wakely.com

Summary of Draft CY 2026 Part D Redesign Program Instructions

January 22, 2025

Prepared by:
Wakely Consulting Group, LLC

Sarah Legatt, FSA, MAA
Consulting Actuary

Casey Gardner, ASA, MAAA
Consulting Actuary

Table of Contents

Executive Summary

On January 10, 2025, the Centers for Medicare and Medicaid Services (CMS) released draft instructions on the CY2026 Part D Redesign. These instructions contain detailed descriptions and guidance to all Inflation Reduction Act (IRA)-related changes newly in place for CY2026, including benefit design changes, adjustments to MLR calculations, meaningful difference testing, creditable coverage, non-calendar EGWPs, the selected drug subsidy, and draft guidance on the successor regulation exception to the IRA's formulary inclusion requirements for selected drugs.

CMS is soliciting comments on these instructions until 2/15/2025. Comments should be sent to the PartDRedesignPI@cms.hhs.gov inbox with the subject line "Draft CY 2026 Part D Redesign Program Instructions". Final instructions will be published after comments are considered.

10. Introductions

Unchanged guidance and instructions implemented in previous years are not repeated in these instructions. Readers should reference previous years' Advance Notice and Rate Announcements and Final CY 2025 Program Instructions for changes made for CY 2023 – CY2025. Please see 'Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026' and 'Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027' for more guidance on the Negotiation Program.

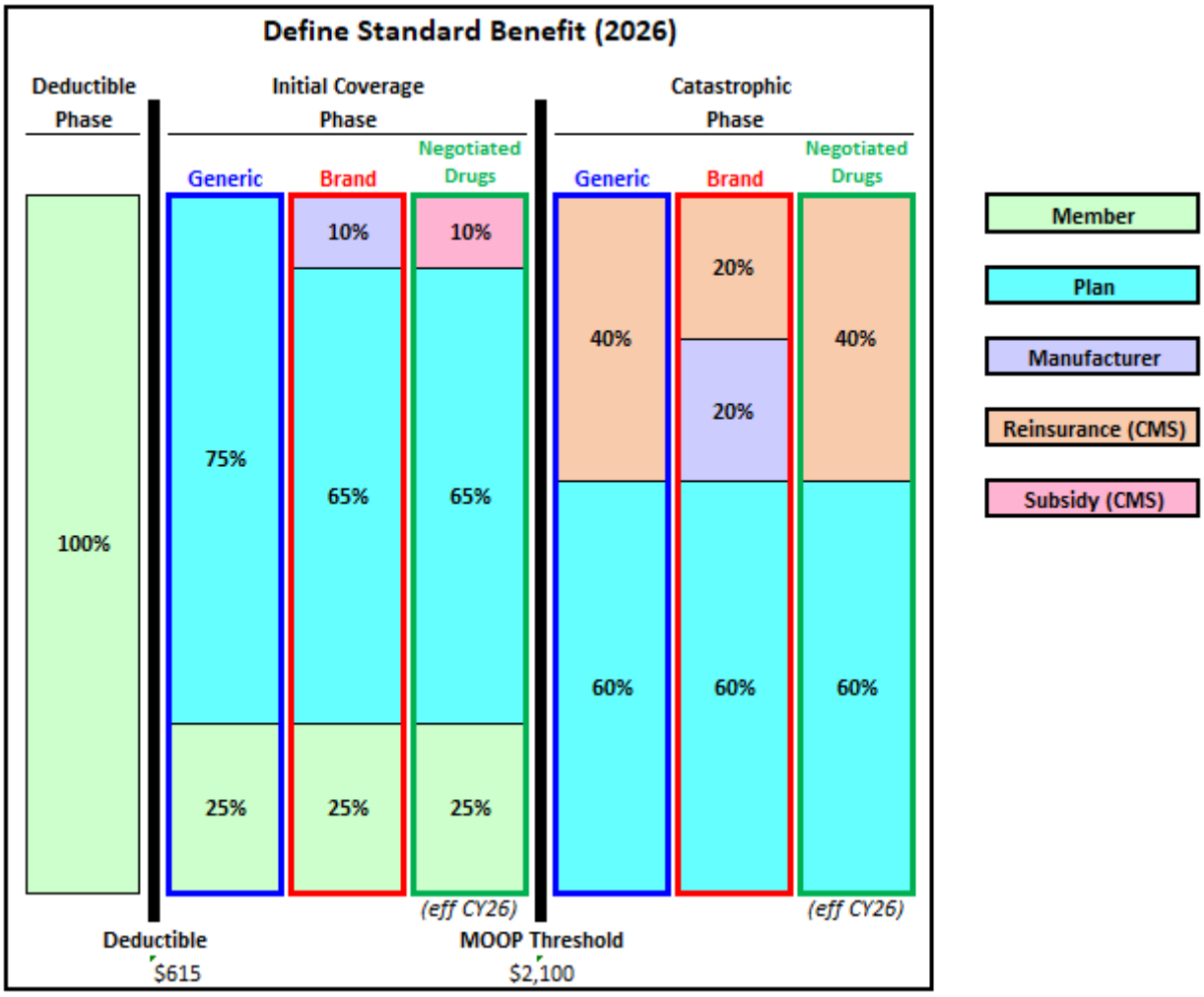
20. Redesigned Part D Benefit in CY 2026

With the introduction of the maximum fair prices (MFP) under the Negotiated Program in CY2026, the IRA makes changes to payment obligations related to the drugs that MFPs were negotiated, titled 'selected drugs'.

Table A illustrates the defined standard (DS) benefit for CY2026. The CY2026 is consistent with CY2025 benefit, with the addition of:

- selected drug subsidy for 'selected drugs' in the initial coverage phase, which CMS will pay, and
- similar to non-applicable (generic) drugs in the catastrophic phase, CMS will provide 40% reinsurance for 'selected drugs'.

Table A – 2026 Defined Standard Benefit



30. Creditable Coverage

Creditable coverage refers to prescription drug coverage (often provided by an employer) that is at least as good as the coverage under Medicare Part D. If this requirement is not met and eligible members are not enrolled in Part D, members could incur a late enrollment penalty.

CMS is revising the simplified creditable coverage determination methodology to reflect the richer Part D Defined Standard benefit under the IRA. Instead of being required to cover at least 60% of participants' drug expenses, plans will now be required to cover 72%.

40. Definition of Enhanced Alternative Benefit Design

Plans can alter the defined standard (DS) benefit in the following ways to create an enhanced alternative (EA) plan:

1. reduce or eliminate the DS deductible
2. reduce the cost sharing in the initial coverage phase
3. cover drugs that are specifically excluded from Medicare-covered Part D drugs

As the options for offering enhancements is limited, CMS believes it is critical to continue to ensure that beneficiaries receive value relative to the DS benefit when purchasing an EA plan through the measurement of out-of-pocket costs (OOPC).

Because excluded drugs have shown they do not add much additional value, CMS is proposing removing the ability for a plan to be considered an EA benefit when only offering excluded drugs as an enhancement.

CMS will continue to use OOPC as a tool to measure EA benefits against DS benefits. The OOPC value does not reflect the impact of LICS, which would be available to most (if not all) D-SNP and MMP beneficiaries, so OOPC is not a true measure of out-of-pocket spending for these cohorts. Consistent with CY2025, CMS will not be measuring PACE or EGWP plans with OOPC. In addition, for CY2026, CMS will also exclude measuring Dual Eligible Special Needs Plans (D-SNPs) and Medicare-Medicaid Plans (MMPs).

While OOPC thresholds did not exist for CY2025 when measuring PD EA plans, CMS is establishing an OOPC threshold of 15% for EA plans, when compared to DS plan with the same formulary. CMS noted that this 15% difference in OOPC (between EA benefits and DS benefits) was the 5th percentile of CY2025 submitted bids nationwide, so this change will likely not lead to a substantial burden for most plans.

Table B demonstrates how OOPC is to be tested. Final percentage of 33% is above the 15% threshold, so this plan would pass the EA OOPC test.

Table B – PD OOPC Test for EA Plans

Calculation	Value	Source	Description	Example
[A]	EA OOPC	PD OOPC model	OOPC value for EA plans (formulary & intended plan design)	$70
[B]	DS EA OOPC	PD OOPC model	OOPC value for EA plan's formulary run with DS benefit	$105
[C] = [B] – [A]	Difference	Calculation	Absolute OOPC difference between EA plan and DS plan with EA formulary	$35
[D] = [B]/[A]-1	Percent Difference	Calculation	Percentage OOPC difference between EA plan and DS plan with EA formulary	33%

In the Rx section of the CY2026 PBPs, text boxes will be available again for description the "Reduced Initial Coverage Phase cost shares". Information entered in these boxes should be specific, using phrases such as '$0 cost sharing for generic tiers', 'placement of drugs on the lowest cost share tier', or 'reduced cost sharing for tier 1 drugs at preferred pharmacies', and avoid entries such as 'reduction of cost sharing in initial coverage phase', 'placeholder', or 'entry of Part A/B or MA supplemental benefits"

50. PDP Meaningful Difference

CMS requires that the benefits and formulary coverage offered by standalone-PDP plans be meaningfully different from each other. This ensures beneficiaries can easily make enrollment decisions that accurately reflect their needs.

Last year, CMS changed the OOPC value threshold from a dollar value to a percentage differential. This simplifies the process and accounts for differences in the richness of the base plan. Additionally, they changed the OOPC test so that it is comprised of two components – formulary robustness and benefit design/tier placement. The purpose of this change was to eliminate instances where plans were "gaming" the meaningful difference test by placing additional high-cost low utilization drugs on the formulary until they could pass. For CY2026, this test will be increasingly difficult, as:

- OOPC between the plan's enhanced and basic plans must achieve 15% threshold,
- Greater than 50% of the meaningful difference in OOPC values must come from benefit design/tier placement, and
- The portion attributed to formulary robustness must be positive.

Table C demonstrates how PDP meaningful difference is to be tested. Final percentages in steps F, G, & H are above the thresholds of 0%, 50%, and 15%, respectively, so this plan passes PDP meaningful difference tests.

Table C – PDP Meaningful Difference Tests for EA Plans

Calculation	Value	Source	Description	Example
[A]	Basic OOPC	OOPC Model	OOPC value of basic plan (formulary and intended plan design)	$100
[B]	DS Basic OOPC	OOPC Model	OOPC value of the basic plan's formulary run through DS benefit	$110
[C]	EA OOPC	OOPC Model	OOPC value of EA plan (formulary and intended plan design)	$70
[D]	DS EA OOPC	OOPC model	OOPC value of the EA plan's formulary run through DS benefit	$104

[E] =[A]−[C]	Meaningful Difference	Calculation	The differential in OOPC between the EA plan and the basic plan. This value must be positive, indicating the EA plan is better (i.e., lower) than the basic plan	$30
[F] =([B]−[D]) / ([E])	Formulary Component	Calculation	The proportion of meaningful difference attributed to formulary robustness	20%
[G] =1 - [F]	Benefit Component	Calculation	The proportion of meaningful difference attributed to benefit design / tier placement	80%
[H] = ([A]−[C]) / [A]	PDP Meaningful Difference	Calculation	The percent difference between the enhanced plan and the basic plan	30%

60. Non-Calendar Year (NCY) EGWPs

EGWPs must continue to meet the actuarial standards set out in § 423.104(e) and Section 20.13 of Chapter 12 of the Prescription Drug Benefit Manual, along with mapping EGWP PDEs to the DS benefit.

Part D sponsors offering a NCY EGWP whose plan year starts in CY2025 must complete the following:

- Map PDEs to the 2025 PD Basic benefit for both the CY2025 and CY2026 portions of its NCY plan year using the 2025 DS deductible and annual OOP threshold.
    - Any difference in cost sharing from the DS benefit constitutes Other Health Information (OHI). Starting in CY2025, OHI became TrOOP eligible.
- Not increase plan deductible during its NCY plan year.
- Implement the 2025 DS deductible and annual OOP threshold for the entirety of the NCY plan year when applying discounts under the Discount Program.

However, under the Discount Program, there are specified and specified-small manufacturers that receive a phased-in discount percentage. The phase-in discount percentage applied to claims must align with the calendar year expectations of the phase-in, even though benefits are on a non-calendar year basis. CY2025's phase in percentage of 1% applies for 1/1/2025-12/31/2025, while CY2026's phase in percentage of 2% applies to dates of service 1/1/2026 – 12/31/2026.

70. Selected Drug Subsidy

The IRA allowed Medicare to negotiate prices with manufacturers on 10 drugs for CY2026, under the Negotiated Program. These drugs are subject to a Selected Drug Subsidy. This subsidy, paid by the government, covers the same costs that would otherwise be incurred by the Manufacturer through the Discount Program. This payment, like the low-income cost-sharing subsidy (LICS), will be paid prospectively to plans and then reconciled at the end of the PDE submission window for a year. There are a few important things to note with respect to selected drug adjudication:

- Selected drug subsidy amounts are not earned until the member incurs enough drug costs to reach the Defined Standard deductible amount, even in an Enhanced plan.
- Selected drugs are treated as non-applicable drugs for the purposes of the reinsurance calculation.

80. Medical Loss Ratio (MLR)

With the implementation of the IRA, new subsidies & programs were introduced and needed to be considered in the calculation of the MLR.

For CY2023, the Inflation Reduction Act Subsidy Amount (IRASA), a one-year subsidy was introduced for pass-through expenses for vaccines & insulins to pass through to CMS, was excluded from both the numerator and denominator of the MLR.

The Discount Program, introduced in CY2025, serving in a similar role as the Coverage Gap Discount Program (CGDP) is excluded from both the numerator and denominator of the MLR, starting in CY2025 and continuing for CY2026.

Effective with CY2026 IRA changes, the selected drug subsidy will be excluded from the numerator and denominator of the MLR. The removal of these expenses from the numerator and denominator of the MLR calculation is consistent with the treatment of other subsidies and pass-through expenses, such as LICS and CGDP.

90. Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs

Starting in 2026, Part D plans generally *must* include "selected drugs" on their formularies. Plans *can* remove a selected drug if they replace it with a corresponding generic or interchangeable biosimilar drug that is on the same or lower cost-sharing tier and has the same or less restrictive utilization management criteria (prior authorization, step therapy, quantity limits). Notably, an authorized generic or an unbranded biological product marketed under the same license as the selected drug *is considered the same selected drug.* Therefore, plans *cannot* remove a selected

brand-name drug simply by adding its authorized generic. The substitution must be with a *different* generic manufacturer.

If a generic or interchangeable biosimilar becomes available *after* a plan submits its formulary to CMS, the plan can substitute the selected drug until they can place the generic or biosimilar on the formulary. However, if the generic or interchangeable biosimilar was available *before* the formulary submission, the plan *must* include the selected drug on the formulary and cannot use the substitution exception.

CMS is considering whether to expand the exception beyond immediate substitutions to include "maintenance changes" (routine formulary updates for generics and biosimilars). This would allow plans more flexibility but would also need to comply with specific timing and notice requirements.