Draft CY 2025 Part D Redesign Program Instructions
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10. Introduction

The purpose of these Draft CY 2025 Part D Redesign Program Instructions is to provide interested parties with draft guidance regarding the implementation of section 11201 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169), signed into law on August 16, 2022, which made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 (DS) Part D drug benefit.

These draft program instructions contain a detailed description of, and guidance related to, all IRA-related changes newly in place for CY 2025 made by sections 11201(a) and (b) of the IRA to the Part D benefit, certain changes in place for CY 2025 made by sections 11201(c) and (e) of the IRA, as well as guidance for CY 2023 MLR reporting related to the Inflation Reduction Act Subsidy Amount (IRASA) established by section 11406(c) of the IRA.[1] These draft program instructions are being published concurrently with the CY 2025 Advance Notice, which announces updates to Part D parameters. Some of those updates are impacted by provisions discussed in this document.[2]

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, and section 11406(d) of the IRA directs the Secretary to implement section 11406 of the IRA for 2023, 2024, and 2025 by program instruction or other forms of program guidance. In accordance with the law, the Centers for Medicare & Medicaid Services (CMS) is issuing these draft program instructions for implementation of section 11201 of the IRA for 2025 and for implementation of MLR reporting instructions related to the IRASA for 2023. Changes made by section 11201 of the IRA specific to CY 2023 are described in separate guidance.[3] Changes specific to CY 2024 are discussed in the CY 2024 Advance Notice and Rate Announcement.[4] For detailed guidance

[1] These draft program instructions also provide guidance on how certain IRA changes discussed herein intersect with the Maximum Monthly Cap on Cost-Sharing Payments Program (hereafter the Medicare Prescription Payment Plan), which was established by section 11202 of the IRA. Section 11202(c) directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. For additional information on the Medicare Prescription Payment Plan, see Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments (August 21, 2023), available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf, which CMS plans to finalize in 2024 along with part two guidance.

[2] Please see the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

[3] Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin (Sept. 26, 2022), available at: https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf.

[4] Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Feb. 1, 2023), available at: https://www.cms.gov/files/document/2024-advance-notice-pdf.pdf; Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (March 31, 2023), available at: https://www.cms.gov/files/document/2024-announcement-pdf.pdf.

on the new Manufacturer Discount Program (Discount Program), see the Medicare Part D Manufacturer Discount Program Final Guidance and the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers.[5, 6]

CMS solicited comments on specific aspects of the IRA Part D redesign provisions in April 2023.[7] The comment solicitation specifically requested feedback on how CMS should define Standalone Prescription Drug Plan (PDP) meaningful difference, the parameters for an enhanced benefit plan, tiered cost-sharing thresholds, and potential modification to the formulary tier models. We took the comments we received into consideration when preparing the draft program instructions on the parameters for an enhanced benefit plan and meaningful difference requirements for PDPs in Sections 120 and 130 of this document. We will consider feedback related to tiered cost-sharing thresholds and formulary tier models in future guidance.

CMS is voluntarily soliciting comment on these draft program instructions. Please send comments regarding these draft program instructions to PartDRedesignPI@cms.hhs.gov with the subject line "Draft CY 2025 Part D Redesign Program Instructions." CMS will consider comments received by 6:00 PM Eastern Time Friday, March 1, 2024. CMS will issue final program instructions for 2025 after considering the public comments received in response to these draft program instructions. 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 for 2025 are subject to change in subsequent years.

If any provision in these program instructions is held to be invalid or unenforceable, it shall be severable from the remainder of these program instructions, and shall not affect the remainder thereof, or the application of the provision to other persons or circumstances.

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[5] Medicare Part D Manufacturer Discount Program Final Guidance (November 17, 2023), available at: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf. Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers (November 17, 2023), available at: https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf.

[6] Unless otherwise specified, all references in this memorandum to the "Discount Program" and any relevant terminology refer to the new Manufacturer Discount Program beginning on January 1, 2025, consistent with section 1860D-14C of the Act.

[7] Health Plan Management System (HPMS) email dated April 11, 2023.

20. Detailed Description of the Redesigned Part D Benefit in 2025

The IRA has already adjusted the payment obligations of enrollees, sponsors, and CMS in 2023 and 2024.

A number of significant changes to the Part D benefit took effect in 2023 or will take effect in 2024 as a result of the IRA. A summary of the features of the Part D benefit as it will exist before the 2025 redesign is provided below.

Beginning in CY 2023, the IRA changed the Part D benefit by specifying that no deductible or cost sharing be applied with respect to adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and that out-of-pocket costs for insulin be capped at $35 per month's supply of a covered insulin product. We note that previous guidance regarding these two changes applies to CY 2025 unless clarified by subsequent guidance specific to CY 2025. This previous guidance is:

- PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023
- Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin
- REVISION – Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines
- Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies
- Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies
- Final Contract Year (CY) 2024 Part D Bidding Instructions

For CY 2024, the DS benefit consists of the following phases:[8]

- **Annual deductible**. The enrollee pays 100 percent of their gross covered prescription drug costs (GCPDC) until the deductible is met**.**
- **Initial coverage**. The enrollee pays 25 percent coinsurance for covered Part D drugs, with the plan covering the remainder. This phase ends when total drug spending reaches the initial coverage limit.

[8] See Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, page 134 (Feb. 1, 2023), available at: https://www.cms.gov/files/document/2024-announcement-pdf.pdf.

- **Coverage gap**. The enrollee pays 25 percent, with the remainder paid either by the plan and manufacturers (5 percent and 70 percent, respectively) in the case of applicable drugs or entirely by the plan in case of non-applicable drugs. This phase ends when the enrollee has reached the annual out-of-pocket (OOP) spending threshold.
- **Catastrophic**. The enrollee pays no cost sharing for Part D drugs. The plan covers 20 percent of the cost of covered Part D drugs. CMS, through a federal reinsurance subsidy, pays 80 percent of the cost of covered Part D drugs.

For 2025, the IRA will make further substantial changes to the existing Part D benefit design. IRA policy changes for CY 2025 include:

- Reduction of the annual OOP threshold to $2,000 and elimination of the coverage gap phase.
- Sunsetting of the Coverage Gap Discount Program (CGDP) on January 1, 2025.
- Establishment of the Discount Program to require participating manufacturers to provide discounts on applicable drugs in the initial coverage and catastrophic phases.
- Changes in the liability of enrollees, sponsors, manufacturers, and CMS in the new standard Part D benefit design.

Each of these provisions is discussed in more detail below.

Elimination of coverage gap phase and reduction in the annual OOP threshold. For CY 2025, the IRA makes a number of significant changes to the phases of the Part D benefit. The new benefit will have three phases instead of four: the deductible phase, the initial coverage phase, and the catastrophic phase. The coverage gap phase will be eliminated. Consequently, the CGDP sunsets as of January 1, 2025 (see further explanation below). Under section 1860D-2(b)(4)(B)(i)(VII) of the Act, as amended by section 11201 of the IRA, the annual OOP threshold will be set at $2,000 for CY 2025. After meeting such threshold, the enrollee will enter the catastrophic phase. As in 2024, there will be no cost sharing for Part D drugs for enrollees in the catastrophic phase.

Manufacturer Discount Program. Section 11201 of the IRA added section 1860D-14C of the Act, which creates the Discount Program beginning January 1, 2025. Under section 1860D-14C(b)(1)(A) of the Act, participating manufacturers that enter into a Discount Program

agreement will provide discounts on applicable drugs, typically[9] amounting to 10 percent of the negotiated price for enrollees in the initial coverage phase and 20 percent of the negotiated price for enrollees in the catastrophic phase in CY 2025. Detailed information about the Discount Program is provided in the Medicare Part D Manufacturer Discount Program Final Guidance and Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers, both of which were released on November 17, 2023.

Summary of Enrollee, Sponsor, Manufacturer, and CMS Liabilities. The DS benefit for CY 2025 will consist of the following phases:

- **Annual deductible**. The enrollee pays 100 percent of their GCPDC until the deductible is met.
- **Initial coverage**. The enrollee pays 25 percent coinsurance for covered Part D drugs. The sponsor typically pays 65 percent of the costs of applicable drugs and 75 percent of the costs of all other covered Part D drugs. The manufacturer, through the Discount Program, typically covers 10 percent of the costs of applicable drugs.[10] This phase ends when the enrollee has reached the annual OOP spending threshold of $2,000.
- **Catastrophic**. The enrollee pays no cost sharing for Part D drugs. Sponsors typically pay 60 percent of the costs of all covered Part D drugs. The manufacturer pays a discount, typically equal to 20 percent, for applicable drugs. CMS pays a reinsurance subsidy equal to 20 percent of the costs of applicable drugs, and equivalent to 40 percent of the costs of all other covered Part D drugs that are not applicable drugs.[11]

These changes, effective January 1, 2025, apply to all Part D plans, including employer group waiver plans (EGWPs). This guidance covers certain EGWP issues, including Section 140 on non-calendar year (NCY) EGWPs, which discusses how NCY EGWPs must implement IRA changes that take effect on January 1, 2025. Please see the appendix for a diagram demonstrating the phases of the DS benefit in 2025 relative to the 2024 DS benefit.

[9] Liability of plan sponsors and manufacturers for applicable drugs in the initial coverage and catastrophic phases is described as "typically" a certain percentage because these percentages differ for applicable drugs that are subject to the phase-ins described in section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance.

[10] Starting in 2026, CMS will pay a 10 percent subsidy for selected drugs (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act).

[11] Starting in 2026, CMS will also provide 40 percent reinsurance for selected drugs.

30. Changes in True Out-Of-Pocket Costs (TrOOP)

Section 11201 of the IRA amended section 1860D-2(b)(4)(C) of the Act to update the definition of incurred costs and, thus, which costs count toward TrOOP spending. TrOOP is spending on covered Part D drugs by the beneficiary or on their behalf by certain third parties. TrOOP costs determine when a beneficiary becomes an applicable beneficiary for the Discount Program (as discussed in Section 40 below), reaches the annual OOP threshold, and subsequently enters the catastrophic coverage phase. As described in Section 20 of this document, for CY 2025, the annual OOP threshold will be $2,000.

Unless otherwise stated below, guidance for prior years with respect to incurred or TrOOP-eligible costs—including guidance on costs that do and do not count as incurred costs and TrOOP-eligible and ineligible payers—continues to apply for CY 2025.[12] The following third-party arrangements will continue to contribute to TrOOP: LIS cost-sharing support, qualified State Pharmacy Assistance Programs, Indian Health Service and certain other Native American organizations, and AIDS Drug Assistance Programs.[13]

For 2025, section 1860D-2(b)(4)(C)(iii)(II) of the Act, as added by the IRA, makes changes to which costs count toward TrOOP by amending the definition of incurred costs to include costs incurred for covered Part D drugs that are reimbursed through insurance or a group health plan, excluding basic prescription drug coverage. That is, supplemental Part D coverage provided by enhanced alternative (EA) Part D plans and other health insurance (OHI) will be counted as incurred costs and included in the calculation of TrOOP. This includes supplemental coverage provided by EGWPs as well as plan reductions in cost sharing for enrolled beneficiaries, such as reductions by Medicare-Medicaid Plans and D-SNPs.

Note that, under section 1860D-2(b)(4)(C)(iii)(II) of the Act, only amounts reimbursed by supplemental coverage will be newly included in the calculation of TrOOP. For EA plans, plan liability is mapped to the DS benefit to distinguish between basic and supplemental benefits provided under the Part D sponsor. Because of this, if beneficiary cost-sharing is greater than what it would have been under the DS benefit, a negative value is recorded on a Prescription Drug Event (PDE) record for the field representing the value of the supplemental coverage. Such negative values will be disregarded (i.e., be treated as zero) when calculating TrOOP because they do not represent reimbursement to the beneficiary.

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[12] See Medicare Prescription Drug Benefit Manual – Chapter 5, Section 30, available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5_093011.pdf.

[13] See sections 1860D-2(b)(4)(C)(iii) and (F) of the Act.

Additionally, section 1860D-2(b)(4)(C)(iii)(II) of the Act states that reimbursements through "certain other third party payment arrangements" are to be included in the calculation of TrOOP. Because the statute does not specify which certain other third party payments count as incurred costs, CMS maintains discretion on this matter. For 2025, we are not counting as incurred, TrOOP-eligible costs any other third party payments not considered TrOOP-eligible prior to 2025, as CMS is unaware of any third party payment arrangements in addition to those described above that the Act or existing regulations do not otherwise exclude from the calculation of TrOOP. For instance, primary payer amounts paid on Medicare as secondary payer (MSP) claims are one category of third party payments that CMS considered for TrOOP eligibility. CMS has determined that these payments should remain excluded from TrOOP due to the requirements at section 1862(b) of the Act, which was not amended by the IRA.[14] However, CMS seeks comment on whether interested parties are aware of other third party payments that could be included under section 1860D-2(b)(4)(C)(iii)(II) of the Act.

Further, section 1860D-2(b)(4)(C)(iii)(II) of the Act now also requires that, in 2025, any manufacturer payments made under the Discount Program, which was newly created under the IRA, do not count as incurred costs and are not included in the calculation of TrOOP. Note that the treatment of manufacturer payments made under the Discount Program is different from how manufacturer payments are treated under the CGDP which, by statute, counts manufacturer payments as incurred costs and includes such payments in the calculation of TrOOP.

Finally, for beneficiaries who have opted into the Medicare Prescription Payment Plan described in section 1860D–2(b)(2)(E) of the Act, as added by section 11202 of the IRA, election into such program will not impact how a beneficiary moves through the Part D benefit or what counts towards TrOOP. Under section 1860D–2(b)(4)(F) of the Act, a Medicare Prescription Payment Plan participant's TrOOP-eligible costs that are paid by their Part D plan under the Medicare Prescription Payment Plan shall be treated as incurred costs.

Part D sponsors must update their systems to ensure that TrOOP accumulators appropriately account for these costs in 2025. CMS will provide PDE reporting instructions later in 2024 with additional examples to demonstrate how this policy should be implemented.

40. Policy for Drugs Not Subject to the Defined Standard Deductible

As noted in Section 20 of this document, the IRA eliminates the CGDP and creates the Discount Program in CY 2025. Manufacturer discounts are available under the Discount Program once a

[14] For example, if a Medicare beneficiary is covered under Workers' Compensation because of a job-related illness or injury, Workers' Compensation is the primary payer for covered Part D drugs related to that illness or injury. Any payments made by Workers' Compensation for covered Part D drugs remain excluded from TrOOP under section 1862(b) of the Act.

beneficiary becomes an "applicable beneficiary." Section 1860D-14C(g)(1)(C) of the Act defines an "applicable beneficiary" as an individual who, on the date of dispensing a covered Part D drug, is enrolled in a Part D or MA-PD plan, is not enrolled in a qualified retiree prescription drug plan, and has incurred TrOOP-eligible costs that exceed the DS deductible specified in section 1860D-2(b)(1) of the Act. TrOOP-eligible costs for drugs not subject to the DS deductible, specifically covered insulin products, as well as TrOOP-eligible costs for drugs not subject to a non-DS plan deductible or drugs subject to a reduced deductible under non-DS plans, all count towards a beneficiary's satisfaction of the DS deductible.

As a result, in CY 2025, if a beneficiary has not satisfied their plan deductible but has incurred sufficient TrOOP-eligible costs to satisfy the DS deductible, they will be both an applicable beneficiary under the Discount Program, as defined at section 1860D-14C(g)(1)(C) of the Act, and be deemed to have satisfied their plan deductible. This guidance is similar to the pre-2025 guidance provided in the September 10, 2010 Health Plan Management System (HPMS) memorandum, "Additional Guidance Concerning Closing the Coverage Gap in 2011," which is that a Part D deductible ceases to apply once a beneficiary's total GCPDC exceed the initial coverage limit, even if the beneficiary has not satisfied their plan deductible.[15] That guidance was also established for consistency with the definition of "applicable beneficiary" under the CGDP. Section 1860D-14A(g)(1) of the Act defines an "applicable beneficiary" for purposes of the CGDP as an individual who, on the date of dispensing of a covered Part D drug, has reached or exceeded the initial coverage limit, while also satisfying additional requirements.[16]

If a plan offers a non-DS plan deductible—whether that be a lower deductible than the DS deductible or a deductible that applies for a subset of covered Part D drugs—and a beneficiary incurs sufficient costs to satisfy the plan deductible but has not incurred TrOOP-eligible costs cumulatively across all drugs at or above the DS deductible amount, discounts under the Discount Program are not available. As such, the plan is responsible for covering the portion of costs that would be covered by the manufacturer discount if the beneficiary was an applicable beneficiary until the beneficiary's TrOOP exceeds the DS deductible and they become an applicable beneficiary. The same guidance applies when a beneficiary under any Part D plan is dispensed a covered insulin product or ACIP-recommended vaccine before they have incurred TrOOP-eligible costs at or above the DS deductible amount.

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[15] https://www.cms.gov/httpseditcmsgovresearch-statistics-data-and-systemscomputer-data-and-systemshpmshpms-memos-archive/hpms-memos-qtr-1-4

[16] An applicable beneficiary under the CGDP is an individual who, on the date of dispensing a covered Part D drug, is enrolled in a Part D or MA-PD plan, is not enrolled in a qualified retiree prescription drug plan, is not eligible for an income-related subsidy under section 1860D-14(a) of the Act, has reached or exceeded the initial coverage limit, and has not incurred costs for covered Part D drugs equal to the annual out-of-pocket threshold.

For example, an Enhanced Alternative plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20% coinsurance for drugs in that tier. A beneficiary's first fill of the year is for a $200 tier 1 drug, meaning they pay $40 out of pocket. The beneficiary has not incurred sufficient TrOOP-eligible costs to satisfy the DS deductible of $590 (and has $550 remaining TrOOP eligible costs before they satisfy the deductible) and does not meet the definition of an applicable beneficiary under the Discount Program. Therefore, the plan must cover the 10% of costs that would be covered by the manufacturer discount if the beneficiary were an applicable beneficiary.

CMS will provide PDE reporting instructions later in 2024 with additional examples to demonstrate how this policy should be implemented.

50. Changes to Gross Covered Prescription Drug Costs (GCPDC) and Allowable Reinsurance Costs Definitions to Include Costs Paid by the Manufacturer Discount Program (§ 423.308)

Section 1860D–15(b)(3) of the Act defines GCPDC as, "with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan…regardless of whether the coverage under the plan exceeds basic prescription drug coverage." Section 1860D-15(b)(2) of the Act defines allowable reinsurance costs as "…such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan…"

GCPDC and allowable reinsurance costs are defined and used at section 1860D–15(b) of the Act for the purpose of describing the methodology for calculating the reinsurance payment amount.

Among other costs, manufacturer discounts paid under the CGDP (as described in section 1860D-14A of the Act) have always been included in the calculation of GCPDC. This policy is consistent with the statutory and regulatory definition of GCPDC, which generally requires the inclusion of all costs incurred under the plan, including those paid on behalf of the Part D beneficiary. As noted in Section 20 of this document, the IRA sunsets the CGDP as of January 1, 2025. As such, these costs will no longer be included in the calculation of GCPDC.

Section 11201(b)(3) of the IRA amends section 1860D-15(b)(3) of the Act in two places to also require the inclusion of manufacturer discounts paid under the Discount Program in the calculation of GCPDC (first, by specifying that the definition of GCPDC is subject to paragraph

(2)(B) of section 1860D-15(b) of the Act and second, by adding language specifying that, in the case of an applicable drug, as defined in section 1860D-14C(g)(2) of the Act, GCPDC shall be determined whether the costs are paid by the individual, under the plan, or by a manufacturer).[17]

Moreover, section 11201(b)(2) of the IRA also amends section 1860D-15(b)(2) of the Act to require the inclusion of manufacturer discounts paid under the Discount Program under section 1860D–14C of the Act in the calculation of allowable reinsurance costs (see Section 60 of this document), as defined in section 1860D–15(b)(2)(A) of the Act, in 2025.

Therefore, pursuant to the requirement in section 11201(f) of the IRA that CMS use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025 and to mirror the statutory language in sections 1860D-15(b)(2) and (3) of the Act, as amended by the IRA, the regulatory definitions of "gross covered prescription drug costs" and "allowable reinsurance costs" at § 423.308 shall be considered to have been revised for CY 2025 as follows:

1. In "gross covered prescription drug costs," costs incurred include "all amounts paid by manufacturers under the Discount Program (as defined in section 1860D-14C of the Act)," such that the definition reads as follows, with revisions to the current definition reflected in bold and italicized font:

> *Gross covered prescription drug costs* means those costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:
>
> (1) The share of actual costs (as defined by § 423.100 of this part) paid by the Part D plan that is received as reimbursement by the pharmacy, or other dispensing entity, reimbursement paid to indemnify an enrollee when the reimbursement is associated with an enrollee obtaining covered Part D drugs under the Part D plan, or payments made by the Part D sponsor to other parties listed in § 423.464(f)(1) of this part with which the Part D sponsor must coordinate benefits, including

[17] As noted in the final rule, "Medicare Program; Contract Year 2024 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," 88 Fed. Reg. 22259 (April 12, 2023), there are two important differences between the CGDP and the Discount Program that would result in manufacturer discounts paid under the two programs being treated differently for purposes of calculating allowable reinsurance costs and GCPDC, absent the explicit statutory requirement to include manufacturer discounts paid under the Discount Program in the calculation of these amounts. First, unlike manufacturer discounts paid under the CGDP, manufacturer discounts paid under the Discount Program do not count toward incurred costs per section 1860D–2(b)(4)(C)(iii)(II) of the Act and thus are not considered paid by or on behalf of Part D beneficiaries. Second, the Discount Program creates a new manufacturer discount obligation in the catastrophic phase, so the treatment of such discounts has a direct impact on the calculation of the reinsurance payment amount for the first time in 2025. However, the difference in treatment of manufacturer discounts under the Discount Program and under the CGDP will not otherwise change the calculation of GCPDC.

other Part D plans, or as the result of any reconciliation process developed by CMS under § 423.464 of this part.

(2) Nominal cost-sharing paid by or on behalf of an enrollee which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100 of this part, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) All amounts paid by manufacturers under the Discount Program (as defined in section 1860D-14C of the Act).

2. In "allowable reinsurance costs," costs actually paid include "the portion of the negotiated price (as defined in section 1860D-14C(g)(6) of the Act) of an applicable drug (as defined in section 1860D-14C(g)(2) of the Act) paid by manufacturers under the Discount Program (as defined in section 1860D-14C of the Act)," such that the definition reads as follows with revisions to the current definition reflected in bold and italicized font:

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan ***and the portion of the negotiated price (as defined in section 1860D-14C(g)(6) of the Act) of an applicable drug (as defined in section 1860D-14C(g)(2) of the Act) paid by manufacturers under the Discount Program (as defined in section 1860D-14C***

of the Act). The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.

60. Reinsurance Methodology (§§ 423.308, 423.329)

As noted above, the IRA significantly modifies the reinsurance subsidy under the Part D benefit in CY 2025. Specifically, under section 1860D-15(b) of the Act, as amended by section 11201(b) of the IRA, in 2025, the reinsurance payment amount for a Part D beneficiary will decrease from 80 percent of the allowable reinsurance costs incurred after the beneficiary exceeds the annual OOP threshold to 20 percent for applicable drugs or 40 percent for non-applicable drugs.[18, 19] Therefore, a different calculation applies to applicable drugs versus non-applicable drugs for the reinsurance payment amount, and the methodology for calculating the reinsurance subsidy, and in particular for allocating direct and indirect remuneration (DIR) towards reinsurance, must also be reconsidered. In this section, CMS is establishing a revised reinsurance subsidy calculation methodology, including the calculation of allowable reinsurance costs and final reinsurance subsidy for applicable versus non-applicable drugs.

Allowable Reinsurance Costs and Changes to DIR Allocation Methodology

Section 1860D-15(b) of the Act defines allowable reinsurance costs as the portion of GCPDC that are attributable to basic prescription drug coverage and that are actually paid by the sponsor or by (or on behalf of) the beneficiary. As noted in Section 50 of this document, for CY 2025, the definitions of GCPDC and allowable reinsurance costs have been revised to mirror the statutory language in section 1860D-15(b)(2) and (3) of the Act, as amended by the IRA. Allowable

[18] Consistent with the definition in section 130 of the Medicare Part D Manufacturer Discount Program Final Guidance, non-applicable drug means any Part D drug that is not an applicable drug and not a selected drug (as defined in section 1192(c) of the Act) during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug. Selected drugs for the first year of the Medicare Drug Price Negotiation Program will not enter a price applicability period until January 1, 2026.

[19] As defined at section 1860D-14C(g)(2) of the Act and in section 40.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, applicable drugs under the Discount Program are all Part D drugs approved under a new drug application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (PHSA), other than a selected drug (as referred to under section 1192(c) of the Act) dispensed during a price applicability period (as defined in section 1191(b)(2) of the Act). Because the statute defines in part an applicable drug as a Part D drug that is approved under an NDA under section 505(c) of the FDCA or is licensed under section 351 of the PHSA, a Part D drug that meets such criteria will be considered an applicable drug regardless of whether the plan sponsor treats such product as a brand name or generic product under its benefit. See Medicare Part D Manufacturer Discount Program Final Guidance (November 17, 2023), available at: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf.

reinsurance costs will include the portion of the negotiated price of an applicable drug that was paid by a manufacturer under the Discount Program (see Section 50 of this document).[20]

Under section 1860D-15(b)(2) of the Act, CMS's reinsurance payment to Part D plan sponsors is based on the reinsurance costs that were actually paid during the coverage year. "Actually paid," defined at § 423.308, means that the costs must be actually incurred by the Part D sponsor and must be net of any DIR.[21] Each year, sponsors report their DIR to CMS as part of the annual DIR reporting process, and CMS uses this information, along with cost data reported on PDE records, to allocate a portion of the DIR towards reducing allowable reinsurance costs. Historically, CMS allocated DIR to reduce allowable reinsurance costs and calculate final reinsurance subsidy payments in accordance with the methodology provided in the CY 2006 Advance Notice.[22] Through such DIR allocation, CMS complies with the statutory requirement that the government's final reinsurance subsidy payment reflect net drug costs. The remainder of the DIR that is not allocated towards reducing the reinsurance subsidy is accounted for in the calculation of allowable risk corridor costs as detailed in the CY 2006 Advance Notice.

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 drug costs that fall in the catastrophic phase. This methodology otherwise aligns with the historical approach for apportioning DIR.

Calculation of Final Reinsurance Subsidy

After the end of the coverage year, CMS will reconcile reinsurance subsidies for applicable drugs as follows:

- Identify incurred reinsurance costs for applicable drugs above the annual OOP threshold at the individual beneficiary level (from PDE records).
- Sum incurred reinsurance costs for applicable drugs at the plan level.

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[20] Negotiated price is defined in section 1860D-14C(g)(6) of the Act.

[21] DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source, including manufacturers, pharmacies, enrollees, or any other person, that would serve to decrease the costs incurred by the Part D sponsor for the drug. In addition, please refer to the definition of price concessions at § 423.100.

[22] Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates (Feb. 18, 2005), available at: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2006.pdf.

- Allocate DIR for applicable drugs to incurred reinsurance costs for applicable drugs by applying the ratio of total DIR to total allowed costs. (The allocated DIR for reinsurance is referred to as "reinsurance DIR.")
- Subtract reinsurance DIR for applicable drugs from incurred reinsurance costs for applicable drugs, then multiply the difference by 20 percent (the reinsurance payment amount percentage for applicable drugs).

After the end of the coverage year, CMS will reconcile reinsurance subsidies for non-applicable drugs as follows:

- Identify incurred reinsurance costs for non-applicable drugs above the annual OOP threshold at the individual beneficiary level (from claims).
- Sum incurred reinsurance costs for non-applicable drugs at the plan level.
- Allocate DIR for non-applicable drugs to incurred reinsurance costs for non-applicable drugs by applying the ratio of total DIR to total allowed costs.
- Subtract reinsurance DIR for non-applicable drugs from incurred reinsurance costs for non-applicable drugs, then multiply the difference by 40 percent (the reinsurance payment amount percentage for non-applicable drugs).

The calculation formulas for applicable drugs are:

Reinsurance DIR for applicable drugs = (total DIR / total allowed costs) × incurred reinsurance costs for applicable drugs

Adjusted reinsurance for applicable drugs = (incurred reinsurance costs for applicable drugs – reinsurance DIR for applicable drugs) × 0.20

The calculation formulas for non-applicable drugs are:

Reinsurance DIR for non-applicable drugs = (total DIR / total allowed costs) × incurred reinsurance costs for non-applicable drugs

Adjusted reinsurance for non-applicable drugs = (incurred reinsurance costs for non-applicable drugs – reinsurance DIR for non-applicable drugs) × 0.40

The sum of the adjusted reinsurance amounts for applicable and non-applicable drugs will then be reconciled with prospective reinsurance payment amounts made to plans during the coverage year.

To determine the appropriate category (applicable or non-applicable) for drugs, CMS will use the 11-digit National Drug Code (NDC) submitted on each PDE record and assign it with an

applicable or non-applicable designation based on the marketing category listed for that NDC in the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements (NSDE) file used for PDE processing.

70. Part D Calendar Year EGWP Prospective Reinsurance Amount - Methodology

CMS has authority under sections 1857(i) and 1860D-22(b) of the Act to waive or modify requirements that hinder the design of, offering of, or enrollment in, Part D plans that combine the Part D benefit with supplemental drug coverage offered by an employer. EGWPs are either administered by insurance companies (800-series EGWPs) or by employers or unions (Direct Contract EGWPs). Under this authority, CMS waived the requirement of bid submission for Part D Calendar Year EGWPs and paid these plans only a retrospective reinsurance amount, and not a prospective reinsurance amount, beginning in payment year (PY) 2008. Since CY 2017, however, in response to increasing drug costs in the catastrophic phase, CMS has made prospective reinsurance payments to all Part D Calendar Year EGWP sponsors based on the average per member-per month (PMPM) actual (final) reinsurance amounts paid to Part D Calendar Year EGWP sponsors for the most recently reconciled payment year. For CY 2025, this would be CY 2022.[23]

Due to the reduction in the reinsurance percentage in CY 2025 (discussed in detail above), using the reconciled CY 2022 actual reinsurance payment amounts for CY 2025 Part D Calendar Year EGWP prospective reinsurance payments would result in CMS paying these plans significantly more than is needed to cover the government's share of Part D drug costs incurred throughout the year and then recovering sizable amounts during the Part D reconciliation process. Therefore, for CY 2025, CMS is calculating the prospective reinsurance payments to all Part D Calendar Year EGWP sponsors using the weighted average of PMPM prospective reinsurance amounts submitted by Part D sponsors for EA plans as part of the Part D bid submissions for the payment year in question. The weights will be based on the projected number of enrollees in each EA plan. Specifically, the weight for each EA plan reinsurance amount will be a percentage calculated with the numerator equal to the projected enrollment in the plan bid and the denominator equal to the total projected enrollment in all applicable EA plans' bids. CMS is taking this approach to ensure that Part D Calendar Year EGWPs are paid an appropriate prospective reinsurance payment amount. Table 70 compares the Part D Calendar Year EGWP prospective reinsurance amounts published in prior Rate Announcements to what the prospective amount would have been using the new calculation.

[23] See the CY 2017 Rate Announcement for further information. Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (April 4, 2016), available at: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/announcement2017.pdf.

Table 70. Comparison of Part D Calendar Year EGWP Prospective Reinsurance Amounts

Calendar Year	Part D Calendar Year EGWP Prospective Reinsurance Amounts (Published in Prior Rate Announcements)	Part D Calendar Year EGWP Prospective Reinsurance Amounts (Calculated Based on EA Plan Prospective Reinsurance Amounts)
2022	$65.68	$64.27
2023	$67.56	$66.41
2024	$71.09	$65.32

CMS will not have final reconciled CY 2025 reinsurance amounts, reflecting the new benefit and the associated new reinsurance percentages, which could allow CMS to revert to the previous methodology for calculating prospective reinsurance payments for Part D Calendar Year EGWP sponsors, until at least CY 2028. A determination with respect to the methodology and amount of prospective reinsurance payments for Part D Calendar Year EGWP sponsors for plan years beyond CY 2025 will be made at a later time.

Given that the CY 2025 prospective reinsurance payment amount for Part D Calendar Year EGWPs will rely on CY 2025 bid submissions, CMS plans to announce the CY 2025 prospective reinsurance payment amount for Part D Calendar Year EGWPs with the annual release of the Part D National Average Monthly Bid Amount (NAMBA), Part D base beneficiary premium (BBP), and related Part D bid information in the summer of 2024.

80. Risk Corridor Methodology (§§ 423.308, 423.336)

Risk corridors are designed to limit exposure to unexpected expenses not already included in the reinsurance subsidy or taken into account through health status risk adjustment. The federal government and the plan share the profits or losses resulting from expenses for the standard benefit within defined symmetrical risk corridors around a target amount. Risk corridors are applied by determining the difference between the target amount and a plan's actual allowable costs not including administrative expenses.[24] A plan's actual allowable costs are limited to those costs actually incurred or paid by the plan and must be net of any DIR. Also, if a plan provides supplemental coverage, CMS takes into account how the presence of such coverage increases

[24] Per section 1860D-15(e)(3)(B) of the Act, the target amount is the total amount of payments (from both CMS and by or on behalf of enrollees) to a Part D plan for the coverage year based on the standardized bid amount, less the administrative expenses assumed in the standardized bid.

utilization beyond what it would be if the coverage were DS coverage. Finally, CMS will subtract out all federal reinsurance payments and low-income subsidy payments related to cost-sharing.

Calculating risk corridor payments can be considered a 4-step process:
• Calculate the plan's target amount
• Calculate associated risk corridor threshold amounts
• Calculate the plan's adjusted allowable risk corridor costs
• Determine where costs fall with respect to the risk corridor threshold amounts, then calculate payment adjustment

While the methodology for allocating DIR to allowable reinsurance costs is being updated to align with the CY 2025 changes (discussed above in Section 60 of this document), the existing risk corridor methodology, does not need to be revised. As established in the CY 2006 Advance Notice,[25] the risk corridor methodology allows the higher plan liability and smaller share of DIR allocated toward reinsurance anticipated as a result of the Part D benefit redesign to be appropriately reflected in the calculation of the risk corridor amounts. Specifically, because the calculation for risk corridor payments incorporates a plan's allowable costs net of DIR not allocated to allowable reinsurance costs, the existing methodology can remain unchanged.

As stated in the CY 2025 Advance Notice, section 1860D-15(e)(3)(C) of the Act does not permit CMS to narrow the risk corridors relative to the CY 2011 thresholds; instead, the statute only permits CMS to widen them. We do not believe it is appropriate to adjust the parameters in the manner allowed by the statute at this time, and thus we will apply no changes to the current threshold risk percentages for CY 2025. We will continue to evaluate the risk sharing amounts each year to determine if wider corridors should be applied for Part D risk sharing.

90. Creditable Coverage (§ 423.56)

Section 1860D-22(a) of the Act requires that CMS pay a subsidy to sponsors of qualified retiree prescription drug plans that provide equivalent or better coverage than the actuarial value of standard prescription drug coverage. Medicare beneficiaries may incur a late enrollment penalty (LEP) 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 but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage. The current regulatory definition of creditable prescription drug coverage at § 423.56(a) specifies

[25] Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates (Feb. 18, 2005), available at: https://www.cms.gov/medicare/health-plans/medicareadvtgspecratestats/downloads/advance2006.pdf.

that the actuarial value of such coverage does not take into account the value of any discount or coverage provided in the coverage gap through the CGDP under section 1860D-14A of the Act or coverage provided in the gap under section 1860D-2(b) of the Act.

The IRA eliminates the coverage gap phase and the CGDP as of January 1, 2025, and revises section 1860D-22(a)(2)(A) of the Act to specify that any discount provided pursuant to the Discount Program established by the IRA under section 1860D-14C of the Act is not taken into account when determining the actuarial value of qualified retiree coverage. Additionally, section 1860D-14C(g)(1)(B) of the Act excludes enrollees in a qualified retiree prescription drug plan from the definition of applicable beneficiary.

The changes made by the IRA require CMS to revise the existing regulatory definition of creditable prescription drug coverage in § 423.56(a). Pursuant to the requirement in section 11201(f) of the IRA that CMS use program instruction or other forms of program guidance to implement section 11201 of the IRA for 2025, the definition of creditable prescription drug coverage for CY 2025 reads as follows with the revisions to the current definition reflected in bold and italicized font:

> Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount ***provided under section 1860D-14C of the Social Security Act***, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

Sections 1860D-14C(g)(4)(B) and (C) of the Act establish lower percentages for applicable discounts for certain applicable drugs of participating manufacturers that meet the definition of a specified manufacturer or a specified small manufacturer during a multi-year phase-in period.[26] Since the applicable discount reduces the plan liability for applicable drugs, the Part D sponsor is liable for the remaining amount of the negotiated price, less enrollee cost sharing, for applicable drugs subject to a phased-in discount percentage. Because the Part D sponsor therefore is responsible for covering any differential between the full discount (i.e., 10 percent or 20 percent of the negotiated price, depending on the benefit phase, based on the enrollee's incurred costs) and the phased-in discount, such differential is included for purposes of determining creditable prescription drug coverage.

[26] See section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance, available at: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf-0

Actuarial equivalence is based on plan liability and does not include subsidies such as low-income cost sharing (LICS) or federal reinsurance. Consistent with the existing policy, the value of any selected drug subsidy under section 1860D-14D of the Act is not included in the determination of actuarial value.

Given the significant changes that the IRA made to the Part D benefit, as of CY 2025, the creditable coverage simplified determination methodology released in the "Updated Creditable Coverage Guidance" on September 18, 2009 will no longer be a valid methodology to determine whether an entity's prescription drug coverage is creditable or not.

100. Retiree Drug Subsidy Parameters/Requirements

While the IRA amends the parameters of the standard prescription drug coverage, sunsets the CGDP effective January 1, 2025, and creates the Discount Program under section 11201 of the IRA, there are no changes to the requirements for qualified retiree prescription drug plans. A qualified retiree prescription drug plan[27] must provide creditable coverage (see the changes to the creditable coverage definition described in Section 90 of this document).

Per section 1860D-22 of the Act, qualified retiree prescription drug plans are required to annually attest that the actuarial value of prescription drug coverage under the plan (as described in section 1860D-11(c) of the Act) is at least equal to the actuarial value of standard prescription drug coverage, not taking into account the value of any discount provided under the Discount Program as established in section 1860D-14C of the Act, and disclose that coverage under the plan is creditable in accordance with section 1860D-13(b)(6)(B) of the Act. See Section 90 of this document for a discussion of IRA impacts on creditable coverage.

The following IRA policies are in effect for 2025 and are considered in determining the actuarial value of the DS benefit:

- In CY 2025, the coverage gap phase will be eliminated, and DS Part D prescription drug coverage will consist of a three-phase benefit. As such, there will be no initial coverage limit and the initial coverage phase will extend to the maximum annual OOP threshold, at which point the catastrophic phase will begin.
- The annual OOP threshold is statutorily set at $2,000 for CY 2025.
- As in CY 2024, there is no beneficiary cost sharing above the annual OOP threshold in CY 2025.

[27] As defined in 42 CFR § 423.882, qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in 42 CFR § 423.884 for a Part D eligible individual who is a retired participant or the spouse or dependent of a retired participant under the coverage.

- The CGDP sunsets effective January 1, 2025 and is replaced by the Discount Program. Under the Discount Program, the manufacturer will typically pay a 10 percent discount for applicable drugs in the initial coverage phase.[28] In the catastrophic phase, manufacturers will typically pay a 20 percent discount for applicable drugs. In certain circumstances, manufacturer discounts will be phased in and may be less than 10 percent in the initial coverage phase and 20 percent in the catastrophic coverage phase.
- The reinsurance payment amount for CY 2025 for a Part D beneficiary is decreased from 80 percent to 20 percent for applicable drugs and to 40 percent for non-applicable drugs of the allowable reinsurance costs incurred after the beneficiary exceeds the annual OOP threshold.
- As noted in Section 30 of this document, effective in CY 2025, the definition of incurred costs at section 1860D-2(b)(4)(C) of the Act will include, among other categories of costs, supplemental coverage and OHI, which was previously excluded from the definition of incurred costs. Manufacturer discounts provided under the Discount Program will be excluded from the definition of incurred costs.
- During CY 2025, Part D plans must not apply the deductible to any Part D covered insulin product and must charge no more than $35 per month's supply of a covered insulin product in the initial coverage phase.
- During CY 2025, Part D plans must not apply the deductible to an ACIP-recommended adult vaccine and must charge no cost-sharing at any point in the benefit for such vaccines.

Note that the IRA did not change the calculation of the annual cost limits and thresholds. As such, these will be adjusted in the same manner as the Part D deductible and annual OOP threshold, as required by sections 1860D-2(b)(1)(A)(ii) and 1860D–2(b)(4)(B)(i)(VIII) of the Act, respectively. The annual updates to the cost limits and thresholds are discussed in the CY 2025 Advance Notice.[29]

110. Impact of 2025 Part D Redesign Changes on the Capitated Payments to PACE Organizations

The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit that provides comprehensive, community-based medical and social services to certain frail, elderly people. Under sections 1894(b)(1)(A)(i) and 1934(b)(1)(A)(i) of the Act, PACE organizations are precluded from charging Medicare beneficiaries and Medicaid-eligible enrollees any form of

[28] See footnote 19.

[29] See footnote 2.

cost sharing. As a result, in 2025, PACE organizations, unlike typical Part D plans, will be responsible for paying 100% of the drug's costs below the annual OOP threshold after accounting for manufacturer discounts under the Discount Program and any amount of the basic Part D beneficiary premium that is greater than the regional low-income premium subsidy amount for dual-eligible beneficiaries.

Under section 1894(d)(2) of the Act, Medicare payments to PACE organizations may be adjusted to include "such other factors as the Secretary determines to be appropriate." Since 2006, CMS has used this authority to make an additional capitated payment of 2% of all projected costs below the annual OOP threshold for dual-eligible beneficiaries in order to cover the nominal co-payments that Low-Income Subsidy (LIS) enrollees would have paid under a typical Part D plan. This is also known as the PACE cost-sharing add-on amount. Under the same authority, CMS also makes an additional capitated payment to PACE organizations on behalf of dual-eligible PACE enrollees in plans with premiums above the regional low-income premium subsidy amount.

CMS has reviewed the methodology for calculating the cost sharing and premium add-on payments for PACE organizations and determined that, although the IRA alters the structure of the Part D benefit, including by setting the annual OOP threshold at $2,000 for CY 2025, which will impact the calculation of the PACE cost-sharing add-on amount, the PACE methodology for calculating the cost-sharing add-on amount should continue to result in sufficient amounts to cover what PACE organizations pay on behalf of their dual-eligible enrollees for nominal cost-sharing below the annual OOP threshold under the current methodology.

PACE organizations should also note the following IRA-related changes that will impact PACE organizations in 2025:

- Changes to Incurred Costs Definition: As noted in Section 30 of this document, in 2025, Part D supplemental coverage will count toward TrOOP. This change will affect beneficiary progression through the Part D benefit under PACE organizations and increase the number of Medicare-only and dual-eligible PACE beneficiaries who incur sufficient TrOOP to enter the catastrophic phase of the benefit.
- Sunset of the CGDP and Implementation of the Discount Program: As noted in Section 20 of this document, the IRA eliminates the CGDP and creates the Discount Program beginning in CY 2025. Under section 1860D-14A(c)(2) of the Act, Part D supplemental benefits are applied prior to calculating the manufacturer discounts under the CGDP. Under the Discount Program, there is no such special rule for supplemental benefits. As such, manufacturer discounts will be calculated prior to the application of supplemental benefits in both the initial coverage phase and catastrophic phase of the benefit in CY

2025. This means that many PACE organizations will receive manufacturer discounts for applicable beneficiaries for the first time. PACE organizations should refer to the Medicare Part D Manufacturer Discount Program Final Guidance for additional information.

- Definition of Applicable Beneficiaries Under the Discount Program: Under the Discount Program, both LIS and non-LIS beneficiaries are included in the definition of applicable beneficiary. As such, manufacturer discounts will apply in both the initial coverage phase and catastrophic coverage phase for both LIS and non-LIS PACE participants for the first time.

PACE organizations must account for the changes in the Part D DS benefit in the cost estimates in their bids, which will be used to calculate PACE payments in 2025, including the PACE cost-sharing add-on amount.

120. Definition of Enhanced Alternative Benefit Design (§ 423.104(f))

Part D sponsors have the flexibility to offer non-DS plans, under which they can modify certain benefit parameters. This includes two types of basic plans—actuarially equivalent and basic alternative—in addition to EA plans. EA coverage must meet the requirements of alternative prescription drug coverage and, in accordance with § 423.104(f), includes both required basic prescription drug coverage and supplemental benefits. Supplemental benefits include: the coverage of drugs that are specifically excluded from the definition of a Part D drug in § 423.100 under subparagraph (2)(ii) and/or any one or more of the following changes that increase the actuarial value of benefits above the actuarial value of DS prescription drug coverage:

- Reduction (or elimination) of the DS deductible
- Reduction of cost-sharing in the initial coverage phase
- Increase of the initial coverage limit threshold
- Additional cost-sharing reduction in the coverage gap phase
- Reduction (or elimination) of cost-sharing in the catastrophic phase

Given that the IRA eliminates cost-sharing in the catastrophic phase beginning in 2024, caps annual out-of-pocket costs (OOPC) for Part D prescription drugs at $2,000 beginning in 2025 (modified by the annual percentage increase (API) for subsequent years), and eliminates the coverage gap phase and replaces the CGDP with the Discount Program beginning in 2025, only the following supplemental benefits remain as possible enhancement features for 2025: The coverage of drugs that are specifically excluded from the definition of a Part D drug and/or

- Reduction (or elimination) of the DS deductible

- Reduction of cost-sharing in the initial coverage phase

We note that, to date, reducing the annual deductible and cost-sharing in the initial coverage phase are the most common features of Part D EA plans, and these features are still available in 2025. However, because the IRA increases the value of the standard Part D benefit, the options for further enhancement features that Part D sponsors may include in their EA plan offerings will be more limited beginning in 2024. Therefore, we believe this warrants reconsidering how to define an EA benefit design under the Medicare Part D program.

As discussed in Section 10 of this document, CMS solicited comment on the Part D EA plan benefit design. Some commenters recommended allowing EA plans to reduce the initial coverage limit and/or reduce the annual OOP maximum. However, under the IRA Part D benefit redesign provisions, the initial coverage limit threshold will no longer exist beginning in 2025. If the commenters meant that EA plans should be able to reduce the DS deductible and/or cost-sharing in the initial coverage phase, we clarify that, as explained earlier in this section, those options will remain available. We also note that section 1860D-2 of the Act does not permit modifying the annual OOP threshold.

We also received comments that suggested CMS take an approach to EA plans that would be similar to a "rider" or "wrap" approach. Under such an approach, every EA plan would have an underlying basic benefit and charge a supplemental premium for any enhancements, or rider/wrap, coverage. In other words, a basic and enhanced plan offered by the same parent organization would share a basic benefit design, and the enhanced plan would have an additional set of enhancements resulting in a supplemental premium. CMS considered such an approach in a 2014 proposed rule.[30] In that proposed rule, we solicited comment on whether we should propose that EA coverage be redefined to consist of supplemental coverage added to the sponsor's one basic benefits offering for an additional premium. We explained that this could be thought of as basic benefits plus a supplemental benefit rider. We received overwhelmingly negative comments on this approach and did not pursue it further. We do not believe it would be prudent to reconsider the "rider/wrap" approach at this time, given the numerous other changes to the Part D program effective in 2025.

After consideration of the options, we believe that CMS should evaluate the *value* (emphasis added) of EA plan designs in 2025. Since limited options (i.e., reducing the deductible and/or cost sharing in the initial coverage phase) now remain for EA plans to increase the value of the benefit above that of DS coverage, CMS believes it is critical to establish a process for ensuring

[30] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 1918, 1963 (January 10, 2014).

that beneficiaries receive value relative to the DS benefit when they enroll in an enhanced plan. By ensuring value is added, this approach would help to address our concerns that beneficiaries are paying more in OOPC in EA plans, especially in light of the supplemental premiums they may pay for these plans.

As we noted above, EA plans may also still offer excluded drug coverage, and CMS is not establishing a process for assessing the value of such coverage at this time. CMS already reviews individual drugs offered under excluded drug coverage, compares their prices to the cost sharing submitted, and works with Part D sponsors to make changes to benefits under our negotiation authority if a plan's proposed benefit does not appear to offer enhanced value.

For CY 2025, CMS will utilize the Part D OOPC model as a mechanism to estimate the value of EA plans relative to the value of the DS benefit. The Part D OOPC model estimates the relative OOPC (i.e., the estimated beneficiary cost per month) for beneficiaries in Part D plans and, as discussed in Section 130 of this document, is used to evaluate meaningful differences between standalone PDPs during annual bid reviews. For the purpose of evaluating EA plan value for all Part D sponsors, as illustrated in Table 120, under this approach, CMS will calculate an OOPC estimate for each submitted Part D EA plan that has indicated a reduction of the deductible and/or cost-sharing in the initial coverage phase. Using the same formulary that is submitted for an EA plan, CMS will also calculate an OOPC estimate for the DS benefit. Given that CY 2025 will be the first year CMS is using this approach, and that the DS benefit is changing significantly as a result of the IRA, we are not establishing a specific threshold for such value—rather, we are establishing that the OOPC value for an EA plan must be better (i.e., lower) than that of the OOPC value resulting from running the formulary of that EA plan through the DS benefit.

Table 120. Calculation to Evaluate EA Plan Offerings

Value	Source	Description	Calculation	CY 2025 Requirement	Example
[A] EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan (formulary and intended plan design)	N/A	N/A	$70
[B] DS EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan's formulary run through DS benefit	N/A	N/A	$105
[C] Difference	Calculation	OOPC value of EA plan (formulary and intended plan design)	[B] – [A]	For CY 2025, this value must be >0	$35

To assist Part D plan sponsors in bid preparations ahead of the CY 2025 bid deadline, the CY 2025 Bid Review OOPC Model will incorporate functionality for plans to run the formulary tied to the EA plan through a DS benefit design. The CY 2025 Plan Benefit Package (PBP) will also include a field where sponsors must describe how their intended benefit design lowers cost sharing for beneficiaries in the initial coverage phase.

CMS will evaluate these comparisons for CY 2025 and consider establishing a more rigorous requirement for CY 2026 and beyond. We believe this approach will be an important step toward ensuring that beneficiaries who choose a Part D EA plan with supplemental benefits are receiving value relative to the value they would receive from a DS benefit and is consistent with CMS efforts to ensure healthy competition in the plan market and improved transparency for beneficiaries to find the plan that best meets their needs.

130. PDP Meaningful Difference (§ 423.265(b)(2))

The IRA's amendments to section 1860D-2 of the Act impact Part D plan benefit design by capping enrollees' annual OOP costs, eliminating the coverage gap phase, and eliminating cost-sharing in the catastrophic phase. These changes to the benefit offer an opportunity for CMS to adopt a new approach to defining meaningful difference between an EA plan and a basic plan for standalone PDPs for CY 2025.

CMS has the authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds "necessary and appropriate," as well as authority, under section 1860D–11(d)(2)(B) of the Act, to propose regulations imposing "reasonable minimum standards" for Part D sponsors. Under this authority, we can deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area (§ 423.272(b)(3)(i)). This is an important protection, as it ensures beneficiaries are able to better distinguish between the plans available to them and ultimately make the best plan choice for their needs. Under our application of this authority, we have limited PDP sponsors to offering only one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the DS benefit structure required under section 1860D-2(c)(1) of the Act. PDP sponsors also may only offer two EA plans in a PDP region.

Effective CY 2019, CMS eliminated the PDP EA-to-EA meaningful difference requirement, while maintaining the requirement that EA plans be meaningfully different from the basic plan

offered by a plan sponsor in a service area.[31] CMS has used a Part D OOPC model since CY 2012 to conduct the annual PDP meaningful difference evaluation.

The Part D OOPC model estimates the relative OOPC (i.e., the estimated beneficiary cost per month) for beneficiaries in PDPs. Annually, CMS determines meaningful difference thresholds for the upcoming contract year by evaluating the Part D OOPC estimates using the prior year's approved bid and formulary data. Between CY 2012 and CY 2022, CMS used an absolute dollar threshold to assess whether the Part D OOPC estimate for the EA plan(s) is equal to or lower than the established dollar threshold compared to the Part D OOPC estimate for the basic plan offered in the same region.

Beginning in CY 2023, CMS moved to an outlier approach to ensure that PDP offerings meet the requirements under § 423.272(b)(3)(i) due to significant updates CMS made to the Part D OOPC model. To improve upon the accuracy and timeliness of Part D OOPC estimates, CMS enhanced the model to estimate Part D OOPC based on a cohort of a 0.1% sample of all Part D beneficiaries and their associated PDEs, as opposed to the previous approach of using the Medicare Current Beneficiary Survey (MCBS) data, which lagged in some cases by many years and required complex and sometimes inaccurate mapping of survey data.

These enhancements were supported by interested stakeholders who agreed the change provided for a larger, more representative cohort, more timely data, and up-to-date drug estimates, compared to the fee-for-service cohort from the MCBS data. Based on commenters' additional feedback, CMS released a subsequent version of the model that further enhanced Part D OOPC estimates by accounting for therapeutic alternatives and formulary exception cost-sharing when a model drug is not on a plan sponsor's formulary.[32] Whereas the model had historically estimated OOPC for non-formulary drugs at their full cash price, the current model simulates real-world beneficiary behavior and considers therapeutic alternative and exception tier cost sharing. In its June 2022 "Report to Congress: Medicare and the Health Care Delivery System,"[33] the Medicare Payment Advisory Commission (MedPAC) stated that the actuaries MedPAC interviewed felt these combined enhancements were an improvement to the model and would make the meaningful difference requirement more rigorous.

[31] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16613 (April 16, 2018).

[32] November 19, 2021 HPMS memorandum: Enhanced Out-of-Pocket Cost Model Update

[33] June 2022 MedPAC Report to Congress: Medicare and the Health Care Delivery System

Given the impact of these various model changes on Part D OOPC estimates, CMS chose to evaluate submitted bids using a distribution analysis approach to establish an outlier threshold, rather than an absolute dollar amount, until we gain more experience with the model updates. For CY 2023, CMS communicated concerns at the 75th percentile, or 7.5 percent difference, between PDP basic and EA plan(s). In other words, an EA plan had to have a Part D OOPC estimate at least 7.5 percent lower than the basic plan Part D OOPC estimate in the same region. For CY 2024, CMS again used an outlier approach at the same 75th percentile, resulting in a minimum 10.65 percent difference between basic and EA plan(s).

Following the enactment of the IRA and changes to the Part D benefit, as noted in Section 10 of this document, CMS requested input from interested stakeholders on the meaningful difference requirement in April 2023. The following is a summary of the comments CMS received on this topic and our responses.

1. CMS should evaluate the number of drugs offered by a plan or within classes, as well as the number of drugs subject to copays versus coinsurance, or coverage of excluded drugs.
2. CMS should expand meaningful difference criteria to include patient access metrics, such as the comprehensiveness of a formulary, or require greater coverage across all therapeutic areas, on lower formulary tiers, or of innovative treatments.
3. CMS should no longer utilize coverage gap cost-sharing reductions.
4. CMS should simply dictate that the OOPC values associated with a sponsor's basic plan be higher than that of its EA plan offerings.
5. CMS should use a different approach to the OOPC model and take into account a plan's preferred and non-preferred pharmacy networks and/or utilization management (UM).
6. CMS should stop using an outlier test to evaluate meaningful difference.

The current Part D OOPC model already addresses the recommendations raised in comment summaries 1 and 2 above, with the exception of coverage of excluded drugs. For purposes of evaluating whether the meaningful difference requirement is met, CMS considers plan-specific formularies and benefit packages, accounting for the number of drugs and associated cost-sharing. We refer interested stakeholders to the methodology documents included with our biannual OOPC model postings. The Part D OOPC model does not consider excluded drugs, as the intent of the model has been to estimate plan-specific beneficiary costs under the Part D benefit, and by definition, excluded drugs are not covered under Part D. Further, the value of excluded drugs offered by PDPs has been limited and would not have a substantial impact on the overall value of an EA plan.

With respect to comment summary 3 above, we note that the CY 2025 OOPC model will no longer consider coverage gap cost-sharing reductions in accordance with the IRA's Part D benefit changes in 2025. With respect to comment summary 4, CMS does not believe this is a sufficient requirement to ensure a meaningful difference between plan offerings. Regarding comment summary 5, we note that if a plan has a split network with standard and preferred cost-sharing, the Part D OOPC model uses the preferred cost-sharing amounts. If a plan only has a standard network, then the model uses the standard cost-sharing amounts. In addition, also regarding comment summary 5, since UM involves a clinical evaluation of the enrollee vis-à-vis a prescribed drug, it is difficult to conceive of an approach that could evaluate the impact of a plan's UM across its enrollees, much less across enrollees in all PDPs. Further, since CMS reviews UM to ensure it is clinically appropriate, inclusion in a meaningful difference evaluation might imply that UM is employed or evaluated strictly for financial reasons.

After consideration of the statutory changes under the IRA and the comments we received, we are establishing an absolute percent threshold approach for evaluating PDP meaningful difference for CY 2025. This approach aligns with comment summary 6 above, and also aligns with a longstanding CMS goal to move the meaningful difference evaluation from an absolute dollar differential to a percent differential. Once established, a percent differential will not require annual updates for inflation and will establish a stable, consistent requirement from year to year. This approach also considers the richness of the comparator basic plan in the evaluation – for instance a basic plan with an OOPC of $100 will not be held to the same dollar threshold as a basic plan with an OOPC of $150.

CMS undertook an analysis of the historic threshold values used for the PDP meaningful difference requirement as shown in table 130a. This analysis looked at the annual meaningful difference thresholds and calculated the average percent differences between the basic and first enhanced plan for each parent organization. We then prepared distributions and evaluated the percentile that was used to establish the dollar threshold for each year. Averaging the years together, we determined that a threshold of 18 percent would align with the observed dollar differentials from previous years.

Table 130a. Historic Meaningful Difference Analysis

Threshold Contract Year	Bid Data Contract Year Used to Establish Threshold	Meaningful Difference Threshold	Percentile Used to Establish Meaningful Difference Threshold	Corresponding Percent Change Aggregated by Parent Organization
2015	2014	$20	95th	18%
2016	2015	$18	95th	15%
2017	2016	$23	50th	20%
2018	2017	$20	50th	20%
2019	2018	$22	50th	18%

Given the limited enhancements available to plans under Part D benefit redesign, we acknowledge that this may no longer be a reasonable expectation. For CY 2024, all plans were able to achieve nearly a 12 percent differential without having an established threshold to target when preparing their bids. As a middle ground between these two values of 12 percent and 18 percent, for CY 2025, we will require a 15 percent differential. Under this approach, the plan sponsor must demonstrate that each EA plan Part D OOPC value generated from the OOPC model is at least 15 percent better than the basic plan offered by the same parent organization in the same region.

In addition to this requirement, CMS will conduct a sub-analysis to determine the proportion of meaningful difference derived from formulary robustness as opposed to benefit design/tier placement for the enhanced plan. Based on past CMS experience in bid review, there are instances in which a sponsor's EA plan within a region appears to offer higher cost sharing for individual formulary tiers when compared to its basic plan in that region. Such sponsors achieve an adequate OOPC differential by adding drugs to the formulary without offering a richer benefit (e.g., lower deductible or lower copays) compared to the basic plan. CMS does not consider this type of enhancement to be entirely transparent to the beneficiary. We also note that such an enhancement is of limited scope, given that only beneficiaries who utilize the added drugs benefit from the enhancement. Further, in addressing CMS meaningful difference review concerns, we often find that sponsors simply add drugs to their formularies, particularly those that are high cost but with low utilization, rather than improving on the benefit. To address this issue, our sub-analysis will allow CMS to differentiate between the two metrics of formulary robustness and benefit design/tier placement. CMS will run each plan's formulary (basic and enhanced) through the Part D OOPC model using a DS benefit design, allowing us to determine the proportion of meaningful difference that is attributed solely to formulary robustness. By

subtracting this calculated value associated with formulary robustness from the overall Part D OOPC difference, CMS can estimate the proportion of meaningful difference resulting from benefit design/tier placement. A description of our calculations follows below in Table 130b. For CY 2025, CMS is requiring that each metric—formulary robustness and benefit design/tier placement—is no worse for the EA plan compared to the basic plan.

As illustrated in Table 130b, values [A] – [D] are outputs from the Part D OOPC Model. Values [E] – [H] will be calculated by plan sponsors when preparing bid submissions and by CMS when evaluating bid submissions.

Table 130b. Output from Part D OOPC Model and Calculations to Evaluate Part D Meaningful Difference

Value	Source	Description	Calculation	CY 2025 Requirement	Example
[A] Basic OOPC	Output from the Part D OOPC model	OOPC value of basic plan (formulary and intended plan design)	N/A	N/A	$100
[B] DS Basic OOPC	Output from the Part D OOPC model	OOPC value of the basic plan's formulary run through DS benefit	N/A	N/A	$110
[C] EA OOPC	Output from the Part D OOPC model	OOPC value of EA plan (formulary and intended plan design)	N/A	N/A	$70
[D] DS EA OOPC	Output from the Part D OOPC model	OOPC value of the EA plan's formulary run through DS benefit	N/A	N/A	$105
[E] 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	[A] − [C]	N/A	$30

Value	Source	Description	Calculation	CY 2025 Requirement	Example
[F] Formulary component	Calculation	The amount of meaningful difference attributed to formulary robustness	[B] − [D]	For CY 2025, this value must be ≥ 0	$5
[G] Benefit component	Calculation	The amount of meaningful difference attributed to benefit design / tier placement	[E] − [F]	For CY 2025, this value must be ≥ 0	$25
[H] PDP Meaningful Difference (%)	Calculation	The percent difference between the enhanced plan and the basic plan	$\frac{[A]-[C]}{[A]} \times 100$	For CY 2025, the enhanced plan must be at least 15% better than the basic plan	30%

We note that for CY 2023 and CY 2024, CMS calculated meaningful difference by subtracting the basic plan OOPC from the EA plan OOPC, which resulted in a negative value. In CY 2025, CMS will calculate meaningful difference by subtracting the EA plan OOPC from the basic plan OOPC, resulting in a positive value.

In summary, for CY 2025, in addition to meeting the 15 percent overall differential between PDP basic and EA plan(s), as calculated in [H] in Table 130b, CMS will require that both the share of meaningful difference attributed to formulary robustness, as calculated in [F], and the share of meaningful difference attributed to benefit design/tier placement, as calculated in [G], be no worse than the respective values for the basic plan offered in the same region.

To assist plan sponsors ahead of the CY 2025 bid deadline, the CY 2025 Bid Review Part D OOPC Model will incorporate the ability for Part D sponsors to run each of their plan's formularies through a DS benefit. We believe this approach will be transparent for beneficiaries and ensure that those who choose an EA plan are paying for value relative to a basic plan offered by the same sponsor in the same region.

140. Non-Calendar Year EGWPs

A CMS waiver permits Part D sponsors offering EGWPs to establish NCY plan benefit packages in HPMS in order to allow employer groups to determine benefits (including deductibles, OOP limits, etc.) on a NCY basis. See Prescription Drug Benefit Manual; Chapter 12, section 20.13.

As a result of this waiver, a small proportion of EGWPs currently have NCY plan benefit packages, meaning their NCY plan year will start sometime during 2024 and continue into 2025.

The guidance in this section addresses how Part D sponsors offering such NCY EGWPs must implement IRA changes that take effect on January 1, 2025, during the middle of their NCY plan year. Specifically, this section discusses how such sponsors must implement the following statutory requirements effective January 1, 2025:

- Changes to the Part D DS benefit, including elimination of the coverage gap phase and lowering of the DS catastrophic threshold from $8,000 in 2024 to $2,000 in 2025;
- Discontinuation of coverage gap discounts under the CGDP;
- Implementation of the Discount Program; and
- Changes to the definition of incurred costs.

Since January 1, 2014, supplemental benefits provided by EGWPs beyond the parameters of the DS benefit are always considered non-Medicare OHI. (See 77 FR 22072 (April 12, 2012); and 80 FR 7912 (February 12, 2015).) Accordingly, this section provides guidance for EGWPs' DS benefit. Employer contributions can result in EGWP benefits of greater value than the DS benefit; however, EGWPs should follow current rules and guidance unless modified by the guidance in this document.

As specified on page 204 of the "Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," dated April 4, 2016, EGWP benefits, including NCY EGWP benefits (meaning, the Part D benefits, taking into consideration employer OHI) must continue to meet the following applicable actuarial standards in § 423.104(e):

- Deductible is limited to no greater than the DS deductible;
- Total benefit is at least actuarially equivalent to the basic benefit; and
- Catastrophic benefit is at least actuarially equivalent to the basic catastrophic benefit.

Existing CMS guidance[34] specifies that a NCY EGWP must satisfy these actuarial requirements for the portion of its NCY plan year that falls in a given calendar year and will meet this standard if it is actuarially equivalent for the calendar year in which the NCY plan year starts, and no design change is made for the remainder of the NCY plan year. However, given the significant

[34] See Prescription Drug Benefit Manual Chapter 12, Section 20.13, available at: https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/dwnlds/r6pdbpdfpdf.

IRA changes to the DS benefit effective on January 1, 2025, this guidance revises the current guidance specifically for EGWPs with NCY plan years that begin in 2024 and continue into 2025.

For PDE reporting, since 2014, we have required all EGWPs to "map" to the DS benefit: This means for 2024, all EGWPs report the Part D benefit as the DS benefit. Any difference in cost sharing from the DS benefit would constitute OHI. As noted above, NCY EGWPs report actuarial requirements for the portion of their NCY plan year that falls in a given calendar year. Therefore, they will map to the Part D benefit for the calendar year in which the portion of the NCY plan year falls. As discussed in Section 30 of this document, OHI, including supplemental coverage provided by EGWPs, will be TrOOP-eligible in 2025. CMS will provide PDE reporting instructions later in 2024 with examples demonstrating how OHI will be reported on PDEs in 2025. NCY EGWPs should consult the forthcoming instructions to ensure that they are correctly reporting their supplemental benefits for the portion of their NCY plan year that falls in 2025.

General Rule

A Part D sponsor offering a NCY EGWP with a NCY plan year that starts sometime in 2024 and continues into 2025 must map the EGWP benefit to the 2024 Part D DS benefit for the portion of its NCY plan year that falls in 2024 and to the 2025 Part D DS benefit for the portion of its NCY plan year that falls in 2025. Part D sponsors must carry over and utilize enrollee TrOOP balances from 2024 to determine an enrollee's DS benefit phase and TrOOP as of January 1, 2025. We provide further detail on how to apply this rule below.

Increased Part D DS Deductible in 2025: Part D sponsors must map NCY EGWPs to the 2025 Part D DS deductible beginning on January 1, 2025. However, the plan deductible for NCY EGWPs starting in 2024 cannot exceed the 2024 Part D DS deductible, and the plan deductible cannot increase during the NCY plan year.

- Enrollees who did not meet the plan deductible during the 2024 portion of the NCY plan year will start the 2025 portion of the NCY plan year in both the plan deductible and the DS deductible phase.
- Enrollees who met the plan and/or 2024 DS deductible during the 2024 portion of the NCY plan year but did not incur costs that meet the 2025 Part D DS deductible threshold will start the 2025 portion of the NCY plan year in the 2025 DS deductible phase but will have already satisfied their plan deductible.
- Enrollees who incurred costs in the 2024 portion of the NCY plan year that met or exceeded the 2025 DS deductible will start the 2025 portion of the NCY plan year in

either the 2025 DS initial coverage phase or catastrophic phase depending on their TrOOP balance as of January 1, 2025.

Elimination of the Coverage Gap Phase in 2025: As discussed in Section 20 of this document, there will no longer be a coverage gap phase beginning January 1, 2025. Part D sponsors must map NCY EGWPs to the 2025 Part D DS benefit without the coverage gap phase beginning on January 1, 2025.

Decreased DS Catastrophic Threshold in 2025: Section 1860D-2(b)(4)(B)(i)(VII) of the Act, as amended by section 11201 of the IRA, decreases the annual Part D DS catastrophic threshold from $8,000 in 2024 to $2,000 in 2025. Part D sponsors must map NCY EGWPs to the 2025 DS catastrophic threshold beginning on January 1, 2025.

- Enrollees who have a beginning TrOOP balance carried over from 2024 that is less than $2,000 as of January 1, 2025 will start in either the Part D DS deductible or initial coverage phase when their first claim is adjudicated in 2025.

- Enrollees who have a beginning TrOOP balance carried over from 2024 that is equal to or greater than $2,000 as of January 1, 2025 will start in the 2025 Part D catastrophic phase when their first claim is adjudicated in 2025. If the 2024 TrOOP balance exceeds $2,000, the TrOOP balance must be reset to $2,000 on January 1, 2025. Enrollees whose TrOOP reaches $2,000 in the 2024 portion of the NCY plan year cannot enter the catastrophic coverage phase in 2024 unless their TrOOP reaches the 2024 requirement of $8,000.

Transition from Coverage Gap Discount Program to Manufacturer Discount Program: Along with elimination of the coverage gap phase as of January 1, 2025, section 11201 of the IRA adds subsection (h) to section 1860D-14A of the Act, which sunsets the CGDP as of January 1, 2025, and section 1860D-14C, which replaces the CGDP with the Discount Program. Accordingly, Part D sponsors offering NCY EGWPs that continue into 2025 must cease applying coverage gap discounts for claims with dates of service after December 31, 2024, and begin applying discounts under the Discount Program beginning on January 1, 2025, based on where the enrollee is in the 2025 DS benefit when a claim is adjudicated. See the Medicare Part D Manufacturer Discount Program Final Guidance[35] for more information.

[35] https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf

Definition of Incurred Costs Applies within each Calendar Year

As discussed in Section 30 of this document, section 11201 of the IRA amended section 1860D-2(b)(4)(C) of the Act to update the definition of incurred costs and, thus, what counts toward TrOOP spending. To avoid administrative complications, Part D sponsors must only carry over from the 2024 portion of the NCY plan year a dollar figure that represents costs that qualified as incurred costs under laws and guidance applicable through December 31, 2024. The IRA definition of incurred costs applies for all claims with dates of service starting on or after January 1, 2025.

Medicare Prescription Payment Plan

Section 11202 of the IRA added section 1860D-2(b)(2)(E) of the Act, which requires that, "for plan years beginning on or after January 1, 2025," Part D sponsors provide an option for enrollees to elect into the Medicare Prescription Payment Plan to pay out-of-pocket costs in monthly amounts that are spread throughout the plan year and are subject to maximum monthly caps. Because the Medicare Prescription Payment Plan applies only to plan years beginning on or after January 1, 2025, NCY EGWPs are not required to provide enrollees with the option to participate in the program during any portion of the NCY plan year that starts in 2024 and continues into 2025. However, for the NCY plan year that starts in 2025, NCY EGWPs will be required to offer enrollees the option to participate in the Medicare Prescription Payment Plan. For additional information regarding the Medicare Prescription Payment Plan, see Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, which CMS plans to finalize in 2024 along with part two guidance.[36]

150. Different TrOOP-Eligible Costs in Basic Alternative and Enhanced Alternative Plans with Non-Defined Standard Deductible

Part D sponsors may offer plans with non-DS deductibles (e.g., lower deductibles for some or all covered Part D drugs) as either basic alternative (BA) or EA plans. A BA plan with a plan deductible below the DS deductible offers such coverage as part of its basic benefit prescription drug coverage. An EA plan that eliminates or lowers the plan deductible below the DS deductible for covered Part D drugs that would otherwise be subject to the DS deductible provides such coverage as part of its Part D supplemental benefit. In CY 2025, amounts reported

[36] Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments (August 21, 2023), available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf.

as Part D supplemental benefits will be TrOOP-eligible costs and count as incurred towards the DS deductible threshold.

As noted in Section 40 of this document, manufacturer discounts will be available under the Discount Program in both the initial coverage and catastrophic phases once a beneficiary incurs TrOOP-eligible costs that exceed the DS deductible as specified in section 1860D-2(b)(1) of the Act, regardless of whether the enrollee must pay a deductible under their plan. This includes TrOOP-eligible costs incurred with respect to drugs not subject to the deductible, including costs incurred with respect to covered insulin products under the DS benefit and, for non-DS plans, costs incurred with respect to drugs not subject to the plan deductible. Additionally, manufacturer discounts will not be available for covered insulin products and ACIP-recommended adult vaccines until a beneficiary incurs sufficient TrOOP-eligible costs to satisfy the DS deductible.

Because Part D supplemental benefits count towards TrOOP in CY 2025, but basic prescription drug coverage does not, the cost impact for a BA plan with a reduced deductible is much higher than for an EA plan. Under the BA plan, only the patient pay amounts count towards the DS deductible, whereas under the EA plan, both the Part D supplemental benefits paid by the plan and patient pay amounts count towards the DS deductible. Consequently, enrollees in BA plans with lower deductibles will take longer to exceed the DS deductible threshold before the Discount Program discounts are available. Given the disparate treatment of plan paid amounts between basic prescription drug coverage and Part D supplemental benefits for purposes of incurring TrOOP-eligible costs towards the DS deductible, and the resulting disparate impact on plan costs, it is unclear to CMS if Part D plans will continue to offer BA plans with lower deductibles. If we were to prohibit BA plans from lowering the deductible, there would be no need for CMS to continue permitting BA plans because they would never be able to offer a different benefit from actuarially equivalent (AE) plans. We solicit comment on whether CMS should continue to allow BA plans with lower deductibles beyond 2025.

160. Medical Loss Ratio (MLR) (§§ 423.2420 and 423.2460)

Section 1857(e)(4) of the Act requires that Medicare Advantage (MA) organizations be subject to financial and other penalties for a failure to have an MLR of at least 85 percent. Since section 1860D-12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, the minimum MLR requirement and sanctions also apply to Part D sponsors. The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds, a prohibition on enrolling new members, and ultimately contract termination.

MA organizations and Part D sponsors are required to report their MLR at the contract level for each contract year, pursuant to the regulations at §§ 422.2460 and 423.2460. The MLR is computed as a percentage of revenue used for patient care (including incurred claims for clinical services and prescription drug costs, and quality improvement activities) rather than for such other items as administrative expenses or profit.

The MLR regulations at § 423.2420(c) specify that the following Part D plan payments from the federal government are included in the MLR denominator: the direct subsidy, prospective federal reinsurance subsidy, reconciliation adjustments to the federal reinsurance subsidy, LIPS amount, and risk corridor payments. In the preamble of the implementing MLR regulation, CMS-4173-F, we explained that we viewed LICS and CGDP payments as pass-through payments for which plans do not retain any liability, and that these amounts should therefore be excluded from the MLR calculation; accordingly, LICS and CGDP payments are excluded from both the MLR numerator and denominator.[37]

The IRA introduced new categories of Part D plan payments from the federal government, as described below:

- Discount Program payment: As noted in Section 20 of this document, the IRA sunsets the CGDP and creates the Discount Program starting January 1, 2025. The Medicare Part D Manufacturer Discount Program Final Guidance describes the payment process for the Discount Program payments, including a cost-based reconciliation intended to make Part D sponsors whole for the manufacturer discount amounts they advance on behalf of the manufacturer.[38]

- Inflation Reduction Act Subsidy Amount (IRASA): CMS provided Part D plan sponsors with a Part D payment for CY 2023 referred to as the IRASA. This temporary retrospective subsidy was paid to Part D plans for the reduction in cost sharing and elimination of the deductible for ACIP-recommended adult vaccines and covered insulin products during the 2023 plan year (i.e., to cover the difference between the beneficiary cost sharing for the covered insulin, or ACIP-recommended adult vaccine, under the plan's 2023 benefit design, and the applicable statutory maximum cost sharing ($35 for insulins and $0 for vaccines)).

[37] Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 78 FR 31284, 31290-92 (May 23, 2013).

[38] See Medicare Part D Manufacturer Discount Program Final Guidance, available at: https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf

The new Part D plan payments for the Discount Program and IRASA are excluded from the denominator of the MLR calculation, and associated expenditures are excluded from the numerator of the MLR calculation. Excluding these payments and associated expenditures is consistent with the exclusion of LICS and CGDP payments from the MLR on the basis that they are pass-through payments collected by a plan on behalf of a third party rather than revenue to the plan.

Additionally, under section 1860D-2(b)(2)(E)(v)(VI) of the Act, any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan "shall be treated as plan losses, and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids." Instructions for the treatment of any bad debt resulting from this program in the MLR calculation will be included in the Medicare Prescription Payment Plan draft part two guidance, which is set to be released in early 2024.

170. Appendix

Part D Benefit Parameters for Defined Standard Benefit for CY 2024 and CY 2025 for Non-LIS Beneficiaries

<table>
<tr><td></td><td colspan="2">2024</td><td colspan="2">2025[39]</td></tr>
<tr><td>Deductible Phase</td><td colspan="2">Cost sharing: 100%</td><td colspan="2">Cost sharing: 100%</td></tr>
<tr><td></td><td colspan="2">Deductible: $545</td><td colspan="2">Deductible: $590</td></tr>
<tr><td>Initial Coverage Phase</td><td colspan="2">Cost sharing: 25%
Plan Pays: 75%</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 65%
Manufacturer Discount: 10%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td></tr>
<tr><td></td><td colspan="2">Initial Coverage Limit: $5,030</td><td colspan="2">Initial Coverage Limit:
Not Applicable</td></tr>
<tr><td>Coverage Gap</td><td>Applicable Drugs
Cost sharing: 25%
Plan Pays: 5%
Manufacturer Discount: 70%</td><td>Non-Applicable Drugs
Cost sharing: 25%
Plan Pays: 75%</td><td colspan="2">N/A</td></tr>
<tr><td></td><td colspan="2">Out-of-Pocket Threshold: $8,000</td><td colspan="2">Out-of-Pocket Threshold: $2,000</td></tr>
<tr><td>Catastrophic Phase</td><td colspan="2">Plan Pays: 20%
Reinsurance: 80%</td><td>Applicable Drugs
Plan Pays: 60%
Manufacturer Discount: 20%
Reinsurance: 20%</td><td>Non-Applicable Drugs
Plan Pays: 60%
Reinsurance: 40%</td></tr>
</table>

[39] Note that the IRA provides for lower applicable discounts for certain manufacturers' applicable drugs marketed as of August 16, 2022 during a multi-year phase-in period, which concludes by 2031. For drugs that are subject to a phased-in discount, plans are responsible for covering the difference between the phased-in discount and the full discount that otherwise would have applied (10 percent in initial coverage phase and 20 percent in the catastrophic phase). As such, the liability of plan sponsors and manufacturers for applicable drugs in the initial coverage and catastrophic phases may vary based on whether a drug is subject to a phase-in discount.