DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: September 8, 2014

TO: All Medicare Part D Sponsors

FROM: Amy K. Larrick
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SUBJECT: Contract Year 2013 Part D Formulary Administration Analysis (FAA) Results

Through Part D program audits, complaints tracking, compliance actions, the transition monitoring program, and other sources, CMS is aware that Medicare Part D beneficiaries sometimes experience interruptions or delays in drug access as a result of inappropriate rejections of prescription drug claims. Because of this, we piloted a formulary administration analysis (FAA) for CY 2013. Through this analysis, we evaluated whether a sample of Part D sponsors were appropriately adjudicating prescription drug claims consistent with their approved Part D formularies. We sought to determine whether we could apply claims review logic, similar to that which has been performed on single organizations during program audits, to a larger sample of Part D contracts in a single analysis. The FAA was announced in the July 9, 2013 Health Plan Management System (HPMS) memo entitled "Contract Year 2013 Part D Formulary Administration Analysis". The purpose of the current memo is to provide Part D sponsors with an overview of the results of the FAA along with some of the more commonly observed administration errors.

CY 2013 FAA Results

A total of 89 contracts were selected for participation in the CY 2013 FAA and were 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). Larger plans (≥ 20,000 enrollees) submitted rejected claims data for service dates of April 1, 2013 through April 14, 2013, while smaller plans (< 20,000 enrollees) submitted rejected claims data for service dates of April 1, 2013 through April 30, 2013. CMS reviewed the submitted rejected claims data and identified a sample of rejects that were potentially inappropriate with respect to the plan's CMS-approved formularies. Sponsors were then required to respond to each claim in the sample, verifying whether the claim rejected correctly or incorrectly and providing supporting documentation where necessary. A final review of the sample was performed by CMS. An overall score was then calculated for each contract by dividing the number of failures (numerator) by the number of cases (denominator, maximum of 30) to determine whether the Part D sponsor met a failure threshold of greater than 20%.

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.

A total of 2,640 sampled rejected claims were reviewed during this analysis, of which 213 claims (8.1%) were determined by CMS to be inappropriate. The following information details some common areas of concern regarding file submissions and areas of non-compliance identified during the CY 2013 FAA:

Common Concerns Regarding Universe Submissions and Claims Responses:

1. Failure to correctly identify the reason for which a claim rejected (i.e., non-formulary, PA, ST or QL).
2. Failure to provide complete and/or detailed explanations for why a claim rejected.
3. Incorrectly identifying claims that rejected due to exceeding plan benefit limitations (e.g., 120 days supply) as claims rejecting for QLs.

Common Areas of Non-Compliance:

Quantity Limits:

1. Sponsors identified coding issues that caused claims to reject with a QL edit erroneously.
2. Some sponsors applied inappropriate QLs to drugs that required prior authorization.
3. Sponsors applied unapproved QLs that were not found on their CMS-approved formularies.
4. Sponsors applied inappropriate QLs to drugs that had not yet exceeded the approved QL at the time of adjudication.

Step Therapy:

1. Sponsors applied unapproved ST edits that were not found on their CMS-approved formularies.
2. Some sponsors failed to update their adjudication files to reflect enhancements to the CMS-approved formularies.
3. Sponsors noted that ST edits were not coded correctly.

Prior Authorization:

1. Some sponsors had previously removed PA edits from a drug but those updates were not effective at the time of adjudication.
2. Sponsors improperly coded drugs with a PA edit.
3. Some sponsors observed inappropriate rejections due to a historical PA in the member's profile that prevented proper adjudication.
4. Sponsors erroneously applied PA to members' profiles when the members should have been "grandfathered."

Non-Formulary:

1. Some sponsors erroneously coded a formulary drug in their system as non-formulary.
2. Sponsors failed to update adjudication files to include drugs added to the CMS-approved formulary.

We are concerned with the number and variety of errors that were identified through this analysis. As a result, Part D sponsors who met the failure threshold or had a high number of rejects for protected class drugs will be receiving, at a minimum, a notice of non-compliance. We urge all Part D sponsors to routinely monitor their rejected claims so that any potential errors are identified and corrected quickly. In addition, we recommend that all sponsors review the July 30, 2013 HPMS memo entitled "Best Practices and Common Findings Memo #2 from 2012 Program Audits." This memo includes common findings, best practices, and CMS recommendations relating to formulary administration.

Finally, given the number of issues identified, we intend to repeat the FAA for CY 2014. Details regarding the 2014 FAA will be provided in a subsequent HPMS communication. Questions related to the FAA should be directed to LeAnn Poole at leann.poole@cms.hhs.gov or Réna McClain at rena.mcclain@cms.hhs.gov.