DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

MEDICARE PARTS C & D OVERSIGHT AND ENFORCEMENT GROUP

April 24, 2014

VIA EMAIL: (SoistmanF@Aetna.com**)**

Mr. Francis Soistman
Executive Vice President and Head of Government Services
Aetna, Inc.
151 Farmington Avenue
Hartford, CT 06156
Phone: 860-273-4158

Re: Notice of Imposition of Civil Money Penalty for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H0318, H0523, H0901, H1109, H1110, H1419, H2112, H3152, H3312, H3597, H3623, H3931, H4523, H4524, H4910, H5414, H5521, H5793, H5813, H5832, H5950, H6923, H7908, H8684, S5810

Dear Mr. Soistman:

Pursuant to 42 C.F.R. § 422.752(c)(1) and § 423.752(c)(1), the Centers for Medicare & Medicaid Services (CMS) is providing notice to Aetna, Inc. (Aetna), that CMS has made a determination to impose a civil money penalty (CMP) in the total amount of **$101,500** for violations found in the following Medicare Advantage-Prescription Drug (MA-PD) and Prescription Drug Plan (PDP) contracts: H0318, H0523, H0901, H1109, H1110, H1419, H2112, H3152, H3312, H3597, H3623, H3931, H4523, H4524, H4910, H5414, H5521, H5793, H5813, H5832, H5950, H6923, H7908, H8684, and S5810.

CMS has determined that Aetna failed to provide its enrollees with benefits in accordance with CMS requirements. A Medicare Advantage Organization or Prescription Drug Plan sponsors' central mission is to provide Medicare beneficiaries with medical services and prescription drug benefits within a framework of Medicare requirements that provide plan enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit of Aetna's Medicare Part C and D operations from August 5, 2013 through August 9, 2013. During the audit, CMS conducted reviews of Aetna's operational areas to determine if Aetna was following CMS rules, regulations, and guidelines. CMS auditors reported that Aetna failed to comply with Medicare requirements related to Part D formulary and benefit administration, Part C and Part D coverage/organization determinations, appeals, and

grievances in violation of 42 C.F.R. Part 422, Subparts M and F and 42 C.F.R. Part 423, Subparts C and M. CMS found that Aetna's failures in these areas were widespread and systemic and resulted in enrollees experiencing inappropriate delays or denials in receiving covered medical services or prescription drugs, and/or increased out of pocket costs. These violations directly adversely affected (or had the substantial likelihood of adversely affecting) Aetna's enrollees.

Formulary and Benefit Administration 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 a contract 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, including any 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 prescribed 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 a 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 help to contain costs.

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 and Transition of Coverage

CMS identified serious violations of Part D requirements in Aetna's formulary and benefit administration operations. Aetna's violations include:

- Failure to properly administer its CMS-approved formulary by applying unapproved prior authorization edits. This is in violation of 42 C.F.R. § 423.120(b)(2) and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2, 30.2.2, and 30.2.2.1.

- Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits. This is in violation of 42 C.F.R. § 423.120(b)(2) and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.2.2.1, and Chapter 7, Section 60.6.

Part C and Part D Grievance, Organization Determination, Coverage Determination, and Appeal 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 service or 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 Grievances, Organization Determinations, Coverage Determinations and Appeals

CMS identified serious violations of Part C and Part D requirements in the processing of grievances, organization determinations, coverage determinations, and appeals. Aetna's violations include:

- Failure to properly effectuate prior authorizations or exception requests. This is in violation of 42 C.F.R. § 423.120(b)(2); § 423.578(c)(3-4); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2 and Chapter 18, Sections 30.2 and 130.

- Failure to notify, effectuate and process organization determinations in a timely manner. This is in violation of 42 C.F.R. § 422.572(a) and IOM Pub 100-16 Medicare Managed Care Manual, Chapter 13, Sections 40.1, Paragraph 1, 50.1, Paragraph 1, Bullet 3, and 50.4, Paragraph 1, Bullet 1.

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. § 422.752(c) and § 423.752(c), CMS has determined that Aetna's violations of Parts C and D requirements are significant enough to warrant the imposition of a CMP. In violating Parts C and D requirements, Aetna failed substantially to carry out the terms of its MA-PD and PDP contracts with CMS and failed to carry out its contracts with CMS in a manner consistent with the effective and efficient implementation of the program. 42 C.F.R § 422.510 (a)(1) and (2) and § 423.509(a)(1) and (2). Aetna's violations directly adversely affected (or had the substantial likelihood of adversely affecting) enrollees. 42 C.F.R § 422.760 (b) and § 423.760(b).

Right to Request a Hearing

Aetna 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. Aetna 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 June 24, 2014. 42 C.F.R. § 422.1006, § 423.1006, § 422.1020 and § 423.1020. The request for hearing must identify the specific issues and the findings of fact and conclusions of law with which Aetna disagrees. Aetna 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:

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

If Aetna 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 June 25, 2014. Aetna may choose to have the penalty deducted from its monthly payment, transfer the funds electronically, or mail a check to CMS.

Please note that further failures by Aetna 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 Aetna 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 & D Oversight and Enforcement Group

cc: Mr. Tod Anderson, CMS/CMHPO, Region VIII
Ms. Anne Kane, CMS/CMHPO, Region VIII
Mr. Don Marik, CMS/CMHPO, Region VIII