

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 lisaneely@fsclabs.com; petersteelman@fsclabs.com

FSC Laboratories, Inc.
Lisa Neely, Director, Managed Markets
6000 Fairview Road, Suite 600
Charlotte, NC 28210

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1201

Dear Lisa Neely:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to FSC Laboratories, Inc. that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$19,483.12.

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 \$19,483.12 to FSC Laboratories, Inc. 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:

- 59 Part D Sponsors \$77,932.47 (Breakdown on Attachment 1)

The CMP that your company owes is equal to:

- The 25% penalty, \$19,483.12

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 FSC 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 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

Ms. Lisa Neely
June 9, 2016
Page 3 of 11

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	H0150	Cigna-HealthSpring	900.48
2	H0303	UnitedHealth Group	802.56
3	H0316	UnitedHealth Group	491.29
4	H0504	Blue Shield of California	704.09
5	H0524	Kaiser Permanente	3,977.09
6	H0543	UnitedHealth Group	564.23
7	H1026	Blue Cross & Blue Shield of Florida	1,012.12
8	H1032	WellCare Health Plans	69.39
9	H1415	Cigna-HealthSpring	2,004.02
10	H1716	Humana Inc.	383.42
11	H1961	Peoples Health	72.57
12	H2001	UnitedHealth Group	800.49
13	H2150	Kaiser Permanente	453.60
14	H3107	UnitedHealth Group	633.54
15	H3154	Horizon Healthcare Services, Inc	256.54
16	H3251	Health Care Service Corporation	407.40
17	H3307	UnitedHealth Group	1,939.43
18	H3327	Touchstone Health HMO	98.32
19	H3330	EmblemHealth	1,026.55
20	H3347	Elderplan	1,002.78
21	H3359	Healthfirst Management Services	116.72
22	H3907	UPMC Health Plan, Inc.	37.35
23	H3916	Highmark Inc	907.36
24	H3959	Coventry Health Care, Inc	228.80
25	H4003	InnovaCare Inc.	1,355.21
26	H4007	Humana Inc.	2,577.19
27	H4011	InnovaCare Inc	133.68
28	H4152	Blue Cross Blue Shield of RI	9.22
29	H4454	Cigna-HealthSpring	3,349.44
30	H5253	UnitedHealth Group	332.82
31	H5420	UnitedHealth Group	518.25
32	H5425	SCAN Health Plan	1,618.11
33	H5521	Aetna Health Management	1,224.00
34	H5774	Triple S Managment	4.63
35	H6609	Humana Inc.	247.32
36	H8634	Health Care Service Corporation	718.35
37	H9572	Blue Cross Blue Shield of Michigan	276.24
38	R5287	UnitedHealth Group	2,433.05

Ms. Lisa Neely

June 9, 2016

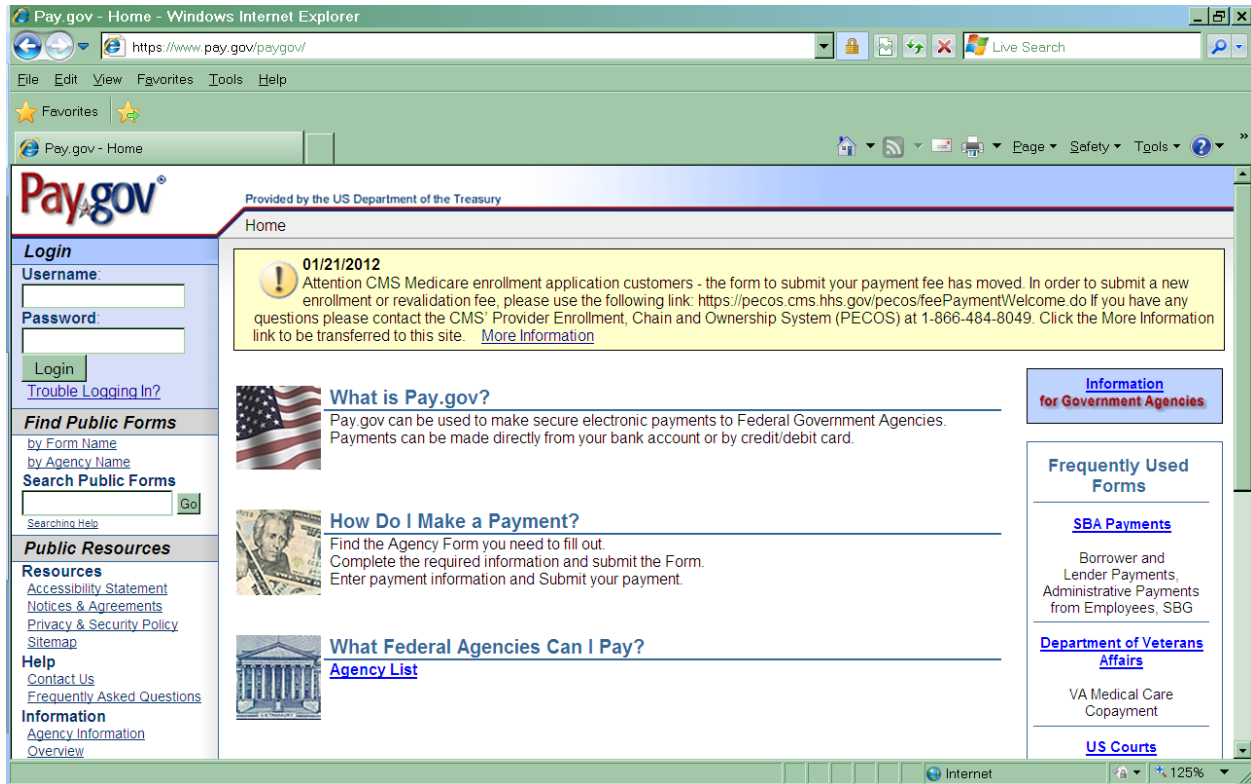
Page 5 of 11

39	R5342	UnitedHealth Group	802.00
40	S2893	NE Joint Venture / Blue Medicare Rx	1,129.70
41	S3474	Heartland Fidelity Insurance	683.54
42	S5540	Blue Cross and Blue Shield of NC	446.69
43	S5552	Humana Inc.	19.30
44	S5596	Anthem, Inc.	105.95
45	S5601	CVS Health	7,371.40
46	S5617	CIGNA	1,140.82
47	S5660	Express Scripts	18,137.68
48	S5715	Health Care Service Corporation	863.63
49	S5805	UnitedHealth Group	2,566.04
50	S5810	Aetna Health Management	691.09
51	S5820	UnitedHealth Group	2,730.89
52	S5884	Humana Inc.	595.37
53	S5904	Blue Cross & Blue Shield of Florida	456.96
54	S5921	UnitedHealth Group	450.52
55	S5966	EmblemHealth	640.27
56	S7230	Meridian Health Plan	461.80
57	S7950	Express Scripts	3,543.56
58	S8841	SXC Health Solutions	710.06
59	S9579	MedImpact Healthcare Systems, Inc.	697.55
			\$77,932.47

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

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 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".

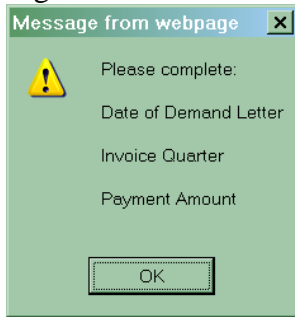
- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment
 - **Point of Contact Phone:** (***_**_****) telephone number must include dashes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

Ms. Lisa Neely

June 9, 2016

Page 9 of 11



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.

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.

All information provided on this website copyright © 2005.
United States Department of the Treasury, Financial Management Service,
401 14th Street SW, Washington, DC 20227
[Contact Us](#) | [Frequently Asked Questions](#) | [Notices & Agreements](#) | [Accessibility Policy](#) | [Privacy and Security Policy](#)

- 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.

