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 29, 2016

Mr. Jay Gellert
Chief Executive Officer
Health Net, Inc.
21650 Oxnard Street, 21st Floor
Woodland Hills, CA 91367

Jay.M.Gellert@healthnet.com

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug
Contract Numbers: H0351, H0562, H3237, H5439, H5520 and H6815

Dear Mr. Gellert:

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 Net, Inc. (Health Net), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$458,250** for Medicare Advantage-Prescription Drug (MA-PD) Contract Numbers: H0351, H0562, H3237, H5439, H5520 and H6815.

CMS has determined that Health Net 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 Health Net's Medicare operations from October 5, 2015 through October 19, 2015. In a program audit report issued on February 26, 2016, CMS auditors reported that Health Net failed to comply with Medicare requirements related to Part D formulary and benefit administration and Part C and 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. Health Net'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.

Violations Related to Formulary & Benefit Administration

CMS identified a violation of Part D formulary and benefit administration requirements that resulted in Health Net's enrollees being delayed and/or denied access to covered-drugs. Health Net's violation includes:

1. Failure to properly administer its CMS-approved formulary by applying unapproved utilization management practices. 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. §§ 423.104(a) and 120(b)(2); IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.3.3.3; IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 7, Section 20.4; Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter Memo, pages 143–147, HPMS, April 1, 2013; and CMS Part D Utilization Management Policies and Requirements Memo, HPMS, October 22, 2010, page 2–3.

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 Health Net's enrollees being delayed and/or denied access to medical services and/or drugs, and experiencing the substantial likelihood of inappropriate out-of-pocket expenses. Health Net's violations include:

2. Failure to conduct sufficient outreach to prescribers to obtain additional information necessary to make appropriate clinical decisions. As a result, enrollees' requests for coverage decisions had the substantial likelihood of being inappropriately denied because Sponsor failed to conduct sufficient outreach to prescribers to obtain additional information needed to process the case. This is in violation of 42 C.F.R. §§ 423.566(a), 578 and 586; and Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 10.2, 30.2, 70.5, 70.7 and 70.8.

3. Failure to notify enrollees, or providers, of its decision within 72 hours after receipt of expedited reconsideration requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions for pre-service appeals for medical services that required expedited review. This is in violation of 42 CFR § 422.590(d)(1) and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Section 80.1, Paragraph 3.

4. Failure to notify enrollees, or providers, of its decisions within 30 days after receipt of standard pre-service reconsideration requests. As a result, enrollees experienced unnecessary delays in receiving coverage decisions for medical services that required pre-service reviews. This is in violation of 42 CFR §§ 422.590(a)(1), 590(a)(2) and 618(a)(1); and IOM Pub 100-16, Medicare Managed Care Manual, Chapter 13, Section 70.7.1, Paragraph 1.

5. Inappropriately denied payments to providers for services rendered to enrollees. As a result, enrollees may experience financial harm and be held responsible for the charges by the provider, especially in cases where the providers were not given a sufficient explanation of their appeal rights. This is in violation of 42 CFR §§

422.101(a) and 101(b); and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 4, Sections 10.2 and 10.4.

6. Inappropriately dismissed pre-service and claims requests prior to the conclusion of the appeal timeframe. As a result, enrollees experienced the substantial likelihood of being inappropriately delayed and/or denied access to medical care and/or financial hardship as a result of their pre-service and claims requests being prematurely dismissed. This is in violation of IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Sections 10.4.1, Paragraph 8 and 60.1.1.

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 Health Net'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. Health Net 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 Net 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. Health Net 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 29, 2016. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Health Net disagrees. Health Net 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
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-07
Email: Vikki.Ahern@cms.hhs.gov

If Health Net 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 May 2, 2016. Health Net 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 Net 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 Health Net 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: Brenda Suiter, CMS/ CMHPO/ Region X
Roya Rezai, CMS/ CMHPO/Region X
Bella Roytberg, CMS/ CMHPO/Region X
Kristin Sugarman-Coats, CMS/CMHPO/Region IX
Vikki Ahern, CMS/CM/MOEG/DCE
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