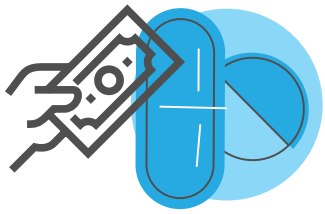
# Fact Sheet: Draft CY 2026 Part D Redesign Program Instructions



Today, the Centers for Medicare & Medicaid Services (CMS) released the Draft Calendar Year (CY) 2026 Part D Redesign Program Instructions (the Draft CY 2026 Program Instructions) concurrently with the Advance Notice of Methodological Changes for CY 2026 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the CY 2026 Advance Notice). CMS will accept comments on the Draft CY 2026 Part D Redesign Program Instructions through 11:59 PM Eastern Time on February 10, 2025, before publishing the final program instructions no later than April 7, 2025.

The purpose of the Draft CY 2026 Part D Redesign Program Instructions is to provide interested parties with draft guidance for CY 2026 regarding the implementation of section 11201 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022,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 draft program instructions also provide guidance on the successor regulation exception to the IRA's formulary inclusion requirement for selected drugs, a topic relevant to the Medicare Part D program that also relates to the Medicare Drug Price Negotiation Program (Negotiation Program) and implementation of sections 11001 and 11002 of the IRA.

The draft program instructions contain a detailed description of and guidance related to changes newly in place for CY 2026 made by sections 11201(a) and (b) of the IRA to the Part D benefit and certain changes in place for CY 2026 made by sections 11201(c) and (e) of the IRA. Changes to the Part D benefit for CY 2025 are discussed in the Final CY 2025 Part D Redesign Program Instructions (the Final CY 2025 Program Instructions), and the policies described in the Final CY 2025 Program Instructions also apply in CY 2026 unless otherwise stated in the Draft CY 2026 Program Instructions. The Draft CY 2026 Program Instructions only include policies updated or modified from CY 2025 and new policies for CY 2026. For policies that continue to apply for CY 2026 but are not addressed in the Draft CY 2026 Program Instructions, please refer to the Final CY 2025 Program Instructions at **https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf**.

CMS is voluntarily soliciting comment on the Draft CY 2026 Program Instructions, including on policies originally adopted in the Final CY 2025 Program Instructions that will continue to apply in CY 2026.

The draft program instructions are being published concurrently with the CY 2026 Advance Notice that, among other things, announces updates to Part D parameters, some of which are impacted by provisions in the draft program instructions.

## Overview of Changes to the Part D Benefit:

In CY 2026, the structure of the Part D benefit will be updated to reflect provisions of the IRA that become effective on January 1, 2026. The CY 2026 updates include the following:

- The CY 2026 annual out-of-pocket (OOP) threshold of $2,100, which is the original 2025 out-of-pocket cap of $2,000, adjusted based on the annual percentage increase in average expenditures for covered Part D drugs in the U.S. for Part D eligible individuals in the previous year (API). Changes to the liability of enrollees, sponsors, manufacturers, and CMS in the new standard Part D benefit design, specifically to account for the start of the Negotiation Program in 2026; and
- The establishment of the selected drug subsidy program.

## Summary of Key Policies in the Draft Guidance: Creditable Coverage

Medicare beneficiaries who are not enrolled in Medicare Part D and do not have other creditable prescription drug coverage may incur a late enrollment penalty if there is a continuous period of 63 days or more at any time after the end of the individual's Part D initial enrollment period during which the individual was eligible for Part D but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage. Creditable coverage must have an actuarial value that equals or exceeds the actuarial value of the defined standard Part D coverage. Since the start of the Part D program, CMS has permitted entities offering group health plans that are not applying for the retiree drug subsidy to make the creditable coverage determination through actuarial equivalence testing or a simplified determination methodology provided by CMS. With the enhancements to the Part D benefit under the IRA, the current simplified determination methodology no longer reflects actuarial equivalence with defined standard Part D coverage. Accordingly, we will permit the use of a revised, simplified determination methodology that better reflects actuarial equivalence with the richer Part D defined standard benefit under the IRA. Most notably, the revised simplified determination methodology would specify that coverage must be designed to pay, on average, at least 72% of a participant's drug expenses—an increase from 60% under the current methodology—to be considered creditable coverage.

## Selected Drug Subsidy

Under the selected drug subsidy program created by the IRA, Part D sponsors will receive a government subsidy for selected drugs equal to 10% of the drug's negotiated price. The selected drug subsidy applies to a covered Part D drug that would be an applicable drug with respect to the Manufacturer Discount Program but for being a selected drug during a price applicability period. The subsidy applies to selected drugs dispensed to an applicable beneficiary who is enrolled in a prescription drug plan (PDP) or a Medicare Advantage prescription drug (MA-PD) plan and has not incurred costs that are equal to or exceed the annual out-of-pocket (OOP) threshold. Under the selected drug subsidy program, once an enrollee incurs costs exceeding the annual deductible under the defined standard benefit, the selected drug subsidy is available in the initial coverage phase of the benefit. The selected drug subsidy lowers Part D sponsor liability on the negotiated price of the selected drug. The PIA addresses several topics related to the selected drug subsidy, including the policy for drugs not subject to the defined standard deductible; selected drug subsidy prospective payments; medical loss ratio; and reinsurance methodology.

## Successor Regulation Exception Permitting Formulary Substitutions of Selected Drugs

The IRA requires Part D sponsors to include on their formularies selected drugs for which a maximum fair price is in effect, starting in 2026. The IRA also provides an exception for Part D sponsors to remove a selected drug if such removal would be permitted under § 423.120(b)(5)(iv) or "any successor regulation." At the time the IRA was enacted, then-current § 423.120(b)(5)(iv) permitted a plan to immediately substitute on the formulary a newly available generic drug for its brand name drug if certain notice and timing requirements were met. However, due to changes made to the regulations in the CY 2025 Parts C & D Final Rule[1], § 423.120(b)(5)(iv) no longer exists. Under the current Part D regulations, the approval requirements for immediate substitutions, which were revised to provide for the substitution of additional types of products, are now codified at § 423.120(e)(2)(i), and the corresponding notice requirements for such formulary changes are now codified at § 423.120(f)(2), (3), and (4). In these Draft CY 2026 Program Instructions, we are identifying the updated, immediate substitution regulatory provisions at § 423.120(e)(2)(i), (f)(2), (3), and (4) as the "successor regulation" and we are also soliciting comment on alternative approaches.

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

- **Annual deductible.** The enrollee pays 100% of their gross covered prescription drug costs (GCPDC) until the deductible of $615 for CY 2026 is met.

[1]Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE), 89 FR 30448, 30511 (April 23, 2024), available at **https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit**.

- **Initial coverage.** The enrollee pays 25% coinsurance for covered Part D drugs. The sponsor typically pays 65% of the cost of applicable drugs and selected drugs and 75% of the cost of all other covered Part D drugs. The manufacturer, through Manufacturer Discount Program (Discount Program), typically covers 10% of the cost of applicable drugs. CMS pays a 10% subsidy for selected drugs during a price applicability period. This phase ends when the enrollee has reached the annual OOP spending threshold of $2,100, for CY 2026.
- **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 40% of the costs of all other covered Part D drugs that are not applicable drugs, including selected drugs, during a price applicability period.

## For more information about topics related to the Part D Benefit Redesign, please go to:

- **Medicare Prescription Payment Plan** – **https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan**
- **Manufacturer Discount Program** – **https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers**
- **Medicare Drug Price Negotiation Program** – **https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation**

## To submit comments:

CMS is voluntarily soliciting comment on the draft program instructions. CMS will accept comments on the Draft CY 2026 Part D Redesign Program Instructions through 11:59 PM Eastern Time on February 10, 2025, before publishing the Final CY 2026 Part D Redesign Program Instructions no later than April 7, 2025.

Please send comments about the draft program instructions to **PartDRedesignPI@cms.hhs.gov** with the subject line "Draft CY 2026 Part D Redesign Program Instructions."

As noted above, CMS will accept comments on the proposals set forth in the CY 2026 Advance Notice through 11:59 PM Eastern Time on February 10, 2025. The 2026 Rate Announcement will be published no later than Monday, April 7, 2025.

To submit comments or questions on the Advance Notice electronically, go to **www.regulations.gov**, enter the docket number "CMS-2024-0360" in the "search" field, and follow the instructions for ''submitting a comment.''

The 2026 Advance Notice may be viewed by going to: **https://www.cms.gov/Medicare/Health- Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents** and selecting "2026 Advance Notice."

Section 11201(f) of the IRA directs the Secretary to implement section 11201 of the IRA for 2024, 2025, and 2026 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing the draft program instructions for implementation of section 11201 of the IRA for 2026. In the final program instructions, CMS may change any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues. Policies established in the final program instructions are for CY 2026 and are subject to change in subsequent years.