

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



Center of Medicare

April 27, 2017

VIA EMAIL: jennifer.crosswell@arborpharma.com; jason.mccarthy@arborpharma.com

XenoPort
Atten: Jennifer Crosswell
6 Concourse Pkwy, Suite 1800
Atlanta, GA 30328

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1345

Dear Jennifer Crosswell:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to XenoPort of a civil money penalty (CMP) assessment in the amount of \$116,502.83.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$116,502.83 on XenoPort 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 second 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:

- 108 Part D Sponsors: \$466,011.31 (Breakdown on Attachment 3)

The CMP that your company owes is equal to:

- The 25% penalty, \$116,502.83

The determination by CMS to impose a CMP will become final and due no later than June 25, 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 XenoPort 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. If you have any questions about this notice, please contact Sonia Eaddy at Sonia.eaddy@cms.hhs.gov.

Sincerely,

/s/

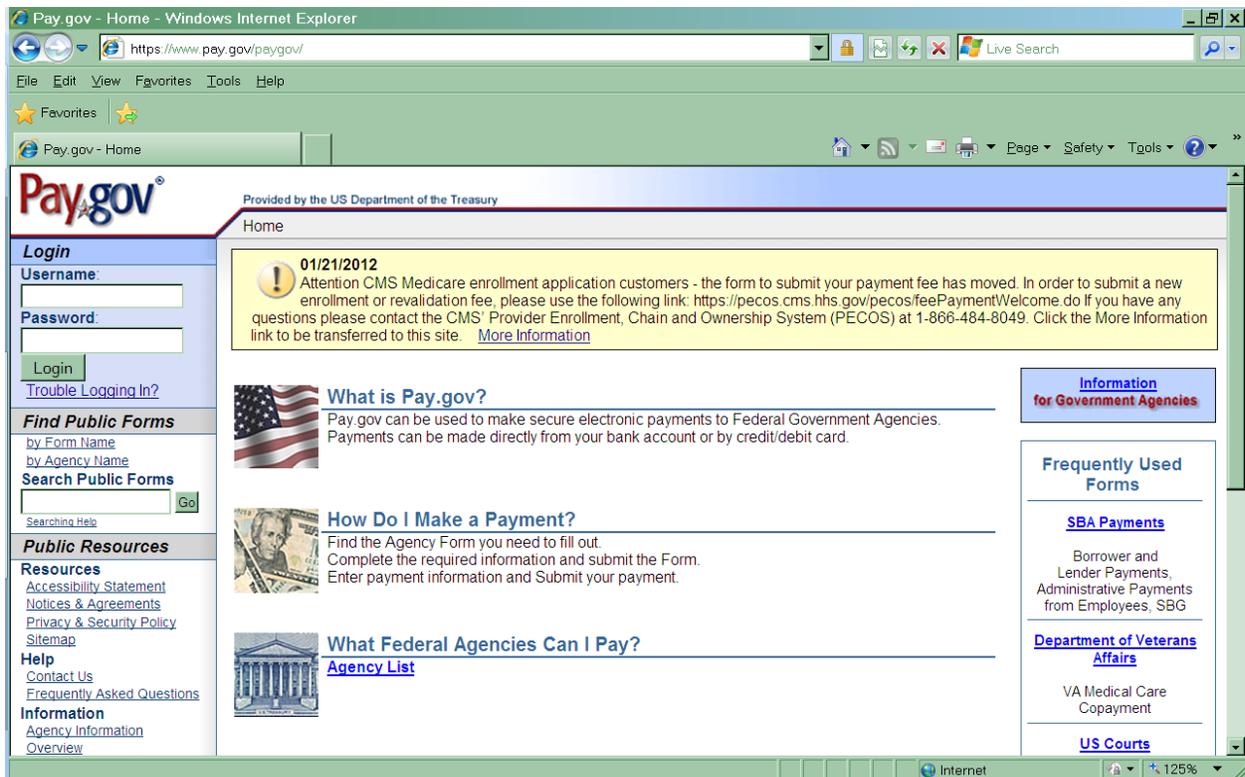
Amy K. Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG
Ms. 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 search results on the pay.gov website. The search query is "medicare Coverage gap discount", which returned 3 results. The results are sorted by Form Name. The first result is "CMS Data Payment Form" (Form Number: CMS Data Payment), the second is "CMS Medicare Application Fee" (Form Number: Medicare-app-fee-1), and the third is "Medicare Coverage Gap Discount Program CMPs" (Form Number: Medicare CGDP CMPs). Each result includes a brief description, a link to the Department of Health and Human Services, and a "View PDF" button. The left sidebar contains navigation links for Password, Find Public Forms, Search Public Forms, Public Resources, and Information. The bottom of the page shows the "Internet" status bar at 125% zoom.

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.

Pay.gov - Form Instance - Windows Internet Explorer
https://www.pay.gov/paygov/forms/formInstance.html?nc=1330705111240&agencyFormId=38616929&userFormr

File Edit View Favorites Tools Help

Pay.gov - Form Instance

This website wants to run the following add-on: 'Microsoft Vector Graphics Rendering(VML)' from 'Microsoft Corporation'. If you trust the website and the add-on and want to allow it to run, click here...

Health & Human Services
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare Coverage Gap Discount Program
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)

Submit Data
PDF Preview

Done Internet 70%

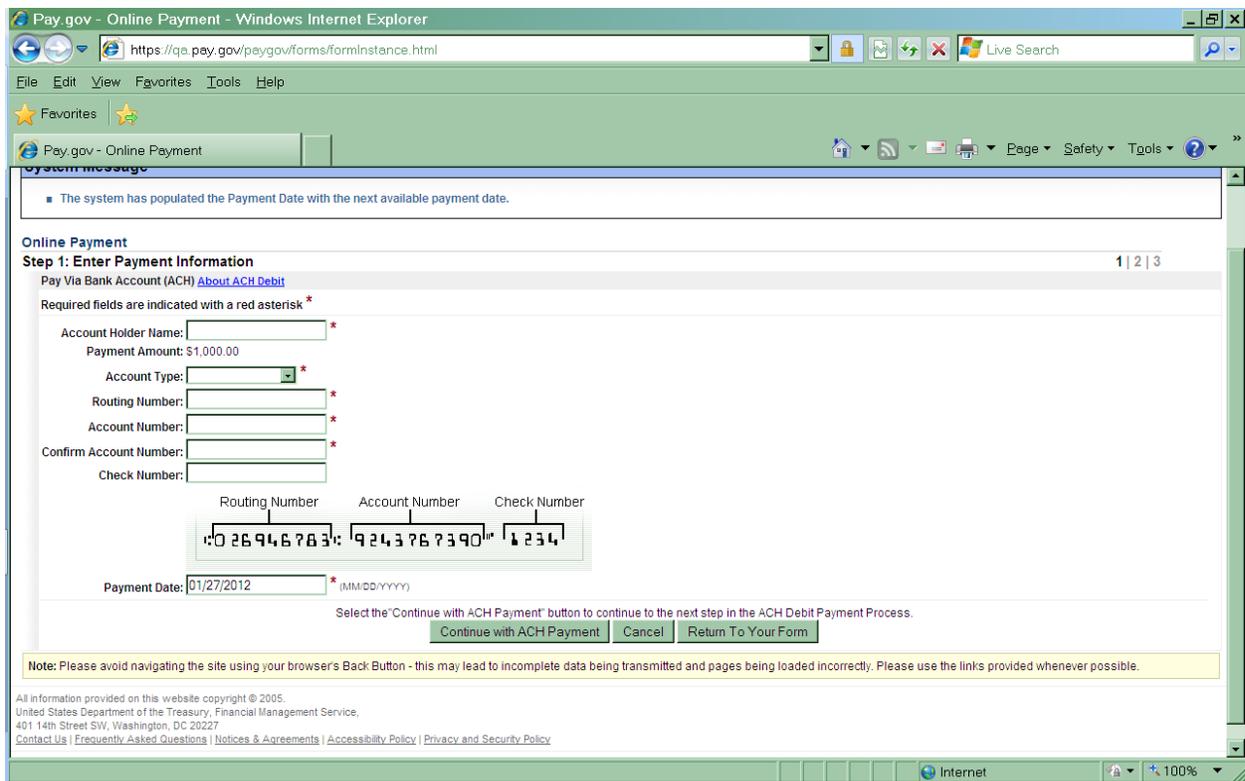
- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment
 - **Point of Contact Phone:** (***_**_****) telephone number must include dashes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

The screenshot shows the Pay.gov online payment interface in Internet Explorer. The browser address bar shows the URL: <https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html>. The page title is "Pay.gov - Online Payment".

Step 2: Authorize Payment

Payment Summary [Edit this information](#)

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

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.

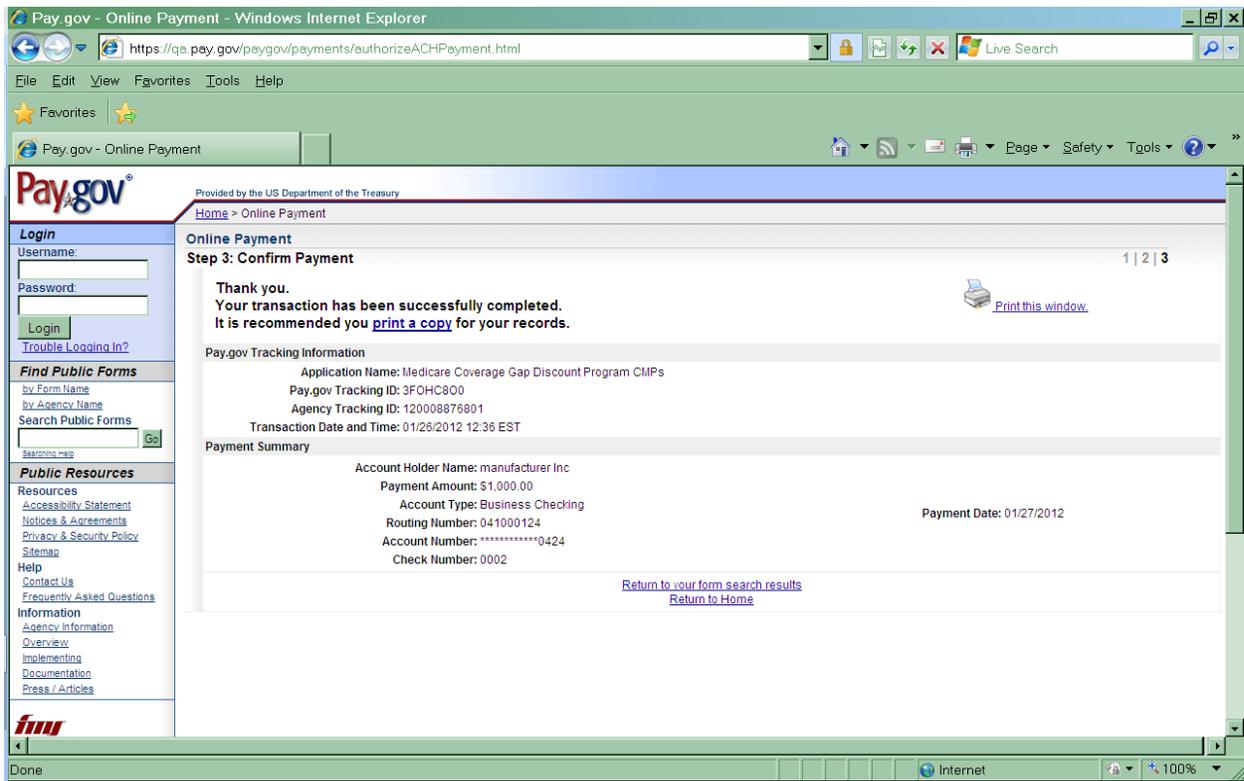
- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdp_manufacturers@cms.hhs.gov
- Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization and disclosure language*

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.

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	Invoiced Amount
1	E3014	Public School Employees' Retirement System (PSERS)	\$655.35
2	H0107	HCSC Insurance Services Company	\$616.18
3	H0154	VIVA Health, Inc.	\$301.85
4	H0354	Cigna HealthCare of Arizona Inc	\$1,831.38
5	H0439	HealthSpring Life & Health	\$177.43
6	H0504	Blue Shield of California	\$451.00
7	H0524	Kaiser Foundation Health Plan Inc	\$188.88
8	H0543	UnitedHealth Group Inc	\$4,084.41
9	H0562	Health Net of California Inc	\$1,220.47
10	H0609	UnitedHealth Group Inc	\$3,081.11
11	H0630	Kaiser Foundation Health Plan Inc	\$1,029.93
12	H0755	UnitedHealth Group Inc	\$393.01
13	H1350	Blue Cross of Idaho Health Service, Inc.	\$161.57
14	H1509	UnitedHealth Group Inc	\$167.02
15	H1994	SelectHealth, Inc.	\$1,109.92
16	H2001	UnitedHealth Group Inc	\$23,230.22
17	H2150	Kaiser Foundation Health Plan Inc	\$253.22
18	H2230	Blue Cross and Blue Shield of MA HMO Blue, Inc.	\$825.55
19	H2320	PRIORITY HELATH	\$325.71
20	H2649	HUMANA INSURANCE COMPANY	\$377.48
21	H2663	Coventry Health and Life Insurance Company	\$1,852.42
22	H2906	Home Town Health Plan Inc	\$652.22
23	H3107	UnitedHealth Group Inc	\$283.28
24	H3328	New York State Catholic Health Plan	\$744.33
25	H3330	Health Insurance Plan of Greater NY	\$832.42
26	H3335	Excellus Health Plan	\$1,019.43
27	H3342	Anthem, Inc.	\$335.03
28	H3344	Independent Health Association	\$1,170.61
29	H3351	Excellus Health Plan	\$846.63
30	H3362	Independent Health Association	\$382.54
31	H3379	UnitedHealth Group Inc	\$394.96
32	H3384	HEALTHNOW NEW YORK INC.	\$650.24
33	H3388	Capital District Physicians Health Plan, Inc.	\$44.08
34	H3655	Anthem, Inc.	\$110.01
35	H3668	MOUNT CARMEL HEALTH PLAN	\$451.99
36	H3755	CommunityCare HMO	\$611.80
37	H3810	AllCare Health Plan, Inc.	\$489.16
38	H3813	Moda Health Plan, Inc.	\$165.24
39	H3832	HAWAII MEDICAL SERVICE ASSOCIATION	\$1,988.75

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40	H3890	Hopkins Health Advantage Inc.	\$75.43
41	H3907	UPMC Health Plan, Inc.	\$1,163.78
42	H3916	Highmark, Inc.	\$1,908.81
43	H3923	Capital Advantage Insurance Company	\$333.84
44	H3952	Keystone Health Plan East, Inc.	\$386.63
45	H4036	Anthem, Inc.	\$479.83
46	H4523	Aetna Health Management	\$337.02
47	H4605	Regence BlueShield of Idaho	\$527.79
48	H5009	Regence BlueShield of Idaho	\$447.73
49	H5042	Capital District Physicians Health Plan, Inc.	\$83.26
50	H5141	CAREPOINT INSURANCE COMPANY	\$333.84
51	H5215	NETWORK HEALTH INSURANCE CORPORATION	\$167.52
52	H5253	UnitedHealth Group Inc	\$975.34
53	H5415	HUMANA INSURANCE COMPANY	\$1,060.04
54	H5425	SCAN Health Plan	\$1,462.08
55	H5434	Blue Cross and Blue Shield of FL - Health Options	\$1,354.56
56	H5508	ADVANTAGE Health Solution, Inc	\$47.54
57	H5520	Health Net of California Inc	\$323.44
58	H5521	Aetna Health Management	\$7,820.08
59	H5526	HEALTHNOW NEW YORK INC.	\$2,169.47
60	H5528	Health Insurance Plan of Greater NY	\$162.56
61	H5938	Capital Health Plan, Inc.	\$169.32
62	H6609	HUMANA INSURANCE COMPANY	\$5,613.84
63	H7917	BlueCross BlueShield of Tennessee, Inc.	\$1,646.49
64	H9302	Soundpath Health	\$331.06
65	H9572	Blue Cross Blue Shield of Michigan	\$617.52
66	H9615	MVP Health Plan, Inc.	\$1,738.84
67	H9947	Anthem, Inc.	\$12.05
68	R3332	Blue Cross and Blue Shield of FL - Health Options	\$441.39
69	R5287	UnitedHealth Group Inc	\$165.93
70	R5342	UnitedHealth Group Inc	\$664.99
71	R5826	HUMANA INSURANCE COMPANY	\$3,716.95
72	R5941	Anthem, Inc.	\$325.80
73	R9896	UnitedHealth Group Inc	\$68.59
74	S1030	Blue Cross and Blue Shield of Alabama	\$1,448.48
75	S2468	Blue Shield of California	\$1,913.32
76	S2893	CVS Health	\$2,051.50
77	S3474	Heartland Fidelity Insurance Company	\$956.96
78	S3521	Excellus Health Plan	\$668.68
79	S4607	Merit Health Insurance Company	\$679.56
80	S5540	Blue Cross and Blue Shield of North Carolina	\$1,076.95
81	S5580	United American Insurance Company	\$1,430.30
82	S5584	Blue Cross Blue Shield of Michigan	\$514.99
83	S5596	Anthem, Inc.	\$8,238.58
84	S5601	CVS Health	\$120,584.20

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85	S5617	Connecticut General Life Ins. Co.	\$7,643.10
86	S5660	Medco Containment Life Insurance Company	\$131,922.80
87	S5715	HCSC Insurance Services Company	\$1,499.69
88	S5726	Anthem, Inc.	\$611.28
89	S5743	Northern Plains Alliance (BCBS MN, MT, NE, ND, WY,	\$832.07
90	S5755	United American Insurance Company	\$9,443.08
91	S5768	Coventry Health and Life Insurance Company	\$5,630.36
92	S5805	UnitedHealth Group Inc	\$3,176.14
93	S5810	Aetna Health Management	\$2,551.75
94	S5820	UnitedHealth Group Inc	\$34,977.26
95	S5884	HUMANA INSURANCE COMPANY	\$6,010.71
96	S5904	Blue Cross and Blue Shield of FL - Health Options	\$2,256.14
97	S5916	Regence BlueShield of Idaho	\$167.52
98	S5921	UnitedHealth Group Inc	\$5,119.66
99	S5960	Anthem, Inc.	\$406.00
100	S5966	Health Insurance Plan of Greater NY	\$3,898.12
101	S5967	WellCare Prescription Insurance, Inc.	\$1,069.08
102	S5993	Horizon Healthcare Services, Inc.	\$331.06
103	S7230	HEALTH PLAN OF MICHIGAN, INC.	\$853.66
104	S7610	HEALTH PLAN OF MICHIGAN, INC.	\$475.53
105	S7694	Envision Insurance Company	\$1,801.65
106	S8841	Catamaran Insurance of Ohio, Inc.	\$3,399.61
107	S9579	STONEBRIDGE LIFE INSURANCE COMPANY	\$11,565.80
108	S9701	Dean Health Plan	\$165.53
		Total	\$466,011.31