#### 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**

July 14, 2015

#### VIA:

EMAIL (keenan.arlene@endo.com; oehler.sesilie@endo.com; lortie.brian@endo.com)

Auxilium Pharmaceuticals, Inc Arlene Keenan, Government Contracts Senior Manager 1400 Atwater Drive Malvern, PA 19355

# RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1025

Dear Ms. Arlene Keenan:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Auxilium Pharmaceuticals, Inc. that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$105,918.29.

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

This action is based on your organization's failure to pay specified Part D sponsors within 38 calendar days of receipt of the quarterly invoice from the third party administrator, in violation of 42 CFR §423.2315(b)(3) and Section II(b) of the Medicare Coverage Gap Discount Program Agreement (Discount Agreement).

Based on the payment confirmation report provided by your organization and the payment confirmations provided by Part D sponsors, CMS has determined to impose a CMP of \$105,918.29 to Auxilium Pharmaceuticals, Inc. due to untimely payments for the 2014 first quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

• 163 Part D Sponsors \$423,673.15 (Breakdown on Attachment 2)

Ms. Arlene Keenan July 14, 2015 Page 2 of 14

The CMP that your company owes is equal to:

• 25% on the amount paid late, \$105,918.29

The determination by CMS to impose a CMP will become final and due no later than September 14, 2015 if you do not request a hearing to appeal in the manner and timeframe described below. Please see the required payment method below under Method to Submit CMP Payments.

Please note that any further failures by Auxilium Pharmaceuticals, 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.

#### Right to Request a Hearing

Your organization may request a hearing to appeal CMS' determination in accordance with Section VIII (c) of the Discount Agreement. You must send a written request for a hearing to the Departmental Appeals Board office listed below, and a copy to CMS at the address listed below, within 60 calendar days from receipt of this notice. Your request must be received no later than September 14, 2015. The request for a hearing must identify the specific issues, the findings of fact and conclusions of law with which you disagree, and specify the basis for each contention that the finding or conclusion of law is incorrect. Your request should be sent to:

Karen Robinson
Civil Remedies Division
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6132
330 Independence Ave., S.W.
Cohen Building Room G-644
Washington, D.C. 20201

A copy of your hearing request should also be sent to CMS at the following address:

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

Email: <u>Craig.miner@cms.hhs.gov</u>

#### **Method to Submit CMP Payments**

All CMP payments must be made using Pay.gov (See Attachment for instructions). Pay.gov provides a free service to Federal government agencies and to the entities that make online payments to a Federal government agency. The Pay.gov Collection Service collects and processes the Internet-authorized

Ms. Arlene Keenan July 14, 2015 Page 3 of 14

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 in Pay.gov.

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

Acknowledgement of this letter is required, please reply to <u>CGDPandManufacturers@cms.hhs.gov</u>. If you have any questions about this notice, please contact Sonia Eaddy at <u>Sonia.eaddy@cms.hhs.gov</u>.

Sincerely,

/s/

Amy K. Larrick Acting Director, Medicare Drug Benefit and C & D Data Group

cc: Ms. Cheri Rice, CMS/CM/MPPG

Mr. John Scott, CMS/CM/MPPG

Ms. Frankeena Wright, CMS/OL

Ms. Jill Abrams, DHHS/OGC

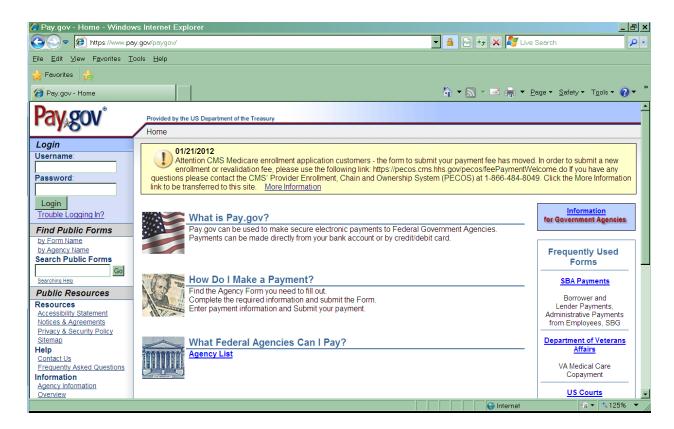
Ms. Jennifer Garver, DHHS/OGC

Ms. Karen Robinson, DHHS/DAB

#### **Attachment 1**

## Step 1

Access Pay.gov at <a href="https://www.pay.gov">https://www.pay.gov</a>

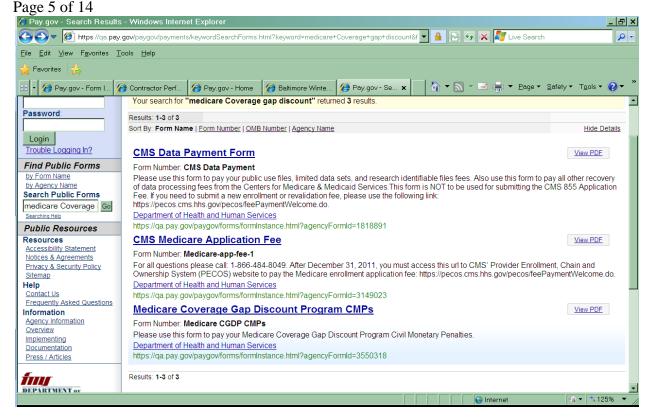


#### Step 2

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

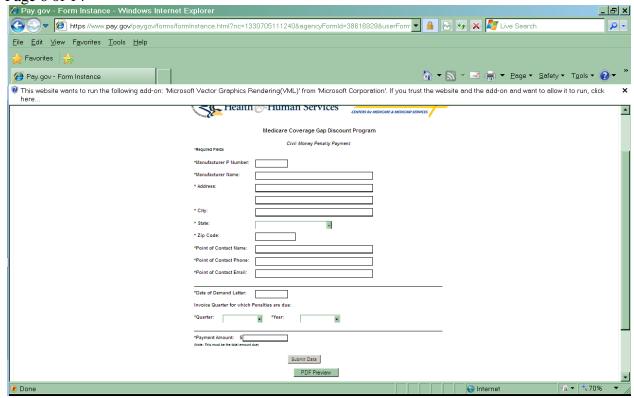
Ms. Arlene Keenan July 14, 2015



## 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.

## Page 6 of 14



- 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
  - Ouarter: (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.

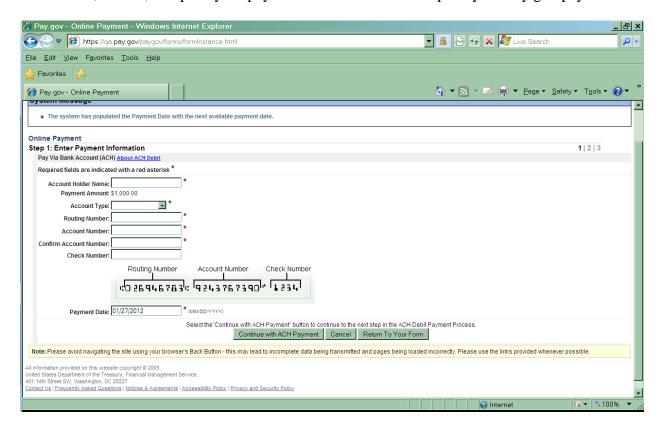
## Ms. Arlene Keenan July 14, 2015

## Page 7 of 14



#### 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

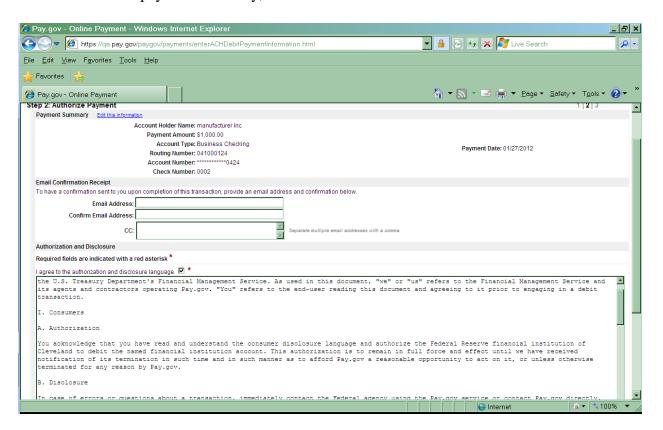
Notice the payment amount you entered on the previous screen has populated. Click on Return To Your Form to correct the payment amount.

- 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,

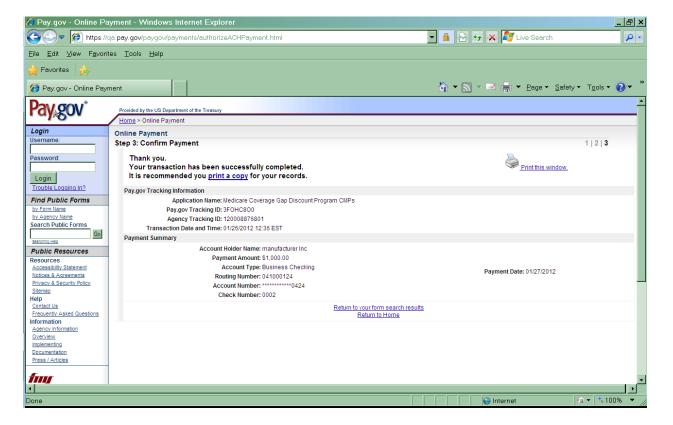


- Enter email address(es) to receive the payment confirmation
- ° Please add to the CC box: cgdp\_manufacturers@cms.hhs.gov
- ° Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization and disclosure language*

**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**

	Contract		
	Number	Contract Name	Amount
1	E3014	PSERS HOP PROGRAM	\$ 825.06
2	E7316	UNION PACIFIC RAILROAD	\$ 176.64
3	E7848	OKLAHOMA STATE AND EDUC	\$ 364.67
4	H0104	BLUE CROSS AND BLUE SHI	\$ 427.00
5	H0154	VIVA HEALTH INC.	\$ 0.32
6	H0303	PACIFICARE OF ARIZONA	\$ 6,330.42
7	H0316	UNITEDHEALTHCARE OF ARI	\$ 170.37
8	H0318	AETNA HEALTH INC.	\$ 178.32
9	H0332	KS PLAN ADMINISTRATORS,	\$ 882.13
10	H0351	HEALTH NET OF ARIZONA	\$ 331.39
11	H0435	GLOBALHEALTH, INC.	\$ 279.04
12	H0504	CA PHYSICIANS SERV/DBA	\$ 2,843.71
13	H0543	PACIFICARE OF CALIFORNI	\$ 4,457.98
14	H0544	CALIFORNIA HEALTH PLAN	\$ 42.50
15	H0545	INTER VALLEY HEALTH PLA	\$ 383.95
16	H0562	HEALTH NET_OF CA	\$ 5,645.49
17	H0609	PACIFICARE OF COLORADO	\$ 331.64
18	H0755	HEALTH NET OF CONNECTIC	\$ 289.82
19	H1016	AVMED INC	\$ 136.38
20	H1026	HEALTH OPTIONS INC	\$ 529.79
21	H1035	FLORIDA HEALTH CARE PLA	\$ 153.35
22	H1076	VISTA HEALTH PLAN, INC	\$ 0.0
23	H1080	UNITED HEALTHCARE OF FL	\$ 375.75
24	H1111	UNITED HEALTHCARE OF GE	\$ 285.27
25	H1112	WELLCARE OF GEORGIA IN	\$ 182.40
26	H1406	HUMANA HEALTH PLAN INC	\$ 183.13
27	H1509	UNITED HEALTHCARE INSUR	\$ 16,962.83
28	H1607	ANTHEM INSURANCE COMPAN	\$ 655.56
29	H1806	HUMANA INSURANCE COMPAN	\$ 179.09
30	H1961	TENET CHOICES INC. / P	\$ 0.0
31	H2001	UNITED HEALTHCARE INSUR	\$ 340.75
32	H2230	BLUE CROSS AND BLUE SHI	\$ 624.36

Ms. Arlene Keenan July 14, 2015 Page 11 of 14

rage	11 01 14	1	ı	
33	H2256	TUFTS ASSOCIATED HMO I	\$	3,207.69
34	H2261	BLUE CROSS & BLUE SHIEL	\$	12.50
35	H2320	PRIORITY HEALTH	\$	706.05
36	H2450	MEDICA INSURANCE COMPAN	\$	887.95
37	H2610	ESSENCE INC.	\$	20.92
38	H2649	HUMANA HEALTH PLAN INC	\$	178.57
39	H2654	UNITED HEALTHCARE OF TH	\$	608.82
40	H2667	MERCY HEALTH PLANS OF M	\$	180.50
41	H2672	COVENTRY HEALTH CARE OF	\$	179.26
42	H2931	HEALTH PLAN OF NEVADA	\$	539.37
43	H3107	OXFORD HEALTH PLANS (NJ	\$	870.19
44	H3132	AIDS HEALTHCARE FOUNDAT	\$	710.03
45	H3154	HORIZON HEALTHCARE OF N	\$	514.27
46	H3156	AMERIHEALTH HMO_INC	\$	592.75
47	H3307	OXFORD HEALTH PLANS (NY	\$	1,300.84
48	H3330	HIP HEALTH PLAN OF NY	\$	186.24
49	H3335	EXCELLUS HEALTH PLAN I	\$	1,412.50
50	H3342	EMPIRE HEALTHCHOICE ASS	\$	3,806.39
51	H3351	EXCELLUS HEALTH PLAN I	\$	1,552.01
52	H3361	WELLCARE_OF NEW YORK I	\$	183.97
53	H3370	EMPIRE HEALTHCHOICE HMO	\$	1,827.34
54	H3404	PARTNERS NATIONAL HEALT	\$	745.31
55	H3447	HEALTHKEEPERS, INC.	\$	153.75
56	H3449	PARTNERS NATIONAL HEALT	\$	495.58
57	H3456	UNITED HEALTHCARE OF NO	\$	332.06
58	H3528	CONNECTICARE, INC.	\$	1,487.85
59	H3597	AETNA HEALTH	\$	364.67
60	H3653	PARAMOUNT CARE INC	\$	178.53
61	H3655	COMMUNITY INSURANCE COM	\$	847.24
62	H3668	MT. CARMEL HEALTH PLAN	\$	357.06
63	H3749	PACIFICARE OF OKLAHOMA	\$	43.20
64	H3755	COMMUNITY CARE HMO INC	\$	358.22
65	H3805	PACIFICARE OF OREGON I	\$	964.36
66	H3907	UNIVERSITY OF PITTSBURG	\$	411.18
67	H3916	HIGHMARK INC.	\$	3,276.60
68	H3957	KEYSTONE HEALTH PLAN WE	\$	85.73
69	H3959	HEALTHAMERICA PENNSYLVA	\$	2,262.06
70	H4003	MMM HEALTHCARE INC.	\$	192.20
71	H4209	BLUE CROSS AND BLUE SHI	\$	27.50
72	H4454	HEALTHSPRING INC.	\$	15.90
				202.27
73	H4456	JOHN DEERE HEALTH PLAN	\$	282.27

Ms. Arlene Keenan July 14, 2015 Page 12 of 14

Page	12 01 14		
75	H4524	AETNA LIFE INSURANCE CO	\$ 178.32
76	H4527	PSO HEALTH SERVICES LL	\$ 282.27
77	H4590	PACIFICARE OF TEXAS IN	\$ 153.53
78	H4605	REGENCE BLUECROSS BLUES	\$ 179.26
79	H4909	ANTHEM HEALTH PLANS OF	\$ 535.89
80	H5009	REGENCE BLUESHIELD	\$ 1,022.83
81	H5106	MOUNTAIN STATE BLUE CRO	\$ 771.72
82	H5253	UNITED HEALTHCARE OF WI	\$ 2.54
83	H5262	GUNDERSEN LUTHERAN HEAL	\$ 233.50
84	H5415	HUMANA HEALTH INSURANCE	\$ 175.08
85	H5425	SCAN HEALTH PLAN	\$ 1,573.27
86	H5471	SIMPLY HEALTHCARE PLANS	\$ 136.70
87	H5509	COVENTRY HEALTH AND LIF	\$ 173.51
88	H5520	HEALTH NET LIFE INSURAN	\$ 0.0
89	H5521	AETNA LIFE INSURANCE CO	\$ 1,014.46
90	H5522	HEALTH ASSURANCE PENNSY	\$ 2,872.40
91	H5528	GROUP HEALTH INCORPORAT	\$ 357.89
92	H5529	COMMUNITY INSURANCE COM	\$ 268.89
93	H5530	ANTHEM HEALTH PLANS OF	\$ 392.40
94	H5576	VANTAGE HEALTH PLAN, I	\$ 180.75
95	H5577	RED MEDICA DE PUERTO RI	\$ 349.37
96	H5594	OPTIMUM HEALTHCARE, INC	\$ 201.03
97	H5652	UNITED HEALTHCARE INSUR	\$ 9.99
98	H5817	AMERIGROUP TEXAS INC.	\$ 101.40
99	H5852	AIDS HEALTHCARE FOUNDAT	\$ 919.74
100	H5938	CAPITAL HEALTH PLAN	\$ 35.03
101	H6169	THE PYRAMID LIFE INSURA	\$ 143.87
102	H6609	HUMANA INSURANCE COMPAN	\$ 1,281.95
103	H6923	AETNA HEALTH	\$ 178.32
104	H7006	MARION POLK COMMUNITY H	\$ 179.79
105	H7917	BLUE CROSS BLUE SHIELD	\$ 642.31
106	H8145	HUMANA INSURANCE COMPAN	\$ 536.06
107	H8552	ANTHEM BLUE CROSS LIFE	\$ 1,945.89
108	H8578	HEALTH NEW ENGLAND, INC	\$ 201.79
109	H8649	ALTIUS HEALTH PLANS, IN	\$ 22.30
110	H9003	KAISER FOUNDATION HP OF	\$ 186.43
111	H9047	PROVIDENCE HEALTH PLAN	\$ 175.60
112	H9302	PUGET SOUND HEALTH PART	\$ 683.65
113	H9572	BLUE CROSS BLUE SHIELD	\$ 679.83
114	H9615	MVP HEALTH PLAN, INC.	\$ 475.08
115	H9859	MVP HEALTH PLAN, INC,	\$ 179.41

Ms. Arlene Keenan July 14, 2015

Page	13	of	1	4
1 ago	10	$\mathbf{o}_{\mathbf{I}}$	1	7

	13 01 14	1	l .
117	R3332	BLUE CROSS AND BLUE SHI	\$ 422.51
118	R5287	UNITED HEALTHCARE INSUR	\$ 823.16
119	R5826	HUMANA INSURANCE COMPAN	\$ 675.76
120	R5941	ANTHEM INSURANCE COMPAN	\$ 443.28
121	R7439	HAWAII MEDICAL SERVICE	\$ 182.71
122	R9896	CARE IMPROVEMENT PLUS S	\$ 0.0
123	S0655	TUFTS INSURANCE COMPANY	\$ 1,956.29
124	S2468	CA PHYSICIANS SERVICE	\$ 3,909.26
125	S2893	BLUE CROSS BLUE SHIELD	\$ 4,067.40
126	S3521	EXCELLUS HEALTH PLAN I	\$ 438.99
127	S4802	STERLING LIFE INSURANCE	\$ 1,291.86
128	S5540	BLUE CROSS AND BLUE SHI	\$ 1,680.43
129	S5552	HUMANA INSURANCE COMPAN	\$ 181.27
130	S5569	CAMBRIDGE LIFE INSURANC	\$ 396.72
131	S5584	BLUE CROSS BLUE SHIELD	\$ 618.53
132	S5593	HIGHMARK SENIOR RESOURC	\$ 592.52
133	S5596	ANTHEM INSURANCE COMPAN	\$ 7,030.63
134	S5601	SILVERSCRIPT INSURANCE	\$ 79,558.10
135	S5609	ASURIS NORTHWEST HEALTH	\$ 179.26
136	S5617	CONNECTICUT GENERAL LIF	\$ 16,633.34
137	S5660	MEDCO HEALTH SOLUTIONS	\$ 57,266.13
138	S5715	HCSC INSURANCE SERVICES	\$ 47.14
139	S5726	BLUE CROSS BLUE SHIELD	\$ 337.15
140	S5743	BLUE CROSS BLUE SHIELD	\$ 773.81
141	S5753	WISCONSIN PHYSICIAN SER	\$ 578.51
142	S5755	UNITED AMERICAN INSURAN	\$ 1,220.82
143	S5766	FIRST CARE INC.	\$ 759.01
144	S5768	FIRST HEALTH LIFE & HEA	\$ 978.68
145	S5795	ARKANSAS BCBS A MUTUAL	\$ 355.40
146	S5803	MEMBERHEALTH INC.	\$ 147.47
147	S5805	UNITED HEALTHCARE INSUR	\$ 38,739.97
148	S5810	AETNA LIFE INSURANCE CO	\$ 1,144.13
149	S5820	UNITED HEALTHCARE INSUR	\$ 21,414.39
150	S5884	HUMANA INSURANCE COMPAN	\$ 925.89
151	S5904	BLUE CROSS AND BLUE SHI	\$ 1,432.83
152	S5916	REGENCE LIFE AND HEALTH	\$ 177.70
153	S5921	PACIFICARE LIFE AND HEA	\$ 24,258.82
154	S5960	UNICARE	\$ 389.99
155	S5966	GROUP HEALTH INCORPORAT	\$ 1,100.73
156	S5967	WELLCARE PRESCRIPTION I	\$ 9,294.81
157	S5975	ODS HEALTH PLAN	\$ 353.82
158	S5993	HORIZON HEALTHCARE SERV	\$ 1,016.41
100	33333	HOMZON HEALTHCARE SERV	1,010.41 د

Ms. Arlene Keenan July 14, 2015 Page 14 of 14

159	S6506	BLUE CROSS AND BLUE SHI	\$ 39.33
160	S7694	ENVISION INSURANCE COMP	\$ 2,791.01
161	S7950	EXPRESS SCRIPTS INSURAN	\$ 33,881.98
162	S8841	NMHC GROUP SOLUTION INS	\$ 813.31
163	S9579	STONEBRIDGE LIFE INSURA	\$ 2,465.93
			\$423,673.15