DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Drug and Health Plan Choice
7500 Security Boulevard, Mail Stop C4-23-07
Baltimore, Maryland 21244-1850

April 5, 2010

VIA:
FEDERAL EXPRESS DELIVERY
EMAIL (McCauleyFG@aetna.com)
AND FACSIMILE (1-860-273-2908)

Mr. Frank McCauley
CEO, Senior Official for Contracting
Aetna Life Insurance Company
151 Farmington Avenue RT 11
Hartford, CT 06156
Phone: 860-273-2576

Re: Notice of Intent to Impose Intermediate Sanctions (Suspension of Enrollment and Marketing) For All Medicare Advantage/Prescription Drug Contracts and All Standalone Prescription Drug Plan Contracts.

Dear Mr. McCauley:

Pursuant to 42 C.F.R. §422.756 and 42 C.F.R. §423.756, the Centers for Medicare & Medicaid Service (CMS) is hereby providing notice to Aetna Life Insurance Company (Aetna) of the imposition of intermediate sanctions for contract numbers: H0318, H0523, H0901, H1109, H1110, H1419, H2112, H3152, H3312, H3597, H3623, H3931, H4523, H4524, H4910, H5414, H5521, H5736, H5793, H5813, H5832, H5950, H6923, H7908, H8684 and S5810.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries (42 C.F.R. §422.750(a)(1), 42 C.F.R. §423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. §422.750(a)(3), 42 C.F.R. §423.750(a)(3)). This determination to impose intermediate sanctions will be effective 15 calendar days after the date of this notice, or on April 21, 2010, and will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur.

Summary of Noncompliance

Transition Process

Aetna went from an open formulary in contract year 2009 to a closed formulary in contract year 2010 for many of its plan benefit packages (PBPs). This move from an open formulary to one that is closed resulted in the removal of certain drugs from its formulary, as well as the imposition of Drug Utilization Management (D.U.M.) requirements on drugs where it had not previously been required.

In accordance with CMS regulations and guidelines, Aetna was required to effectuate a meaningful transition for current enrollees from the old formulary to the new formulary prior to the start of the 2010 contract year. This meaningful transition includes the receipt of a claim for an on formulary drug or the processing of a drug formulary exception request. While Aetna notified members of changes in drug coverage via their Annual Notice of Coverage (ANOC), they failed to aggressively work to effectuate this transition for their current enrollees prior to January 1, 2010 in violation of 42 CFR § 423.120(b)(3) and sections 30.4.1 and 30.4.5 of Chapter 6 of the Prescription Drug Benefit Manual. For example, in the first 2 months of 2010, there were approximately 15,000 to 20,000 members affected by this non-compliance, with approximately 135,000 prescription denials due to the failure to properly effectuate the formulary transition. Aetna's failure to furnish transition fills affected all of Aetna's contracts and all existing members who were stabilized on drugs in 2009 that were no longer covered in 2010. The Aetna transition problems implicated drugs from multiple classes and categories including mental health, analgesia, hypertension, and bone metabolism, as well as others.

Additionally, Aetna compounded the transition problems by failing to implement a systems override that would have allowed a pharmacist to resolve the claim denial and provide the enrollee with a transition fill of their prescription. A review of Complaint Tracking Module (CTM) complaints demonstrated that beneficiaries continue to face incorrect denials of needed medications. These denials are leading to unacceptable delays in beneficiaries receiving access to their medications. For example, a beneficiary called to complain on March 23, 2010 that she had been attempting to obtain her medications through Aetna for almost 30 days to no avail. This demonstrates that as of March 23, 2010 Aetna has not corrected the transition problems.

Coverage Determinations and Appeals

In January 2010, Aetna received roughly 40,000 exception requests from enrollees requesting they be allowed to stay on their current medications. According to Aetna, the move to a closed formulary, coupled with their increase in enrollment (i.e., new members who were switching from their old plan's formulary to Aetna's formulary and likewise requesting an exception) resulted in their inability to process exception requests timely.

The improper handling of the formulary exception requests resulted in a large number of requests for expedited determination. Under 42 CFR §423.570, Aetna must provide an expedited determination if the enrollee's physician states "that applying the standard timeframe for making a determination could seriously jeopardize the life or health of the enrollee." *(See 42 CFR §423.570(c)(2)(i)).* In those cases where an expedited determination is required, Aetna must make a decision "as expeditiously as the enrollee's health requires, but no later than 72 hours after receiving the request." *(See 42 CFR §423.568(a)).* In the majority of these cases, Aetna failed to meet the adjudication timeframes specified in 42 CFR §423.568(a). As a result, these exception cases were auto-forwarded to CMS' independent review entity (IRE), Maximus. In the month of January 2010, Aetna accounted for 43.5% of the auto-forwarded cases and from February 1, 2010 to February 15, 2010, Aetna accounted for 61.17% of the auto-forwarded cases. In the majority of these cases (approximately 80%) Aetna failed to send the complete case file to Maximus, which is required by section 40.4 in chapter 18 of the Prescription Drug Benefit Manual and is needed for Maximus to complete their reconsideration.

A review of CTM complaints revealed that despite Aetna's assertions that appeals and coverage determination deficiencies are being corrected, the deficiencies persist. For example, on March 30, 2010, a beneficiary complained that she had appealed Aetna's denial of her existing prescription and had, in fact, requested an expedited appeal with Maximus. Maximus overturned Aetna's decision on March 24, 2010. Aetna is required to effectuate this decision within 72 hours, or by March 27, 2010. As a result of the member complaint, Aetna researched the complaint and did not affect payment until April 1, 2010 which is 4 days past the regulatory deadline. These deficiencies continue to cause unacceptable delays in Medicare enrollees obtaining access to needed medications.

Unapproved Prior Authorization (PA) and Step Therapy (ST)

Part D plan sponsors must submit their formulary to CMS for review and approval, including their DUM edits, such as any PA and ST edits, as is required by 42 C.F.R. §423.120. Administration of a formulary or use of edits not approved by CMS is in direct violation of CMS' requirements. A review of Aetna's website revealed that they have not only listed PA and ST requirements for drugs that were not approved by CMS, but also for drugs that were not on their CMS approved formulary. These deficiencies further demonstrate that Aetna does not have sufficient management controls to determine if they are in compliance with above-referenced CMS requirements. As a result, CMS cannot be assured that Aetna is complying with the Part D requirements. Therefore, CMS will continue to analyze available data regarding claims denials and continue to monitor Aetna's compliance efforts to ensure that enrollees are provided access to needed medications as required by CMS.

Best Available Evidence (BAE)

Aetna also failed to follow section 70.5.2 of chapter 13 of the Prescription Drug Benefit Manual by failing to accept and properly process Best Available Evidence (BAE) documentation from LIS beneficiaries within the required timeframe.
The BAE policy involves the use of data to establish a beneficiary's eligibility and cost-sharing level for the Medicare Part-D low-income subsidy (LIS). Section 70.5.2 of Chapter 13 of the Prescription Drug Benefit Manual states that Part D sponsors will be required to update their systems within 48-72 hours of their receipt of BAE documentation. The requirement that Part D sponsors update their systems within 48-72 hours is in addition to the requirement that Part D sponsors provide access to covered Part D drugs as soon as BAE is presented to them.

Conclusion

CMS concludes that Aetna has demonstrated a substantial failure to comply with important Part D requirements that are critical to protecting the health of its Medicare Prescription Drug Plan (PDP) enrollees. This substantial noncompliance has resulted in significant impediments to enrollees' ability to promptly access needed Part D drugs, and potentially puts Aetna's current and future enrollees' health at risk. Among other findings of non-compliance, Aetna has: (1) failed to ensure that beneficiaries taking a drug that is not on Aetna's new formulary receive continued coverage of the drug under Part D transition requirements in violation of 42 C.F.R. 423.120(b)(3); and (2) failed to adhere to required coverage determination timeframes pursuant to 42 C.F.R. §§ 423.568(a) and 423.572(d) intended to ensure prompt enrollee access to needed drugs.

Basis of Intermediate Sanctions

CMS has determined that Aetna's compliance deficiencies, as described above, provide sufficient basis for the imposition of intermediate sanctions (42 C.F.R. §422.752(b) and 42 C.F.R. §423.752(b)).

CMS' determination to impose intermediate sanctions is based on the following regulatory bases for the imposition of intermediate sanctions, each of which provides an independent basis for the imposition of an intermediate sanction, and which are supported by examples of Aetna's noncompliance, as described below:

Aetna substantially failed to carry out the terms of its MA Organization and Prescription Drug Plan contracts with CMS (42 C.F.R. §422.510(a)(1) and 42 C.F.R. §423.509(a)(1)).

- Aetna failed to aggressively work to ensure meaningful transition to its existing members to their 2010 formulary prior to January 1, 2010 in violation of 42 CFR

§ 423.120(b)(3) and sections 30.4.1 and 30.4.5 of Chapter 6 of the Prescription Drug Benefit Manual.

- Aetna failed to properly provide for transition fills of current medications as required under section 30.4.5 of Chapter 6 of the Prescription Drug Benefit Manual.
- Aetna's non-compliance with transition fill requirements improperly delayed therapies and/or prevented access to medically necessary drugs and therapies. Aetna's delaying and/or preventing access to these types of drugs results in a failure to provide medically necessary services which adversely affects or has the substantial likelihood of adversely affecting enrollees.

Aetna is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program (42 C.F.R. §422.510(a)(2) and 42 C.F.R. §423.509(a)(2)).

- Aetna failed to accept and properly process BAE documentation from LIS beneficiaries within the required timeframe in violation of section 70.5.2 in Chapter 13 of the Prescription Drug Benefit Manual.

Aetna failed to comply with the requirements in subpart M of Part 423 related to appeals and grievances (42 C.F.R. §422.510(a)(6) and 42 C.F.R. §423.509(a)(6)).

- Aetna failed to adhere to requirements regarding timely coverage determinations on expedited PA requests. Additionally, Aetna subsequently failed to provide to CMS' independent review entity (IRE) with a complete case file as required by section 40.4 in chapter 18 of the Prescription Drug Benefit Manual.

Aetna failed to comply with the requirements in subpart C of part 423 related to qualified prescription drug coverage (42 C.F.R. §423.104(a)).

- Aetna has improperly listed on its website drugs that were not included in Aetna's 2010 CMS approved formulary.
- Aetna has improperly applied PA and Step therapy to drugs that were not included in Aetna's 2010 CMS approved formulary.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. §422.756(a)(2) and 42 C.F.R. §423.756(a)(2), Aetna has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or on April 16, 2010. If the 10th day falls on a weekend or federal holiday, you have until the next regular business day to provide a written rebuttal. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, or in this case, April 6, 2010. If you choose to submit a rebuttal, please send it to the attention of Brenda

J. Tranchida at the address noted below.

Right to Request a Hearing

Aetna may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§423.650 through 662. Pursuant to 42 C.F.R. §422.756(b) and 42 C.F.R. §423.756(b), your written request for a hearing must be received by CMS within 15 calendar days of your receipt of this notice, or by April 21, 2010. Please note, however, a request for a hearing will not delay the date specified by CMS when the sanction becomes effective. If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

Aetna must submit a request for hearing to the following CMS official:

Brenda J. Tranchida
Director, Program Compliance and Oversight Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
MAIL STOP: C1-22-06
Baltimore, MD 21244
Email: brenda.tranchida@cms.hhs.gov
FAX: 410-786-6301

You must also send a courtesy copy of your request by e-mail to the CMS Hearing Officer on the date you mail your request. CMS will consider the date the Office of Hearings receives your e-mail or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of your request. Your request for a hearing must include the name, fax number and e-mail address of the contact within your organization (or the attorney who has a letter of authorization to represent your organization) with whom you wish us to communicate regarding the hearing request. The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive, Suite L
Mail Stop LB-01-22
Baltimore, MD 20244-2670
Phone: (410) 786-3169

E-Mail: Benjamin.Cohen@cms.hhs.gov

Please note that we are closely monitoring your organization and Aetna may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Part 422, Subparts K and O and 42 C.F.R. Part 423, Subparts K and O. CMS believes these issues to be of such a serious nature that if left uncorrected, CMS will consider taking action to immediately terminate your contract.

If you have any questions about this determination, please do not hesitate to contact Jennifer Smith directly at (410) 786-1404 or jennifer.smith2@cms.hhs.gov.

Sincerely,

Brenda Tranchida
Director
Program Compliance and Oversight Group

cc: Mr. Jonathan Blum, CMS/CPC
Mr. Timothy Hill, CMS/CPC
Ms. Cynthia Tudor, CMS/CPC/MDBG
Ms. Jennifer Shapiro, CMS/CPC/MDBG
Ms. Judith Geisler, CMS/CPC/MDBG
Ms. Danielle Moon, CMS/CPC/MCAG
Ms. Heidi Arndt, CMS/CPC/MCAG
Mr. Thomas Hutchinson, CMS/CPC/MPPG
Mr. Randy Brauer, CMS/CPC/MPPG
Mr. Anthony Culotta, CMS/CPC/MEAG
Ms. Mary A. Laureno, CMS/OBIS
Mr. Peter Ashkenaz, CMS/OEA
Ms. Laura McWright, CMS/OL
Mr. Greg Jones, CMS/OL
Ms. Kimberly Brandt, CMS/OFM/PI
Mr. James Kerr, CMS/OA/CMHPO
Ms. Patricia Farris, CMS/CMHPO/Region I
Mr. Thomas Devins, CMS/CMHPO/Region I
Ms. Carol Bennett, DHHS/OGC
Ms. Leslie Stafford, DHHS/OGC
Ms. Jill Abrams, DHHS/OGC
Ms. Julie Burns, DHHS/OGC

Ms. Nancy Brown, DHHS/OIG/OCIG
Mr. Paul Collura, CMS/CMHPO
Mr. Benjamin Cohen, CMS/OA
Ms. Jennifer Smith, CMS/CPC/PCOG