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

TO: All Medicare Part D Sponsors

FROM: Amy K. Larrick, Acting Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Transition Monitoring Program

DATE: March 10, 2015

The Part D transition requirements, as outlined in 42 CFR § 423.120 (b)(3), are an important protection under Medicare Part D. The provision of a temporary fill of a non-formulary drug and accompanying notice affords enrollees the opportunity to work with prescribers to switch to formulary alternatives, or to pursue necessary prior authorizations or formulary exceptions.

Beginning in CY 2012, CMS implemented the transition monitoring program analysis (TMPA). The purpose of the TMPA was to evaluate point-of-sale (POS) rejected claims to ensure that Part D sponsors were adequately administering Medicare Part D formulary transition requirements. As a result of these analyses CMS continues to identify instances where some sponsors have not provided the required transition supplies.

Given that we are entering into the tenth year of the Part D program, we are very concerned that some Part D sponsors have not fully complied with our transition requirements. As a result, CMS will be repeating the TMPA for CY 2015. The purpose of this memo is to provide Part D sponsors with an overview of the CY 2014 TMPA results and details regarding the CY 2015 TMPA. Questions relating to TMPA should be directed to PartDTransition@cms.hhs.gov.

CY 2014 TMPA

For the CY 2014 TMPA, CMS conducted two analyses on rejected claims data provided by all contracts that utilize a formulary for Part D and had beneficiaries enrolled in January of 2014

(with the exception of National PACE Plans) to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2014 for a drug that qualified for a transition fill, and 2) rejected POS claims for Part D drugs for new members from January 1, 2014 to January 21, 2014. Sponsors responded to each claim in question, providing explanations as to whether the claim was rejected correctly or incorrectly. After analyzing the results of all of the contracts included in the sample, approximately 11.3% of contracts exceeded the protected class and/or non-protected class drug failure threshold. The analysis was repeated on a sample of employer group waiver plans (EGWPs). The preliminary results of the EGWP portion of the analysis show that 3.8% of the plans sampled met the failure threshold. We are encouraged that the percentage of contracts that met the failure threshold in CY 2014 decreased when compared to CY 2013 (22%).

Transition claims that were rejected inappropriately generally fell into three categories. There were numerous inappropriate rejections relating to errors in the coding of specific drugs that resulted in the failure to recognize these drugs as transition-eligible. Several claims that should have paid via transition were rejected due to errors contained within enrollment and eligibility files. Finally, errors in the loading of CY 2013 claims history caused inappropriate transition rejects.

Similar to the CY 2013 TMPA, the following submission errors were identified in the universe submissions:

1. Submission of early refill rejections in the POS rejected claims universe, which should be limited to non-formulary, prior authorization (PA), and step therapy (ST) rejects.
2. Inclusion of HICNs for continuing beneficiaries in the new enrollee universe.
3. Errors in reporting rejected claims for compounded drugs.
4. Incorrect formatting and/or values were reported within the universes.

CY 2015 TMPA

The TMPA will again be performed for CY 2015 on all Part D sponsors. Please note that employer group waiver plans (EGWPs) and Medicare-Medicaid Plans (MMPs) are again eligible for inclusion in the CY 2015 analysis, but PACE organizations will continue to be excluded. Part D sponsors that are selected for analysis will be notified and provided additional information.

The methodology below describes how CMS will complete the CY 2015 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 rejected POS claims for dates of service from January 4, 2015 through January 24, 2015 for the following 3 categories: 1) Non- formulary status; 2) Prior Authorization (PA); and 3) Step Therapy (ST).
- Sponsors will provide electronically a list of new enrollees with a January 1, 2015 effective date.
- Sponsors will upload the POS rejected claims and a list of new enrollees as a .txt file between March 25, 2015 and March 31, 2015 (11:59 PM EDT).
- Selected EGWPs will upload two formulary files: 1) Last formulary file effective December 2014 and 2) first formulary file effective January 2015. Additional details regarding the file formats will be provided upon notification of selection.

HPMS formulary file extracts for CY 2014 and CY 2015 will be used to identify drugs that were deleted from the formulary or were subject to the addition of PA and/or ST. A list of these drugs will be selected. Once this list is identified, CY 2014 Prescription Drug Event (PDE) data will be used to identify continuing beneficiaries taking the affected drugs. We will then conduct two analyses to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2015 for a drug that qualified for a transition fill and, 2) rejected POS claims for Part D drugs for new members from January 4, 2015 to January 24, 2015.

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 Members file layout." The Formulary and Benefits Monitoring Website (formerly known as 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.

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.

We will apply a failure threshold when reviewing the rejected claims sample. We 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 the failure threshold will receive a notice of non-compliance, at a minimum, 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 CY 2015 TMPA in a separate communication. Please see the schedule of events below that describes the expected actions and corresponding deadlines for this analysis.

CY 2015 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the 2015 Part D Transition Monitoring Program Analysis.

Action	Date
Medicare Compliance Officer (MCO) will identify up to five authorized users for Acumen's Formulary and Benefits Monitoring website. For each user, verify and authorize access permissions through Acumen's User Security Website – MCOs 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 EDT on 3/12/15
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 3/16/15
Participating sponsors can upload Rejected Claims Files and Transition-New Members Files – see attachment titled "Rejected Claims Template and New Members file layout." EGWPs can also begin uploading Formulary Files.	On or about 3/25/15 through 3/31/15 (11:59 PM EDT)

For questions related to data extraction, submission or the secure website, please contact Acumen at FormularyBenefits@AcumenLLC.com. For questions regarding the TMPA, please contact Anna Polk at anna.polk@cms.hhs.gov.