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

July 26, 2019

VIA EMAIL: anarendon@trisourceph.com; eldrisdespaigne@amatheon.com

NextSource Biotechnology, LLC
4300 SW 73rd Avenue, STE 108
Miami, FL 33155

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1393

Dear NextSource Biotechnology, LLC:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to NextSource Biotechnology, LLC of a civil money penalty (CMP) assessment in the amount of $46,258.23.

Basis for Civil Money Penalty

CMS is imposing a CMP of $46,258.23 on NextSource Biotechnology, LLC, P1393, 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 first quarter 2019 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:

- 20 Part D Sponsors: $37,006.58 (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; $37,006.58
- Plus the 25% late payment penalty; $9,251.65

The determination by CMS to impose a CMP will become final and due no later than September 24, 2019 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 NextSource Biotechnology, 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

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:

- 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
- 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 at Sonia.eaddy@cms.hhs.gov.

Sincerely,

/s/

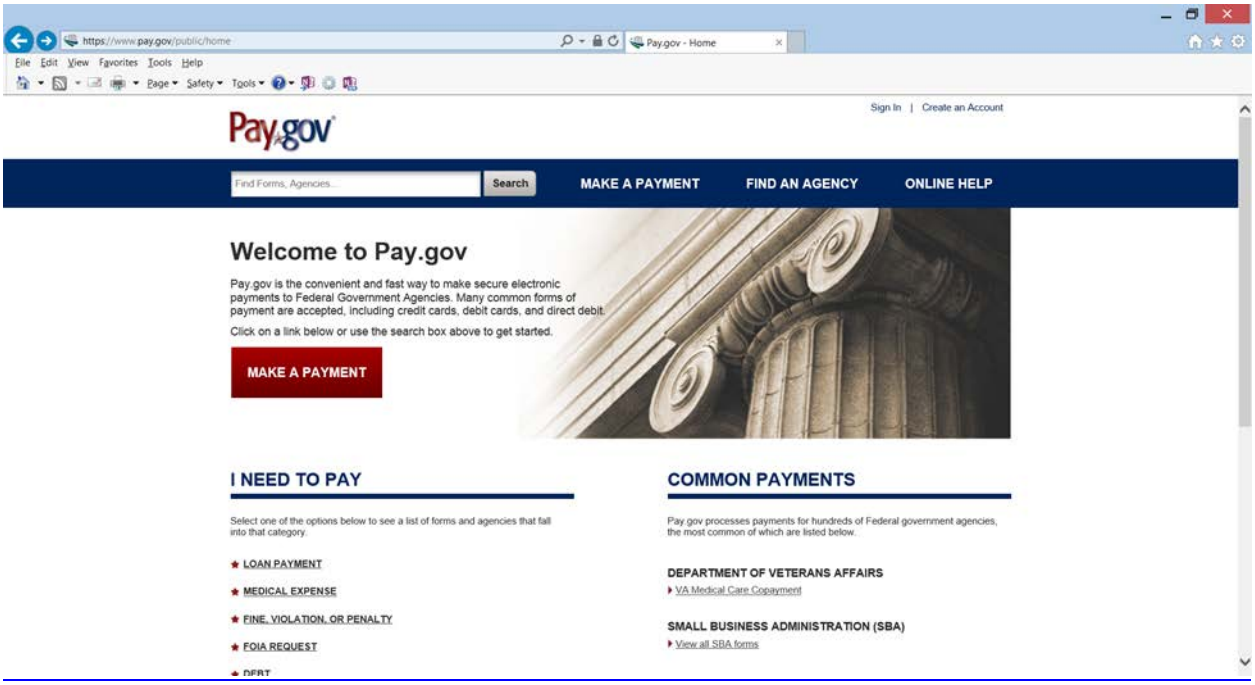
Amy K. Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG
Ms. Christine Machon, CMS/CM/MPPG
Mr. Ray Thorn, CMS/OC
Ms. Jill Abrams, DHHS/OGC
Ms. Jennifer Garver, DHHS/OGC

Attachment 1

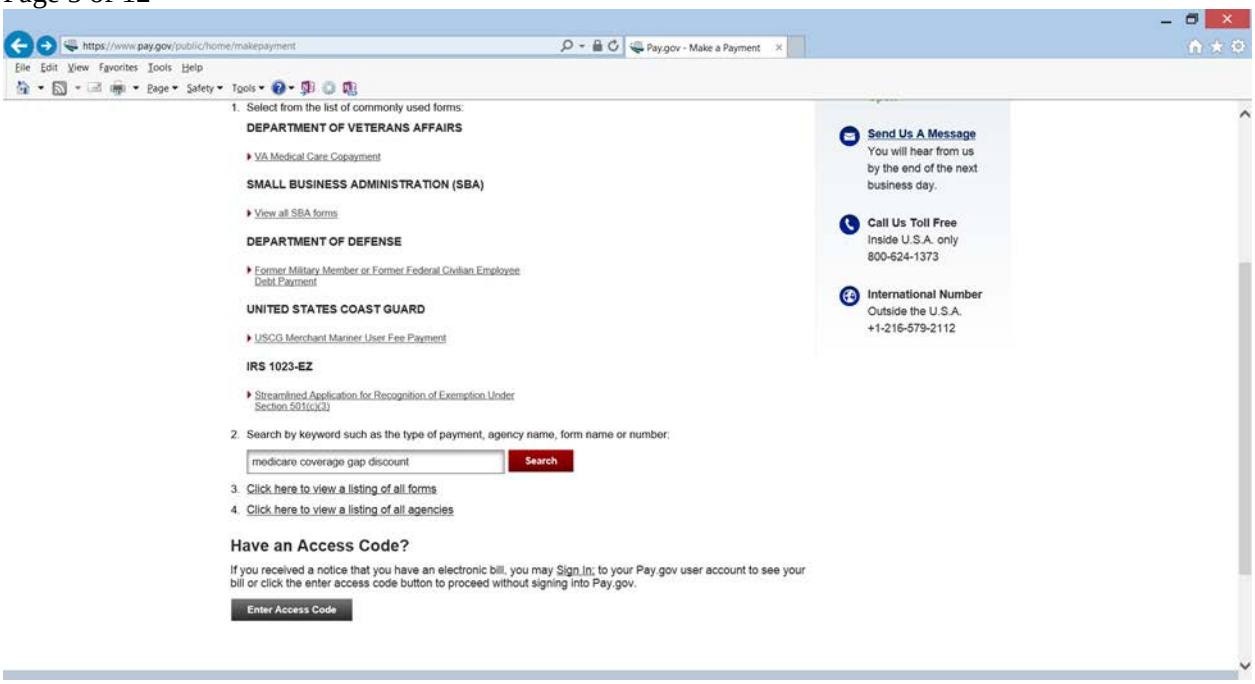
Step 1

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



Step 2

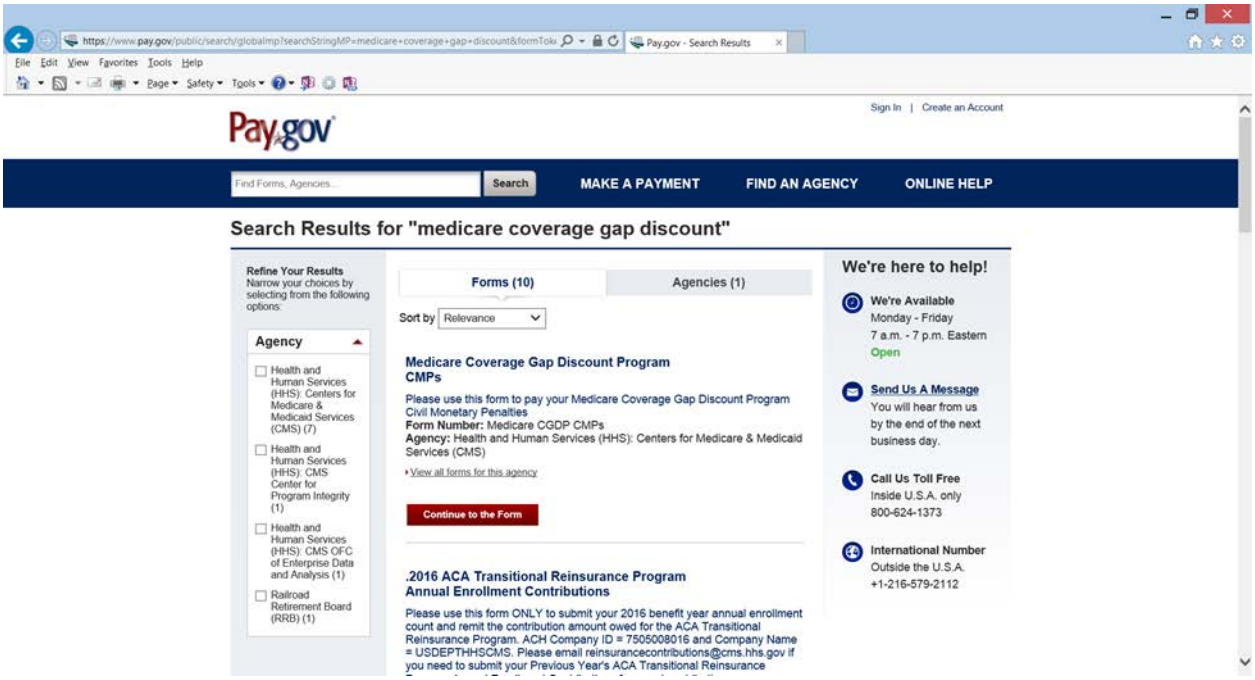
- In the **Search by keyword…** box (under number 2), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Search



Step 3

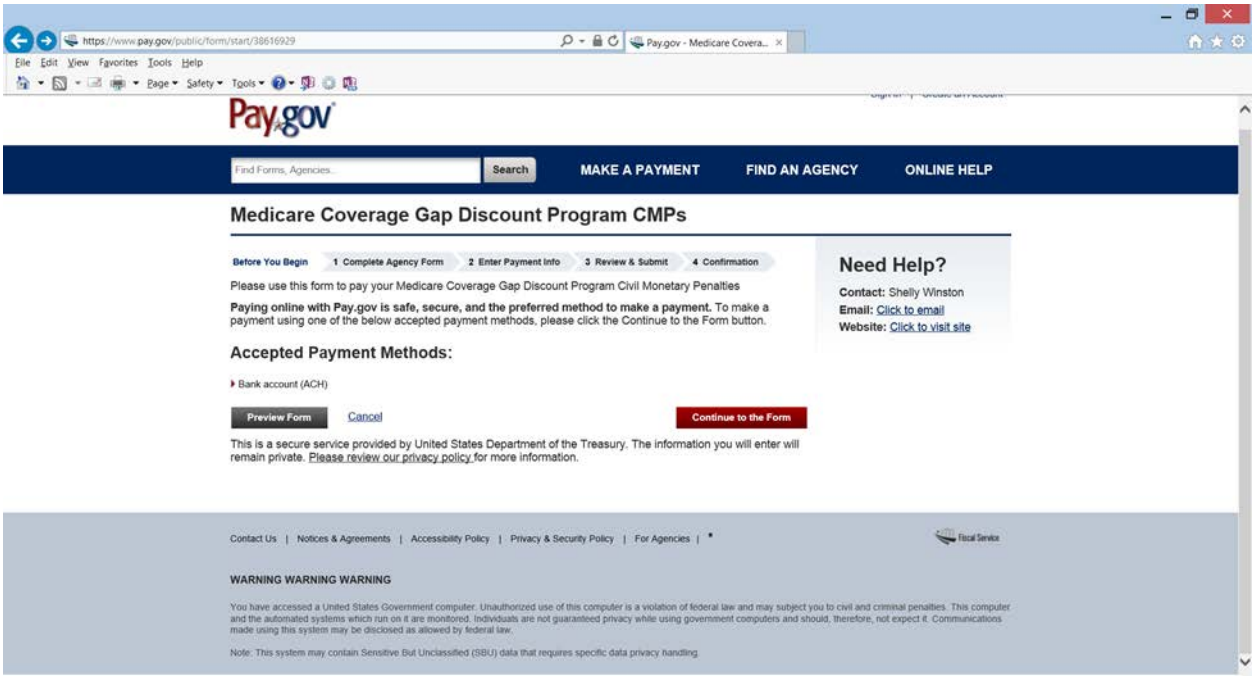
Medicare Coverage Gap Discount Program CMPs

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



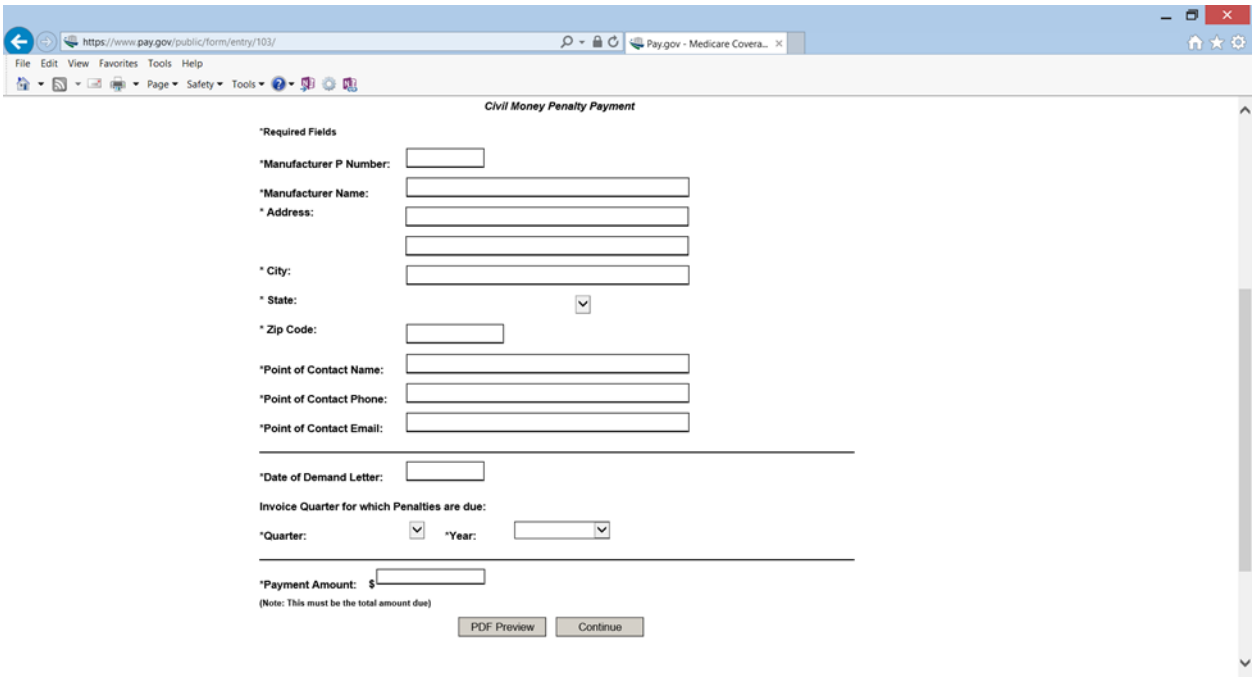
Step 4

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



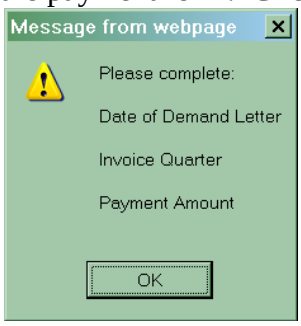
Step 5

- 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



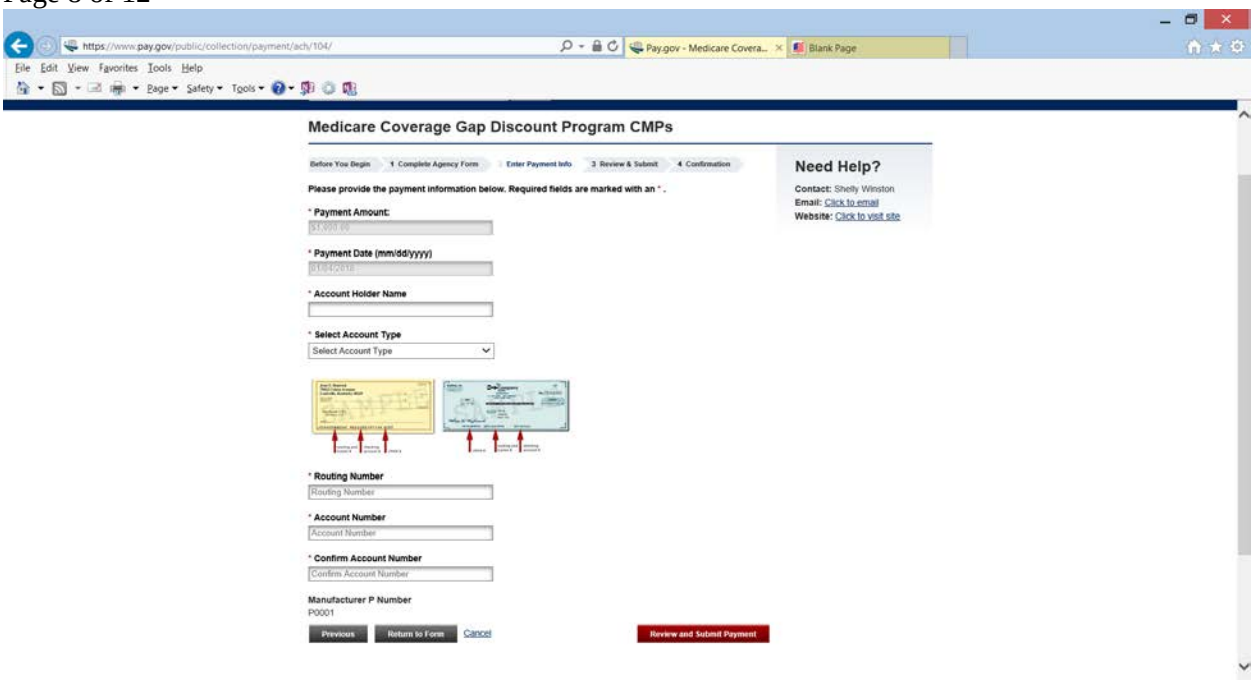
- Review
- Click on Submit Data

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.



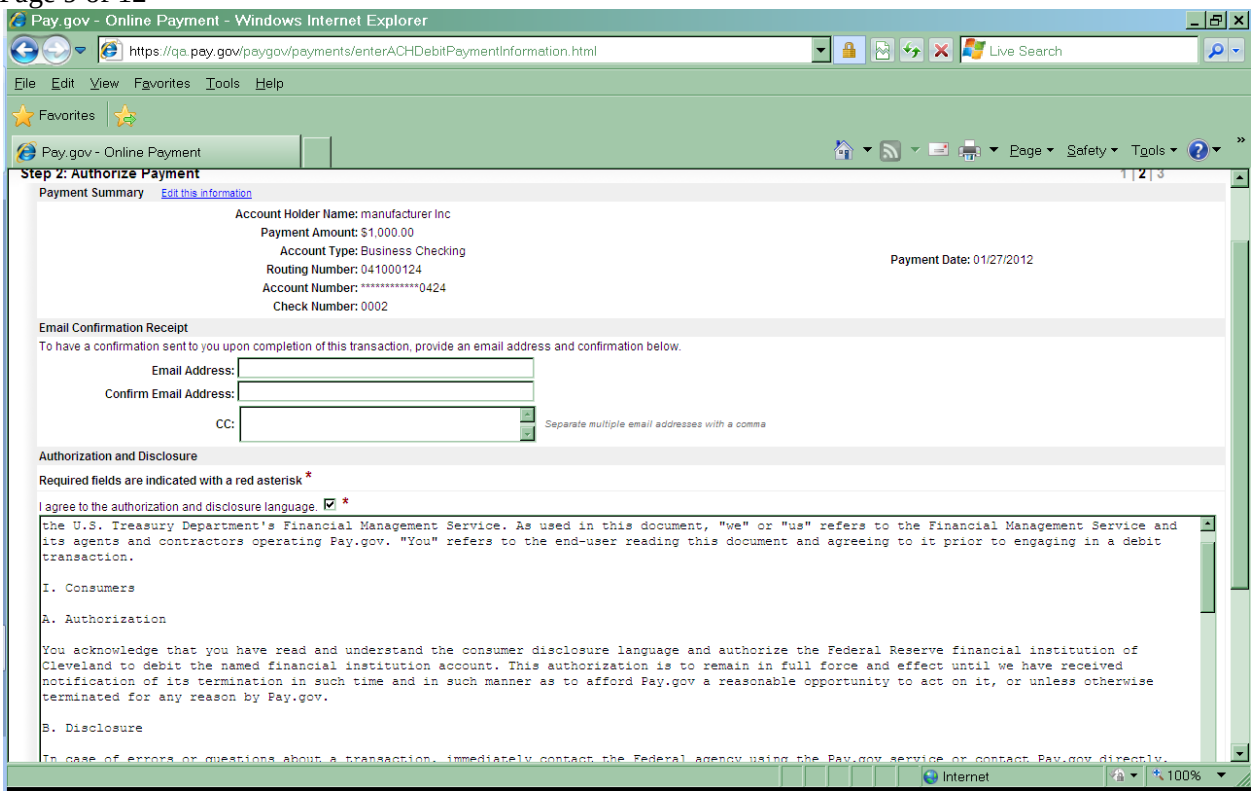
Notice the payment amount you entered on the previous screen has populated. Click on Return to Form at the bottom of the screen to correct the payment amount.

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

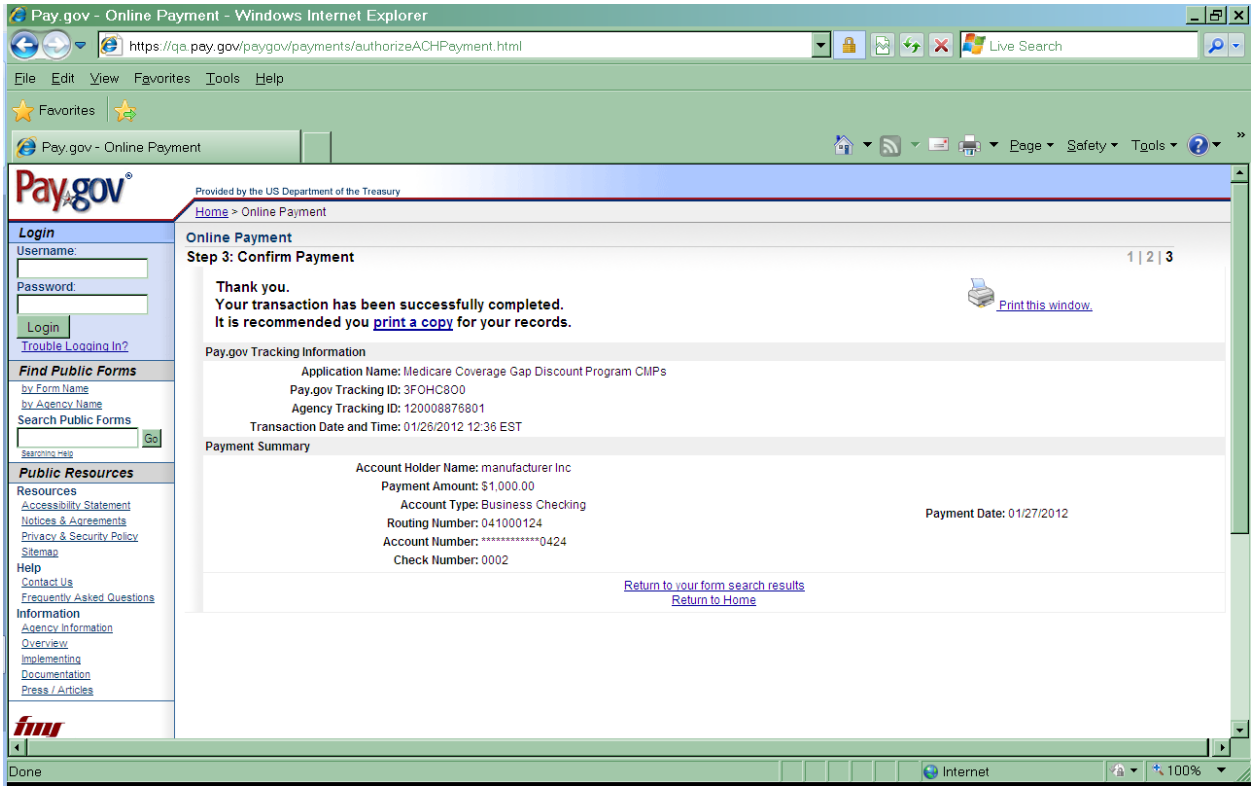
- Review the payment summary,



- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdp_manufacturers@cms.hhs.gov
- 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
Live Search
File Edit View Favorites Tools Help
Favorites
Pay.gov - Online Payment
Page Safety Tools
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
Go
Searching Help
Public Resources
Resources
Accessibility Statement
Notices & Agreements
Privacy & Security Policy
Sitemap
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: 3FOHC8O0
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
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.

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 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

	Contract Number	Contract Name	Line Item Invoiced Amount
1	E3014	PSERS HOP PROGRAM	$ 294.16
2	H0524	Kaiser Permanente	$ 1,328.84
3	H1944	UNITEDHEALTHCARE OF NEW ENGLAND, INC.	$ 1,511.92
4	H1951	HUMANA HEALTH BENEFIT PLAN OF LOUISIANA, INC.	$ 1,353.39
5	H2001	SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.	$ 841.78
6	H2450	MEDICA INSURANCE COMPANY	$ 635.28
7	H2802	UNITEDHEALTHCARE OF THE MIDLANDS, INC.	$ 28.50
8	H3655	COMMUNITY INSURANCE COMPANY	$ 565.51
9	H4875	PRIORITY HEALTH	$ 1,310.11
10	H5216	HUMANA INSURANCE COMPANY	$ 1,522.39
11	H5521	AETNA LIFE INSURANCE COMPANY	$ 2,762.93
12	H8768	UNITEDHEALTHCARE INSURANCE CO OF THE RIVER VALLEY	$ 758.50
13	S5601	SILVERSCRIPT INSURANCE COMPANY	$ 4,743.38
14	S5660	MEDCO CONTAINMENT LIFE AND MEDCO CONTAINMENT NY	$ 6,716.28
15	S5743	WELLMARK IA & SD, & BCBS MN, MT, NE, ND,& WY	$ 432.53
16	S5810	AETNA LIFE INSURANCE COMPANY	$ 5,660.67
17	S5820	UNITEDHEALTHCARE INSURANCE COMPANY	$ 1,102.87
18	S5884	HUMANA INSURANCE COMPANY	$ 3,587.14
19	S5921	UNITEDHEALTHCARE INS. CO. & UHC INS. CO. OF NY	$ 1,607.55
20	S8841	OPTUM INSURANCE OF OHIO, INC.	$ 242.85
			$ 37,006.58