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

March 21, 2024

Mr. Alexander Uhm
Vice President, Medicare
California Physicians' Service
3840 Kilroy Airport Rd.
Long Beach, CA 90806

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H5928, H4937, H0504, and S2468

Dear Mr. Uhm:

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 California Physicians' Service (California Physicians), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$30,160** for Medicare Advantage-Prescription Drug (MA-PD) and Prescription Drug Plan (PDP) Contract Numbers H5928, H4937, H0504, and S2468.

An MA-PD and PDP 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 California Physicians failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of California Physicians' Medicare operations from May 1, 2023, through May 19, 2023. In a program audit report issued on August 23, 2023, CMS auditors reported that California Physicians 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 and Part D coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subpart M. Two (2) failures were systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees. The enrollees experienced, or likely experienced a delay in access to medications, paid out-of-pocket costs for medications, never received medications, paid more for requested medications, or did not receive the correct appeal rights timely or at all.

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 and PDP's overall audit performance.

Part D Formulary and Benefit Administration Relevant Requirements
(42 C.F.R. Part 423, Subpart C (§§423.104 and 423.120(b)); Chapter 5, Section 20.1 and Chapter 6, Section 30.3 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18))

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. 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.

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.

Utilization Management Techniques
(42 C.F.R. § 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. A Part D sponsor must not reject a medication for prior authorization without receiving approval from CMS for the prior authorization edit.

Violation Related to Part D Formulary and Benefit Administration

CMS determined that California Physicians failed to properly administer its CMS-approved formulary by applying unapproved prior authorization edits at the point of sale (POS). Specifically, California Physicians inappropriately rejected claims for protected class medications due to an incorrect reject code that prevented recognition of when an enrollee had a prior claim for the medication and therefore should have been able to access the medication without obtaining approval from California Physicians. As a result, enrollees were

inappropriately denied coverage for medications at the POS and there is a substantial likelihood that enrollees experienced a delay in access to medication, paid for medications out-of-pocket, or never received their medication. This failure violates 42 C.F.R. §§ 423.104(a) and 423.120(b).

Part D Coverage Determinations, Appeals, and Grievances Relevant Requirements
(42 C.F.R. Part 423, Subpart M)

A Medicare enrollee has the right to contact his or her plan sponsor to express general dissatisfaction with the plan sponsor's operations, activities, or behavior, or to make a specific complaint about the denial of coverage for Part D drugs which the enrollee believes he or she is entitled to receive. Plan sponsors are required to classify general complaints about benefits or the plan sponsor's operations or activities as grievances. Plan sponsors are required to classify complaints about coverage for drugs and payment as Part D coverage determinations. It is critical for a plan sponsor to properly classify each complaint as a grievance, coverage determination/appeal, or both. Improper classification may result in enrollees not receiving the required level of review and/or experiencing delayed access to medically necessary or life-sustaining drugs.

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 § 1862(a) of the Social Security Act if applied to Medicare Part D. An enrollee who has received a coverage determination may appeal the decision by requesting that it be redetermined. Generally, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination.

Violation Related to Part D Coverage Determinations, Appeals, and Grievances

CMS determined that California Physicians failed to appropriately classify complaints about coverage for drugs and payment as Part D coverage determinations or appeals. First, California Physicians failed to process requests for coverage and payment of drugs when received as part of a grievance. More specifically, California Physicians' workflow document did not clearly require call center agents to initiate a coverage determination or appeal on behalf of an enrollee when received as part of a grievance. As a result, enrollees did not receive their Part D drug timely or at all, paid more for the requested drug, or did not receive their appeal rights timely or at all. This is in violation of 42 C.F.R. § 423.564(b).

Second, California Physicians incorrectly handled appeals as initial coverage determinations. More specifically, California Physicians inappropriately processed medication requests received within 60 days of coverage determination denials as second coverage determinations rather than as redeterminations when the medication, dosage, prescriber were the same as the initial request. As a result, enrollees did not receive the correct appeal rights for denials. This is in violation of 42 C.F.R. § 423.580.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 422.752(c)(1)(ii) and 423.752(c)(1)(ii), CMS may impose a CMP for any determination made under 42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1). Specifically, CMS may issue a CMP if an MA-PD or PDP has failed substantially to follow Medicare requirements according to 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 California Physicians failed substantially:

- To carry out the terms of its contract with CMS (42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1));
- To comply with Part D service access requirements in 42 C.F.R. § 423.120 (42 C.F.R. § 423.509(a)(4)(iv)); and
- To comply with the requirements in Subpart M relating to grievances and appeals (42 C.F.R. § 423.509(a)(4)(ii)).

California Physicians 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

California Physicians 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. California Physicians must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by May 21, 2024.[1] The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which California Physicians disagrees. California Physicians 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

[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.

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
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: kevin.stansbury@cms.hhs.gov

If California Physicians 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 May 22, 2024. California Physicians 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 California Physicians 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 California Physicians 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
Adrianne Carter, CMS/ OPOLE
Nyetta Patton, CMS/OPOLE
Deanna Gee, CMS/OPOLE
Charlie Chaleunsy, CMS/OPOLE