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 Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Transition Monitoring Program

DATE: December 29, 2016

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 the TMPA for CY 2017 to evaluate Part D sponsors' compliance with the transition requirements. The purpose of this memo is to provide Part D sponsors with an overview of the CY 2016 TMPA results and details regarding the CY 2017 TMPA. Questions relating to TMPA should be directed to PartDTransition@cms.hhs.gov.

CY 2016 TMPA

For the CY 2016 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 2016 (with the exception of National PACE Plans) to identify: 1) continuing beneficiaries who had a rejected POS claim in CY 2016 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 6.1% of contracts exceeded the protected class failure threshold of 10% and/or the non-protected class failure threshold of 20%. 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% of the plans sampled met the failure threshold. We are encouraged that the percentage of non-EGWP and EGWP contracts decreased when compared to CY 2015 scores which were 6.8% and 3.8% respectively.

Common Areas of Non-Compliance:

1. Several claims that should have paid via transition were rejected due to errors in determining enrollment status and history. 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.
2. Errors in the loading of CY 2015 claims history 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 negative formulary change across contract years.
3. 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.
4. Sponsors rejected claims with the justification that these medications were determined to be "high risk" in the elderly, however, a high risk medication prior authorization (PA) is not considered a safety edit that would stop transition fills.
5. Numerous claims were determined to be appropriate rejections by sponsors, despite the drug experiencing a negative formulary change from 2015 to 2016. Sponsors should ensure that all drugs that undergo a negative formulary change between contract years are correctly loaded into adjudication systems.

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. Please note: for CY 2017, this universe will also include quantity limit (QL) 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. Errors in the response columns, such that a sponsor's response did not refer to the claim in question.

CY 2017 TMPA

The TMPA will again be performed for CY 2017 on all Part D sponsors. Please note that EGWPs and Medicare-Medicaid Plans (MMPs) are again eligible for inclusion in the CY 2017 analysis, but PACE organizations will continue to be excluded. 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 2017 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, 2017 through January 24, 2017 for the following 4 categories: 1) Non-formulary status; 2) Prior Authorization (PA); 3) Step Therapy (ST); and 4) Quantity Limit (QL).
- Sponsors will upload the POS rejected claims as a .txt file between February 6, 2017 and February 10, 2017 (11:59 PM EST).
- Selected EGWPs will also upload two formulary files: 1) Last formulary file effective December 2016 and 2) first formulary file effective January 2017. 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 2016 and CY 2017 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 2016 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 2017 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, 2017 to January 24, 2017.

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." 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 Template includes a field relating to the reject category that sponsors must populate. The possible values include: 1=non-formulary, 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. 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 2017 TMPA in a separate communication.

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

CY 2017 TMPA Schedule of Events:

The following table summarizes expected actions and timelines for the 2017 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 PM EST on 1/13/17
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 1/13/17
Participating sponsors can upload Rejected Claims Files – see attachment titled "Rejected Claims Template." EGWPs can also begin uploading Formulary Files.	On or about 2/6/17 through 2/10/17 (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.