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

November 27, 2017

Agnes Sandberg
Senior Vice President, Medicare
Kaiser Foundation Health Plan, Inc.
1800 Harrison St., 11th Floor
Oakland, CA 94612

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Medicare Cost Plan Contract Numbers: H0524, H0630, H1170, H1230, H2150, and H9003

Dear Ms. Sandberg:

Pursuant to 42 C.F.R. §§ 422.752(c)(1), 422.760(b), 423.752(c)(1), and 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Kaiser Foundation Health Plan, Inc. (Kaiser), that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$45,900** for Medicare Advantage-Prescription Drug (MA-PD) and Medicare Cost Plan Contract Numbers H0524, H0630, H1170, H1230, H2150[1], and H9003.

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

Summary of Noncompliance

CMS conducted an audit of Kaiser's Medicare operations from April 3, 2017 through April 14, 2017. In a program audit report issued on August 21, 2017, CMS auditors reported that Kaiser failed to comply with Medicare requirements related to Part D formulary and benefit administration in violation of 42 C.F.R. Part 423, Subpart C. Kaiser's failures in these areas were systemic and adversely affected, or had the substantial likelihood of adversely affecting, enrollees. The enrollees experienced, or likely experienced, delayed or denied access to covered benefits, and/or increased out-of-pocket costs.

[1] Contract H2150 is a Medicare Cost Plan with a qualified prescription drug plan. Pursuant to 42 C.F.R. §417.440(b)(2)(ii), a Medicare Cost Plan may elect to provide qualified prescription drug coverage (as defined in 42 C.F.R. §423.104) as an optional supplemental service in accordance with the applicable requirements under 42 C.F.R. Part 423. Therefore, all Part D requirements in 42 C.F.R. Part 423 cited in this notice apply to H2150.

Part D 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.

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))

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.

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 risky drugs are prescribed only if clinically necessary. The goal of step therapy is to control costs and minimize clinical risks.

Violations Related to Formulary & Benefit Administration

CMS determined that Kaiser violated the following Part D formulary and benefit administration requirement:

1. Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits and utilization management practices. As a result, enrollees experienced inappropriate denials of coverage at the point of sale, which impeded their access to prescription drugs. Enrollees may have experienced delays, paid out-of-pocket, or never received the prescriptions drugs. Some of the prescription drugs denied are used to treat acute conditions that require immediate treatment. This deficiency violates 42 CFR §§ 423.104(h), 423.120(b)(2) and 423.100.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 423.752(c)(1) and § 423.760(b), CMS has determined that Kaiser's violations of Parts C and D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. Kaiser failed substantially:

- To carry out the terms of its contract with CMS (42 C.F.R. § 423.509(a)(1));
- To comply with the Part D service access requirements in § 423.120 (42 C.F.R. § 423.509(a)(4)(iv)).

Right to Request a Hearing

Kaiser 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. Kaiser must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by January 29, 2018. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Kaiser disagrees. Kaiser 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
Acting 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 Kaiser 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 January 30, 2018. Kaiser 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.

Impact of CMP

Please note, this action will factor into Kaiser's Past Performance calculations. For Past Performance, your organization will receive one negative past performance point.

Further failures by Kaiser 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 Kaiser has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

Vikki Ahern
Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Ann Duarte, CMS/ CMHPO/Region IX
Ayanna Busby-Jackson CMS/ CMHPO/Region IX
Jullin Kwok, CMS/ CMHPO/Region IX
Kevin Stansbury, CMS/CM/MOEG/DCE