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 22, 2016

Mr. Steve Nelson
CEO
UnitedHealthcare Medicare & Retirement
9800 Health Care Lane
Minnetonka, MN 55343

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

Dear Mr. Nelson:

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 notifying UnitedHealth Group, Inc. (UnitedHealth) that it imposing a civil money penalty (CMP) in the amount of **$2,498,850** for 56 of UnitedHealth's Medicare Advantage-Prescription Drug (MA-PD) and Prescription Drug Plan (PDP) contracts (see the attached list of contract numbers).

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 UnitedHealth failed to meet that responsibility.

Summary of Noncompliance

CMS conducted an audit of UnitedHealth's Medicare operations from May 2, 2016 through May 13, 2016. In a program audit report issued on October 31, 2016, CMS auditors stated that UnitedHealth failed to comply with Medicare requirements related to Part D formulary, benefit administration, and coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. UnitedHealth's 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 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.

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 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.

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 in certain situations. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan. 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 or quantity limits). In the long-term care setting, the temporary supply must be for at least 91 days and up to 98 days, with refills provided if needed. 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.

Violations Related to Formulary & Benefit Administration

CMS identified violations of Part D formulary and benefit administration requirements that resulted in UnitedHealth's enrollees experiencing inappropriate denials of and/or delayed access to Part D prescription drugs at the point of sale. UnitedHealth's violations include:

1. Failure to properly administer the CMS transition policy. Enrollees experienced inappropriate denials of coverage for drugs at the point of sale and were delayed access to medications, never received the medications, or incurred increased out-of-pocket costs in order to receive the medications. Some of the denials were for prescription drugs that are used to treat acute conditions that require immediate treatment. The failure violates 42 C.F.R. § 423.120(b)(3) and Chapter 6, Section 30.4.4.1 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

2. Failure to properly administer its CMS-approved formulary by applying unapproved utilization management requirements. Enrollees experienced inappropriate denials of coverage for drugs at the point of sale and were delayed access to medications, never received the medications, or incurred increased out-of-pocket costs in order to receive the medications. Some of the denials were for prescription drugs that are used to treat acute conditions that require immediate treatment. This failure violates 42 C.F.R. § 423.120(b)(2) and Chapter 6, Section 30.2.2.1 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

3. Failure to properly administer its CMS-approved formulary by applying unapproved prior authorization edits for protected-class medications during the transition phase. Enrollees experienced inappropriate denials of coverage for drugs at the point of sale and were delayed access to medications, never received the medications, or incurred increased out-of-pocket costs in order to receive the medications. Some of the denials were for prescription drugs that are used to treat acute conditions that require immediate treatment. This failure violations 42 C.F.R. § 423.120(b)(2) and Chapter 6, Section 30.2.5 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

Part D Coverage Determination, Appeal, and Grievance Requirements
(42 C.F.R. Part 423, Subpart M; Chapter 18 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18))

Medicare enrollees have the right to contact their plan sponsors to express general dissatisfaction with the operations, activities, or behavior of the plan sponsors, or to make specific complaints about denials of coverage for drugs to which the enrollees believe they are entitled. Sponsors are

required to classify general complaints about benefits or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for drugs as coverage determinations. It is critical for a sponsor to properly classify each complaint as a grievance, coverage determination, or both. Improper classification of a coverage determination denies an enrollee of his or her due process and appeal rights, and may delay an enrollee's access to medically necessary or life-sustaining drugs.

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or other prescriber may request a coverage determination. The sponsor is responsible for processing the coverage determination request, making a decision, and providing notice of the decision in accordance with CMS rules. If the 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 redetermination, is handled by the sponsor and must be conducted by a person who was not involved in the coverage determination decision. If the original denial was based on a lack of medical necessity, the redetermination must be performed by a physician who was not involved in the coverage determination decision. If a redetermination decision is not in an enrollee's favor, the enrollee may file an appeal with an independent review entity (IRE) that contracts with CMS. If a sponsor does not make and provide notice of a coverage determination or redetermination decision timely, the sponsor must automatically forward the request to the IRE for processing.

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

CMS identified one violation of the Part D coverage determination, appeal, and grievance requirements that resulted in some of UnitedHealth's enrollees inappropriately experiencing denied and/or delayed access to Part D prescription drugs:

4. Failure to effectuate exception approvals through the end of the plan year. Enrollees would receive inappropriate denials at the point of sale when refills were requested, which would result in delayed access to medications, never receiving the medications, or incurring increased out-of pockets costs in order to receive the medications. The failure violates 42 C.F.R. §§ 423.578(c)(3) and 423.578(c)(4), and Chapter 18, Sections 30.2 and 130 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

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 UnitedHealth's violations of CMS' Parts C and D requirements directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees and warrants the imposition of a CMP. UnitedHealth 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. § 423.509(a)(4)(ii)).

Right to Request a Hearing

UnitedHealth 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. UnitedHealth 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 UnitedHealth disagrees. UnitedHealth 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 UnitedHealth 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. United 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 UnitedHealth 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 UnitedHealth 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: Ann Duarte, CMS/ CMHPO/Region IX
Deanna Gee, CMS/CMHPO/Region IX
Nicole Edwards, CMS/CMHPO/Region IX
Arthur Pagan, CMS/ CMHPO/Region VI
April Forsythe, CMS/CMHPO/Region VI
Marlon Bankston, CMS/CMHPO/Region VI
Heather Lang, CMS/ CMHPO/Region V
Lisa Riley, CMS/CMHPO/Region V
Carlest Jenkins, CMS/CMHPO/Region V
John Scott, CMS/CM/MOEG/DCE
Kevin Stansbury, CMS/CM/MOEG/DCE
Leila Zaharna, CMS/CM/MOEG/DCE

Attachment

UnitedHealth Contracts Associated with the Civil Money Penalty:
H0151, H0251, H0294, H0321, H0408, H0543, H0609, H0624, H0710, H0755, H1045, H1111, H1286, H1537, H1944, H2001, H2226, H2228, H2406, H2531, H2654, H2802, H2905, H2931, H3107, H3113, H3307, H3379, H3387, H3749, H3794, H3805, H4514, H4527, H4590, H4604, H5008, H5253, H5322, H5420, H5435, H5652, H6528, H7187, H7833, H8748, R3175, R3444, R5287, R5342, R6801, R7444, R9896, S5805, S5820, and S5921.