

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



CENTER FOR MEDICARE

DATE: December 30, 2020

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

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

SUBJECT: CY 2021 Transition Requirements Analysis (TRA)

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 coverage determinations or formulary exceptions.

CY 2019 TRA

CMS piloted the Transition Requirements Analysis (TRA) in Contract Year (CY) 2019 to replace the former Transition Monitoring Program Analysis (TMPA). The purpose of the TRA is to evaluate transition procedures using prescription drug event (PDE) data to ensure sponsors are meeting Part D transition requirements. The TRA identifies Part D enrollees that were taking a maintenance drug that underwent a negative formulary change across plan years, and looks for affected enrollees who did not appear to have a transition fill or a fill for a therapeutic alternative during the months of January – March. For this analysis, the Centers for Medicare & Medicaid Services (CMS) selected ten enrollees per parent organization and asked plan sponsors for additional information or justification for the absence of a transition fill.

The CY 2019 TRA included a sample of 1,427 enrollees. It was determined that 25.7% (367) of enrollees were not transition eligible for various reasons such as the enrollee not experiencing a negative formulary change or because the enrollee had already been denied a coverage determination due to using the drug for a non-medically accepted indication. Another 20.2% (288) of enrollees ultimately received a fill for a target drug or therapeutic alternative from January – March 2019. Of the remaining 54.1% (772) of enrollees that did not have a PDE for the transition-eligible drug or an alternative, the most common reason reported was that the enrollee did not request a fill for the target drug or a substitution drug during the transition period. While the review did not reveal any major concerns related to Part D transition

requirements, the TRA pilot year was informative and helped CMS to modify the TRA methodology moving forward. Updates to the CY 2021 methodology include refining the identification of eligible enrollees, expanding the analysis to include new enrollees, and adding a select number of Employer Group Waiver Plans (EGWPs).

CY 2021 TRA

CMS will again conduct the TRA for CY 2021. CMS will select one plan per parent organization to participate in the analysis. Please note that Medicare-Medicaid Plans (MMPs) and Program of All-inclusive Care of the Elderly (PACE) organizations that submit a Part D formulary via HPMS are eligible for inclusion, as well as a select group of EGWPs. Part D plans selected for the analysis will receive a notification that will provide additional information. Organizations that are undergoing a program audit will be excluded from the analysis.

CMS will use HPMS formulary file extracts for both CY 2020 and CY 2021 to identify maintenance drugs that became non-formulary across contract years, PDE data to identify enrollees taking the affected drugs, and enrollment data to distinguish between new and continuing enrollees. The analysis will then identify eligible enrollees who do not appear to have received a transition fill or therapeutic alternative in January – March 2021.

Selected plans will use a TRA Response Form to provide information necessary for the analysis. The TRA Response Form will include a sample of up to 10 enrollees, each identified by a unique ticket number, who experienced a formulary deletion across CY 2020 and CY 2021 and do not appear to have received a transition fill or therapeutic alternative in January – March 2021. Selected plans will provide a response for each record identified in the TRA Response Form detailing why the identified enrollee did not receive a transition fill or therapeutic alternative and, if necessary, submit supporting documentation such as the transition notice provided to the enrollee. Selected plans must complete the TRA Response Form in its entirety before uploading the form to the Web Portal along with any relevant supplemental documentation in a zip file.

Selected Part D plans will complete the following steps:

1. Complete/update user authorization.
Before downloading the TRA Response Form, the contract's Medicare Compliance Officer (MCO) will need to identify the appropriate authorized users (up to five) for Acumen's Formulary and Benefits Monitoring Web Portal.
2. Download the TRA Response Form.
Download the response form from Acumen's Formulary and Benefits Monitoring Web Portal
3. Complete the TRA Response Form.
4. Gather relevant supplemental documentation.
Relevant supplemental documentation may include the Part D transition letter the selected enrollee received for each corresponding ticket, if available. This includes notices for enrollees transitioned proactively prior to the end of CY 2020. CMS

encourages EGWPs to include a PDF copy of the CY 2020 and CY 2021 formulary variation for the selected employer in the submission.

5. Package the completed TRA Response Form and any supplemental documentation into a zip file and upload it to Acumen's Formulary and Benefits Monitoring Web Portal.

Part D plans selected for the analysis will receive instructions for completion of the user authorization process and additional details regarding the CY 2021 TRA in a separate communication.

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

CY 2021 TRA Schedule of Events

Actions anticipated for May/June 2021:

- Selected plans will receive an email with instructions for completing data uploads.
- 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 Web Portal.
- Selected plans to provide details regarding each contract's sample in the TRA Response Form and upload the form, along with any accompanying supplemental documentation, to Acumen's Formulary and Benefits Monitoring Web Portal.

It is CMS's expectation that Part D sponsors work aggressively and promptly to address problems identified by this analysis. Failure to comply with CMS transition policy requirements may result in a compliance action. For questions related to submission or the secure Web Portal, please contact Acumen at FormularyBenefits@acumenllc.com. For questions regarding the TRA, please contact CMS at PartDTransition@cms.hhs.gov.