

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



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: December 30, 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. CMS has continued to identify instances where some sponsors have not provided the required transition supplies.

Given the maturity 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 2016. The purpose of this memo is to provide Part D sponsors with an overview of the CY 2015 TMPA results and details regarding the CY 2016 TMPA. Questions relating to TMPA should be directed to PartDTransition@cms.hhs.gov.

CY 2015 TMPA

For the CY 2015 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 2015

(with the exception of National PACE Plans) to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2015 for a drug that qualified for a transition fill as a result of a cross-contract year negative formulary change, and 2) rejected POS claims for Part D drugs for new members. Sponsors responded to each claim in question, providing explanations as to whether the claim was rejected appropriately or inappropriately. After analyzing the results of all of the contracts included in the sample, approximately 6.8% 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 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 non-EGWP contracts that met the failure threshold in CY 2015 decreased when compared to both CY 2014 (11.3%) and CY 2013 (22%), although the EGWP failure threshold remained constant from CY 2014.

Common Areas of Non-Compliance:

1. Sponsors failed to allow transition fills for some Part D drugs that required prior authorization (PA), citing the Appropriate Utilization of Prior Authorization Requirements to Determine Part D Drug Status policies set forth in the CY 2015 Call Letter; however, their explanation failed to sufficiently explain why the drug was appropriate for this type of PA. In brief, that policy notified sponsors of the requirements to verify payment for Part D uses and that these types of POS PA edits are appropriate even during transition. Consistent with the CY 2015 Call Letter, these edits should only be applied to drugs and/or drug classes that pose the greatest risk for non-Part D covered uses and CMS would not expect to see excessive use of POS PA edits during transition as a result of this clarified guidance.
2. Several claims that should have paid via transition were rejected due to errors in determining enrollment status and history. Sponsors noted this often occurred when enrollment dates were entered manually. There were also instances where beneficiaries were considered continuing enrollees although they had a gap in their enrollment that should have qualified them as new enrollees.
3. Errors in the loading of CY 2014 claims history caused inappropriate transition rejects. Sponsors reported that a change in either software or pharmacy benefit manager could cause claims to be loaded incorrectly. There were also instances of a delay in loading the 2014 claims data, which erroneously caused a drug to be considered a new therapy for a continuing enrollee that would have otherwise been eligible to receive a transition fill due to a formulary change across coverage years.
4. Sponsors failed to use an adequate look-back period (90 days as opposed to 108 days) to determine if a claim was for continuing therapy. The look-back should be long enough to identify prescriptions for an extended day supply.

Common Concerns Regarding Universe Submissions:

1. Submission of early refill rejections in the POS rejected claims universe, which should be limited to non-formulary, PA, and step therapy (ST) rejects.
2. Errors in reporting rejected claims for compounded drugs.
3. Incorrect formatting and/or values were reported within the universes.
4. Inconsistent formatting of formulary IDs and Employer Names within and between Rejected Claims and Formulary Files (EGWP-only).
5. Submission of incorrect Formulary File (EGWP-only).
6. Errors in the response columns, such that a sponsor's response did not refer to the claim in question.

CY 2016 TMPA

The TMPA will again be performed for CY 2016 on all Part D sponsors. Please note that EGWPs and Medicare-Medicaid Plans (MMPs) are again eligible for inclusion in the CY 2016 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 2016 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, 2016 through January 24, 2016 for the following 3 categories: 1) Non-formulary status; 2) Prior Authorization (PA); and 3) Step Therapy (ST).
- Sponsors will upload the POS rejected claims as a .txt file between January 28, 2016 and February 3, 2016 (11:59 PM EDT).
- Selected EGWPs will also upload two formulary files: 1) Last formulary file effective December 2015 and 2) first formulary file effective January 2016. Additional details regarding the file formats will be provided upon notification of selection.

Please note that CMS performs an automated initial review on all submitted data at the same time, and as such, we cannot accommodate file resubmissions in the event of sponsor error. Sponsors that submit incorrect files will fail the TMPA and receive a formal compliance action.

HPMS formulary file extracts for CY 2015 and CY 2016 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 2015 Prescription Drug Event (PDE) data will be used to identify beneficiaries taking the affected drugs and enrollment data will be used to distinguish new and continuing beneficiaries. We will then conduct two analyses to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2016 for a drug that qualified for a transition fill due to a negative formulary change and, 2) rejected POS claims for Part D drugs for new members from January 4, 2016 to January 24, 2016.

Part D sponsors will use a secure website to upload the required POS rejected claims following the format outlined in the attachment titled "Rejected Claims Template layout." EGWPs will also upload formulary files. 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 2016 TMPA in a separate communication.

Please see the schedule of events below that describes the expected actions and corresponding deadlines for this analysis.

CY 2016 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the 2016 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 EST on 1/14/16
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 1/21/16
Participating sponsors can upload Rejected Claims Files – see attachment titled “Rejected Claims Template.” EGWPs can also begin uploading Formulary Files.	On or about 1/28/16 through 2/3/16 (11:59 PM EST)

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 PartDTransition@cms.hhs.gov.