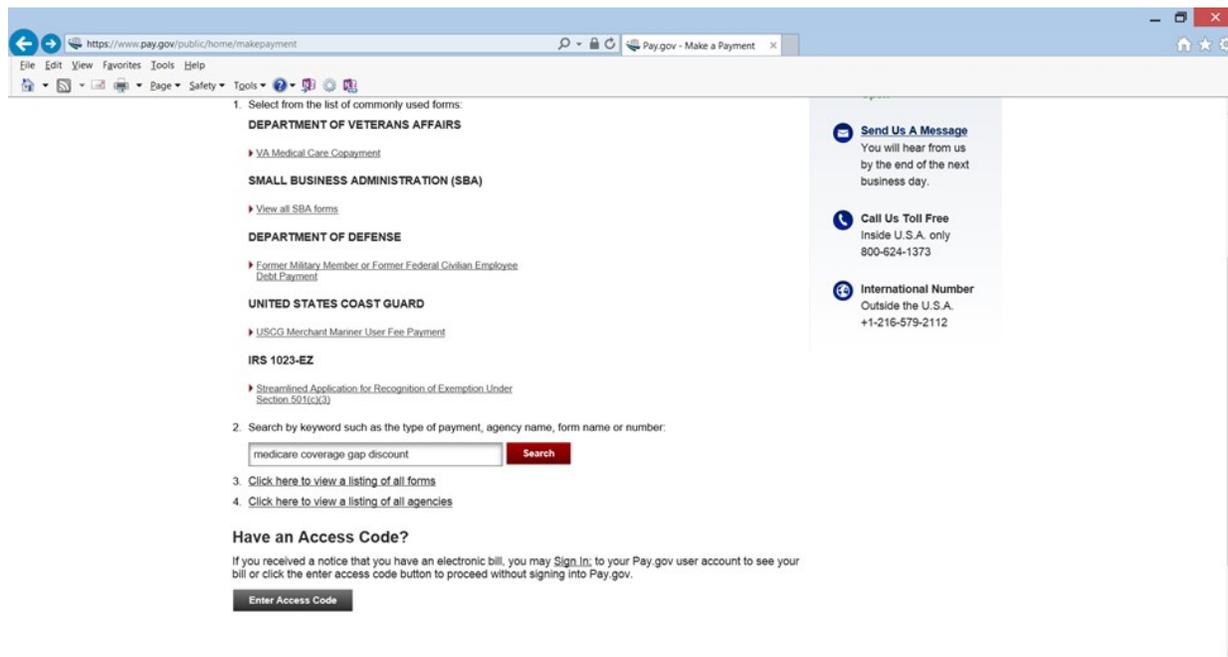
Step 1

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



Step 2

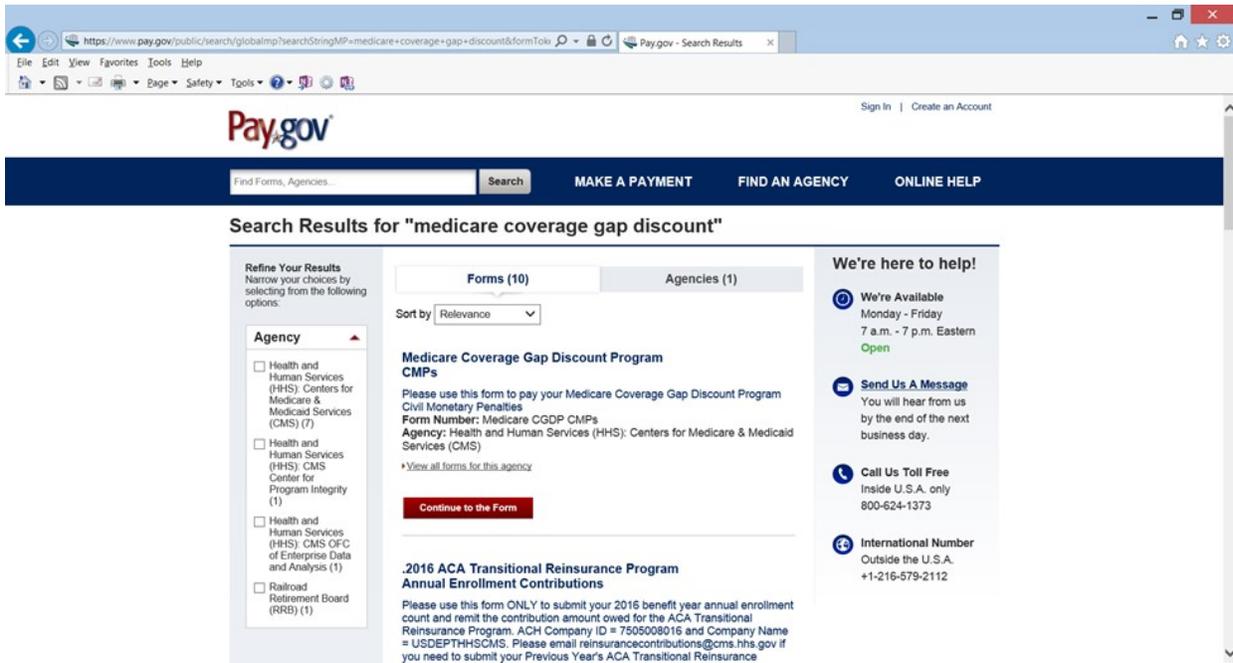
- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount* (not case sensitive)
- then click on Search



Step 3

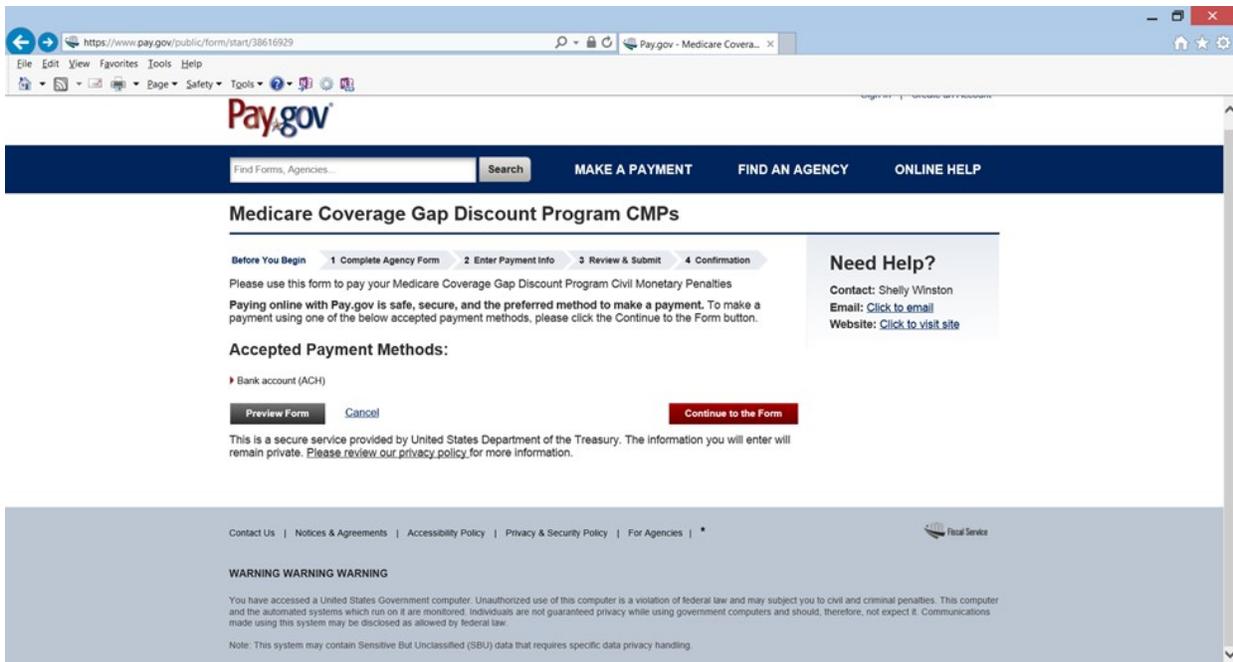
Medicare Coverage Gap Discount Program CMPs

- Click on **Continue to the Form**.



Step 4

- You may Preview Form, cancel, or Continue to Form.
- Click on Continue to the Form. Have available your payment demand letter from CMS.



Step 5

- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment

- o **Point of Contact Phone:** (***_**_****) telephone number must include dashes
- o **Point of Contact Email:** email address
- o **Mailing address:** Street, city, state, and zip code
- o **Date of Demand Letter:** (MM/DD/YEAR) typed date on the demand letter received from CMS
- o **Quarter:** (Q1, Q2, Q3, Q4) use the drop arrow to select the calendar year quarter in which the invoice payment was late or unpaid
- o **Year:** use the drop down arrow to select the calendar year in which the invoice payment was late or unpaid
- o **Payment Amount:** the total amount indicated on the demand letter from CMS

- Review
- Click on Submit Data

NOTE: You will immediately receive a message if **any** of the required information is missing on the payment form. Click OK, complete the missing information, and click on Submit Data.



Step 6

Have your banking information available to enter the payment information. Enter bank information, review, and print your payment confirmation to complete your Pay.gov payment.

Medicare Coverage Gap Discount Program CMPs

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

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

* Payment Amount: \$1,000.00

* Payment Date (mm/dd/yyyy): 07/04/2019

* Account Holder Name: _____

* Select Account Type: Select Account Type

* Routing Number: _____

* Account Number: _____

* Confirm Account Number: Confirm Account Number

Manufacturer P Number: P0001

Buttons: Previous, Return to Form, Cancel, Review and Submit Payment

Need Help?
 Contact: Shelly Winston
 Email: [Click to email](#)
 Website: [Click to visit site](#)

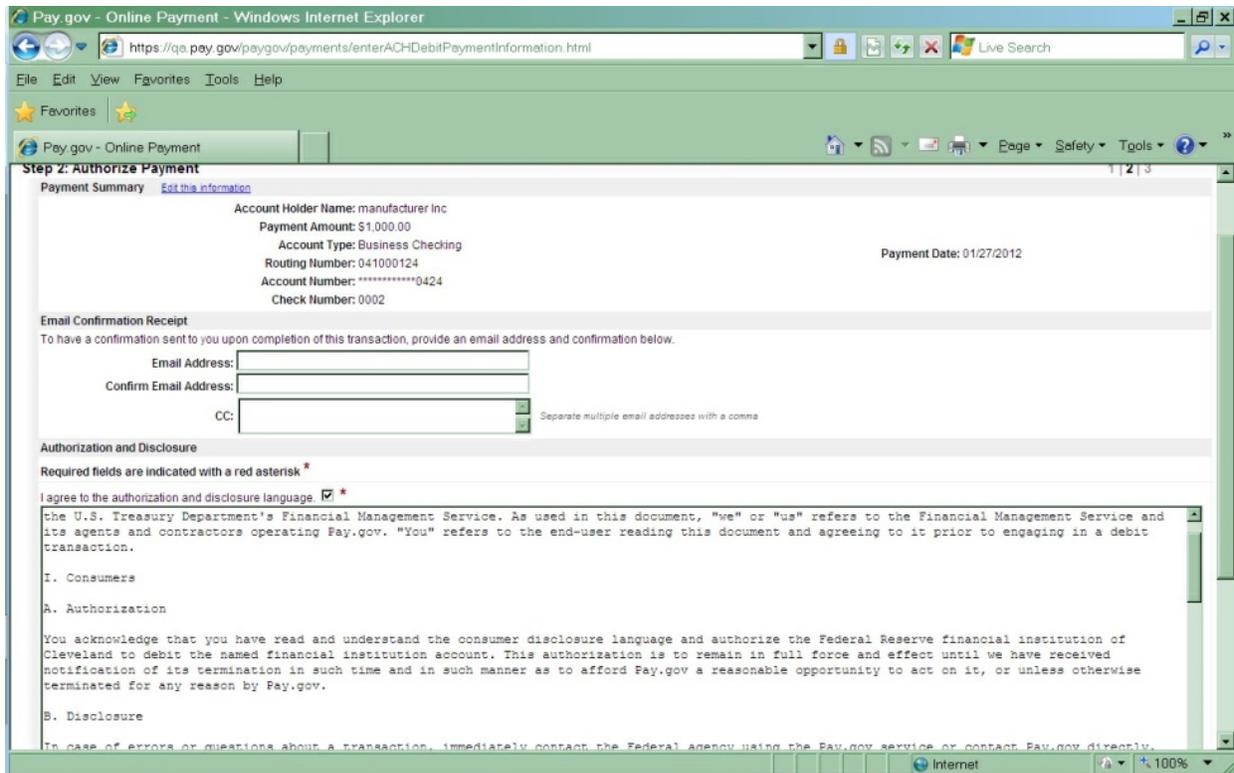
Notice the payment amount you entered on the previous screen has populated. Click on Return to Form at the bottom of the screen to correct the payment amount.

Enter,

- **Payment Amount**
- **Payment Date:** automatically populates the next available date in which the financial institutes can initiate the payment transaction
- **Account Holder Name:** name as it appears on the actual banking account
- **Select Account Type:** (Personal Checking, Personal Savings, Business Checking, or Business 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 your bank account number

Click on Review and Submit Payment when you are ready

- Review the payment summary,



- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdp_manufacturers@cms.hhs.gov
- Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization and disclosure language*

Submit Payment- will submit your payment and move you to the final step of your payment

Cancel- will cancel all information entered during this session

Return To Your Form- will take you back to the Civil Money Penalty form

- Print the payment confirmation.

Pay.gov - Online Payment - Windows Internet Explorer
 https://qa.pay.gov/paygov/payments/authorizeACHPayment.html

File Edit View Favorites Tools Help

Pay.gov - Online Payment

Pay.gov
 Provided by the US Department of the Treasury
[Home](#) > Online Payment

Login
 Username:
 Password:
 Login
[Trouble Logging In?](#)

Find Public Forms
 by Form Name
 by Agency Name
 Search Public Forms

Public Resources
 Resources
[Accessibility Statement](#)
[Notices & Agreements](#)
[Privacy & Security Policy](#)
[Sitemaps](#)
 Help
[Contact Us](#)
[Frequently Asked Questions](#)
 Information
[Agency Information](#)
[Overview](#)
[Implementing](#)
[Documentation](#)
[Press / Articles](#)

Online Payment
 Step 3: Confirm Payment 1 | 2 | 3

Thank you.
 Your transaction has been successfully completed.
 It is recommended you [print a copy](#) for your records.  [Print this window.](#)

Pay.gov Tracking Information
 Application Name: Medicare Coverage Gap Discount Program CMPs
 Pay.gov Tracking ID: 3FOHC800
 Agency Tracking ID: 120008878801
 Transaction Date and Time: 01/25/2012 12:36 EST

Payment Summary

Account Holder Name: manufacturer Inc	Payment Date: 01/27/2012
Payment Amount: \$1,000.00	
Account Type: Business Checking	
Routing Number: 041000124	
Account Number: *****0424	
Check Number: 0002	

[Return to your form search results](#)
[Return to Home](#)

inw

Done Internet 100%

Attachment 2

Department of Health and Human Services, Departmental Appeals Board (DAB)

Registering to Use DAB E-File

To file a new appeal using DAB E-File, you first need to register a new account by:

- clicking “Register” on the DAB E-File home page;
- entering the information requested on the “Register New Account” form; and
- clicking “Register Account” at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB-File on your behalf.

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 dabctactechsupport@hhs.gov.

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