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

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

April 1, 2025

Mr. Antonio Hernandez
Interim President
Presbyterian Health Plan
9521 San Mateo Blvd NE
Albuquerque, NM 87113

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Number: H3204

Dear Mr. Hernandez:

Pursuant to 42 C.F.R. §§ 422.752(c)(1), 422.760(c), 423.752(c)(1), and 423.760(c), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Presbyterian Health Plan (Presbyterian Health), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$14,152** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number H3204.

An MA-PD organization's primary responsibility is to provide Medicare enrollees with medical services and prescription drug benefits in accordance with Medicare requirements. CMS has determined that Presbyterian Health failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of Presbyterian Health's Medicare operations from July 8, 2024, through July 26, 2024. In a program audit report issued on December 30, 2024, CMS auditors reported that Presbyterian Health failed to comply with Medicare requirements related to Part D coverage determinations and prior authorizations or exceptions requests in violation of 42 C.F.R. Part 423, Subparts C and M. One (1) failure was systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees because the enrollees experienced delayed access to medications, paid out-of-pocket costs for medications, or never received medications. CMS reviews audit findings individually to determine if an enforceable violation has occurred warranting a CMP. CMPs are calculated and imposed when a finding of non-compliance adversely affected or had a substantial likelihood of adversely affecting enrollees. The determination to impose a CMP on a specific finding does not correlate with the MA-PD's overall audit performance.

Part D Coverage Determinations, Formulary, and Benefit Administration Relevant Requirements

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan Sponsors and to Medicare Advantage organizations that offer Part D prescription drug benefits. Sponsors that offer these plans are required to enter into agreements with CMS by which the sponsors agree to comply with a number of statutory, regulatory, and sub-regulatory requirements.

Qualified Prescription Drug Coverage
(42 C.F.R. § 423.104; Chapter 5, Section 20.1 of the Medicare Prescription Drug Benefit Manual, (IOM Pub. 100-18))

A Part D sponsor must provide its enrollees with qualified prescription drug coverage. Qualified prescription drug coverage, which consists of either standard or alternative prescription drug coverage, may be provided directly by the Part D sponsor or through arrangements with other entities.

Formulary
(42 C.F.R. §§ 423.120(b)(2)(iv) and 423.120(b)(4)-(6); Chapter 6, Section 30.3 of the Medicare Prescription Drug Benefit Manual, (IOM Pub. 100-18))

As part of the qualified prescription drug coverage, each Part D sponsor maintains a drug formulary or list of prescription medications covered by the sponsor. A number of Medicare requirements govern how Part D sponsors create and manage their formularies. Each Part D sponsor is required to submit its formulary for review and approval by CMS on an annual basis. The formulary review and approval process includes reviewing the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare Part D prescription drug claims. Once CMS approves a sponsor's formulary, the sponsor cannot change the formulary unless it obtains CMS approval and subsequently notifies its enrollees of the changes.

Part D Coverage Determinations and Utilization Management Techniques
(42 C.F.R. §§ 423.576 and 423.120(b)(2)); Chapter 6, Section 30.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18))

A Part D coverage determination is any determination made by the plan sponsor, or its delegated entity, with respect to a decision about whether to provide or pay for a drug that an enrollee believes may be covered by the plan sponsor, including a decision related to a Part D drug that is not on the plan's formulary, determined not to be medically necessary, furnished by an out-of-network pharmacy, or otherwise excluded under section 1862(a) of the Social Security Act if applied to Medicare Part D.

Prior authorization is a utilization management technique used by Part D sponsors and other health insurers that requires enrollees to obtain approval from the sponsor, through the coverage determination process, for coverage of certain prescriptions prior to being dispensed the medication.

Prior authorization guidelines are determined on a drug-by-drug basis and may be based on Food and Drug Administration (FDA) and manufacturer guidelines, medical literature, safety, appropriate use, and benefit design.

Although Part D sponsors may require beneficiaries to obtain a prior authorization for certain medications on its approved formulary, once a prior authorization is approved, plan sponsors must provide the benefits to the enrollee as approved because the effect of an approved coverage determination is binding on the Part D sponsor.

Violations Related to Part D Coverage Determinations, Formulary, and Benefit Administration

CMS determined that Presbyterian Health failed to properly effectuate approved prior authorizations because it denied medications during the time period when the beneficiary had an approved prior authorization for the medication. More specifically, when Presbyterian Health switched to a new pharmacy benefit manager, active authorizations were not properly carried over and Presbyterian Health rejected claims even though an enrollee had an approved prior authorization. As a result, enrollees were inappropriately denied coverage for medications at the point of sale and there is a substantial likelihood that enrollees experienced delayed access to medication, paid for medications out-of-pocket, or never received their medication. Presbyterian's failure to Part D coverage determinations, formulary and benefit administration requirements violates 42 C.F.R. §§ 423.104, 423.120(b)(2), and 423.576.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c)(1)(i) and 423.752(c)(1)(i), CMS may impose a CMP for any determination made under 42 C.F.R. §§ 422.510(a) and 423.509(a). Specifically, CMS may issue a CMP if an MA-PD plan sponsor has failed substantially to carry out its contract. Pursuant to 42 C.F.R. §§ 422.760(b)(2) and 423.760(b)(2), a penalty may be imposed for each enrollee directly adversely affected (or with the substantial likelihood of being adversely affected) by the deficiency.

CMS has determined that Presbyterian Health failed substantially to carry out the terms of its contract with CMS (42 C.F.R. § 423.509(a)(1)). Additionally, CMS determined that Presbyterian Health failed substantially to comply with the service access requirements in 42 C.F.R. § 423.120 (42 C.F.R. § 423.509(a)(4)(iv)) and requirements in Subpart M relating to Part D Coverage Determinations (42 C.F.R. § 423.509(a)(4)(ii)). Presbyterian Health's violation of Part D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP.

Right to Request a Hearing

Presbyterian Health may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Presbyterian Health must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by

June 2, 2025.[1] The request for hearing must identify the specific issues and the findings of fact or conclusions of law with which Presbyterian Health disagrees. Presbyterian Health must also specify the basis for each contention that the finding or conclusion of law is incorrect.

The request should be filed through the DAB E-File System (https://dab.efile.hhs.gov) unless the party is not able to file the documents electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to the Civil Remedies Division using a postal or commercial delivery service at the following address:

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

Please see https://dab.efile.hhs.gov/appeals/to_crd_instructions for additional guidance on filing the appeal.

A copy of the hearing request should also be emailed to CMS at the following address:

Kevin Stansbury
Director
Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
Email: kevin.stansbury@cms.hhs.gov

If Presbyterian Health does not request an appeal in the manner and timeframe described above, the initial determination by CMS to impose a CMP will become final and due on June 3, 2025. Presbyterian Health may choose to have the penalty deducted from its monthly payment or transfer the funds electronically. To notify CMS of your intent to make payment and for instructions on how to make payment, please email the enforcement contact provided in the email notification.

Impact of CMP

Further failures by Presbyterian Health to provide its enrollees with Medicare benefits in accordance with CMS requirements may result in CMS imposing additional remedies available under law, including contract termination, intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

[1] Pursuant to 42 C.F.R. §§ 422.1020(a)(2) and 423.1020(a)(2), the organization must file an appeal within 60 calendar days of receiving the CMP notice. The 60th day falls on a weekend or holiday, therefore the date reflected in the notice is the next regular business day for you to submit your request.

If Presbyterian Health has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/
John A. Scott
Director

Medicare Parts C and D Oversight and Enforcement Group
cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Ashley Hashem, CMS/OPOLE
Michael Taylor, CMS/OPOLE
Verna Hicks, CMS/OPOLE
Jeff Mouakket, CMS/OPOLE