

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: joannb@amneal.com

Amneal Pharmaceuticals, LLC
JoAnn Bute
400 Crossing Blvd
3rd floor
Bridgewater, NJ 08807

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1287

Dear JoAnn Bute:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Amneal Pharmaceuticals, LLC that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$10,788.20.

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 \$10,788.20 to Amneal Pharmaceuticals, LLC due to untimely payments for the 2015 third quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

- 103 Part D Sponsors \$43,152.81 (Breakdown on Attachment 1)

The CMP that your company owes is equal to:

- The 25% penalty, \$10,788.20

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 Amneal 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 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

Attachment 1

	Contract Number	Contract Name	Line Item Invoiced Amount
1	E4744	MODOT, MSHP Medical and Life Insurance Plan	163.05
2	E7848	OMES-Employees Group Insurance Divi	60.53
3	H0104	BlueCross BlueShield of Alabama	106.53
4	H0303	UnitedHealth Group	79.72
5	H0332	KS Plan Administrators, LLC	3.64
6	H0351	Health Net Inc.	151.14
7	H0504	Blue Shield of California	33.32
8	H0524	Kaiser Permanente	4,849.83
9	H0543	UnitedHealth Group	41.54
10	H0562	Health Net Inc.	117.15
11	H0630	Kaiser Permanente	1,479.77
12	H0755	UnitedHealth Group	13.77
13	H1016	AvMed Health Plans	11.85
14	H1019	Humana Inc.	4.76
15	H1026	Blue Cross & Blue Shield of Florida	385.05
16	H1032	WellCare Health Plans	18.25
17	H1036	Humana Inc.	33.53
18	H1099	Health First Health Plans, Inc.	10.18
19	H1170	Kaiser Permanente	191.04
20	H1230	Kaiser Permanente	200.91
21	H1406	Humana Inc.	99.74
22	H1509	UnitedHealth Group	20.34
23	H1666	Health Care Service Corporation	143.80
24	H1849	Anthem, Inc.	9.38
25	H1951	Humana Inc.	160.44
26	H1961	Peoples Health	9.38
27	H2001	UnitedHealth Group	956.76
28	H2012	Humana Inc.	34.27
29	H2150	Kaiser Permanente	1,713.56
30	H2256	Tufts Health Plan	26.69
31	H2654	UnitedHealth Group	125.51
32	H2663	Coventry Health Care, Inc	256.44
33	H3351	Excellus BlueCross BlueShield	26.65
34	H3362	Independent Health	63.50
35	H3384	HealthNow NY Inc	20.34
36	H3449	Blue Cross and Blue Shield of NC	85.82

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37	H3655	Anthem, Inc.	12.15
38	H3668	Medigold	8.00
39	H3813	Moda Health Plan, Inc.	26.17
40	H3907	UPMC Health Plan, Inc.	149.55
41	H3916	Highmark Inc	163.29
42	H3931	Aetna Health Management	7.05
43	H3952	Independence Blue Cross	151.32
44	H3954	Geisinger Health Plan	4.80
45	H3957	Highmark Inc	16.03
46	H3959	Coventry Health Care, Inc	27.15
47	H3962	Capital BlueCross	13.50
48	H4152	Blue Cross Blue Shield of RI	17.50
49	H4454	Cigna-HealthSpring	18.00
50	H4461	Humana Inc.	17.85
51	H5415	Humana Inc.	199.89
52	H5420	UnitedHealth Group	40.25
53	H5434	Blue Cross & Blue Shield of Florida	3.00
54	H5520	Health Net Inc.	151.14
55	H5521	Aetna Health Management	195.27
56	H5526	HealthNow NY Inc	18.41
57	H5813	Aetna Health Management	160.50
58	H5883	Blue Care Network	5.80
59	H6609	Humana Inc.	166.85
60	H7917	Blue Cross Blue Shield of Tennessee	4.29
61	H9001	Fallon Health	18.85
62	H9572	Blue Cross Blue Shield of Michigan	60.88
63	R3332	Blue Cross & Blue Shield of Florida	292.03
64	R5287	UnitedHealth Group	62.61
65	R5826	Humana Inc.	44.23
66	R5941	Anthem, Inc.	55.44
67	S0064	Express Scripts	26.06
68	S0522	Symphonix Health Insurance	337.81
69	S0655	Tufts Health Plan	17.09
70	S1030	BlueCross BlueShield of Alabama	717.03
71	S2468	Blue Shield of California	263.62
72	S2893	NE Joint Venture / Blue Medicare Rx	65.98
73	S3389	UPMC Health Plan	25.42
74	S3474	Heartland Fidelity Insurance	18.00
75	S4802	WellCare Windsor/Sterling	10.86
76	S5540	Blue Cross and Blue Shield of NC	14.34
77	S5593	Highmark Inc	132.37
78	S5596	Anthem, Inc.	27.82
79	S5601	CVS Health	1,527.06

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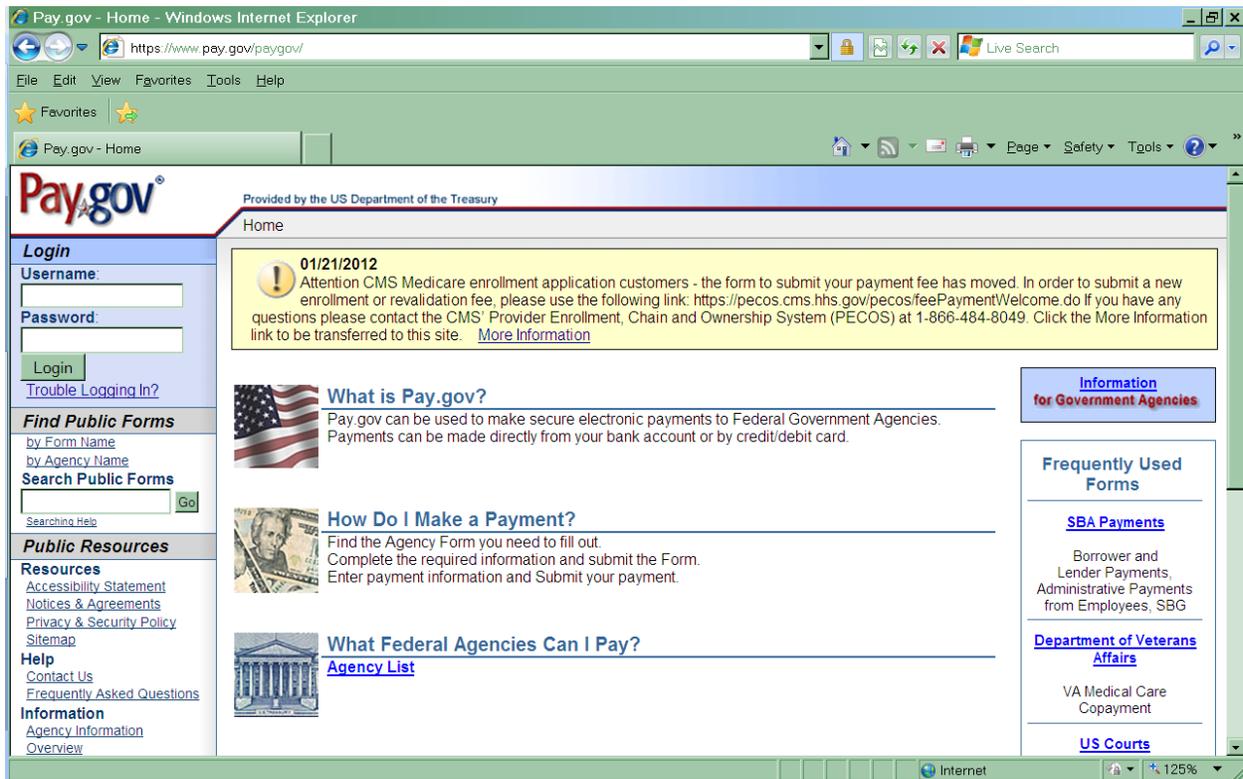
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80	S5617	CIGNA	324.86
81	S5660	Express Scripts	4,118.51
82	S5715	Health Care Service Corporation	2,469.95
83	S5743	ClearStone Solutions	235.60
84	S5755	United American	275.61
85	S5768	Coventry Health Care, Inc	252.15
86	S5805	UnitedHealth Group	176.08
87	S5810	Aetna Health Management	713.51
88	S5820	UnitedHealth Group	9,970.14
89	S5884	Humana Inc.	1,286.14
90	S5904	Blue Cross & Blue Shield of Florida	98.34
91	S5921	UnitedHealth Group	1,835.35
92	S5953	BlueCross BlueShield of SC	16.90
93	S5966	EmblemHealth	117.97
94	S5967	WellCare Health Plans	1,144.08
95	S5975	Moda Health Plan, Inc.	9.19
96	S5983	Express Scripts	20.34
97	S6875	Independence Blue Cross	4.83
98	S7694	Envision Insurance Company	202.70
99	S7950	Express Scripts	967.71
100	S8067	Capital BlueCross	26.49
101	S8841	SXC Health Solutions	1,004.28
102	S9579	MedImpact Healthcare Systems, Inc.	811.88
103	S9701	Dean Health Plan	66.76
			\$ 43,152.81

Attachment 2

Step 1

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



The screenshot shows the Pay.gov website in a Windows Internet Explorer browser window. The address bar displays <https://www.pay.gov/paygov/>. The page header includes the Pay.gov logo and the text "Provided by the US Department of the Treasury". The main content area features a yellow alert box dated 01/21/2012 regarding CMS Medicare enrollment application customers. Below the alert, there are three main sections: "What is Pay.gov?", "How Do I Make a Payment?", and "What Federal Agencies Can I Pay?". The left sidebar contains a "Login" section with fields for "Username:" and "Password:" and a "Login" button. Below the login section is a "Find Public Forms" section with a search box and a "Go" button. The bottom right sidebar lists "Frequently Used Forms" including "SBA Payments", "Department of Veterans Affairs", and "US Courts".

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 query is "medicare Coverage gap discount" and it 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 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".

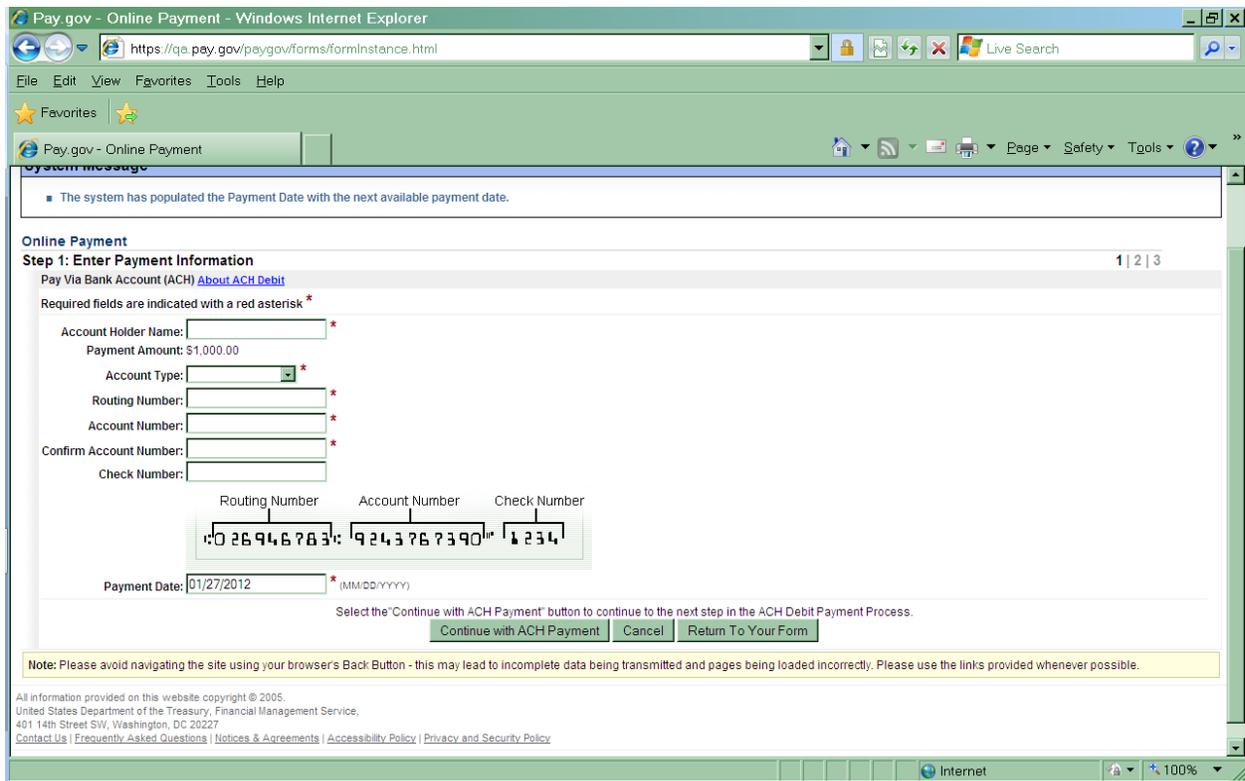
- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment
 - **Point of Contact Phone:** (***_**_****) telephone number must include dashes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



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.

Internet 100%

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- 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.

