

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C1-26-16  
Baltimore, Maryland 21244-1850



## **Center for Medicare**

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June 1, 2017

VIA EMAIL: [jdatz@galenabiopharma.com](mailto:jdatz@galenabiopharma.com); [ssenthil@pharmametrics.com](mailto:ssenthil@pharmametrics.com)

Galena BioPharma, Inc.  
James Datz  
4640 SW Macadam Ave., Suite 270  
Portland, OR 97239

### **RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1378**

Dear Galena BioPharma, Inc.:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to Galena BioPharma, Inc. of a civil money penalty (CMP) assessment in the amount of \$3,529.40.

#### **Basis for Civil Money Penalty**

CMS is imposing a CMP of \$3,529.40 on Galena BioPharma, Inc. 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 fourth quarter 2016 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:

- 12 Part D Sponsors: \$14,117.60 (Breakdown on Attachment 3)

The CMP that your company owes is equal to:

- The 25% penalty, \$3,529.40

The determination by CMS to impose a CMP will become final and due no later than July 31, 2017 if you do not request a hearing to appeal in the manner and timeframe described below under Right to Request a Hearing. Please see the required payment method below under Method to Submit CMP Payments.

Please note that any further failures by Galena BioPharma, 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**

All 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:

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- 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 (Instructions on Attachment 2); and
- mail a copy of your hearing request to CMS:

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

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 at [Sonia.eaddy@cms.hhs.gov](mailto:Sonia.eaddy@cms.hhs.gov).

Sincerely,

/s/

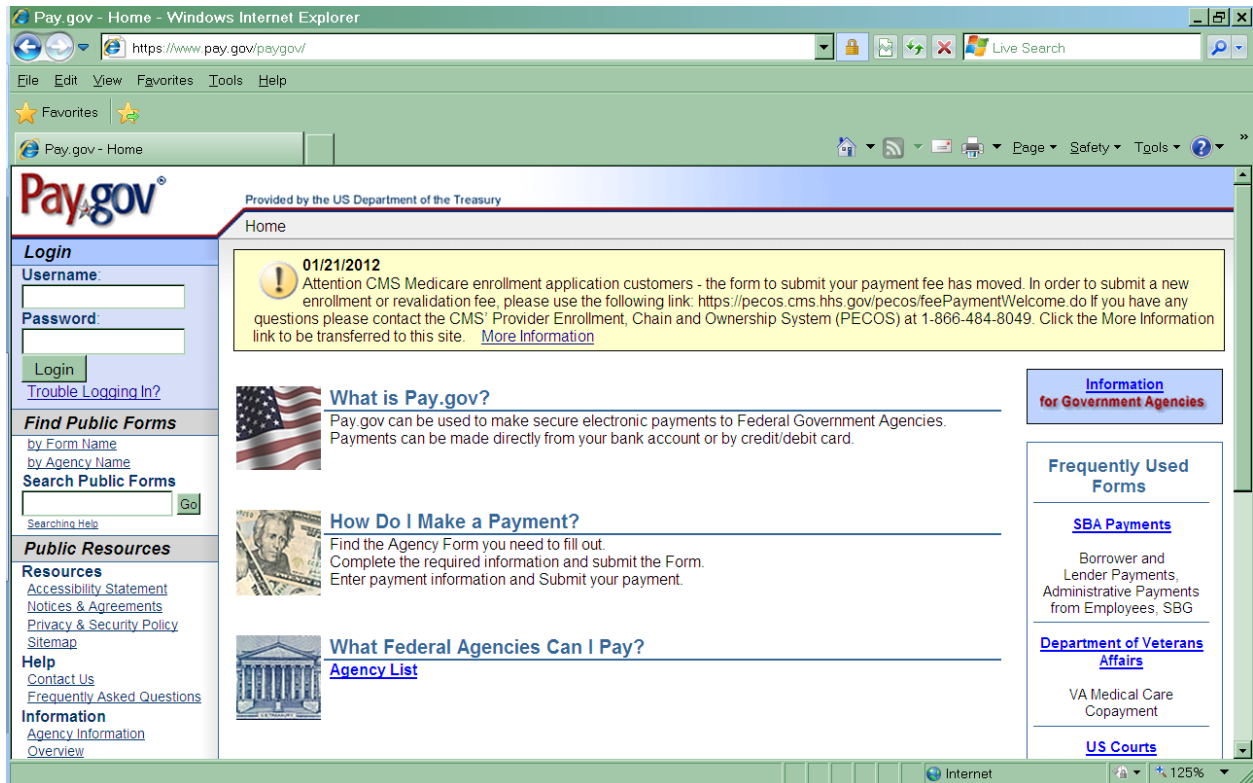
Amy K. Larrick Chavez-Valdez  
Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG  
Ms. Cheri Rice, CMS/CM/MPPG  
Ms. Amanda Johnson, CMS/CM/MPPG  
Ms. Whitney Hubbard, CMS/OL  
Mr. Ray Thorn, CMS/OC  
Ms. Jill Abrams, DHHS/OGC  
Ms. Jennifer Garver, DHHS/OGC

## Attachment 1

### Step 1

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



### Step 2

On the Pay.gov home page,

- In the **Search Public Forms** box (on the left side of the home page), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Go

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The screenshot shows a Windows Internet Explorer browser window displaying the Pay.gov website. The address bar shows the URL: <https://qa.pay.gov/paygov/payments/keywordSearchForms.html?keyword=medicare+Coverage+gap+discount&f>. The search results indicate that the search for "medicare Coverage gap discount" returned 3 results. The results are sorted by Form Name, Form Number, OMB Number, and Agency Name. The first result is the "CMS Data Payment Form" (Form Number: CMS Data Payment), which is a link to a PDF. The second result is the "CMS Medicare Application Fee" (Form Number: Medicare-app-fee-1), which is a link to a PDF. The third result is the "Medicare Coverage Gap Discount Program CMPs" (Form Number: Medicare CGDP CMPs), which is a link to a PDF. The left sidebar contains links for "Find Public Forms", "Search Public Forms", "Public Resources", "Resources", "Help", and "Information". The bottom of the page shows the "fmu" logo and the text "DEPARTMENT OF".

Pay.gov - Search Results - Windows Internet Explorer

https://qa.pay.gov/paygov/payments/keywordSearchForms.html?keyword=medicare+Coverage+gap+discount&f

File Edit View Favorites Tools Help

★ Favorites ★

Pay.gov - Form I... Contractor Perf... Pay.gov - Home Baltimore Winte... Pay.gov - Sa... x

Your search for "medicare Coverage gap discount" returned 3 results.

Results: 1-3 of 3

Sort By: **Form Name** | Form Number | OMB Number | Agency Name [Hide Details](#)

**CMS Data Payment Form** [View PDF](#)

Form Number: CMS Data Payment

Please use this form to pay your public use files, limited data sets, and research identifiable files fees. Also use this form to pay all other recovery of data processing fees from the Centers for Medicare & Medicaid Services. This form is NOT to be used for submitting the CMS 855 Application Fee. If you need to submit a new enrollment or revalidation fee, please use the following link:  
<https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do>.  
[Department of Health and Human Services](#)  
<https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=1818891>

**CMS Medicare Application Fee** [View PDF](#)

Form Number: Medicare-app-fee-1

For all questions please call: 1-866-484-8049. After December 31, 2011, you must access this url to CMS' Provider Enrollment, Chain and Ownership System (PECOS) website to pay the Medicare enrollment application fee: <https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do>.  
[Department of Health and Human Services](#)  
<https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=3149023>

**Medicare Coverage Gap Discount Program CMPs** [View PDF](#)

Form Number: Medicare CGDP CMPs

Please use this form to pay your Medicare Coverage Gap Discount Program Civil Monetary Penalties.  
[Department of Health and Human Services](#)  
<https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=3550318>

Results: 1-3 of 3

**Find Public Forms**  
by Form Name  
by Agency Name  
**Search Public Forms**  
medicare Coverage   
[Searching Help](#)

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

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## Step 3

Click on **Medicare Coverage Gap Discount Program CMPs** link. You will be taken to the civil money penalty collection form. Have available your payment demand letter from CMS.

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The screenshot shows a web browser window titled "Pay.gov - Form Instance - Windows Internet Explorer". The address bar shows the URL: <https://www.pay.gov/paygov/forms/formInstance.html?nc=1330705111240&agencyFormId=38816929&userFormId=1330705111240>. The browser's status bar at the bottom shows "Done" and "Internet".

The main content area displays the "Medicare Coverage Gap Discount Program" form, titled "Civil Money Penalty Payment". The form includes the following fields:

- \*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: \$

Below the fields, there is a "Submit Data" button and a "PDF Preview" button. A note at the bottom of the form states: "(Note: This must be the total amount due)".

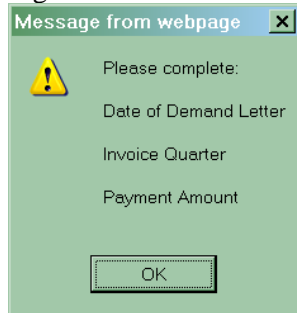
- Complete the required fields
  - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
  - **Manufacturer Name:** manufacturer's complete name
  - **Point of Contact:** person authorized to make the payment
  - **Point of Contact Phone:** (\*\*\*\_\*\*\_\*\*\*\*) telephone number must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

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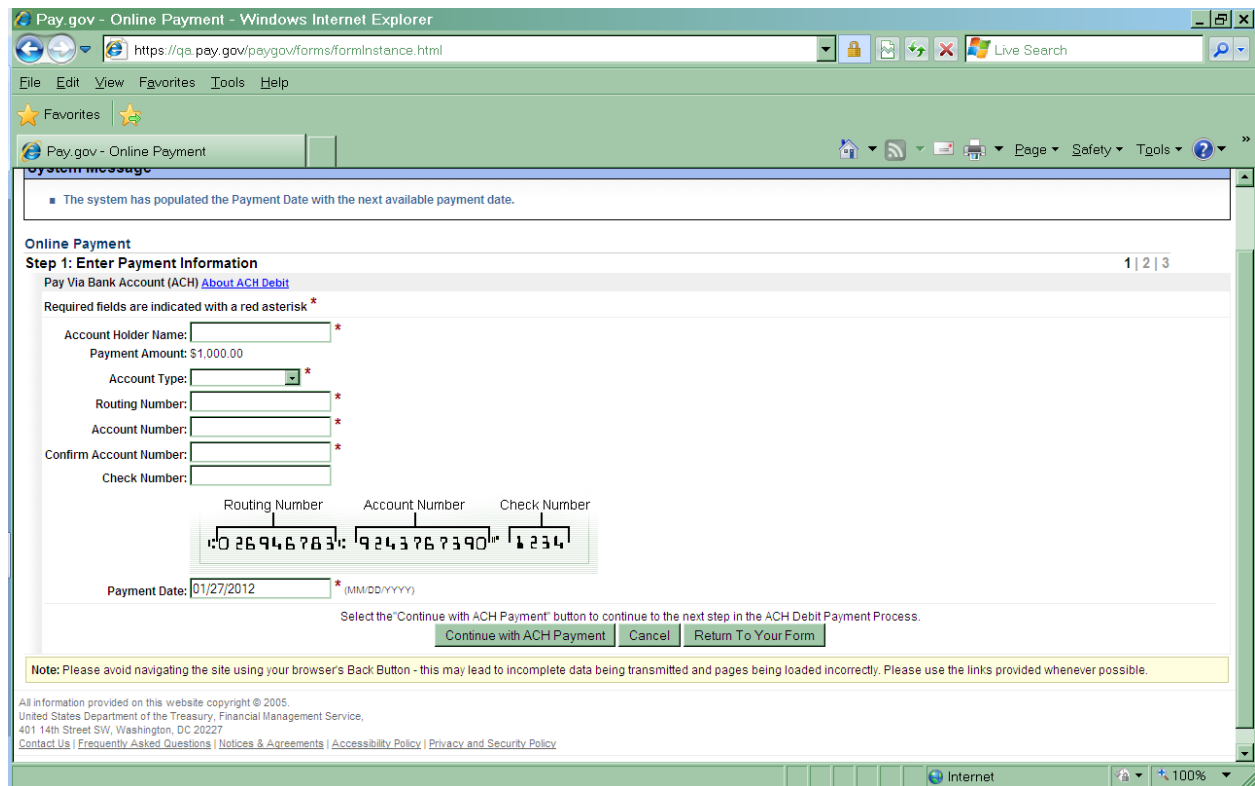
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#### Step 4

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.



- Enter Payment Information
  - **Account Holder Name:** name as it appears on the actual banking account

***Notice the payment amount you entered on the previous screen has populated. Click on Return To Your Form to correct the payment amount.***

- **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
- **Check Number:** check number used for this payment
- **Payment Date:** automatically populates the next available date in which the financial institutes can initiate the payment transaction

**Continue with ACH Payment-** will move you the next 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

**Note: You will be redirected to the Pay.gov home page to start a new session if you click on Continue with ACH Payment before the account information is entered.**

- 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.

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- 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.

The screenshot shows a web browser window titled "Pay.gov - Online Payment - Windows Internet Explorer". The address bar shows the URL "https://qa.pay.gov/paygov/payments/authorizeACHPayment.html". The browser's Favorites bar shows "Pay.gov - Online Payment". The page content includes the Pay.gov logo, a navigation menu on the left with links like "Login", "Find Public Forms", and "Public Resources", and a main content area titled "Online Payment Step 3: Confirm Payment". The main area displays a confirmation message: "Thank you. Your transaction has been successfully completed. It is recommended you print a copy for your records." Below this, it shows "Pay.gov Tracking Information" including Application Name, Pay.gov Tracking ID, Agency Tracking ID, and Transaction Date and Time. A "Payment Summary" section lists Account Holder Name, Payment Amount, Account Type, Routing Number, Account Number, and Check Number. At the bottom, there are links to "Return to your form search results" and "Return to Home". The browser's status bar at the bottom shows "Done" and "Internet".

Pay.gov - Online Payment - Windows Internet Explorer

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

File Edit View Favorites Tools Help

★ Favorites ★

Pay.gov - Online Payment

Pay.gov®

Provided by the US Department of the Treasury

Home > Online Payment

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: 120008876801  
Transaction Date and Time: 01/26/2012 12:36 EST

Payment Summary

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

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

Resources

Accessibility Statement  
Notices & Agreements  
Privacy & Security Policy  
Sitemap  
Help  
Contact Us  
Frequently Asked Questions  
Information  
Agency Information  
Overview  
Implementing  
Documentation  
Press / Articles

Done

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## **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).

**Attachment 3**

	<b>Contract Number</b>	<b>Contract Name</b>	<b>Invoiced Amount</b>
1	H0543	UnitedHealth Group Inc	\$ 2,741.85
2	H2001	UnitedHealth Group Inc	\$ 2,023.97
3	H3342	Anthem, Inc.	\$ 484.55
4	H3916	Highmark, Inc.	\$ 480.16
5	H5521	Aetna Health Management	\$ 1,494.05
6	H5938	Capital Health Plan, Inc.	\$ 524.54
7	S2468	Blue Shield of California	\$ 55.12
8	S5601	CVS Health	\$ 2,481.71
9	S5660	Medco Containment Life Insurance Company	\$ 867.42
10	S5805	UnitedHealth Group Inc	\$ 73.91
11	S5820	UnitedHealth Group Inc	\$ 2,642.39
12	S5921	UnitedHealth Group Inc	\$ 247.93
			\$ 14,117.60