DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C1-26-16 Baltimore, Maryland 21244-1850

Center for Medicare



February 15, 2018

VIA EMAIL: daddis@medimetriks.com; bglassman@medimetriks.com; <u>blenczycki@medimetriks.com</u>; agoldstein@medimetriks.com

Medimetriks Pharmaceuticals 364 Route 46 West Fairfield, NJ 07004

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1037

Dear Medimetriks Pharmaceuticals:

Pursuant to 42 CFR §423.2340 the Centers for Medicare & Medicaid Services (CMS) is providing notice to Medimetriks Pharmaceuticals of a civil money penalty (CMP) assessment in the amount of \$790.76.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$790.76 on Medimetriks Pharmaceuticals, P1037, based on a report provided by the Third Party Administrator (TPA) for the Coverage Gap Discount Program. The information which the TPA provided indicates that your organization failed to pay specified Part D sponsors for applicable discounts within 38 calendar days from receipt of the third quarter 2017 invoice. This is a violation of 42 CFR §423.2315(b)(3) and Section II(b) of the Medicare Coverage Gap Discount Program Agreement (Discount Agreement).

Specifically, the following Part D sponsors did not receive payments within the requisite 38-day time period:

•	6 Part D Sponsors: \$3,163.02								
	0	H2001	UnitedHealth Group Inc	\$660.06					
	0	H5434	Blue Cross and Blue Shield of FL - Health Options	\$247.58					
	0	H5521	Aetna Health Management	\$104.01					
	0	S5601	CVS Health	\$933.63					
	0	S5660	Medco Containment Life Insurance Company	\$1,105.62					
	0	S5810	Aetna Health Management	\$112.12					

The CMP that your company owes is equal to:

• The 25% late payment penalty; \$790.76

Mr. David Addis February 15, 2018 Page 2 of 11

The determination by CMS to impose a CMP will become final and due no later than April 16, 2018 if you do not request a hearing to appeal in the manner and timeframe described below under Right to Request a Hearing. Please see the required payment method below under Method to Submit CMP Payments.

Please note that any further failures by Medimetriks Pharmaceuticals 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.

Method to Submit CMP Payments

All CMP payments must be made using Pay.gov (Instructions on Attachment 1). Pay.gov provides a free service to entities that make online payments to a Federal government agency. The Pay.gov Collection Service collects and processes the Internet-authorized 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.

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

Right to Request a Hearing

Your organization may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board (DAB) to appeal CMS' determination to impose a civil money penalty in accordance with Section IV(b) of the Discount Agreement. Procedures governing this process are set out in 42 C.F.R. § 423.2340.

You must:

Mr. David Addis February 15, 2018 Page 3 of 11

- file your hearing request electronically by using the Departmental Appeals Board's Electronic Filing System (DAB E-File) at https://dab.efile.hhs.gov no later than sixty (60) days after receiving this letter (Instructions on Attachment 2); and
- mail a copy of your hearing request to CMS:

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

Acknowledgement of this letter is required, please reply to <u>CGDPandManufacturers@cms.hhs.gov</u>. If you have any questions about this notice, please contact Sonia Eaddy at <u>Sonia.eaddy@cms.hhs.gov</u>.

Sincerely,

/s/

Amy K. Larrick Chavez-Valdez Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG Ms. Amanda Johnson, CMS/CM/MPPG Ms. Whitney Hubbard, CMS/OL Mr. Ray Thorn, CMS/OC Ms. Jill Abrams, DHHS/OGC Ms. Jennifer Garver, DHHS/OGC Mr. David Addis February 15, 2018 Page 4 of 11

Attachment 1

<u>Step 1</u>

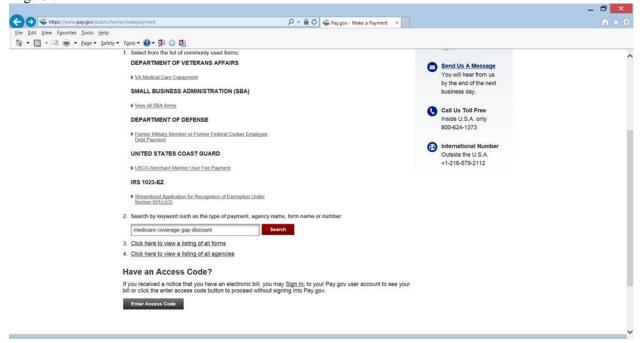
Access Pay.gov at <u>https://www.pay.gov</u>

				- 8 <mark>- ×</mark>
🕒 🕘 🧠 https://www.pay.gov/pu	ublic/home	🔎 = 🔒 🖒 📿 Pay.gov - Home	×	♠★♥
Elle Edit View Favorites Tools E				
📴 • 🖾 • 📼 👼 • Eade •	Safety 🕶 Tools 🕶 😰 💿 🕵			
	Pay,gov		Sign In Create an Accou	nt
	101000			
	Find Forms, Agencies	Search MAKE A PAYMENT	FIND AN AGENCY ONLINE HELP	
			11/10	
	Welcome to Pay.gov			
	Pay.gov is the convenient and fast way to make se	ecure electronic		
	payments to Federal Government Agencies. Many payment are accepted, including credit cards, deb			
	Click on a link below or use the search box above	to get started.		
	MAKE A DAVMENT			
	MAKE A PAYMENT			
	I NEED TO PAY	COM	MON PAYMENTS	
	Select one of the options below to see a list of forms and a	mencies that fall Pay one or	ocesses payments for hundreds of Federal government agencies	-
	into that category.	the most co	mmon of which are listed below.	
	LOAN PAYMENT	DEPART	MENT OF VETERANS AFFAIRS	
	MEDICAL EXPENSE		al Care Copayment	
	* FINE, VIOLATION, OR PENALTY	SMALL F	SUSINESS ADMINISTRATION (SBA)	
	* FOIA REQUEST	View all S		
				~

Step 2

- In the **Search by keyword...** box (under number 2), Type: *Medicare Coverage Gap Discount (not case sensitive)*
- then click on Search

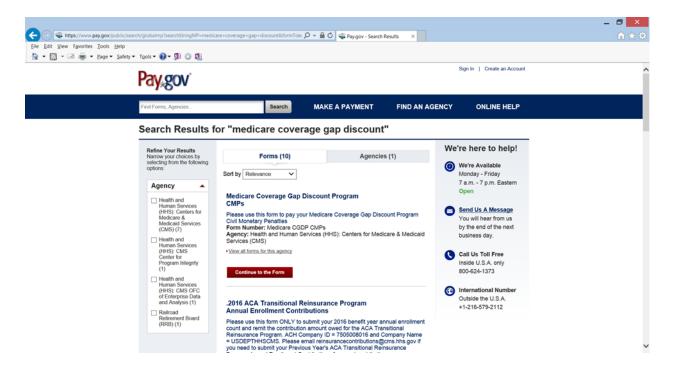
Mr. David Addis February 15, 2018 Page 5 of 11



Step 3

Medicare Coverage Gap Discount Program CMPs

• Click on **Continue to the Form**.



Mr. David Addis February 15, 2018 Page 6 of 11

<u>Step 4</u>

- You may Preview Form, cancel, or Continue to Form.
- Click on Continue to the Form. Have available your payment demand letter from CMS.

			_ 🗖 🗡
	form/start/38616929 🔎 🗧 🖒 🐫 Pay.gov - Medicare Covera 🗴		↑ ★ ♥
Eile Edit View Favorites Tools Help			
🐴 🕶 🔝 👻 🖃 👼 💌 <u>P</u> age 🕶 <u>S</u> afe	ty * Tools * 🚱 * 🗊 😳 🕅	organia 1 occorromaniaooonine	
	Pavgov		^
	/ /0-1		
	Find Forms, Agencies Search MAKE A PAYMENT FIND AN A	AGENCY ONLINE HELP	
	Medicare Coverage Gap Discount Program CMPs		
	Before You Begin 1 Complete Agency Form 2 Enter Payment Info 3 Review & Submit 4 Confirmation	Need Help?	
	Please use this form to pay your Medicare Coverage Gap Discount Program Civil Monetary Penalties	Contact: Shelly Winston	
	Paying online with Pay.gov is safe, secure, and the preferred method to make a payment. To make a payment using one of the below accepted payment methods, please click the Continue to the Form button.	Email: <u>Click to email</u> Website: <u>Click to visit site</u>	
	Accepted Payment Methods:		
	Bank account (ACH)		
	Preview Form Continue to the Form		
	This is a secure service provided by United States Department of the Treasury. The information you will enter will remain private. Please review our privacy policy for more information.		
		10	
	Contact Us Notices & Agreements Accessibility Policy Privacy & Security Policy For Agencies *	Fiscal Service	
	WARNING WARNING WARNING		
	You have accessed a United States Government computer. Unauthorized use of this computer is a violation of federal law and may subject and the automated systems which run on it are monitored. Individuals are not guaranteed privacy while using government computers and si made using this system may be disclosed as allowed by federal law.		
	Note: This system may contain Sensitive But Unclassified (SBU) data that requires specific data privacy handling.		~

<u>Step 5</u>

- Complete the required fields
 - ^o Manufacturer P Number: (P####) must be a P followed by 4-digits
 - ^o 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
 - ^o Mailing address: Street, city, state, and zip code
 - ^o **Date of Demand Letter:** (MM/DD/YEAR) typed date on the demand letter received from CMS
 - ^o **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

Mr. David Addis February 15, 2018 Page 7 of 11

		- 8 ×
ttps://www.pay.gov/public/form/entry/103/	🔎 👻 🗎 🖒 📿 Pay.gov - Medicare Covera 🗙	合 🛧 🕸
File Edit View Favorites Tools Help		
🚵 💌 🖾 👻 🖃 👘 💌 Page 🕶 Safety 💌 Tools 💌 🚱 🖉 🧔 🖡		
	Civil Money Penalty Payment	^
"Required Fields		
*Manufacturer P I	Number:	
*Manufacturer Na	me:	
* Address:		
* City:		
* State:	Y	
* Zip Code:		
*Point of Contact	Name:	
"Point of Contact	Phone:	
*Point of Contact	Email:	
"Date of Demand	Letter:	
Invoice Quarter fo	or which Penalties are due:	
"Quarter:	V "Year:	
*Payment Amoun	t: \$	
(Note: This must be th	he total amount due)	
	PDF Preview Continue	
		~

- 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 6

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.

Mr. David Addis February 15, 2018 Page 8 of 11

			_ 0
https://www.pay.gov/public/collect https://www.pay.gov/public/collect https://www.pay.gov/public/collect	tion/payment/ach/104/ $D \sim \square O$ 👾 Pay.gov - Medicare Covera	× 🦺 Blank Page	n :
🔊 • 🖃 🚔 • Page • Safety • 1	Taols 🕶 👰 🕶 🔞 🚳		
□ ·····	*** * ** **		
	Medicare Coverage Gap Discount Program CMPs		
	Before You Begin 1 Complete Agency Form 2 Enter Payment Info 3 Review & Submit 4 Confirmation	Need Help?	
	Please provide the payment information below. Required fields are marked with an * .	Contact: Shelly Winston	
	* Payment Amount:	Email: Click to email	
	\$1,000.00	Website: <u>Click to visit site</u>	
	* Payment Date (mm/ddlyyyy)		
	01/04/2018		
	* Account Holder Name		
	* Select Account Type		
	Select Account Type		
	* Routing Number		
	Routing Number		
	* Account Number		
	* Confirm Account Number		
	Confirm Account Number		
	Manufacturer P Number		
	P0001	_	
	Previous Return to Form Cance Review and Submit Payment		

Notice the payment amount you entered on the previous screen has populated. Click on Return to Form at the bottom of the screen to correct the payment amount.

Enter,

- Payment Amount
- **Payment Date:** automatically populates the next available date in which the financial institutes can initiate the payment transaction
- Account Holder Name: name as it appears on the actual banking account
- Select 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

Click on Review and Submit Payment when you are ready

• Review the payment summary,

Mr. David Addis February 15, 2018 Page 9 of 11

Pay.gov - Online Payment - Windows Internet Explorer		_ <u>-</u>				
💽 🗢 🖉 https://qa.pay.gov/paygov/payments/enterACHDebitPaymentInformation.html	💌 🔒 🔯 🍫 🗙 ಶ Live Search	₽ -				
Eile Edit View Favorites Iools Help						
🙀 Favorites 🙀						
🤔 Pay.gov - Online Payment	🐴 🔻 🔝 👻 🖃 👘 👻 <u>P</u> age 👻 <u>S</u> afety 👻 T <u>o</u> ols 🕶 (? ▼ "				
Step 2: Authorize Payment	1 2 3					
Payment Summary Edit this information						
Account Holder Name: manufacturer Inc						
Payment Amount: \$1,000.00						
Account Type: Business Checking	B (B ()) (B70010					
Routing Number: 041000124	Payment Date: 01/27/2012					
Account Number: **********0424						
Check Number: 0002						
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 comm	na -					
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 autho Cleveland to debit the named financial institution account. This authorization is to remain : notification of its termination in such time and in such manner as to afford Pay.gov a reaso terminated for any reason by Pay.gov.	in full force and effect until we have received					
B. Disclosure						
In case of errors or questions about a transaction, immediately contact the Federal agency u	sing the Pay.gov service or contact Pay.gov directly.	• * •				

- [°] Enter email address(es) to receive the payment confirmation
- ° Please add to the CC box: <u>cgdp_manufacturers@cms.hhs.gov</u>
- ^o 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.

Mr. David Addis February 15, 2018 Page 10 of 11

🔏 Pay.gov - Online Pa	yment - Windows	Internet Explorer								_ 8 ×
🔆 🗢 🖉 https://d	qa. pay.gov /paygov/pa	ayments/authorizeACHPayment.html		-			🔸 🗙 灯 Live Search			₽ -
<u>F</u> ile <u>E</u> dit ⊻iew F <u>a</u> vorit	es <u>T</u> ools <u>H</u> elp									
숨 Favorites 🛛 😪										
🥖 Pay.gov - Online Payr	nent				<u>}</u>	- 🔊	▼ 🖃 🚗 ▼ <u>P</u> age ▼	<u>S</u> afety ▼ T	<u>o</u> ols • (? ▼ "
Pay gov°	Provided by the US Depa									<u> </u>
Login	Online Payment									
Username:	Step 3: Confirm P	ayment						1	2 3	
Password:		tion has been successfully completed. Inded you <u>print a copy</u> for your records.					Print this win	dow.		
Trouble Logging In?	Pay.gov Tracking I	Information								
Find Public Forms by Form Name by Agency Name Search Public Forms Go	Pa Ag	Application Name: Medicare Coverage Gap Discount Program CM y.gov Tracking ID: 3F0HC300 lency Tracking ID: 120008876801 on Date and Time: 01/26/2012 12:36 EST	IPs							
Searching Help	Payment Summar									
Public Resources Resources Accessibility Statement Notices & Agreements Privacy & Security Policy Sitemap Help		Account Holder Name: manufacturer Inc Payment Amount: \$1,000,00 Account Type: Business Checking Routing Number: 041000124 Account Number: ************************************					Payment Date: 01/27/2012			
Contact Us Frequently Asked Questions	Return to your from search results									
Information Agency Information Overview Implementing Documentation Press / Articles			Return to Home							
<i>fmr</i>										•
↓							😜 Internet		100	
Done							unternet	1.1	100	~ //

Attachment 2

Department of Health and Human Services, Departmental Appeals Board (DAB)

Registering to Use DAB E-File

To file a new appeal using DAB E-File, you first need to register a new account by:

- clicking "Register" on the DAB E-File home page;
- entering the information requested on the "Register New Account" form; and
- clicking "Register Account" at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB-File on your behalf.

Filing an Appeal through DAB E-File

The e-mail address and password provided during registration must be entered on the login screen at http://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he is a party or authorized representative. Once registered, you may file your appeal by:

- clicking the "File New Appeal" link on the "Manage Existing Appeals" screen, then clicking "Civil Remedies Division" on the "File New Appeal" screen; and
- entering and uploading the requested information and documents on the "File New Appeal Civil Remedies Division" form.

At a minimum, the Civil Remedies Division (CRD) requires a party to file a signed request for hearing and the underlying notice letter from CMS that sets forth the action taken and the party's appeal rights. All documents must be submitted in Portable Document Format ('PDF"). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files, or CRD issues on behalf of the Administrative Law Judge, via DAB E-File. Correspondingly, CMS will also be deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

The DAB no longer accepts requests for a hearing submitted by U.S. mail or commercial carrier, unless you do not have access to a computer or internet services. In those circumstances you may contact the Civil Remedies Division to request a waiver from e-filing and provide an explanation as to why you cannot file electronically or you may mail a written request for a waiver along with your written request for a hearing. A written request for a hearing must be filed no later than sixty (60) days after receiving this letter, by mailing to the following address:

Department of Health and Human Services Departmental Appeals Board, MS 6132 Director, Civil Remedies Division 330 Independence Avenue, S.W. Cohen Building – Room G-644 Washington, D.C. 20201 (202) 565-9462

The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect. 42 C.F.R. § 423.1020(b).