# Final CY 2025 Part D Redesign Program Instructions
# Fact Sheet

Today, the Centers for Medicare & Medicaid Services (CMS) released the Final Calendar Year (CY) 2025 Part D Redesign Program Instructions (the Final Program Instructions) concurrently with the CY 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Rate Announcement). The purpose of the Final Program Instructions is to provide interested parties with guidance for CY 2025 regarding, among other topics, the implementation of section 11201 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, which made several amendments and additions to the Social Security Act ("the Act") that affect the structure of the defined standard Part D drug benefit.

The Final Program Instructions contain a detailed description of, and guidance related to, changes newly in place for CY 2025 made by the IRA, as well as guidance for CY 2023 Medical Loss Ratio (MLR) reporting related to the Inflation Reduction Act Subsidy Amount (IRASA). The Final Program Instructions are published concurrently with the Rate Announcement that, among other things, announces updates to Part D parameters, some of which are impacted by provisions in the Final Program Instructions.

Following the publication of the CY 2025 Draft Program Instructions, it came to CMS' attention that the methodology codified at 42 C.F.R. § 423.104(d)(2)(iv)(D)(3) will no longer be valid when the Initial Coverage Limit (ICL) is eliminated in 2025. As such, CMS has included a new methodology in the Final Program Instructions to determine the specialty tier coinsurance/deductible ranges under the redesigned Part D benefit.

**Overview of Changes to the Part D Benefit:**

In CY 2025, the structure of the Part D benefit is updated to reflect provisions of the IRA that become effective on January 1, 2025. The CY 2025 updates include the following:

- A newly defined standard Part D benefit design consisting of three phases: annual deductible, initial coverage, and catastrophic coverage;
- A lower annual out-of-pocket (OOP) threshold of $2,000;

- The sunset of the Coverage Gap Discount Program (CGDP) and establishment of the Manufacturer Discount Program (Discount Program); and
- Changes to the liability of enrollees, Part D sponsors, manufacturers, and CMS in the newly defined standard Part D benefit design.

**Summary of Key Policies in the Final Program Instructions:**

**Costs Counted Toward True Out-of-Pocket Costs (TrOOP)**

TrOOP is the portion of spending on covered Part D drugs made by the beneficiary or on their behalf by certain third parties. The IRA updates which categories of payments count toward TrOOP spending. TrOOP is the spending that determines when a beneficiary enters the initial coverage phase, becomes an applicable beneficiary for the Discount Program, reaches the annual OOP threshold, and subsequently enters the catastrophic coverage phase. In addition to the third-party arrangements that already count toward TrOOP, the IRA specifically amends the definition of incurred costs that count toward TrOOP for CY 2025 to *include* payments for previously excluded supplemental benefits provided by Part D sponsors and Employer Group Waiver Plans (EGWPs) and *exclude* payments under the new Discount Program.

**Creditable Coverage**

Consistent with IRA changes, we are revising the regulatory definition of creditable coverage at § 423.56(b) to reflect that discounts paid under the Manufacturer Discount Program are not taken into account when determining actuarial value. Given various concerns raised by commenters and the significant changes to the Part D benefit for CY 2025 as a result of the redesign, CMS will continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for non-EGWP group health plan sponsors not applying for the retiree drug subsidy under section 1860D-22(a) of the Act. The Final Program Instructions also specify that CMS will re-evaluate the continued use of the existing simplified determination methodology or establish a revised one for CY 2026 in future guidance.

**Policy for Drugs Not Subject to Defined Standard Deductible**

In CY 2025, the IRA eliminates the coverage gap phase and the related CGDP and, in its place, establishes the new Discount Program. The IRA also alters the defined standard benefit to exempt certain drugs (certain insulins and vaccines) from the deductible. For CY 2025, if a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible, they will be both an applicable beneficiary under the Discount Program and deemed to have satisfied their plan deductible. If the beneficiary satisfies the plan's deductible or utilizes a drug not subject to the deductible but is not eligible for the Discount Program because they have not incurred sufficient TrOOP-eligible costs to satisfy the defined standard deductible amount, then the Part D sponsor will be required to cover the portion of costs a manufacturer would have owed had Discount Program discounts begun.

**Government Reinsurance Methodology**

The IRA changes the government reinsurance calculation methodology for CY 2025 to be dependent on drug type. These changes to the reinsurance payment amount require CMS to revise the Direct and Indirect Remuneration (DIR) allocation methodology. Specifically, since the reinsurance amount must be calculated differently for different types of drugs, the DIR allocation methodology must correspondingly vary for different types of drugs in CY 2025. CMS will calculate the reinsurance subsidy separately for applicable and non-applicable drugs and allocate the share of DIR for applicable and non-applicable drugs based on their respective share of gross covered prescription drug costs that fall in the catastrophic phase.

**EGWP Prospective Reinsurance Amount**

Because the Part D redesign reduces the government reinsurance percentage in CY 2025, using the existing methodology for Part D Calendar Year EGWP prospective reinsurance payments would result in CMS prospectively paying significantly more than necessary for CY 2025. CMS would then need to recover sizable funds from EGWPs during the Part D payment reconciliation process. Therefore, CMS is updating the methodology to ensure that Part D Calendar Year EGWPs are paid a more appropriate prospective reinsurance amount in CY 2025. CMS will calculate the prospective reinsurance payments to all Part D Calendar Year EGWP sponsors using the weighted average of per-member-per-month (PMPM) prospective reinsurance amounts

submitted by Part D sponsors for Enhanced Alternative (EA) plans as part of the Part D bid submissions for the payment year in question (for example, CMS will use CY 2025 Part D bids submitted in June 2024 to calculate prospective reinsurance payments for Calendar Year EGWPs for CY 2025).

**Definition of EA Benefit Design**

In CY 2025, the Part D benefit redesign provisions under the IRA limit the available options for sponsors to enhance their benefits to offer an EA plan to the following:

- Coverage of drugs that are specifically excluded from Part D drug coverage; and/or
- Any one or more of the following changes that increase the actuarial value of benefits above the actuarial value of the defined standard prescription drug coverage:
    - Reduction (or elimination) of the defined standard deductible
    - Reduction of cost sharing in the initial coverage phase.

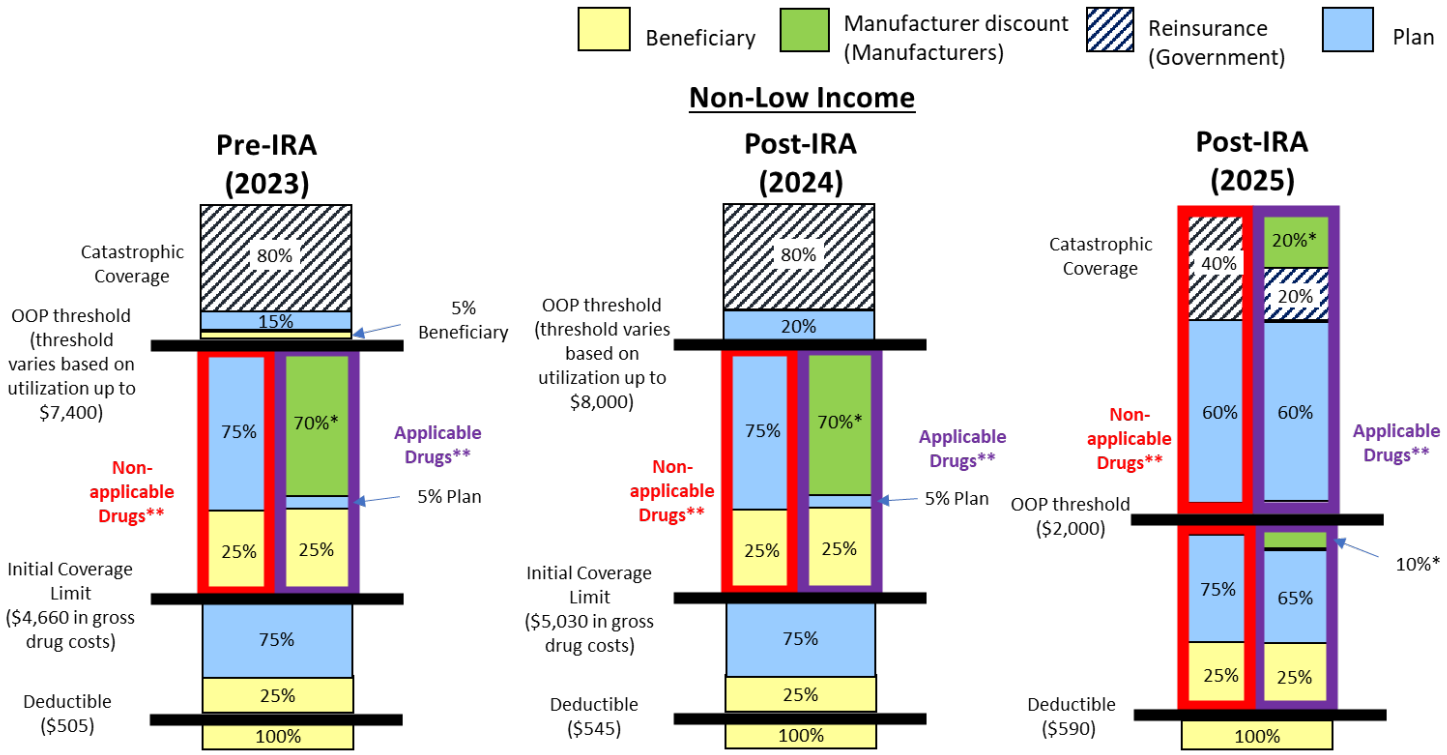
Because the Part D benefit redesign reduces available options for EA plan design, CMS reconsidered what constitutes a permissible EA benefit design. The Final Program Instructions establish a process for ensuring that individuals receive value relative to the defined standard benefit when they enroll in an EA plan. Specifically, for CY 2025, CMS will use the Part D Out-of-Pocket Costs (OOPC) model to estimate the value of EA plans relative to the value of the defined standard benefit.

**For more details on the updated structure of the defined standard Part D drug benefit, please see the notes and the graphic below.**

- **Annual deductible**. The enrollee pays 100% of their gross covered prescription drug costs (GCPDC) until the deductible of $590 for CY 2025 is met.
- **Initial coverage**. The enrollee pays 25% coinsurance for covered Part D drugs. The sponsor typically pays 65% of the cost of applicable drugs and 75% of the cost of all other covered Part D drugs. The manufacturer, through the Discount Program, typically covers 10% of the cost of applicable drugs. This phase ends when the enrollee has reached the annual OOP threshold of $2,000 for CY 2025.

– **Catastrophic**. The enrollee pays no cost sharing for covered Part D drugs. Sponsors typically pay 60% of the costs of all covered Part D drugs. The manufacturer pays a discount, typically equal to 20%, for applicable drugs. CMS pays a reinsurance subsidy equal to 20% of the costs of applicable drugs and equivalent to 40% of the costs of all other covered Part D drugs that are not applicable drugs.

**Part D Benefit in CY 2025 and Past Years (Non-Low Income Subsidy Beneficiary)**




*The Discount Program is phased in for certain drugs of qualifying drug manufacturers during the initial coverage phase from 2025 through 2028 and in the catastrophic phase from 2025 through 2030. For drugs subject to the phase-in, Part D sponsors will be responsible for the additional cost that would have otherwise been covered by the manufacturer discount.

**For more information about topics related to the Part D Benefit Redesign, please go to** https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements.