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

February 6, 2018

Mr. Mostafa Kamal
Chief Executive Officer
Merit Health Insurance Company
77 Water Street, Suite 811
New York, NY 10005

Re: Notice of Imposition of Civil Money Penalty for Prescription Drug Plan Contract Number: S4607

Dear Mr. Kamal:

Pursuant to 42 C.F.R. §§ 423.752(c)(1) and 423.760(b), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Merit Health Insurance Company (Merit) that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **$1,368,200** for Prescription Drug Plan (PDP) Contract Number (S4607).

A PDP's primary responsibility is to provide Medicare beneficiaries with prescription drug benefits in accordance with Medicare requirements. CMS has determined that Merit failed to meet that responsibility.

Summary of Noncompliance

CMS conducted two audits of Merit's Medicare operations from April 17, 2017 through May 1, 2017 and again September 5, 2017 through September 14, 2017. In program audit reports issued on August 9, 2017 and November 20, 2017, CMS auditors reported that Merit failed to comply with Medicare requirements related to Part D formulary and benefit administration and coverage determinations, appeals, and grievances in violation of 42 C.F.R. Part 423, Subparts C and M. Merit'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, increased out-of-pocket costs, and/or inadequate grievance or appeal rights.

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.

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 determined that Merit violated the following Part D formulary and benefit administration requirement(s):

1. Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits. As a result, enrollees experienced inappropriate denials of coverage at the point of sale which impeded their access to prescription medications. Enrollees may have experienced delays in access to medications, never received the medications, or paid out-of-pocket costs in order to receive their medications. Some of the prescription drugs denied are used to treat acute conditions that require immediate treatment This deficiency violates 42 CFR § 423.120(b)(2); Chapter 6, Appendix C, Sections 30.2, 30.2.2, 30.2.2.1, 30.2.2.3, 30.2.5, 30.3.3.1, and 30.3.3.3 and Chapter 7, Section 60.6 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

2. Failure to properly administer the CMS transition policy and failure to provide new enrollees transition supplies of medications with CMS-approved quantity limits. As a result, enrollees experienced inappropriate denials of coverage at the point of sale, which impeded their access to prescription medications. 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 § 423.120(b)(3); Chapter 6, Sections 30.4, 30.4.1, 30.4.10, 30.4.10.1, 30.4.2, 30.4.3, 30.4.4, 30.4.4.1, 30.4.4.2, 30.4.4.3, 30.4.5, and 30.4.8 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

3. Failure to properly administer its CMS-approved formulary by applying unapproved utilization management practices. As a result, enrollees experienced inappropriate denials of coverage at the point of sale, which impeded their access to prescription medications. 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(a) and 423.120(b)(2); Chapter 6, Sections 30.2, 30.2.2.1, 30.2.2.3, 30.2.5, 30.3.3.1, and 30.3.3.3 and Chapter 7, Section 20.4 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18); and Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare

Advantage and Part D Payment Policies and Final Call Letter Memo, pages 146-147, Health Plan Management System (HPMS), April 1, 2013

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))

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, or to make a specific complaint about the denial of coverage for drugs to which the enrollee believes he or she is entitled to receive. 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 may result in enrollees not receiving the required level of review, and/or experiencing delayed access to medically necessary or life-sustaining drugs.

The first level of review is the coverage determination, which is conducted by the plan sponsor. The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for a coverage determination. If the coverage determination is adverse (i.e., not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of appeal - called a redetermination – is handled by the plan sponsor and must be conducted by a person who was not involved in the coverage determination decision. The second level of appeal is made to an independent review entity (IRE) that contracts with CMS.

There are different decision making timeframes for the review of coverage determinations and appeals. If the sponsor does not issue the coverage determination or reconsideration decision timely, the decision is considered to be unfavorable to the enrollee and must be automatically sent to the IRE.

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

CMS determined that Merit violated the following Part D coverage determination, appeal, and grievance requirement(s):

1. Failure to demonstrate sufficient outreach to prescribers or enrollees to obtain additional information necessary to make appropriate clinical decisions. As a result, enrollees may have experienced inappropriate denials of coverage due to insufficient provider outreach. This deficiency violates 42 CFR §§ 423.566(a), 423.578, and 423.586; Chapter 18, Sections 10.2, 30.2.2.3, 30.3.2, 40.2, 70.5 and 70.7 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

2. Misclassified coverage determination requests as grievances and/or customer service inquiries. As a result, enrollees' access to the coverage determination and/or appeals process was impeded, which had the substantial likelihood of causing delays or denials in access to medications. This deficiency violates 42 CFR § 423.564(b);

Chapter 18, Sections 20.2, 20.2.4.1, 20.2.4.2 and 30.4 of the Medicare Prescription Drug Benefit Manual (IOM Pub. 100-18).

3. Failure to auto-forward coverage determinations and/or redeterminations (standard and/or expedited) that exceeded the CMS required timeframe to the Independent Review Entity (IRE) for review and disposition. As a result, enrollees experienced delayed access to the appeal process and may have experienced inappropriate delays or denials of medications. This deficiency violates 42 C.F.R. §§ 423.568(h), 423.572(d), 423.578(c)(2), 423.590(c), and 423.590(e); 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).

Right to Request a Hearing

Merit 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. Merit must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by April 9, 2018. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Merit disagrees. Merit 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 Merit 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 April 10, 2018. Merit 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 Merit's Past Performance calculations. For Past Performance, your organization will receive one negative past performance point.

Further failures by Merit 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 Merit 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: Heather Lang, CMS/CMHPO/Region V
Raymond Swisher, CMS/CMHPO/Region V
Timothy Lape, CMS/CMHPO/Region V
Kevin Stansbury, CMS/CM/MOEG/DCE