



CENTER FOR MEDICARE

---

September 01, 2023

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

Contract ID: P1383

Manufacturer Name: kaleo, Inc.

David Smiy  
Primary Contact  
111 Virginia Street  
Suite 300  
Richmond, Virginia 23219

VIA EMAIL: david.smiy@kaleo.com

**RE: 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 42 CFR §423.2340, CMS is providing notice of a civil money penalty (CMP) assessment in the amount of \$953.07.

**Basis for Civil Money Penalty**

CMS is imposing a CMP of \$953.07 on kaleo, Inc., P1383 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 2023 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:

- 6 Part D Sponsors: \$3,812.26
  - See Attachment 3

The CMP that your company owes is equal to:

- The 25% late payment penalty; 953.07

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 October 31, 2023 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 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.

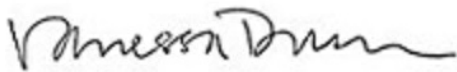
You must:

- 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; October 31, 2023 (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](mailto:CGDPandManufacturers@cms.hhs.gov).

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

Sincerely,



Vanessa Duran, Acting Director

Medicare Drug Benefit and C & D Data Group  
Center for Medicare

CC via email:

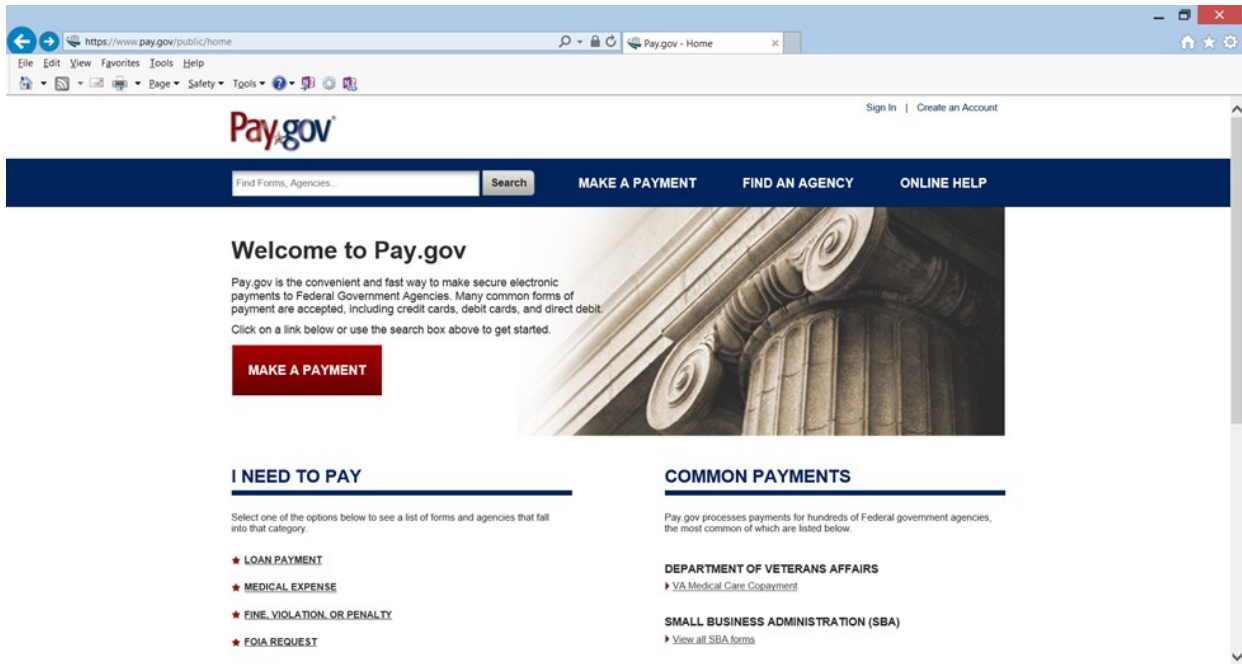
[CGDPandManufacturers@cms.hhs.gov](mailto:CGDPandManufacturers@cms.hhs.gov)

MDBG, MPPG, OC, OGC

**Attachment 1**

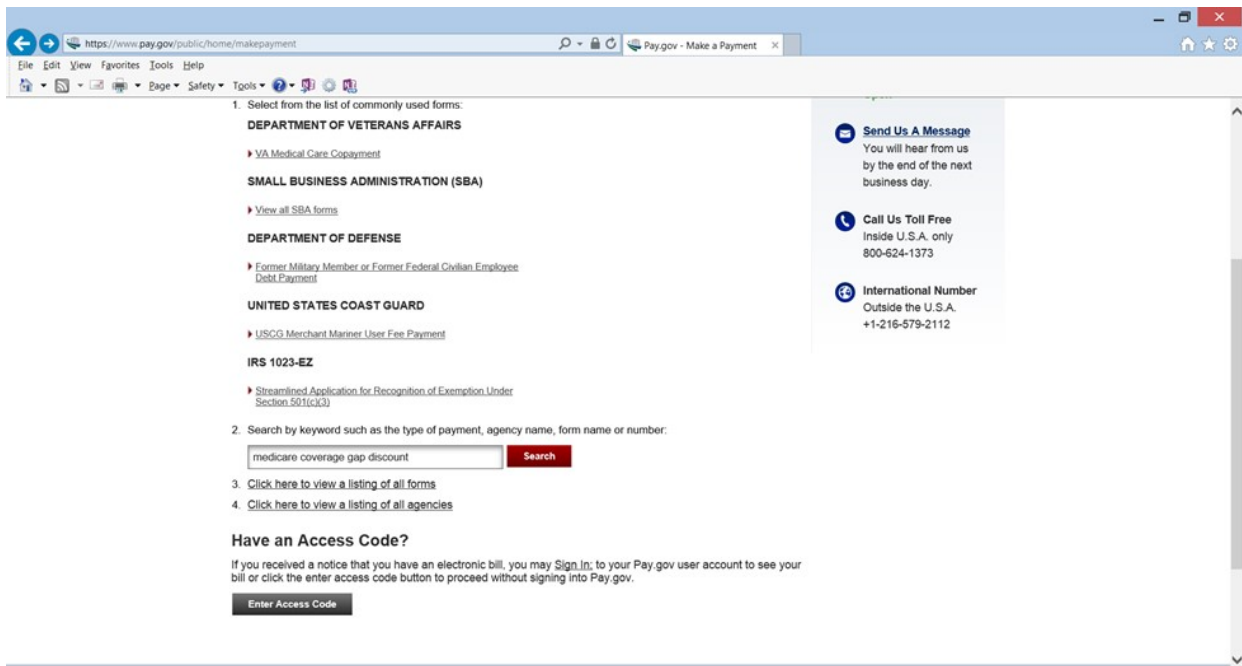
Step 1

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



**Step 2**

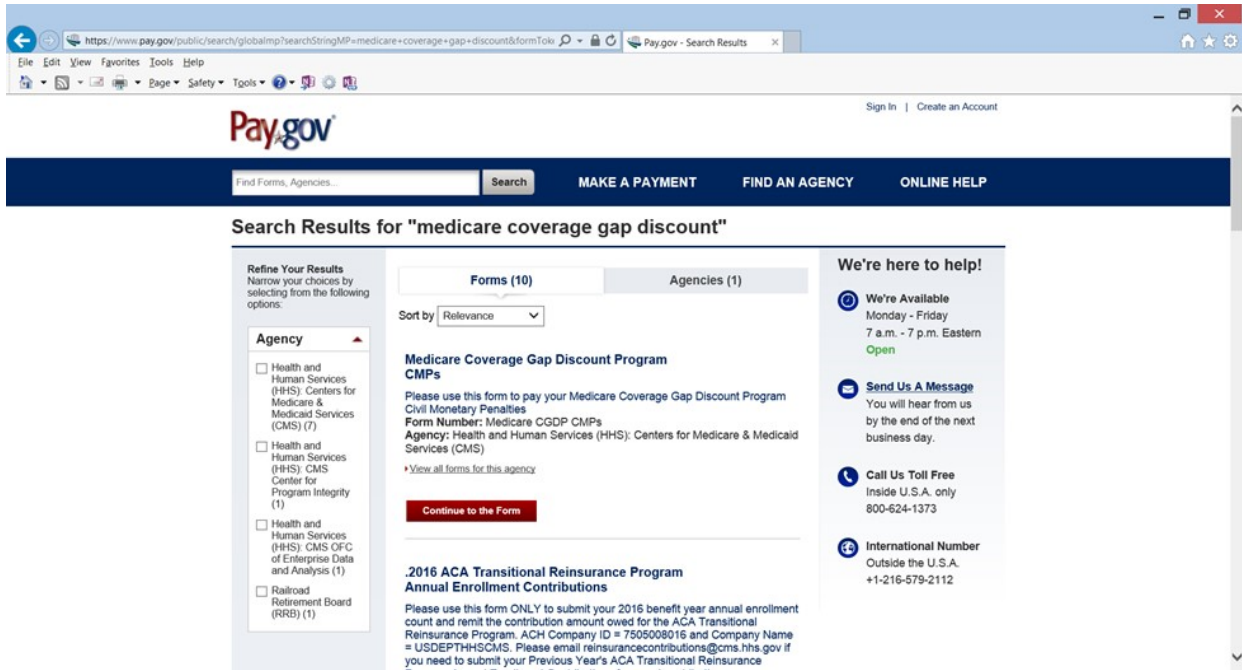
- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Search



**Step 3**

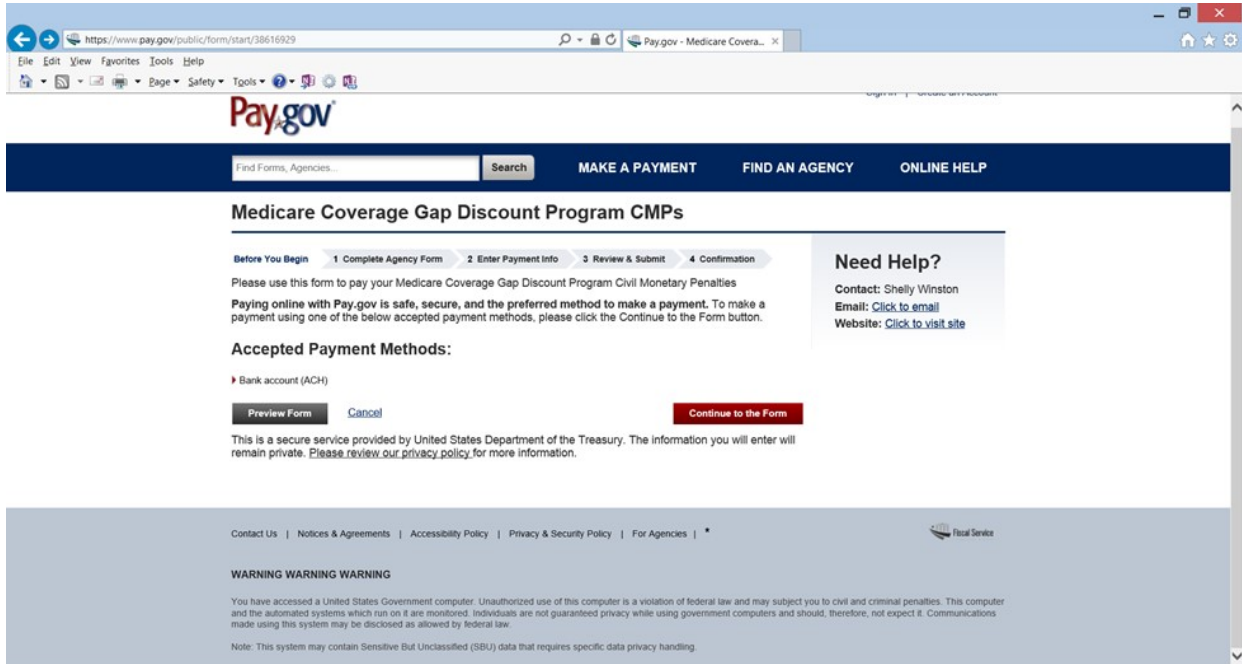
Medicare Coverage Gap Discount Program CMPs

- 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
  - **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

- 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.

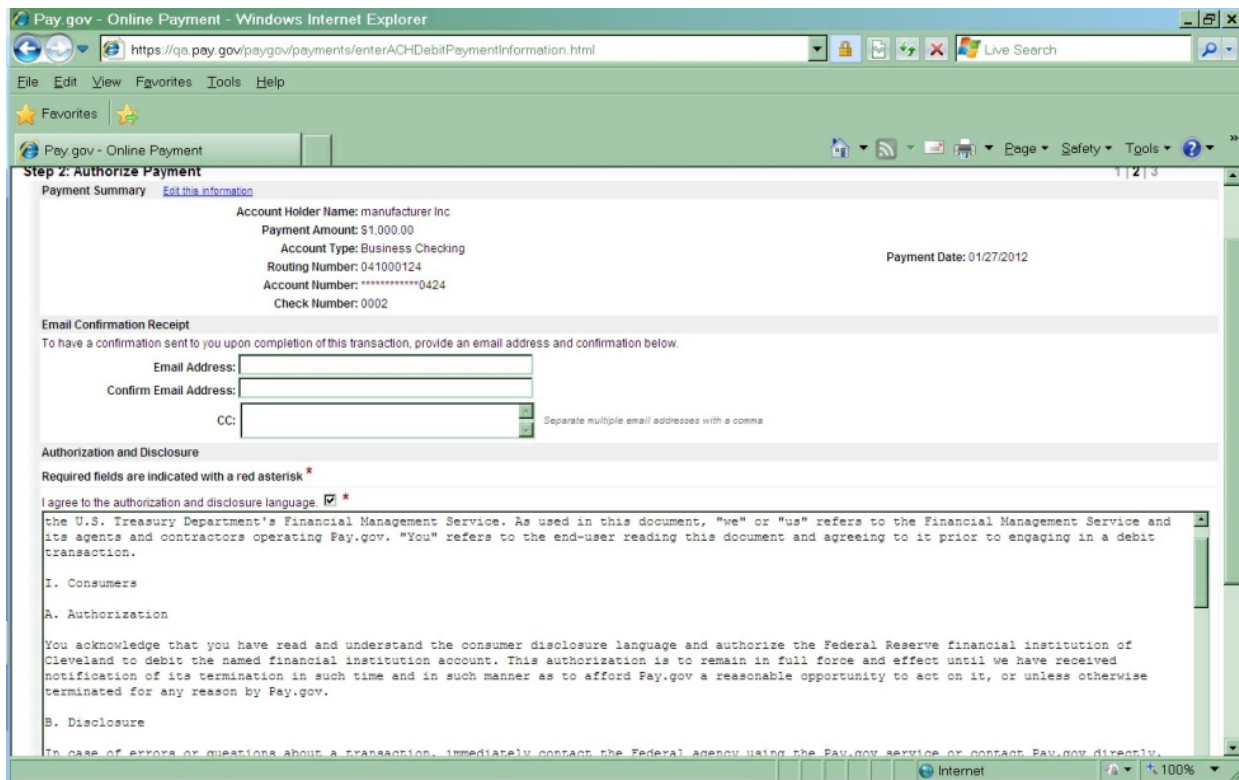
*Notice the payment amount you entered on the previous screen has populated. Click on Return to Form at the bottom of the screen to correct the payment amount.*

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](mailto: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*

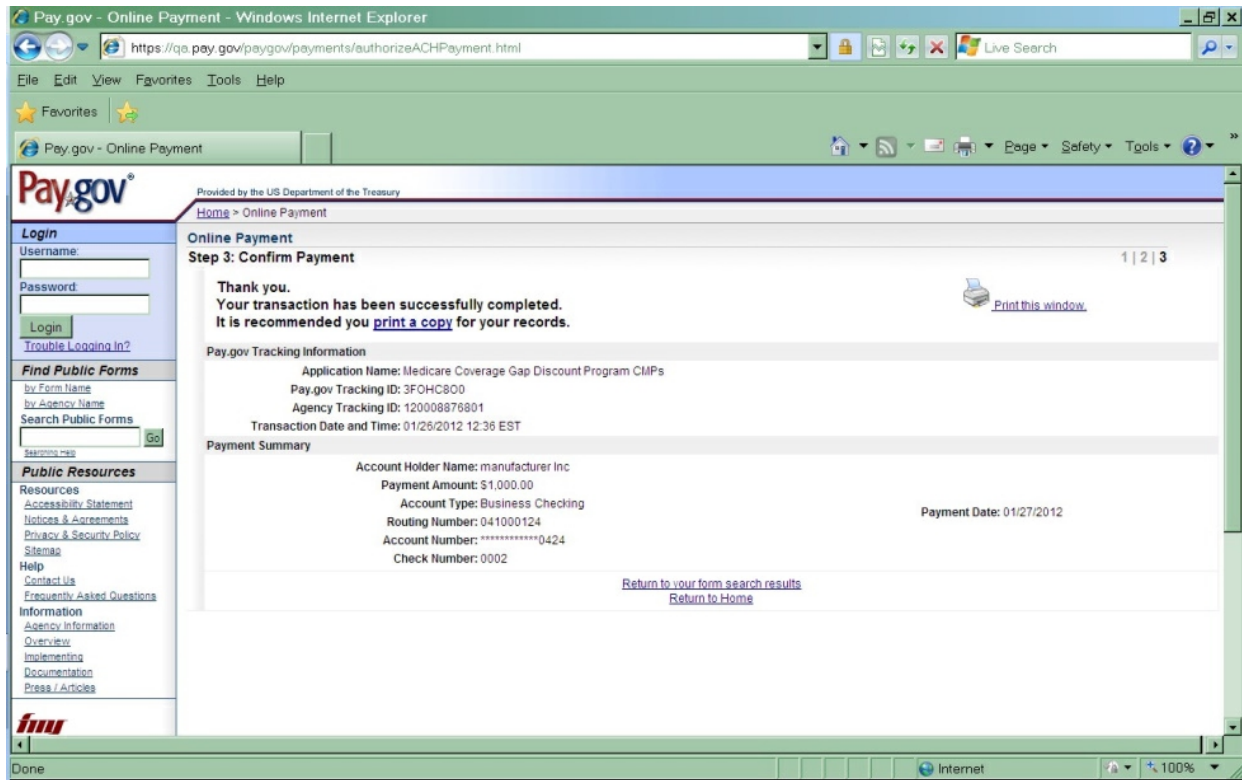
**Submit Payment-** will submit your payment and move you to the final step of your payment

**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.

### *Filing an Appeal through DAB E-File*

The e-mail address and password provided during registration must be entered on the login screen at [http://dab.efile.hhs.gov/user\\_sessions/new](http://dab.efile.hhs.gov/user_sessions/new) to access DAB E-File. A registered user’s access to DAB E-File is restricted to the appeals for which he is a party or authorized representative. Once registered, you may file your appeal by:

- clicking the “File New Appeal” link on the “Manage Existing Appeals” screen, then clicking “Civil Remedies Division” on the “File New Appeal” screen; and
- entering and uploading the requested information and documents on the “File New Appeal - Civil Remedies Division” form.

At a minimum, the Civil Remedies Division (CRD) requires a party to file a signed request for hearing and the underlying notice letter from CMS that sets forth the action taken and the party’s appeal rights. All documents must be submitted in Portable Document Format (“PDF”). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the Administrative Law Judge, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

The DAB no longer accepts requests for a hearing submitted by U.S. mail or commercial carrier, unless you do not have access to a



computer or internet services. In those circumstances you may contact the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:

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  
(202) 565-9462

The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect. 42 C.F.R. § 423.1020(b).