DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: July 9, 2013

TO: All Part D Sponsors

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

SUBJECT: Contract Year 2013 Part D Formulary Administration Analysis

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 adjudicating in accordance with their approved formulary.

Formulary Administration Analysis

In an effort to help ensure plan sponsors are adjudicating prescription drug claims properly, we are announcing an enhanced formulary administration analysis for CY 2013. This program will evaluate whether Part D sponsors are appropriately adjudicating Medicare Part D drug claims consistent with Part D requirements and sponsors' CMS-approved benefits.

The methodology below describes how we will complete this monitoring. Part D sponsors that are selected for analysis will be notified during the second week of July 2013 and will be provided detailed instructions on how to submit requested information to CMS. All sponsors should have the ability to provide the following information to CMS within 48 hours of request at any time during the plan year, however only those sponsors selected by CMS will be required to submit data in this timeframe for this analysis.

- 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 April 1, 2013 through April 14, 2013 and smaller plans (< 20,000 enrollees) should submit rejected claims data for service dates of April 1, 2013 through April 30, 2013.

- CMS will select a targeted sample of rejected claims for analysis.

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

- Each rejected claim 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. Attached is the Rejected Claims Template layout that selected Part D sponsors will be required to upload to the secure website. In order to standardize the rejections across all sponsors, the Rejected Claims Template 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 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.

Routine monitoring and evaluation of rejected POS claims is an important exercise for Part D sponsors to perform; therefore, CMS will be providing all plan sponsors a self-monitoring protocol for use as a guide to assist sponsors in regularly tracking and monitoring the volume and accuracy of rejected POS claims for both transition and formulary administration. A forthcoming HPMS communication will provide more detail regarding this protocol.

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 .