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 21, 2016

Mr. William S. George CEO Health Partners Plans, Inc. 901 Market Street, Suite 500 Philadelphia, PA 19107

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

Contract Number: H9207

Dear Mr. George:

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 Health Partners Plans, Inc. (Health Partners) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of \$32,600 for Medicare Advantage-Prescription Drug (MA-PD) Contract Number H9207.

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 Health Partners failed to meet that responsibility.

# **Summary of Noncompliance**

CMS conducted an audit of Health Partners' Medicare operations from April 18, 2016 through April 29, 2016. In a program audit report issued on October 17, 2016, CMS auditors stated that Health Partners failed to comply with Medicare requirements related to Part D formulary and benefit administration, and Part C and Part D organization/coverage determinations, appeals, and grievances, which violates 42 C.F.R. Part 422, Subpart M, and Part 423, Subparts C and M. Health Partners' failures in these areas were systemic and resulted in enrollees inappropriately experiencing delayed or denied access to benefits and/or increased out-of-pocket costs.

### 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.

#### <u>Utilization Management Techniques</u>

(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 Memorandum "CMS Part D Utilization Management Policies and Requirements" dated October 22, 2010)

Prior authorization is a utilization management tool 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 the medication being dispensed. 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 tool 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 the 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 identified a violation of Part D formulary and benefit administration requirements that resulted in Health Partners' enrollees experiencing inappropriate denials of and/or delayed access to Part D prescription drugs at the point of sale. Health Partners' violation includes:

1. Sponsor improperly effectuated prior authorizations (PAs) and exception requests. As a result, beneficiaries were inappropriately denied coverage for medications when they attempted to pick up refills for prescriptions that had existing PA approvals. The beneficiaries either experienced delayed access to the medications or had to pay additional out-of-pocket costs as a result of needing to request additional prior authorizations or exceptions. This failure violates 42 CFR § 423.120(b)(2), and Chapter 6, Sections 30.2.2 and 30.2.2.1 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

# Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Requirements

(42 C.F.R. Part 422, Subpart M; 42 C.F.R. Part 423, Subpart M; Chapter 18 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18); Chapter 13 of the Medicare Managed Care Manual (IOM Pub. 100-16))

A Medicare enrollee has the right to contact his or her plan sponsor to express general dissatisfaction with the sponsor's operations, activities, or behavior. These types of complaints must be processed as grievances. An enrollee can also make a specific complaint about the denial of coverage for Part C medical services or Part D drugs to which the enrollee believes he or she is entitled. Sponsors are required to classify these types of complaints as organization determinations (Part C medical services) or coverage determinations (Part D drugs). It is critical for a sponsor to properly classify each complaint as a grievance, organization/coverage determination, 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 treatments.

The enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination (Part C) or coverage determination (Part D). The sponsor is responsible for processing the organization/coverage determination request, making a decision, and providing notice of the decision in accordance with CMS rules. If the organization/coverage determination decision is adverse (i.e., not in the enrollee's favor), the enrollee has the right to file an appeal. The first level of appeal, which is called a reconsideration (Part C) or redetermination (Part D), is handled by the sponsor. The second level of appeal is made to an independent review entity (IRE) that contracts with CMS. If the sponsor does not issue the reconsideration/redetermination decision timely, the decision is considered to be unfavorable to the enrollee and the sponsor must automatically forward the request to the IRE for processing.

# Violations Related to Part C and Part D Organization/Coverage Determinations, Appeals and Grievances

CMS identified four violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in Health Partners' enrollees inappropriately experiencing delayed access to Part D prescription drugs and Part C medical services. Health Partners' violations include:

- 2. Sponsor did not appropriately auto-forward coverage determinations and/or redeterminations (standard and/or expedited) to the Independent Review Entity (IRE) for review and disposition within the CMS required timeframe. When a sponsor fails to auto-forward a case to the IRE, the enrollee's case is not reviewed by the IRE timely and access to needed medications may be delayed. This is in violation of 42 CFR §§ 423.568(h), 423.572(d), 423.578(c)(2), 423.590(c), 423.590(e), and Chapter 18, Sections 40.4, 50.6, 70.7.1, and 70.8.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).
- 3. Sponsor did not notify beneficiaries or their prescribers, as appropriate, of its decisions within 24 hours after receiving expedited coverage determination requests, or, for exceptions requests, physicians' or other prescribers' supporting statements. Because the enrollees were not notified timely, they may have experienced delayed access to needed medications. This deficiency violates 42 CFR §§ 423.572(a),

- 423.572(b), and Chapter 18, Sections 50.4, 50.5.1, and 50.5.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).
- 4. Sponsor did not effectuate exception approvals through the end of the plan year. As a result, enrollees needing refills were required to file additional exception requests for the refills or pay out-of-pocket in order to receive the refills. This deficiency violates 42 CFR §§ 423.578(c)(3), 423.578(c)(4), and Chapter 18, Sections 130 and 30.2 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).
- 5. Sponsor failed to issue Notices of Medicare Non-Coverage (NOMNCs) at least 2 days prior to beneficiaries' Comprehensive Outpatient Rehabilitation Facility (CORF) or Home Health Agency (HHA) services ending, and/or 2 days prior to termination of Skilled Nursing Facility (SNF) services. As a result, beneficiaries received denials for services that were provided after the date the NOMNC should have been provided. This deficiency violates 42 CFR § 422.624(b)(1), and Chapter 13, Section 90.5, Paragraph 1 of the Medicare Managed Care Manual (IOM Pub. 100-16).

## **Basis for Civil Money Penalty**

Pursuant to 42 C.F.R. § 422.752(c)(1), § 422.760(b), § 423.752(c)(1), and § 423.760(b), CMS has determined that Health Partners' 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. Health Partners failed substantially:

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

#### Right to Request a Hearing

Health Partners may appeal CMS's determination by requesting a hearing in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Health Partners must send a written request for a hearing to the Departmental Appeals Board office listed below within 60 calendar days from receipt of this notice or by January 23, 2017. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Health Partners disagrees. Health Partners must also specify the basis for each contention that the finding or conclusion of law is incorrect. The request should be sent to:

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

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

John A. Scott
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: John.Scott@cms.hhs.gov

If Health Partners Plans, Inc. 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 24, 2017. Health Partners Plans, Inc. 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.

Please note that further failures by Health Partners Plans, Inc. may result in the imposition of additional remedies available under law, up to and 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 Health Partners Plans, Inc. has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

Gerard J. Mulcahy Director Medicare Parts C and D Oversight and Enforcement Group

cc: James McCaslin, CMS/ CMHPO/Region III
Ruth Lande-Rogers, CMS/ CMHPO/Region III
John Whalen CMS/ CMHPO/Region III
John Scott, CMS/CM/MOEG/DCE
Kevin Stansbury, CMS/CM/MOEG/DCE
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