DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: December 14, 2012

TO: All Medicare Part D Sponsors

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

SUBJECT: Contract Year 2013 Part D Transition Monitoring Program Analysis

Consistent with 42 CFR § 423.120 (b)(3), a Part D sponsor must provide for an appropriate transition process for new enrollees, and in some cases current enrollees who are prescribed Part D drugs that are not on the Part D sponsor's formulary. As stated in the CY 2012 Call Letter, CMS requires that Part D sponsors provide documentation that their transition policy is correctly implemented in their claims system and that beneficiaries are receiving their required transition supplies. In the December 30, 2011 Health Plan Management System (HPMS) memo entitled "Contract Year 2012 Part D Transition Monitoring Program Analysis (TMPA)", CMS announced an enhanced transition monitoring program for CY 2012. The purpose of the CY 2012 TMPA was to ensure that Part D sponsors were adequately administering Medicare Part D formulary transition policies consistent with Part D regulations and requirements.

In the CY 2012 TMPA, CMS conducted two analyses on rejected claims data provided by a sample of selected sponsors: 1) to identify continuing beneficiaries who had a rejected POS claim in CY 2012 for a drug that qualified for a transition fill; and, 2) to identify rejected POS claims for Part D drugs for new enrollees from January 1, 2012 to January 21, 2012. Sponsors responded to each claim in question, providing explanations for whether the claim was rejected correctly or incorrectly. After analyzing the results of all of the contracts included in the sample, approximately 27% of contracts exceeded the protected class and/or non-protected class drug failure threshold. Based on the failure rate in the CY 2012 transition monitoring analysis, Part D audit findings, and self-disclosed transition errors, CMS continues to be concerned that sponsors are not appropriately adjudicating transition supplies.

In order to ensure beneficiaries receive appropriate supplies of transition medications, we are repeating the transition monitoring program for CY 2013. For CY 2013, the TMPA will include all contracts that utilize a formulary for Part D, with the exception of National PACE, Medicare-Medicaid Plans, and Non Employer- Direct 800 series employer group waiver plans. The methodology and schedule of events for the CY 2013 TMPA are provided below. In addition, the following information details some common areas of concern regarding universe submissions and areas of non-compliance identified during the CY 2012 TMPA, as well as best practices identified during 2012 Program Audits:

Common Concerns Regarding Universe Submissions:

1. Many sponsors submitted refill too soon (RTS) rejections in their universe despite the fact that CMS requested the submission of all POS rejects be limited to non-formulary, prior authorization (PA, including both administrative and clinical), and step therapy (ST) claim rejects.
2. Sponsors failed to correctly identify new versus continuing beneficiaries.

3. Some sponsors questioned whether beneficiaries who switched contracts or plans within the same parent organization should be identified as new enrollees. For the purposes of this analysis, sponsors should identify these beneficiaries as new enrollees if their transition policies provide transition fills consistent with that of beneficiaries new to the organization altogether. However, if sponsors' transition policies provide for transition fills consistent with that of continuing beneficiaries not experiencing a change in contract or plan, these beneficiaries should not be identified as new enrollees.

Common Areas of Non-Compliance:

1. Sponsors processed transition fills for only some of the drugs that were subject to a cross-contract year formulary change. This type of error was often the result of either the sponsor not providing a complete list of drugs to their claims processor for transition fills, or coding errors on the processor's part when implementing the new formulary.
2. Sponsors processed potentially high risk medications with CMS-approved PA requirements as if they were concurrent drug utilization review (DUR) safety edits, thereby inappropriately restricting drug access during the transition period.
3. Sponsors denied beneficiary access to transition fills as a result of errors in enrollment data. For example, beneficiaries who were new enrollees were coded as continuing enrollees.
4. Sponsors denied transition fills because the sponsors' systems did not register beneficiaries' historical claims in a timely manner. These delays led to sponsors not properly identifying beneficiaries' historical drug regimen and eligible transition fills.

Best Practices:

The HPMS memo entitled "Best Practices and Common Findings from 2012 Program Audits" released on September 10, 2012 identified some best practices for transitioning new and existing beneficiaries. As noted in the memo, it is not always possible to determine if a beneficiary has previously received a particular medication (due to circumstances such as physician samples and incomplete on-line records); therefore, providing new beneficiaries with the protections of the transition policy allows them to receive a transition fill and the information necessary to request an exception for future dispensing. Some features noted in effective transition programs include:

1. Identifying the presence of existing medications by looking back across the multiple strengths and dose forms of the medication to account for any dosing adjustments.
2. Utilizing a look-back period that is long enough to identify the presence of prescriptions that were obtained for an extended day supply, through providers such as mail order pharmacies.

Avoiding the common areas of concern regarding universe submissions and non-compliance and considering the best practices outlined above can help sponsors ensure compliance with CMS transition requirements.

CY 2013 TMPA Methodology:

The methodology below describes how CMS will complete the CY 2013 TMPA. 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:

- Sponsors will be required to submit all POS claims rejected for the following 3 categories: 1) non-

formulary status; 2) PA; and 3) ST from January 1, 2013 through January 21, 2013.

- Sponsors will provide electronically a list of new enrollees with a January 1, 2013 effective date.

- Sponsors will upload the POS rejected claims and a list of new enrollees as a .txt file between January 23, 2013 and 11:59 PM EST January 27, 2013.

HPMS formulary file extracts for CY 2012 and CY 2013 will be used to identify drugs that were deleted from the formulary or had an addition of PA and/or ST. A list of drugs that were subject to a formulary change will be selected. Once this list is identified, CY 2012 Prescription Drug Event (PDE) data will be used to identify beneficiaries taking the affected drugs. CMS will then conduct two analyses: 1) to identify continuing beneficiaries who had a rejected POS claim in CY 2013 for a drug that qualified for a transition fill; and, 2) to identify rejected POS claims for Part D drugs for new enrollees from January 1, 2013 to January 21, 2013.

Part D sponsors will use a secure website to upload the required POS rejected claims and the list of new enrollees, following the format outlined in the attachment titled **"**Rejected Claims Template and New Enrollees file layout." The Benefit Administration Website will serve as a secure centralized collaboration tool between CMS, Acumen, LLC (Acumen), and selected Part D sponsors. Medicare Compliance Officers will have access and authority to designate access to the secure website. Please ensure contact information is up-to-date in HPMS. Only authorized users will have access to the secure website which is separately secured from all other Part D Sponsors.

CMS recognizes that non-formulary drugs are generally rejected under an NCPDP reject code of 70, and PA under a reject code of 75. However, there is more variability in how ST is rejected. 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. The possible values include: 1= non-formulary, 2= PA, 3= ST.

CMS will apply a failure threshold when reviewing the rejected claims sample. CMS will calculate an overall score to determine if the Part D sponsor is compliant with Part D transition requirements. For non-protected class drugs, the number of failures (numerator) will be divided by the number of claims sampled (denominator) to calculate an overall compliance score. If the number of failures results in more than a 20% failure rate, an overall failure will have occurred for this area. For protected class drugs, the number of failures (numerator) will be divided by the number of claims sampled (denominator) to calculate an overall compliance score. If the number of failures results in more than a 10% failure rate, an overall failure will have occurred for this area. Sponsors who meet or exceed this failure threshold will receive a compliance action, along with a report containing the details regarding each failed sample. Additional samples 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 may 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 CY2013 TMPA in a separate communication. Please see the schedule of events below that describes the expected actions and corresponding deadlines for this analysis.

CY 2013 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the 2013 Part D Transition Monitoring Program Analysis.

Action	Date
Medicare Compliance Officer will identify up to five authorized users for Acumen's Benefit Administration 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.	New user requests and current user validation due by 5:00 PM EST on 1/7/13
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 1/10/13
Participating sponsors can begin uploading Rejected Claims Files and Transition-New Enrollees Files – see attachment titled **"**Rejected Claims Template and New Enrollees file layout."	On or about 1/23/13 through 1/27/13 (11:59 PM EST)

In addition to plans being responsible for an appropriate transition process, plans are expected to properly adjudicate claims consistent with their CMS approved formulary. Therefore, to ensure that Part D sponsors are adequately administering the benefit, CMS will be conducting a formulary administration analysis to identify if there is appropriate claims adjudication with respect to CMS approved formularies. More information on the formulary administration analysis will be provided in a subsequent memo.

During the scheduled December 19, 2012 Part C&D User Call, the Division of Formulary and Benefit Operations (DFBO) will discuss Part D Transition requirements and the CY 2012 Transition Monitoring Program Analysis. For questions related to data extraction, submission or the secure website, please contact Acumen at BenefitAdmin@AcumenLLC.com. For questions regarding the Transition monitoring program analysis, please contact June Page at june.page@cms.hhs.gov or Réna McClain at rena.mcclain@cms.hhs.gov.

Thank you.