

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: P1653

Manufacturer Name: Woodward Pharma Services LLC

Ellen Gettenberg
Primary Contact
47220 Cartier Drive, Suite A
Wixom, Michigan 48393

VIA EMAIL: egettenberg@woodwardpharma.com

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number Contract ID: P1653

Dear Ellen Gettenberg:

The Centers for Medicare & Medicaid Services (CMS) is issuing this notice of determination to impose a civil money penalty to Woodward Pharma Services LLC, P1653. Pursuant to 42 CFR §423.2340, CMS is providing notice of a civil money penalty (CMP) assessment in the amount of \$206,316.84.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$206,316.84 on Woodward Pharma Services LLC, P1653 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:

- 40 Part D Sponsors: \$165,053.47
 - 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; \$165,053.47
- Plus the 25% late payment penalty; \$41,263.37

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 Woodward Pharma Services LLC 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.

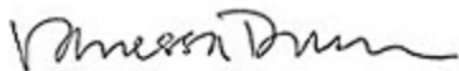
You must:

- 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

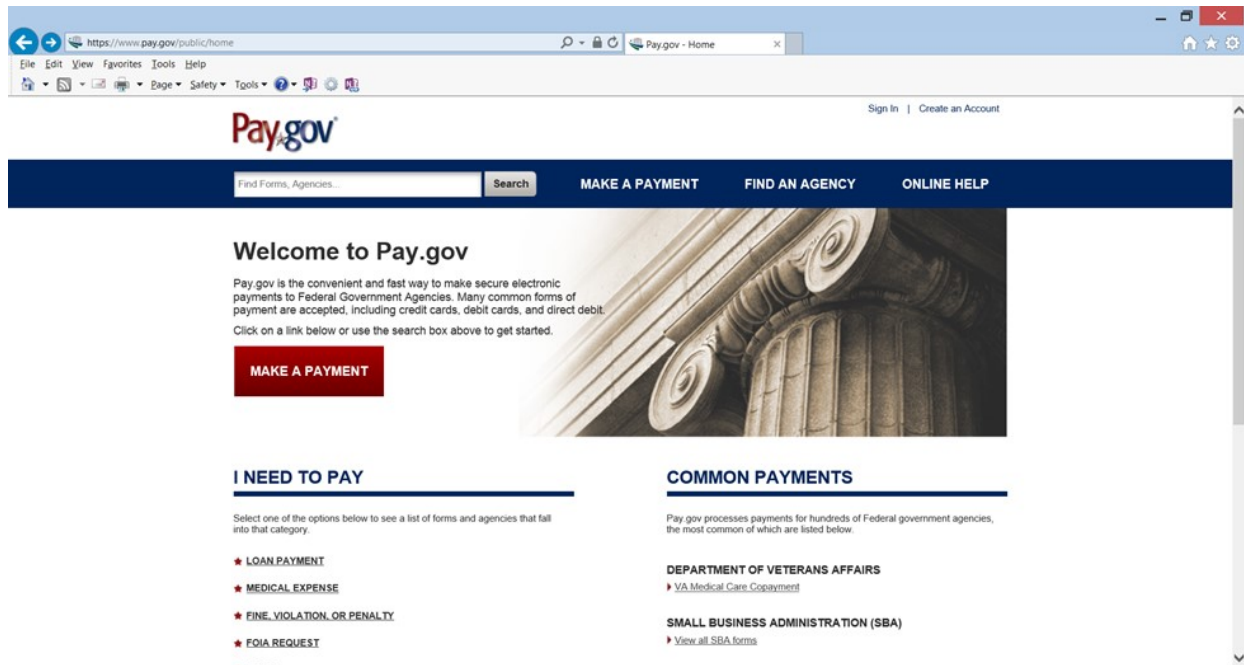
CC via email:

CGDPandManufacturers@cms.hhs.gov

Attachment 1

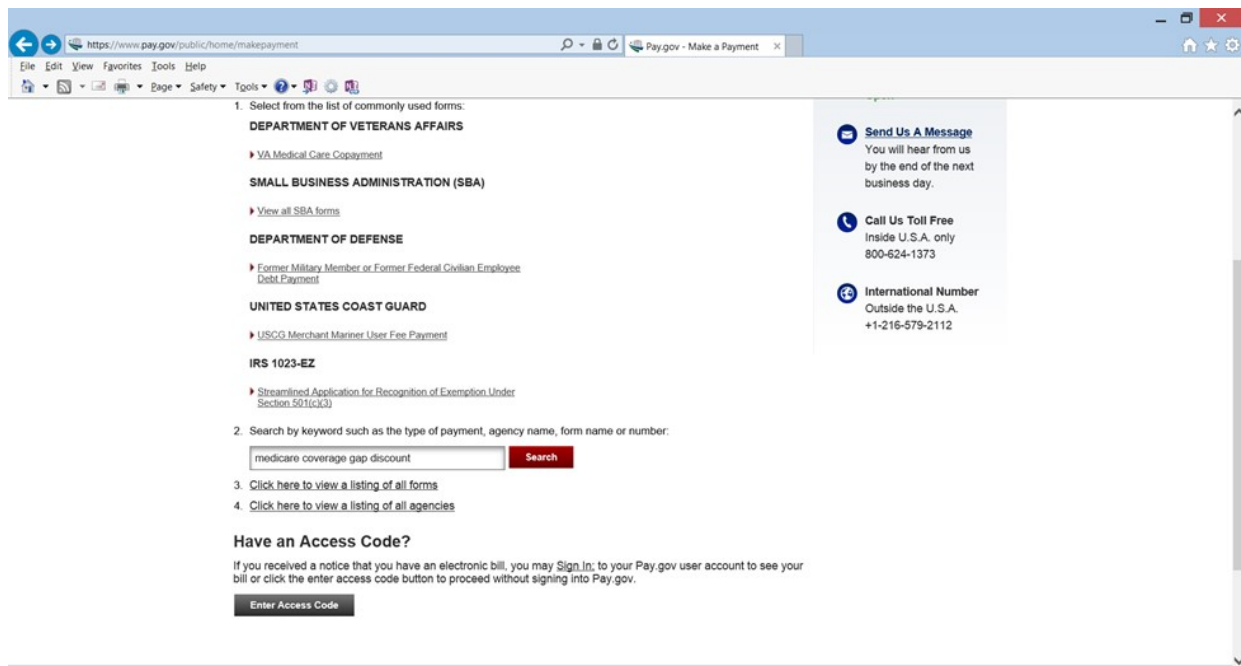
Step 1

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



Step 2

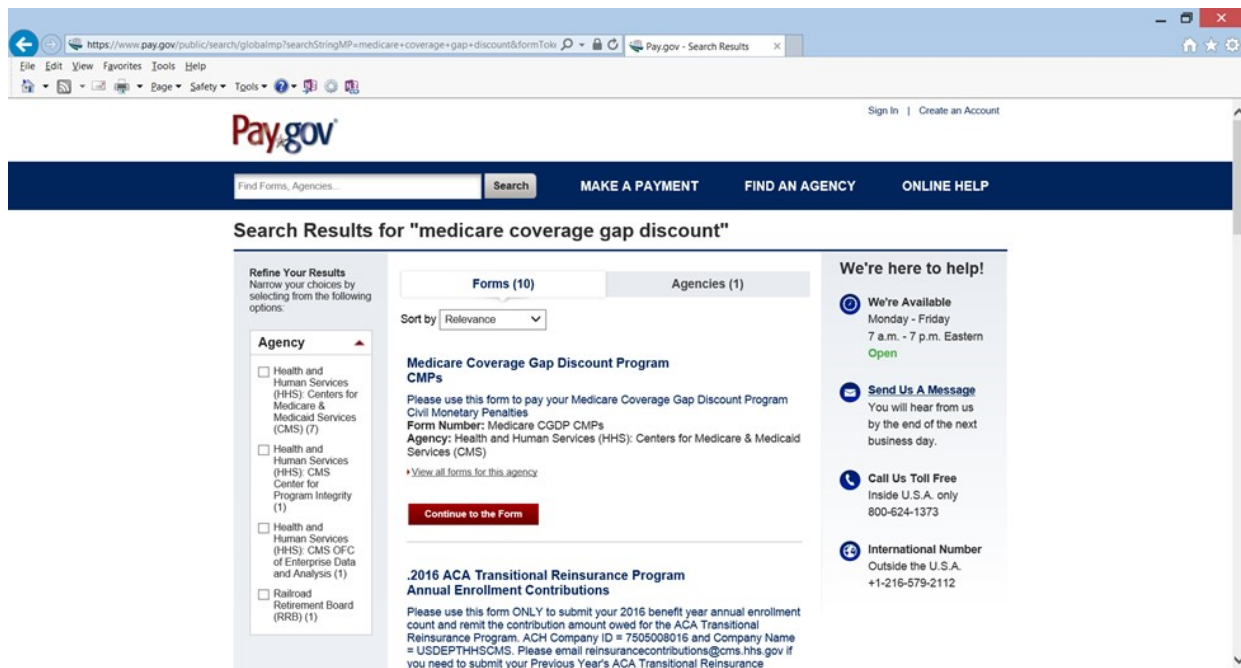
- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount* (not case sensitive)
- then click on Search



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.

The screenshot shows a web browser window with the URL <https://www.pay.gov/public/form/start/38616929>. The browser's address bar and menu bar are visible. The Pay.gov logo is at the top left of the page. A dark blue navigation bar contains a search box with the text "Find Forms, Agencies...", and three links: "MAKE A PAYMENT", "FIND AN AGENCY", and "ONLINE HELP".

Medicare Coverage Gap Discount Program CMPs

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

Please use this form to pay your Medicare Coverage Gap Discount Program Civil Monetary Penalties

Paying online with Pay.gov is safe, secure, and the preferred method to make a payment. To make a payment using one of the below accepted payment methods, please click the Continue to the Form button.

Accepted Payment Methods:

▶ Bank account (ACH)

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

This is a secure service provided by United States Department of the Treasury. The information you will enter will remain private. [Please review our privacy policy](#) for more information.

Need Help?

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

[Contact Us](#) | [Notices & Agreements](#) | [Accessibility Policy](#) | [Privacy & Security Policy](#) | [For Agencies](#) | *

WARNING WARNING WARNING

You have accessed a United States Government computer. Unauthorized use of this computer is a violation of federal law and may subject you to civil and criminal penalties. This computer and the automated systems which run on it are monitored. Individuals are not guaranteed privacy while using government computers and should, therefore, not expect it. Communications made using this system may be disclosed as allowed by federal law.

Note: This system may contain Sensitive But Unclassified (SBU) data that requires specific data privacy handling.

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

https://www.pay.gov/public/form/entry/103/ Pay.gov - Medicare Covera... X

File Edit View Favorites Tools Help

Page Safety Tools

Civil Money Penalty Payment

***Required Fields**

*Manufacturer P Number:

*Manufacturer Name:

*Address:

*City:

*State:

*Zip Code:

*Point of Contact Name:

*Point of Contact Phone:

*Point of Contact Email:

*Date of Demand Letter:

Invoice Quarter for which Penalties are due:

*Quarter: *Year:

*Payment Amount: \$

(Note: This must be the total amount due)

PDF Preview Continue

- 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.

Message from webpage X

 Please complete:

Date of Demand Letter

Invoice Quarter

Payment Amount

OK

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 Form 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)
01/01/2018

* Account Holder Name
[Text Field]

* Select Account Type
Select Account Type

* Routing Number
[Text Field]

* Account Number
[Text Field]

* Confirm Account Number
[Text Field]

Manufacturer P Number
P0001

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,

Pay.gov - Online Payment - Windows Internet Explorer

https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html

File Edit View Favorites Tools Help

Pay.gov - Online Payment

Step 2: Authorize Payment

Payment Summary [Edit this information](#)

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

Email Confirmation Receipt
 To have a confirmation sent to you upon completion of this transaction, provide an email address and confirmation below.

Email Address:
 Confirm Email Address:
 CC: Separate multiple email addresses with a comma

Authorization and Disclosure
 Required fields are indicated with a red asterisk *

I agree to the authorization and disclosure language ☒ *

the U.S. Treasury Department's Financial Management Service. As used in this document, "we" or "us" refers to the Financial Management Service and its agents and contractors operating Pay.gov. "You" refers to the end-user reading this document and agreeing to it prior to engaging in a debit transaction.

I. Consumers

A. Authorization
 You acknowledge that you have read and understand the consumer disclosure language and authorize the Federal Reserve financial institution of Cleveland to debit the named financial institution account. This authorization is to remain in full force and effect until we have received notification of its termination in such time and in such manner as to afford Pay.gov a reasonable opportunity to act on it, or unless otherwise terminated for any reason by Pay.gov.

B. Disclosure
 In case of errors or questions about a transaction, immediately contact the Federal agency using the Pay.gov service or contact Pay.gov directly.

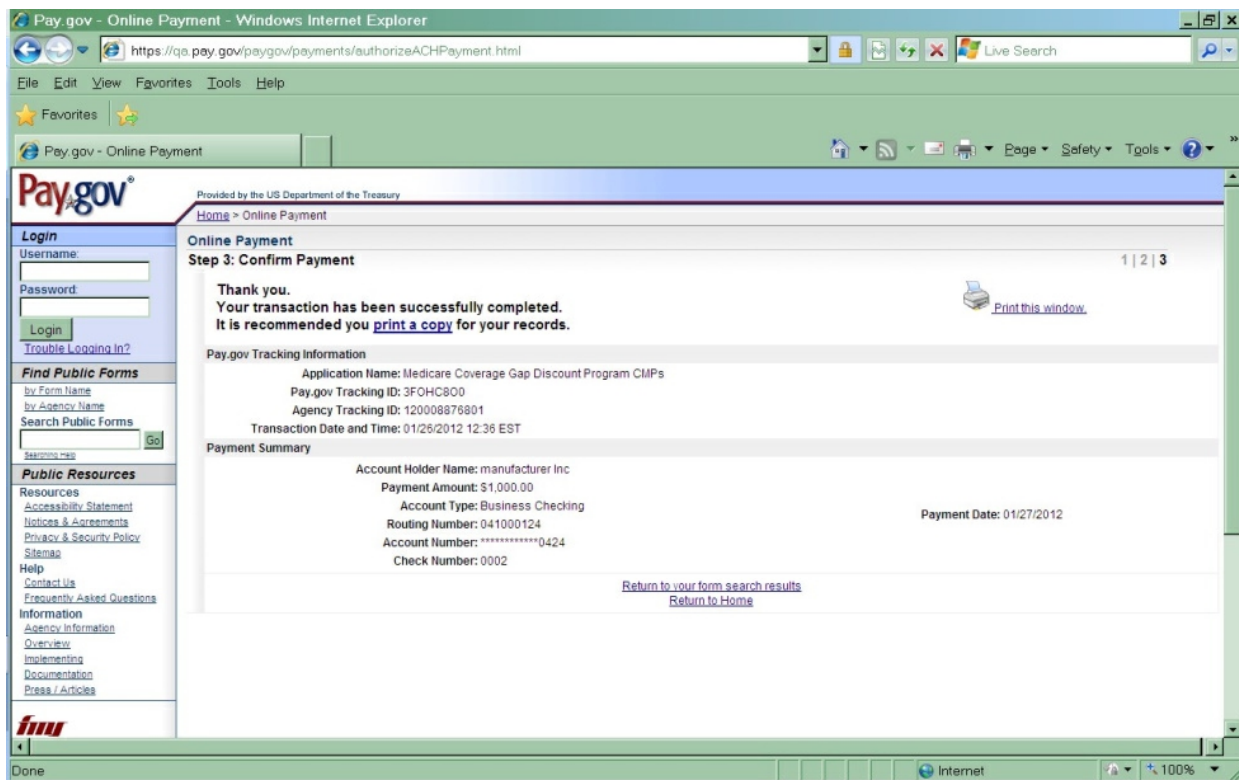
- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdp_manufacturers@cms.hhs.gov
- Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization and disclosure language*

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.



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.