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DATE: November 25, 2022

TO: All Medicare Advantage Organizations, Section 1876 Cost Plans and Part D Plan Sponsors

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SUBJECT: Proposed Part D Out-of-Pocket Cost Model Updates

The purpose of this memorandum is to solicit feedback on two proposed updates to the Part D Out-of-Pocket Cost (OOPC) Model used by stand-alone Prescription Drug Plans (PDPs) to evaluate meaningful difference between plan offerings and by Medicare Advantage Organizations (MAOs) in calculating changes in Total Beneficiary Cost (TBC) from one year to the next. The first proposed enhancement would incorporate therapeutic alternatives and formulary exceptions into the model. The second proposed update would be an annual release of a refreshed OOPC model that incorporates changes from the May Formulary Reference File (FRF) prior to the bid submission deadline.

Update to Non-Formulary Drug Cost Sharing

CMS is updating the Part D OOPC model to account for potential formulary alternatives and formulary exceptions in the model. In the November 19, 2021 HPMS memorandum titled “Enhanced Out-of-Pocket Cost Model Update,” CMS released an update to the Part D OOPC model that included an enhancement to randomly assign non-formulary drugs to one of the following three outcomes: cash price, therapeutic alternative, or formulary exception. This enhancement was incorporated in the CY 2022 Part D Baseline OOPC model released on December 30, 2021. CMS later reissued the CY 2022 Part D Baseline OOPC model on January 21, 2022 without the enhancement due to an issue identified in the coding of the model. CMS has updated the logic for this enhancement and proposes to reincorporate it back into the model.

Annual Part D OOPC Model Drug List Refresh

The bid review OOPC model has historically been based on the March version of the formulary reference file (FRF). CMS releases a May version of the FRF, ahead of the deadline for sponsors

to use in their formulary preparation. Any changes in the May version of the FRF, however, have not previously been reflected in the OOPC model. In CY 2023, some new generic drugs added to the May FRF had a significant impact on OOPC calculations. As such, an updated OOPC version was released after the bid deadline on June 21, 2022 and this updated version was used in bid review. In order to avoid a similar scenario in future years, CMS is proposing to release a refreshed version of the Bid Review OOPC model annually to account for changes in the May FRF. Moving forward, CMS intends to continue to release the Bid Review OOPC model in April. In addition, we would also publish a refreshed Bid Review OOPC model approximately one week ahead of the bid deadline that includes the FRF changes.

Next Steps

With this memorandum, CMS is releasing an updated version of the CY 2023 Part D Bid Review OOPC Model, inclusive of the proposed additional updates detailed in this memorandum. Technical User Guides and Methodology documents with instructions regarding how to execute the files and run the models are posted on the CMS website on the [OOPC Resources page](#). In order to confirm reproducibility of this model update, CMS is also releasing OOPC values to each plan to ensure sponsors are able to reproduce the CMS-generated value. Part D OOPC values can be viewed in HPMS under: **Quality and Performance > Performance Metrics > Costs > Part C Out-of-Pocket Costs** for MAOs and **Quality and Performance > Performance Metrics > Costs > Part D Out-of-Pocket Costs** for PDPs. Previous versions of the OOPC and TBC data will continue to be accessible in HPMS. This information will allow MAOs, PDP sponsors, and interested stakeholders to gain familiarity with the changes in advance of their use in bid evaluation. Please note that MAOs will not be receiving Part C OOPC values with this release.

The updated versions of the Part D OOPC Models will be used for bid evaluation purposes starting with CY 2024 bid submissions. We intend for the CY 2023 Baseline OOPC Model (expected to be issued in December 2022/January 2023), as well as all other future model releases, to include the proposed enhancement to account for potential formulary alternatives and formulary exceptions for bid evaluation purposes.

Request for Comments

Please submit any questions or comments related to the proposed non-formulary randomization enhancement to the OOPC model and/or the proposed release of a full refresh of the Bid Review OOPC model based on the updated May FRF approximately one week ahead of the bid deadline to OOPC@cms.hhs.gov by December 7, 2022.