Final CY 2025 Part D Redesign Program Instructions

The purpose of these Final Calendar Year (CY) 2025 Part D Redesign Program Instructions (Final Program Instructions) is to provide interested parties with final guidance for CY 2025 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, among other topics described in Section A. This memorandum includes four Sections:

A. Overview

These Final 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 Medical Loss Ratio (MLR) reporting related to the IRASA established by section 11406(c) of the IRA.[1] These Final Program Instructions are being published concurrently with the Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, which announces updates to Part D parameters. Some of those updates are affected 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,

[1] These Final 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) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. Refer CMS' Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments and Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments Memorandums.

[2] Refer to CMS' Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

and 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing these Final Program Instructions for implementation of section 11201 of the IRA for 2025 and for implementation of Medical Loss Ratio (MLR) reporting instructions related to the Inflation Reduction Act Subsidy Amount (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 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]

Policies established in these Final Program Instructions for CY 2025 are subject to change in subsequent years.

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

[3] Refer to CMS' Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin Memorandum.

[4] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

[5] Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance and Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers Memorandums.

[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.

B. Summary of Key Changes in These Final Program Instructions

CMS received many thoughtful and helpful comments from consumer and patient groups, manufacturers, pharmacies, Part D sponsors, consulting companies, standards setting organizations, individuals, and other interested parties on the Draft Program Instructions released on January 31, 2024. This Section provides a summary of key changes made to the Draft Program Instructions. Please note that we have not included an exhaustive list of the changes. CMS has provided responses to the comments received in Section C and has made corresponding changes in these Final Program Instructions, as summarized below.

Creditable Coverage: CMS revised Section 90 to state that we will continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for group health plan[7] sponsors not applying for the retiree drug subsidy (RDS) under section 1860D-22(a) of the Act. These Final Program Instructions also specify that CMS will re-evaluate the continued use of the existing creditable coverage simplified determination methodology, or establish a revised one, for CY 2026 in future guidance.

Specialty Tier Cost Sharing Thresholds: Annually, CMS sets the maximum allowable cost sharing for the specialty tier based on the plan's deductible, in accordance with § 423.104(d)(2)(iv)(D). However, in CY 2025, the initial coverage limit (ICL) will be eliminated and, therefore, the methodology codified at § 423.104(d)(2)(iv)(D)(3) will no longer be valid. CMS must therefore establish a new methodology to determine the specialty tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the redesigned Part D benefit. As noted in the Draft Program Instructions, CMS reserved the right to change any policies, including policies on which CMS had not expressly solicited comment, in these Final Program Instructions based on the agency's further consideration of relevant issues. Accordingly, 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, we are establishing a new methodology to determine the specialty tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the redesigned Part D benefit. This new methodology is described in the newly added Section 170.

[7] "Group health plan" as used here and in Section 90 of these Final Program Instructions refers to a group health plan described at § 423.56(b)(3). It does not include EGWPs, which are Part D plans, and, as such, cannot use the simplified determination methodology.

C. Summary of Public Comments on the Draft Program Instructions and CMS' Responses

Detailed Description of the Redesigned Part D Benefit in 2025 (Section 20)

Comment: Several commenters noted that aspects of the Part D redesign have the potential to increase the financial liability of plans, especially those with beneficiaries taking high-cost drugs. They suggested that plans may respond by limiting the accessibility of medications to control costs. In particular, commenters expressed concerns that plans may employ utilization management tools, move drugs to a less favorable beneficiary cost-sharing tier, or remove drugs from their formularies altogether. Some commenters suggested that CMS should proactively take steps to maintain the accessibility of needed medications. A number of these commenters stated that CMS should strengthen its formulary review and oversight processes. Several commenters specifically asked CMS to scrutinize the formulary position of drugs belonging to the Part D six protected classes (antidepressants, antipsychotics, anticonvulsants, antiretrovirals, antineoplastics, and immunosuppressants for treatment of transplant rejection). Furthermore, several commenters requested that CMS restate or clarify guidance outlining formulary requirements and the appropriate use of utilization management tools.

One commenter expressed the opposite perspective and asserted that the low annual out-of-pocket (OOP) threshold created by the IRA will make plan enrollees less sensitive to high drug costs. The commenter stated that, in order to control costs, CMS should grant plans greater flexibility to implement utilization management tools.

Response: We thank the commenters for expressing their concerns. CMS understands that, by significantly altering the Part D benefit design, the IRA changes the structure of liabilities of all Part D sponsors, which may result in impact to their benefit offerings. CMS maintains, and will continue to maintain, a robust clinical formulary review process to ensure that all Medicare Part D plans meet applicable formulary requirements. Consistent with the requirements at §§ 423.120(b)(2) and 423.272(b)(2)(i), CMS evaluates formularies based on the sufficiency of categories and classes, tier placement, and utilization management restrictions. This review process is based in part on section 1860D-11(e)(2)(D)(i) of the Act, which authorizes CMS to approve a prescription drug plan only if the agency "does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." In addition, under § 423.272(b)(2)(i), "CMS does not approve a bid if it finds that the design of the plan and its benefits (including any formulary and tiered formulary structure) or its utilization management program are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan." Furthermore, § 423.120(b)(2)(iii) requires each Part D plan formulary to "include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as

recognized in national treatment guidelines." In addition, § 423.120(b)(1)(v) requires that in making decisions about formulary design, the entity designing the formulary must base "clinical decisions on the strength of scientific evidence and standards of practice." Our current formulary review process includes evaluation of the placement of drugs in the Part D six protected classes, and CMS will continue to ensure that these drugs remain accessible to all enrollees who need them.

We are aware that the changes in liability as a result of the redesigned Part D benefit may create incentives for plans to alter their formularies, and we will continue to monitor year-over-year formulary and utilization management changes to assess if these changes have the potential to reduce access to vital medications.

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

Comment: Several commenters disagreed with CMS' inclusion of enhanced alternative (EA) supplemental benefits in the definition of true out-of-pocket costs (TrOOP) for CY 2025. Commenters raised both legal and policy-based objections to the inclusion of EA supplemental benefits. Some commenters argued that the term "reimbursed through insurance" refers only to non-Part D commercial insurance as the Act typically uses the term "coverage provided by a prescription drug plan or an MA-PD" when referring to Part D prescription drug coverage. Several commenters observed that section 1860D-2(b)(4)(C)(iii) of the Act does not directly address EA supplemental benefits and asserted that the provision is, at best, ambiguous as to whether EA supplemental benefits are included. Commenters also opined that CMS' interpretation that section 1860D-2(b)(4)(C)(iii) of the Act includes EA supplemental benefits is contrary to the legislative history and intent of the provision, which they asserted was to address the unique situation of Employer Group Waiver Plan (EGWP) beneficiaries who faced higher OOP costs because EGWP supplemental coverage's exclusion from TrOOP in the coverage gap led to EGWP beneficiaries spending longer in the coverage gap phase of the benefit and, therefore, paying more OOP.

Commenters also raised policy concerns with the inclusion of EA supplemental benefits in TrOOP. Several commenters observed that the inclusion of EA supplemental benefits could incentivize beneficiaries to select a higher-cost drug over a less expensive alternative within the same formulary tier because the beneficiary would pay less OOP and reach the annual OOP threshold faster when EA supplemental benefits are included in TrOOP. Commenters stated that this could have implications for beneficiary premiums by increasing the cost of standardized bids and reducing the incentives for Part D sponsors to offer EA plans. Commenters also stated that the inclusion of EA supplemental benefits may create confusion for beneficiaries who may not understand how their actual OOP expenses relate to the annual OOP threshold. Finally,

commenters stated that this policy could be difficult to operationalize and require significant changes to Part D data systems, reporting mechanisms and coordination of benefit processes.

Response: CMS thanks the commenters for their input. CMS disagrees that EA supplemental benefits are not included in TrOOP under section 1860D-2(b)(4)(C)(iii) of the Act. The statute does not draw a distinction between non-Part D commercial insurance and coverage under Part D when it uses the term "reimbursed through insurance" in this provision. By excluding "coverage provided by a prescription drug plan or an MA-PD plan that is basic prescription drug coverage" from the definition of costs "reimbursed through insurance," the plain text of section 1860D-2(b)(4)(C)(iii)(II) indicates that drug coverage provided by Part D plans other than basic prescription drug coverage is included in the definition of costs "reimbursed through insurance." While CMS agrees that one goal of the IRA amendments to section 1860D-2(b)(4)(C)(iii) of the Act was to address the unique situation of EGWP beneficiaries who faced higher OOP costs due to the treatment of EGWP supplemental coverage, if the provision were meant only to include EGWP supplemental coverage in the definition of costs "reimbursed through insurance," then Congress would have done so by explicitly including EGWP supplemental coverage in the definition of "costs reimbursed through insurance" and expanding the exclusion clause to apply to both basic prescription drug coverage and EA supplemental coverage. However, Congress did not do so and instead enacted a broader provision for which the plain text requires any costs "reimbursed through insurance" be treated as incurred unless such costs constitute basic prescription drug coverage provided by a prescription drug plan or an MA–PD plan.

CMS acknowledges that the inclusion of EA benefits in TrOOP may affect the incentives available to beneficiaries enrolled in EA plans, including by incentivizing beneficiaries to choose higher-cost drugs over lower-cost ones in certain circumstances. However, as stated above, we do not believe the statute can be reasonably read to exclude EA supplemental benefits. We also do not believe that beneficiaries enrolled in EA plans will be unduly confused by moving through the benefit more quickly than they anticipated as a result of the inclusion of EA supplemental benefits in TrOOP. Beneficiaries already have experience with costs they have not personally paid counting toward TrOOP, such as manufacturer discounts under the Coverage Gap Discount Program (CGDP). CMS understands that the Part D redesign may pose certain operational challenges for plans and will release detailed Prescription Drug Event (PDE) instructions to aid plans in making the necessary systems updates later in 2024.

Comment: A commenter stated that CMS mistakenly includes third-party payment arrangements enumerated at section 1860D-2(b)(4)(C)(iii)(I) of the Act (e.g., Low Income Subsidy cost-sharing support, qualified State Pharmaceutical Assistance Programs (SPAPs), Indian Health Service and certain other Native American organizations, and AIDS Drug Assistance Programs, among others) as TrOOP for CY 2025 because the Act uses the operative word "or" between subclauses (I) and (II). Section 1860D-2(b)(4)(C)(iii) of the Act makes a distinction between the

sources that have historically applied as TrOOP-eligible incurred costs outlined in subclause (I), and those sources that would count as TrOOP-eligible incurred costs "for 2025 and subsequent years" outlined in subclause (II).

Response: CMS thanks the commenter for their input. CMS believes that section 1860D-2(b)(4)(C)(iii)(I) of the Act continues to apply in CY 2025 as that section is not expressly limited to specific years of applicability. The commenter's interpretation is inconsistent with the plain text of the statute, which clearly states that incurred costs include the options listed in subclause (I) "or" subclause (II). Moreover, Congress' use of the temporal limitation in subclause (II)—but the lack of a similar limitation in subclause (I)—indicates that the costs outlined in subclause (I) continue to apply. If Congress had intended to impose a time limit on subclause (I), then it would have explicitly done so as it did elsewhere in the IRA (e.g., with respect to the initial coverage limit and the CGDP, see sections 1860D-2(b)(3)(A) and 1860D-14A(h) of the Act). Because there is no language expressly limiting (I) to specific years of applicability, the plain reading and structure of section 1860D-2(b)(4)(C)(iii) of the Act are clear that TrOOP in CY 2025 includes any costs that meet the criteria in either subclauses (I) or (II).

Comment: Several commenters disagreed with CMS' exclusion of negative values in the field on the PDE representing supplemental coverage from the calculation of TrOOP. Commenters stated that disregarding negative values representing supplemental coverage overstates the overall value of supplemental benefits provided to beneficiaries. A commenter also stated that this treatment appears inconsistent with section 1860D-2(b)(4)(C)(iii)(II) of the Act, which excludes costs paid by Part D plans for basic prescription drug coverage from TrOOP costs.

Response: CMS thanks the commenters for their input. As stated in the Draft Program Instructions, negative values in the field representing supplemental coverage do not represent amounts reimbursed to the beneficiary. While excluding such negative values from TrOOP can overstate the net value of total supplemental benefits provided to beneficiaries over the course of the year, including negative values in TrOOP would inappropriately disregard any beneficiary cost sharing in excess of the DS cost sharing amount when calculating TrOOP. This would particularly disadvantage certain beneficiaries who have patterns of utilization that disproportionately include this situation. For example, if a beneficiary in an EA plan has higher cost sharing than the DS benefit for a maintenance medication, including the negative values in TrOOP could significantly disadvantage that beneficiary as these negative values would continually offset part of the payments the beneficiary actually paid OOP. This will create some circumstances where certain beneficiaries have a net negative value for their supplemental benefits when they reach $2,000 OOP, which means they would have to pay more than $2,000 OOP to reach the catastrophic phase for CY 2025. This is clearly prohibited by section 1860D-2(b)(4)(B)(i)(VII) of the Act, which establishes a $2,000 annual OOP threshold for CY 2025. CMS also disagrees that its approach is inconsistent with section 1860D-2(b)(4)(C)(iii)(II) of the

Act. Section 1860D-2(b)(4)(C)(iii)(II) of the Act specifically excludes only basic prescription drug coverage from the definition of costs reimbursed to the beneficiary through insurance, a group health plan, or certain other third party payment arrangements. Negative values are not amounts reimbursed to the beneficiary and, therefore, do not fall within the definition of costs reimbursed to the beneficiary.

Comment: Several commenters requested clarification on whether the inclusion of EA supplemental benefits in TrOOP includes coverage of supplemental drugs not covered under Part D.

Response: CMS thanks the commenters for their questions. Costs incurred for supplemental drugs not covered under Part D are not included in TrOOP. Under section 1860D-2(b)(4)(C)(i) of the Act, only costs incurred with respect to covered part D drugs are included in the definition of incurred costs and, therefore, are TrOOP-eligible.

Comment: Several commenters requested clarification as to whether payments by independent charitable copay foundations (ICCF) are included in TrOOP in CY 2025.

Response: CMS thanks the commenters for their questions. As stated in the Prescription Drug Benefit Manual Chapters 5 & 14, financial assistance provided by a legitimate charity that reimburses a portion of the cost for a covered Part D drug is TrOOP-eligible. The treatment of covered Part D prescription drug costs reimbursed by ICCFs is not implicated by the changes to TrOOP for CY 2025.

Comment: Several commenters requested clarification as to the interaction between the changes in TrOOP-eligible costs and Center for Medicare and Medicaid Innovation (CMMI) model benefits that reimburse covered Part D drug costs. Specifically, commenters requested clarification regarding model benefits provided under the Medicare Advantage (MA) Value Based Insurance Design (VBID) Model.

Response: CMS thanks the commenters for their questions. Because CMMI model benefits are benefits provided by a Part D sponsor that are not basic prescription drug coverage, those benefits that reimburse covered Part D drug costs are TrOOP-eligible costs for CY 2025, unless stated otherwise in a CMMI model's Request for Applications.

Comment: A commenter requested clarification on the impact that changes in the costs counted toward TrOOP could have on the treatment of integrated Dual Eligible Special Needs Plans (D-SNPs) versus coordination-only D-SNPs. The commenter stated that they believe Medicaid costs that are paid through an integrated D-SNP would be considered incurred costs, but those paid through a coordination-only non-integrated D-SNP would not.

Response: CMS thanks the commenter for their questions. Supplemental benefits provided through a D-SNP are incurred costs for CY 2025 because those benefits are reimbursed by the Part D sponsor. Any costs directly reimbursed by Medicaid are not TrOOP-eligible for CY 2025. Section 1860D-2(b)(4)(C)(ii) of the Act states that "...costs shall be treated as incurred only if they are paid by the part D eligible individual ... and the part D eligible individual (or other person) is not reimbursed through insurance *or otherwise*, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs..." (emphasis added). At § 423.100, CMS has defined the term "or otherwise" to mean "through a government funded health program," including the Medicaid program. As the IRA did not amend this term or state that reimbursement through a government funded health program are incurred costs as defined in section 1860D-2(b)(4)(C) of the Act, it continues to have the same meaning, and benefits provided by Medicaid continue to be excluded from TrOOP.

Comment: Several commenters responded to CMS' solicitation of comment regarding other third-party payment arrangements that could be included in TrOOP. Commenters supported CMS' policy to refrain from adding any TrOOP-eligible costs to the "other third party payment arrangements" in the TrOOP calculation. No commenters identified additional third-party payments that they believed should be included in TrOOP.

Response: CMS appreciates commenters' thoughtful input and will continue with its policy as described in the Draft Program Instructions.

Comment: Several commenters requested specific guidance on how to populate PDEs for 2025 consistent with the changes in TrOOP-eligible costs.

Response: As stated in the Draft Program Instructions, CMS will release detailed PDE reporting instructions later in 2024 with additional examples to demonstrate how this policy should be implemented.

Comment: Some commenters requested additional information regarding how the changes in which costs count toward TrOOP intersect with the Medicare Prescription Payment Plan, including how an EA plan's supplemental benefits counting toward TrOOP may change Medicare Prescription Payment Plan payments, how to incorporate changes in TrOOP in the processes of identifying enrollees likely to benefit from the Medicare Prescription Payment Plan, and if there will be different Medicare Prescription Payment Plan program requirements for different plan types (e.g., DS versus EA).

Response: CMS thanks commenters for their questions. For the Medicare Prescription Payment Plan, the changes in what costs count toward TrOOP will be incorporated into the calculation of

the first month maximum cap.[8] However, for the calculation of the maximum cap in subsequent months, only the OOP costs that the Part D enrollee is directly responsible for paying are included (note that this does not include other TrOOP-eligible amounts, such as any amount paid by an EA plan or EGWP for supplemental benefits). As stated in section 30 of the Medicare Prescription Payment Plan final part one guidance,[9] opting into the program will not impact how a program participant moves through the Part D benefit or what counts towards their TrOOP costs. Opting into the program only provides participants with the ability to spread OOP costs over the year—the total incurred costs and the timing of TrOOP accumulation do not change. Additionally, under section 1860D-2(b)(4)(F) of the Act, a participant's TrOOP-eligible costs under the program will still be treated as incurred based on the date each Part D claim is adjudicated.

For example, an EA plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20 percent coinsurance for drugs in that tier. An enrollee's first fill of the year (in January) is for a $200 tier 1 drug, meaning they pay $40 OOP but have $200 in TrOOP accumulation. In February, prior to refilling their medication for that month, the enrollee opts into the Medicare Prescription Payment Plan. Their first month's maximum monthly cap would be calculated as: ($2,000 - $200)/11 = $163.64. The plan will bill $40 for February, since the OOP incurred amount is lower than the cap.

Requirements for Part D sponsors to identify enrollees likely to benefit from the Medicare Prescription Payment Plan, both at the pharmacy point-of-sale and prior to or during the plan year, are based on OOP costs. Changes in which costs count toward TrOOP do not alter those requirements. Finally, CMS confirms that the requirements and processes outlined in the Medicare Prescription Payment Plan guidance apply to all Part D sponsors, regardless of whether the enrollee is in a DS, basic, or EA plan.

CMS directs commenters to the final part one and draft part two guidance documents for the Medicare Prescription Payment Plan.[10] CMS will publish final part two guidance for the Medicare Prescription Payment Plan in summer 2024.

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[8] Under section 1860D–2(b)(2)(E)(iv)(I) of the Act, for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan, the term "maximum monthly cap" means an amount calculated by taking the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year.

[9] Refer to CMS' Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments Memorandum.

[10] Refer to CMS' Medicare Prescription Payment Plan Guidance Documents.

Policy for Drugs Not Subject to the Defined Standard Deductible (Section 40)

Comment: Several commenters expressed opposition to CMS' policy for drugs not subject to the deductible because they feel the methodology is confusing and likely to create an incentive for plans to raise deductibles. A commenter recommended CMS utilize the plan deductible as the threshold for when a beneficiary becomes an applicable beneficiary. Another commenter recommended that a beneficiary should become an applicable beneficiary once "drug spend" meets or exceeds the DS deductible amount. CMS assumes that by "drug spend," the commenter means Gross Covered Prescription Drug Costs (GCPDC).

Response: CMS understands that the Part D redesign may result in changes to plan offerings. However, 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. As such, once a beneficiary has incurred sufficient TrOOP-eligible costs to satisfy the DS deductible, they will be an applicable beneficiary under the Discount Program. Because the threshold for when a beneficiary becomes an applicable beneficiary is defined in statute, CMS cannot choose an alternative threshold.

Comment: Several commenters requested clarification as to whether only the $35 applicable copayment amount or the total cost is treated as TrOOP-eligible with respect to covered insulin products under the Part D redesign.

Response: CMS thanks the commenters for their questions. Only the applicable copayment amount is TrOOP-eligible with respect to covered insulin products. The portion of the actual cost for which the plan is responsible is basic prescription drug coverage and excluded from TrOOP. Any discounts paid under the Discount Program on covered insulin products are also excluded from TrOOP. As stated in the April 4, 2023 HPMS memorandum, Final Contract Year (CY) 2024 Part D Bidding Instructions, the statute prohibits cost sharing that exceeds the applicable copayment amount, but does not require that cost sharing be equal to the applicable copayment amount.[11] Accordingly, the standard prescription drug coverage requirement includes the value of the Part D plan's coverage of covered insulin products (regardless of whether cost sharing under the plan is equal to the IRA maximum of $35 per month's supply per product or a lower amount), which will always be reflected in the plan bid as a basic benefit.

Comment: A commenter expressed concern that the policy for drugs not subject to the plan deductible could cause beneficiary confusion as the beneficiary may not understand when

[11] Refer to CMS' Final Contract Year (CY) 2024 Part D Bidding Instructions Memorandum.

discounts under the Discount Program begin to apply. The commenter recommended that CMS require Part D sponsors to explain the Discount Program in plain language to ensure that beneficiaries understand the relative benefits of selecting different plan types and notify beneficiaries when they become eligible for discounted drugs.

Response: CMS thanks the commenter for their input. Under section 1860D–14C(b)(1)(B) of the Act, discounts paid under the Discount Program generally do not affect beneficiary cost sharing obligations in the initial coverage phase. As such, CMS does not believe it is necessary to require Part D sponsors to ensure that beneficiaries understand the specifics of the program. However, there will be information about the Discount Program in the CY 2025 Annual Notice of Change and Evidence of Coverage.

Comment: Several commenters requested specific guidance on how to populate PDEs for 2025 consistent with the policy for drugs not subject to the deductible.

Response: As stated in the Draft Program Instructions, CMS will release detailed PDE reporting instructions later in 2024 with additional examples to demonstrate how this policy should be implemented.

Comment: Several commenters asked for clarification regarding the example that CMS provided in this Section on page 10 of the Draft Program Instructions. Specifically, commenters observed that CMS stated that the hypothetical beneficiary would have $550 in remaining TrOOP-eligible costs before the beneficiary satisfies the DS deductible, which is inconsistent with the policy stated in Section 30 of the Draft Program Instructions, under which EA supplemental benefits are TrOOP-eligible costs for CY 2025.

Response: CMS thanks the commenters for their questions. The example on page 10 of the Draft Program Instructions was incorrect as originally published. As stated in the February 13, 2024, HPMS email, Correction in Example in Draft CY 2025 Part D Redesign Program Instructions, and on the Inflation Reduction Act Part D Improvements webpage, the correct amount of remaining TrOOP-eligible costs is $390, not $550. The example has also been revised in these Final Program Instructions.

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 50)

Comment: One commenter asked CMS to clarify whether the costs of covered Part D drugs covered by store/non-manufacturer discount programs, perhaps even through out-of-network coverage, are included in GCPDC.

Response: This guidance only clarifies how manufacturer discounts provided under the Discount Program are treated in relation to GCPDC, as directed by the IRA; all other prior guidance related to GCPDC applies.

Reinsurance Methodology (§§ 423.308, 423.329) (Section 60)

Comment: A few commenters expressed support for revising the direct and indirect remuneration (DIR) allocation methodology.

Response: CMS thanks the commenters for expressing their support.

Comment: Some commenters requested clarification on the terms and equations described in the Draft Program Instructions for the calculation of the final reinsurance subsidy, including additional details related to incurred reinsurance costs, total DIR, total allowed costs, using PDE records or claims for identifying costs, and marketing categories in the Food and Drug Administration's (FDA's) Comprehensive National Drug Code (NDC) Structured Product Labeling (SPL) Data Elements (NSDE) file used for PDE processing. A few commenters requested CMS provide feedback on specific sample calculations.

Response: CMS thanks the commenters for their questions and requests for clarification. We clarify that in Section 60 of this document, where CMS uses the term "incurred reinsurance costs for applicable drugs," we are referring to the total allowed costs for applicable drugs in the catastrophic phase. Similarly, the term "incurred reinsurance costs for non-applicable drugs" refers to the total allowed costs for non-applicable drugs in the catastrophic phase. The term "total DIR" is the sum of all reported DIR, including applicable and non-applicable drugs. The term "total allowed costs" refers to allowable reinsurance costs, which includes both applicable and non-applicable drugs. As such, the same fraction (total DIR / total allowed costs) is used in calculating the reinsurance DIR for both applicable and non-applicable drugs.

In Section 60 of the Draft Program Instructions, CMS stated that the calculation for the final reinsurance subsidy for non-applicable drugs would use claims to identify incurred reinsurance costs, which was the terminology used in the CY 2006 Advance Notice establishing the DIR allocation methodology. In practice, PDE records have been used for this purpose. In these Final Program Instructions, we have revised Section 60 to state that PDE records will be used to identify those costs.

As noted in Section 60 of these Final Program Instructions, the marketing category from the FDA's NSDE file used for PDE processing will be used to determine if a drug is categorized as an applicable or non-applicable drug. General information regarding the NSDE file and

marketing categories can be found on the FDA's website.[12] Additional details regarding assigning PDE records as an applicable or non-applicable drug can be found in the HPMS memo titled, "2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations," published March 8, 2024.[13]

In lieu of CMS responding to individual requests for sample calculation validation, we are providing a simplified example here to demonstrate the components of the revised final reinsurance subsidy calculation. Note that CMS performs the below calculations as part of the Part D reconciliation process; Part D sponsors should follow the Part D Bid Pricing Tool (BPT) instructions when completing their Part D bid.[14]

	Applicable Drugs	**Non-Applicable Drugs**	**Total**
Allowed costs	$500	$200	$700
Incurred reinsurance costs	$400	$50	$450
DIR	$200	$10	$210
Reinsurance DIR	($210/$700) * $400 = $120	($210/$700) * $50 = $15	$135
Adjusted Reinsurance	($400 - $120) * 0.2 = $56	($50 - $15) * 0.4 = $14	$70

The calculation formulas for applicable drugs are:

> Reinsurance DIR for applicable drugs = (total DIR / total allowed costs) × incurred reinsurance costs for applicable drugs, or ($210 / $700) * $400 = $120
>
> Adjusted reinsurance for applicable drugs = (incurred reinsurance costs for applicable drugs – reinsurance DIR for applicable drugs) × 0.20, or ($400 - $120) * 0.2 = $56

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, or ($210/$700) * $50 = $15

[12] Refer to FDA's Structured Process Labeling Resources NSDE.

[13] Refer to CMS' HPMS Memos for WK 2 March 4-8.

[14] Refer to CMS' CY 2025 Part D BPT Instructions where it will be made available to access.

Adjusted reinsurance for non-applicable drugs = (incurred reinsurance costs for non-applicable drugs – reinsurance DIR for non-applicable drugs) × 0.40, or ($50 - $15) * 0.4 = $14

The sum of the adjusted reinsurance amounts for applicable and non-applicable drugs ($70 in the above example) will then be reconciled with prospective reinsurance payment amounts made to the plan during the coverage year.

Part D Calendar Year EGWP Prospective Reinsurance Amount - Methodology (Section 70)

Comment: A few commenters expressed support for the updated methodology for Part D Calendar Year EGWP prospective reinsurance amount.

Response: CMS appreciates commenters' support.

Comment: In response to the CY 2025 Advance Notice, a commenter expressed opposition to a CY 2025 change in methodology for Part D Calendar Year EGWP prospective reinsurance payment amounts. They stated that IRA-related changes to Part D for CY 2025 may impact not only the accuracy of Part D sponsors' projections of spend in their bids, but also the general availability of EA plans. As such, the commenter stated that CY 2025 EA bids may not align well with CY 2025 EGWP populations, and thus should not be used for EGWP prospective reinsurance payment amounts. The commenter also requested that, as in prior years, CMS announce the prospective EGWP reinsurance payment amount in the spring instead of summer to provide plans with more time to understand the potential impact on cash flow and budget projections. Another commenter requested CMS clarify if all EGWP plans are considered to be EA plans and, if not, suggested that CMS consider another method for calculating the Part D Calendar Year EGWP prospective reinsurance amount. In addition, the commenter expressed concern that EGWP prospective reinsurance payments will be lower in CY 2025 and that may result in changes in how EGWPs cover specialty products; the commenter requested CMS monitor these changes, both for EGWPs and other Part D plans.

Response: CMS thanks the commenters for their input. However, given the significant changes to the reinsurance percentages for CY 2025, we believe it is appropriate to adjust prospective reinsurance payments Part D Calendar Year EGWPs in the manner described in Section 70 of this document. As described in that Section, using the historical approach for Part D Calendar Year EGWP prospective reinsurance amounts in CY 2025 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. The CY 2025 policy established in Section 70 will ensure that Part D Calendar Year EGWPs are paid an appropriate prospective reinsurance payment amount.

Additionally, this methodology does not change the final reinsurance amount that will ultimately be paid through the Part D reconciliation process; hence, this methodology for a prospective payment should not affect coverage decisions made by Part D sponsors. The Part D Calendar Year EGWP prospective reinsurance amount will be announced slightly later than in previous years; however, we believe that should not have a meaningful impact on operations, since the payment amount will still be known well in advance of the payment year. CMS notes that no commenters proposed alternative methodologies that would both address the reduction in the reinsurance percentages for CY 2025 and allow for a spring publication of the Part D Calendar Year EGWP prospective reinsurance amount.

Finally, while EGWP plans are not considered to be EA plans, as shown in Table 70 in Section D, calculations using prior years' data from EA plan bid submissions result in a reasonable prospective reinsurance amount for Part D Calendar Year EGWPs. CMS is establishing the approach described in Section 70 for CY 2025 and will continue to evaluate Part D Calendar Year EGWP prospective reinsurance amounts for plan years beyond CY 2025.

Comment: A commenter requested that CMS make the CY 2025 prospective reinsurance amount for Part D Calendar Year EGWPs publicly accessible and not available only through HPMS for plan sponsors.

Response: As noted in Section 70, 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. As in prior years, this information will be publicly available on CMS.gov.

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

Comment: Many commenters suggested that CMS explore alternative solutions to narrow risk corridors for 2025 and later years, given the significant changes to the Part D program that will take effect in 2025. Commenters expressed concern that maintaining the existing risk corridor thresholds could increase uncertainty and instability in the Part D market and result in upward pressure on Part D premiums. Several of these commenters recommended that CMS use its demonstration authority under section 402 of the Act to narrow the risk corridors, stating that CMS previously proposed a comparable demonstration in 2019 for CY 2020 regarding a proposed rule modifying safe harbor protection under the Anti-Kickback Statute.

Response: CMS appreciates the concerns raised by the commenters. As noted in the CY 2025 Advance Notice, under section 1860D-15(e)(3)(C) of the Act and § 423.336(a)(2)(ii), CMS may establish a risk corridor with higher threshold risk percentages for Part D risk sharing. However,

the statute does not permit CMS to narrow the corridors relative to the CY 2011 thresholds. While CMS acknowledges commenters' suggestions to use demonstration authority under section 402 of the Act to narrow the risk corridors, we note that doing so is outside of the authority of these Final Program Instructions. Moreover, CMS does not believe that narrowing risk corridors would reduce or stabilize premiums any more than will already be accomplished by the premium stabilization provision in the IRA.

Comment: A few commenters expressed support for not widening the risk corridors.

Response: CMS thanks these commenters for their support.

Creditable Coverage (§ 423.56) (Section 90)

Comment: Commenters expressed concerns that the Part D benefit changes in the IRA will increase the actuarial value of the Part D benefit in 2025 to the point where group health plans—both active employee plans s and retiree plans that cover Part D eligible individuals—that have met Part D creditable coverage requirements in previous years may no longer meet those requirements. One commenter specifically referenced the $2,000 annual OOP threshold in CY 2025 that will decrease costs for Part D enrollees and increase costs for plans. Commenters noted that employers must balance the robustness of their benefit offerings with maintaining affordability. Some commenters warned that requiring group health plans to make substantial enhancements to their benefit offerings in order to maintain creditable coverage could cause significant disruption in the employer group market. Specifically, commenters were concerned about subjecting all group health plan enrollees (regardless of Medicare eligibility) to unaffordable premium increases resulting from such benefit changes. Commenters were also concerned about the potential for significant numbers of Medicare-eligible individuals losing creditable coverage if the group health plan forgoes such enhancements, resulting in these individuals needing to enroll in a Part D plan or risking future penalties when they enrollee in Part D later. One commenter suggested that CMS consider how to mitigate the impact of Part D redesign, particularly on Medicare-eligible, active employees covered by group health plans that do not receive the RDS. A few commenters stated that sponsors of group health plans have an immediate need for more detailed guidance in order to understand whether their plans will continue to meet creditable coverage requirements for CY 2025. All of these commenters opposed elimination of the creditable coverage simplified determination methodology. Several commenters noted that the simplified methodology provides a needed fallback option for group health plans that do not receive the retiree drug subsidy (RDS) at a time of significant changes to the Part D benefit that puts access to creditable coverage at risk for Part D eligible individuals who receive benefits through a group health plan.

Response: CMS thanks these commenters for their feedback and sharing their concerns about potential impacts of the Part D redesign on the group health plan market as a whole and on Part D eligible individuals who have had creditable coverage through a group health plan. We recognize that the changes to the Part D benefit under the redesign may require group health plans to make changes to their plan benefit offerings in order to continue to meet creditable coverage requirements and, depending on the decisions made by group health plan sponsors, may result in either some of these plans no longer meeting creditable coverage requirements or higher costs for group health plan sponsors and enrollees, regardless of Part D eligibility. We also appreciate commenters' feedback regarding the importance of the creditable coverage simplified determination for non-RDS plans, particularly their concerns about potential unintended adverse impacts on Part D eligible individuals who receive creditable coverage through such plans.

CMS recognizes that the sweeping changes the IRA makes to the Part D benefit, if coupled with the retirement of the creditable coverage simplified determination methodology, could pose various challenges for group health plan sponsors and could have an adverse effect on certain Part D eligible individuals who could lose creditable coverage and be at risk for the Part D LEP. Considering all of the comments received, and to mitigate potential disruptive effects of the Part D redesign on the group health plan market as well as on certain Part D eligible individuals, we have revised Section 90 of these Final Program Instructions to continue to permit use of the creditable coverage simplified determination methodology for CY 2025 for those sponsors not applying for the RDS. By permitting continued use of the creditable coverage simplified determination methodology for CY 2025, CMS also will have additional time to better assess the various impacts of the Part D redesign in CY 2025 and evaluate the modifications to the methodology that may be needed in future years to ensure that Part D eligible individuals with creditable coverage continue to have prescription drug coverage that is at least as good as DS Part D coverage. As such, we will re-evaluate the continued use of the existing simplified determination methodology, or establish a revised one, for CY 2026 in future guidance.

Comment: We received several comments requesting clarification on various aspects of calculating actuarial value to determine creditable coverage. Two commenters requested clarification about whether federal reinsurance in the catastrophic coverage phase is treated as part of the plan paid amount when determining actuarial value, noting that not including federal reinsurance in the plan payment can make a significant difference. The commenter also requested that CMS clarify whether actuarial value for a group health plan is determined by the member paid amount or by the plan paid amount. One commenter sought clarification about the meaning of "not taking into account the value" when determining the actuarial value of qualified retiree coverage.

Response: CMS thanks the commenters for their questions. The intent of Section 90 was to update the regulatory definition of creditable coverage to reflect the IRA's revisions to section 1860D-22(a)(2)(A) of the Act, and it does not make any changes to existing CMS policy related to the determination of actuarial value. "Not taking into account the value of any discount" provided under the Discount Program means that discounts paid by manufacturers are not included in the plan paid amount when making a determination about creditable coverage. The actuarial value is based on the plan paid amount, which does include the federal reinsurance subsidy in the catastrophic phase. We have revised the language in Section 90 to correct an error made in the Draft Program Instructions that incorrectly stated the federal reinsurance subsidy in the catastrophic phase is not included.

Comment: A few commenters recommended that CMS provide additional guidance addressing implications of the Discount Program on determining creditable coverage. Two commenters asked CMS to confirm that discounts paid by manufacturers should not be included as part of the plan payment when calculating actuarial value, with one noting they support this approach as it would not disadvantage commercial plans that do not receive manufacturer discounts and would result in more group health plans continuing to meet criteria for RDS and creditable coverage. A commenter requested clarification about whether the differential amounts paid by plan sponsors for claims subject to phase-in discounts for specified manufacturers and specified small manufacturers are included in the plan paid amounts, and another commenter requested more guidance on the impact of phase-ins on plan liability and creditable coverage.

Response: Section 90 of these Final Program Instructions revises the regulatory definition of creditable coverage to specify that the determination of actuarial value of payments by the plan does not take into account (that is, does not include) the value of discounts paid by manufacturers under the Discount Program, as required by section 1860D-22(a)(2)(A) of the Act. Section 90 also states that the differential amounts for applicable drugs subject to phase-ins that are paid by plan sponsors are included in the plan paid amount.

Comment: A commenter noted that group health plans are impacted by other laws that make it more difficult for them to meet creditable coverage requirements, including requirements under the Affordable Care Act, which contains a different set of requirements concerning annual cost sharing limitations, and the Medicare Secondary Payer statute, which prohibits a group health plan from providing an active employee that opts into Medicare with Medicare-covered benefits. The commenter also noted that group health plans seeking to meet Part D creditable coverage requirements often offer medical and prescription drug benefits through an integrated plan, and that any changes to benefits in attempting to meet creditable coverage requirements could be cost-prohibitive because the changes would need to be made for the entire population of the group.

Response: CMS appreciates this feedback and will take it into consideration for future guidance. As noted above, CMS has revised Section 90 of these Final Program Instructions to continue to permit use of the existing creditable coverage simplified determination methodology for CY 2025 and will re-evaluate the continued use of the existing or a revised simplified determination methodology for CY 2026 in future guidance.

Comment: Several commenters opposed elimination of the creditable coverage simplified determination methodology for CY 2025. Commenters noted that the need for a simplified methodology has not changed, that it is only used by non-RDS plans, and that it provides an efficient test for such plans to determine whether their coverage is creditable. One commenter stated that eliminating the simplified methodology leaves non-RDS plans with no clear methodology to test active health plan coverage. Some of the commenters opined that, without a simplified methodology, non-RDS plans would be required to make an annual actuarial determination regarding the expected amount of paid claims under their plan, which would represent a substantial new burden on these sponsors. One commenter noted that employers will have no choice but to determine the actuarial value of their prescription drug benefits using claims and demographic data of Part D eligible participants and may not have access to the necessary data. We received no comments supporting elimination of the simplified methodology.

Response: As noted in a preceding response, CMS has revised Section 90 of the Final Program Instructions to continue to permit use of the existing creditable coverage simplified determination methodology for CY 2025 and will re-evaluate the continued use of the existing or a revised simplified determination methodology for CY 2026 in future guidance.

Comment: Most of the commenters opposed to eliminating the simplified methodology recommended that CMS consider either retaining the current simplified methodology for CY 2025 or developing a revised simplified determination methodology or another alternative to actuarial attestation. One commenter suggested a methodology that considers creditable coverage to be met if a group health plan meets the mandated benefits under the Affordable Care Act, or a test that does not require sponsors of active employee plans to collect and use claims data where it does not have access to such data. One commenter urged CMS to consider limiting when the creditable coverage test must be applied. Another commenter proposed that CMS adjust the minimum percentage of prescription drug expenses that the plan must be expected to cover in the existing creditable coverage simplified determination methodology. A commenter asked if 60 percent would still be an allowable threshold for determining creditable coverage if CMS does not release a revised simplified methodology. Some commenters specifically requested that a revised simplified methodology be posted for public comment.

Response: While CMS did not refer to a revised or alternative simplified determination methodology, we thank commenters for sharing their ideas and will take them under

consideration for future guidance. As noted above, CMS has revised Section 90 of these Final Program Instructions to continue to permit use of the existing creditable coverage simplified determination methodology for CY 2025 and will re-evaluate the continued use of the existing or a revised simplified determination methodology for CY 2026 in future guidance.

Comment: A few commenters raised concerns that the combination of the Part D redesign and elimination of the creditable coverage simplified determination methodology would leave employers without sufficient time to plan for such significant cost changes or to redesign their benefits and enrollment systems for 2025. A commenter suggested that group health plan sponsors may not have sufficient time to notify plan participants about significant benefit changes, and that Part D eligible plan participants would have very little time to make important decisions about their coverage for 2025.

Response: CMS thanks the commenters for sharing this helpful information. As noted above, CMS has revised Section 90 of these Final Program Instructions to continue to permit use of the existing creditable coverage simplified determination methodology for CY 2025 and will re-evaluate the continued use of the existing or a revised simplified determination methodology for CY 2026 in future guidance.

Comment: One commenter stated that the IRA enhancements to the Part D benefit may disrupt Part D eligible individuals' access to high deductible health plans because it will be more difficult for such plans to meet the requirements for creditable coverage.

Response: We agree that it may be more difficult for high deductible health plans to qualify as creditable coverage. Sponsors of group health plans can address this by offering plan choices that do meet creditable coverage requirements. Requiring plans offering creditable coverage to provide coverage that is comparable to or better than standard Part D coverage is an important protection for Medicare-eligible individuals, who also have the option to enroll in a Part D plan. Under section 1860D-13(b) of the Act, Part D eligible individuals that choose not to enroll in Part D or a plan that provides creditable coverage may face a Part D late enrollment penalty (Part D LEP) later if they do enroll in Part D.

Comment: Several commenters asked about the Part D LEP or recommended that CMS waive the Part D LEP for Part D eligible individuals who lose creditable coverage in CY 2025. One commenter recommended that CMS not enforce the Part D LEP for Part D eligible individuals covered under an EGWP or other retiree drug coverage in CY 2025 to protect these individuals during the transition to the new Part D benefit structure. Another commenter suggested that Part D eligible individuals who had creditable coverage before CY 2025 be exempt from the Part D LEP if they do not have creditable coverage in CY 2025.

Response: CMS thanks these commenters for their feedback. We share the commenters' concerns about Part D eligible individuals who may face unintended consequences as a result of losing access to creditable coverage through their group health plan if the plan no longer meets creditable coverage criteria. However, the Act permits a Part D LEP waiver only under very limited circumstances: under section 1860D-13(b)(6)(C) of the Act if the individual subject to the penalty establishes that they were not adequately informed that the coverage was not creditable, and under section 1860D-13(b)(8) of the Act, if the individual is determined to be a subsidy eligible individual under section 1860D-14(a)(3) of the Act. CMS does not have authority to waive the Part D LEP merely because an individual subject to the penalty no longer has access to creditable coverage through a group health plan. While we appreciate that a combination of changes to the Part D benefit in CY 2025 and decisions that may be made by group health plans may present Part D eligible individuals with difficult choices, such individuals could avoid the Part D LEP by timely enrolling in a Part D plan. Under § 423.38, such an individual could enroll in a Part D plan during the annual election period (AEP), under the special election period for involuntary loss of creditable coverage, or under the special election period for individuals disenrolling from an employer or union group health plan.

Comment: One commenter recommended that CMS permit both Part D plans and other group health plans to request waivers to allow more flexibility in plan offerings. This commenter also requested additional guidance on what types of EGWP coverage would qualify as creditable coverage.

Response: We are not entirely certain what this commenter was recommending CMS permit plans to request waivers for, but note that all Part D plans are statutorily required to provide enrollees with qualified prescription drug coverage, and group health plans offering creditable coverage are required under section 1860D-13(b)(5) of the Act to provide coverage with an actuarial value that equals or exceeds the actuarial value of standard Part D coverage. Non-RDS group health plans have been permitted since the start of the Part D program in CY 2006 to use the simplified determination methodology in lieu of the actuarial attestation. As stated above and in section 90 of these Final Program Instructions, CMS will continue to permit such plans to use the existing simplified methodology for CY 2025. The purpose of requiring group health plans to demonstrate that they offer creditable coverage—that is, coverage that is as good as or better than standard Part D coverage—and to provide notice to Part D eligible plan enrollees about whether the coverage is creditable is to ensure that Medicare beneficiaries receive the same high quality coverage they would receive if enrolled in a Part D plan. While CMS understands the concerns commenters raised regarding the Part D redesign, it would be inappropriate for CMS to provide expansive opportunities for plans to provide substantively less comprehensive coverage than the law requires under Part D, particularly when such plans are being paid by CMS to provide coverage either as a Part D plan or a qualified retiree plan. Finally, we note that EGWPs are Part D plans and thus must meet the actuarial equivalence requirement.

Retiree Drug Subsidy Parameters/Requirements (Section 100)

No comments were received.

Impact of 2025 Part D Redesign Changes on the Capitated Payments to PACE Organizations (Section 110)

No comments were received.

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

Comment: Several commenters expressed support for the definition of an EA benefit design in the Draft Program Instructions.

Response: CMS thanks the commenters for their support.

Comment: A few commenters requested clarification on various aspects of the EA benefit design requirement, including:

1. Whether the addition of excluded drugs will be considered in the assessment of EA plan value,
2. Whether the Part D cost reductions offered through the VBID demonstration will be considered in this evaluation, and
3. Whether EGWPs will be evaluated for this requirement.

Response: Our responses to the questions commenters raised follow:

1. We clarify that the offering of excluded drugs remains an available option to Part D sponsors to enhance their benefit; however, utilization of excluded drugs is not included in the Part D Out-of-Pocket Costs (OOPC) model. CMS will continue to review EA plans' excluded drug submissions separately and consistent with our current approach.
2. We clarify that for VBID plans that offer Part D cost sharing reductions, the VBID component of the Part D benefit design is not evaluated as part of the Part D OOPC estimate and therefore will not be considered as part of our assessment of EA plan value. CMS' evaluation will be based on the submitted Part D benefit package not inclusive of the VBID submission. VBID supplemental benefits are only available to a subset of enrollees within a plan. Our evaluation aims to assess the value offered in the EA plan regardless of participation in the voluntary VBID program.
3. CMS will not be reviewing EGWPs for purposes of implementing this requirement. We confirm this is also true for PACE organizations.

Comment: One commenter asked whether the annual OOP threshold could be lowered below $2,000 for CY 2025.

Response: CMS confirms that the annual OOP threshold cannot be lowered below $2,000 for CY 2025. Section 1860D-2(b)(4)(B)(i)(VII) of the Act establishes that the annual OOP threshold for CY 2025 is equal to $2,000. Moreover, section 1860D-2(a)(2)(A)(i) of the Act does not include a reduction in the annual OOP threshold in its list of permissible supplemental benefits, and CMS has never interpreted such provision to allow for a reduction in the annual OOP threshold. Because the IRA established a defined annual OOP threshold of $2,000 for CY 2025 and did not modify the list of permissible supplemental benefits in section 1860D-2(a)(2)(A)(i) of the Act to include a reduction in the annual OOP threshold, such a reduction in the annual OOP threshold is not permitted for CY 2025.

Comment: One commenter requested additional clarification as to what should be entered into the new free-text field in the Rx section of the Plan Benefit Package (PBP) where sponsors are expected to describe features of their supplemental benefit.

Response: We clarify that the purpose of the new free-text field in the Rx section of the PBP in HPMS is for Part D sponsors offering EA benefit designs to describe the features of their supplemental benefit, such as lower cost sharing on a tier-by-tier basis, addition of drugs to the formulary, or placement of drugs on lower cost-sharing tiers that contribute to a meaningful enhancement.

Comment: One commenter requested that CMS provide plain language guidance to prospective enrollees regarding EA plans' enhanced value.

Response: CMS thanks the commenter for their recommendation. While CMS shares the goal of increasing transparency, the estimated OOPC values that will be evaluated for this requirement are based on the aggregated claims of a random sample of Part D enrollment and do not reflect an individual beneficiary's utilization or experience. We do not believe providing OOPC values would be helpful to a beneficiary in selecting the best plan for their unique needs. CMS strongly encourages Medicare enrollees to use the Medicare Plan Finder and other resources to choose the prescription drug plan that is the best fit for them.

Comment: A few commenters requested that CMS consider other factors in the definition of an EA plan, specifically beneficiary access, satisfaction, and convenience measures.

Response: We appreciate the commenters' suggestions but note that the recommendations did not provide enough detail for CMS to evaluate them in time for incorporation into our final

guidance for CY 2025. We also note that some of these factors, such as beneficiary access and patient experience of care, are captured in measures included in the Part C and D Star Ratings.

Comment: A few commenters requested CMS make the Part D OOPC model available to Part D sponsors earlier given the changes to the CY 2025 Part D benefit that sponsors will have to incorporate into their plan bids and benefit packages for CY 2025.

Response: We appreciate that sponsors would like to have the Part D OOPC model as early as possible for bid development. CMS intends to make the Part C and Part D OOPC models available in mid-April 2024 as we have in previous years. This timing allows for CMS to incorporate the March CY 2025 Part D Formulary Reference File available at the end of March, as well as the significant changes resulting from the redesigned Part D benefit for CY 2025, into the Part D OOPC model so that plans can accurately evaluate their Part D submissions.

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

Comment: The majority of commenters expressed support for implementing an absolute percent threshold for evaluating meaningful difference between a sponsor's PDP basic and EA plan offerings in a region for CY 2025, as opposed to conducting an outlier type of review as has been done in recent years. A few commenters, however, did not support setting an absolute threshold for CY 2025 and proposed alternatives to review meaningful difference. Of these, one commenter encouraged CMS to examine meaningful difference by looking at the number of drugs covered by an EA plan versus a basic plan. One commenter stated that there were shortcomings with the meaningful difference calculations due to insufficient accounting for differences in populations. One commenter was concerned that providing a threshold in advance would allow sponsors to ensure they meet the requirement by making their basic plan benefits less rich than they might have otherwise.

Response: CMS thanks the commenters for their feedback and for the overall support for implementing an absolute percent threshold percent for evaluating meaningful difference. In response to the comment that suggested formulary inclusion (i.e., number of drugs) alone be considered in our meaningful difference analysis, we point to the requirement at § 423.272(b)(3)(i) for CMS to consider benefit package and plan costs in determining meaningful difference. A simple count of formulary drugs does not consider benefit costs or utilization. While the Part D OOPC model does not account for plan-specific populations, CMS has made enhancements to the model, used for this bidding requirement since CY 2012, in recent years and is committed to improving the accuracy and timeliness of Part D OOPC estimates. CMS will continue to examine opportunities for enhancements to the Part D OOPC model to ensure it is an accurate and rigorous evaluation of plan value. While plans will be able to design both their basic and EA plans with advance knowledge of the absolute percent difference for meaningful

difference, basic plans must still meet all of the Part D formulary and benefit review requirements, including providing access to a wide range of medications at nondiscriminatory cost-sharing amounts.

Comment: A small number of commenters expressed concern with the 15 percent absolute percent threshold for CY 2025 in the Draft Program Instructions. These commenters stated that due to significant changes to the Part D benefit effective in CY 2025, CMS should reduce the percent threshold for CY 2025. A subset of these commenters further recommended that CMS reduce the 15 percent overall differential between PDP basic and EA plans to 12 percent (to be consistent with the differential achieved by all plans in the 2024 outlier review). One commenter recommended decreasing the threshold to between 8 percent and 10 percent.

Response: After considering commenters' feedback, we are finalizing the 15 percent threshold for CY 2025. While there are fewer options for Part D sponsors to enhance their benefits under the IRA's Part D redesign provisions, CMS believes that EA plans will be able to both ensure added value and meet the meaningful difference OOPC threshold of 15 percent due to changes to the Part D benefit that require supplemental benefits provided under EA plans count towards TrOOP in CY 2025. These changes will be accounted for in the CY 2025 Part D OOPC model.

Comment: We received a few comments regarding the sub-analysis we described in the Draft Program Instructions that CMS will use to determine the proportion of meaningful difference that is attributed to formulary robustness as opposed to benefit design/tier placement for an EA plan. One commenter requested that CMS confirm that the sub-analysis will be an outlier analysis. One commenter suggested that CMS require the plans meet only one of the two thresholds: 1) a total OOPC threshold, or 2) a lower, benefit-only threshold.

Response: CMS confirms that we will not use an outlier approach for this sub-analysis and that we will proceed with the meaningful difference requirements as outlined in Section 130 of this document. For CY 2025, we are not setting thresholds for these sub-analysis parameters; however, sponsors will receive a review concern during the CY 2025 Part D benefit review period if either the share of meaningful difference attributed to formulary robustness or benefit design/tier placement (refer to the description of these calculations in Section 130 of this document) is worse than their respective values for the basic plan offered by the sponsor in the same region.

Comment: Some commenters interpreted our statement in the Draft Program Instructions that the addition of drugs to plan formularies alone does not provide for a richer benefit as disincentivizing plans from adding high cost, low utilization drugs for treating rare diseases.

Response: CMS did not intend by this statement to disincentivize plans from adding high cost, low utilization drugs to their formularies for treating rare diseases. We clarify that the statement to which the commenters refer was intended to describe CMS' experience of having sponsors request to add drugs to their formulary as an enhancement only after CMS identified a review concern for the meaningful difference requirement, in order to resolve that review concern. In our longstanding experience, we have found that drugs added in this scenario are often no longer clinically relevant. For example, a sponsor might add a drug to address meaningful difference review concerns that at one time was considered a first line therapy for a disease, but where more recent guidelines now recommend newer agents. Such a drug is unlikely to be utilized due to the updated recommendations in treatment guidelines, even though the addition of the drug technically resolves the meaningful difference review concern. CMS does not consider the addition of this drug to be an enhancement, as beneficiaries motivated by the addition of this drug are likely unaware of the updated treatment guidelines. Again, our intent was not to discourage plans from adding Part D drugs to their formularies to address meaningful difference review concerns; rather, our intent was to clarify that our methodology will not rely on formulary robustness alone to achieve a meaningful difference value.

Comment: A few commenters requested CMS make the Part D OOPC model available to Part D sponsors earlier given the changes to the CY 2025 Part D benefit that sponsors will have to incorporate into their plan bids and benefit packages for CY 2025.

Response: We appreciate that sponsors would like to have the Part D OOPC model as early as possible for bid development. CMS intends to make the Part C and Part D OOPC models available in mid-April 2024, as we have in previous years. This timing allows for CMS to incorporate the March CY 2025 Part D Formulary Reference File, available at the end of March, as well as the significant changes resulting from the redesigned Part D benefit for CY 2025, into the Part D OOPC model so that plans can accurately evaluate their Part D submissions.

Non-Calendar Year (NCY) EGWPs (Section 140)

Comment: A commenter asked us to confirm whether a NCY EGWP that administers TrOOP on a calendar year basis, and other benefit parameters such as premiums and cost-sharing on a NCY basis, would apply TrOOP accumulations from the 2024 plan year to set the member's benefit phase as of January 1, 2025.

Response: If an EGWP is administering TrOOP and its accumulation on a calendar year basis for the entire 12 months of 2024, then no 2024 TrOOP accumulation can apply for 2025. Rather, the TrOOP accumulator would reset on January 1, 2025. This is the case even if an EGWP is otherwise administering benefits such as premiums and cost-sharing on a NCY basis.

Comment: A commenter asked that we discontinue NCY benefit plans due to the complexities of administration and the need for CMS to develop guidelines and processing capabilities. Another commenter expressed that existing EGWP guidance is difficult to identify and track and urged the agency to reissue complete guidance at regular intervals, with highlights and citations to identify the source of updates.

Response: We appreciate that EGWPs—and especially NCY EGWPs—present levels of complexity in their administration. However, we decline to discontinue NCY EGWPs. CMS does not require Part D sponsors to offer NCY EGWPs. Rather, because statutes or union contracts may mandate NCY plan years, we previously issued a waiver to permit NCY EGWPs. This way, employers that are only permitted to provide retiree coverage on a NCY basis have the option to offer Medicare EGWP coverage to their retirees. We will take under consideration the recommendation to consolidate and update all EGWP guidance; however, note that guidance affecting EGWPs, as is the case for all MA, MA-PD, or PDP plans, encompasses diverse subject matter areas ranging from benefits (both MA and Part D) to payment, to enrollment, and to appeals.

Comment: A couple of commenters asked for detailed PDE and other examples for NCY EGWP plans. One commenter asked for examples in which an enrollee's TrOOP is met or not met from a previous year (which we take to refer to whether or not the TrOOP balance carried over from the 2024 portion of the plan year is equal to or greater than the $2,000 catastrophic threshold set for 2025 by section 11201 of the IRA) and reversal from the previous year (which we take to refer to when retroactive changes are made to PDE records from the 2024 portion of the plan year that affect TrOOP accumulation carried forward into the 2025 portion of the plan year). The commenter asked if there were any changes or special considerations regarding the Total Gross Covered Drug Cost (TGCDC) Accumulator that need to be made for NCY EGWPs. Another commenter asked how the transition between calendar years should be reflected on an enrollee's Explanation of Benefits (EOB).

Response: Please refer to the CY 2025 PDE guidance when it is released. Regarding reversals and the TGCDC accumulator, we note that there are no changes from prior guidance as a result of the IRA. Part D sponsors with questions about NCY EGWPs and the IRA should send detailed descriptions of the facts and specific issues to the following mailbox: PartDPaymentPolicy@cms.hhs.gov.

The first EOB issued for a 2025 claim will need to reflect the reset parameters of the 2025 benefit and where a given enrollee is within the benefit. For instance, $3,000 TrOOP spending accumulated during the 2024 portion of the plan year that begins in mid-2024 would reset to $2,000 on January 1, 2025, while $1,200 TrOOP spending from the 2024 portion of the plan year

would carry over to 2025 as is. After that, EOB reporting would build upon the 2025 parameters until the end of the plan year.

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

Comment: Several commenters supported the continuation of BA plans with lower deductibles beyond 2025. Several commenters stated that BA plans with lower deductibles are an important option available to beneficiaries. A commenter stated that by maintaining BA plans, plan sponsors and beneficiaries will maintain choice regarding plans design. Another commenter stated that it would be premature to eliminate BA plans with lower deductibles until there is actual program experience with BA plans offering lower deductibles.

Response: CMS appreciates the commenters' thoughtful input. CMS will continue to allow for BA plans with lower deductibles in CY 2025 and will take commenters' recommendations into consideration when CMS considers whether to continue allowing such plans in future years.

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

Comment: A commenter expressed support for CMS' policy on excluding discount program payments under the Discount Program and IRASA from the MLR calculation.

Response: CMS thanks the commenter for their support.

Out of Scope Comments

We received several comments related to Part D formulary design, utilization management and monitoring, the formulary exception process, including access metrics in the assessment of meaningful difference, accessibility of treatments (including many that are covered by other parts of the Medicare program, as opposed to Part D), the Discount Program,[15] PDE guidance for CY 2025, the Medicare Prescription Payment Plan,[16] the Medicare Drug Price Negotiation Program,[17] the timeline for IRA-related changes, standard calculation of risk corridor payments,[18] rebate reallocation, and medications not covered by insurers. While we appreciate this feedback, these comments are outside the scope of this guidance and are not addressed in this memorandum.

[15] Refer to CMS' Manufacturer Discount Program guidance for questions on this topic.

[16] Refer to CMS' Medicare Prescription Payment Plan guidance for questions on this topic.

[17] Refer to CMS' Medicare Drug Price Negotiation Program guidance for questions on this topic.

[18] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates for questions on this topic.

D. Final CY 2025 Part D Redesign Program Instructions

Table of Contents

10. Introduction

The purpose of these Final CY 2025 Part D Redesign Program Instructions is to provide interested parties with final guidance regarding the implementation of section 11201 of the IRA, which made several amendments and additions to the Act that affect the structure of the DS Part D drug benefit.

These Final 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 IRASA established by section 11406(c) of the IRA.[19] These Final Program Instructions are being published concurrently with the Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, which announces updates to Part D parameters. Some of those updates are impacted by provisions discussed in this document.[20]

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, CMS is issuing these Final 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.[21] Changes specific to CY 2024 are discussed in the CY 2024 Advance Notice and Rate Announcement.[22] For detailed guidance on the Discount Program, see the Medicare Part D Manufacturer Discount Program Final Guidance and the Medicare Part D Manufacturer Discount

[19] These Final 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) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. Refer CMS' Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments and Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments Memorandums.

[20] Refer to CMS' Announcement of Calendar Year (CY) 2025 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

[21] Refer to CMS' Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin Memorandum.

[22] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers.[23, 24]

CMS voluntarily solicited comment on the Draft Program Instructions in February 2024, and took the comments we received into consideration when preparing these Final Program Instructions. We stated in the Draft Program Instructions that CMS may change any policies in these Final Program Instructions, including policies on which CMS did not expressly solicit comment, based on the agency's further consideration of the relevant issues. Policies established in these Final Program Instructions for CY 2025 are subject to change in subsequent years.

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

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 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 OOP 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

[23] Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance and Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers memorandums.

[24] 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.

- 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:[25]

- **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, with the plan covering the remainder. This phase ends when total drug spending reaches the initial coverage limit.
- **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 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 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. As the coverage gap phase will be eliminated, the CGDP sunsets as of January 1, 2025 (see further explanation below). Under section 1860D-

[25] Refer to CMS' Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

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[26] 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.[27] 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.[28]

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

[26] 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.

[27] 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).

[28] Starting in 2026, CMS will also provide 40 percent reinsurance 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).

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.

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.[29] 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.[30]

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, plan reductions in cost sharing for enrolled beneficiaries, such as reductions by Medicare-Medicaid Plans and D-SNPs, and CMMI model benefits that reimburse costs for covered Part D drugs (unless stated otherwise in a Request for Applications).

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

[29] Refer to CMS' Medicare Prescription Drug Benefit Manual – Chapter 5, Section 30.

[30] See section 1860D-2(b)(4)(C)(iii) of the Act.

negative values will be disregarded (i.e., be treated as zero) when calculating TrOOP because they do not represent reimbursement to the beneficiary.

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.[31]

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

[31] 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.[32] 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.[33]

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 were 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.

For example, an EA plan has a tiered formulary, does not charge a deductible for tier 1 drugs, and charges 20 percent coinsurance for drugs in that tier. A beneficiary's first fill of the year is

[32] Refer to CMS' 2010 HPMS Memos Qtr 1-4.

[33] 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 OOP threshold.

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 $390 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 percent 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).[34] 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 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-

[34] 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.

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.[35, 36] 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 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).[37]

Under section 1860D-15(b)(2) of the Act, CMS' 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.[38] Each year, sponsors report their DIR to CMS as part of the annual DIR

[35] 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.

[36] 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. Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance.

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

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.[39] 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.
- 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 PDE records).
- Sum incurred reinsurance costs for non-applicable drugs at the plan level.

[38] 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.

[39] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates.

- 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 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 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.[40]

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.

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.

[40] Refer to CMS' Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.

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.[41] 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 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,[42] the risk corridor methodology allows for 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.

[41] 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.

[42] Refer to CMS' Advance Notice of Methodological Changes for Calendar Year (CY) 2006 Medicare Advantage (MA) Payment Rates.

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. Under section 1860D-13(b) of the Act, Medicare beneficiaries may incur a Part D late enrollment penalty (Part D 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 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.[43] 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.

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

Since the start of the Part D program in 2006, an entity offering a group health plan that is not applying for the RDS under section 1860D-22(a) of the Act has been permitted to use the creditable coverage simplified determination methodology,[44] which CMS most recently released as part of the "Updated Creditable Coverage Guidance" on September 18, 2009, to determine whether its prescription drug coverage is creditable. In the Draft Program Instructions, CMS stated that as of CY 2025 the simplified determination methodology will no longer be a valid methodology to determine whether such an entity's prescription drug coverage is creditable or not, given the significant changes that the IRA made to the Part D benefit.

As discussed in more detail in Section C of this document, CMS received several comments raising concerns about unintended consequences of the Part D redesign on group health plans and Part D eligible individuals who have creditable coverage through such plans, including significantly higher premiums for all plan enrollees, and potential risk that a large number of Part D eligible individuals may no longer have creditable coverage through their employee or retiree plan, which ultimately could put such individuals at risk for the Part D LEP. Commenters also stated that if the existing simplified determination methodology were no longer available, group health plan sponsors would not have sufficient time to consider the impact of the Part D benefit changes to make decisions about their own benefit offerings in time for CY 2025 coverage.

As noted in our responses to these comments, CMS recognizes that the IRA makes sweeping changes to the Part D benefit in CY 2025, which, if coupled with the retirement of the creditable

[43] Refer to CMS' Section 50.1 of the Medicare Part D Manufacturer Discount Program Final Guidance.

[44] Refer to CMS' Creditable Coverage Simplified Determination.

coverage simplified determination methodology, could pose various challenges for group health plan sponsors and could have an adverse effect on certain Part D eligible individuals who could lose creditable coverage and be at risk for the Part D LEP. After consideration of the comments received and available options, to mitigate potential disruptive effects of the Part D redesign on the group health plan market and the Part D eligible individuals served by such group health plans, CMS will continue to permit use of the creditable coverage simplified determination methodology, without modification to the existing parameters, for CY 2025 for group health plan[45] sponsors not applying for the RDS. By permitting continued use of the creditable coverage simplified determination methodology for CY 2025, CMS also will have additional time to better assess the various impacts of the Part D redesign in CY 2025 and evaluate modifications to this methodology that may be needed in future years to ensure Part D eligible individuals with creditable coverage continue to have prescription drug coverage that is at least as good as DS Part D coverage. As such, we will re-evaluate the continued use of the existing simplified determination methodology, or establish a revised one, for CY 2026 in future guidance.

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[46] 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

[45] "Group health plan" as used in this Section refers to a group health plan described at § 423.56(b)(3). It does not include EGWPs, which are Part D plans, and, as such, cannot use the creditable coverage simplified determination methodology.

[46] As defined in § 423.882, qualified retiree prescription drug plan means employment-based retiree health coverage that meets the requirements set forth in § 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.

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 (i.e., in the catastrophic phase of coverage) in CY 2025.
- The CGDP sunsets as of 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.[47] 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.[48]

[47] See footnote 19.

[48] See footnote 2.

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 cost sharing. As a result, in 2025, PACE organizations, unlike typical Part D plans, will be responsible for paying 100 percent 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 percent 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

Section 1860D-2(b)(4)(B)(i)(VII) of the Act establishes that the annual OOP threshold for CY 2025 is equal to $2,000. Moreover, section 1860D-2(a)(2)(A)(i) of the Act does not include a reduction in the annual OOP threshold in its list of permissible supplemental benefits, and CMS has never interpreted such provision to allow for a reduction in the annual OOP threshold.

Because the IRA established a defined annual OOP threshold of $2,000 for CY 2025 and did not modify the list of permissible supplemental benefits in section 1860D-2(a)(2)(A)(i) of the Act to include a reduction in the annual OOP threshold, Part D sponsors may not lower the annual OOP threshold below $2,000 for CY 2025. Additionally, the IRA eliminates cost-sharing in the catastrophic phase beginning in 2024, eliminates the coverage gap phase and replaces the CGDP with the Discount Program beginning in 2025. Thus, 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 that Part D sponsors have to further enhance 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.

For CY 2025, CMS will evaluate the *value* (emphasis added) of EA plan designs. 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 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 out-of-pocket costs (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. We note that the OOPC model does not include the excluded drug benefit in the OOPC estimate values, but CMS will continue to perform separate reviews of individual drugs offered under excluded drug coverage, such as comparing drug prices to the cost sharing submitted, and working 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, this value is used to evaluate meaningful differences

between standalone PDPs during annual bid reviews. CMS will not be reviewing PACE organizations or EGWPs for purposes of implementing this requirement. Among other variables, the Part D OOPC model utilizes the benefit parameters available in the Rx section of the PBP, which is not submitted by Part D sponsors offering PACE organizations or EGWPs. We also note that the VBID component of the Part D benefit design is not evaluated as part of the Part D OOPC estimate and therefore will not be considered as part of our assessment of EA plan value. CMS' evaluation will be based on the submitted Part D benefit package not inclusive of the VBID submission. VBID supplemental benefits are only available to a subset of enrollees within a plan. Our evaluation aims to assess the value offered in the EA plan regardless of participation in the voluntary VBID program.

For the purpose of evaluating EA plan value for all Part D sponsors, as illustrated in Table 120, 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 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. Part D sponsors should use the free-text field in the Rx section of the PBP in HPMS to describe the features of their supplemental benefit, such as lower cost sharing

on a tier-by-tier basis, addition of drugs to the formulary, or placement of drugs on lower cost-sharing tiers that contribute to a meaningful enhancement.

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. As a result of these changes to the benefit, CMS is adopting a new approach to defining meaningful difference between an EA plan and a basic plan for standalone PDPs for CY 2025 in these Final Program Instructions.

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.[49] 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

[49] 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).

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 percent 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.[50] 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,"[51] 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.

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).

[50] Refer to HHS' November 19, 2021, HPMS memorandum: Enhanced Out-of-Pocket Cost Model Update.

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

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 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 responding to CMS meaningful difference review concerns, we often find that sponsors respond by simply adding drugs to their formularies, particularly those that are high cost but with low utilization, rather than improving on the benefit. Our intent is not to discourage plans from adding Part D drugs to their formularies and, while plans will receive credit in the OOPC model for adding drugs to their formulary, our methodology will not rely on formulary robustness alone to achieve a meaningful difference value. To address this issue, our sub-analysis will allow CMS to differentiate between the two metrics of formulary robustness and benefit design/tier placement. To assess these two metrics, 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

Value	Source	Description	Calculation	CY 2025 Requirement	Example
[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
[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 (NCY) 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[52] 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 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.

[52] Refer to Prescription Drug Benefit Manual Chapter 12, Section 20.13.

- 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 depending on their TrOOP balance as of January 1, 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 CGDP to 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 of the Act, 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[53] for more information.

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 OOP 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 Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments, published February 29, 2024, and Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments, published February 15, 2024.[54]

[53] Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance.

[54] Refer to CMS' Medicare Prescription Payment Plan guidance documents, fact sheets, and timeline.

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 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. CMS will continue to allow BA plans with lower deductibles in CY 2025 and will consider whether to continue to allow such plans in future years.

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.[55]

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.[56]

- 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

[55] 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).

[56] Refer to CMS' Medicare Part D Manufacturer Discount Program Final Guidance.

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)).

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 is included in the Medicare Prescription Payment Plan draft part two guidance.

170. Specialty Tier Cost Share Thresholds

Annually CMS sets the maximum allowable cost sharing for the specialty tier based on the plan's deductible, in accordance with § 423.104(d)(2)(iv)(D). The intent of this policy is to ensure a plan's value is reflective of the DS benefit. The regulation limits a plan with the full DS deductible to a 25 percent coinsurance on its specialty tier but allows a plan that fully eliminates the deductible up to a 33 percent coinsurance. Based on the pre-IRA benefit design, CMS determined that the 33 percent maximum coinsurance was mathematically equivalent to the effective coinsurance for a beneficiary who would have paid the DS deductible for any given year plus the 25 percent coinsurance in the initial coverage phase until their drug costs reached the initial coverage limit. In other words, prior to CY 2025, beneficiary OOP costs divided by total drug costs equaled a 33 percent effective coinsurance for the beneficiary regardless of the plan deductible, represented by the following equation:

$$\frac{(Beneficiary\ OOP\ \cos t\ s)}{(Total\ drug\ \cos t\ s)} = Effective\ coinsurance$$

To operationalize the concept of maximum allowable cost sharing for the specialty tier based on the plan's deductible, CMS codified the following calculation at § 423.104(d)(2)(iv)(D)(3) to

determine the deductible range that corresponded to each incremental specialty tier coinsurance percentage point from 25 percent through 33 percent. Thus, under the pre-IRA Part D benefit design, CMS used this equation for the calculation:

$$\frac{Deductible + Coinsurance\ (ICL - Deductible)}{ICL} = 33\%$$

Consistent with the first equation, the numerator here represents beneficiary OOP costs while the denominator represents total drug costs, resulting in an effective coinsurance of 33 percent, to align with the DS benefit. This equation was then solved for the deductible, and each incremental specialty tier coinsurance percentage was inserted, to calculate the maximum allowable deductible value corresponding to that coinsurance percentage.

Following the publication of the Draft Program Instructions, it came to CMS' attention that the methodology codified at § 423.104(d)(2)(iv)(D)(3) will no longer be valid when the ICL is eliminated. As such, CMS must establish a new methodology to determine the specialty tier coinsurance/deductible ranges to represent the effective coinsurance for a beneficiary under the redesigned Part D benefit.

To ensure that a plan's value is reflective of the DS benefit, CMS is adopting for CY 2025 a similar methodology used to calculate the cost-sharing requirements in § 423.104(d)(2)(iv)(D) in these Final Program Instructions. For Part D plans with the full deductible provided under the DS benefit, the coinsurance is 25 percent, consistent with the DS benefit. Using the CY 2025 DS benefit parameters of a $590 deductible, a $2,000 annual OOP threshold, and a 25 percent coinsurance after the deducible is met and before the annual OOP threshold is reached, the total drug costs can be calculated at $6,230. This results in an effective coinsurance of 32.1 percent. To better facilitate implementation of the IRA Part D benefit redesign for CY 2025 while continuing to ensure that coinsurance for the specialty tier remains in alignment with cost sharing under the DS benefit, CMS is retaining the 33 percent maximum coinsurance currently effective at § 423.104(d)(2)(iv)(D)(2).

As in previous years, CMS will use an effective coinsurance equation to calculate the deductible that corresponds to each incremental specialty tier coinsurance percentage from 25 percent through 33 percent. Consistent with CMS' decision to retain the 33 percent maximum coinsurance, CMS is also using 33 percent to calculate the deductible that corresponds to each incremental specialty tier coinsurance percentage. This equation will continue to represent beneficiary OOP costs in the numerator divided by total drug costs in the denominator. The following equation illustrates how CMS will calculate the effective coinsurance for the CY 2025 Part D benefit for purposes of calculating specialty tier cost-sharing percentages:

$$\frac{(OOP\ Threshold)}{\left(\frac{(OOP\ Threshold\ -\ Deductible)}{Maximum\ allowable\ specialty\ tier\ coinsurance} +\ Deductible\right)} = 33\%$$

As with the previous methodology, the equation is solved for the deductible, and each maximum allowable specialty tier coinsurance value is inserted, to determine the maximum allowable deductible value corresponding to that coinsurance. The results of the methodology for CY 2025 are shown in Table 170.

Table 170. CY 2025 Specialty Tier Coinsurance Thresholds

Deductible Range	Maximum Allowable Specialty Tier Coinsurance
$573.31 to $590	25%
$498.14 to $573.30	26%
$420.89 to $498.13	27%
$341.45 to $420.88	28%
$259.75 to $341.44	29%
$175.68 to $259.74	30%
$89.14 to $175.67	31%
$0.01 to $89.13	32%
$0	33%

For CY 2025, sponsors may not charge a coinsurance for their specialty tier(s) that exceeds the thresholds established in Table 170 for the applicable deductible range in their approved PBP.

180. 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[57]</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>

[57] 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 the 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.