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

Ms. Karen Murphy
President
Geisinger Health Plan
100 North Academy Avenue
Danville, PA 17822

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Contract Numbers H3924 and H3954

Dear Ms. Murphy:

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 Geisinger Health Plan and Geisinger Indemnity Insurance Company (Geisinger), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$5,800** for Medicare Advantage-Prescription Drug (MA-PD) Contract Numbers H3924 and H3954.

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 Geisinger failed to meet that responsibility

Summary of Noncompliance

CMS conducted an audit of Geisinger's Medicare operations from July 15, 2024 through August 2, 2024. In a program audit report issued on November 27, 2024, CMS auditors reported that Geisinger failed to comply with Medicare requirements related to Part D formulary and benefits administration in violation of 42 C.F.R. Part 423, Subpart C. 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 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), 423.272(b)(2); Chapter 6, Section 30.3 of the Medicare Prescription Drug Benefit Manual, (IOM Pub. 100-18))

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.

Utilization Management Techniques
(42 C.F.R. § § 423.120(b), 423.272(b)(2); Chapter 6, Section 30.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18); Health Plan Management System (HPMS) Memorandum "CMS Part D Utilization Management Policies and Requirements" dated October 22, 2010)

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 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.

Quantity limits are another utilization management technique used by Part D sponsors. A sponsor may place a quantity limit on a drug for a number of reasons. For example, a quantity limit may be placed on a medication in order to ensure that the quantity and/or dosage does not exceed the maximum daily dose limits established by the FDA. Quantity limits may also be placed on a drug to optimize dosage, which helps to contain costs.

Part D sponsors and other health insurers use step therapy to ensure that first drug prescribed for an enrollee who is beginning drug therapy is cost-effective and safe, and other more costly or Page risky drugs are prescribed only if clinically necessary. The goal of step therapy is to control costs and minimize clinical risks.

Transition of Coverage
(42 C.F.R. § 423.120(b)(3); Chapter 6, Section 30.4 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18))

A Part D sponsor must provide for an appropriate transition process for enrollees who are prescribed non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but are subject to prior authorization, step therapy, or quantity limits in certain situations). Part D sponsors must have processes in place to provide an enrollee in transition with a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but are subject to prior authorization, step therapy, or quantity limits). The transition process is designed to accommodate the immediate needs of an enrollee, and to allow the sponsor and/or enrollee sufficient time to switch to a therapeutically equivalent medication or request an exception to maintain coverage of an existing drug.

Violation Related to Part D Formulary and Benefit Administration Requirements

CMS determined that Geisinger failed to properly administer the CMS transition policy. Specifically, an incorrect "Individual Start Date" was loaded into its pharmacy benefit manager's' adjudication system. This caused inaccurate transition timeframes for certain members and as a result, Geisinger inappropriately rejected medications that should have been approved for a transition supply and there is a substantial likelihood that enrollees experienced delayed access to medications, paid for medications out-of-pocket, or never received their medications. Geisinger's failure of Part D formulary and benefit administration requirements violates 42 C.F.R. §§ 423.104(a) and 423.120(b)(3).

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 Geisinger failed substantially to carry out the terms of its contract with CMS (42 C.F.R. § 423.509(a)(1)) because it substantially failed to comply with requirements related to the administration of the Part D transition policy at 42 C.F.R. § 423.120(b)(3). Geisinger'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

Geisinger 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. Geisinger 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 Geisinger disagrees. Geisinger 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 Geisinger does not request an appeal in the manner and timeframe described above, the initial

[1] Pursuant to 42 C.F.R. §§ 422.1020(a)(2) and 423.1020(a)(2), the plan sponsor 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.

determination by CMS to impose a CMP will become final and due on June 2, 2025. Geisinger 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 Geisinger 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.

If Geisinger 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: Ashley Hashem, CMS/OPOLE
Michael Taylor, CMS/OPOLE
Ruth-Lande Rogers, CMS/OPOLE
Maureen Savory, CMS/OPOLE
Kevin Stansbury, CMS/CM/MOEG/DCE