

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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March 8, 2019

VIA EMAIL: [michael@gemini-labs.com](mailto:michael@gemini-labs.com); [jim@gemini-labs.com](mailto:jim@gemini-labs.com); [Matthew.Elder@dlss.com](mailto:Matthew.Elder@dlss.com);  
[lynn@gemini-labs.com](mailto:lynn@gemini-labs.com)

Gemini Laboratories, LLC  
1200 US Highway 22 East  
Suite 3  
Bridgewater NJ 08807

### **RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1433**

Dear Gemini Laboratories, LLC:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to Gemini Laboratories, LLC of a civil money penalty (CMP) assessment in the amount of \$6,107.90.

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

CMS is imposing a CMP of \$6,107.90 on Gemini Laboratories, LLC, P1433, 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 third quarter 2018 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:

- 94 Part D Sponsors: \$24,431.59 (See Attachment 3)

The CMP that your company owes is equal to:

- The 25% late payment penalty; \$6,107.90

The determination by CMS to impose a CMP will become final and due no later than May 7, 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 Gemini Laboratories, 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:

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

Sincerely,

/s/

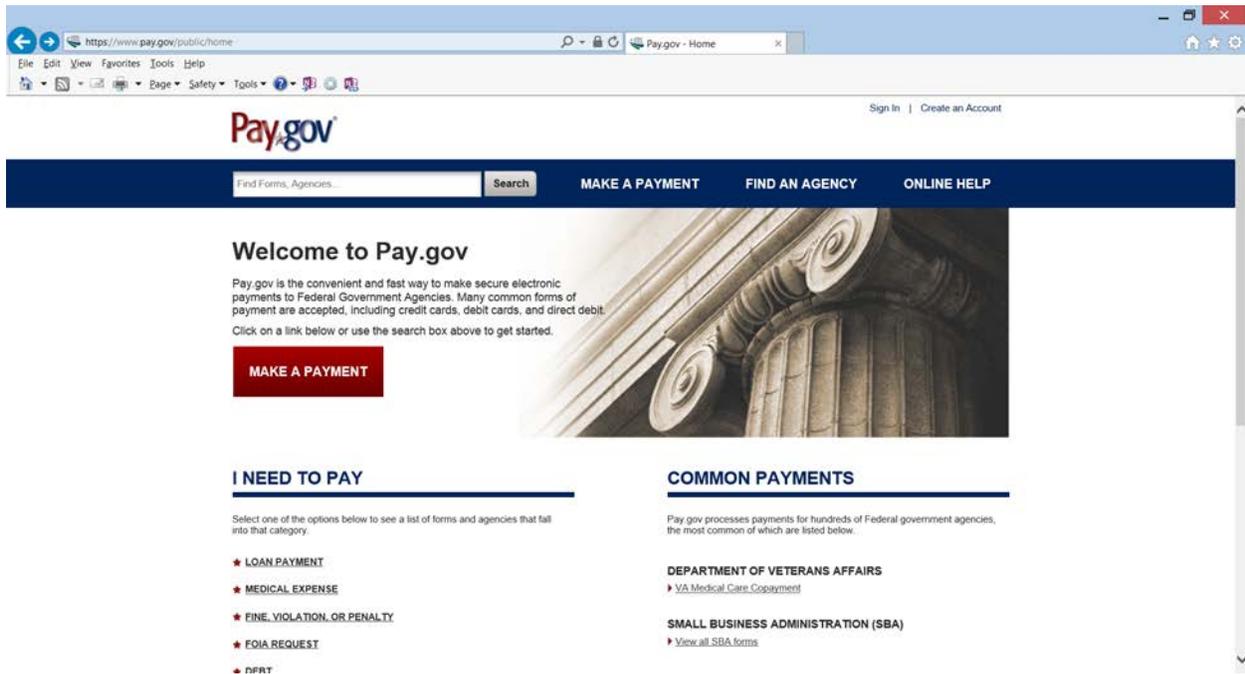
Amy K. Larrick Chavez-Valdez  
Director, Medicare Drug Benefit and C & D Data Group

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

## Attachment 1

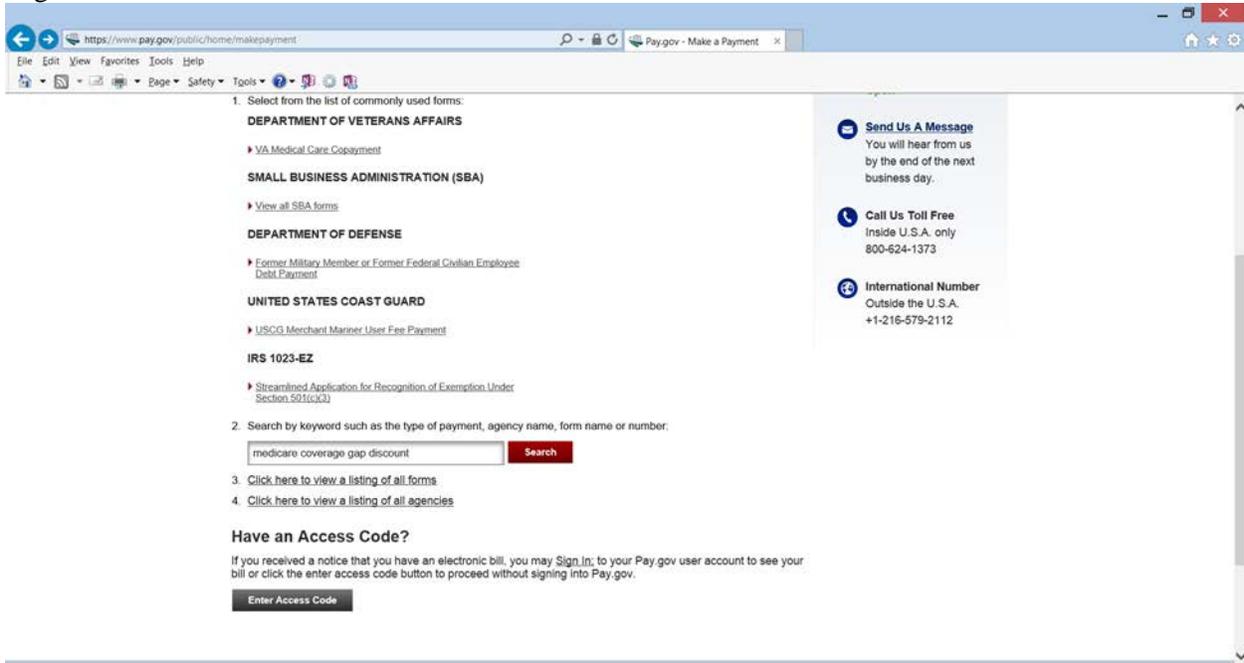
### Step 1

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



### Step 2

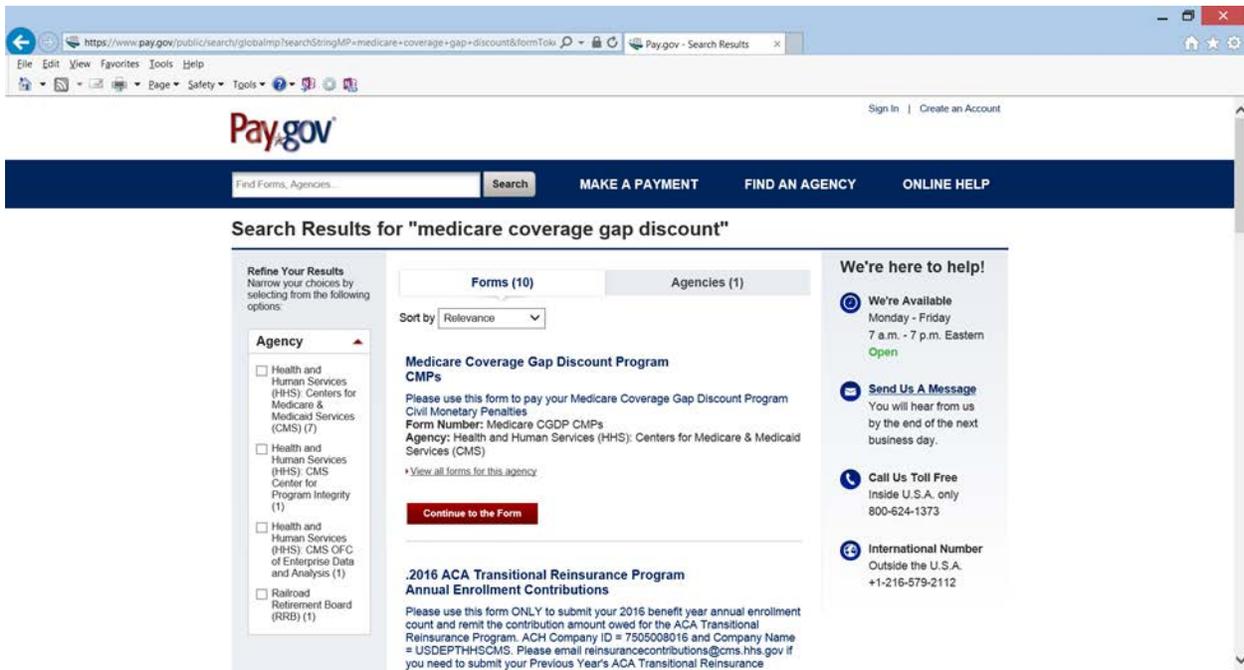
- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Search



### 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.

The screenshot shows a web browser window with the URL <https://www.pay.gov/public/Form/start/38616929>. The page title is "Pay.gov - Medicare Coverage...". The main heading is "Medicare Coverage Gap Discount Program CMPs". Below the heading is a progress bar with steps: "Before You Begin", "1 Complete Agency Form", "2 Enter Payment Info", "3 Review & Submit", and "4 Confirmation". The current step is "2 Enter Payment Info". The text reads: "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." Under "Accepted Payment Methods:", there is a link for "Bank account (ACH)". At the bottom of the form area are three buttons: "Preview Form", "Cancel", and "Continue to the Form". A "Need Help?" section on the right provides contact information for Shelly Winston, including email and website links. At the bottom of the page, there is a "WARNING WARNING WARNING" section with a disclaimer about the security of the system and a note about sensitive data.

## 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

The screenshot shows a web browser window with the URL <https://www.pay.gov/public/form/entry/103/>. The page title is "Civil Money Penalty Payment". The form contains 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: \$

(Note: This must be the total amount due)

Buttons: 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.



### 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): 03/08/2019

\* Account Holder Name: \_\_\_\_\_

\* Select Account Type: \_\_\_\_\_

\* Routing Number: \_\_\_\_\_

\* Account Number: \_\_\_\_\_

\* Confirm Account Number: \_\_\_\_\_

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,



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/authorizeACHPayment.html>. The page title is "Pay.gov - Online Payment".

The main content area displays a confirmation message: "Thank you. Your transaction has been successfully completed. It is recommended you [print a copy](#) for your records." There is a "Print this window" icon and link to the right of the message.

Below the confirmation message, there is a section for "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

Below that is a "Payment Summary" section:

- 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

At the bottom of the summary section, there are two links: [Return to your form search results](#) and [Return to Home](#).

The left sidebar contains navigation links under "Login", "Find Public Forms", "Public Resources", and "Information". The "fmu" logo is visible at the bottom left of the sidebar.

The browser's status bar at the bottom shows "Done" and "Internet" with a 100% zoom level.

## 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	E0654	United American Insurance Company	\$ 75.21
2	E3014	Public School Employees' Retirement System (PSERS)	\$ 56.08
3	H0609	UnitedHealth Group Inc	\$ 131.96
4	H0755	UnitedHealth Group Inc	\$ 458.41
5	H1016	AvMed, Inc.	\$ 7.13
6	H1026	Blue Cross and Blue Shield of FL - Health Options	\$ 19.50
7	H1036	HUMANA INSURANCE COMPANY	\$ 138.46
8	H1099	Health First Health Plans	\$ 17.66
9	H1609	Coventry Health and Life Insurance Company	\$ 3.84
10	H1666	HCSC Insurance Services Company	\$ 23.51
11	H1944	UnitedHealth Group Inc	\$ 37.30
12	H1961	Peoples Health, Inc	\$ 43.37
13	H2001	UnitedHealth Group Inc	\$ 488.58
14	H2228	UnitedHealth Group Inc	\$ 23.95
15	H2230	Blue Cross and Blue Shield of MA HMO Blue, Inc.	\$ 11.60
16	H2256	Tufts Associated Health Maintenance Org., Inc.	\$ 2.94
17	H2320	PRIORITY HELATH	\$ 20.43
18	H2649	HUMANA INSURANCE COMPANY	\$ 117.80
19	H2773	Quality Health Plans of New York ,	\$ 13.80
20	H3307	UnitedHealth Group Inc	\$ 147.65
21	H3330	Health Insurance Plan of Greater NY	\$ 9.25
22	H3335	Excellus Health Plan	\$ 35.24
23	H3384	HEALTHNOW NEW YORK INC.	\$ 23.42
24	H3449	Blue Cross and Blue Shield of North Carolina	\$ 23.65
25	H3528	ConnectiCare, Inc.	\$ 17.50
26	H3655	Anthem, Inc.	\$ 114.82
27	H3668	MOUNT CARMEL HEALTH PLAN	\$ 2.00
28	H3907	UPMC Health Plan, Inc.	\$ 331.64
29	H3916	Highmark, Inc.	\$ 89.22
30	H3931	Aetna Health Management	\$ 27.41
31	H3952	Keystone Health Plan East, Inc.	\$ 12.16
32	H3957	Highmark, Inc.	\$ 67.80
33	H3959	Coventry Health and Life Insurance Company	\$ 35.88
34	H4141	HUMANA INSURANCE COMPANY	\$ 27.75
35	H4152	BLUE CROSS & BLUE SHIELD OF RHODE I	\$ 30.20
36	H4497	Medical Mutual of Ohio	\$ 2.00
37	H4506	CVS Health	\$ 12.40
38	H4513	HealthSpring Life & Health	\$ 45.00
39	H4523	Aetna Health Management	\$ 14.50

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40	H4527	UnitedHealth Group Inc	\$ 22.72
41	H4590	UnitedHealth Group Inc	\$ 17.18
42	H5216	HUMANA INSURANCE COMPANY	\$ 338.87
43	H5253	UnitedHealth Group Inc	\$ 7.03
44	H5434	Blue Cross and Blue Shield of FL - Health Options	\$ 24.25
45	H5521	Aetna Health Management	\$ 144.50
46	H5522	Coventry Health and Life Insurance Company	\$ 149.68
47	H5525	HUMANA INSURANCE COMPANY	\$ 206.01
48	H5526	HEALTHNOW NEW YORK INC.	\$ 57.18
49	H5793	Aetna Health Management	\$ 0.96
50	H5854	Anthem, Inc.	\$ 52.45
51	H5883	Blue Care Network	\$ 6.60
52	H6453	HMO Louisiana, Inc.	\$ 2.86
53	H7728	Anthem, Inc.	\$ 276.30
54	H8432	Anthem, Inc.	\$ 29.26
55	H8552	Anthem, Inc.	\$ 21.42
56	H8634	HCSC Insurance Services Company	\$ 21.00
57	H9572	Blue Cross Blue Shield of Michigan	\$ 5.72
58	R3332	Blue Cross and Blue Shield of FL - Health Options	\$ 49.58
59	R3392	Humana, Inc.	\$ 196.45
60	R4182	Humana, Inc.	\$ 144.95
61	R5342	UnitedHealth Group Inc	\$ 22.37
62	R6801	UnitedHealth Group Inc	\$ 45.46
63	R7444	UnitedHealth Group Inc	\$ 575.66
64	S0522	UnitedHealth Group Inc	\$ 376.13
65	S2468	Blue Shield of California	\$ 546.56
66	S2893	CVS Health	\$ 119.92
67	S3521	Excellus Health Plan	\$ 26.99
68	S4607	Merit Health Insurance Company	\$ 50.10
69	S4802	Windsor Health Plan, Inc.	\$ 195.51
70	S5540	Blue Cross and Blue Shield of North Carolina	\$ 25.73
71	S5552	HUMANA INSURANCE COMPANY	\$ 4.25
72	S5584	Blue Cross Blue Shield of Michigan	\$ 22.86
73	S5593	Highmark, Inc.	\$ 28.65
74	S5596	Anthem, Inc.	\$ 1,267.87
75	S5601	CVS Health	\$ 2,666.54
76	S5617	Connecticut General Life Ins. Co.	\$ 506.91
77	S5660	Medco Containment Life Insurance Company	\$ 2,595.65
78	S5715	HCSC Insurance Services Company	\$ 266.77
79	S5753	Wisconsin Physicians Service Insurance Corporation	\$ 6.50
80	S5768	Coventry Health and Life Insurance Company	\$ 58.82
81	S5805	UnitedHealth Group Inc	\$ 75.86
82	S5810	Aetna Health Management	\$ 1,342.22
83	S5820	UnitedHealth Group Inc	\$ 2,526.80
84	S5884	HUMANA INSURANCE COMPANY	\$ 4,034.87

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85	S5904	Blue Cross and Blue Shield of FL - Health Options	\$ 55.57
86	S5921	UnitedHealth Group Inc	\$ 537.82
87	S5953	BlueCross BlueShield of South Carolina	\$ 4.72
88	S5966	Health Insurance Plan of Greater NY	\$ 98.12
89	S5993	Horizon Healthcare Services, Inc.	\$ 20.67
90	S6506	Blue Cross and Blue Shield of Arizona	\$ 23.85
91	S7694	Envision Insurance Company	\$ 230.20
92	S8841	Catamaran Insurance of Ohio, Inc.	\$ 1,411.83
93	S9579	STONEBRIDGE LIFE INSURANCE COMPANY	\$ 98.08
94	S9701	Dean Health Plan	\$ 25.74
			\$ 24,431.59