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 16, 2023

Mr. Rob Hitchcock
Chief Executive Officer
Intermountain Health Care, Inc.
5381 S. Green Street
Murray, UT 84123

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug Contract Number H1994

Dear Mr. Hitchcock:

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 Intermountain Health Care, Inc. (Intermountain), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$17,980** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number H1994.

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 Intermountain failed to meet that responsibility

Summary of Noncompliance

CMS conducted an audit of Intermountain's Medicare operations from August 8, 2022 through August 30, 2022. In a program audit report issued on November 30, 2022, CMS auditors reported that Intermountain 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. Two of those failures adversely affected, or had the substantial likelihood of adversely affecting enrollees. The enrollees experienced, or likely experienced, delayed or denied access to prescription drugs.

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 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 the 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. §§ 423.576 423.120(b)(2)); Chapter 6, Section 30.2 of the Medicare Prescription Drug BenefitManual (IOM Pub.100-18); Health Plan Management System (HPMS) Memorandum "Additional Guidance on Contract Year 2019 Formulary-Level Opioid Point-of-Sale Safety Edits, and the Frequently Asked Questions (FAQs) about Formulary-Level Opioid Point-of-Sale (POS) Safety Edits, available on the CMS Part D Overutilization website: https://www.cms.gov/medicare/prescription-drug coverage/prescriptiondrugcovcontra/rxutilization dated October 23, 2010)

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 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.

Prior authorization is one type of utilization management technique that Part D sponsors and health insurers may use to prevent and combat opioid overuse. For example, Part D sponsors are permitted to implement prior authorization techniques, such as an edit for an initial opioid fill for beneficiaries that are opioid naïve. In general, once a beneficiary has an approved prior authorization on file for an initial opioid medication, the MA-PD must not deny subsequent opioid prescriptions because the effect of an approved coverage determination is binding on the Part D sponsor unless it is revised.

Violations Related to Formulary and Benefit Administration

CMS determined that Intermountain failed to properly effectuate approved prior authorizations because it denied opioid medications when the beneficiary already had an approved prior authorization for the opioid medication. This deficiency violates 42 C.F.R. §§ 423.104, 423.120(b)(2), and 423.576. Although Intermountain may require beneficiaries to obtain a prior authorization for a certain medication on its approved formulary, once that prior authorization is approved, Intermountain must provide the benefits to the enrollee as approved because the effect of an approved coverage determination is binding on the Part D sponsor.

As a result of these denials, enrollees may have experienced delayed access to their medications, never received their medications, or incurred increased out-of-pocket expenses in order to receive their medications. Some of these denials were for prescription medications that are used to treat acute conditions that require immediate treatment.

Part D Coverage Determinations and Exception Request Requirements
(42 C.F.R. §§423.566(a)-(b), and 423.578(a)-(b); Section 40.5, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance)

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 Act if applied to Medicare Part D. Part D coverage determinations include a plan sponsor's decision on an enrollee's exception request to the plan sponsor's tiered cost-sharing structure, or formulary or utilization management requirement. An exception request may include a request for benefits, a request for payment, or both.

An exception request must include a physician's or other prescriber's supporting statement. A physician's or other prescriber's supporting statement is any statement, verbal or written, that

indicates the drug is medically necessary. If the exceptions request is specific to a plan sponsor's tiering structure, the supporting statement must state that the preferred drug(s) for the treatment of the enrollee's condition: would not be as effective for the enrollee as the requested drug; would have adverse effects for the enrollee; or both. If the exceptions request is for a non-formulary drug, the supporting statement must state that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition. If the exception request is received without a supporting statement and the plan sponsor does not have sufficient information to approve, for example, through claims history or information contained in a previously adjudicated exception, the plan sponsor must conduct outreach to obtain it.

The plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours in the case of an expedited decision) after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever occurs first (see 42 CFR §423.568(b) and 423.570(d)(1)). If the supporting statement is not received by the end of the 14 calendar days, then the plan sponsor must notify the enrollee (and prescriber, as appropriate) of its decision no later than 72 hours (24 for expedited cases) from the end of the 14 calendar days from receipt of the exception request.

Violations related to Part D Coverage Determinations and Exception Requests

CMS determined that Intermountain inappropriately denied exception requests without a prescriber's supporting statement. Intermountain misinterpreted CMS requirements by treating the receipt of an exception request from a prescriber as the receipt of a supporting statement. As a result, enrollees were prematurely denied exception requests for certain medications. This failure violates 42 C.F.R. §§ 423.566(a)-(b), and 423.578(a)-(b).

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)(1) and 423.509(a)(1). Specifically, CMS may issue a CMP if a Medicare Advantage Prescription Drug Plan 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 Intermountain failed substantially to carry out the terms of its contract (42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1)). Additionally, CMS determined that Intermountain failed substantially to comply with requirements in Subpart C relating to formulary and benefit administration (42 C.F.R. § 423.120(b)), and requirements in Subpart M relating to Part D Coverage Determinations, exception requests, and tolling requirements (42 C.F.R. (§§ 423.562(a), 423.566(a)-(b), and 423.578(a)-(b)).

Intermountain violations 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

Intermountain 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. Intermountain must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by May 16, 2023[1]. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Intermountain disagrees. Intermountain 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 sent 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 Intermountain 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 17, 2023. Intermountain may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS. To notify CMS of your intent to make payment and for instructions on how to make payment, please call or email the enforcement contact provided in the email notification.

[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.

Impact of CMP

Further failures by Intermountain 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 Intermountain 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
Anthony Jordan, CMS/OPOLE
Verna Hicks, CMS/OPOLE