

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

September 12, 2013

VIA:

EMAIL (mmcgrane@columbialabs.com; lgyenes@columbialabs.com)

Columbia Laboratories, Inc
Mr. Michael McGrane
SVP & General Counsel
354 Eisenhower Parkway, Plaza 1, 2nd Floor
Livingston, NJ 07039

**RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer
Contract Number P1106**

Dear Mr. Michael McGrane:

Pursuant to 42 CFR §423.2335(d), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Columbia Laboratories, Inc. that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$58.69.

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 \$58.69 to Columbia Laboratories, Inc due to untimely payments for the 2013 first quarter invoices. Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

- H6609 Humana Insurance Co \$59.72
- S5884 Humana Insurance Co \$175.05

The CMP that your company owes is equal to:

- 25% on the amount paid late, \$58.69

The determination by CMS to impose a CMP will become final and due no later than November 11, 2013 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 Columbia 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 November 11, 2013. 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/

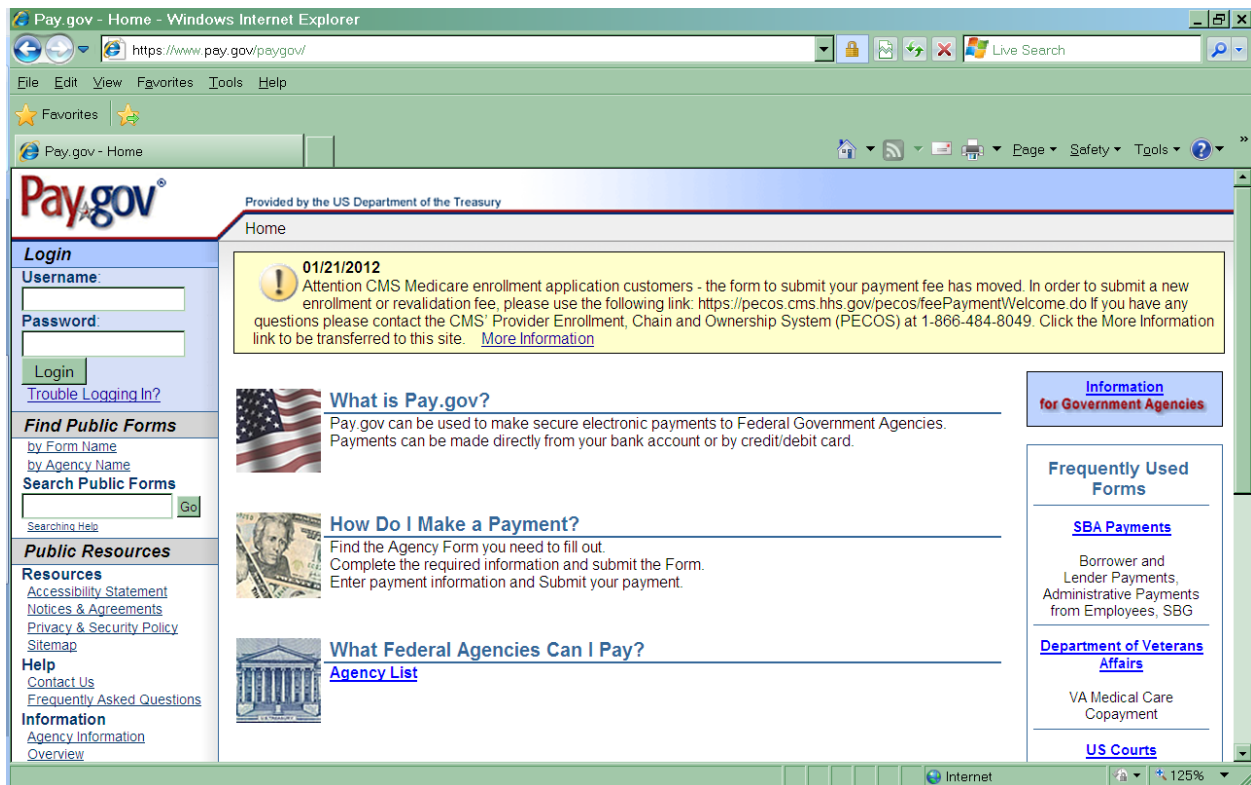
Cynthia G. Tudor, Ph.D.
Director, Medicare Drug Benefit and C & D Data Group

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 the Pay.gov search results for the keyword "medicare Coverage gap discount". The search returned 3 results. The left sidebar contains navigation links for "Find Public Forms", "Search Public Forms", "Public Resources", "Resources", "Help", and "Information". The main content area lists three results:

- CMS Data Payment Form** (Form Number: CMS Data Payment) with a "View PDF" link.
- CMS Medicare Application Fee** (Form Number: Medicare-app-fee-1) with a "View PDF" link.
- Medicare Coverage Gap Discount Program CMPs** (Form Number: Medicare CGDP CMPs) with a "View PDF" link.

The bottom of the page shows the "Internet" status bar and a zoom level of 125%.

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 displays the URL: <https://www.pay.gov/paygov/forms/forminstance.html?nc=1330705111240&agencyFormId=386169298&userFormId=...>. The browser's address bar shows "Pay.gov - Form Instance". A security warning is visible: "This website wants to run the following add-on: 'Microsoft Vector Graphics Rendering(VML)' from 'Microsoft Corporation'. If you trust the website and the add-on and want to allow it to run, click here...".

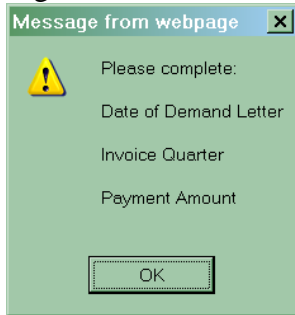
The main content area displays the "Medicare Coverage Gap Discount Program" form. The form is titled "Civil Money Penalty Payment" and includes the following fields:

- *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: \$
(Note: This must be the total amount due)

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.

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

00 25 94 6 7 8 3 :: 9 2 4 3 7 6 7 3 9 0 | 1 2 3 4

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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United States Department of the Treasury, Financial Management Service,
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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.

- Enter email address(es) to receive the payment confirmation
- Please add to the CC box: cgdp_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.

The screenshot shows a web browser window titled "Pay.gov - Online Payment - Windows Internet Explorer". The address bar displays the URL: <https://qa.pay.gov/paygov/payments/authorizeACHPayment.html>. The page content includes a "Pay.gov" logo, a navigation menu, and a confirmation message: "Thank you. Your transaction has been successfully completed. It is recommended you print a copy for your records." Below this, there is a "Pay.gov Tracking Information" section with the following details: Application Name: Medicare Coverage Gap Discount Program CMPs; Pay.gov Tracking ID: 3FOHC800; Agency Tracking ID: 120008876801; Transaction Date and Time: 01/26/2012 12:36 EST. A "Payment Summary" section lists: 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. The page also features a "Print this window" button and links for "Return to your form search results" and "Return to Home".