

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

June 29, 2018

VIA EMAIL: smcclure@icontracts.com; bfamariss@virtusrx.com; dfinio@virtusrx.com

Virtus Pharmaceuticals, OpCo II, LLC
Atten: Sarah McClure
1011 US Route 22 West, Suite 104
Bridgewater, NJ 08807

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1376

Dear Virtus Pharmaceuticals, OpCo II, LLC:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to Virtus Pharmaceuticals, OpCo II, LLC of a civil money penalty (CMP) assessment in the amount of \$48,041.14.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$48,041.14 on Virtus Pharmaceuticals, OpCo II, LLC, P1376, 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 2017 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:

- 85 Part D Sponsors: \$192,164.54 (Breakdown on Attachment 3)

The CMP that your company owes is equal to:

- The 25% late payment penalty; \$48,041.14

The determination by CMS to impose a CMP will become final and due no later than August 28, 2018 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 Virtus Pharmaceuticals, OpCo II, 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.

Ms. Sarah McClure
Virtus Pharmaceuticals, OpCo II, LLC
June 29, 2018
Page 3 of 14

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
- 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/

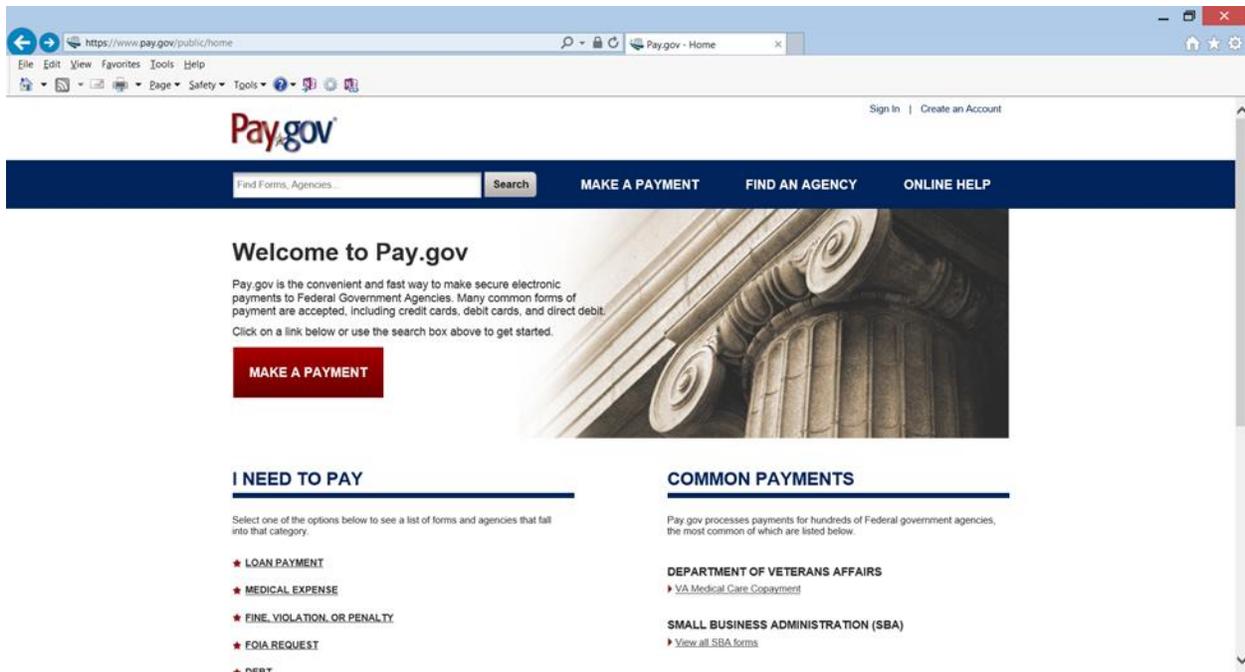
Amy K. Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG
Ms. 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

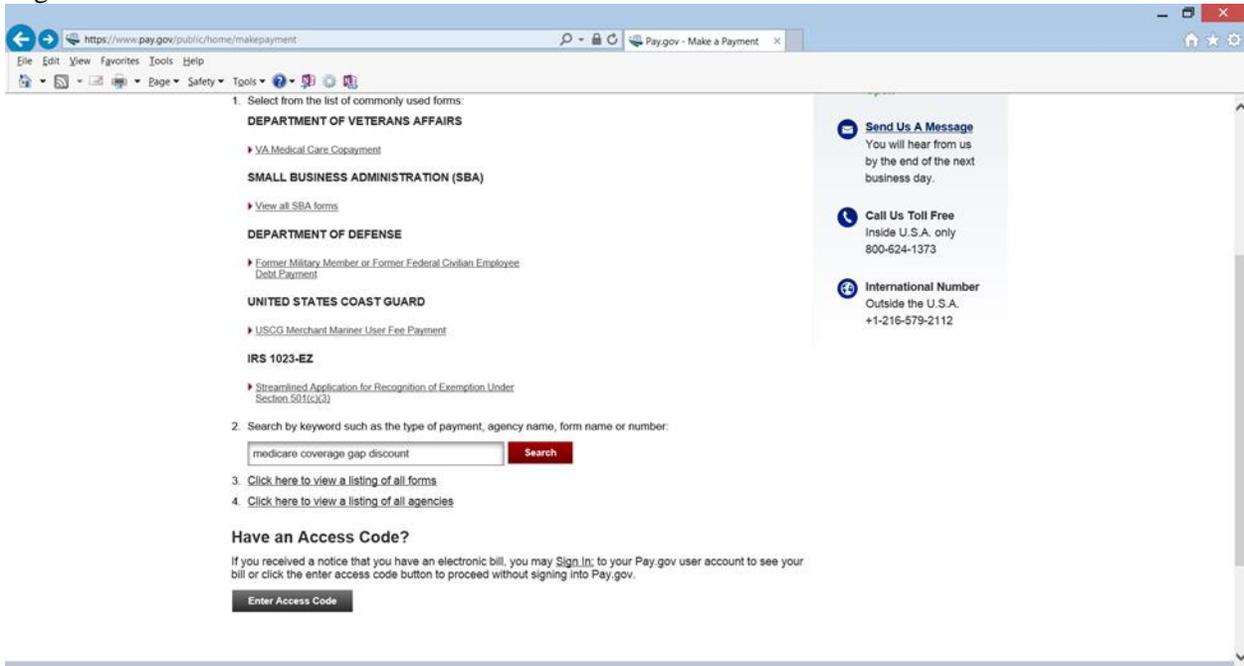
Step 1

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



Step 2

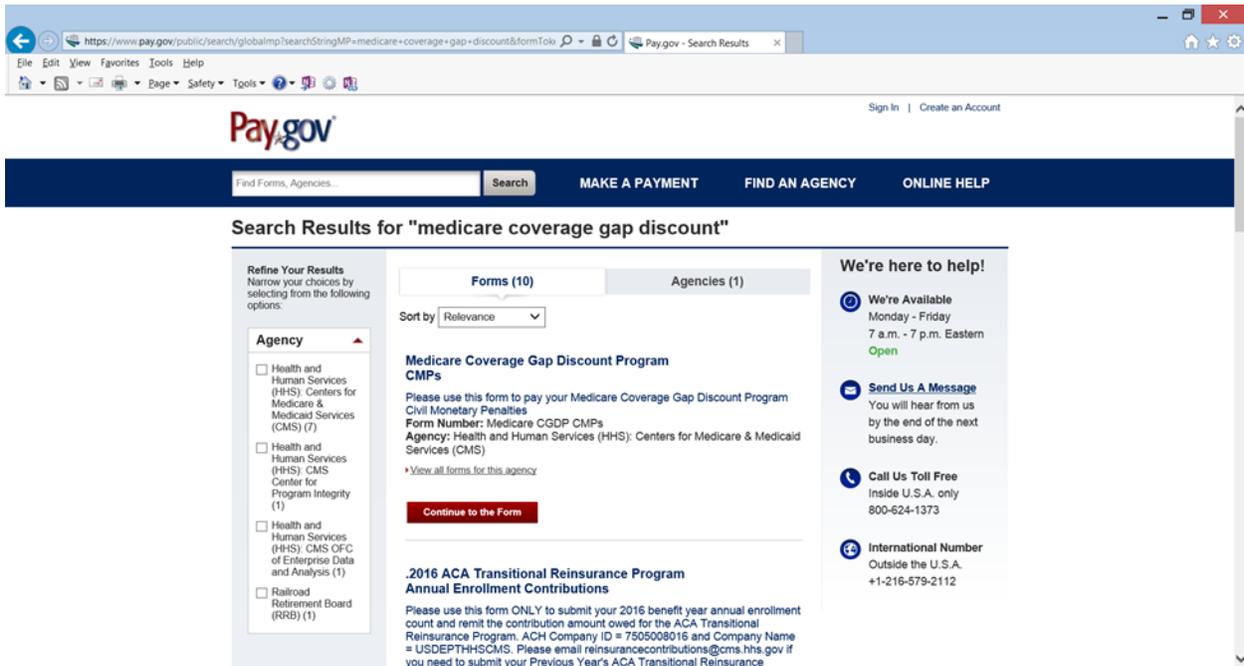
- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Search



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 at 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". A progress bar indicates the current step: "Before You Begin" (selected), "1 Complete Agency Form", "2 Enter Payment Info", "3 Review & Submit", and "4 Confirmation". Below the progress bar, 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 radio button for "Bank account (ACH)". At the bottom of the form area, there are three buttons: "Preview Form", "Cancel", and "Continue to the Form". A "Need Help?" section on the right provides contact information for Shelly Winston: "Email: [Click to email](#)" and "Website: [Click to visit site](#)". A footer section contains links for "Contact Us", "Notices & Agreements", "Accessibility Policy", "Privacy & Security Policy", and "For Agencies". A "WARNING WARNING WARNING" section at the bottom states: "You have accessed a United States Government computer. Unauthorized use of this computer is a violation of federal law and may subject you to civil and criminal penalties. This computer and the automated systems which run on it are monitored. Individuals are not guaranteed privacy while using government computers and should, therefore, not expect it. Communications made using this system may be disclosed as allowed by federal law. Note: This system may contain Sensitive But Unclassified (SBU) data that requires specific data privacy handling."

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

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)

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): 07/04/2018

* Account Holder Name: _____

* Select Account Type: _____

* Routing Number: _____

* Account Number: _____

* Confirm Account Number: _____

Manufacturer P Number: P0001

Buttons: 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 the 'Step 2: Authorize Payment' page on the Pay.gov website. The browser window title is 'Pay.gov - Online Payment - Windows Internet Explorer'. The address bar shows the URL: <https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html>. The page content includes:

- 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.
- Email Confirmation Receipt:** A form with fields for 'Email Address:', 'Confirm Email Address:', and 'CC:'. A note says 'To have a confirmation sent to you upon completion of this transaction, provide an email address and confirmation below.' and 'Separate multiple email addresses with a comma'.
- Authorization and Disclosure:** A section with a red asterisk indicating required fields. It contains a checkbox for 'I agree to the authorization and disclosure language.' which is checked. Below is a scrollable text area containing the following text:
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.

Ms. Sarah McClure
Virtus Pharmaceuticals, OpCo II, LLC
June 29, 2018
Page 10 of 14

Pay.gov - Online Payment - Windows Internet Explorer
https://qa.pay.gov/paygov/payments/authorizeACHPayment.html

Pay.gov - Online Payment

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: 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	Payment Date: 01/27/2012
Routing Number: 041000124	
Account Number: *****0424	
Check Number: 0002	

[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 #	Name	Invoice Amount
1	H5009	Regence BlueShield of Idaho	\$ 35.02
2	H5050	Group Health Cooperative	\$ 27.11
3	H5215	NETWORK HEALTH INSURANCE CORPORATION	\$ 580.24
4	H5253	UnitedHealth Group Inc	\$ 1,114.92
5	H5262	Gundersen Health Plan	\$ 49.95
6	H5302	Coventry Health and Life Insurance Company	\$ 7.49
7	H5415	HUMANA INSURANCE COMPANY	\$ 474.30
8	H5425	SCAN Health Plan	\$ 127.30
9	H5520	Health Net of California Inc	\$ 110.76
10	H5521	Aetna Health Management	\$ 7,419.08
11	H5522	Coventry Health and Life Insurance Company	\$ 87.26
12	H5525	HUMANA INSURANCE COMPANY	\$ 611.05
13	H5526	HEALTHNOW NEW YORK INC.	\$ 1,265.75
14	H5533	UPMC Health Plan, Inc.	\$ 18.81
15	H5576	Vantage Health Plan, Inc.	\$ 20.66
16	H5577	MCS ADVANTAGE INC	\$ 97.87
17	H5591	Martin's Point Generations, LLC	\$ 192.89
18	H5793	Aetna Health Management	\$ 2.50
19	H5883	Blue Care Network	\$ 136.68
20	H5928	CARE1ST HEALTH PLAN, INC.	\$ 14.99
21	H6328	Care N' Care Insurance Company, Inc.	\$ 51.60
22	H6528	UnitedHealth Group Inc	\$ 74.95
23	H6609	HUMANA INSURANCE COMPANY	\$ 1,850.41
24	H6622	HUMANA INSURANCE COMPANY	\$ 116.85
25	H6743	ATRIO HEALTH PLANS INC	\$ 40.05
26	H6815	Health Net of California Inc	\$ 138.92
27	H7020	HealthSpring Life & Health	\$ 91.79
28	H7149	Coventry Health and Life Insurance Company	\$ 89.40
29	H7245	Premera Blue Cross	\$ 10.98
30	H7917	BlueCross BlueShield of Tennessee, Inc.	\$ 432.88
31	H8145	HUMANA INSURANCE COMPANY	\$ 188.20
32	H8552	Anthem, Inc.	\$ 291.26
33	H8634	HCSC Insurance Services Company	\$ 673.55
34	H8649	Coventry Health and Life Insurance Company	\$ 29.69
35	H8748	UnitedHealth Group Inc	\$ 218.04
36	H8908	HUMANA INSURANCE COMPANY	\$ 92.25
37	H9001	Fallon Community Health Plan, Inc.	\$ 173.00
38	H9047	PROVIDENCE HEALTH PLAN	\$ 52.78

39	H9302	Soundpath Health	\$ 87.26
40	H9572	Blue Cross Blue Shield of Michigan	\$ 1,846.12
41	H9615	MVP Health Plan, Inc.	\$ 54.26
42	R3444	UnitedHealth Group Inc	\$ 238.35
43	R5329	unitedHealth Group	\$ 222.65
44	R5342	UnitedHealth Group Inc	\$ 100.22
45	R5826	HUMANA INSURANCE COMPANY	\$ 743.32
46	R5941	Anthem, Inc.	\$ 454.59
47	R6801	UnitedHealth Group Inc	\$ 789.29
48	R7444	UnitedHealth Group Inc	\$ 1,034.84
49	S0522	UnitedHealth Group Inc	\$ 1,237.88
50	S1030	Blue Cross and Blue Shield of Alabama	\$ 156.59
51	S2468	Blue Shield of California	\$ 426.36
52	S2668	Members Health Insurance Company	\$ 40.74
53	S2893	CVS Health	\$ 2,134.32
54	S3521	Excellus Health Plan	\$ 15.31
55	S3875	GRANITE ALLIANCE	\$ 424.29
56	S4501	Independent Health Association	\$ 48.60
57	S4607	Merit Health Insurance Company	\$ 358.82
58	S4802	Windsor Health Plan, Inc.	\$ 2,458.32
59	S5540	Blue Cross and Blue Shield of North Carolina	\$ 112.77
60	S5584	Blue Cross Blue Shield of Michigan	\$ 904.15
61	S5593	Highmark, Inc.	\$ 840.12
62	S5596	Anthem, Inc.	\$ 2,086.81
63	S5601	CVS Health	\$ 31,941.66
64	S5609	Regence BlueShield of Idaho	\$ 79.60
65	S5617	Connecticut General Life Ins. Co.	\$ 4,838.63
66	S5660	Medco Containment Life Insurance Company	\$ 44,238.40
67	S5715	HCSC Insurance Services Company	\$ 1,869.47
68	S5743	Northern Plains Alliance (BCBS MN, MT, NE, ND, WY,	\$ 2,988.01
69	S5753	Wisconsin Physicians Service Insurance Corporation	\$ 126.06
70	S5768	Coventry Health and Life Insurance Company	\$ 3,921.11
71	S5805	UnitedHealth Group Inc	\$ 1,916.31
72	S5810	Aetna Health Management	\$ 5,480.57
73	S5820	UnitedHealth Group Inc	\$ 31,207.14
74	S5877	EDUCATORS MUTUAL INSURANCE ASSOCIAT	\$ 28.35
75	S5884	HUMANA INSURANCE COMPANY	\$ 13,470.72
76	S5921	UnitedHealth Group Inc	\$ 2,947.58
77	S5953	BlueCross BlueShield of South Carolina	\$ 120.82
78	S5966	Health Insurance Plan of Greater NY	\$ 631.66
79	S5975	Moda Health Plan, Inc.	\$ 248.04
80	S5983	Medco Containment Life Insurance Company	\$ 82.17
81	S5993	Horizon Healthcare Services, Inc.	\$ 37.24
82	S7694	Envision Insurance Company	\$ 1,169.34

Ms. Sarah McClure
Virtus Pharmaceuticals, OpCo II, LLC
June 29, 2018
Page 14 of 14

83	S8841	Catamaran Insurance of Ohio, Inc.	\$ 7,602.64
84	S9579	STONEBRIDGE LIFE INSURANCE COMPANY	\$ 3,124.09
85	S9701	Dean Health Plan	\$ 267.72
			\$ 192,164.54