

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 \$12,366.76.

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 \$12,366.76 to Amneal Pharmaceuticals, LLC 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:

- 123 Part D Sponsors \$49,467.03 (Breakdown on Attachment 1)

The CMP that your company owes is equal to:

- The 25% penalty, \$12,366.03

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	E3014	PSERS Hop Program	40.35
2	E4744	MODOT, MSHP Medical and Life Insurance Plan	163.05
3	E7848	OMES-Employees Group Insurance Divi	334.38
4	H0104	BlueCross BlueShield of Alabama	184.99
5	H0150	Cigna-HealthSpring	11.76
6	H0302	Banner MediSun	111.22
7	H0303	UnitedHealth Group	128.17
8	H0351	Health Net Inc.	151.14
9	H0504	Blue Shield of California	33.32
10	H0524	Kaiser Permanente	5,875.19
11	H0543	UnitedHealth Group	118.39
12	H0545	Inter Valley Health Plan	2.48
13	H0562	Health Net Inc.	182.60
14	H0630	Kaiser Permanente	1,459.86
15	H0755	UnitedHealth Group	12.90
16	H1016	AvMed Health Plans	8.58
17	H1019	Humana Inc.	104.01
18	H1026	Blue Cross & Blue Shield of Florida	311.39
19	H1032	WellCare Health Plans	74.49
20	H1099	Health First Health Plans, Inc.	111.79
21	H1170	Kaiser Permanente	95.52
22	H1230	Kaiser Permanente	234.46
23	H1406	Humana Inc.	137.22
24	H1509	UnitedHealth Group	6.78
25	H1666	Health Care Service Corporation	169.88
26	H1849	Anthem, Inc.	18.76
27	H1951	Humana Inc.	201.26
28	H1961	Peoples Health	14.07
29	H1994	SelectHealth, Inc	45.08
30	H2001	UnitedHealth Group	793.75
31	H2012	Humana Inc.	114.12
32	H2150	Kaiser Permanente	2,243.73
33	H2230	Blue Cross Blue Shield of MA	41.60
34	H2256	Tufts Health Plan	8.39
35	H2261	Blue Cross Blue Shield of MA	41.41
36	H2322	Health Alliance Plan of Michigan	1.49

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37	H2450	Medica Health Plans	59.58
38	H2663	Coventry Health Care, Inc	72.71
39	H2944	Humana Inc.	44.94
40	H3251	Health Care Service Corporation	81.56
41	H3312	Aetna Health Management	63.50
42	H3335	Excellus BlueCross BlueShield	78.50
43	H3362	Independent Health	38.13
44	H3449	Blue Cross and Blue Shield of NC	252.58
45	H3528	Connecticare	31.72
46	H3655	Anthem, Inc.	24.30
47	H3668	Medigold	4.00
48	H3755	CommunityCare HMO, Inc.	128.25
49	H3907	UPMC Health Plan, Inc.	185.20
50	H3916	Highmark Inc	269.22
51	H3921	UnitedHealth Group	8.46
52	H3931	Aetna Health Management	27.40
53	H3952	Independence Blue Cross	60.67
54	H3954	Geisinger Health Plan	14.40
55	H3957	Highmark Inc	62.20
56	H3962	Capital BlueCross	9.00
57	H4003	InnovaCare Inc.	8.41
58	H4152	Blue Cross Blue Shield of RI	17.50
59	H4454	Cigna-HealthSpring	36.00
60	H4461	Humana Inc.	17.85
61	H4513	Cigna-HealthSpring	6.00
62	H5009	Cambia Health Solutions	6.94
63	H5050	Group Health Cooperative	178.74
64	H5415	Humana Inc.	124.10
65	H5420	UnitedHealth Group	78.46
66	H5434	Blue Cross & Blue Shield of Florida	0.93
67	H5520	Health Net Inc.	151.14
68	H5521	Aetna Health Management	373.33
69	H5526	HealthNow NY Inc	34.66
70	H5577	MEDICAL CARD SYSTEM, INC.	17.04
71	H5813	Aetna Health Management	258.45
72	H5883	Blue Care Network	69.64
73	H6328	Care N' Care Insurance Company, Inc	54.00
74	H6609	Humana Inc.	180.24
75	H7917	Blue Cross Blue Shield of Tennessee	7.96
76	H8145	Humana Inc.	197.06
77	H8578	Health New England	14.35
78	H8634	Health Care Service Corporation	203.21
79	H9110	Cambia Health Solutions	74.01

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80	H9572	Blue Cross Blue Shield of Michigan	92.34
81	R3332	Blue Cross & Blue Shield of Florida	406.59
82	R5287	UnitedHealth Group	179.16
83	R5342	UnitedHealth Group	4.47
84	R5826	Humana Inc.	430.69
85	R5941	Anthem, Inc.	166.32
86	R7444	UnitedHealth Group	20.53
87	S0522	Symphonix Health Insurance	169.72
88	S0655	Tufts Health Plan	41.74
89	S1030	BlueCross BlueShield of Alabama	568.29
90	S2468	Blue Shield of California	741.49
91	S2893	NE Joint Venture / Blue Medicare Rx	141.03
92	S3474	Heartland Fidelity Insurance	24.60
93	S4802	WellCare Windsor/Sterling	21.10
94	S5540	Blue Cross and Blue Shield of NC	108.64
95	S5584	Blue Cross Blue Shield of Michigan	2.47
96	S5593	Highmark Inc	11.11
97	S5596	Anthem, Inc.	117.63
98	S5601	CVS Health	1,645.25
99	S5617	CIGNA	455.79
100	S5660	Express Scripts	4,310.96
101	S5674	Coventry Health Care, Inc	12.50
102	S5715	Health Care Service Corporation	1,781.43
103	S5743	ClearStone Solutions	500.41
104	S5753	WPS Insurance Corporation	151.95
105	S5755	United American	311.33
106	S5768	Coventry Health Care, Inc	354.83
107	S5795	Arkansas Blue Cross Blue Shield	50.96
108	S5805	UnitedHealth Group	203.79
109	S5810	Aetna Health Management	410.86
110	S5820	UnitedHealth Group	8,392.01
111	S5884	Humana Inc.	2,790.37
112	S5904	Blue Cross & Blue Shield of Florida	122.05
113	S5921	UnitedHealth Group	2,595.51
114	S5953	BlueCross BlueShield of SC	124.26
115	S5966	EmblemHealth	143.78
116	S5967	WellCare Health Plans	1,511.35
117	S6506	Blue Cross Blue Shield of Arizona	41.34
118	S7694	Envision Insurance Company	341.16
119	S7950	Express Scripts	625.25
120	S8067	Capital BlueCross	26.49
121	S8841	SXC Health Solutions	1,107.12
122	S9579	MedImpact Healthcare Systems, Inc.	974.11

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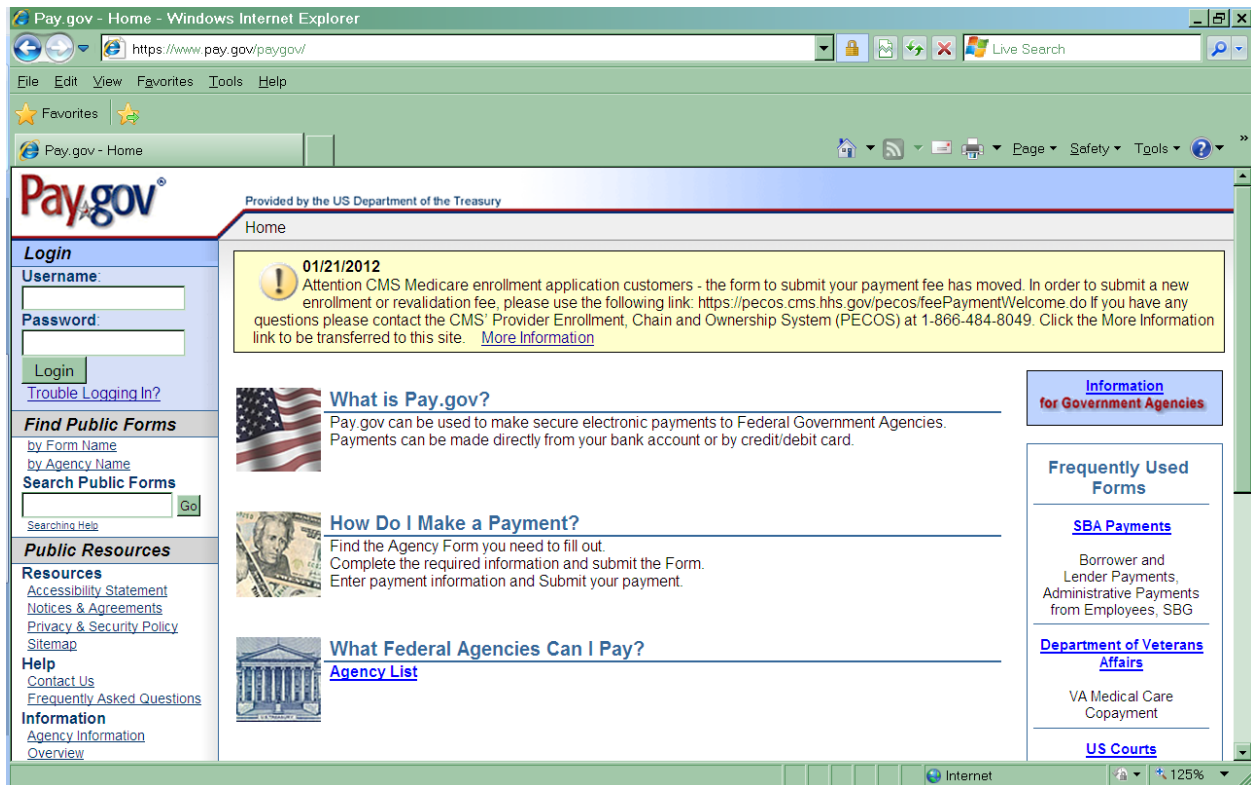
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123	S9701	Dean Health Plan	20.33
			\$ 49,467.03

Attachment 2

Step 1

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



The screenshot shows the Pay.gov website home page in Internet Explorer. The browser 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", a "Find Public Forms" section with search options, and a "Public Resources" section with links to "Resources", "Help", and "Information". The right sidebar contains an "Information for Government Agencies" section and a "Frequently Used Forms" section with links to "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 with the URL <https://qa.pay.gov/paygov/payments/keywordSearchForms.html?keyword=medicare+Coverage+gap+discount&f>. The search results are as follows:

- Search Results:** Your search for "medicare Coverage gap discount" returned 3 results. Results: 1-3 of 3. Sort By: **Form Name** | Form Number | OMB Number | Agency Name. [Hide Details](#)
- Form 1:**
 - CMS Data Payment Form** [View PDF](#)
 - Form Number: **CMS Data Payment**
 - Please use this form to pay your public use files, limited data sets, and research identifiable files fees. Also use this form to pay all other recovery of data processing fees from the Centers for Medicare & Medicaid Services. This form is NOT to be used for submitting the CMS 855 Application Fee. If you need to submit a new enrollment or revalidation fee, please use the following link: <https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do>.
 - [Department of Health and Human Services](#)
 - <https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=1818891>
- Form 2:**
 - CMS Medicare Application Fee** [View PDF](#)
 - Form Number: **Medicare-app-fee-1**
 - For all questions please call: 1-866-484-8049. After December 31, 2011, you must access this url to CMS' Provider Enrollment, Chain and Ownership System (PECOS) website to pay the Medicare enrollment application fee. <https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do>.
 - [Department of Health and Human Services](#)
 - <https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=3149023>
- Form 3:**
 - Medicare Coverage Gap Discount Program CMPs** [View PDF](#)
 - Form Number: **Medicare CGDP CMPs**
 - Please use this form to pay your Medicare Coverage Gap Discount Program Civil Monetary Penalties.
 - [Department of Health and Human Services](#)
 - <https://qa.pay.gov/paygov/forms/formInstance.html?agencyFormId=3550318>

Results: 1-3 of 3

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".

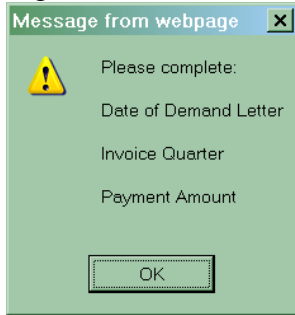
The main content area of the browser displays the "Medicare Coverage Gap Discount Program" form. The form is titled "Medicare Coverage Gap Discount Program" and "Civil Money Penalty Payment". It includes a section for "Required Fields" with the following fields:

- *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".

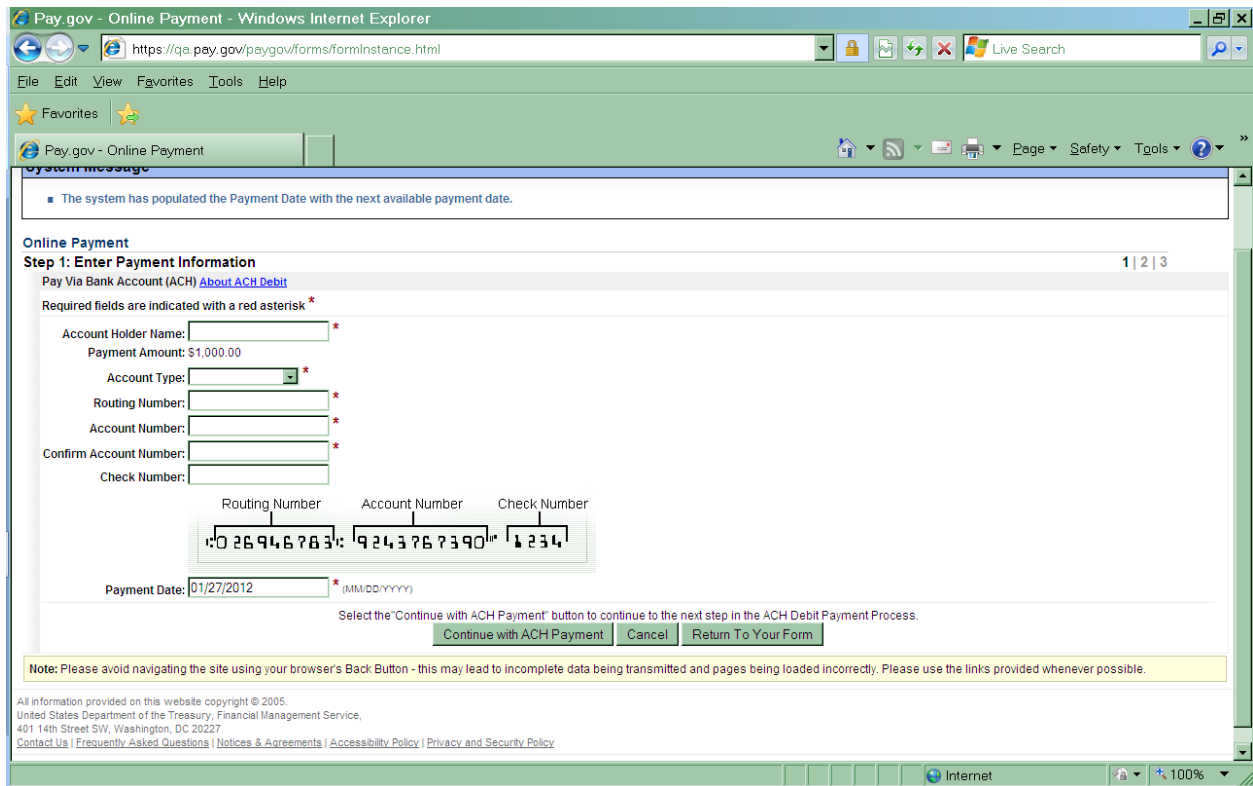
- Complete the required fields
 - **Manufacturer P Number:** (P####) must be a P followed by 4-digits
 - **Manufacturer Name:** manufacturer's complete name
 - **Point of Contact:** person authorized to make the payment
 - **Point of Contact Phone:** (***_**_****) telephone number must include dashes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



- 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](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.

