

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

August 22, 2014

VIA:

EMAIL (slin@prometheuslabs.com; jlimber@prometheuslabs.com)

Prometheus Laboratories Inc.
Ms. Susan Lin
Manager, Managed Care Operations
9410 Carroll Park Drive
San Diego, CA 92121

**RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer
Contract Number P1189**

Dear Ms. Susan Lin:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Prometheus Laboratories Inc. that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$115,562.29.

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 \$115,562.29 to Prometheus Laboratories Inc. due to untimely payments for the 2013 fourth quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

- 143 Part D Sponsors \$462,249.16 (Breakdown on Attachment 2)

The CMP that your company owes is equal to:

- 25% on the amount paid late, \$115,562.29

The determination by CMS to impose a CMP will become final and due no later than October 21, 2014 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 Prometheus Laboratories Inc. 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 October 21, 2014. 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: Craig.miner@cms.hhs.gov

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. Susan Lin
August 22, 2014
Page 3 of 13

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 CGDPandManufacturers@cms.hhs.gov. If you have any questions about this notice, please contact Sonia Eaddy at Sonia.eaddy@cms.hhs.gov.

Sincerely,

/s/

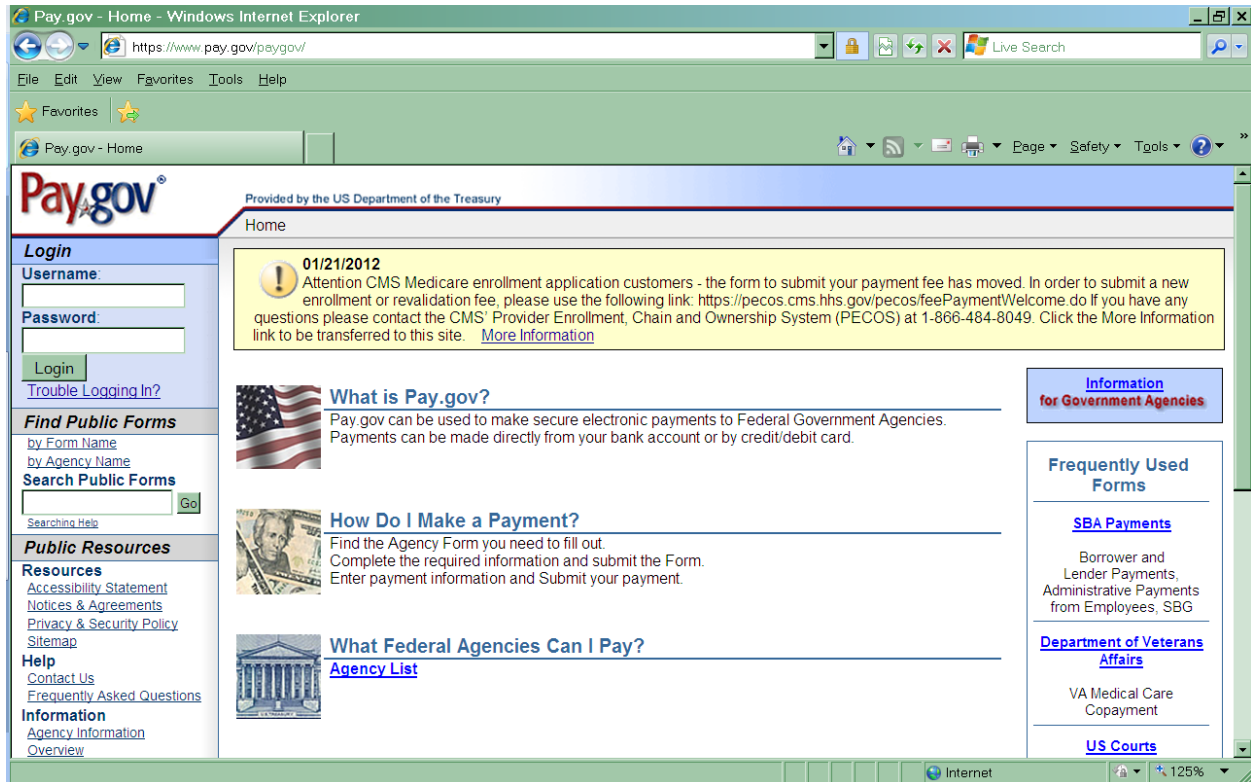
Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

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

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

The screenshot shows a Windows Internet Explorer browser window displaying search results on the pay.gov website. The search term 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 and a "View PDF" link. The left sidebar contains navigation links for Password, Find Public Forms, Search Public Forms, Public Resources, and Information. The bottom of the page features the HHS Department of Health and Human Services logo.

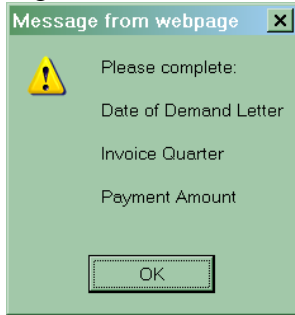
Step 3

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.

The screenshot shows a web browser window displaying the Medicare Coverage Gap Discount Program form. The form is titled "Medicare Coverage Gap Discount Program" and "Civil Money Penalty Payment". It contains several required fields for data entry, including 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, and Payment Amount. There are also dropdown menus for Quarter and Year. At the bottom of the form, there are buttons for "Submit Data" and "PDF Preview".

- 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,

Pay.gov - Online Payment - Windows Internet Explorer

https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html

File Edit View Favorites Tools Help

Pay.gov - Online Payment

Step 2: Authorize Payment

Payment Summary [Edit this information](#)

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
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](mailto:cgdg_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.

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

Pay.gov - Online Payment

Provided by the US Department of the Treasury
Home > Online Payment

Pay.gov

Login
Username:
Password:
Login
[Trouble Logging In?](#)

Find Public Forms
by Form Name
by Agency Name
Search Public Forms
 Go

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: 01/29/2012 12:38 EST

Payment Summary

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	

[Return to your form search results](#)
[Return to Home](#)

Done Internet 100%

Attachment 2

1	E2332	NATIONAL RURAL ELECTRIC	\$ 22.03
2	E3014	PSERS HOP PROGRAM	\$ 1,171.58
3	E4744	MO DOT AND MSHP MEDICAL	\$ 892.18
4	E7316	UNION PACIFIC RAILROAD	\$ 1,893.17
5	E7848	OKLAHOMA STATE AND EDUC	\$ 2,110.98
6	H0084	CARE IMPROVEMENT PLUS O	\$ 153.06
7	H0150	HEALTHSPRING OF ALABAMA	\$ 1,028.10
8	H0303	PACIFICARE OF ARIZONA	\$ 1,129.26
9	H0307	HUMANA HEALTH PLAN INC	\$ 542.44
10	H0504	CA PHYSICIANS SERV/DBA	\$ 2,817.80
11	H0524	KAISER FOUNDATION HP I	\$ 5,935.86
12	H0543	PACIFICARE OF CALIFORNI	\$ 2,316.71
13	H0562	HEALTH NET_OF CA	\$ 1,071.62
14	H0602	ROCKY MOUNTAIN HEALTH P	\$ 544.59
15	H0630	KAISER FOUNDATION HP OF	\$ 626.70
16	H1016	AVMED INC	\$ 474.14
17	H1019	CAREONE HEALTH PLAN IN	\$ 653.34
18	H1026	HEALTH OPTIONS INC	\$ 173.43
19	H1080	UNITED HEALTHCARE OF FL	\$ 402.93
20	H1110	AETNA LIFE INSURANCE CO	\$ 267.59
21	H1112	WELLCARE OF GEORGIA IN	\$ 547.41
22	H1304	REGENCE BLUE SHIELD OF	\$ 1,083.18
23	H1509	UNITED HEALTHCARE INSUR	\$ 2,452.76
24	H1510	HUMANA INSURANCE COMPAN	\$ 29.23
25	H1951	HUMANA HEALTH BENEFIT P	\$ 586.39
26	H1961	TENET CHOICES INC. / P	\$ 1,226.38
27	H2108	ELDER HEALTH MID-ATLANT	\$ 546.24
28	H2150	KAISER FNDN HP OF THE M	\$ 912.03
29	H2312	HEALTH ALLIANCE PLAN OF	\$ 12.50
30	H2320	PRIORITY HEALTH	\$ 1,023.28
31	H2354	HEALTH PLUS OF MICHIGAN	\$ 353.37
32	H2450	MEDICA INSURANCE COMPAN	\$ 1,464.61
33	H2459	UCARE MINNESOTA	\$ 1,205.60
34	H2649	HUMANA HEALTH PLAN INC	\$ 1,045.44
35	H2663	GROUP HEALTH PLAN INC.	\$ 1,022.78
36	H3154	HORIZON HEALTHCARE OF N	\$ 1,788.71
37	H3204	PRESBYTERIAN HEALTH PLA	\$ 96.06
38	H3307	OXFORD HEALTH PLANS (NY	\$ 4.88
39	H3330	HIP HEALTH PLAN OF NY	\$ 481.82

40	H3335	EXCELLUS HEALTH PLAN I	\$ 1,076.02
41	H3342	EMPIRE HEALTHCHOICE ASS	\$ 788.83
42	H3351	EXCELLUS HEALTH PLAN I	\$ 2,944.55
43	H3362	INDEPENDENT HEALTH ASSO	\$ 918.45
44	H3384	HEALTHNOW NEW YORK INC	\$ 1,343.06
45	H3388	CAPITAL DISTRICT PHYSIC	\$ 1,033.65
46	H3404	PARTNERS NATIONAL HEALT	\$ 0
47	H3528	CONNECTICARE, INC.	\$ 742.79
48	H3655	COMMUNITY INSURANCE COM	\$ 1,685.37
49	H3668	MT. CARMEL HEALTH PLAN	\$ 451.75
50	H3813	ODS HEALTH PLAN	\$ 195.78
51	H3909	INDEPENDENCE BLUE CROSS	\$ 75.00
52	H3916	HIGHMARK INC.	\$ 4,143.57
53	H3949	ELDER HEALTH PENNSYLVAN	\$ 0
54	H3952	KEYSTONE HEALTH PLAN EA	\$ 607.18
55	H3954	GEISINGER HEALTH PLAN	\$ 1,599.90
56	H3957	KEYSTONE HEALTH PLAN WE	\$ 0
57	H3959	HEALTHAMERICA PENNSYLVA	\$ 541.71
58	H4003	MMM HEALTHCARE INC.	\$ 348.98
59	H4005	TRIPLE-S INC.	\$ 444.92
60	H4012	TRIPLE-S INC.	\$ 754.51
61	H4270	UCARE WISCONSIN INSURAN	\$ 494.13
62	H4461	CARITEN HEALTH PLAN IN	\$ 4,393.31
63	H4506	SELECTCARE OF TEXAS	\$ 80.79
64	H4513	TEXAS HEALTHSPRING I L	\$ 1,336.44
65	H4525	SHA L.L.C	\$ 533.30
66	H5009	REGENCE BLUESHIELD	\$ 2,113.17
67	H5050	GROUP HEALTH COOPERATIV	\$ 155.15
68	H5106	MOUNTAIN STATE BLUE CRO	\$ 339.71
69	H5211	SECURITY HEALTH PLAN OF	\$ 256.04
70	H5215	NETWORK HEALTH INSURANC	\$ 285.74
71	H5414	AETNA HEALTH INC.	\$ 228.66
72	H5415	HUMANA HEALTH INSURANCE	\$ 560.28
73	H5425	SCAN HEALTH PLAN	\$ 60.00
74	H5426	METCARE HEALTH PLANS I	\$ 702.11
75	H5434	BLUE CROSS AND BLUE SHI	\$ 230.50
76	H5520	HEALTH NET LIFE INSURAN	\$ 937.69
77	H5521	AETNA LIFE INSURANCE CO	\$ 1,202.92
78	H5522	HEALTH ASSURANCE PENNSY	\$ 812.58
79	H5526	HEALTHNOW NEW YORK INC.	\$ 1,838.24
80	H5529	COMMUNITY INSURANCE COM	\$ 523.38
81	H5530	ANTHEM HEALTH PLANS OF	\$ 480.64
82	H5594	OPTIMUM HEALTHCARE, INC	\$ 0

83	H5868	HUMANA INSURANCE COMPAN	\$ 72.72
84	H5938	CAPITAL HEALTH PLAN	\$ 1,118.20
85	H6528	CARE IMPROVEMENT PLUS S	\$ 523.02
86	H6609	HUMANA INSURANCE COMPAN	\$ 7,315.32
87	H7149	COVENTRY HEALTH CARE OF	\$ 520.75
88	H7301	PERSONAL CARE INSURANCE	\$ 517.62
89	H7917	BLUE CROSS BLUE SHIELD	\$ 1,645.64
90	H8145	HUMANA INSURANCE COMPAN	\$ 790.53
91	H8552	ANTHEM BLUE CROSS LIFE	\$ 573.95
92	H8822	ADVANTAGE HEALTH SOLUTI	\$ 33.37
93	H9003	KAISER FOUNDATION HP OF	\$ 458.77
94	H9572	BLUE CROSS BLUE SHIELD	\$ 4,207.59
95	H9615	MVP HEALTH PLAN, INC.	\$ 978.86
96	R5342	UNITED HEALTHCARE INSUR	\$ 406.84
97	R5826	HUMANA INSURANCE COMPAN	\$ 2,628.11
98	R5941	ANTHEM INSURANCE COMPAN	\$ 0
99	S1030	BCBS OF ALABAMA AND BCB	\$ 4,318.23
100	S2321	QCC INS CO D/B/A AMERIH	\$ 16.36
101	S2468	CA PHYSICIANS SERVICE	\$ 2,788.18
102	S2893	BLUE CROSS BLUE SHIELD	\$ 1,588.67
103	S3521	EXCELLUS HEALTH PLAN I	\$ 583.53
104	S4219	HEALTH ALLIANCE MEDICAL	\$ 2,868.58
105	S4802	STERLING LIFE INSURANCE	\$ 6,934.45
106	S5540	BLUE CROSS AND BLUE SHI	\$ 987.04
107	S5552	HUMANA INSURANCE COMPAN	\$ 827.49
108	S5584	BLUE CROSS BLUE SHIELD	\$ 1,623.09
109	S5593	HIGHMARK SENIOR RESOURC	\$ 1,321.75
110	S5596	ANTHEM INSURANCE COMPAN	\$ 9,612.96
111	S5601	SILVERSCRIPT INSURANCE	\$ 59,188.85
112	S5617	CONNECTICUT GENERAL LIF	\$ 5,513.76
113	S5660	MEDCO HEALTH SOLUTIONS	\$ 99,174.63
114	S5670	COVENTRY HEALTH AND LIF	\$ 397.73
115	S5674	FIRST HEALTH LIFE AND H	\$ 1,224.09
116	S5678	PENNSYLVANIA LIFE INSUR	\$ 660.06
117	S5715	HCSC INSURANCE SERVICES	\$ 4,054.85
118	S5726	BLUE CROSS BLUE SHIELD	\$ 477.62
119	S5743	BLUE CROSS BLUE SHIELD	\$ 1,569.84
120	S5753	WISCONSIN PHYSICIAN SER	\$ 1,064.97
121	S5755	UNITED AMERICAN INSURAN	\$ 1,701.74
122	S5766	FIRST CARE INC.	\$ 1,083.44
123	S5768	FIRST HEALTH LIFE & HEA	\$ 9,187.46
124	S5795	ARKANSAS BCBS A MUTUAL	\$ 2,176.67
125	S5805	UNITED HEALTHCARE INSUR	\$ 22,749.57

126	S5810	AETNA LIFE INSURANCE CO	\$ 1,347.40
127	S5820	UNITED HEALTHCARE INSUR	\$ 34,887.64
128	S5825	AMERICAN PROGRESSIVE LI	\$ 0
129	S5884	HUMANA INSURANCE COMPAN	\$ 9,936.00
130	S5904	BLUE CROSS AND BLUE SHI	\$ 1,758.69
131	S5921	PACIFICARE LIFE AND HEA	\$ 8,494.57
132	S5937	LOUISIANA HEALTH SERVIC	\$ 538.63
133	S5953	BLUE CROSS AND BLUE SHI	\$ 544.18
134	S5966	GROUP HEALTH INCORPORAT	\$ 2,365.03
135	S5967	WELLCARE PRESCRIPTION I	\$ 2,399.71
136	S5975	ODS HEALTH PLAN	\$ 2,624.94
137	S5983	MEDCO HEALTH SOLUTIONS	\$ 538.63
138	S5993	HORIZON HEALTHCARE SERV	\$ 983.96
139	S7694	ENVISION INSURANCE COMP	\$ 2,254.63
140	S7950	EXPRESS SCRIPTS INSURAN	\$ 45,860.55
141	S8067	AVALON HEALTH LTD	\$ 533.30
142	S8841	NMHC GROUP SOLUTION INS	\$ 510.26
143	S9579	STONEBRIDGE LIFE INSURA	\$ 3,813.16
			\$ 462,249.16