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

TO: All Medicare Part D Sponsors

FROM: Amy K. Larrick
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SUBJECT: Contract Year 2014 Part D Formulary Administration Analysis (FAA)

DATE: October 8, 2014

Consistent with 42 CFR § 423.505(n)(1), CMS may determine that a Part D plan sponsor is out of compliance with a Part D requirement when a sponsor fails to meet performance standards articulated in the Part D statutes, regulations, or guidance. It is CMS' expectation that plan sponsors make every effort possible to make sure that prescription drug claims are adjudicated in accordance with their approved formulary. To that end, CMS evaluated Part D sponsors in 2013 and intend to conduct this analysis once again in 2014.

CY 2013 FAA Results

In the July 9, 2013 Health Plan Management System (HPMS) memo entitled "Contract Year 2013 Part D Formulary Administration Analysis", CMS announced an enhanced formulary administration analysis for CY 2013. The purpose of the CY 2013 FAA was to evaluate whether Part D sponsors were appropriately adjudicating Medicare Part D drug claims consistent with Part D requirements and sponsors' CMS-approved benefits.

In the CY 2013 FAA, Part D sponsors that were selected to participate were required to submit rejected claims from April 2013. These rejected claims were compared to the CMS-approved formulary information to identify potentially inappropriate rejections. A targeted sample of rejections was selected for each participating contract, and sponsors were provided an opportunity to review and comment on the claim rejects. Sponsors were deemed as failing FAA when greater than 20% of the sampled rejects were determined to be inappropriate. After analyzing the results of all of the contracts included in the analysis, it was determined that 9 out of 88 contracts (10.2%, one contract was excluded due to insufficient enrollment) met the failure threshold. Based on the failure rate in the CY 2013 formulary administration analysis and the areas of non-compliance identified during the analysis, CMS continues to be concerned that sponsors are not appropriately adjudicating claims consistent with their approved formularies and as a result will be repeating the formulary administration analysis for 2014.

CY 2014 FAA Methodology

All Part D sponsors will be included in the CY 2014 FAA. Please note that employer group waiver plans (EGWPs) are eligible for inclusion in the analysis as well as Programs of All-

inclusive Care for the Elderly (PACE) organizations that submit a Part D formulary via HPMS. The following contracts will be excluded from participation in the CY 2014 FAA: 1) contracts selected to participate in a program audit in 2013 that also participated in a Medicare Part D Formulary and Benefits Administration (FA) Validation Audit in 2014, and 2) contracts selected to participate in a 2014 Program Audit. Part D sponsors that are selected for participation in the analysis will be notified and provided additional information.

The methodology below describes how CMS will complete the CY 2014 FAA. Although sponsors should have the ability to provide the following information to us within 48 hours of request at any time during the plan year, for the purpose of this monitoring program, data will be required to be submitted in the timeframes outlined below. Please note EGWPs will be evaluated separately and thus rejected claims for EGWPs should only be submitted if the specific employer plans are selected for inclusion.

- Sponsors will be required to submit all point-of-sale (POS) rejected claims relating to the following 4 categories: 1) non-formulary status; 2) Prior Authorization (PA); 3) Step Therapy (ST); and 4) Quantity Limits (QL) [1].
- Larger plans (≥ 20,000 enrollees) should submit rejected claims data for service dates of June 1, 2014 through June 14, 2014 and smaller plans (< 20,000 enrollees) should submit rejected claims data for service dates of June 1, 2014 through June 30, 2014.
- EGWPs will be required to submit a Formulary File detailing the employer group formulary for each employer, including any enhancements not contained on the approved HPMS formulary file that was effective on May 1, 2014.
- CMS will select a targeted sample of rejected claims for analysis.
- Each rejected claim selected will be investigated by the Part D sponsor to verify whether the rejection is consistent with the approved formulary status.
- Each claim within the sample will be assigned a pass or fail depending on the appropriateness of the rejection.
- An overall score will be calculated to determine if the Part D sponsor meets the failure threshold. CMS will take the number of failures (numerator) divided by the number of cases (denominator, maximum of 30) and calculate an overall score. If the number of failures results in more than 20%, an overall failure has occurred for this area.

Selected Part D sponsors will use a secure website to upload the documentation required. Medicare Compliance Officers of the selected organizations will receive a notification email that provides detailed instructions about accessing and designating access to the secure website. Following the attached FAA File Layouts, all selected Part D sponsors will be required to upload a Rejected Claims file and EGWPs will additionally be required to upload a Formulary File to the secure website. In order to standardize the rejections across all sponsors, the Rejected Claims File Layout includes a field relating to the reject category that sponsors must populate.

Sponsors who meet or exceed the failure threshold will receive a notice of non-compliance, at a minimum, along with a report containing the details regarding each failed sample. A failure threshold that includes a large number of rejected claims as it relates to protected class drugs

[1] Do not include concurrent drug utilization review edits such as a daily maximum dose limitation rejections.

may be subject to additional compliance actions. Additional samples and/or screenshots from the sponsor may be required in order to demonstrate compliance. CMS will require Part D sponsors to work aggressively to promptly address problems identified by this monitoring program. Failure to correct any confirmed errors will subject your organization to additional compliance actions.

Part D sponsors will be notified with instructions for completing the user authorization process and additional details regarding the CY 2014 FAA in a separate communication. Please see the schedule of events below that describes the expected actions and corresponding deadlines for this analysis.

CY 2014 FAA Schedule of Events:

The following table summarizes expected actions and timelines for the 2014 Part D Formulary Administration Analysis.

Action	Date
Medicare Compliance Officer will identify up to five authorized users for Acumen's Formulary and Benefits Monitoring website. For each user, submit contact information through the Acumen User Security Website. Medicare Compliance Officers will be notified with instructions for completing the user authorization process in a separate communication – see Attachment B.	New user requests and current user validation due by 5:00 PM EDT on 10/10/14
Authorized users will receive a welcome email with their username and a User Guide with detailed instructions for submitting data and downloading reports. Letters containing login passwords will arrive separately via USPS.	On or about 10/10/14
Participating sponsors can begin uploading Rejected Claims Files, and EGWPs can begin uploading Formulary Files– see Attachment A.	On or about 10/16/14 through 10/22/14 (5:00 PM EDT)

For questions related to data extraction, submission or the secure website, please contact Acumen at FomularyBenefits@AcumenLLC.com. For questions regarding the Formulary Administration Analysis, please contact LeAnn Poole at leann.poole@cms.hhs.gov or Réna McClain at rena.mcclain@cms.hhs.gov.

Thank you