



Center for Medicare

May 13, 2021

VIA EMAIL: David.Benharris@midatechpharmaus.com; John.Petrolino@midatechpharmaus.com

Midatech Pharma
David Benharris
8601 Six Forks Road Suite 160
Raleigh, North Carolina 27615-2965

RE: Notice of Determination to Impose a Civil Money Penalty for Pharmaceutical Manufacturer Contract Number P1348

Dear Midatech Pharma US, Inc.:

The Centers for Medicare & Medicaid Services (CMS) is issuing this notice of determination to impose a civil money penalty to Midatech Pharma US, Inc, P1348. Pursuant to 42 CFR §423.2340, CMS is providing notice of a civil money penalty (CMP) assessment in the amount of \$25,669.78.

Basis for Civil Money Penalty

CMS is imposing a CMP of \$25,669.78 on Midatech Pharma US, Inc, P1348 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 fourth quarter 2020 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:

- 14 Part D Sponsors: \$20,535.82
 - See Attachment 2

The CMP that your company owes is equal to:

- Any invoiced amounts your company has failed to pay to Part D sponsors; \$20,535.82
- Plus the 25% penalty component; \$5,133.96

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:

- 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; July 12, 2021 (Instructions on Attachment 1); and
- email a copy of your hearing request to CMS:

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- Centers for Medicare & Medicaid Services, Craig Miner, Deputy Director, Division of Part D Policy at CGDPandManufacturers@cms.hhs.gov

This notice is not a demand for payment. In light of the bankruptcy case, this penalty has been referred to the attention of our Office of the General Counsel and to the Office of the U.S. Attorney.

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 Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

cc: Mr. Craig Miner, CMS/CM/MDBG
Ms. Christine Machon, CMS/CM/MPPG
Mr. Ray Thorn, CMS/OC
Ms. Jill Abrams, DHHS/OGC
Ms. Jennifer Garver, DHHS/OGC
Mr. Greg Bongiovanni

Attachment 1

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).

Attachment 2
2020 Q4 P1348 Midatech Pharma

	Contract Number	Contract Name	Invoiced Amount
1	H0504	Blue Shield of California	\$ 1,868.32
2	H2001	SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.	\$ 614.91
3	H5216	HUMANA INSURANCE COMPANY	\$ 269.27
4	H5521	AETNA LIFE INSURANCE COMPANY	\$ 716.66
5	S1822	HEALTHPARTNERS, INC.	\$ 90.18
6	S3285	MG Insurance Company	\$ 123.70
7	S5601	SILVERSCRIPT INSURANCE COMPANY	\$ 4,524.58
8	S5617	CIGNA HEALTH AND LIFE INSURANCE COMPANY	\$ 602.91
9	S5660	MEDCO CONTAINMENT LIFE AND MEDCO CONTAINMENT NY	\$ 2,189.28
10	S5715	HCSC INSURANCE SERVICES COMPANY	\$ 2,268.91
11	S5884	HUMANA INSURANCE COMPANY	\$ 2,037.10
12	S5904	BLUE CROSS AND BLUE SHIELD OF FLORIDA, INC.	\$ 108.52
13	S5966	GROUP HEALTH INCORPORATED	\$ 629.70
14	S8841	OPTUM INSURANCE OF OHIO, INC.	\$ 4,491.78
			\$20,535.82