

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 (cgiroux@akrimax.com; arubino@akrimax.com)

Akrimax Pharmaceuticals, LLC
Ms. Carrie Giroux, Contr & Gov. Pricing Administrator
11 Commerce Drive, First Fl
Cranford, NJ 07016

**RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer
Contract Number P1151**

Dear Ms. Carrie Giroux:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Akrimax Pharmaceuticals, LLC that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$31,350.06.

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 \$31,350.06 to Akrimax Pharmaceuticals, LLC 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:

- 117 Part D Sponsors \$125,400.23 (Breakdown on Attachment 2)

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The CMP that your company owes is equal to:

- 25% on the amount paid late, \$31,350.06

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 Akrimax 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: 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

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

Sincerely,

/s/

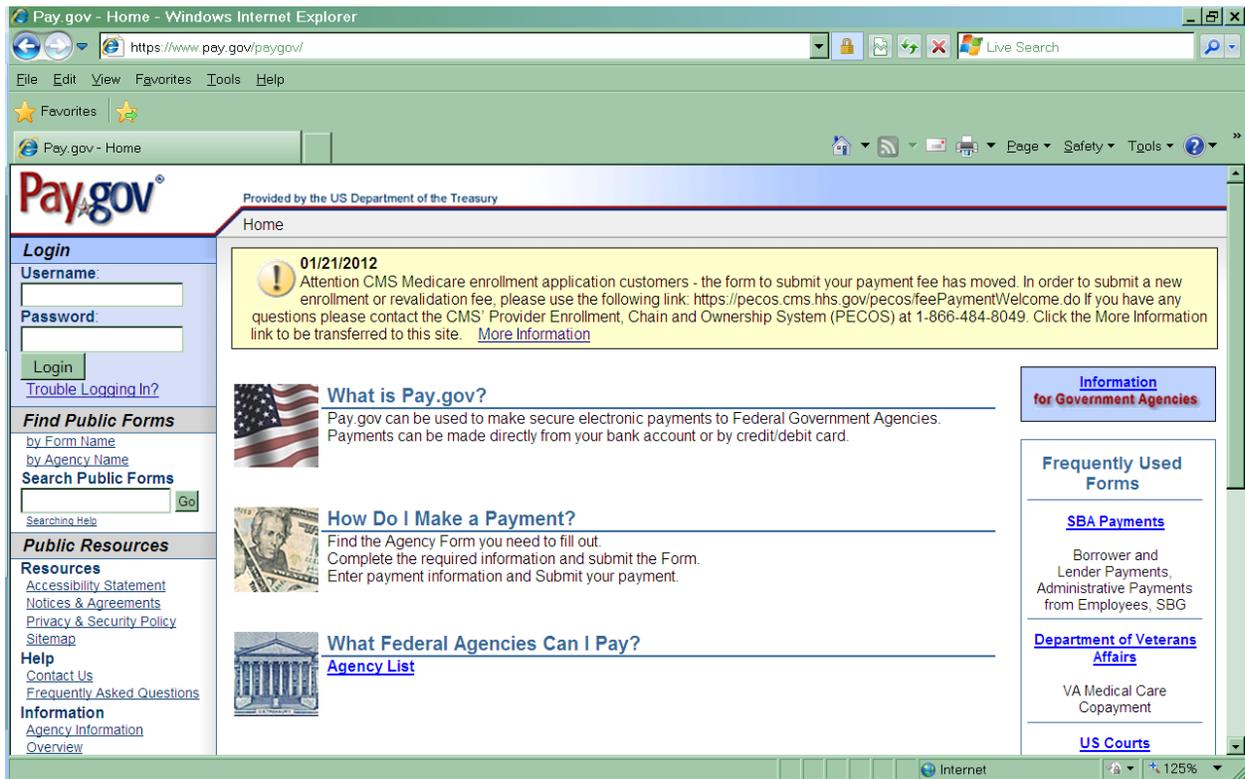
Amy K. Larrick
Acting Director, Medicare Drug Benefit and C & D Data Group

cc: Ms. Cheri Rice, CMS/CM/MPPG
Mr. John Scott, CMS/CM/MPPG
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 <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" and it returned 3 results. The results are listed in a table with columns for Form Name, Form Number, OMB Number, and Agency 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.

Form Name	Form Number	OMB Number	Agency Name
CMS Data Payment Form	CMS Data Payment		Department of Health and Human Services
CMS Medicare Application Fee	Medicare-app-fee-1		Department of Health and Human Services
Medicare Coverage Gap Discount Program CMPs	Medicare CGDP CMPs		Department of Health and Human Services

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 titled "Pay.gov - Form Instance - Windows Internet Explorer". The address bar shows the URL: <https://www.pay.gov/paygov/forms/forminstance.html?nc=1330705111240&agencyFormId=38616929&userForm>. The browser's address bar also shows "Live Search". The browser's menu bar includes "File", "Edit", "View", "Favorites", "Tools", and "Help". The browser's status bar shows "Done" and "Internet".

The main content area displays the "Medicare Coverage Gap Discount Program" form. The form is titled "Civil Money Penalty Payment" and includes the following fields:

- *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: \$

At the bottom of the form, there are two buttons: "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.

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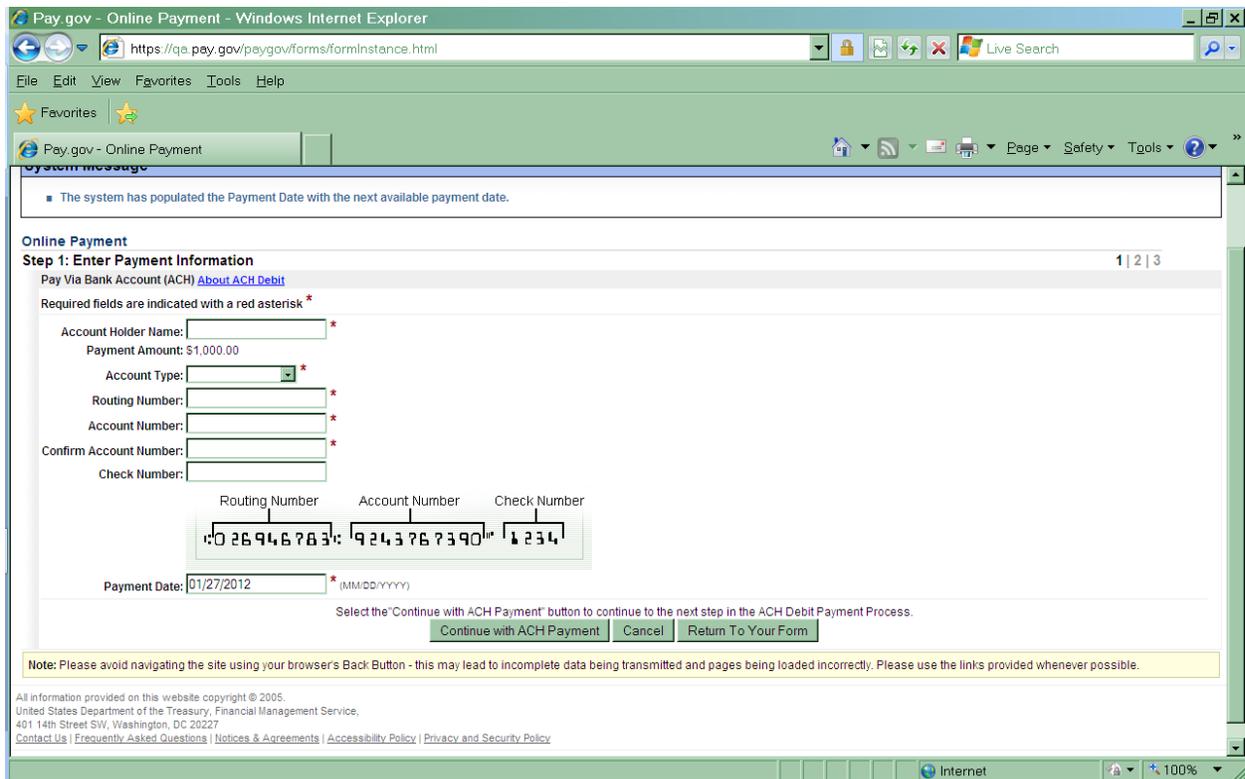
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Step 4

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 a web browser window titled "Pay.gov - Online Payment - Windows Internet Explorer". The address bar shows the URL: <https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html>. The page content is titled "Step 2: Authorize Payment" and includes a "Payment Summary" section with the following details:

- 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

Below the summary is an "Email Confirmation Receipt" section with input fields for "Email Address:", "Confirm Email Address:", and "CC:". A note indicates to "Separate multiple email addresses with a comma".

The "Authorization and Disclosure" section contains a checkbox for "I agree to the authorization and disclosure language." which is checked. Below this is a scrollable area with 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.

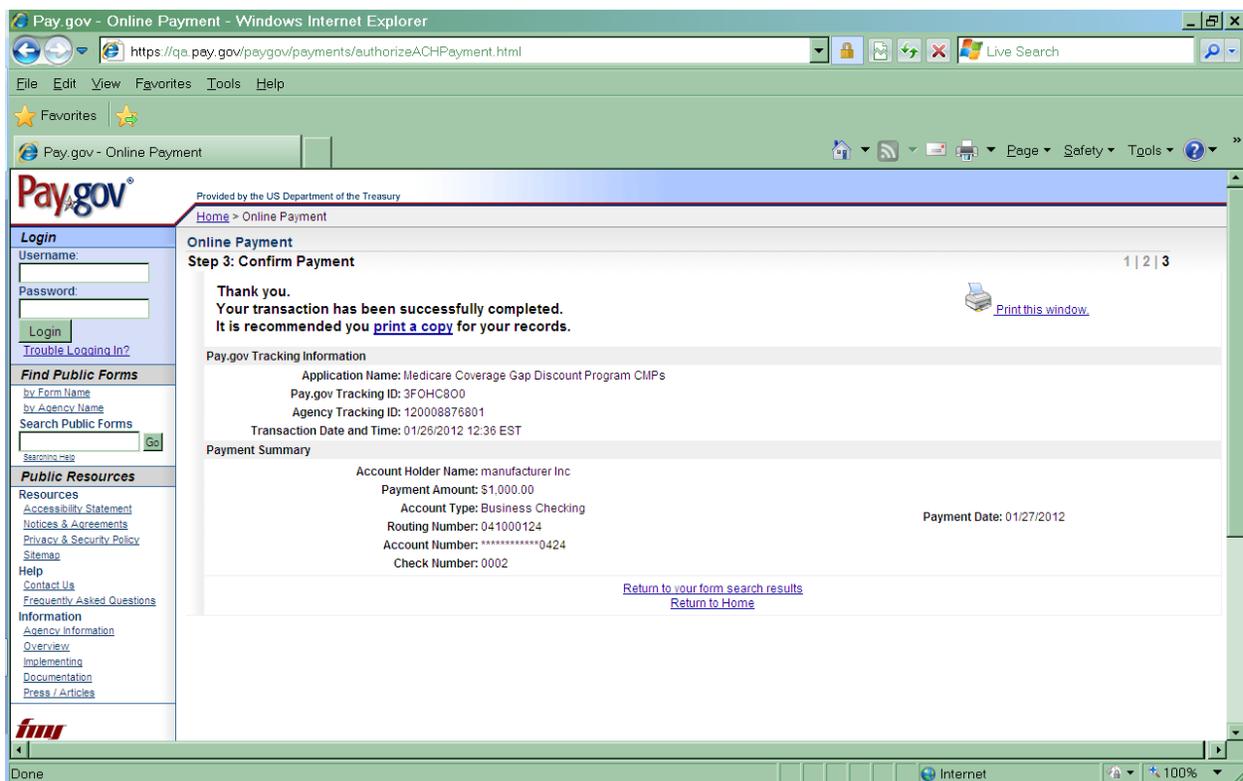
- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdg_manufacturers@cms.hhs.gov
- Read and/or print the Authorization and Disclosure. If you agree, Click, *I agree to the authorization and disclosure language*

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.



Attachment 2

	Contract Number	Contract Name	Invoiced Amount
1	E3014	PSERS HOP PROGRAM	\$ 260.16
2	E7848	OKLAHOMA STATE AND EDUC	\$ 1,249.87
3	H0154	VIVA HEALTH INC.	\$ 62.28
4	H0303	PACIFICARE OF ARIZONA	\$ 835.72
5	H0332	KS PLAN ADMINISTRATORS,	\$ 854.92
6	H0354	CIGNA HEALTHCARE OF ARI	\$ 16.69
7	H0504	CA PHYSICIANS SERV/DBA	\$ 35.87
8	H0524	KAISER FOUNDATION HP I	\$ 197.66
9	H0543	PACIFICARE OF CALIFORNI	\$ 788.96
10	H0544	CALIFORNIA HEALTH PLAN	\$ 85.00
11	H0562	HEALTH NET_OF CA	\$ 271.21
12	H0564	BLUE CROSS OF CALIFORNI	\$ 169.39
13	H0609	PACIFICARE OF COLORADO	\$ 683.70
14	H0630	KAISER FOUNDATION HP OF	\$ 62.72
15	H0755	HEALTH NET OF CONNECTIC	\$ 93.72
16	H1013	VISTA HEALTH PLAN OF SO	\$ 29.18
17	H1016	AVMED INC	\$ 36.54
18	H1036	HUMANA MEDICAL PLAN IN	\$ 138.95
19	H1080	UNITED HEALTHCARE OF FL	\$ 31.24
20	H1509	UNITED HEALTHCARE INSUR	\$ 1,496.79
21	H1666	HCSC INSURANCE SERVICES	\$ 29.89
22	H1951	HUMANA HEALTH BENEFIT P	\$ 178.00
23	H1994	SELECTHEALTH, INC.	\$ 171.84
24	H2150	KAISER FNDN HP OF THE M	\$ 217.35
25	H2425	BLUE PLUS	\$ 413.36
26	H2450	MEDICA INSURANCE COMPAN	\$ 359.07
27	H2459	UCARE MINNESOTA	\$ 157.39
28	H2462	HEALTHPARTNERS	\$ 471.84
29	H2663	GROUP HEALTH PLAN INC.	\$ 31.81
30	H2810	GROUP HEALTH OPTIONS	\$ 258.01
31	H3107	OXFORD HEALTH PLANS (NJ	\$ 31.24
32	H3154	HORIZON HEALTHCARE OF N	\$ 180.93
33	H3330	HIP HEALTH PLAN OF NY	\$ 177.37
34	H3342	EMPIRE HEALTHCHOICE ASS	\$ 30.10

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35	H3404	PARTNERS NATIONAL HEALT	\$ 131.35
36	H3449	PARTNERS NATIONAL HEALT	\$ 205.92
37	H3528	CONNECTICARE, INC.	\$ 23.55
38	H3619	HUMANA INSURANCE COMPAN	\$ 177.86
39	H3653	PARAMOUNT CARE INC	\$ 81.69
40	H3660	SUMMACARE INC.	\$ 490.12
41	H3668	MT. CARMEL HEALTH PLAN	\$ 322.11
42	H3755	COMMUNITY CARE HMO INC	\$ 206.71
43	H3812	UNITED HEALTHCARE INSUR	\$ 57.50
44	H3907	UNIVERSITY OF PITTSBURG	\$ 105.41
45	H3909	INDEPENDENCE BLUE CROSS	\$ 55.95
46	H3916	HIGHMARK INC.	\$ 216.57
47	H3931	AETNA HEALTH INC	\$ 146.28
48	H3952	KEYSTONE HEALTH PLAN EA	\$ 277.20
49	H3957	KEYSTONE HEALTH PLAN WE	\$ 499.24
50	H3959	HEALTHAMERICA PENNSYLVA	\$ 18.76
51	H3962	KEYSTONE HEALTH PLAN CE	\$ 141.44
52	H4003	MMM HEALTHCARE INC.	\$ 180.88
53	H4141	HUMANA EMPLOYERS HEALTH	\$ 72.80
54	H4454	HEALTHSPRING INC.	\$ 198.66
55	H4506	SELECTCARE OF TEXAS	\$ 22.50
56	H4514	EVERCARE OF TEXAS LLC	\$ 64.75
57	H4523	AETNA HEALTH INC.	\$ 31.65
58	H4590	PACIFICARE OF TEXAS IN	\$ 681.39
59	H5211	SECURITY HEALTH PLAN OF	\$ 237.07
60	H5425	SCAN HEALTH PLAN	\$ 384.39
61	H5509	COVENTRY HEALTH AND LIF	\$ 29.18
62	H5520	HEALTH NET LIFE INSURAN	\$ 357.29
63	H5521	AETNA LIFE INSURANCE CO	\$ 140.91
64	H5522	HEALTH ASSURANCE PENNSY	\$ 123.01
65	H5533	UPMC HEALTH NETWORK	\$ 19.38
66	H6328	CARE N' CARE INSURANCE	\$ 29.01
67	H6360	KAISER FOUNDATION HP OF	\$ 171.88
68	H6609	HUMANA INSURANCE COMPAN	\$ 1,763.47
69	H7220	CLARIAN HEALTH PLANS, I	\$ 120.21
70	H8145	HUMANA INSURANCE COMPAN	\$ 58.90
71	H8552	ANTHEM BLUE CROSS LIFE	\$ 2.50
72	H9001	FALLON COMMUNITY HEALTH	\$ 45.00
73	H9047	PROVIDENCE HEALTH PLAN	\$ 29.54
74	H9572	BLUE CROSS BLUE SHIELD	\$ 235.36
75	H9615	MVP HEALTH PLAN, INC.	\$ 65.84
76	H9847	COVENTRY HEALTH AND LIF	\$ 242.47

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77	H9859	MVP HEALTH PLAN, INC,	\$ 101.30
78	H9947	BLUE CROSS BLUE SHIELD	\$ 278.91
79	R5287	UNITED HEALTHCARE INSUR	\$ 73.16
80	R5826	HUMANA INSURANCE COMPAN	\$ 535.84
81	S0064	UNITED PROSPERITY LIFE	\$ 114.68
82	S1030	BCBS OF ALABAMA AND BCB	\$ 538.78
83	S2321	QCC INS CO D/B/A AMERIH	\$ 59.07
84	S2468	CA PHYSICIANS SERVICE	\$ 353.44
85	S2893	BLUE CROSS BLUE SHIELD	\$ 8.68
86	S3521	EXCELLUS HEALTH PLAN I	\$ 1,007.64
87	S4802	STERLING LIFE INSURANCE	\$ 1,387.95
88	S5540	BLUE CROSS AND BLUE SHI	\$ 367.15
89	S5569	CAMBRIDGE LIFE INSURANC	\$ 26.57
90	S5580	UNITED AMERICAN INSURAN	\$ 488.26
91	S5593	HIGHMARK SENIOR RESOURC	\$ 463.61
92	S5596	ANTHEM INSURANCE COMPAN	\$ 546.00
93	S5601	SILVERSCRIPT INSURANCE	\$ 15,899.36
94	S5609	ASURIS NORTHWEST HEALTH	\$ 401.86
95	S5617	CONNECTICUT GENERAL LIF	\$ 1,098.65
96	S5660	MEDCO HEALTH SOLUTIONS	\$ 28,819.78
97	S5670	COVENTRY HEALTH AND LIF	\$ 32.08
98	S5674	FIRST HEALTH LIFE AND H	\$ 173.77
99	S5715	HCSC INSURANCE SERVICES	\$ 936.56
100	S5726	BLUE CROSS BLUE SHIELD	\$ 32.17
101	S5743	BLUE CROSS BLUE SHIELD	\$ 1,824.03
102	S5755	UNITED AMERICAN INSURAN	\$ 241.49
103	S5766	FIRST CARE INC.	\$ 85.70
104	S5768	FIRST HEALTH LIFE & HEA	\$ 2,541.84
105	S5795	ARKANSAS BCBS A MUTUAL	\$ 1,045.67
106	S5805	UNITED HEALTHCARE INSUR	\$ 3,803.79
107	S5810	AETNA LIFE INSURANCE CO	\$ 662.68
108	S5820	UNITED HEALTHCARE INSUR	\$ 10,634.89
109	S5884	HUMANA INSURANCE COMPAN	\$ 398.29
110	S5904	BLUE CROSS AND BLUE SHI	\$ 62.42
111	S5921	PACIFICARE LIFE AND HEA	\$ 19,110.14
112	S5966	GROUP HEALTH INCORPORAT	\$ 379.60
113	S5975	ODS HEALTH PLAN	\$ 338.58
114	S7694	ENVISION INSURANCE COMP	\$ 136.20
115	S7950	EXPRESS SCRIPTS INSURAN	\$ 9,693.26
116	S8841	NMHC GROUP SOLUTION INS	\$ 1,416.46
117	S9579	STONEBRIDGE LIFE INSURA	\$ 706.05

\$125,400.83

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