

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

June 9, 2016

VIA

EMAIL: Fpetranich@Heritagepharma.com; hhuang@heritagepharma.com

Heritage Pharmaceuticals Inc.
Frank Petranich
105 Fieldcrest Ave Suite 100
Edison, NJ 08837

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1249

Dear Mr. Frank Petranich:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Heritage Pharmaceuticals Inc. that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$36,610.76.

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 \$36,610.76 to Heritage Pharmaceuticals Inc. due to untimely payments for the 2015 fourth quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

- 96 Part D Sponsors \$146,443.03 (Breakdown on Attachment 1)

The CMP that your company owes is equal to:

- The 25% penalty, \$36,610.76

The determination by CMS to impose a CMP will become final and due no later than August 7, 2016 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 Heritage Pharmaceuticals 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 August 7, 2016. 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:

Nancy K. Rubenstein
Director, Civil Remedies Division
Departmental Appeals Board
U.S. Department of Health & Human Services
330 Independence Avenue, SW
Cohen Building, Room G-644
Washington, DC. 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 2 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
Director, Medicare Drug Benefit and C & D Data Group

cc: Ms. Cheri Rice, CMS/CM/MPPG
Ms. Amanda Johnson, CMS/CM/MPPG
Ms. Whitney Hubbard, CMS/OL
Mr. Aaron Albright, CMS/OC
Mr. Ray Thorn, CMS/OC
Ms. Jill Abrams, DHHS/OGC
Ms. Jennifer Garver, DHHS/OGC
Ms. Nancy Rubenstein, DHHS/DAB

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Attachment 1

	Contract Number	Contract Name	Line Item Invoice Amount
1	H5211	Security Health Plan of Wisconsin,	10.03
2	H5215	Network Health Insurance Corp	373.40
3	H5253	UnitedHealth Group	34.01
4	H5414	Aetna Health Management	3.12
5	H5425	SCAN Health Plan	48.13
6	H5435	UnitedHealth Group	302.07
7	H5509	Coventry Health Care, Inc	11.14
8	H5520	Health Net Inc.	70.32
9	H5521	Aetna Health Management	308.56
10	H5522	Coventry Health Care, Inc	128.98
11	H5525	Humana Inc.	2,133.65
12	H5526	HealthNow NY Inc	157.34
13	H5529	Anthem, Inc.	36.57
14	H5591	Martin's Point Generations, LLC	226.75
15	H5609	Gemcare Health Plan	190.74
16	H5749	UnitedHealth Group	1.00
17	H5774	Triple S Managment	277.81
18	H5793	Aetna Health Management	292.92
19	H5850	Coventry Health Care, Inc	4.92
20	H5883	Blue Care Network	33.30
21	H5928	Care1st Health Plan	2.50
22	H5938	Capital Health Plan	211.64
23	H6528	UnitedHealth Group	89.43
24	H6609	Humana Inc.	5,978.21
25	H7220	Indiana University Health Plans,Inc	70.63
26	H7301	Coventry Health Care, Inc	16.53
27	H7306	Coventry Health Care, Inc	11.47
28	H7917	Blue Cross Blue Shield of Tennessee	12.74
29	H8145	Humana Inc.	1,208.92
30	H8393	Coventry Health Care, Inc	6.10
31	H8552	Anthem, Inc.	50.63
32	H8554	Advantage Health Care Management Co	81.72
33	H8649	Coventry Health Care, Inc	28.59
34	H9047	Providence Health Plan	129.60
35	H9385	SCAN Health Plan	2.34

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36	H9572	Blue Cross Blue Shield of Michigan	924.90
37	H9615	MVP Health Care	235.65
38	H9847	Coventry Health Care, Inc	3.25
39	H9859	MVP Health Care	20.63
40	H9947	Anthem, Inc.	41.25
41	R3332	Blue Cross & Blue Shield of Florida	82.63
42	R3444	UnitedHealth Group	4.68
43	R5287	UnitedHealth Group	392.11
44	R5342	UnitedHealth Group	135.43
45	R5826	Humana Inc.	704.74
46	R5941	Anthem, Inc.	207.53
47	R6801	UnitedHealth Group	52.80
48	R7439	Hawaii Medical Service Association/Withdrawn 2015	86.89
49	R9896	UnitedHealth Group	157.75
50	S0064	Express Scripts	94.75
51	S0655	Tufts Health Plan	165.89
52	S1030	BlueCross BlueShield of Alabama	688.41
53	S1822	HealthPartners, Inc.	8.06
54	S2468	Blue Shield of California	2,095.64
55	S2505	WellCare Windsor/Sterling	359.77
56	S2893	NE Joint Venture / Blue Medicare Rx	382.97
57	S3474	Heartland Fidelity Insurance	74.18
58	S3521	Excellus BlueCross BlueShield	119.80
59	S3875	Granite Alliance Insurance Company	661.93
60	S4501	Independent Health	4.50
61	S4802	WellCare Windsor/Sterling	320.83
62	S5540	Blue Cross and Blue Shield of NC	244.90
63	S5552	Humana Inc.	241.45
64	S5569	Coventry Health Care, Inc	360.19
65	S5584	Blue Cross Blue Shield of Michigan	29.98
66	S5593	Highmark Inc	318.49
67	S5596	Anthem, Inc.	964.72
68	S5601	CVS Health	32,237.57
69	S5617	CIGNA	4,351.92
70	S5660	Express Scripts	27,304.41
71	S5670	Coventry Health Care, Inc.	56.89
72	S5674	Coventry Health Care, Inc	96.83
73	S5715	Health Care Service Corporation	2,078.78
74	S5726	Anthem, Inc.	50.91
75	S5743	ClearStone Solutions	665.04
76	S5753	WPS Insurance Corporation	90.10
77	S5755	United American	997.15

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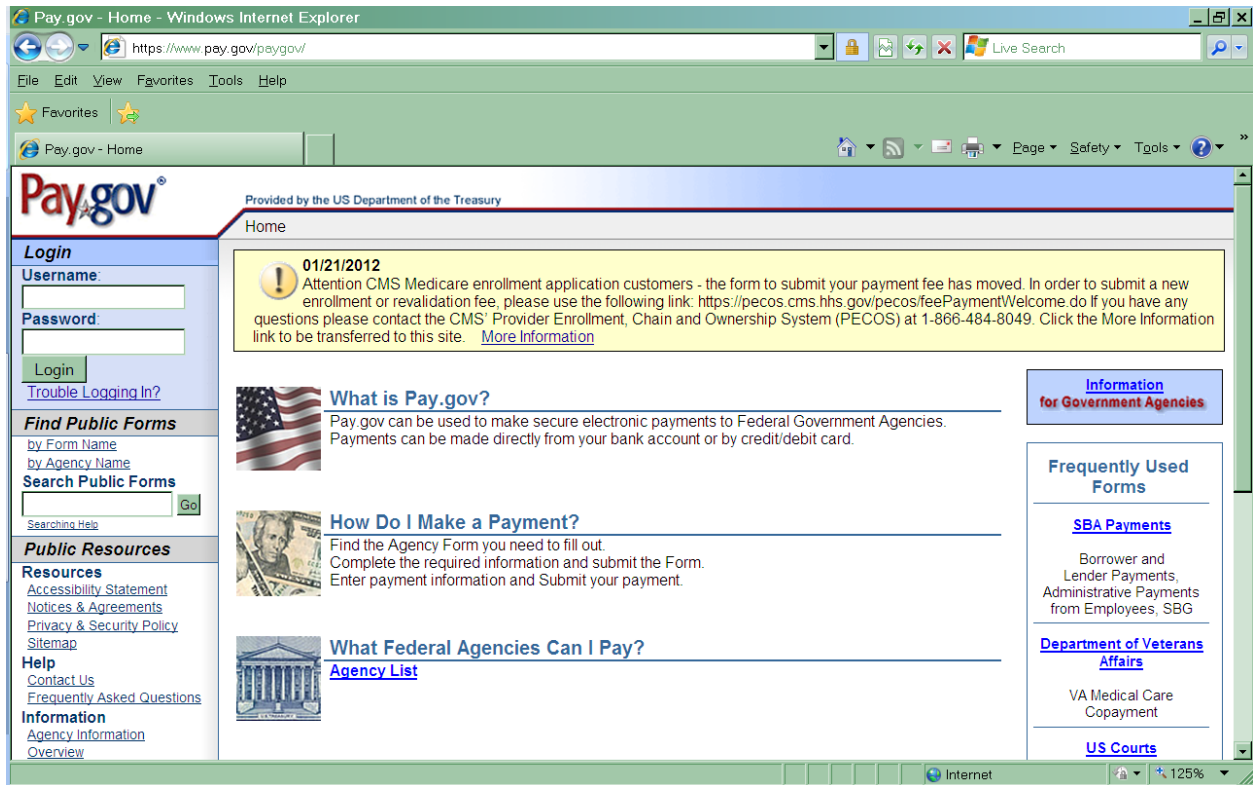
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78	S5768	Coventry Health Care, Inc	2,050.63
79	S5795	Arkansas Blue Cross Blue Shield	213.13
80	S5805	UnitedHealth Group	2,230.96
81	S5810	Aetna Health Management	351.00
82	S5820	UnitedHealth Group	14,312.86
83	S5884	Humana Inc.	11,184.57
84	S5904	Blue Cross & Blue Shield of Florida	198.45
85	S5921	UnitedHealth Group	3,278.13
86	S5960	Anthem, Inc.	379.72
87	S5966	EmblemHealth	113.40
88	S5967	WellCare Health Plans	1,556.43
89	S5975	Moda Health Plan, Inc.	187.43
90	S5983	Express Scripts	77.49
91	S6875	Independence Blue Cross	1.71
92	S7950	Express Scripts	8,303.15
93	S8841	SXC Health Solutions	3,640.16
94	S9014	THE HEALTH PLAN/Withdrawn 2015	2.94
95	S9579	MedImpact Healthcare Systems, Inc.	6,400.19
96	S9701	Dean Health Plan	1,298.57
			\$146,443.03

Attachment 2

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 an Internet Explorer browser window with the URL <https://qa.pay.gov/paygov/payments/keywordSearchForms.html?keyword=medicare+Coverage+gap+discount&f>. The search results are for "medicare Coverage gap discount" and 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 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 of the browser displays a form titled "Medicare Coverage Gap Discount Program" with the subtitle "Civil Money Penalty Payment". The form 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".

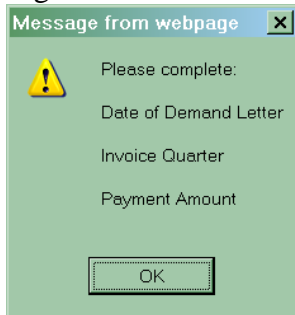
- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment
 - **Point of Contact Phone:** (***_**_*_****) telephone number must include dashes
 - **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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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.

Pay.gov - Online Payment - Windows Internet Explorer

https://qa.pay.gov/paygov/forms/formInstance.html

System message

The system has populated the Payment Date with the next available payment date.

Online Payment

Step 1: Enter Payment Information 1 | 2 | 3

Pay Via Bank Account (ACH) [About ACH Debit](#)

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

⑈026946783⑈ 9243767390⑈ 1234⑈

Payment Date: 01/27/2012 * (MM/DD/YYYY)

Select the "Continue with ACH Payment" button to continue to the next step in the ACH Debit Payment Process.

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.

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- 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.

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- 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.

