

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



MEDICARE DRUG BENEFIT AND C & D DATA GROUP

CORRECTIVE ACTION REQUEST

July 17, 2012

Kristi A. Matus
Executive Vice President
Aetna Government Services
Aetna, Inc.
151 Farmington Avenue, Mail Code RC2A
Hartford, Connecticut 06156

Delivered via email to MatusK@aetna.com

Re: Corrective Action Plan – Formulary and Benefits Administration

Contract IDs: All

Dear Miss Matus,

The purpose of this letter is to request that Aetna, Inc. (hereinafter “Aetna”) submit a corrective action plan (CAP) to the Centers for Medicare & Medicaid Services (hereinafter “CMS”) to address areas of non-compliance related to Part D Formulary and Benefits administration identified during CMS’ January – March 2012 audit of Aetna’s Medicare contract operations.

Recent Noncompliance History

On Monday April 5, 2010, CMS notified Aetna that it would be subjected to marketing and enrollment sanctions effective April 21, 2010, for failing to comply with numerous Part D requirements concerning formulary, transition fills, protected class drugs, drug utilization management (use of unapproved prior authorizations and step therapy) and claims adjudication. CMS conducted an on-site audit and inspection of Aetna’s Medicare Part C and D operations from April 6 to April 8, 2010. In addition to the aforementioned areas of noncompliance, CMS also discovered during the audit Aetna’s failure to continue (or “grandfather”) members’ eligibility for certain drugs from one plan year to the next appropriately.

On May 31, 2011 – June 1, 2011, CMS conducted an extensive review of Aetna's Part D operations to determine whether the non-compliance that had been the basis for the sanction had been corrected. CMS performed this review, referred to as "sanction validation exercises," by remotely accessing Aetna's prescription drug claims data system. During the sanction validation activities, CMS determined that Aetna had come sufficiently into compliance with Part D requirements to justify the release of the sanction. However, during the same review, CMS found a number of new deficiencies in the areas of mail order to specialty pharmacy, grandfathering, high cost edits, and drug utilization management. While the discovery of these deficiencies did not prevent CMS from releasing Aetna from sanctions, CMS did determine that all of the deficiencies merited corrective action. CMS issued a notice to Aetna on June 16, 2011, detailing each deficiency and the corrective action required to come into compliance.

As part of the same notice, CMS noted that it could not conduct a mid-year evaluation of Aetna's correction of one of the bases of the sanction, the Part D formulary transition coverage requirements, as such coverage is normally needed only during the start of a plan benefit year. Aetna had previously disclosed to CMS that it had failed to update the records of 72,000 members in its system to indicate their eligibility to receive a transition supply of medication, including 555 members who attempted to obtain drugs at a pharmacy from 1/1/2011 – 1/4/2011 and were not provided a transition supply. CMS informed Aetna we would conduct another validation audit of transition claims processing during the CY 2012 transition period.

Transition of Coverage (TOC) Claims Processing Audit

From January through March 2012, CMS conducted a CY 2012 TOC Claims Processing validation audit using a sample from Aetna's rejected claims files. CMS has concluded its audit and has determined that Aetna failed to process claims according to Part D requirements in 14 of the 30 cases reviewed. Therefore, Aetna has failed the CY 2012 Transition Claims Processing validation audit and is out of compliance with Part D formulary administration requirements.

TOC Claims Processing Audit Results:

CMS reviewed a targeted sample of 30 distinct rejected claims files from January 1, 2012 – January 15, 2012. CMS also reviewed prescription drug event (PDE) data we had on file for all members for which we identified rejected point-of-sale (POS) claims data. CMS has determined that Aetna failed 14 of the 30 cases reviewed (7 involving protected class (PC) drugs, 7 involving non-protected class (NPC) drugs). That is, Aetna inappropriately rejected 14 claims at POS.

Based on the audit results, CMS has determined that Aetna is out of compliance with the following Part D program requirements:

1) Pursuant to 42 CFR 423.120(b)(3) and sections 30.4.1 and 30.4.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual Part D sponsors are required to provide an appropriate coverage transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary.

A Part D sponsor must provide for an appropriate transition process for new enrollees, and in some cases current enrollees, prescribed Part D drugs that are not on the Part D sponsor's formulary or are subject to utilization management requirements. Under the transition process, to meet the immediate needs of an enrollee, Part D sponsors must provide a one-time, temporary supply of drugs that are part of an enrollee's ongoing therapy when the application of a new formulary (because of either the enrollee's election of a new plan or the sponsor's adoption of a new formulary) would otherwise result in a rejection of the claims because the drugs are not on the formulary or are subject to utilization management requirements. Eleven of the rejected claims indicated that Aetna did not comply with Part D transition requirements.

a) Multisource Brand Transition Error (3 claims) – Aetna failed to provide its members a transition fill of a previously covered brand drug that the sponsor had removed from its formulary for the 2012 plan benefit year.

b) Failure to Classify Some Members as New Enrollees (3 claims) – Aetna failed to provide transition fills to new enrollees in its Part D plans. These beneficiaries had previously been Aetna plan members, so its systems incorrectly treated them as continuing members not eligible for a transition fill.

c) Failure to Recognize Eligibility for Continuing Member Transition Fills (3 claims) – Aetna's claims processing system failed to review its members' 2011 plan year claims history to determine at POS that the members were entitled a transition fill when their prescribed medication had been removed from Aetna's 2012 formulary.

d) Improper Application of Dose Optimization Quantity Limits During the Coverage Transition Period (1 claim) – Aetna rejected a claim for Zyprexa to which Aetna had applied a dose optimization edit (e.g., required that a drug prescribed at 5 mg tablets, two tablets per day, be changed to 10 mg tablets, once per day). The Drug Benefit Manual, Chapter 6, Section 30.4.8 states that such sponsors needs to allow a pharmacy to override such edits during a transition period if the prescriber will not authorize the change in dose strength and quantity at POS.

e) Improper Application of Prior Authorizations (1 claim) – Aetna improperly applied a prior authorization requirement on a claim for Fentora presented by a new plan member in January 2012. The member was entitled to a one-time transition supply to be provided at the point of sale.

2) Pursuant to 42 CFR § 423.120(b)(2)(iv), Part D sponsors may administer only those formularies that CMS has approved consistent with the bidding process provisions of 42 CFR §423.272(b)(2).

a) Unapproved Step Therapy Edit (2 claims) – Aetna applied a step therapy requirement that was not approved by CMS to claims for Detrol. This resulted in an inappropriate rejection of claims for 75 plan members.

3) Pursuant to Section 1860D-4(b)(3)(G) of the Social Security Act and Section 30.2.5 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may not

implement prior authorization or step therapy criteria requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking the drug.

a) Failure to Grandfather Protected Class Drug (1 claim) – Aetna rejected the antipsychotic drug Fanapt, a protected class medication, based on the application of step therapy requirements for a member whose claims history included a paid claim for the same drug during the last quarter of 2011.

4) Pursuant to 42 CFR §423.504(b)(4)(ii), Part D sponsors must have in place personnel and systems sufficient for it to organize, implement, control, and evaluate the furnishing of prescription drug services.

A number of the claims CMS reviewed indicated that Aetna was not following its own established policies for administration of its Part D benefit plans. The inconsistent adherence to the policies presents the risk that not all plan members are receiving the same set of contracted benefits. It also indicates that the plan sponsor's management is not maintaining the level of accountability necessary to ensure the effective oversight of its Part D operations.

a) Transfer of Mail Order Pharmacy Claim to Specialty Pharmacy (1 claim) – Aetna's mail order pharmacy rejected a member's prescription for Gleevec based on its availability from its contracted specialty pharmacy. Aetna transferred the prescription to the specialty pharmacy without seeking the member's permission, as required by Aetna policy.

b) High Cost Edits – CMS reviewed claims for Neulasta and Gleevec rejected by Aetna based on the application of a "high cost" edit (i.e., claims is initially rejected when its cost is above an established threshold) by its claims processing system. Aetna provided CMS reviewers a copy of the methodology it adopted for establishing the cost above which a claim for a drug would be rejected. CMS found that the costs for each of the rejected claims were below the costs that should have been applied to the claims under Aetna's adopted methodology.

Corrective Action Request

The non-compliance with Part D requirements demonstrated by these audit results causes concern that enrollees are not getting access to prescription drugs to which the enrollees are entitled, particularly since a number of the cases which failed concerned protected class drugs. Additionally, these are recurring failures in areas in which CMS has given Aetna prior notice and opportunity to correct. Based on the results of the audit CMS does not have assurances that no future serious transition of coverage issues will occur.

As a result of this continued noncompliance, CMS requests that Aetna develop and implement a corrective action plan (CAP) that will address the deficiencies described above. At a minimum, the CAP should address how Aetna has:

- 1) Conducted a root cause analysis for each type of non-compliance identified in this letter:

- a. Failure to provide plan members a transitional fill of medications when required by the Part D transition policy. If Aetna determines that other medications were affected, Aetna must complete the above steps and promptly disclose any new issues to CMS.
 - b. Failure to administer the Part D plan formulary as approved by CMS.
 - c. Failure to administer the Part D benefit consistent with Aetna's own policies and procedures concerning prescription transfers between network pharmacies and the application of high cost edits on point-of-sale claims.
- 2) Corrected all issues described above, including:
- a. Completing necessary system coding modifications to correct the identified transition policy issues and conducting system testing to ensure correct implementation at the point of sale.
 - b. Reviewing policies and procedures identified by audit failures (e.g. high cost edits) and ensure organizational personnel are following established procedures for system implementation.
 - c. Ensured that beneficiary outreach has been performed for all of the aforementioned issues, and that members have received their medications or appropriate reimbursement if they paid out of pocket.
- 3) Completed end-to-end compliance testing in the areas of formulary administration, application of high cost edits, transfer of prescriptions from mail order pharmacy to specialty pharmacy, drug utilization management, transition, grandfathering, and protected class drugs and determined that the non-compliance in each of these areas has been corrected and is not likely to recur.

CMS requests that Aetna submit a copy of the CAP within 30 days of the date of this notice via e-mail to Patricia Farris at Patricia.Farris@cms.hhs.gov and Clarisse Owens at Clarisse.Owens@cms.hhs.gov.

Please note that any further failures by Aetna to comply with these or any other CMS requirements may subject Aetna to other applicable remedies available under law, including the imposition of intermediate sanctions, civil money penalties and/or contract termination or non-renewal as described in 42 C.F.R. Parts 422 and 423, Subparts K and O.

Low-Income Subsidy (LIS) Eligible Auto-Enrollment/Annual Reassignment Ban

In Aetna's sanction release notice, CMS informed Aetna that it would remain ineligible to receive automatic enrollments or reassigned enrollments of LIS-eligible beneficiaries until at least March 1, 2012. CMS will consider lifting this restriction pending successful completion of this CAP and Aetna's performance during the 2012 LIS readiness audit. LIS readiness audits are conducted on certain organizations whose Part D bids make them eligible for automatically assigned and reassigned enrollments. CMS will consider lifting this restriction pending the results of Aetna's performance during the 2012 LIS readiness audit.

We appreciate your prompt attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "C. Tudor". The signature is fluid and cursive, with a large initial "C" and a long, sweeping underline.

Cynthia G. Tudor, Ph.D.
Director
Medicare Drug Benefit and
C&D Data Group