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**CENTERS FOR MEDICARE & MEDICAID SERVICES**

**CY 2021 ENHANCED BASELINE**

**PART D OUT-OF-POCKET COST MODEL**

**METHODOLOGY**

**NOVEMBER 2021**

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# 1. Introduction

The Center for Medicare & Medicaid Services (CMS) uses Out-of-Pocket-Cost (OOPC) estimates to evaluate Part D Plan (PDP) submitted bids. The estimates are generated by the OOPC software available on the OOPC Resources, CMS.gov website (<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources>).

For Contract Year (CY) 2021 OOPC estimates, a random 0.1% sample of all Part D beneficiaries and their associated Prescription Drug Event (PDE) data were identified. The event data for these cohorts are combined with CY 2021 Plan Benefit Packages (PBPs) to produce the estimates.

The Part D calculations apply average prices from the Medicare Prescription Drug Event (PDE) claims data for 2019.

This document describes the general methodology underlying the CY 2021 Enhanced Baseline Part D OOPC Model. The *CY 2021 Enhanced Baseline Part D OOPC Model User Guide September 2021* provides the information on how to run the model and generate the output.

## 2. Selection of the OOPC Cohort Based on the 2019 Medicare Population

A random 0.1% sample of Part D beneficiaries are selected from the Medicare CME Database and then associated with their 2019 PDE events selected from the Medicare Part D Claims database. The CMS documentation that includes a basic description of Part D Claims Data used for the model development is provided at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PartDData>

The 0.1% PDE sample resulted in approximately 46,000 beneficiaries, and their drug utilization, being included in the calculations.

## 3. Development of OOPC Estimates

Average monthly Part D OOPCs are calculated for each plan offering Part D benefits. The model uses the data entered into the PBP and the associated plan's formulary to calculate the OOPC.

To calculate OOPCs the following steps are performed:

- National Drug Codes (NDCs) from PDE records are mapped into RxCUI (RxNorm Concept Unique Identifiers) codes to apply a particular plan's tier-formulary based cost sharing.
- PDE records are based on the utilization of the 0.1% cohort.
- PDE records were used to calculate average drug prices.
- Each PDE records is considered a one-month (30-day) prescription and the prescription is filled at an in-network pharmacy. If a plan has a preferred and standard pharmacy network structure, the prescription is assumed to filled at the preferred pharmacy.
- The model incorporates the Free First Fill benefits offered by selected plans.
- The model incorporates the Senior Savings benefits offered by selected plans.
- The model incorporates the deductible applied by a plan.
- The model incorporates substitution, such that when a generic or authorized generic version of a brand drug exists on the plan's formulary, the model assigns the cost sharing associated with the generic or authorized generic version of the drug in the calculations, provided it has lower cost sharing.

- The model incorporates an algorithm to assign cost sharing for the cost of a drug that is not on a plan's formulary; assignment includes either a non-covered status (i.e., cash price), an exception tier status (based on plan specific exceptions tier), or to a potential formulary alternative status, as described below.

## 4. Part D OOPC

The estimated OOPC values are based upon the drug information found in the PDE file provided for the individual sample beneficiaries. The beneficiary cohort used to identify the drug utilization come from a random 0.1% sample of all Part D beneficiaries and their associated 2019 PDE data. The data are used in conjunction with the CY 2021 PBPs submitted by plans that detail the drug benefit cost sharing and plan coverage as well as the CY 2021 plan-level formulary submissions. The NDC on each PDE record is mapped into an RxCUI using the appropriate CMS formulary reference file (FRF) released in September 2020.

An average price for each RxCUI is calculated using 2019 PDE claims data. The average price is calculated as the total gross expenditure (ingredient cost + dispensing fee + taxes + vaccination fee) divided by the number of 30-day equivalent prescriptions.

Using each plan's drug coverage status and PBP-based cost sharing information (deductible, initial coverage limit, co-copayments and/or coinsurance, gap coverage, free first fill, senior savings etc.), the beneficiary's OOPCs are calculated. The calculations are performed according to the type of Part D plan (Defined Standard, Basic Alternative, Actuarially Equivalent, or Enhanced Alternative) and the associated cost share structure. The calculations are based on the assumption that each prescription is for a one-month (30-day) supply of drugs (rather than a 60- or 90-day supply) from an In-Network Pharmacy. In the event that both a preferred and a non-preferred pharmacy exist, the calculations are based on the preferred pharmacy cost-sharing.

Substitution is assumed, such that when a generic or authorized generic version of a drug exists on the plan's formulary, the model assigns the cost sharing associated with the generic or authorized generic version of the drug in the calculations, provided it has lower cost sharing. In addition, Food and Drug Administration (FDA) application type is utilized to determine the applicable/nonapplicable status of drugs for purposes of coverage gap cost-sharing estimates.

If the RxCUI is not on a plan's formulary, this drug is assumed to be non-covered by the plan. Historically the OOPC model would assign the full cost, as reflected by the average price, for a non-formulary drug to a plan's OOPC value. CMS recognized this as a potential limitation of the historical OOPC model as it assumes that all beneficiaries will remain on the non-formulary drug, and pay full cost out of pocket. Stakeholders have expressed concern that the model does not account for other possible outcomes, whereby the beneficiary may request a formulary exception to remain on the non-formulary drug at the exception tier cost share or switch to a formulary alternative. As part of our continual efforts for process improvements, CMS is updating the Part D OOPC methodology related

to the estimation of non-formulary drug costs in the model. Specifically, CMS is incorporating an approach whereby non-formulary drug cost sharing will be randomly assigned to one of the following weighted outcomes:

- 1) Beneficiary pays the full retail cost, based on PDE average price [there is a 49% probability of this outcome],
- 2) Beneficiary pays the cost sharing for a potential alternative covered on the formulary, where the model selects the cost sharing for one of the covered potential formulary alternatives [there is a 36% probability of this outcome], or
- 3) Beneficiary pays the cost sharing for the formulary exception tier(s) [there is a 15% probability of this outcome].

These proportions were quantified through a 2018-2019 PDE analysis to determine the behavior of enrollees when faced with non-formulary coverage of drugs that were offered by their plan in 2018 but were dropped from coverage in 2019. This enhancement of the Part D OOPC methodology will enable the model to better predict real-world occurrences and will provide for a more accurate reflection of the estimated Part D OOPC.

The beneficiary/prescription event level data is then aggregated to the plan level using beneficiary sample weights and the associated prescription level cost estimates.

The CY 2021 Enhanced Baseline Part D OOPC Model is being made available to plan sponsors to allow sponsors the opportunity to gain familiarity with the enhancement changes before implementing them for bid review purposes.

## Appendix A: 2021 Part D Benefit Assumptions – MA-PD & PDP Plans

Appendix A Table 1				
CY 2021 Medicare Part D Cost Share and Cost Limit Parameters	Defined Standard	Actuarially Equivalent	Basic Alternative	Enhanced Alternative
Pre-ICL Cost Shares	25%	25% or Tiers	25% or Tiers	25% or Tiers or No Cost Sharing
Pre-Deductible	No Coverage	No Coverage	Yes, optional	Yes, optional
Deductible	\$445	\$445	\$445 or Plan-specified or No Deductible	\$445 or Plan-specified or No Deductible
ICL	\$4,130	\$4,130	\$4,130 or Plan-specified or No ICL	\$4,130 or Plan-specified or No ICL
Gap Coverage	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost	25% Generic Beneficiary Cost 25% Brand Beneficiary Cost
Additional Gap Coverage	N/A	N/A	N/A	No Additional Coverage or Gap Tiers
Threshold (TROOP)	\$6,550	\$6,550	\$6,550	\$6,550
Catastrophic Coverage Threshold	\$10,048.39	\$10,048.39	\$10,048.39	\$10,048.39
Post-Threshold Cost Shares	Greater of \$3.70 or 5% for generics (including brands treated as generic, or Greater of \$9.20 or 5% for all other drugs	Greater of \$3.70 or 5% for generics (including brands treated as generic, or Greater of \$9.20 or 5% for all other drugs or Post-Threshold Tiers or No Cost Sharing	Greater of \$3.70 or 5% for generics (including brands treated as generic, or Greater of \$9.20 or 5% for all other drugs or Post-Threshold Tiers or No Cost Sharing	Greater of \$3.70 or 5% for generics (including brands treated as generic, or Greater of \$9.20 or 5% for all other drugs or Post-Threshold Tiers or No Cost Sharing
Charge Lesser of Copayment or Cost of the Drug	N/A	Yes, optional.	Yes, optional	Yes, optional

<b>List of Acronyms</b>	
CMS	Centers for Medicare & Medicaid Services
CY	Contract Year
FDA	Food and Drug Administration
FRF	Formulary reference file
MCBS	Medicare Current Beneficiary Survey
NDC	National Drug Codes
OOPC	Out-of-pocket Cost
PDE	Prescription Drug Event
PBP	Plan Benefit Package
RXCUI	RxNorm Concept Unique Identifiers