# From Coverage Gap to Member Cap: Understanding the New Landscape of Medicare Part D Manufacturer Discounts

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## Introduction

On November 17, 2023, the Centers for Medicare & Medicaid Services (CMS) released final program guidance to pharmaceutical manufacturers and Part D plan sponsors for implementing the Medicare Part D Manufacturer Discount Program (Discount Program or MDP)[1] for 2025 and 2026. This program, which was enacted as part of H.R. 5376 (commonly referred to as the Inflation Reduction Act or IRA), contains several key changes to Part D financing and operations starting in 2025. This paper summarizes the key provisions of the MDP final guidance and other subsequent guidance, including a summary of programmatic differences and similarities to the previous Coverage Gap Discount Program (CGDP), an analysis of the impact of a phase-in of manufacturer discounts, and its potential implications to various stakeholders.

*The Manufacturer Discount Program has several changes from the current Coverage Gap Discount Program, with financial and operational implications for plan sponsors, manufacturers, and other stakeholders.*

### Background

Starting on January 1, 2025, the MDP will replace the existing CGDP. The CGDP, which has been in place since 2011, provides a 70% discount off the negotiated price to members not eligible for the low-income subsidy (LIS) for certain "applicable" drugs (mostly brand and biological products). This discount is provided to members at the point of sale (POS) by the plan sponsor and is later reconciled so that the ultimate discount liability falls on drug manufacturers.

Under the IRA, several significant changes will be made to the current Part D benefit design. These changes, which were outlined in more detail in October 2022[2] and February 2024[3] Wakely white papers, include cost sharing reductions for vaccines and insulins, an expansion of LIS eligibility, a new $2,000

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

[2] https://www.wakely.com/sites/default/files/files/content/inflation-reduction-act-review-summary.pdf

[3] https://www.wakely.com/sites/default/files/files/content/summary-draft-cy2025-part-d-redesign-program-instructions.pdf

maximum member out-of-pocket cost (MOOP), an overall shift in the distribution of claim liabilities among stakeholders, and the removal of the gap coverage phase. Therefore, starting in 2025, the four phases of the standard Part D benefit design will be reduced to three: the Deductible phase, the Initial Coverage phase, and the Catastrophic phase. Under the MDP, manufacturer discounts are available for applicable drugs in both the Initial Coverage and Catastrophic phases, as outlined in more detail below.

## Drug Classifications Under the MDP

Under the MDP, there are three categories defined for all Part D drugs. These mutually exclusive categories determine whether a drug is eligible for a discount under the MDP and the conditions under which the drugs can be covered under Part D.

- **Applicable drugs**, which are primarily brand drugs and biological products, are defined by CMS as drugs that are 1) approved under a new drug application under section 505(c) of the Federal Food Drug, and Cosmetic Act (FDCA) or licensed under section 351 of the Public Health Service Act, and 2) available on the formulary or as a benefit on the PDP/MA-PD for the enrollee.
- **Selected drugs** are drugs that are selected for price negotiation during a price applicability period[4]. CMS has published an initial list of ten drugs which will be subject to price negotiation, with prices taking effect in 2026[5]. Therefore, this drug category is not applicable for the 2025 plan year. Additional drugs will be added to this list in future years.
- **Non-applicable drugs** include all other Part D eligible drugs that are not applicable and not selected.

Under CGDP, only definitions for applicable and non-applicable drugs existed. Drugs included in the selected category for MDP could be in either applicable or non-applicable categories under the CGDP.

The policies regarding Part D coverage under the MDP are similar to the policies under the CGDP. For selected and applicable drugs to be covered under Part D, the manufacturers of those drugs must sign an MDP agreement with CMS.

## Eligibility for Manufacturer Discounts

In general, discounts will be available under the MDP when all the following conditions are met:

✓ The drug is an applicable drug covered under Part D with a manufacturer that has an MDP agreement in place.

Selected and non-applicable drugs do not qualify for an MDP discount from manufacturers. However, selected drugs will qualify for a 10% drug subsidy from CMS in the initial coverage phase and a 20% drug subsidy from CMS in the catastrophic phase

[4] As defined in section 1191(b)(2) of the Social Security Act

[5] https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf

(in addition to the current 20% CMS federal reinsurance) starting in 2026. Therefore, CMS will be responsible for the MDP payments that manufacturers would otherwise pay for selected drugs if they were applicable drugs[6]. Medicare as Secondary Payer (MSP) and subrogation claims are excluded from the Discount Program.

✓ The drug is dispensed to an applicable beneficiary[7]. Discounts are available to both Low Income (LI) and Non-Low Income (NLI) members covered under Part D.

a. **Note:** Under the CGDP, only NLI members' claims are eligible for discounts.

✓ The claim occurs after a Part D enrollee has incurred costs exceeding the Defined Standard deductible (which is $590 for 2025). This rule applies regardless of whether the enrollee must pay a deductible under their plan benefits (e.g., through LIS, enhanced benefits/reduced deductibles, or drugs not subject to the deductible such as insulins or vaccines).

b. **Note:** Discounts under the CGDP occurred once an enrollee's allowed costs exceeded the Initial Coverage Limit (ICL) threshold, which is $5,030 for 2024.

## Calculation and Phase-In of Discounts

If the criteria above are met, discounts will apply to applicable drugs as detailed in the table below, with an exception that is also outlined below. Discounts under the MDP are applied to the total negotiated price[8] of the drug, including the dispensing fee, based on current CMS definitions. Discounts under the CGDP were applied to the negotiated price of the drug excluding dispensing fees.

**Table 1 – General Application of Manufacturer Discounts for Applicable Drugs**

| Discount Program | Deductible Phase | Initial Coverage Phase | Coverage Gap Phase | Catastrophic Phase |
|---|---|---|---|---|
| Coverage Gap Discount Program | 0% | 0% | 70% | 0% |
| Manufacturer Discount Program | 0% | 10% | N/A – phase eliminated | 20% |

While the discount amounts shown are lower (10% vs. 70%) for claims that would have otherwise been in the coverage gap under pre-IRA rules, manufacturers now have uncapped liability in the catastrophic phase, which may lead to increased manufacturer liability for high-cost members, all else equal.

[6] https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.

[7] "Applicable beneficiary" is defined in MDP guidance as an individual who, on the date of dispensing a Part D drug, 1) is enrolled in a PDP or MA-PD plan, 2) is not enrolled in a qualified retiree prescription drug plan and 3) has incurred costs exceeding the Defined Standard deductible.

[8] The negotiated price includes the ingredient cost plus any dispensing fee, vaccine administration fee, sales tax, and POS price concessions from network pharmacies.

The final MDP guidance, along with the Final CY 2025 Part D Redesign Program Instructions[9] contain the following additional details about the calculation and adjudication of MDP payments. Please see the February 2024 Wakely white paper[10] summarizing the Draft CY 2025 Part D Redesign Program instructions for additional details.

1. An enrollee will pay the lesser of the discounted price and the cost sharing as specified under the plan.

2. The discounts under the MDP will be applied before the application of any supplemental Part D benefits and before the application of any other health insurance coverage. This is a notable difference from the current rules under the CGDP, in which discounts are applied after any supplemental benefits. Therefore, plan sponsors are no longer implicitly penalized for offering enhanced benefits under the MDP.

3. When determining an enrollee's coverage phase for a given claim, manufacturer discounts under the MDP will not count towards an enrollee's MOOP ($2,000 for 2025) to enter the catastrophic phase. This contrasts with the rules under the CGDP, in which both member out-of-pocket costs and manufacturer discounts counted towards an enrollee's TrOOP threshold in reaching the catastrophic phase.

4. In the case of an Enhanced Alternative (EA) plan with a deductible lower than the Defined Standard (DS), if the member has met the plan deductible but has not yet met the DS deductible, the plan sponsor will be responsible for paying MDP discounts that otherwise would have been paid by the manufacturer.

Furthermore, CMS has noted that further guidance will be forthcoming regarding the calculation of the selected drug subsidy. As noted above, this amount is 10% for selected drugs in the initial coverage phase, payable from CMS. Selected drugs are not eligible for manufacturer discounts under the MDP.

### Exception: Phase-In of Applicable Discounts

In the final guidance, CMS defined two manufacturer and beneficiary types in which lower, phased-in discounts will be applied for future years. These lower discounts will be phased out each year, with all manufacturers being required to provide the full 10%/20% discount in 2031 and beyond. The criteria for reduced discount eligibility are outlined in Table 2 below. As the table shows, the "specified manufacturer" type will only apply to LI members, while the "specified small manufacturer" type will apply to all applicable members. Under both scenarios, the applicable drug must have been marketed as of August 16, 2022, to qualify for the phase-in.

[9] https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf
[10] https://www.wakely.com/sites/default/files/files/content/summary-draft-cy2025-part-d-redesign-program-instructions.pdf

**Table 2 – Phase-In of Applicable Discounts for Specified Manufacturers and Specified Small Manufacturers**

| Manufacturer Type | Eligible Population for Phased-In Discounts | Manufacturer Eligibility Criteria |
|---|---|---|
| Specified manufacturers | Low Income (LI) members | The manufacturer had:<br>1. A CGDP agreement in place in 2021,<br>2. Total expenditures for its CGDP applicable Part D drugs less than 1% of total expenditures for all Part D drugs in 2021, and<br>3. Total expenditures for its specified Part B single-source and biological products less than 1% of total expenditures for all Part B drugs and biological products in 2021. |
| Specified small manufacturers | All applicable members | The manufacturer:<br>1. Qualifies as a "specified manufacturer" based on the criteria above, and<br>2. Had total expenditures for any one of its specified small manufacturer drugs covered under the Part D CGDP in 2021 greater than or equal to 80% of total expenditures for all of its specified small manufacturer drugs covered under Part D in 2021. |

If either criterion outlined in Table 2 are met for a given manufacturer, that manufacturer's applicable drugs will qualify for phased-in discounts as outlined in Table 3 below. Plan sponsors will be responsible for the difference in discount between the general discount amount and the phased-in discount amount. For example, for 2025, plan sponsors are responsible for an additional 9% (10% - 1%) in the initial coverage phase and 19% (20% - 1%) in the catastrophic coverage phase for drugs eligible for the MDP discount phase-in.

**Table 3 – Applicable Phase-In Discount Amounts by Year**

| Coverage Phase | 2025 | 2026 | 2027 | 2028 | 2029 | 2030 | 2031+ |
|---|---|---|---|---|---|---|---|
| Initial coverage | 1% | 2% | 5% | 8% | 10% | 10% | 10% |
| Catastrophic | 1% | 2% | 5% | 8% | 10% | 15% | 20% |

CMS has published additional detail outlining the calculation methodology and data that will be used to identify manufacturers eligible for the phase-in scenarios[11]. Based on this methodology, CMS has published a list of all labeler codes that will participate in the MDP program beginning on 1/1/2025[12]. In

[11] https://www.cms.gov/files/document/manufacturer-discount-program-specified-and-specified-small-manufacturer-methodology.pdf-0

[12] https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers

this initial list, approximately 62% of labeler codes that are participating in the program are eligible for phased-in discounts. Furthermore, on May 9, 2024, CMS released an initial list of which specific NDCs will be eligible for MDP in 2025. CMS will release updated NDC lists starting in December 2024.

Based on the list of labeler codes that was published in April 2024, Wakely has conducted an analysis using publicly available CMS data[13] to understand the percentage of brand spend across different manufacturer types (and thus different discount types).

The results of this analysis are shown in Table 4 below.

**Table 4 – Percentage of Part D Brand[14] Spend by Manufacturer Type[15]**

| Phase-In Eligibility | 2018 | 2019 | 2020 | 2021 | 2022 |
|---|---|---|---|---|---|
| ***Specified Manufacturer*** | 13.5% | 12.2% | 10.4% | 9.3% | 8.7% |
| ***Specified Small Manufacturer*** | 5.6% | 6.3% | 6.8% | 7.0% | 7.4% |
| ***Not Eligible*** | 81.0% | 81.5% | 82.8% | 83.7% | 83.9% |
| **Total** | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

These results show that in 2022, approximately 16.1% of Part D spend for brand drugs came from manufacturers that are eligible for the MDP phase-in (which would apply to LI members only) and 7.4% of Part D spend for brand drugs came from Specified Small Manufacturers (which would apply to all applicable members).

To further understand the implications of the MDP phase-in on health plan liability, Wakely estimated the impact of the phase-in on average plan liability per brand script (before rebates and other DIR). The results of this analysis are found in the following Table 5.

[13] CMS Part D Spending by Drug Data: https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug

[14] "Brand" spend is defined based on drugs that either a) only have one manufacturer in the CMS Part D Spending by Drug data or b) are identified as brand drugs based on drug name according to the Comprehensive NDC SPL Data Elements File (NSDE) definition.

[15] Note that because the CMS Part D Spending by Drug data only contains drug names and manufacturer names (and does not include codes or other identifiers such as NDCs or labeler codes), manufacturer names were mapped to the CMS data based on the list of MDP labeler codes and manufacturer names released by CMS. Results may vary if a more precise mapping is completed by NDC or by labeler code. Manufacturers that were not able to be easily mapped (which represented approximately 0.3% of total spend in 2022) were excluded from the analysis.

**Table 5 – Estimated Impact of MDP Phase-In**
*Estimated Defined Standard Plan Liability per Brand Script*

| Coverage Phase | LI Status | 2018 | 2019 | 2020 | 2021 | 2022 |
|---|---|---|---|---|---|---|
| *Initial Coverage* | ***LI without Phase-In*** | $449 | $499 | $571 | $646 | $706 |
| | ***NLI without Phase-In*** | $355 | $394 | $451 | $510 | $557 |
| | ***Total without Phase-In*** | $394 | $437 | $501 | $566 | $619 |
| | ***LI with Phase-In*** | $462 | $513 | $586 | $661 | $723 |
| | ***NLI with Phase-In*** | $358 | $398 | $456 | $515 | $564 |
| | ***Total with Phase-In*** | $401 | $445 | $510 | $576 | $629 |
| | ***% Increase from Phase-In*** | 1.8% | 1.8% | 1.8% | 1.7% | 1.7% |
| *Catastrophic* | ***LI without Phase-In*** | $486 | $540 | $619 | $700 | $764 |
| | ***NLI without Phase-In*** | $384 | $427 | $489 | $553 | $604 |
| | ***Total without Phase-In*** | $427 | $474 | $543 | $613 | $670 |
| | ***LI with Phase-In*** | $514 | $569 | $650 | $733 | $800 |
| | ***NLI with Phase-In*** | $391 | $435 | $499 | $564 | $617 |
| | ***Total with Phase-In*** | $441 | $490 | $562 | $634 | $693 |
| | ***% Increase from Phase-In*** | 3.5% | 3.5% | 3.4% | 3.3% | 3.4% |

The results of this analysis show that, on average, Defined Standard plan liability on brand drugs is estimated to increase by approximately 1.7%-1.8% in the Initial Coverage phase and by approximately 3.3%-3.5% in the Catastrophic phase because of the phase-in rules for 2025. This is driven by the additional 9% and 19% in liability that plan sponsors will be responsible for in the Initial Coverage and Catastrophic phases, respectively, for phase-in eligible claims. These amounts would decrease in future years as the reduced discount amounts for specified and specified small manufacturers are phased out.

Because CMS drug-level Part D data includes aggregate spend (not differentiated by LI/NLI status or coverage phase), several assumptions were required to estimate discount and plan liability amounts in Table 5, including:

- 6% of total Part D allowed spend occurs in the Deductible Phase of the benefit[16]

[16] Source: 2021 CMS Program Statistics – Medicare Part D; https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/cms-program-statistics-medicare-part-d. Deductible amounts assume $266 average drug cost per utilizer in the Deductible Phase multiplied by total number of utilizers. Amounts exclude EGWP and PACE.

- 47% of total Part D allowed spend on brand drugs and 41% of total Part D brand scripts come from Low Income-eligible beneficiaries[17]
- Due to data limitations, these estimates do not include the impact of enhanced Part D coverage outside of the Defined Standard benefit, Low Income cost sharing, or insulin/vaccine Defined Standard cost sharing.
- These estimates also assume that all specified and specified small manufacturer drugs would be eligible for the phase-in. This does not account for any new drugs marketed after August 16, 2022, that would not be eligible for the phased-in discount.

## Similarities and Differences from Prior Coverage Gap Discount Program

Below is a summary of the provisions in the MDP final guidance and similar provisions in the CGDP:

**Table 6 – CGDP and MDP Provision Summaries**

| Provision | CGDP | MDP |
|---|---|---|
| Timeframe | Effective 1/1/2011 - 12/31/2024, with payment runout until 2028 | Effective 1/1/2025 |
| Drug classifications | Applicable and non-applicable | Selected, applicable, and non-applicable |
| Discounts apply to | Applicable drugs only | Applicable drugs only |
| Low-Income eligibility | NLI only | Both LI and NLI |
| Selected drug subsidy amounts | N/A | 10% in the initial coverage phase for selected drugs (starting in 2026) |
| Discount amounts | 70% in coverage gap phase | 10% in initial coverage phase & 20% in catastrophic phase[18] |
| Discounts as % of | Negotiated price, excluding dispensing fees | Negotiated price, including dispensing fees |
| Discount application to supplemental benefits | Discounts calculated after the application of any supplemental benefits | Discounts calculated before the application of any supplemental benefits |
| Discount applicability to TrOOP / MOOP | Discounts count toward TrOOP | Discounts do not count toward MOOP |
| Applicable benefit phases | Coverage gap phase | Initial coverage phase and catastrophic phase |

[17] Source: 2021 CMS Program Statistics – Medicare Part D; https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/cms-program-statistics-medicare-part-d.

[18] Discounts are phased in at lower levels until 2031 for certain manufacturers.

| Provision | CGDP | MDP |
|---|---|---|
| Discount payment processes | Discounts provided to members by plan sponsor at POS, with prospective payments from CMS, invoicing of manufacturers, and reconciliation of payments by a TPA | |

## Open Questions and Potential Implications

As described above, CMS plans to release additional guidance with more detail outlining several items, including the calculation of the selected drug subsidy and the submission of PDE records for MDP payments and selected drug subsidies.

As plan sponsors, manufacturers, and other stakeholders begin to review and understand the final MDP guidance, they should be aware of its potential implications. As shown above, the MDP will largely operationally function like the CGDP, but there are several key differences in payment eligibility and financial responsibility:

- Manufacturers are likely to see their Part D claim discount liabilities increase for high-cost members, as they now have unlimited liability in the catastrophic coverage phase.
- Plan sponsors will need to understand how discount changes and other IRA benefit changes will impact their own liabilities and how those changes will impact bid preparation.
- Finally, plan sponsors will need to be prepared to operationalize these changes at the POS when adjudicating claims and managing plan benefits.

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If you have any questions or want to follow up on any of the concepts presented here, please contact any of the following authors:

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