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

MEDICARE DRUG BENEFIT AND C & D DATA GROUP

Date: January 17, 2018

To: All Medicare Part D Sponsors

From: Jennifer R. Shapiro
Acting Director, Medicare Drug Benefit and C & D Data Group

Subject: Part D Transition Monitoring Program Analysis (TMPA)

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.

The transition monitoring program analysis (TMPA) was implemented in CY 2012 to evaluate point-of-sale (POS) rejected claims to ensure that Part D sponsors are meeting Medicare Part D formulary transition requirements. CMS is continuing this important analysis for CY 2018. The purpose of this memo is to provide Part D sponsors with an overview of the CY 2017 TMPA results and details regarding the CY 2018 TMPA. Questions relating to the TMPA should be directed to PartDTransition@cms.hhs.gov.

CY 2017 TMPA

For the CY 2017 TMPA, CMS conducted two analyses on rejected claims data provided by all contracts that utilized a formulary and that also had beneficiaries enrolled in January 2017. Programs of All-Inclusive Care for the Elderly (PACE) organizations were excluded from the CY 2017 TMPA. The purpose of these analyses was to identify potentially inappropriate POS rejections for continuing or new members that may have been eligible for a transition fill. After analyzing the results of all of the contracts included in the sample, approximately 5.7% of contracts exceeded the protected class failure threshold of 10% and/or the non-protected class failure threshold of 20% (compared to 6.1% for CY 2016). The analysis was repeated on a sample of employer group waiver plans (EGWPs). The results of the EGWP portion of the analysis show that 1.8% of the

plans sampled exceeded the failure threshold (1% in CY 2016).

Some of the errors that were identified that resulted in inappropriate POS rejections included:

1. Sponsors indicated in their response that certain claims were rejected during transition due to a high-dose safety edit, however, the dose in the rejected claim did not exceed the FDA-labeled maximum daily dose.
2. Claims were rejected due to errors in processing the transition logic, such that an override was not provided to allow a transition fill for members experiencing a negative formulary change across contract years.
3. Sponsors rejected transition-eligible claims with the justification that the drug in question had a high-likelihood of non-Part D use, however, the responses failed to clearly support this determination.
4. Plan sponsor failure to identify all drugs that were eligible for transition fills due to cross-calendar year formulary changes. Sponsors should ensure that all drugs that undergo a negative formulary change between contract years are correctly loaded into adjudication systems.

In addition to the transition fill errors, some sponsors encountered difficulties in submitting necessary information for the TMPA. These included:

1. Submission of rejected claims not related to one of the four rejection categories (non-formulary (NF), prior authorization (PA), step therapy (ST), and quantity limit (QL)) in the POS rejected claims universe. For example, early refill rejections, invalid patient residence, and missing/invalid date of birth rejected claims.
2. Errors in categorization of rejected claims into one of the four rejection categories of NF, PA, ST, or QL. For example, claims that were non-formulary were categorized as a PA rejection.
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).

CY 2018 TMPA

The TMPA will again be performed for CY 2018 for all Part D sponsors. Please note that EGWPs and Medicare-Medicaid Plans (MMPs) are eligible for inclusion in the CY 2018 analysis, and PACE organizations that submit a Part D formulary via HPMS will now be included in the analysis. Part D sponsors that are selected for the analysis will be notified and provided additional information.

The methodology below describes how CMS will complete the CY 2018 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 1, 2018 through January 31, 2018 for the following 4 categories: 1) Non-formulary (NF) status; 2) Prior Authorization (PA); 3) Step Therapy (ST); and 4) Quantity Limit (QL). Rejected claims must be correctly categorized relative to the approved formulary and prescription drug claims processing. This is necessary so that rejections can be standardized across all sponsors. Past analyses have been hindered by plan sponsors submitting incorrectly categorized claims. The categorization should be based on the formulary status of the drug and only rejections relating to these categories should be submitted. Please consider the following prior to claims submission:
    - NF – Rejections for drugs not on the formulary. Claims that reject due to reasons such as missing prescriber identifiers should not be submitted.
    - PA – Rejections for drugs that are on the formulary but require PA. Rejections for reasons other than those related to the requirement for PA should not be included.
    - ST – Rejections for drugs due to ST requirements on the formulary only.
    - QL – Rejections related to exceeding the quantity limits on the approved formulary. Rejections resulting from benefit limitations (e.g., 120 days supplies) or safety edits, such as cumulative morphine milligram equivalent dose rejections should not be submitted.
- Rejected claims that are categorized incorrectly will be reviewed as initially submitted. CMS will not re-run the analysis in the event that incorrect information was submitted, thus you will be unable to correct at a later date.
- Sponsors will upload the POS rejected claims as a .txt file between February 12, 2018 and February 16, 2018 (11:59 p.m. EST).
- Selected EGWPs will be required to submit the following two formulary files for each employer, including any enhancements not contained on the approved HPMS formulary files: 1) last CY 2017 formulary file effective December 2017 and 2) first CY 2018 formulary file effective January 1, 2018. Rejected claims for EGWPs where the plan disagrees with a CMS determination of an inappropriate rejection based on an inaccurate formulary file submission will be failed. In the event that incorrect formulary data is submitted, CMS will not accept a corrected formulary file after the initial formulary file submission window. 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. For example, if you submit a rejected claim with an incorrect categorization, we will review the file accordingly. We will not be re-running the analyses in the event that you submit the incorrect information, and you therefore will be unable to correct at a later date. As such, this could result in a failure of the affected samples, and potentially the TMPA, thus resulting in a formal compliance action.

HPMS formulary file extracts for CY 2017 and CY 2018 will be used to identify drugs that were deleted from the formulary or were subject to the addition of PA, ST and/or QL. A list of these drugs will be selected. Once this list is identified, CY 2017 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 2018 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 1, 2018 to January 31, 2018 whose drugs are non-formulary.

Part D sponsors will use a secure website to upload the required POS rejected claims. EGWPs will also upload formulary files. The Formulary and Benefits Monitoring 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 File Layout includes a field relating to the reject category that sponsors must populate. The possible values include: 1=NF, 2=PA, 3=ST, 4=QL.

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. CMS will take the number of failures (numerator) divided by the number of claims sampled (denominator, maximum of 30) 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. Sponsors who 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 2018 TMPA in a separate communication.

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

CY 2018 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the CY 2018 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 web portal. 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 p.m. EST on 1/24/18
Authorized users will receive a welcome email with a User Guide and detailed instructions for accessing the web portal, downloading reports, and submitting data. New users will receive a separate "Credential Email" with their username and a one-time password link.	On or about 1/24/18
Participating sponsors can upload Rejected Claims Files and EGWPs can also begin uploading Formulary Files.	On or about 2/12/18 through 2/16/18 (11:59 p.m. 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.