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

CENTER FOR MEDICARE

DATE: July 1, 2022

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 2022 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. The purpose of the TRA is to evaluate Part D sponsors' transition processes using prescription drug event (PDE) data to help determine whether sponsors are meeting Part D transition requirements.

CY 2021 TRA

The 2021 TRA identified Part D enrollees that were taking a maintenance drug that was deleted from the formulary across plan years (target drug), and looked for affected enrollees who did not appear to have a transition fill or a fill for a therapeutic alternative drug during the months of January – March of 2021. 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 regarding the absence of a transition fill. Employer Group Waiver Plans (EGWPs), Medicare-Medicaid Plans (MMPs) and Program of All-inclusive Care of the Elderly (PACE) organizations that submit a Part D formulary via HPMS were included in the 2021 TRA.

Not accounting for EGWPs, CMS identified 15,494 transition eligible beneficiaries for the CY 2021 TRA. The TRA included a sample of 416 beneficiary/drug combinations for which the beneficiary utilized a drug in CY 2020 that was removed from their plan's formulary for CY 2021. The results of the 2021 TRA were overwhelmingly positive with only 0.7% (3) of the identified samples not having afforded an appropriate transition fill.

In summary, CMS found that the 416 beneficiary/drug combinations that were sampled fell into one of the following three categories:

- 1.2% (5) of were not transition eligible for various reasons, such as the target drug being covered under Part B or the last fill in 2020 being over 108 days before the attempted transition fill.
- 10.1% (42) of the sample ultimately did receive a fill for a target drug or therapeutic alternative from January – March 2021.
- Of the 88.7% (369) samples that did not have a PDE for the transition-eligible drug or an alternative, the most common reason reported for the lack of a transition fill was that the enrollee did not request a fill for the target drug during the transition period.

CY 2022 TRA

CMS will again conduct the TRA for CY 2022. CMS will select one plan per parent organization to participate in the analysis. As with the 2021 TRA, 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. EGWPs will however not be included in the CY 2022 analysis. Part D plans selected for the analysis will receive a notification that will provide additional information. Organizations that are selected for a CMS CY 2022 Program Audit will also be excluded from the analysis.

CMS will use HPMS formulary file extracts for both CY 2021 and CY 2022 to identify maintenance drugs that had a negative formulary change across contract years, PDE data to identify enrollees taking the affected drugs, and enrollment data to distinguish between new and continuing enrollees. We will then identify eligible enrollees who do not appear to have received a transition fill in January – March 2022.

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 negative formulary change across plan years or new enrollees whose drugs are non-formulary and do not appear to have received a transition fill in January – March 2022. 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 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 2021.

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 2022 TRA in a separate communication.

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

CY 2022 TRA Schedule of Events

Actions anticipated - August 2022:

- Selected plans will receive an email notifying them of their selection for the CY 2022 TRA, along 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, selected plans will need to 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.