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 24, 2016

EMAIL: LSUYENAGA@CENTRALHEALTHPLAN.COM

Lee Suyenaga
Chief Executive Officer
AHMC Central Health LLC
1540 Bridgegate Drive
Diamond Bar, CA 91765

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Number: H5649

Dear Lee Suyenaga:

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 Central Health Plan of California, Inc. (AHMC) that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$153,850** for Medicare Advantage-Prescription Drug (MA-PD) Contract Number: H5649

CMS has determined that AHMC failed to provide its enrollees with Medicare benefits in accordance with CMS requirements. An MA-PD oganization's central mission is to provide Medicare enrollees with medical services and prescription drug benefits within a framework of Medicare requirements that provide enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit of AHMC operations from August 17, 2015 through August 28, 2015. In a program audit report issued on January 14, 2016, CMS auditors reported that AHMC 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 in violation of 42 C.F.R. Part 422, Subpart M and 42 C.F.R. Part 423, Subparts C and M. AHMC's failures in these areas were systemic and resulted in enrollees experiencing inappropriate delays or denials in receiving covered benefits and 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 sponsors that offer prescription drug benefits. Sponsors of these plans (Part D Sponsors) are required to enter into an agreement with CMS by which the sponsor agrees to comply with a number of requirements based upon statute, regulations, and program instructions.

Formulary
(42 C.F.R. §§ 423.120(b)(2)(iv) and 423.120(b)(4)-(6); Internet Only Manual (IOM) Pub.100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.3)

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. A Part D sponsor can change its formulary mid-year, but in order to do so must first obtain prior CMS approval, and then notify its enrollees of any changes, in addition to changes in cost-sharing amounts for formulary drugs. The CMS formulary review and approval process includes a review of the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims).

Utilization Management Techniques
(42 C.F.R. § 423.272(b)(2); IOM Pub.100-18, Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2; Health Plan Management System (HPMS) Memo, CMS Part D Utilization Management Policies and Requirements Memo, October 22, 2010)

Prior authorization is a utilization management technique used by Part D sponsors (as well as commercial and other health insurers) that requires enrollees to obtain approval from the sponsor for coverage of certain prescriptions prior to being dispensed the medication. Part D enrollees can find out if prior authorization is required for a prescription by asking their physician or checking their plan's formulary (which is available online). 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. A quantity limit may be placed on a medication as a safety edit based on FDA maximum daily dose limits. Quantity limits may also be placed on a drug for dosage optimization, which helps to contain costs.

In addition, Part D sponsors (as well as commercial and other health insurers) use step therapy to ensure that when enrollees begin drug therapy for a medical condition, the first drug chosen is cost-effective and safe and other more costly or risky drugs are only prescribed if they prove to be 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) and IOM Pub.100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4)

Additionally, a Part D sponsor must provide for an appropriate transition process for enrollees prescribed any Part D drugs that are not on its formulary in certain designated situations. A Part D Sponsor's transition process must address situations in which an individual brings a prescription for a drug that is not on the formulary to a participating pharmacy. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Part D sponsors must have systems capabilities that allow them to provide a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or quantity limits under a sponsor's utilization management rules). In the long-term care setting, the temporary supply of non-formulary Part D drugs must be for at least 91 days, and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed. The transition process is designed to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

Violations Related to Formulary & Benefit Administration

CMS identified violations of Part D formulary and benefit administration requirements that resulted in AHMC's enrollees being denied coverage at the point of sale. AHMC's violations include:

1. Failure to properly administer the CMS transition policy. As a result, enrollees experienced inappropriate denials of coverage for drugs at the point of sale and were delayed access to their drugs, never received their drugs, or incurred increased out-of-pocket expenses in order to receive their drugs. This is in violation of 42 C.F.R § 423.120(b)(3); IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.4.1, 30.4.10, 30.4.4.2, 30.4.4, 30.4.4.1, 30.4.4.3, 30.4.5, and 30.4.8.

2. Failure to properly administer the CMS approved formulary by applying unapproved quantity limits. As a result, enrollees experienced inappropriate denials of coverage for drugs at the point of sale and were delayed access to their drugs, never received their drugs, or incurred increased out-of-pocket expenses in order to receive their drugs. This is in violation of 42 C.F.R § 423.120(b)(2); IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.2.2.1; Medicare Prescription Drug Benefit Manual, Chapter 7, Section 60.6.

Part C and Part D Organization/Coverage Determination, Appeal, and Grievance Relevant Requirements
(42 C.F.R. Part 422, Subpart M; 42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18; IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13)

Medicare enrollees have the right to contact their plan sponsor to express general dissatisfaction with the operations, activities, or behavior of the plan sponsor or to make a specific complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled. Sponsors are required to classify general complaints about services, benefits, or the sponsor's operations or activities as grievances. Sponsors are required to classify complaints about coverage for drugs or services as organization determinations (Part C – medical services) or coverage determinations (Part D – drug benefits). It is critical for a sponsor to properly classify each complaint as a grievance or an organization/coverage determination or both. Improper classification of an organization or coverage determination denies an enrollee the applicable due process and appeal rights and may delay an enrollee's access to medically necessary or life-sustaining services or drugs.

The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination or coverage determination. The first level of review is the organization determination or coverage determination, which is conducted by the plan sponsor, and the point at which beneficiaries or their physicians submit justification for the benefit.

If the organization or coverage determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. The first level of the appeal – called a reconsideration (Part C) or redetermination (Part D) – is handled by the plan sponsor and must be conducted by a physician who was not involved in the organization determination or coverage determination decision. The second level of appeal is made to an independent review entity (IRE) contracted by CMS.

There are different decision making timeframes for the review of organization determinations, coverage determinations, and appeals. CMS has a beneficiary protection process in place that requires plans to forward coverage determinations and appeals to the IRE when the plan has missed the applicable adjudication timeframe.

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

CMS identified violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in AHMC's enrollees being inappropriately delayed or denied access to medical services and/or drugs. AHMC's violations include:

3. Misclassified coverage determinations and appeals requests as grievances and/or customer service inquiries. As a result, enrollees' requests were not processed with the correct adjudicatory time requirements and appeal rights, which likely resulted in delays in receiving a coverage decision or the inability to appeal adverse decisions. This is in violation of 42 C.F.R § 423.564(b); IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 20.2, 20.2.4.1, 20.2.4.2, and 30.4.

4. Failure to make appropriate clinical decisions when processing pre-service organization determinations. As a result, enrollees experienced the substantial likelihood of being inappropriately delayed and/or denied access to medical care and/or financial hardship. This is in violation of IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Sections 10.2, Paragraph 3 and 40.1.1.

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 AHMC 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. AHMC 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));
- 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

AHMC 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. AHMC 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 April 25, 2016. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which AHMC disagrees. AHMC 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:

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

If AHMC 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 26, 2016. AHMC 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 AHMC may result in additional applicable remedies available under law, up to and including contract termination, the imposition of intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

If AHMC 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: Vikki Ahern, CMS/CM/MOEG/DCE
Kevin Stansbury, CMS/CM/MOEG/DCE
Roya Rezai, CMS/ CMHPO/Region X
Vashiti Whissiel Wren, CMS/ CMHPO/Region X
Brenda Suiter, CMS/ CMHPO/Region IX
Annie Shieh, Sponsor Medicare Compliance Officer