

# **Center of Medicare**

April 18, 2013

VIA:

**EMAIL** (<u>william.soucie@pharmaderm.com</u>, <u>ralph.landau@pharmaderm.com</u>; <u>Theresa.Gribbin@Fougera.com</u>; <u>felim.buckley@novartis.com</u>)

Fougera Pharmaceuticals William Soucie Sr. Director, Managed Markets 210 Park Avenue Florham Park, NJ 07932

### **RE:** Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1049

Dear Mr. William Soucie:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Fougera Pharmaceuticals that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$73,605.43.

# **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 \$73,605.43 to Fougera Pharmaceuticals due to untimely payments for the 2012 third quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

• 197 Part D Sponsors \$294,421.71 (Breakdown on Attachment 2)

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The CMP that your company owes is equal to:

• 25% on the amount paid late, \$73,605.43

The determination by CMS to impose a CMP will become final and due no later than June 17, 2013 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 Fougera Pharmaceuticals 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 June 17, 2013. 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 1 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

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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/

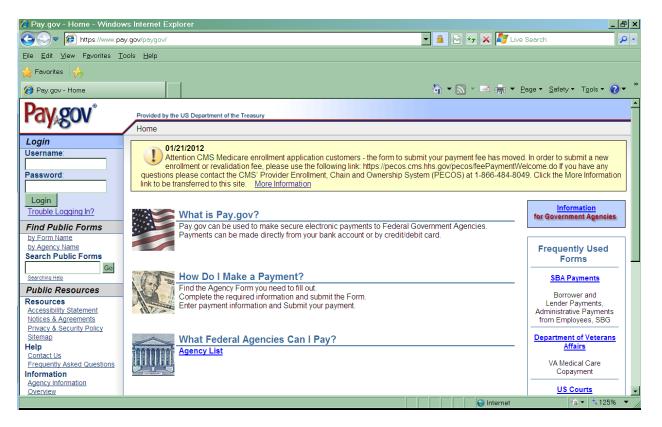
Cynthia G. Tudor, Ph.D. Director, Medicare Drug Benefit and C & D Data Group

cc: Ms. Cheri Rice, CMS/CM/MPPG Mr. John Scott, CMS/CM/MPPG Mr. Brian Cook, CMS/OC Mr. Greg Jones, CMS/OL Ms. Jill Abrams, DHHS/OGC Ms. Jennifer Garver, DHHS/OGC Ms. Karen Robinson, DHHS/DAB Mr. William Soucie April 18, 2013 Page 4 of 14

# Attachment 1

# Step 1

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

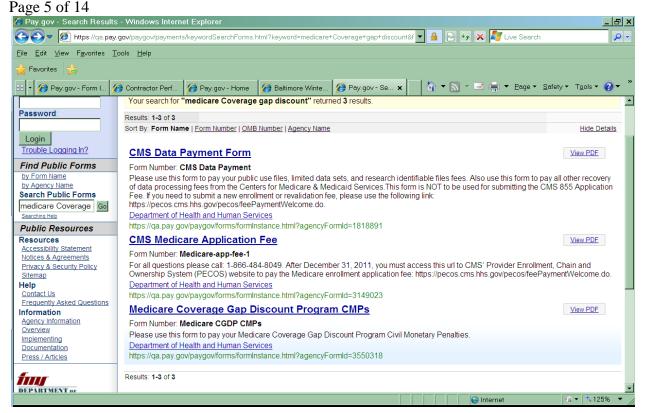


# Step 2

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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### 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.

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Pay.gov - Form Instance - Windows Internet	Explorer	×
Solve for https://www.pay.gov/paygov/forms/for	rminstance.html?nc=1330705111240&agencyFormid=38616929&userForrr 🔽 🔒 🗟 🐓 🗙 🧗 Live Search 🔎	•
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Pay.gov - Form Instance		
I his website wants to run the following add-on: 'Micro here	soft Vector Graphics Rendering(VML)' from 'Microsoft Corporation'. If you trust the website and the add-on and want to allow it to run, click	×
	Health Or Human 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:	
	*Date of Demand Letter:	
	Invoice Quarter for which Penalties are due:	
	"Quarter: W "Year: W	
	*Payment Amount: \$	
	(Mode: This must be fold) amount due)	
	Submit Data	
-	PDF Preview	•
🕐 Done		1

- Complete the required fields
  - <sup>o</sup> Manufacturer P Number: (P####) must be a P followed by 4-digits
  - ° Manufacturer Name: manufacturer's complete name
  - <sup>°</sup> **Point of Contact:** person authorized to make the payment
  - **Point of Contact Phone:** (\*\*\*-\*\*\*\*) telephone number must include dashes
  - **Point of Contact Email:** email address
  - <sup>o</sup> Mailing address: Street, city, state, and zip code
  - <sup>o</sup> **Date of Demand Letter:** (MM/DD/YEAR) typed date on the demand letter received from CMS
  - <sup>o</sup> **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
  - <sup>°</sup> **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.

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# <u>Step 4</u>

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.

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The system has populated the Payment Date with the next available payment date.	<b>_</b>	
Online Payment Step 1: Enter Payment Information 1   2   3		
Pay Via Bank Account (Act) About Act Pabit		
Required fields are indicated with a red asterisk *		
Account Holder Name: * Payment Amount: \$1,000.00		
Account Type:		
Routing Number: *		
Account Number:		
Confirm Account Number:		
Check Number:		
Routing Number Account Number Check Number		
······································		
Payment Date: 01/27/2012 * (MM0D/YYYY)		
Select the "Continue with ACH Payment" button to continue to the next step in the ACH Debit Payment Process.		
Continue with ACH Payment Cancel Return To Your Form		
Note: Please avoid navigating the site using your browser's Back Button - this may lead to incomplete data being transmitted and pages being loaded incorrectly. Please use the links provided whenever possible.		
All information provided on this website copyright © 2005.		
United States Department of the Treasury, Fnancial Management Service, 401 14th Strete SN, Washington, DC 20227		
Contact Us   Frequently Asked Questions   Notices & Agreements   Accessibility Policy   Privacy and Security Policy	-	
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• Enter Payment Information

0

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.

- <sup>°</sup> 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.

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🕞 🗢 🕖 https://qa.pay.gov/paygov/paym	nents/enterACHDebitPaymentInformation.html 🗾 🔒 🔀 🍫 🗙 🗗 Live Sea	arch 🔎 🗸
<u>File E</u> dit ⊻iew F <u>a</u> vorites <u>T</u> ools <u>H</u> elp		
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Pay.gov - Online Payment		▼ <u>S</u> afety ▼ T <u>o</u> ols ▼ 🕗 ▼ "
Step 2: Authorize Payment		1 2 3
Payment Summary Edit this information		_
	Name: manufacturer Inc	
	mount: \$1,000.00	
	It Type: Business Checking Payment Date: 01/27/2012	
	umber: 041000124	
	umber: ********0424	
	umber: 0002	
Email Confirmation Receipt		
	f 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 $^{\star}$		
I agree to the authorization and disclosure language.	V *	
	icial Management Service. As used in this document, "we" or "us" refers to the Financial Manag	
	g Pay.gov. "You" refers to the end-user reading this document and agreeing to it prior to enga	aging in a debit
transaction.		
I. Consumers		
A. Authorization		_
You acknowledge that you have read a	and understand the consumer disclosure language and authorize the Federal Reserve financial in	estitution of
	al institution account. This authorization is to remain in full force and effect until we have	
	such time and in such manner as to afford Pay.gov a reasonable opportunity to act on it, or ur	less otherwise
terminated for any reason by Pay.gov	·	
B. Disclosure		
I In case of errors or questions about	a transaction. immediately contact the Federal agency using the Pay.gov service or contact F	
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• Review the payment summary,

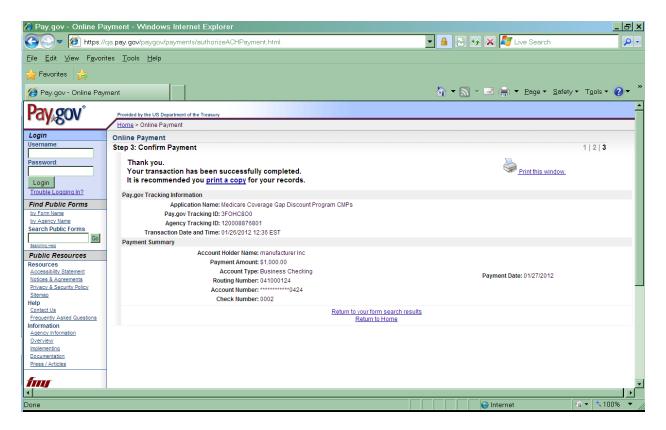
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- <sup>°</sup> Enter email address(es) to receive the payment confirmation
- ° Please add to the CC box: cgdp\_manufacturers@cms.hhs.gov
- <sup>°</sup> Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization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



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# Attachment 2

2012 Q3 P1049		
	Part D Sponsors	Invoice Amount
1	NATIONAL RURAL ELECTRIC	\$19.23
2	PSERS HOP PROGRAM	\$648.02
3	KENTUCKY RETIREMENT SYS	\$225.00
4	UNION PACIFIC RAILROAD	\$279.30
5	OKLAHOMA STATE AND EDUC	\$209.82
6	BLUE CROSS AND BLUE SHI	\$158.38
7	UNITED HEALTHCARE OF AL	\$29.38
8	VIVA HEALTH INC.	\$198.43
9	PACIFICARE OF ARIZONA	\$90.65
10	HUMANA HEALTH PLAN INC	\$86.05
11	HEALTH NET OF ARIZONA	\$39.07
12	CA PHYSICIANS SERV/DBA	\$50.00
13	KAISER FOUNDATION HP I	\$531.36
14	PACIFICARE OF CALIFORNI	\$584.08
15	CALIFORNIA HEALTH PLAN	\$25.00
16	HEALTH NET_OF CA	\$1,004.46
17	HUMANA INSURANCE COMPAN	\$75.78
18	AVMED INC	\$65.27
19	HUMANA MEDICAL PLAN IN	\$356.82
20	PREFERRED CARE PARTNERS	\$104.40
21	VISTA HEALTH PLAN, INC	\$3.14
22	KAISER FOUNDATION HP I	\$7.50
23	HAWAII MED. SRVC. ASSN.	\$286.12
24	UNITED HEALTHCARE INSUR	\$24.43
25	UNITED HEALTHCARE INSUR	\$770.23
26	ANTHEM INSURANCE COMPAN	\$259.62
27	HUMANA INSURANCE COMPAN	\$65.76
28	ANTHEM HEALTH PLANS OF	\$7.50
29	HUMANA HEALTH BENEFIT P	\$516.68
30	TENET CHOICES INC. / P	\$192.39
31	HUMANA HEALTH PLAN, INC	\$301.30
32	KAISER FNDN HP OF THE M	\$13.75
33	UNITED HEALTHCARE INSUR	\$67.34
34	BLUE CROSS AND BLUE SHI	\$74.01
35	TUFTS ASSOCIATED HMO I	\$838.22

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Page	Page 11 of 14			
36	HEALTH ALLIANCE PLAN OF	\$25.00		
37	PRIORITY HEALTH	\$268.44		
38	MEDICA INSURANCE COMPAN	\$290.87		
39	UCARE MINNESOTA	\$292.53		
40	HEALTHPARTNERS	\$624.56		
41	HUMANA MEDICAL PLAN OF	\$121.01		
42	UNITED HEALTHCARE OF TH	\$50.00		
43	AMERICAN PROGRESSIVE LI	\$100.48		
44	ROCKY MOUNTAIN HOSPITAL	\$10.00		
45	OXFORD HEALTH PLANS (NJ	\$373.22		
46	AETNA HEALTH INC.	\$1,032.37		
47	HORIZON HEALTHCARE OF N	\$595.68		
48	PREFERRED CARE	\$524.68		
49	OXFORD HEALTH PLANS (NY	\$603.30		
50	AETNA HEALTH INC.	\$283.91		
51	TOUCHSTONE HEALTH PARTN	\$328.11		
52	NEW YORK STATE CATHOLIC	\$492.90		
53	HIP HEALTH PLAN OF NY	\$16,426.63		
54	EXCELLUS HEALTH PLAN I	\$282.69		
55	EMPIRE HEALTHCHOICE ASS	\$1,124.52		
56	INDEPENDENT HEALTH BENE	\$135.24		
57	PREFERRED CARE	\$2.50		
58	ELDERPLAN INC.	\$630.03		
59	EXCELLUS HEALTH PLAN I	\$1,160.25		
60	INDEPENDENT HEALTH ASSO	\$824.32		
61	EMPIRE HEALTHCHOICE HMO	\$596.33		
62	CAPITAL DISTRICT PHYSIC	\$242.28		
63	PARTNERS NATIONAL HEALT	\$299.83		
64	PARTNERS NATIONAL HEALT	\$128.84		
65	UNITED HEALTHCARE OF NO	\$423.95		
66	CONNECTICARE, INC.	\$196.73		
67	HUMANA INSURANCE COMPAN	\$463.12		
68	COMMUNITY INSURANCE COM	\$86.34		
69	UNITED HEALTHCARE OF OH	\$335.60		
70	MCKINLEY LIFE INSURANCE	\$774.42		
71	MT. CARMEL HEALTH PLAN	\$707.61		
72	ODS HEALTH PLAN	\$166.25		
73	REGENCE BLUECROSS BLUES	\$68.11		
74	UNIVERSITY OF PITTSBURG	\$89.09		
75	HIGHMARK INC.	\$5,074.93		
76	CAPITAL ADVANTAGE INSUR	\$540.24		

Mr. William Soucie April 18, 2013 Page 12 of 14 77 AETNA HEALTH INC

Page	2 12 01 14	
77	AETNA HEALTH INC	\$89.80
78	KEYSTONE HEALTH PLAN EA	\$20.76
79	KEYSTONE HEALTH PLAN WE	\$1,421.80
80	HEALTHAMERICA PENNSYLVA	\$157.60
81	KEYSTONE HEALTH PLAN CE	\$58.65
82	MMM HEALTHCARE INC.	\$176.11
83	PREFERRED MEDICARE CHOI	\$369.21
84	TRIPLE-S INC.	\$58.95
85	MCS LIFE INSURANCE COMP	\$22.50
86	HUMANA HEALTH PLANS OF	\$568.70
87	TRIPLE-S INC.	\$294.29
88	HUMANA EMPLOYERS HEALTH	\$67.34
89	HEALTHSPRING INC.	\$106.16
90	JOHN DEERE HEALTH PLAN	\$50.36
91	CARITEN HEALTH PLAN IN	\$886.06
92	TEXAS HEALTHSPRING I L	\$2.00
93	HUMANA INSURANCE COMPAN	\$65.76
94	AETNA HEALTH INC.	\$50.00
95	AETNA LIFE INSURANCE CO	\$158.26
96	ARCADIAN HEALT PLAN IN	\$49.69
97	PACIFICARE OF TEXAS IN	\$419.15
98	REGENCE BLUECROSS BLUES	\$292.39
99	ANTHEM HEALTH PLANS OF	\$481.27
100	REGENCE BLUESHIELD	\$1,086.95
101	CDPHP UNIVERSAL BENEFIT	\$15.00
102	SECURITY HEALTH PLAN OF	\$8.45
103	HUMANA INSURANCE COMPAN	\$96.92
104	HUMANA INSURANCE COMPAN	\$286.12
105	GUNDERSEN LUTHERAN HEAL	\$5.16
106	HUMANA HEALTH INSURANCE	\$271.60
107	UNITED HEALTHCARE INSUR	\$289.53
108	MEDICAL HEALTHCARE PLAN	\$25.00
109	SCAN HEALTH PLAN	\$279.09
110	UNITED HEALTHCARE INS.	\$232.24
111	AETNA LIFE INSURANCE CO	\$436.13
112	HEALTH ASSURANCE PENNSY	\$249.14
113	HEALTHNOW NEW YORK INC.	\$464.06
114	GROUP HEALTH INCORPORAT	\$2,008.45
115	COMMUNITY INSURANCE COM	\$151.88
116	ANTHEM HEALTH PLANS OF	\$10.50
117	VNS CHOICE	\$839.56

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Page	e 13 of 14	
118	FIDELIS SECURECARE OF N	\$641.37
119	VANTAGE HEALTH PLAN, I	\$155.64
120	RED MEDICA DE PUERTO RI	\$1,680.28
121	MARTINS POINT GENERATIO	\$78.26
122	AMERICAN HEALTH INC.	\$277.36
123	UNIVERSAL HEALTH CARE I	\$274.94
124	MAPFRE LIFE INSURANCE C	\$1.50
125	BLUE CARE NETWORK OF MI	\$588.96
126	CAPITAL HEALTH PLAN	\$1,095.62
127	SCAN HEALTH PLAN	\$279.58
128	AMERIGROUP NEW YORK, LL	\$1,520.58
129	HEALTHPLUS PHSP, INC.	\$77.69
130	KAISER FOUNDATION HP OF	\$10.00
131	HUMANA INSURANCE COMPAN	\$730.70
132	HUMANA INSURANCE COMPAN	\$8.98
133	HUMANA INSURANCE COMPAN	\$51.98
134	HUMANA INSURANCE COMPAN	\$282.39
135	MD CARE, INC.	\$279.25
136	BLUE CROSS BLUE SHIELD	\$279.25
137	HUMANA INSURANCE COMPAN	\$282.71
138	ANTHEM BLUE CROSS LIFE	\$77.24
139	UNITED HEALTHCARE INSUR	\$86.08
140	BLUE CROSS BLUE SHIELD	\$727.30
141	MVP HEALTH PLAN, INC.	\$128.84
142	MVP HEALTH PLAN, INC,	\$30.00
143	BLUE CROSS AND BLUE SHI	\$738.55
144	CARE IMPROVEMENT PLUS S	\$66.06
145	UNITED HEALTHCARE INSUR	\$552.90
146	HUMANA INSURANCE COMPAN	\$395.94
147	ANTHEM INSURANCE COMPAN	\$437.11
148	HAWAII MEDICAL SERVICE	\$283.66
149	CARE IMPROVEMENT PLUS S	\$261.59
150	BCBS OF ALABAMA AND BCB	\$1,042.36
151	QCC INS CO D/B/A AMERIH	\$268.28
152	CA PHYSICIANS SERVICE	\$1,279.07
153	BLUE CROSS BLUE SHIELD	\$1,072.01
154	EXCELLUS HEALTH PLAN I	\$1,393.81
155	STERLING LIFE INSURANCE	\$1,278.88
156	BLUE CROSS AND BLUE SHI	\$769.70
157	HUMANA INSURANCE COMPAN	\$2,434.17
158	CAMBRIDGE LIFE INSURANC	\$282.33
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159	BLUE CROSS BLUE SHIELD	\$1,157.82
160	HIGHMARK SENIOR RESOURC	\$306.31
161	ANTHEM INSURANCE COMPAN	\$5,221.50
162	SILVERSCRIPT INSURANCE	\$33,994.88
163	ASURIS NORTHWEST HEALTH	\$106.76
164	CONNECTICUT GENERAL LIF	\$3,539.12
165	MEDCO HEALTH SOLUTIONS	\$54,441.12
166	COVENTRY HEALTH AND LIF	\$860.17
167	FIRST HEALTH LIFE AND H	\$751.63
168	PENNSYLVANIA LIFE INSUR	\$1,686.36
169	HCSC INSURANCE SERVICES	\$3,624.62
170	BLUE CROSS BLUE SHIELD	\$385.76
171	BLUE CROSS BLUE SHIELD	\$338.50
172	WISCONSIN PHYSICIAN SER	\$232.86
173	UNITED AMERICAN INSURAN	\$2,386.82
174	FIRST CARE INC.	\$1,527.30
175	FIRST HEALTH LIFE & HEA	\$2,106.79
176	ARKANSAS BCBS A MUTUAL	\$41.03
177	MEMBERHEALTH INC.	\$475.24
178	UNITED HEALTHCARE INSUR	\$4,456.05
179	AETNA LIFE INSURANCE CO	\$2,940.45
180	UNITED HEALTHCARE INSUR	\$36,748.37
181	HUMANA INSURANCE COMPAN	\$13,219.32
182	BLUE CROSS AND BLUE SHI	\$1,328.06
183	PACIFICARE LIFE AND HEA	\$7,047.65
184	HEALTHSPRING INC. HEALT	\$279.31
185	LOUISIANA HEALTH SERVIC	\$78.21
186	BLUE CROSS AND BLUE SHI	\$660.46
187	UNICARE	\$356.46
188	GROUP HEALTH INCORPORAT	\$2,674.95
189	ODS HEALTH PLAN	\$14.63
190	MEDCO HEALTH SOLUTIONS	\$1,284.87
191	HORIZON HEALTHCARE SERV	\$1,986.05
192	ELDER HEALTH INSURANCE	\$267.08
193	ENVISION INSURANCE COMP	\$2,485.81
194	EXPRESS SCRIPTS INSURAN	\$25,389.97
195	AVALON HEALTH LTD	\$102.77
196	NMHC GROUP SOLUTION INS	\$15.00
197	STONEBRIDGE LIFE INSURA	\$70.74
	Total	\$294,421.71