Attachment I
Formulary and Benefit Administration
Audit Process and Universe Request

Purpose: To evaluate performance in the four areas outlined below related to Formulary and Benefit Administration. CMS will perform its audit activities using these instructions (unless otherwise noted).

1) Formulary Administration (including protected class medications)

a) Rejected Claims Universe: Sponsor**s** with >=20,000 enrollees will pull a **universe consisting of 30 days** of rejected claims data with dates of service from **<date of audit engagement letter less 30 days> – <date of engagement letter> (**date of audit engagement letter). Sponsors with < 20,000 enrollees will pull a universe consisting of 60 days of rejected claims data with dates of service from **<date of audit engagement letter less 60 days> – < date of audit engagement letter >** (date of audit engagement letter). Submit universe in Attachment I-A (**Rejected Claims_FormularyAdmin Tab**) using Excel format (files may be submitted in CSV or Text format if the file is too large for Excel). The rejected claims universes submitted should not be filtered by the sponsor and no attempts to reprocess claims prior to or during the audit should occur.

b) Sample Selection: CMS will select a sample of 30 claims from the 2013 rejected claims universe as follows: 15 claims for non-protected class drugs and 15 claims for protected class drugs. The sample will consist of rejections relating to formulary administration (e.g. prior authorization, step therapy, non-formulary drugs, and quantity limitations).

c) Documentation: The Part D sponsor will provide documentation for each case selected, such as a screen-print for each CY 2013 paid claim for each beneficiary/drug combination that is determined to be an inappropriate reject.

d) Sample Case Results: CMS will test each of the 30 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

2) Transition

Part 1 - continuing beneficiaries with a cross year formulary change
Part 2 - new members

a) Universe

i) Rejected Claims Universe: Sponsors with >=100,000 enrollees will pull a universe of all rejected claims data with dates of service for January 2013. Sponsors with < 100,000 enrollees will pull a universe of all rejected claims data with dates of service for January and February 2013. Submit universe in Attachment I-A (**Rejected Claims_Transition Tab)** using Excel format (files may be submitted in CSV or Text format if the file is too large for Excel).

ii) Prescription Drug Event Data (PDE) Universe: Sponsor will pull a universe consisting of all prescription drug event data from November and December of 2012 for only those beneficiaries included in the rejected claims universe. **The sponsor needs to ensure that only standing paid claims are submitted**. The PDE universe will be used with the rejected claims universe to test transition for continuing beneficiaries with a cross year formulary change. Submit the universe in the **Standard Prescription Drug Event Data Format**.

iii) New Members Universe: Sponsor will pull a universe consisting of all beneficiaries that CMS authorized the sponsor to enroll effective January 1, 2013. This also includes members enrolled in Part D sponsor's employer plans. This universe will be used with the rejected claims universe to test transition for new enrollees. Submit universe in the attached Attachment I-A (**Transition-New Members Tab)**.

b) Sample Selection:

i) **For continuing beneficiaries with a cross year formulary change** CMS will select a sample of 15 claims from the universe as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs from the 2013 rejected claims universe. CMS will analyze the universes and the CMS approved formulary to identify all beneficiaries and drug combinations where a drug changed formulary status between 2012 and 2013, using the following steps:

(1) Identify all formulary changes between 2012 and 2013 (formulary deletions, addition of prior authorization, step therapy);
(2) Identify beneficiaries who were taking a medication affected by a formulary change;
(3) Identify all 2013 rejected claims for the affected beneficiary/drug combinations.

ii) **For new enrollees** CMS will select a sample of 15 claims from the universe categories as follows: 7 claims for non-protected class drugs and 8 claims for protected class drugs from the 2013 rejected claims universe.

c) Documentation: The Part D Sponsor will provide documentation for each case selected, such as a screen-print for each CY 2013 paid claim for each beneficiary/drug combination that is determined to be an inappropriate reject.

d) Sample Case Results: CMS will test each of the 30 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

3) Website Review

a) Documentation Request: Sponsors will submit a file of all sponsor specific prior authorization (PA), Coverage Determination and Exception Request forms, including all drug specific PA forms. CMS will compare the CMS approved formulary file to the formulary information, utilization management (UM) criteria, and UM request forms posted on the sponsor's website.

b) Sample Selection: CMS will select one contract per formulary ID to review. Contract selection will be made in the following order: PDP; MAPD; and EGWP. CMS will select a sample of:
   i) PA criteria: 5 drugs per contract to compare to the posted PA criteria.
   ii) Formulary information: 10 drugs per contract to compare to the posted formulary to verify the information is correct (e.g., tier, UM, etc.).

c) Documentation: CMS will record the date the website was accessed and screen-print(s) for each sample.

d) Sample Case Results:
   i) PA criteria: CMS will access the sponsor's website and determine if the posted material is accurate based on the CMS approved formulary. In order to result in a pass, all PA criteria within the sample set must be posted consistent with the CMS-approved criteria and PA request forms must not include mechanism(s) to steer beneficiaries to mail order or specialty pharmacies. If either of these are not met the sample set fails and a condition (finding) is documented.

   ii) Formulary information: CMS will access the sponsor's website and determine if the posted material is accurate based on the CMS approved formulary. In order to result in a pass, all drugs within the sample set must be posted correctly. If the information is not posted correctly the sample set fails and a condition (finding) is documented.

4) Pharmacy and Therapeutics (P&T) Committee

a) P&T Committee Membership Universe:

i) The sponsor must submit the following documentation with respect to P&T committee membership:

(1) The criteria utilized to establish that a pharmacist and a physician member are:
   (a) Practicing;
   (b) Independent and free of conflict of interest relative to the Part D sponsor and Part D plan, as well as pharmaceutical manufacturers;
   (c) Experts regarding the care of elderly or disabled individuals. Documentation that the members identified in 4)a)(2) met the criteria submitted in response to 4)a)(1).

(2) Submit membership universe in Attachment I-A (**P&T Committee Membership Tab**).

ii) Answer the following question:
(1) Does the sponsor's P&T committee satisfy the criteria for membership?
Yes = Pass; No = Fail, and a condition is documented

b) P&T Committee Minutes Universe:

This section of the P&T Committee audit element will only be conducted when 1) issues identified during the formulary administration or transition portions of the audit warrant additional P&T audit steps or 2) when concerns are raised during the Compliance team review of Element IV of the MA/Part D Compliance Program Requirement.

The P&T Committee minutes that document the P&T Committee's approval of the initial CY 2013 formulary and all 2013 formulary updates must be submitted. In addition to the minutes, the submission must include all supporting documents relating to the CY 2013 formulary provided to the P&T members prior to, or during the meeting.

i) Sample Selection: CMS will identify all formulary changes between CY 2012 and CY 2013. From this universe, CMS will select a sample of 15 drugs that were either added to the formulary for 2013, deleted from the formulary for 2013, or changed formulary status between 2012 and 2013 from the universe categories as follows:
(1) 10 drugs subject to utilization management;
(2) 5 protected class drugs.

ii) Documentation: CMS will review the submitted P&T committee minutes for evidence documenting the formulary change.

iii) Sample Case Results: CMS will test each of the 15 cases. If changes are not documented in the P&T committee minutes, a sample case fails and a condition (finding) is documented. If changes are documented in the P&T Committee minutes, a sample case passes and no conditions (findings) is documented.