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**DATE:** December 20, 2024

**TO:** Pharmaceutical Manufacturers; All Part D Plan Sponsors

**FROM:** Vanessa S. Duran, Director  
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**SUBJECT:** Revised Medicare Part D Manufacturer Discount Program Final Guidance

This memorandum provides revised final program guidance to pharmaceutical manufacturers and Part D plan sponsors for implementing the Medicare Part D Manufacturer Discount Program (Discount Program). This revised final guidance replaces the Medicare Part D Manufacturer Discount Program Final Guidance (Final Guidance) that CMS released on November 17, 2023. Revisions are limited to sections 100.1.1 and 100.1.2 of the Final Guidance regarding manufacturer initial disputes and independent review and are identified by red italic text.

CMS solicited input on revisions to sections 100.1.1 and 100.1.2 of the Final Guidance via a 30-day public comment period, which closed on December 16, 2024. CMS received one comment, which was supportive of the changes. This memorandum includes a summary of public comments received in response to releasing the Medicare Part D Manufacturer Discount Program Draft Guidance (Draft Guidance) on May 12, 2023 and CMS responses, which begins on page 2, (CMS made no changes to the comment and response section from the November 17, 2023 release) and guidance that establishes final policies on the topics discussed for 2025 and 2026, which begins on page 16.

CMS may supplement this guidance with further program instruction as necessary to implement the program for 2025 and 2026.

The Discount Program was enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public L. 117-169 (IRA) and codified in sections 1860D-14C and 1860D-43 of the Social Security Act (the Act). Section 11201(f) of the IRA directs CMS to implement the Discount Program using program instruction or other forms of program guidance for 2025 and 2026. In accordance with the law, on May 12, 2023, CMS released the Draft Guidance, and voluntarily solicited comment during a 30-day comment period which closed on June 12, 2023. CMS received 18 comment letters, representing health plans, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), and trade associations.

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 and the definitions and requirements set forth in this guidance.

## **A. Summary of Public Comments on the Manufacturer Discount Program Draft Guidance and CMS Responses**

### ***Coverage Gap Discount Program***

**Comment:** One commenter asked CMS to clarify how Coverage Gap Discount Program invoicing will occur after the Discount Program is implemented.

**Response:** The CMS Third Party Administrator (TPA) will continue to coordinate Coverage Gap Discount Program payments between manufacturers and Part D sponsors. This coordination will continue to involve a standard process for invoicing the manufacturers and reimbursing Part D sponsors for Coverage Gap Discount Program discounts. CMS will continue to post the quarterly invoicing and payment calendar on the CMS website at <https://www.cms.gov/medicare/coverage/prescription-drug-coverage/part-d-information-pharmaceutical-manufacturers>. While manufacturers will not incur any liability for discounts under the Coverage Gap Discount Program for dates of service after December 31, 2024, Coverage Gap Discount Program invoicing will continue through January 31, 2028 to allow for prescription drug event (PDE) submission run-out. As reflected in the Coverage Gap Discount Program calendar posted on the page linked above, the final Coverage Gap Discount Program manufacturer invoice will be distributed by April 30, 2028.

### ***Conditions for Coverage Under Part D***

**Comment:** A few commenters requested that CMS clarify in the final guidance how it expects to implement the essential drug provision at section 1860D-43(c)(1)(A) of the Act. One of these commenters recommended that CMS proactively exempt all Part D drugs that it determines through the formulary review process must be included on all formularies, such as protected class drugs. Another commenter advised that CMS should establish, through rulemaking, criteria it will use to determine which drugs are essential under this provision, and offered an example suggesting the criteria could be tied to a declared public health emergency. One commenter recommended that CMS not require essential drugs to be included on Part D formularies to ensure that manufacturers cannot use the essential drug policy to avoid liability under the MDP while afforded guaranteed formulary inclusion. This commenter also suggested that CMS provide a reinsurance subsidy for essential drugs when covered by Part D plans, since such coverage is at the discretion of the Secretary.

**Response:** CMS thanks the commenters for their feedback, but we decline to provide additional criteria or parameters around drugs determined by CMS to be essential to the health of Part D enrollees under section 1860D-43(c)(1)(A) of the Act at this time. While we appreciate the concerns around beneficiary access, a protected class drug under [42 CFR § 423.120\(b\)\(2\)\(v\)](#) does not automatically overcome the exclusion from Part D for a drug that is not otherwise covered by a Discount Program agreement. Proactive exemptions of certain drugs, or categories and classes of drugs, from the requirements for Part D coverage under section 1860D-43(a) of the Act would result in higher costs to Part D sponsors, beneficiaries, and the government because manufacturers of such drugs would have no incentive to participate in the Discount Program. Based on our experience in the Coverage Gap Discount Program, CMS does not anticipate using this exception, and manufacturers should not expect to get their applicable drugs covered under Part D through this exception. We note that the exception provision merely permits coverage under Part D; it does not guarantee or require placement of essential drugs on formularies, nor does it place any particular limitations on utilization management or tier placement.

**Comment:** One commenter argued that the Discount Program should only apply to plans with a standard benefit design (defined standard or actuarially equivalent), and that Congress did not intend for it or the Coverage Gap Discount Program to apply to enhanced plans where manufacturers will be liable earlier because there is a lower or no plan deductible.

**Response:** CMS disagrees that the Discount Program should only apply to standard plans. While the definition of applicable beneficiary in section 1860D-14C(g)(1) of the Act uses a benefit stage calculation based on the defined standard Part D benefit, it otherwise specifies only that the individual be enrolled in a prescription drug or MA-PD plan and not enrolled in a qualified retiree plan. The Coverage Gap Discount Program applies to both basic and enhanced plan designs, and section 1860D-14A(c)(2) of the Act specifies that discounts under the Coverage Gap Discount Program not be provided until after supplemental benefits have been applied. The Discount Program does not contain a provision that specifies discounts be provided after supplemental benefits and, as such, we are clarifying in this final guidance that applicable discounts under the Discount Program be applied before supplemental benefits have been applied.

**Comment:** One commenter disagreed with CMS' inclusion of selected drugs in the definition of non-applicable drug. The commenter opined that, because non-applicable drugs can still be covered under Part D without a Discount Program agreement in place, this would create a significant loophole for a manufacturer of both applicable drugs and a selected drug to have their selected drug covered under Part D at the maximum fair price (MFP) and, by not entering into a Discount Program agreement, without being obligated to provide discounts on their applicable drugs. The commenter believes that selected drugs, that would be applicable drugs but for the fact that they are selected drugs, should be treated differently from generics because selected drugs are fundamentally different from non-applicable drugs (that is, generics) under the Coverage Gap Discount Program.

**Response:** CMS agrees with this commenter that selected drugs under the Medicare Drug Price Negotiation Program (hereafter referred to as the Negotiation Program) must be treated differently than other Part D drugs that are not applicable drugs (e.g., generics). We have made revisions in [section 40](#), as well as the definition of non-applicable drug in [section 130](#), of this final guidance to clarify that selected drugs (as defined in section 1192(c) of the Act) during the price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drugs are not included in the definition of non-applicable drugs, and that the labeler code of a selected drug must be covered by a Discount Program agreement in order for that selected drug to be coverable under Part D.

In the Contract Year 2013 Part D proposed rule ([76 FR 63018, 63025-26](#)) and final rule ([77 FR 22072, 22082-83](#)), we stated that the exclusion from Part D coverage under section 1860D-43(a) of the Act applies only to the applicable drugs of a manufacturer that fails to sign an agreement and participate in the Coverage Gap Discount Program. This interpretation was based on concerns regarding beneficiary access to generic drugs as well as the statutory objectives of ensuring participation by brand name drug manufacturers in the program and alleviating financial burdens for beneficiaries.

While these rationales support maintaining our longstanding interpretation that the exclusion from Part D coverage under section 1860D-43(a) of the Act does not extend to non-applicable drugs (e.g., generics), they do not apply to the new category of drugs established by the IRA (i.e., selected drugs). Selected drugs are products that would otherwise meet the definition of an applicable drug, but for it being a price applicability period following their selection into the Negotiation Program. Therefore, applying section 1860D-43(a) of the Act's coverage exclusion in the absence of a Discount Program agreement to both applicable drugs and selected drugs is consistent with the statutory goals of incentivizing manufacturers of brand name drugs and biological products to participate in the Discount Program (as well as the Negotiation Program, as applicable), while not undermining beneficiary access to generics. Moreover, this interpretation is consistent with the IRA's addition of section 1860D-43(c)(2) of the Act, which prohibits the Secretary from authorizing coverage for a covered Part D drug of a manufacturer without a Discount Program agreement for any period described in section 5000D(c)(1) of the Internal Revenue Code under the exception for drugs determined to be essential to the health of Part D enrollees. This provision further demonstrates that the statute does not allow for a selected drug to be eligible for Part D coverage in the absence of a Discount Program agreement.

### ***Applicable Discounts***

**Comment:** One commenter asked CMS to clarify whether the applicable discount is calculated before or after other discounts, such as pharmacy price concessions or point-of-sale (POS) manufacturer rebates, are applied to the negotiated price. Another commenter asked us to clarify that applicable discounts are calculated on a negotiated price that is net of all concessions, including estimates of retroactive manufacturer rebates that are currently reported to CMS as direct and indirect remuneration (DIR).

**Response:** The draft guidance defined negotiated price by citing only section 1860D-2(d)(1)(B) of the Act. We are clarifying in [section 130](#) of this final guidance that negotiated price has the meaning given such term in [42 CFR § 423.100](#) and that applicable discounts must be calculated based on this definition of negotiated price. Beginning January 1, 2024, [42 CFR § 423.100](#) makes clear that negotiated price is the lowest possible reimbursement that a network dispensing pharmacy or other network dispensing provider will receive, in total, for a particular drug.<sup>1</sup> The negotiated price, therefore, includes all network pharmacy and other network provider price concessions, and is reduced by all price concessions and other DIR that the Part D sponsor passes through at the POS. Accordingly, the applicable discount is always calculated based on a negotiated price that, at a minimum, represents the lowest possible reimbursement to a network dispensing pharmacy or other network dispensing provider.

**Comment:** Several commenters requested clarification about how to operationalize the Discount Program in enhanced plans, where the standard deductible is reduced or eliminated. A commenter noted that this may be difficult to operationalize at POS and may discourage plans from offering reduced deductibles. Another commenter requested guidance detailing the impact of supplemental benefits on the manufacturer's liability, and another asked whether supplemental benefits count towards an enrollee's true out-of-pocket (TrOOP) costs. A commenter who appeared to disagree with our policy in [section 50](#) suggested that CMS specify that applicable discounts will be available in the initial coverage phase, regardless of the enrollee's incurred costs, which would be in the best interest of beneficiaries who, the commenter believes, may not feel they are receiving the full value of the Part D benefit if discount availability is based on incurred costs. The commenter stated that insulin and vaccines will not be reported with deductible accumulators.

**Response:** CMS thanks the commenters for their feedback and questions. Section 1860D-14A(c)(2) of the Act specified that discounts under the Coverage Gap Discount Program not be provided until after supplemental benefits have been applied. The Discount Program does not contain such a provision and, as such, we are clarifying in this final guidance that applicable discounts under the Discount Program be applied before supplemental benefits have been applied. Section 1860D-14C(g)(1) of the Act defines an applicable beneficiary as an individual that incurs TrOOP-eligible costs that exceed the annual defined standard deductible specified in section 1860D-2(b)(1) of the Act. These costs include TrOOP-eligible costs for drugs not subject to the deductible under the defined standard benefit, specifically covered insulin products, as well as TrOOP-eligible costs for drugs not subject to the deductible or drugs subject to a reduced deductible under non-defined standard plans. CMS will release additional policy and operational guidance related to the Part D redesign, including how to operationalize changes at the POS.

**Comment:** One commenter argued that Part D sponsors that are part of vertically integrated organizations that also engage in relabeling, repackaging, or secondary manufacturing should be

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<sup>1</sup> "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" ([87 FR 27704, 27833-51](#)).

responsible for a portion of the applicable discount. Additionally, the commenter encouraged CMS to monitor whether such sponsors prefer products for which they engage in relabeling, repackaging, or secondary manufacturing on their formularies or otherwise capitalize on the other manufacturer's rebates or discounts for such products in a manner that may violate the anti-kickback statute.

**Response:** CMS thanks the commenter for their input and will consider this information as part of ongoing Part D oversight. Consistent with the requirements in section 1860D-14C of the Act, the entity that has executed a Discount Program agreement by which the labeler code for an applicable drug is covered is responsible for paying the applicable discount.

### ***Phase-Ins for Specified Manufacturers and Specified Small Manufacturers***

**Comment:** Several commenters requested that CMS publish its methodology for determining eligibility for phase-ins, as well as any data relied on to make the determination, as far in advance as possible, and provide interested parties an opportunity to provide comment. One of these commenters requested that CMS provide preliminary notification to manufacturers regarding their eligibility for phase-ins and provide such manufacturers with an opportunity to review and comment before a final determination is made.

**Response:** CMS has added a new [section 50.2](#) in this final guidance, which provides more detail about phase-in eligibility determinations. As discussed in that section, CMS is publishing its methodology for determining a manufacturer's eligibility for the Discount Program phase-ins concurrent with the release of this final guidance.<sup>2</sup> Due to time limitations, we are not able to accept comment on the methodology.

In addition, as discussed in [section 50.2.1](#) of this guidance, CMS will provide preliminary, non-binding information regarding whether a manufacturer qualifies for a phase-in to each manufacturer that submits and attests to all required ownership information by the December 8, 2023 deadline, without executing a Discount Program agreement.

**Comment:** A few commenters requested that CMS clarify who is liable for the remaining balance of the applicable discount for applicable drugs that are subject to a phased-in discount percentage. One of these commenters stated that nothing in the IRA prevents CMS from paying the difference, similar to how CMS will pay a selected drug subsidy, and expressed a concern that holding Part D sponsors liable for these amounts could impact formulary design and utilization management because sponsors will want to limit coverage for products for which they have greater liability. Another commenter asked CMS to confirm sponsors are liable.

**Response:** CMS appreciates the opportunity to provide clarification about liability for applicable drugs subject to phase-ins. The IRA establishes lower percentages for applicable discounts on specified drugs when dispensed to applicable beneficiaries who are eligible for a low-income

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<sup>2</sup> See November 17, 2023 HPMS memorandum entitled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" for more information.



subsidy (LIS) under section 1860D-14 of the Act and on specified small manufacturer drugs when dispensed to applicable beneficiaries during a multi-year phase-in. Because the discount, regardless of the discount percentage, reduces the plan liability, the plan is responsible for the remaining liability, less enrollee cost sharing. Furthermore, the statute does not authorize CMS to pay a separate subsidy amount to cover the difference as it does in the case of the selected drug subsidy. We have revised [section 50.1](#) of the final guidance to make this clarification.

**Comment:** A commenter requested clarification on the definition of “is marketed as of August 16, 2022”, specifically whether it refers to drugs first marketed before or after that date. The commenter stated that it should apply to drugs first marketed after August 16, 2022 because such a policy would encourage new competition.

**Response:** We thank the commenter for their input, but we disagree with their suggestion. The statute at sections 1860D-14C(g)(4)(B)(i) and 1860D-14C(g)(4)(C)(i) of the Act refers to the marketing of the manufacturer’s drug on one specific, backward-looking date, i.e., the date of enactment of the IRA. We have revised [section 50](#) to specify that, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-ins, CMS interprets the reference to a drug that “is marketed as of” August 16, 2022 to refer to a drug that was marketed on August 16, 2022.

**Comment:** One commenter requested that CMS count all plasma-derived products as a single drug for purposes of determining phase-in eligibility.

**Response:** While we appreciate this commenter’s concern and recognize the unique aspects of manufacturing plasma-derived products, CMS will not create a special rule under the Discount Program to treat all plasma-derived products as a single drug for purposes of determining eligibility for the specified small manufacturer discount discussed in [section 50.1.2](#) of the guidance. Under the Negotiation Program, section 1192(e)(3)(C) of the IRA excludes plasma-derived products from the definition of qualifying single source drug; however, Congress gave the Secretary no such authority under the IRA to treat plasma-derived products differently than any other Part D drug for purposes of identifying specified small manufacturer drugs eligible for phase-ins. Accordingly, CMS will apply the same methodology for determining phase-in eligibility to plasma-derived products as other Part D drugs.

**Comment:** A few commenters encouraged CMS to establish an appeals process to dispute eligibility determinations for phase-ins. One commenter suggested that the appeals process be accessible to other parties to appeal CMS’ determination with respect to a manufacturer. Another commenter asked for clarification about whether phase-ins would apply retroactively in the case of errors or a successful appeal.

**Response:** CMS appreciates this feedback. We have added [section 50.2.2](#) to this final guidance to provide a process by which a manufacturer can request a recalculation of its phase-in eligibility determination. Under this process, only the manufacturer can make such a request. As discussed in [section 50.2.1](#) of the final guidance, for 2025, CMS will provide manufacturers that

submit and attest to all required ownership information in HPMS by the deadline, without executing a Discount Program agreement, with preliminary, non-binding information about their eligibility for the Discount Program phase-ins. However, because the statute requires the actual eligibility determination to be made in connection with the executed Discount Program agreement, the preliminary, non-binding information provided by CMS under the process set forth in [section 50.2.1](#) of the guidance does not constitute an eligibility determination for which a recalculation can be requested. CMS will provide manufacturers with such eligibility determinations after the March 1, 2024 deadline to enter into a Discount Program agreement for 2025 if their drugs are covered by an executed Discount Program agreement, and such manufacturer will have 30 calendar days from receipt of such determination to request a recalculation under [section 50.2.2](#) of the final guidance.

### ***Point-of-Sale Discounts and Payment Processes***

**Comment:** A commenter requested PDE examples for straddle claims for enhanced alternative plans for applicable drugs that are covered insulin products or ACIP-recommended adult vaccines. The commenter also asked CMS to clarify what does and does not count toward TrOOP.

**Response:** CMS appreciates the need for more guidance on calculating Discount Program payments and submitting PDE records that reflect such payments, and will issue such additional guidance at a later time.

**Comment:** A commenter asked how discounts should be applied to direct member reimbursement (DMR) requests when an enrollee pays full price in cash, both in- and out-of-network, including what portion of the amount the enrollee paid should count towards TrOOP.

**Response:** With respect to processing DMR requests specifically, Part D sponsors should continue to follow the guidance in Chapter 14 of the [Medicare Prescription Drug Benefit Manual](#).

**Comment:** Some commenters objected to the policy in [section 60.1.1](#) of the draft guidance requiring participating manufacturers to provide applicable discounts for claims involving an applicable drug for an applicable beneficiary that are processed as DMRs. One of the commenters expressed concerns that applying discounts on in-network DMR claims would incentivize sponsors to encourage enrollees to use pharmacy discount programs and non-manufacturer discount cards instead of their Part D benefit at the POS at network pharmacies then submit to the plan as a DMR request. The commenter noted that the plan's liability using the DMR process would be reduced in situations where the discounted price is lower than the plan's negotiated price. The commenters argued that, under [42 CFR § 423.124\(b\)](#), CMS should prohibit use of the DMR process for drugs purchased from network pharmacies.

**Response:** While we appreciate the commenters sharing these concerns, CMS disagrees with the comment and declines to make any changes to the policy in [section 60.1.1](#) requiring that



applicable discounts be provided for applicable drugs dispensed to applicable beneficiaries, including claims that are approved under the DMR process. The requirement that manufacturers pay applicable discounts is not limited to claims that process electronically. This policy is consistent with our DMR policy under the Coverage Gap Discount Program. While outside the scope of the Discount Program and this guidance, CMS is not aware of any efforts by Part D sponsors to encourage enrollees to not use their Part D benefit for covered Part D drugs at a network pharmacy. As acknowledged by the commenter, under [42 CFR § 423.120\(c\)\(3\)](#), Part D sponsors are required (since 2011) to require their network pharmacies to submit claims electronically to the plan or its intermediary unless the enrollee expressly requests that a particular claim not be submitted. Under [42 CFR § 423.562\(b\)\(2\)](#), Part D enrollees have the right to request a coverage determination from their plan, including a request for payment (i.e., a DMR), for any drug the enrollee believes is covered, and plans are required to adjudicate such requests in accordance with the rules in Part 423, [Subpart M](#).

**Comment:** A few commenters recommended that CMS prospective payments to Part D sponsors be risk adjusted because the Discount Program involves more plan risk than the Coverage Gap Discount Program, and that risk adjustment would help ensure patient access.

**Response:** CMS will continue to make prospective payments to plans to cover the cost of the discounts advanced at the POS. Part D plan sponsors may incorporate any additional anticipated risks that are attributed to plan design into their annual bids.

**Comment:** Two commenters requested that CMS clarify how applicable discounts will be applied to Medicare as a Secondary Payer (MSP) claims. One commenter requested confirmation about whether Medicaid and Indian Health Service (IHS) subrogation claims are excluded from the Discount Program as they were under the Coverage Gap Discount Program.

**Response:** CMS is unable to definitively ascertain from the PDE how much liability, if any, the Part D plan had on an MSP claim. Medicaid and IHS subrogation claims are handled through the payment reconciliation process, not as claims paid under the Part D benefit. Therefore, consistent with our policies under the Coverage Gap Discount Program, MSP and Medicaid and IHS subrogation claims are excluded from the Discount Program.

**Comment:** A commenter requested clarification about application of applicable discounts to vaccine administration fee-only claims.

**Response:** Under the definition of negotiated price in [section 130](#) of this guidance, the negotiated price for a covered Part D vaccine includes any vaccine administration fee and would be eligible for the discount regardless of ingredient cost.

**Comment:** A commenter requested additional guidance related to employer group waiver plans (EGWPs), including whether CMS will maintain its current process of using the national average bid information to provide discount estimates for EGWPs and perform reconciliation after actual costs are submitted. The commenter also asked how EGWPs will be made whole for unpaid

invoices due to manufacturer bankruptcy if they neither receive prospective payments nor participate in the reconciliation process. The commenter recommended that CMS publish a separate report for all plan types detailing adjusted amounts due to manufacturer bankruptcy, the plan ID, P number, and coverage year. Finally, the commenter asked how non-calendar year EGWPs should transition to the Discount Program during the 2024-2025 plan year.

**Response:** CMS intends to release separate guidance addressing how non-calendar year EGWPs will be required to operationalize various IRA changes for plan year 2024-2025, including the transition to the new Discount Program. Guidance regarding EGWPs being made whole for unpaid invoices due to manufacturer bankruptcy is forthcoming. We thank the commenter for the recommendation and will take it under consideration.

**Comment:** A commenter requested clarification regarding the selected drug subsidy, specifically whether the subsidy will be based on the Maximum Fair Price, how a plan should record the subsidy in the initial and catastrophic coverage phases, and if the subsidy will be included in the rebate retention calculator.

**Response:** Under section 1860D-14D of the Act, the selected drug subsidy will be equal to 10 percent of the drug's negotiated price (as defined in section 1860D-14C(g)(6) of the Act, and as codified at [42 CFR § 423.100](#)). Section 1860D-2(d)(1)(D) of the Act requires that with respect to a price applicability period, the negotiated price of a Part D drug that is a selected drug shall be no greater than the Maximum Fair Price plus any dispensing fees for such drug. CMS appreciates the need for more guidance on calculating the subsidy and submitting on PDEs as well as the methodology for allocating DIR in Part D payment reconciliation and will issue such additional guidance at a later time.

**Comment:** Commenters asked for clarification about whether the Discount Program applies to PACE organizations and Platino plans.

**Response:** The Discount Program applies to both PACE organizations and Platino plans, and we have added clarifying language in [sections 60.1.2](#) and [60.1.3](#), respectively. PACE organizations are prohibited from requiring enrollee cost sharing and offer supplemental benefits to reduce cost sharing to zero. PACE organizations are excluded from the Coverage Gap Discount Program because discounts are applied after supplemental benefits under section 1860D-14A(c)(2) of the Act. Since the Discount Program does not have a special rule for supplemental benefits, there is no statutory basis for excluding PACE from the Discount Program.

Platino plans submit Part D bids that reflect only basic benefits, and do not include any supplemental benefits required by the Commonwealth of Puerto Rico. Supplemental coverage required by the Commonwealth is, therefore, considered other health coverage and, in accordance with section 1860D-14C(c)(1)(C) is applied after any discount available under the Discount Program. As such, Platino plans are not excluded from the Discount Program.

**Comment:** One commenter asked whether Plan Finder price files will reflect negotiated drug prices prior to applying Discount Program discounts.

**Response:** Yes, Medicare Plan Finder price files will reflect negotiated prices before the application of any discount under the Discount Program.

### ***Manufacturer Requirements***

**Comment:** A commenter requested that CMS solicit comment on the Discount Program agreement.

**Response:** We thank the commenter for this feedback; however, CMS is releasing the Discount Program agreement and the TPA agreement as final documents. We note that while, under the Coverage Gap Discount Program, section 1860D-14A(a) of the Act required CMS to create a model agreement in consultation with manufacturers and allow for comment on the model agreement, there is no such language in section 1860D-14C of the Act for the Discount Program.

**Comment:** A commenter recommended that HPMS access be expanded to include primary and at least one backup user for each role to ensure business continuity.

**Response:** HPMS functionality in the Drug Manufacturer Contract Management module already includes optional secondary contact roles, and the option to add such secondary contacts will remain for the Discount Program. CMS will consider improvements for future HPMS updates.

**Comment:** One commenter requested more information regarding Discount Program agreement terminations, specifically whether there are penalties or other consequences for a manufacturer that chooses to terminate their Discount Program agreement.

**Response:** As described in [section 80.1.3.2](#) of the guidance, a participating manufacturer may terminate its Discount Program agreement for any reason and at any time, subject to the statutory requirements related to the effective date of the termination. Following an agreement termination by the manufacturer, the manufacturer remains responsible for reimbursing Part D sponsors for discounts that were incurred under the agreement before the effective date of termination. Importantly, under section 1860D-43(a) of the Act, the manufacturer's applicable drugs and selected drugs cannot be covered under Part D without an agreement in place.

### ***TPA Invoicing and Manufacturer Payment***

**Comment:** A commenter requested that manufacturer payment transactions through the TPA not be limited to transactions under \$100 million as such a policy requires manufacturers in some instances to make quarterly payments through multiple transactions, which increases the risk of untimely payments.

**Response:** The TPA adheres to transaction standards established by the National Automated Clearinghouse Association (NACHA), the organization that sets standards for automated clearinghouse (ACH) networks throughout the U.S. The NACHA standards limit the amount of a single transaction to under \$100 million. Both the manufacturer and sponsor versions of the invoice under the Discount Program will continue to adhere to this standard and will display multiple, separate invoice line items instead of a single line item when the amount owed to a single recipient exceeds this limit.

**Comment:** One commenter requested that CMS or the TPA identify the plans to which manufacturer payments are forwarded.

**Response:** Invoice reports under the Coverage Gap Discount Program, which can be downloaded by manufacturers from the TPA portal, as well as information on the payment tab on the TPA portal, identify the plans and the amounts owed. This information will continue to be available on the TPA portal for invoices under the Discount Program.

**Comment:** One commenter requested that CMS provide guidance on what actions sponsors can take to notify CMS when a manufacturer is delinquent in paying invoices.

**Response:** There is no need for sponsors to take any action to notify CMS when a manufacturer is out of compliance with the 38-day payment requirement as the TPA closely monitors and reports this information to CMS.

**Comment:** Multiple commenters opposed continued use of signed overpunch coding on invoice currency fields, as is currently used for Coverage Gap Discount Program invoices. The commenters stated that such coding does not provide additional security and is unduly burdensome as it requires manufacturers to engage third parties to convert the data into a readable format. One commenter requested that CMS provide a data dictionary to clarify the meaning of the various data elements.

**Response:** CMS thanks the commenters for their input. We are continuing to explore options and will seek input from interested parties to develop improvements to operational policy in this area. File layouts and data dictionaries are available on the TPA website at [www.TPAdministrator.com](http://www.TPAdministrator.com).

**Comment:** Several commenters supported including additional data elements on Discount Program invoices but requested that more elements be added in addition to those listed in [section 80.2.1](#) of the draft guidance. Commenters cited a need for manufacturers to be able to conduct thorough claim validation and noted that the additional information would prevent unnecessary disputes. One commenter requested that manufacturers have access to all claim-level information to ensure they are paying the correct amounts. One commenter requested that CMS continually solicit feedback on invoice data elements. Another commenter indicated that deficiencies in invoice data result in manufacturers being unable to identify secondarily manufactured products in the claims data.

**Response:** CMS thanks the commenters for their support for including the additional data elements referenced in the draft guidance on manufacturer invoices under the Discount Program. In providing this invoice data to participating manufacturers, CMS seeks to limit the disclosure of the claim-level information to the minimum necessary in order for a participating manufacturer to verify payment. Manufacturers should consider that prior to invoicing under the Discount Program, CMS will continue to perform extensive editing on PDE records and conduct outlier analyses to check for duplicates, applicable national drug codes (NDCs), and incorrect discount calculations, among other checks, as it currently does under the Coverage Gap Discount Program. Detailed information on the PDE submission process, including on CMS's extensive PDE editing process, can be found on the Customer Service and Support Center (CSSC) website.<sup>3</sup> CMS believes that the additional data elements provided on manufacturer invoices and listed in [section 80.2.1](#) of this guidance will assist participating manufacturers in understanding the basis and accuracy of the reported discounts and determining whether to dispute a discount amount. CMS welcomes feedback on invoice data elements from interested parties through the TPA.

**Comment:** Commenters requested clarification about whether CMS intends for Gross Drug Cost Below Out-of-Pocket Threshold (GDCB) and Gross Drug Cost Above Out-of-Pocket Threshold (GDCA) to be equivalent to the negotiated drug price.

**Response:** GDCB plus GDCA equals the negotiated drug price, as the negotiated price for the purpose of calculating the discount under the Discount Program includes all cost fields on the PDE record (ingredient cost, sales tax, dispensing fee, and vaccine administration fee or additional dispensing fee).

**Comment:** A commenter indicated that deficiencies in invoice data result in manufacturers being unable to identify secondarily manufactured products in the claims data.

**Response:** As stated elsewhere, the entity that has executed the Discount Program agreement is responsible for paying the applicable discount for all applicable drugs that have NDCs with a labeler code covered by such agreement. The invoice data contains sufficient information to identify the entity that pays the applicable discount.

### *Audits*

**Comment:** One commenter opposed the policy to require prompt payment from manufacturers for all claims but only allowing them to audit one-fifth of their claims once a year. The commenter requested that manufacturers be permitted to view all claims on audit, at least monthly, through a secure portal, or alternatively that CMS allow audit samples to be randomly selected.

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<sup>3</sup> <https://www.csscooperations.com/internet/csscw3.nsf>

**Response:** We thank the commenter for their suggestions. We have updated this guidance at [section 90.1.2](#) to indicate that a manufacturer conducting an audit will be limited to a statistically significant random sample of data held by the TPA.

**Comment:** Multiple commenters supported the policy in [section 90.1](#) of the draft guidance permitting manufacturers to audit the TPA data. These commenters also recommended that CMS allow audits to occur remotely through restricted data portals that will protect the privacy of beneficiary medical information, instead of requiring in-person audits, which are overly burdensome for manufacturers.

**Response:** CMS appreciates the input and intends to explore options with the TPA, taking into account all relevant privacy and security safeguards.

### ***Dispute Resolution***

**Comment:** While commenters were generally supportive of the dispute resolution framework discussed in [section 100](#) of the draft guidance, several commenters requested various process improvements based on experience from the Coverage Gap Discount Program. These suggestions included a longer timeframe for manufacturers to request initial disputes, with some commenters specifically requesting a 90-day filing timeframe instead of the 60-day timeframe described in the draft guidance. Commenters noted that manufacturers may run analyses using their own data to verify information contained on invoices, and having additional time to file may reduce dispute volume. Some commenters requested that CMS specify a deadline for appeal decisions made by the CMS Administrator.

**Response:** After consideration of the comments received regarding the timeframe to file initial disputes, CMS declines to change the 60-day timeframe described in the draft guidance, which is consistent with the filing timeframe under the Coverage Gap Discount Program and with CMS policies for other Medicare appeal processes, including beneficiary and provider benefit appeals. In the interest of increased transparency, we are providing additional invoice data to participating manufacturers in the Discount Program which should increase their confidence in the process.

We appreciate the commenters' desire for administrative finality but decline to establish a decision-making timeframe for disputes subject to review by the CMS Administrator in [section 100.1.3](#). While the agency is committed to resolving disputes as expeditiously as possible, these disputes may involve consideration of a large amount of data, as noted by commenters. Many Part D administrative review processes established in [Part 423](#) that involve a decision by the CMS Administrator do not establish an adjudication timeframe. As it is the final level of administrative appeal, an appellant will not necessarily benefit from a faster decision if it comes at the expense of a more thorough review.

**Comment:** A few commenters objected to the requirement in [section 80.2.3](#) of the draft guidance that manufacturers cannot withhold payment for disputed amounts pending the outcome of the dispute. The commenters expressed a belief that limitations on the dispute



resolution process under the Coverage Gap Discount Program, including a requirement to pay the disputed invoice before CMS will accept a dispute, are too limiting and discourage manufacturers from filing disputes at all.

**Response:** We thank the commenters for their feedback; however, we disagree with the recommendation to eliminate the requirement that manufacturers must pay disputed amounts within the 38-day payment timeframe. While the guidance in [section 80.2.3](#) does provide an exception to the requirement to pay disputed amounts if the dispute relates to invoiced amounts for applicable drugs that do not have labeler codes covered by the manufacturer's agreement, it is essential that manufacturers make timely payments for all other invoiced amounts under the Discount Program. When the manufacturer receives the quarterly invoice, Part D sponsors have already advanced discounts at the POS on the manufacturer's behalf, subject to the pharmacy prompt payment requirements in [section 60.3](#) of this guidance. Under section 1860D-14C(b)(1)(A) of the Act and the Discount Program agreement, participating manufacturers must provide applicable discounts. While the payment due date comes sooner than the deadline by which to file an initial dispute, there is no requirement under the Coverage Gap Discount Program, nor will there be a requirement under the Discount Program, that manufacturers must pay invoices before they can submit a dispute.

**Comment:** One commenter requested that CMS provide guidance about how Part D sponsors should process enrollee appeals regarding claims where a discount is not applied.

**Response:** Because applicable discounts under the Discount Program do not count towards TrOOP and do not generally impact enrollee cost sharing, CMS does not expect that plans will receive coverage determinations or appeals from Part D enrollees specific to the Discount Program. The dispute resolution provision in section 1860D-14C(c)(1)(D) of the Act does not specify a dispute resolution process for enrollees. However, as noted in [section 100.3](#), any Part D enrollee who has a dispute about a plan's decision not to provide or pay for a Part D drug, including a dispute about whether a drug is excluded from Part D or about the amount of cost sharing, has the right to request a coverage determination from the plan and the right to appeal any coverage determination not fully favorable to the enrollee under the procedures specified in [Subpart M](#) of Part 423.

### ***Civil Money Penalties (CMPs)***

**Comment:** Some commenters requested that CMS provide an informal process prior to issuing a CMP notice, and to permit manufacturers to correct errors before pursuing CMPs. Commenters noted that once a CMP is assessed, any dispute must be addressed through a more burdensome hearing process. One commenter noted that the IRA requires manufacturers to comply with many new requirements within a short timeframe.

**Response:** CMS thanks these commenters for their input. Under the Coverage Gap Discount Program, we do have a process in place where a manufacturer that fails to pay invoiced amounts within the 38-day payment timeframe receives a Notice of Non-Compliance. If the manufacturer

cures the non-compliance and demonstrates that the non-compliance is due to a technical or other reason beyond the manufacturer's control, a CMP is generally not assessed. We will follow a similar process for the Discount Program, and have included additional information in [section 120.1](#) of this final guidance. As a reminder, section 1860D-14C(e)(1) of the Act establishes that a manufacturer that fails to provide discounted prices for its applicable drugs dispensed to applicable beneficiaries in accordance with the Discount Program agreement shall be subject to a CMP, and specifies the formula to determine the CMP amount. Under the Discount Program framework established in this final guidance, Part D sponsors advance applicable discounts at the POS on behalf of manufacturers, and it is essential that manufacturers, in turn, provide timely reimbursement.

### ***Other***

**Comment:** A commenter requested that CMS provide standardized Discount Program language that plans can use in enrollee communications materials to describe the phase-in provisions and how discounts vary based on incurred costs.

**Response:** We thank the commenter for this feedback and will take it into consideration as we develop 2025 enrollee communication materials.

### ***Out of Scope***

We received several comments related to the Negotiation Program, changes to LIS eligibility, Part D formulary design and utilization management, DIR fees, and beneficiary education about various aspects of the Part D redesign under the IRA, including the elimination of enrollee out-of-pocket spending in the catastrophic phase and the maximum monthly cap on cost-sharing payments. While we appreciate this feedback, these comments are outside the scope of this guidance and are not addressed in this memorandum.

## **B. Final Guidance**

### **10 – Introduction**

In accordance with section 1860D-14C of the Act, this guidance specifies the requirements for participating manufacturers and Part D plan sponsors under the Part D Manufacturer Discount Program that begins January 1, 2025. The table of contents for this final guidance is as follows:

[Section 10](#) – Introduction

[Section 20](#) – Background

[Section 30](#) – Sunsetting of Coverage Gap Discount Program

[Section 40](#) – Conditions for Coverage Under Part D

[40.1](#) – Applicable Drugs

[40.2](#) – Other Part D Drugs

- [40.3](#) – Exception to Conditions for Coverage Requirement
- [40.4](#) – Coverage Changes
- [Section 50](#) – Applicable Discounts
  - [50.1](#) – Phase-In of Applicable Discounts
    - [50.1.1](#) – Phase-In for Specified Manufacturers
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  - [60.1](#) – Point-of-Sale Discounts
    - [60.1.1](#) – Direct Member Reimbursement
    - [60.1.2](#) – Application of Discount Before Supplemental Coverage
    - [60.1.3](#) – Application of Discount Before Other Health Insurance
    - [60.1.4](#) – Application to Medicare as Secondary Payer (MSP) and Subrogation Claims
    - [60.1.5](#) – Retroactive Adjustments
  - [60.2](#) – Prescription Drug Event (PDE) Requirements
  - [60.3](#) – Pharmacy Prompt Payment
  - [60.4](#) – Prospective Payments to Part D Sponsors for Discount Program
  - [60.5](#) – Reconciliation of Prospective Discount Payments to Sponsors
- [Section 70](#) – Use of Third Party Administrator
- [Section 80](#) – Requirements for Participating Manufacturers
  - [80.1](#) – Part D Manufacturer Discount Program Agreement
    - [80.1.1](#) – Requirements of Agreement
    - [80.1.2](#) – Term and Renewal of Agreement
    - [80.1.3](#) – Termination of Agreement
      - [80.1.3.1](#) – Termination by CMS
      - [80.1.3.2](#) – Termination by the Manufacturer
      - [80.1.3.3](#) – Post-Termination Obligations
    - [80.1.4](#) – Reinstatement
  - [80.2](#) – Manufacturer Invoicing and Reimbursement of Part D Sponsors for Applicable Discounts
    - [80.2.1](#) – Manufacturer Invoices
    - [80.2.2](#) – Requirement to Pay Invoiced Amounts
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  - [80.4](#) – TPA Agreement and Access to the TPA Portal
  - [80.5](#) – Reporting and Maintenance of Required Information
    - [80.5.1](#) – Corporate Ownership

- [80.5.2](#) – Labeler Codes
      - [80.5.2.1](#) – Newly Assigned Labeler Codes
      - [80.5.2.2](#) – Transfer of Existing Labeler Codes Between Agreements
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    - [80.6.1](#) – Terminating Coverage for Active Labeler Codes
      - [80.6.1.1](#) – Active Labeler Code(s) Assigned by the FDA to a Primary Manufacturer Unwilling to Enter Into or Continue its Participation in the Negotiation Program
      - [80.6.1.2](#) – Active Labeler Code(s) of Any Other Manufacturer
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- [Section 90](#) – Audits
- [90.1](#) – Manufacturer Audits of TPA Data
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- [100.1](#) – Manufacturer Disputes
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  - [100.3](#) – Beneficiary Disputes
- [Section 110](#) – Compliance Monitoring
- [Section 120](#) – Civil Money Penalties
- [120.1](#) – Amount of CMP and Required Notice
  - [120.2](#) – CMP Appeals
  - [120.3](#) – Collection of CMPs Imposed by CMS
- [Section 130](#) – Definitions

The Coverage Gap Discount Program, established under section 1860D-14A of the Act, remains in place through December 31, 2024. Coverage Gap Discount Program requirements are codified in [Subpart W](#) of 42 CFR Part 423 and remain in place until the program sunsets, as described in [section 30](#).

While the new program is similar to the Coverage Gap Discount Program with respect to certain requirements and operational processes, and CMS is implementing it in a similar manner, the new program differs from the Coverage Gap Discount Program in several important ways. Unless otherwise specified, all references in this guidance 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 and the definitions and requirements set forth in this guidance.

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

## 20 – Background

Through December 31, 2024, the Coverage Gap Discount Program makes manufacturer discounts available at the POS to Part D enrollees receiving applicable drugs (as defined in [42 CFR § 423.100](#)) while in the coverage gap phase of the Part D benefit. Part D enrollees who are eligible for a low-income subsidy (LIS) under section 1860D-14 of the Act do not receive discounts under the Coverage Gap Discount Program. In general, the discount is 70 percent of the negotiated price (as defined at [42 CFR § 423.2305](#)) of the drug, and applies only to brand name drugs and biological products. Applicable drugs can be covered under Part D only if the participating manufacturer has a signed Coverage Gap Discount Program agreement with CMS to provide the discount on coverage gap claims for all of its applicable drugs and remains compliant with the terms of that agreement.<sup>4</sup> Under the Coverage Gap Discount Program, plan sponsors receive prospective payments from CMS to advance discounts to their enrollees at the POS. The prospective payments are based on plan bids and estimate the expected per member per month manufacturer discount amount. Sponsors report these discount amounts to CMS on prescription drug event (PDE) records, which CMS uses to calculate invoices for manufacturers. A third party administrator (TPA) facilitates discount payments from manufacturers and payment to sponsors through an automated clearing house (ACH) process.

The IRA makes significant changes to the current Part D benefit design. The IRA amends section 1860D-2(b)(4)(A)(i)(II) of the Act so that, beginning in 2024, enrollee cost sharing in the catastrophic phase is eliminated, and plan liability in the catastrophic phase increases from 15 to 20 percent for all covered Part D drugs, with plans continuing to receive an 80 percent federal reinsurance subsidy in 2024. Beginning in 2025, the IRA eliminates the coverage gap benefit phase, introduces manufacturer discounts in the initial and catastrophic coverage phases, changes plan liability in the initial coverage phase, lowers the annual cap on enrollee out-of-pocket costs, and changes plan and government reinsurance liability in the catastrophic phase.

Beginning in 2025, standard Part D prescription drug coverage will consist of a 3-phase benefit:

1. **Annual deductible.** The enrollee pays 100 percent of their gross covered prescription drug costs until the deductible (\$500+ in 2025<sup>5</sup>) is met.

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<sup>4</sup> CMS acknowledges the practice where a participating manufacturer may include labeler code(s) the Food and Drug Administration (FDA) assigned to another manufacturer under the participating manufacturer's Coverage Gap Discount Program agreement.

<sup>5</sup> Amount to be determined based on Annual Percentage Increase.

2. **Initial coverage.** The enrollee pays 25 percent coinsurance for covered Part D drugs. The sponsor typically<sup>6</sup> pays 65 percent for applicable drugs (see [section 130](#) of this guidance) and selected drugs (see [section 130](#) of this guidance)<sup>7</sup>, and 75 percent for non-applicable drugs (see [section 130](#) of this guidance). For applicable drugs, the manufacturer pays a discount through the Discount Program, typically 10 percent, and for selected drugs, CMS pays a 10 percent selected drug subsidy, up to the annual enrollee out-of-pocket threshold (\$2,000 for 2025).
3. **Catastrophic.** Enrollees pay no cost sharing. Plan sponsors typically pay 60 percent for all covered Part D drugs. CMS pays a 40 percent federal reinsurance subsidy for selected drugs and non-applicable drugs (see [section 130](#) of this guidance), and a 20 percent federal reinsurance subsidy for applicable drugs. Manufacturers pay a discount through the Discount Program, typically 20 percent, for applicable drugs.

Under the Discount Program, participating manufacturers are required to provide discounts on their applicable drugs (as described in [section 40.1](#) of this guidance) both in the initial and catastrophic coverage phases of the Part D benefit. There is no manufacturer discount provided during the deductible phase.

Because the administrative requirements of the Discount Program largely mirror those for the Coverage Gap Discount Program, CMS is implementing the program in a similar manner, with some operational enhancements based on stakeholder feedback and extensive program experience, as discussed in this guidance.

### **30 – Sunsetting of Coverage Gap Discount Program**

The IRA adds subsection (h) to section 1860D-14A of the Act, which sunsets the Coverage Gap Discount Program as of January 1, 2025. It also terminates all Coverage Gap Discount Program Agreements as of January 1, 2025, but stipulates that all responsibilities and duties under such agreements continue to apply with respect to applicable drugs under the Coverage Gap Discount Program dispensed prior to January 1, 2025.

### **40 – Conditions for Coverage Under Part D**

Beginning January 1, 2025, Part D coverage for applicable drugs is available only for applicable drugs for which the labeler code is covered by a Discount Program agreement with CMS, as described in section 1860D-14C(b) of the Act.

Any Part D drug that is a selected drug (see [section 130](#) of this guidance) during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug, is excluded from the definition of applicable drug under section 1860D-14C(g)(2)(B) of the Act

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<sup>6</sup> 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 this guidance.

<sup>7</sup> Price applicability periods for selected drugs, as described in section 1191 of the Act, do not begin until 2026.



and, therefore, not subject to applicable discounts under the Discount Program when dispensed during a price applicability period; however, consistent with the policy on applicable drugs, beginning January 1, 2025, Part D coverage for selected drugs during a price applicability period is also available only for selected drugs for which the labeler code is covered by a Discount Program agreement with CMS, as described in section 1860D-14C(b) of the Act.

More specifically, in order for an applicable drug or a selected drug during a price applicability period to be covered under Part D beginning January 1, 2025, and as discussed in more detail in [section 80](#) of this guidance, the FDA-assigned labeler code of such applicable drug or selected drug must be covered under a Discount Program agreement that is fully executed and in effect. We acknowledge that certain labeler codes of applicable drugs under the Coverage Gap Discount Program are covered by a Coverage Gap Discount Program agreement with a participating manufacturer that is not the manufacturer the labeler code is assigned to by the FDA, and that this practice may continue under the Discount Program at this time. As discussed in [section 40.2](#), Part D coverage may be available for non-applicable drugs that otherwise meet the definition of a covered Part D drug, regardless of whether the labeler code of such drug is covered by a Discount Program agreement.

Each participating manufacturer is required to submit a complete list of the labeler codes of applicable drugs and selected drugs covered by its Discount Program agreement. (See [section 80.1](#) of this guidance for more information about Discount Program agreement requirements.) The labeler code is the segment of a drug product's national drug code (NDC) that identifies the manufacturer.

CMS will maintain a list of all participating manufacturers as well as all labeler codes that are covered by Discount Program agreements, updated on a monthly basis. We will distribute the list to Part D sponsors and post it on the CMS website. CMS expects to make public a January 2025 labeler code list in Spring 2024, with updates provided by August 2024. We are assessing the circumstances in which Part D sponsors and others may seek NDC-level coverage information and anticipate addressing this issue through future program instruction or guidance.

#### ***40.1 – Applicable Drugs***

Consistent with section 1860D-14C(g)(2) of the Act, applicable drugs under the Discount Program are 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), but do not include a selected drug during a price applicability period with respect to such drug.<sup>8</sup> Drugs excluded from Part D under

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<sup>8</sup> 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. Likewise, regardless of whether the product is marketed under a trade name and/or is generally thought of as a brand name product, a Part D drug will not be considered an applicable drug

section 1860D-2(e)(2)(A) of the Act are not Part D drugs and, therefore, are not applicable drugs subject to the requirements of the Discount Program, even if covered by the plan under an enhanced benefit.

**Part D Compounds.** Consistent with CMS policy under the Coverage Gap Discount Program, we interpret the definition of an applicable drug for purposes of the Discount Program to exclude Part D compounds. While plans may cover compounds that contain at least one Part D ingredient, and that ingredient would be an applicable drug if dispensed on its own, we believe that the applicable drug determination must be made with respect to the compound as a whole. Because the compound as a whole is not approved under an NDA or BLA, a compound does not meet the definition of an applicable drug.

#### ***40.2 - Other Part D Drugs***

Consistent with our prior interpretation of section 1860D-43(a) of the Act, for purposes of the Discount Program, the exclusion from Part D coverage will apply only to the applicable drugs and selected drugs whose labeler code(s) are not covered by a Discount Program agreement that is fully executed and in effect. Non-applicable drugs (see [section 130](#) of this guidance) of a manufacturer will continue to be coverable under Part D regardless of the manufacturer's participation in the Discount Program. With regard to the Coverage Gap Discount Program, we have previously explained our interpretation that the conditions for coverage described in section 1860D-43(a) must be read together with section 1860D-14A's provision for Part D coverage of non-applicable drugs under certain circumstances in the absence of a Coverage Gap Discount Program agreement ([77 FR 22072, 22082](#)). Congress was aware of this interpretation and ratified it by adopting parallel language for the new Discount Program. Accordingly, for the same reasons described in our prior rulemaking, we adopt the same interpretation here with regard to the parallel provisions of section 1860D-14C, and we read the Act to provide that non-applicable drugs will continue to be coverable under Part D whether or not the manufacturer participates in the Discount Program.

#### ***40.3 – Exception to Conditions for Coverage Requirement***

Consistent with section 1860D-43(c)(1)(A) of the Act, an applicable drug of a manufacturer that has not entered into a Discount Program agreement under section 1860D-14C(b) of the Act is not excluded from Part D coverage if CMS has made a determination that the availability of the applicable drug is essential to the health of Part D enrollees. As specified in section 1860D-43(c)(2) of the Act, this exception to the exclusion from Part D coverage does not apply to any applicable drugs or selected drugs of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to such manufacturer.

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unless it meets the definition of section 1860D-14C(g)(2) of the Act, including the requirement that it is approved under an NDA or is licensed under section 351 of the PHSA.

#### **40.4 – Coverage Changes**

Part D sponsors removing a drug from a formulary must provide notice, consistent with the requirements at [42 CFR § 423.120](#), to affected enrollees (as defined in [42 CFR § 423.100](#)) and others if an applicable drug or selected drug will no longer be covered because the drug is no longer covered by a Discount Program agreement. In addition, because applicable drugs and selected drugs that are not covered by a Discount Program agreement cannot be covered under Part D (unless subject to the exception described in [section 40.3](#) of this memorandum), sponsors cannot cover such products under exceptions, emergency first fill, or transition policies.

As specified in [section 80](#) of this guidance, in limited circumstances, coverage changes may also be triggered by the actions of CMS or manufacturers.

#### **50 – Applicable Discounts**

Under the Discount Program, once an enrollee incurs costs exceeding the annual deductible specified in section 1860D-2(b)(1) of the Act, that is, the deductible under the defined standard benefit, manufacturer discounts are available in both the initial coverage and catastrophic phases of the benefit. The applicable discount lowers Part D sponsor liability on the negotiated price of the drug. For the purposes of the Discount Program, “applicable discount” means, subject to the phase-ins described in [section 50.1](#) and the straddle claims policy described in [section 50.3](#), with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary (as described in [section 130](#)):

- Who has not incurred costs, as determined in accordance with section 1860D-2(b)(4)(C) of the Act, for Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B)(i) of the Act for the year, 10 percent of the negotiated price of such drug; and
- Who has incurred costs, as determined in accordance with section 1860D-2(b)(4)(C) of the Act, for Part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B)(i) of the Act for the year, 20 percent of the negotiated price of such drug.

Unlike under the Coverage Gap Discount Program, manufacturer discounts under the new program are available regardless of whether the Part D enrollee is entitled to an LIS subsidy, and discounts do not count toward the enrollee’s incurred costs. The applicable discount is not available until the enrollee has incurred costs exceeding the annual deductible specified in section 1860D-2(b)(1) of the Act, regardless of whether the enrollee has to pay a deductible (for example, through eligibility for an income-related subsidy or enrollment in an enhanced benefit plan with a reduced or no deductible, or for a drug that is not subject to the deductible, such as a covered insulin product or an Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccine). Because the applicable discount and enrollee cost sharing are both calculated based on the negotiated price of the drug, as described in [section 130](#) of this guidance,

the applicable discount will not affect the application of the standard 25 percent coinsurance under section 1860D-2(b)(2)(A) of the Act or the application of the copayment amount under section 1860D-2(b)(4)(A) of the Act unless, after the discount is applied to the negotiated price of the drug, the enrollee cost sharing would exceed the discounted price. In such a situation, the enrollee will pay the lesser of the discounted price or the enrollee cost sharing specified under the plan.

### ***50.1 – Phase-In of Applicable Discounts***

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. Under section 1860D-14C(g)(4) of the Act, there are two such phase-ins: one for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for LIS under section 1860D-14(a) of the Act and one for certain applicable drugs of specified small manufacturers dispensed to all applicable beneficiaries. Each of these phase-ins is discussed in this section.

For purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers that are subject to phase-ins as discussed in this section, CMS interprets the reference to a drug that “is marketed as of the date of enactment [August 16, 2022]” in sections 1860D-14C(g)(4)(B)(i) and 1860D-14C(g)(4)(C)(i) of the Act, to refer to a drug that was marketed by the manufacturer on one specific, backward-looking date, i.e., the date of enactment of the IRA. Accordingly, for purposes of identifying applicable drugs of specified manufacturers and specified small manufacturers subject to phase-ins, CMS will determine whether an applicable drug had Part D expenditures on or before August 16, 2022, and did not have a marketing end date on the FDA NDC SPL Data Elements File before August 17, 2022.

As discussed in [sections 50.1.1](#) and [50.1.2](#), the IRA establishes lower percentages for discounts on applicable drugs that are subject to these phase-ins. Since the discount reduces the plan liability for applicable drugs, Part D sponsors are responsible for covering the remaining amount of the negotiated price, less enrollee cost sharing, for applicable drugs subject to a phased-in discount percentage as discussed in this section. For example, the applicable discount for applicable drugs in the initial coverage phase is 10 percent. In 2025, the applicable LIS percent (see [section 50.1.1](#)) for a specified drug dispensed to an LIS enrollee during the initial coverage phase is 1 percent. In a defined standard plan, the plan liability in the initial coverage phase is 75 percent of the negotiated price before the discount. With a 10 percent applicable discount, the plan liability would be reduced to 65 percent of the negotiated price. With a 1 percent applicable LIS percent in 2025, the plan liability would be reduced to 74 percent of the negotiated price.

Section 1860D-14C(b)(1)(A) of the Act specifies that a Discount Program agreement shall require the participating manufacturer to provide discounted prices for their applicable drugs when dispensed to applicable beneficiaries. As part of the statutory definition of discounted price at section 1860D-14C(g)(4) of the Act, the discount paid by specified manufacturers for specified drugs dispensed to applicable beneficiaries who are eligible for LIS, referred to in the

statute as the “specified LIS percent,” is defined in section 1860D-14C(g)(4)(B) of the Act (see [section 50.1.1](#)). The discount paid by specified small manufacturers for specified drugs dispensed to all applicable beneficiaries, referred to in the statute as the “specified small manufacturer percent,” is defined in section 1860D-14C(g)(4)(C) of the Act (see [section 50.1.2](#)). These provisions, which also set forth the criteria by which specified manufacturers and specified small manufacturers are defined, require such manufacturers to pay, when applicable, the phased-in discount. The IRA does not provide a mechanism by which CMS could permit specified manufacturers or specified small manufacturers to “opt out” of the phase-in discounts.

Detailed information about how CMS will identify specified manufacturers, specified small manufacturers, as well as their specified drugs and specified small manufacturer drugs, eligible for phase-ins; the opportunity for manufacturers to obtain preliminary, non-binding information about their eligibility for phase-ins; and the process for manufacturers to request recalculations of their phase-in eligibility determinations, is included in [section 50.2](#) of this guidance.

### *50.1.1 – Phase-In for Specified Manufacturers*

#### Applicable LIS Percent

Under section 1860D-14C(g)(4)(B) of the Act, for an applicable drug of a specified manufacturer (as defined below) that is marketed as of August 16, 2022 and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D-14(a)(3) of the Act), the applicable discount is as follows:

- For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—
  - For 2025, 1 percent;
  - For 2026, 2 percent;
  - For 2027, 5 percent;
  - For 2028, 8 percent; and
  - For 2029 and each subsequent year, 10 percent; and
- For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—
  - For 2025, 1 percent;
  - For 2026, 2 percent;
  - For 2027, 5 percent;
  - For 2028, 8 percent;
  - For 2029, 10 percent;
  - For 2030, 15 percent; and
  - For 2031 and each subsequent year, 20 percent.

### Specified Manufacturer

Pursuant to section 1860D-14C(g)(4)(B)(ii) of the Act, a specified manufacturer is a manufacturer of an applicable drug that, in 2021 had:

- A Coverage Gap Discount Program agreement in effect;<sup>9</sup>
- Total expenditures for all of its specified drugs (as defined in [section 130](#) of this guidance) covered by such Coverage Gap Discount Program agreement(s) for 2021 and covered under Part D in 2021 represented less than 1.0 percent of total expenditures for all Part D drugs in 2021; and
- Total expenditures for all of its specified drugs that are single source drugs and biological products for which payment may be made under Part B in 2021 represented less than 1.0 percent of the total expenditures under Part B for all drugs or biological products in 2021.

Pursuant to the aggregation rule set forth in section 1860D-14C(g)(4)(B)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section.

Any manufacturer that otherwise meets the definition of a specified manufacturer that is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer (i.e., the specified manufacturer becomes part of such acquiring manufacturer) is not included in the definition of specified manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

#### *50.1.2 – Phase-In for Specified Small Manufacturers*

### Applicable Small Manufacturer Percent

Under section 1860D-14C(g)(4)(C) of the Act, for an applicable drug of a specified small manufacturer, as defined below, that is marketed as of August 16, 2022 and dispensed for an applicable beneficiary, the applicable discount is as follows:

- For such individual who has not incurred costs equal to or exceeding the annual out-of-pocket threshold for the year—
  - For 2025, 1 percent;
  - For 2026, 2 percent;
  - For 2027, 5 percent;
  - For 2028, 8 percent; and
  - For 2029 and each subsequent year, 10 percent; and

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<sup>9</sup> A manufacturer that participated in the Coverage Gap Discount Program in 2021 by means of an arrangement whereby its labeler code(s) were listed on another manufacturer's Coverage Gap Discount Program agreement would be considered to have had an agreement in effect during 2021. See November 17, 2023 HPMS memorandum entitled, "Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers" for more information.



- For such individual who has incurred costs equal to or exceeding the annual out-of-pocket threshold for the year–
  - For 2025, 1 percent;
  - For 2026, 2 percent;
  - For 2027, 5 percent;
  - For 2028, 8 percent;
  - For 2029, 10 percent;
  - For 2030, 15 percent; and
  - For 2031 and each subsequent year, 20 percent.

### Specified Small Manufacturer

Pursuant to section 1860D-14C(g)(4)(C)(ii) of the Act, a specified small manufacturer is a manufacturer of an applicable drug that, in 2021:

- Is a specified manufacturer as described in [section 50.1.1](#) of this guidance; and
- The total expenditures under Part D for any one of its specified small manufacturer drugs (as described in [section 130](#) of this guidance) covered under a Coverage Gap Discount Program agreement(s) for 2021 and covered under Part D in 2021 are equal to or greater than 80 percent of the total expenditures for all its specified small manufacturer drugs covered under Part D in 2021.

Pursuant to the aggregation rule set forth in section 1860D-14C(g)(4)(C)(ii)(II)(bb) of the Act, all entities, including corporations, partnerships, proprietorships, and other entities treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 are treated as one manufacturer for purposes of this section.

Any manufacturer that otherwise meets the definition of a specified small manufacturer that is acquired after 2021 by another manufacturer that does not meet the definition of a specified small manufacturer (i.e., the specified small manufacturer becomes part of such acquiring manufacturer) is not included in the definition of specified small manufacturer, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

### ***50.2 – Determination of Phase-In Eligibility***

CMS will identify which manufacturers qualify for these phase-ins by analyzing Medicare Part B claims data, Part D PDE data, and ownership information submitted by manufacturers. All manufacturers that sign a Discount Program agreement in time to participate in any year of the phase-in will be considered, and do not need to submit a separate application.

A detailed description of the methodology CMS will use to identify manufacturers eligible for phase-ins is provided in the November 17, 2023 HPMS memorandum entitled “Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and

Specified Small Manufacturers”. Included in the methodology is a description of the data sources and calculations CMS will use for determining each manufacturer’s eligibility for the two Discount Program phase-ins.

For purposes of identifying manufacturers eligible for phase-ins, the aggregation rule at section 1860D-14C(g)(4)(B)(ii)(II)(bb) of the Act for specified manufacturers and section 1860D-14C(g)(4)(C)(ii)(II)(bb) of the Act for specified small manufacturers requires that CMS treat as a single manufacturer all entities that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, and requires that manufacturers provide and attest to necessary information as specified by CMS. Because CMS does not have information about which entities are treated as a single employer under the Internal Revenue Code, manufacturers that wish to participate in the Discount Program must submit information about the company and its products in order for CMS to make a determination about phase-in eligibility. The required information must be submitted through HPMS (see [sections 80.3](#) and [80.5.1](#) of this guidance for more information).

Additional operational instructions related to the submission of required ownership information in HPMS can be found in the November 17, 2023 HPMS memorandum entitled “Instructions for Submitting Required Ownership Information for the Medicare Part D Manufacturer Discount Program; Opportunity to Receive Preliminary Information About Status as a Specified Manufacturer and Specified Small Manufacturer for 2025”.

To assist Part D sponsors in accurately calculating applicable discounts, CMS will publish additional guidance to assist sponsors with identifying NDCs that are eligible for the phase-ins after agreements are executed in Spring 2024.

#### *50.2.1 – Special Opportunity to Receive Preliminary Information About Phase-In Eligibility Prior to Execution of Discount Program Agreement for 2025*

For the first year of the Discount Program, CMS will provide manufacturers that submit and attest to all required ownership information by December 8, 2023, without executing a Discount Program agreement, with preliminary, non-binding information regarding their eligibility for the Discount Program phase-ins. This information will be provided in January 2024 to the primary contact identified in HPMS for each manufacturer that submits and attests to the required ownership information by the deadline.

**Important Note:** Because the statute requires the actual determination about phase-in eligibility be made in connection with a fully executed Discount Program agreement, the preliminary, non-binding information CMS will provide to manufacturers that submit and attest to all required ownership information by the December 8, 2023 deadline, but do not execute the Discount Program agreement, regarding their phase-in eligibility does not constitute an eligibility determination by CMS and, therefore, is not subject to the recalculation process described in [section 50.2.2](#). CMS will notify manufacturers whose drugs are covered by an executed Discount Program agreement of their eligibility determinations after the statutory deadline of March 1,

2024 to enter a Discount Program agreement for 2025. Manufacturers may avail themselves of the recalculation process described in [section 50.2.2](#) only after they have received such eligibility determinations through HPMS.

### *50.2.2 – Recalculation of Phase-In Eligibility Determinations*

While the requirements to qualify as a specified manufacturer or specified small manufacturer are set forth in statute, we recognize that, while unlikely, a manufacturer may wish to raise concerns with the outcome of the application of those statutory requirements. As such, CMS will provide a mechanism for manufacturers that wish to request a recalculation of their phase-in eligibility determination. Such requests can only be filed by the manufacturer that received the determination.

**Timeframe and Method of Filing.** A manufacturer that seeks a recalculation of their phase-in eligibility determination must file the request with CMS no later than 30 calendar days from the date the eligibility determination is electronically sent to the manufacturer by sending an email with the subject line “Phase-In Eligibility Recalculation Request” to [PartDManufacturerDiscountProgram@cms.hhs.gov](mailto:PartDManufacturerDiscountProgram@cms.hhs.gov). The email request must clearly identify the P Number(s) and labeler code(s) relevant to the request, describe the issue(s) forming the basis of the request for recalculation, and include or describe any relevant supporting information.

**Disposition and Notification.** After consideration of the issues raised, CMS will decide whether to perform the recalculation, and will issue a written decision to the manufacturer, delivered by email to the primary contact listed in HPMS, that will include CMS’ decision about whether to perform the requested recalculation and, if such recalculation is performed, the resulting eligibility determination. The decision is final and binding, subject to the requirements of the Discount Program under section 1860D-14C of the Act, this guidance, and the Discount Program agreement.

### *50.3 – Straddle Claims*

In the case of a claim for an applicable drug for an applicable beneficiary that “straddles” multiple phases of the benefit, section 1860D-14C(g)(4)(E) of the Act requires that:

- For claims that do not fall entirely above the annual deductible specified in section 1860D-2(b)(1) of the Act, the manufacturer provides the applicable discount on only the portion of the negotiated price that falls above the deductible; and
- For claims that do not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B)(i) of the Act, the manufacturer provides the applicable discount on each portion of the negotiated price in accordance with this section based on the benefit phase into which each portion of the negotiated price falls.

## **60 – Point-of-Sale Discounts and Payment Processes for Part D Sponsors**

### ***60.1 – Point-of-Sale Discounts***

Under the Discount Program, CMS will require Part D sponsors to provide applicable discounts on applicable drugs at the POS, as currently required under [42 CFR § 423.2325\(a\)](#) for the Coverage Gap Discount Program. Provision of applicable discounts at the POS aligns with the successful process already in place under the Coverage Gap Discount Program. We believe adopting requirements that parallel ones that have been in place since 2011, to which stakeholders are accustomed, coupled with prospective payments to sponsors and the payment reconciliation process discussed below, will minimize burden on plan sponsors, manufacturers, pharmacies, and Part D enrollees.

As part of this process, plan sponsors must determine whether an enrollee is an applicable beneficiary (as described in [section 130](#) of this guidance) and where the enrollee falls in the phases of the Part D benefit based on their gross drug spend and incurred costs at the time an applicable drug is dispensed; whether a drug is an applicable drug (as discussed in [section 40.1](#) of this guidance); whether the applicable beneficiary is LIS eligible; the plan's negotiated price for the drug; and whether the drug is on the plan's formulary or the enrollee has obtained an exception for a non-formulary drug.

#### ***60.1.1 – Direct Member Reimbursement***

Part D sponsors must provide applicable discounts on claims for applicable drugs submitted by applicable beneficiaries as direct member reimbursements (DMRs), including out-of-network and in-network paper claims, if such claims are payable under the Part D plan. While the sponsor must account for the discount in adjudicating the DMR request and the associated PDE submitted to CMS, the POS requirement does not apply.

For purposes of discounting DMR claims for prescriptions filled at out-of-network pharmacies, the negotiated price means the plan allowance as set forth in [42 CFR § 423.124](#). CMS guidance related to DMR processing can be found in Chapter 14, section 50.4.3, of the [Medicare Prescription Drug Benefit Manual](#).<sup>10</sup>

#### ***60.1.2 – Application of Discount Before Supplemental Coverage***

For Part D plans offering supplemental benefits (as defined in [42 CFR § 423.100](#)), including PACE organizations, the value of any applicable discount under the Discount Program is calculated before the application of supplemental benefits.

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<sup>10</sup> <https://www.cms.gov/medicare/enrollment-renewal/part-d-prescribers/prescription-drug-benefit-manual>

### *60.1.3 – Application of Discount Before Other Health Insurance*

In accordance with section 1860D-14C(c)(1)(C) of the Act, the applicable discount for an applicable drug is applied before any coverage or financial assistance under another health or prescription drug benefit plan or program that provides coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries, e.g., State Pharmaceutical Assistance Programs, Indian Health Service (IHS), and Platino plans.

### *60.1.4 – Application to Medicare as Secondary Payer (MSP) and Subrogation Claims*

Medicare as Secondary Payer (MSP) claims are excluded from the Discount Program because CMS is unable to definitively ascertain from the PDE how much liability, if any, the Part D sponsor has on such claims. Medicaid and IHS subrogation claims are handled through the payment reconciliation process, not as claims paid under the standard benefit, and are excluded from the Discount Program.

### *60.1.5 – Retroactive Adjustments*

Part D sponsors must make retroactive adjustments to applicable discounts as necessary to reflect changes to the claim, beneficiary eligibility, or benefit phase determined after the date of service.

## **60.2 – Prescription Drug Event (PDE) Requirements**

Part D sponsors are required to report the applicable discounts made available to their enrollees under the Discount Program on the PDE records associated with such discounts. This information will be used for the cost-based reconciliation of prospective Discount Program payments made to each sponsor (discussed in [section 60.5](#)), and to invoice participating manufacturers for reimbursement of the amount advanced on their behalf by the Part D sponsor at the POS. CMS is reviewing the current PDE data fields and will provide additional guidance on how plans will report the Discount Program applicable discounts.

## **60.3 – Pharmacy Prompt Payment**

Pursuant to section 1860D-14C(c)(1)(B) of the Act, and consistent with CMS pharmacy prompt payment requirements at [42 CFR § 423.520](#), Part D sponsors must reimburse a network pharmacy the amount of the applicable discount no later than the applicable number of calendar days, as defined in [section 130](#), after the date of service of an applicable drug. For long-term care and home infusion pharmacies, the date of service can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

## **60.4 – Prospective Payments to Part D Sponsors for Discount Program**

To ensure that Part D sponsors have the funds available to advance applicable discounts at the POS and to reimburse network pharmacies within the required timeframe (see [section 60.3](#)), CMS will provide monthly prospective Discount Program payments to sponsors. As with the Coverage Gap Discount Program, CMS will calculate these prospective payments based on the projections in each plan's bid and current enrollment. CMS will continue to estimate the per member per month cost of the manufacturer discounts for each plan based on a percentage of the cost assumptions submitted with plan bids under [42 CFR § 423.265](#) and negotiated and approved under [42 CFR § 423.272](#), adjusted as necessary to account for applicable drug costs for applicable beneficiaries.

Each month, CMS will determine the prospective Discount Program payment by multiplying the plan specific manufacturer discount estimate by the number of beneficiaries enrolled in the plan. Part D sponsors will receive the prospective Discount Program payments on the first of each month with their other Part D prospective payments. The Discount Program payments will be reflected as a separate line item on each Part D sponsor's Monthly Membership Detail Reports and included in the Part D payments displayed on the Monthly Membership Summary Reports.

CMS will make the prospective Discount Program payment available to Part D sponsors in order for sponsors to advance manufacturer discounts at the POS. When manufacturers pay their quarterly invoices, sponsors have a duplicate payment from two sources, the participating manufacturer and CMS, for the same expense. After receiving payment from the manufacturer, the Part D sponsor no longer needs the cash flow advance from the prospective Discount Program payment. Therefore, CMS will offset the monthly prospective Discount Program payment, with the offset amount being equal to the total manufacturer discount amount received by the Part D sponsor from the manufacturer in the previous quarter.

***Note regarding Employer Group Waiver Plans (EGWPs):*** EGWPs do not submit Part D bids; therefore, CMS will not have the information necessary to estimate the cost of applicable discounts for these plans, and will not provide prospective Discount Program payments to EGWPs. However, participating manufacturers are required to make discounts available to applicable beneficiaries who are enrolled in an EGWP, and those discounts will be invoiced to the manufacturer for reimbursement to the EGWP through the standard invoicing process described in [section 80.2](#) of this guidance.

### ***60.5 – Reconciliation of Prospective Discount Payments to Sponsors***

Because the prospective discount payments are estimates, Part D sponsors may incur actual Discount Program costs that are greater or less than the prospective payments. CMS will perform a cost-based reconciliation to ensure that Part D sponsors are paid for manufacturer discount amounts as reported on invoiced PDE data submitted for Part D payment reconciliation. This process will occur after Part D payment reconciliation. The purpose of the Discount Program reconciliation is to make Part D sponsors whole for the manufacturer discount amounts they advanced on behalf of the manufacturer. In general, CMS will calculate the discount reconciliation amount by subtracting the prospective discount payments from manufacturer



discount amounts as reported by Part D sponsors on PDE data and invoiced to manufacturers. If the difference is positive, CMS will pay the difference to Part D sponsors. If the prospective discount payments exceed the invoiced manufacturer discount amounts, CMS will recover the difference from Part D sponsors. Manufacturer discount amounts reported on invoiced PDE data submitted by the PDE submission deadline for Part D payment reconciliation are included in the Discount Program reconciliation.

Any manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for Part D payment reconciliation for a plan year will not be subject to the Discount Program reconciliation process described above for that plan year.

**Manufacturer Bankruptcy.** As is currently required under [42 CFR § 423.2320\(c\)](#) for the Coverage Gap Discount Program, in the event that a participating manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, does not pay the quarterly invoices described in [section 80.2](#) of this guidance, CMS will adjust the Discount Program reconciliation amount of each affected Part D sponsor to account for the total unpaid quarterly invoiced amount owed to each Part D sponsor for the contract year being reconciled. See the note in [section 80.2.3](#) of this guidance related to collection of unpaid Discount Program invoices as a result of manufacturer bankruptcy.

## **70 – Use of Third Party Administrator**

Unlike the Coverage Gap Discount Program, section 1860D-14C of the Act does not require CMS to engage a third party administrator (TPA) under the new Discount Program. However, section 1860D-14C(d)(2) of the Act prohibits CMS from receiving or distributing any funds of a manufacturer under the Discount Program. Because of this limitation, under our authority at section 1860D-14C(d)(1) of the Act, CMS will engage a TPA to facilitate program operations for the new program in a similar manner as is currently done for the Coverage Gap Discount Program. In addition to the Discount Program Agreement described in [section 80.1](#) of this guidance, participating manufacturers will also be required to enter into an agreement directly with the TPA in order to participate in the Discount Program and access the Discount Program Payment Portal.

The TPA for the Coverage Gap Discount Program, a CMS contractor, is an accredited Automated Clearing House (ACH) vendor that uses PDE data to invoice participating manufacturers and plan sponsors, process ACH transactions, and report ACH activity to CMS. To minimize burden on all parties and ensure a smooth transition to the new program, CMS intends to leverage the existing Coverage Gap Discount Program TPA arrangement for purposes of the Discount Program.

## **80 – Requirements for Participating Manufacturers**

Participating manufacturers, that is, manufacturers that choose to sign a Discount Program agreement, must comply with all of the requirements described in this guidance. Similar to CMS

policy under the Coverage Gap Discount Program, a participating manufacturer in the Discount Program must cover by its Discount Program agreement all labeler codes assigned by the FDA to the manufacturer that contain NDCs for the manufacturer's applicable drugs and selected drugs.

CMS does not currently prohibit a participating manufacturer from covering by its Discount Program agreement labeler code(s) assigned by the FDA to another manufacturer, provided the other manufacturer does not sign its own Discount Program agreement.

The participating manufacturer that signs the Discount Program agreement by which a given labeler code is covered is responsible for paying all discounts invoiced for NDCs of applicable drugs under that labeler code, regardless of which entity is the FDA-assigned holder of the labeler code or which entity holds the NDA or BLA associated with those NDCs.

### ***80.1 – Part D Manufacturer Discount Program Agreement***

Section 1860D-14C(a) of the Act requires CMS to enter into Part D Manufacturer Discount Program agreements with manufacturers under the Discount Program. Participating manufacturers must comply with all requirements set forth in sections 1860D-14C and 1860D-43 of the Act, any other applicable laws, and any applicable regulations and guidance.

Section 1860D-14A(b)(4)(B)(i) of the Act gives CMS authority to terminate an agreement under the Coverage Gap Discount Program for a knowing and willful violation of the requirements of such agreement or other good cause shown. Section 1860D-14C(b)(4)(B)(i) of the Act gives CMS the same authority to terminate an agreement under the Discount Program. Given the high degree of program similarity and overlap during the transition from the Coverage Gap Discount Program, and consistent with our authority in section 1860D-14C(d)(1) of the Act to implement the Discount Program, we interpret these provisions, taken together, to provide CMS with authority to, at its discretion, refuse to enter into a Discount Program agreement with any manufacturer that had a Coverage Gap Discount Program agreement terminated under [42 CFR § 423.2345\(a\)\(1\)](#).

#### ***80.1.1 – Requirements of Agreement***

Pursuant to section 1860D-14C(b) of the Act, the Discount Program agreement at a minimum requires each participating manufacturer to:

- Reimburse, within the required 38-day timeframe, all applicable discounts provided by Part D sponsors on behalf of the manufacturer to applicable beneficiaries for applicable drugs dispensed on or after January 1, 2025 that have an NDC with a labeler code that the manufacturer has provided to CMS, is covered by its agreement, and invoiced to the manufacturer.
- Provide CMS with all labeler codes covered by its agreement.
- Ensure that the labeler codes that the participating manufacturer provides to CMS include, at a minimum, all labeler codes assigned by the FDA to the manufacturer that

contain NDCs for any of the manufacturer's applicable drugs or selected drugs, and promptly update CMS with any new labeler codes assigned to the manufacturer by the FDA that contain NDCs for any of the manufacturer's applicable drugs or selected drugs no later than 3 business days after learning of a new labeler code assigned by the FDA to the manufacturer.

- Comply with the requirements imposed by CMS for purposes of administering the Discount Program and monitoring compliance with such program, including providing the manufacturer's Employer Identification Number (EIN) and other identifying information to CMS upon request.
- Collect, have available, and maintain appropriate data related to the labeler codes covered by its agreement and any other data CMS determines necessary to carry out the Discount Program and demonstrate compliance with its requirements.
- Ensure that all electronic FDA listings for all NDCs for applicable drugs and selected drugs with labeler codes covered by its agreement are up to date, including providing information about discontinued drugs.
- Ensure that all NDC listings with the electronic database vendors to which NDCs are provided for pharmacy claims processing of all NDCs for applicable drugs and selected drugs with labeler codes covered by its agreement are up to date.
- Comply with all other requirements of the Discount Program.

#### *80.1.2 – Term and Renewal of Agreement*

Consistent with section 1860D-14C(b)(4)(A) of the Act, Discount Program agreements described in this section will be valid for an initial term of not less than 12 months, and will automatically renew for a period of 1 year on each subsequent January 1, except as described below, unless terminated as described in this section.

Under section 1860D-14C(b)(1)(C)(i) of the Act, for calendar year 2025, a participating manufacturer must enter into the agreement no later than March 1, 2024 to participate in the Discount Program in 2025. The initial 12-month term begins on January 1, 2025 and ends on December 31, 2025. Manufacturers wishing to participate in 2025 should be aware that, if they do not enter into a Discount Program agreement by the March 1, 2024 deadline, they will not be able to sign an agreement with an effective date prior to January 1, 2026 because of this statutory requirement.

For calendar year 2026 and subsequent years, an agreement will become effective on the first day of a calendar quarter. A participating manufacturer must enter into the agreement no later than the last day of the first month of a calendar quarter in order for the term to begin on the first day of the next calendar quarter. If a manufacturer enters into the agreement after the last day of the first month of a particular calendar quarter, the initial term will begin on the first day of the second calendar quarter after the calendar quarter in which the manufacturer entered into the agreement.

An initial term that begins on January 1 will end on December 31 of the same calendar year. An initial term that begins on April 1, July 1, or October 1 will end on December 31 of the following calendar year.

The following examples illustrate these requirements:

- Manufacturer enters agreement on March 1, 2024; Agreement is effective on January 1, 2025 and initial term ends on December 31, 2025.
- Manufacturer enters agreement on March 2, 2024; Agreement is effective on January 1, 2026 and initial term ends on December 31, 2026.
- Manufacturer enters agreement on October 31, 2025; Agreement is effective on January 1, 2026 and the initial term ends on December 31, 2026.
- Manufacturer enters agreement on November 1, 2025; Agreement is effective on April 1, 2026 and the initial term ends on December 31, 2027.

### *80.1.3 – Termination of Agreement*

#### 80.1.3.1 – Termination by CMS

Pursuant to section 1860D-14C(b)(4)(B)(i) of the Act, CMS may terminate a Discount Program agreement for a knowing and willful violation of the requirements of the agreement or other good cause shown in relation to a manufacturer's participation in the Discount Program. Consistent with the discussion in [section 80.1](#) of this guidance, CMS may also terminate a Discount Program agreement of a manufacturer whose Coverage Gap Discount Program agreement is terminated for a knowing and willful violation of the requirements of such agreement or other good cause shown as specified at [42 CFR § 423.2345\(a\)](#), or refuse to enter into a Discount Program agreement with such a manufacturer.

Consistent with the guidance and regulations for the Medicare Drug Price Negotiation Program<sup>11</sup> a manufacturer that is a primary manufacturer may submit a request for termination of a Discount Program agreement in connection with a notice of its decision that it is unwilling to participate in, or continue its participation in the Negotiation Program. Specifically, a manufacturer that is the primary manufacturer of a selected drug may provide a notice to CMS stating the primary manufacturer's unwillingness to participate in, or its request to terminate an agreement under, the Negotiation Program that includes a request to terminate the primary manufacturer's agreements under the Medicaid Drug Rebate Program and the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program.<sup>12</sup> To comply with

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<sup>11</sup> See, e.g., sections 40.1 and 40.6 of the Medicare Drug Price Negotiation Program Revised Guidance issued on June 30, 2023 available at <https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf>.

<sup>12</sup> 26 U.S.C. § 5000D(c)(2), as enacted by Section 11003 of the IRA, refers to each of these agreements as an "applicable agreement." In the context of the Discount Program, the primary manufacturer's applicable agreements include any agreement for which the primary manufacturer is the participating manufacturer as well as any

applicable requirements, such notice of a request to terminate a Negotiation Program agreement must incorporate an attestation that provides in part that through the end of the price applicability period (as defined in section 1191(b)(2) of the Act) for the selected drug that the primary manufacturer (1) shall not seek to enter into any subsequent agreement with the Discount Program under section 1860D-14C of the Act; and (2) shall not seek coverage for any of its drugs under the Discount Program under section 1860D-14C of the Act.<sup>13</sup> If CMS determines the primary manufacturer's notice complies with applicable requirements, the primary manufacturer's request will constitute good cause under section 1860D-14C(b)(4)(B)(i) of the Act to terminate any Discount Program agreement for which the primary manufacturer is the participating manufacturer and to terminate coverage for all of the drugs of the primary manufacturer under the Discount Program. See discussion in [section 80.6](#) below for further detail on how CMS will operationalize termination of coverage.

Consistent with section 1860D-14C(b)(4)(B)(i) of the Act, a termination by CMS will not be effective earlier than 30 calendar days after the date of notice to the manufacturer of such termination.

CMS will provide, upon request, a manufacturer a hearing concerning a for-cause termination. This hearing will take place prior to the effective date of the termination with sufficient time for the termination to be repealed prior to the effective date if CMS determines repeal would be appropriate. If a manufacturer or CMS receives an unfavorable decision from the hearing officer, the manufacturer or CMS may request review by the CMS Administrator within 30 calendar days of receipt of the notification of such determination. The decision of the CMS Administrator is final and binding. A timely request for a hearing before a hearing officer or review by the CMS Administrator will stay termination until the parties have exhausted their appeal rights under the Discount Program, which means either the timeframes to pursue a hearing before a hearing officer or review by the CMS Administrator have passed or a final decision by the Administrator has been issued and there is no remaining opportunity to request further review.

In the case of a primary manufacturer of a selected drug under the Negotiation Program that is unwilling to enter into a Negotiation Program agreement or continue its participation in the Negotiation Program and requests to terminate its Discount Program agreement, CMS shall, upon written request from such manufacturer, provide a hearing concerning its termination request under the Discount Program. Such a hearing will be held prior to the effective date of termination with sufficient time for such effective date to be repealed. Such a hearing will be

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arrangement in which FDA-assigned labeler code(s) of the primary manufacturer or drug(s) for which the primary manufacturer is the holder of the NDA or BLA is covered under the Discount Program agreement of another manufacturer. If the primary manufacturer's notice complies with applicable requirements, CMS will effectuate termination of coverage of only the above-described FDA-assigned labeler code(s) and NDC(s) in such an arrangement under the procedures specified in [sections 80.6.1.1](#) and [80.6.2](#) below.

<sup>13</sup> The Coverage Gap Discount Program has substantially similar parameters for participating manufacturers as are adopted in this guidance for the Discount Program for 2025 and 2026. Accordingly, the policies in this guidance regarding the treatment of primary manufacturers and their drugs in the Discount Program reflect how CMS intends to address these scenarios in the context of the Coverage Gap Discount Program.

held solely on the papers; because CMS' determination that there is good cause for termination depends solely on such manufacturer's request for termination to effectuate its decision not to participate in the Negotiation Program, the only question to be decided in the hearing is whether the manufacturer has asked to rescind its termination request prior to the effective date of the termination. CMS will automatically grant such request from the primary manufacturer to rescind its termination request.

#### 80.1.3.2 – Termination by the Manufacturer

In accordance with section 1860D-14C(b)(4)(B)(ii) of the Act, a participating manufacturer may terminate its Discount Program agreement for any reason. If the manufacturer provides notice of termination under clause (ii) before January 31 of a calendar year, such termination will be effective as of January 1 of the succeeding calendar year. If the manufacturer provides notice of termination under clause (ii) on or after January 31 of a calendar year, the termination will be effective as of January 1 of the second succeeding calendar year. The following examples illustrate these requirements:

- If a manufacturer notifies CMS on January 20, 2025 that it wishes to terminate, the termination will be effective as of January 1, 2026.
- If the manufacturer notifies CMS on February 1, 2025 that it wishes to terminate, the termination will be effective as of January 1, 2027.

#### 80.1.3.3 – Post-Termination Obligations

Consistent with section 1860D-14C(b)(4)(B)(iii) of the Act, the termination of a Discount Program agreement under either sections 1860D-14C(b)(4)(B)(i) or 1860D-14C(b)(4)(B)(ii) of the Act will not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with labeler code(s) covered by the manufacturer's agreement that were incurred under the agreement before the effective date of termination.

#### *80.1.4 – Reinstatement*

Reinstatement in the Discount Program subsequent to termination by CMS will be available to a manufacturer only upon payment of any and all outstanding applicable discounts and penalties incurred during any previous Discount Program agreement or Coverage Gap Discount Program Agreement. The timing of any such reinstatement will be consistent with the requirements for entering into an Agreement under section 1860D-14C(b)(1)(C) of the Act.

### ***80.2 – Manufacturer Invoicing and Reimbursement of Part D Sponsors for Applicable Discounts***

As specified in section 1860D-14C(b)(1) of the Act, participating manufacturers are required to provide applicable discounts for applicable drugs of the manufacturer that are dispensed to



applicable beneficiaries on or after January 1, 2025. CMS establishes the specific requirements for discount payments, which are included in the Discount Program agreement. Manufacturers should expect an invoicing and payment operational process that is similar to the process used for the Coverage Gap Discount Program.

#### *80.2.1 – Manufacturer Invoices*

CMS will calculate the amounts owed by participating manufacturers, based on information reported by Part D sponsors, for applicable discounts advanced on behalf of the manufacturer. Manufacturers will receive quarterly invoices, through the TPA portal, which will be itemized at the NDC level and provide certain claim-level detail. Based on feedback from manufacturers participating in the Coverage Gap Discount Program, CMS will provide additional detail on manufacturer invoices under the Discount Program, including new data elements and certain data elements that are currently available only on audit under the Coverage Gap Discount Program. We believe these changes will increase transparency and help manufacturers better understand the basis and accuracy of the reported discounts. The following data elements will be included on each invoice:

- Date of service;
- Service Provider Identifier Qualifier;
- Service Provider Identifier;
- Prescription/Service Reference Number;
- Product/Service Identifier;
- Quantity Dispensed;
- Days Supply;
- Fill Number;
- Reported Discount;
- \*Low-Income Cost Sharing Amount;
- \*Total Gross Covered Drug Cost Accumulator
- \*True Out-of-Pocket Accumulator;
- \*\*Gross Drug Cost Below Out-of-Pocket Threshold (GDCB); and
- \*\*Gross Drug Cost Above Out-of-Pocket Threshold (GDCA).

\* Data element moved from audit-only to invoice

\*\* New data element

#### *80.2.2 – Requirement to Pay Invoiced Amounts*

Participating manufacturers must reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer for all applicable drugs having NDCs with labeler code(s) covered by the Discount Program agreement and invoiced to the manufacturer. Consistent with CMS policy under the Coverage Gap Discount Program, CMS will invoice manufacturer discount amounts from accepted PDE data for 37 months following the end of the benefit year.

### 80.2.3 – Requirement for Timely Payment

Participating manufacturers must pay each Part D sponsor the invoiced amounts no later than 38 calendar days from receipt of the relevant invoice, except as specified below. Payments must be made via electronic funds transfer directly to Part D sponsors through the TPA portal. If the deadline falls on a Saturday, Sunday, or legal holiday, the payment timeframe is extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday.

**Withholding of disputed amounts.** Manufacturers are not permitted to withhold payment for any disputed invoiced amount, including while a dispute is pending, with the sole exception of disputed invoiced amounts for applicable drugs having NDCs that do not correspond to labeler codes covered by its agreement. If payment is withheld in such an instance, the manufacturer must notify the TPA and any affected Part D sponsors within 38 calendar days of the manufacturer's receipt of the applicable invoice that payment is being withheld for this reason.

This policy is consistent with current CMS policy under the Coverage Gap Discount Program, and we believe it continues to strike a reasonable balance between the needs of manufacturers and Part D sponsors. Applicable discounts are owed by manufacturers but are advanced by Part D sponsors at the POS. CMS performs extensive quality assurance with respect to PDE data submitted by sponsors and, based on our experience under the Coverage Gap Discount Program, we believe that prohibiting the withholding of disputed invoices minimizes the risk to Part D sponsors for these discount-related incurred liabilities without significantly increasing the financial risk to a manufacturer. The PDE data used to calculate quarterly invoices are derived from claims for each prescription submitted to Part D sponsors for payment. Part D sponsors validate each claim as part of their process to reimburse pharmacies for the cost of the drug. In addition, CMS implements multiple edits to validate the PDE data submitted by Part D sponsors. Those edits include identification and adjustment of outlier and other erroneous entries for variables such as discount amount, beneficiary eligibility for the discount, NDCs, etc.

**Manufacturer Bankruptcy.** If a participating manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and has not paid all invoiced amounts due under the requirements of this section of this guidance and the Discount Program agreement, including any civil money penalties (CMPs) assessed under [section 120](#) of this guidance, CMS will file a proof of claim with the bankruptcy court to attempt to recover such unpaid amounts. See the note in [section 60.5](#) of this guidance related to plan reconciliation for unpaid Discount Program invoices as a result of manufacturer bankruptcy.

### 80.3 – HPMS Access

As announced in the April 17, 2023 HPMS memorandum, *April 2023 Drug Manufacturer Module Enhancements*, CMS is modifying the Drug Manufacturer Contract Management module of HPMS in support of the IRA, including changes to support the Discount Program. Participating manufacturers will be required to use HPMS to:

- Provide and update required contact, ownership, and other information maintained in the manufacturer's HPMS profile;
- Attest to the completeness and accuracy of the submitted information necessary for CMS to determine whether the manufacturer qualifies as a specified manufacturer or specified small manufacturer, as described in [section 50.1](#);
- Execute Manufacturer Discount Program and TPA agreements;
- Make other updates, as needed.

More information about changes to HPMS is provided in the Part D Manufacturer Discount Program Information Collection Request (ICR) (CMS-10846, OMB control no. 0938-1451). The comment period in response to the 60-day notice closed on April 10, 2023. CMS released a revised version of the ICR on July 7, 2023, and the comment period in response to the 30-day notice closed on August 7, 2023. CMS published the final version of the ICR, approved by the Office of Management and Budget (OMB) through September 30, 2025, on September 12, 2023.<sup>14</sup>

For information about obtaining HPMS access, including requirements for signatory user access, see the May 4, 2023 HPMS memorandum entitled "Instructions for Requesting Drug Manufacturer Access in the Health Plan Management System (HPMS)".<sup>15</sup> Prior to the release of the updated HPMS Discount Program functionality in late 2023, CMS will issue additional operational instructions related to information submission in HPMS for the Discount Program. Manufacturers should expect to utilize HPMS in a manner similar to how it is used under the Coverage Gap Discount Program.

#### ***80.4 – TPA Agreement and Access to the TPA Portal***

Participating manufacturers are required to enter into an agreement with the TPA and to establish and maintain accounts on the TPA's electronic portal for invoicing, payment, and initial dispute filing, and notification of dispute disposition. Additional operational instructions related to the TPA agreement, TPA portal access, invoicing, payment and related processes applicable under the Discount Program will be issued at a later date. The TPA agreement shall only terminate upon the termination of the applicable manufacturer's Discount Program agreement.

#### **80.5 – Reporting and Maintenance of Required Information**

Participating manufacturers are required to collect, have available, and maintain appropriate data related to the labeler codes covered by the participating manufacturer's agreement, including FDA drug approvals, FDA NDC Directory listings, NDC last lot expiration dates, utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other

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<sup>14</sup> The Part D Manufacturer Discount Program ICR, including the supporting statement, information collection instruments, a summary of changes, and responses to comments received during the comment periods can be viewed here: [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202307-0938-003](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-003). Select "all" to see full details.

<sup>15</sup> Also available in the Downloads section at <https://www.cms.gov/about-cms/information-systems/hpms/user-id-process>.

data CMS determines necessary to carry out the Discount Program and demonstrate compliance with its requirements, for a period of not less than 10 years from the date of payment of the invoice, which is consistent with the Part D record retention requirement for Part D sponsors at [42 CFR § 423.505\(d\)](#). Manufacturers should expect these requirements to be operationalized similarly to how such requirements are operationalized in the Coverage Gap Discount Program. Required information is discussed in more detail in the Part D Manufacturer Discount Program ICR referred to in [section 80.3](#).

#### *80.5.1 – Corporate Ownership*

As discussed in [section 50.2](#), CMS will identify which participating manufacturers are specified manufacturers and specified small manufacturers for purposes of applying the phased-in discounts. In order to make an accurate determination, CMS will rely on ownership information provided and attested to in HPMS by manufacturers that submit all required information. As discussed in [section 50.2.1](#) of this guidance, for the first year of the Discount Program, CMS will provide manufacturers that submit and attest to all required ownership information by December 8, 2023, without executing a Discount Program agreement, with preliminary, non-binding information regarding their eligibility for the phase-ins. The specific data CMS requires from all participating manufacturers for purposes of making determinations about phase-in eligibility is available as an attachment to the ICR (CMS-10846, OMB control no. 0938-1451), which is approved by OMB through September 30, 2025.

Participating manufacturers are required to notify CMS of a change in ownership within 30 calendar days after the manufacturers execute a legal obligation for such an arrangement and no later than 45 calendar days prior to the change in ownership taking effect.

In the event of a transfer in manufacturer ownership, the Discount Program agreement is automatically assigned to the new owner, and all terms and conditions of the agreement remain in effect. In the event of an acquisition, CMS will invoice the acquiring entity, and the acquiring entity is required to pay to Part D sponsors all applicable discounts for the acquired company. If CMS was not notified of an ownership change as specified in this section, the original manufacturer will be invoiced and payment will have to be reconciled between the manufacturers involved in the transaction. CMS will not consider untimely notice of a change of ownership to be grounds for a manufacturer to dispute the invoiced amount.

#### *80.5.2 – Labeler Codes*

Each participating manufacturer must cover by its agreement all labeler codes assigned by the FDA to the manufacturer that contain NDCs for the manufacturer's applicable drugs and selected drugs. In addition to its own FDA-assigned labeler codes, CMS does not at this time prohibit a participating manufacturer from covering by its Discount Program agreement applicable drugs or selected drugs with labeler code(s) assigned by the FDA to another manufacturer, provided the other manufacturer has not signed its own Discount Program agreement.

Participating manufacturers are required to provide, through HPMS, all of the following:

- All labeler codes assigned by the FDA to the participating manufacturer that contain NDCs for the participating manufacturer's applicable drugs, for which the participating manufacturer agrees to pay discounts;
- All labeler codes assigned by the FDA to the participating manufacturer that contain NDCs for the participating manufacturer's selected drugs; and
- All labeler codes assigned by the FDA to another manufacturer that the participating manufacturer covers by its agreement and for which the participating manufacturer agrees to pay discounts.

Participating manufacturers are responsible for keeping the list of labeler codes covered by their agreement current on an ongoing basis. A manufacturer's failure to update labeler codes covered by its agreement in accordance with this guidance does not change the manufacturer's responsibility to pay the amounts invoiced for applicable drugs.

#### 80.5.2.1 – Newly assigned labeler codes

Through HPMS, participating manufacturers must submit new labeler code(s) assigned by the FDA to the manufacturer or assigned by the FDA to another manufacturer that the participating manufacturer covers by its agreement and for which the participating manufacturer agrees to pay discounts as soon as possible but no later than 3 business days after having received written notification of the labeler code(s) from the FDA. Manufacturers are required to submit any new labeler code(s) to CMS in advance of providing database vendors such as First DataBank and Medi-Span with any NDCs associated with the new labeler codes. CMS will add new labeler code(s) to the manufacturer's record and the CMS web posting of participating labeler codes. Finally, manufacturers are required to list associated NDCs with the FDA in advance of commercial distribution of the product(s) so that CMS and plans can accurately identify applicable drugs once they are provided to pharmacies for distribution.

#### 80.5.2.2 – Transfer of existing labeler codes between agreements

If two manufacturers participating in the Discount Program wish to transfer existing labeler code(s) from one Discount Program agreement to the other, consistent with the requirements in [section 80.1](#) of this guidance and the Discount Program agreement, CMS requires both manufacturers to take part in the transfer process. A participating manufacturer is not permitted to transfer its own FDA-assigned labeler code(s) to the Discount Program agreement of another manufacturer. The participating manufacturer that covers the labeler code(s) of another manufacturer by its agreement must request that the labeler code(s) be transferred to the other manufacturer, and the manufacturer that assumes coverage by its agreement must request that the labeler code(s) be added to its agreement. If both manufacturers are in agreement and all other Discount Program requirements are met, CMS will confirm the labeler code transfer between agreements.

Transfers of labeler codes from one Discount Program agreement to another are not considered complete until CMS has approved both requests. The participating manufacturer that listed the labeler code as covered under its agreement remains liable for payment of all discounts until the transfer is complete. Once the transfer is complete, the receiving manufacturer assumes responsibility for all Discount Program requirements with respect to the transferred labeler code(s). Discount Program invoices will include the discount amounts by labeler code for the entire quarter. If a manufacturer assumes liability for a labeler code effective the second or third month of a quarter, that manufacturer will be invoiced and is responsible for all discount amounts of that labeler code for the entire quarter, including any claims from dates of service in prior quarters that are included on that quarter's invoice. For example:

- If a labeler code transfer request is approved in February and becomes effective on March 1<sup>st</sup>, the Q1 invoice will be delivered to the new manufacturer.
- If a labeler code transfer request is approved in March and becomes effective April 1<sup>st</sup>, the Q1 invoice will be delivered to the prior manufacturer.

In the event that business needs do not coincide with the timing of the transfer, manufacturers are expected to reconcile any payments among themselves without CMS involvement.

The transfer of labeler codes between Discount Program agreements must include all NDCs associated with that labeler code; CMS will not transfer individual NDCs.

#### 80.5.2.3 – Termination of obsolete labeler codes

Participating manufacturers can submit a request in HPMS to terminate obsolete labeler codes from the list of labeler codes covered under their agreement. In order to submit the request, the manufacturer user must attest in HPMS that the marketing end date on the FDA NDC SPL Data Elements file, defined by the FDA as the date of expiration of the last lot released to the marketplace, has passed for all applicable drugs and selected drugs associated with the labeler code.

#### *80.5.3 – Maintenance of FDA and Related Records*

CMS relies on data available through the FDA to identify applicable drugs in the Discount Program. As such, participating manufacturers must ensure that all labeler codes assigned by the FDA to the manufacturer that contain NDCs for any of the manufacturer's applicable drugs or selected drugs are properly listed on the FDA NDC Directory. Manufacturers must electronically list and maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory.

Accurate NDC listings enable CMS and Part D sponsors to accurately identify applicable drugs and, accordingly, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases (such as First Databank and Medi-Span) used for pharmacy claims processing.



In addition, CMS expects manufacturers to maintain up-to-date listings with the electronic database vendors to whom they provide their NDCs for pharmacy claims processing. Only the manufacturers know the last-lot expiration dates for their NDCs and, therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market. A manufacturer's failure to provide appropriate advance notice to electronic database vendors may result in the participating manufacturer being responsible for discounts after the last-lot expiration date unless the manufacturer can document that it provided such appropriate advance notice to the database vendors, or the manufacturer has provided advance notice to the FDA of the marketing end date.

If the participating manufacturer's agreement covers labeler code(s) that are assigned by the FDA to another manufacturer, the participating manufacturer must ensure that the requirements of this section are met with respect to such labeler codes.

## ***80.6 Terminating Coverage of Active Labeler Codes and NDCs***

As described in [section 80.1.1](#) of this guidance, participating manufacturers are required to cover by their agreement all labeler codes assigned by the FDA to the manufacturer that contain NDCs for the manufacturer's applicable drugs and selected drugs. As such, other than removal of obsolete labeler codes as described in [section 80.5.2.3](#) of this guidance, a participating manufacturer is not permitted to remove any of its FDA-assigned labeler codes from its agreement.<sup>16</sup> However, in circumstances as set forth in this guidance, CMS may effectuate the removal of an active labeler code(s) or specific NDC(s) of applicable drugs and selected drugs from coverage by a participating manufacturer's agreement. An active labeler code refers to a labeler code that contains any NDC for which the marketing end date on the FDA NDC SPL Data Elements File has not passed.

### ***80.6.1 Terminating Coverage for Active Labeler Codes***

If the participating manufacturer covers by its agreement labeler code(s) that are assigned by the FDA to another manufacturer, the participating manufacturer is permitted to remove such labeler codes if such codes are obsolete or to transfer the labeler codes to another manufacturer through the transfer process described above. In addition, CMS may terminate coverage of the active labeler code(s) of another manufacturer on a participating manufacturer's Discount Program agreement in the circumstances described in this section.

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<sup>16</sup> Consistent with the requirement in [section 80.1](#) and the Discount Program agreement, a participating manufacturer cannot transfer any of its own FDA-assigned labeler codes to another manufacturer's Discount Program agreement.

#### 80.6.1.1 – Active Labeler Code(s) Assigned by the FDA to a Primary Manufacturer Unwilling to Enter into or Continue its Participation in the Negotiation Program

Consistent with the regulations and guidance for the Negotiation Program, a primary manufacturer may provide a notice to CMS that it is unwilling to enter into or continue its participation in the Negotiation Program that also seeks to terminate the coverage for all of the manufacturer's drugs under the Medicare Coverage Gap Discount Program and the Manufacturer Discount Program. If CMS determines the notice complies with applicable requirements, including those in [section 80.1](#) of this guidance, CMS will effectuate the removal of the FDA-assigned labeler code(s) of the primary manufacturer from all Discount Program agreements no earlier than 30 days from the date the primary manufacturer provides the required notice to CMS.

#### 80.6.1.2 – Active Labeler Code(s) of Any Other Manufacturer

In any scenario other than that described in [section 80.6.1.1](#), if the participating manufacturer, or the manufacturer assigned by the FDA to the active labeler code(s), seeks to have the labeler code(s) removed from the agreement of the participating manufacturer, CMS will evaluate the request on a case-by-case basis. Such removals, if approved, will be effectuated in accordance with the agreement termination provisions in section 1860D-14C(b)(4)(B)(ii) of the Act. If the request is made before January 31 of a calendar year, removal of the labeler code(s), if approved, will be effective as of January 1 of the succeeding calendar year. If the manufacturer makes the request on or after January 31 of a calendar year, removal of the labeler code(s), if approved, will be effective as of January 1 of the second succeeding calendar year. Examples can be found in [section 80.1.3.2](#) of this guidance. Removal of labeler code(s) will not affect the participating manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with such labeler code(s) that were incurred under the agreement before the effective date of removal.

#### *80.6.2 Terminating Coverage of Specific NDCs of Active Labeler Codes*

Consistent with the regulations and guidance for the Negotiation Program, a primary manufacturer may provide a notice to CMS that it is unwilling to enter into or continue its participation in the Negotiation Program that also seeks to terminate the coverage of all of the manufacturer's drugs under the Coverage Gap Discount Program and the Manufacturer Discount Program. If CMS determines the notice complies with applicable requirements, including those in [section 80.1](#) of this guidance, CMS will effectuate the termination of coverage specific to NDCs for which the primary manufacturer is the holder of the NDA/BLA no earlier than 30 days from the date the primary manufacturer provides the required notice to CMS. Such termination of coverage shall apply to all applicable drug and selected drug NDCs of the primary manufacturer for which the labeler code is assigned to a manufacturer other than the primary manufacturer only to the extent that the primary manufacturer is the NDA/BLA holder for such drug.

## **90 – Audits**

### ***90.1 – Manufacturer Audits of TPA Data***

While the IRA does not specifically permit participating manufacturers to conduct audits of the TPA, CMS will use its authority to provide for implementation of the Discount Program under section 1860D-14C(d)(1) of the Act to permit such manufacturers to conduct periodic audits as specified in this section. We believe continuing to permit participating manufacturers to audit TPA data in a manner similar to the Coverage Gap Discount Program requirements at [42 CFR § 423.2330\(a\)](#) promotes transparency as well as consistency in Part D program operations.

#### ***90.1.1 – Timing***

CMS will permit participating manufacturers to conduct periodic TPA audits no more often than annually, either directly or through a third party. The manufacturer must provide the TPA with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit.

#### ***90.1.2 – Data Subject to Audit***

Manufacturer audits of TPA data are limited to data and information used to determine discounts for the applicable drugs covered by the participating manufacturer's Discount Program agreement. Participating manufacturers are not permitted to audit CMS records or the records of Part D sponsors beyond the data provided to the TPA, which includes claim-level information. In response to feedback from interested parties on the Coverage Gap Discount Program, manufacturer invoices under the new program will include additional data elements that are only available on audit under the Coverage Gap Discount Program (discussed in [section 80.2.1](#)). In addition to the data elements included on invoices, CMS will provide the following additional data to participating manufacturers on audit of TPA data:

- Contract number;
- Plan Benefit Package Identifier;
- Ingredient Cost Paid;
- Dispensing Fee Paid;
- Total Amount Attributed to Sales Tax;
- Non-Covered Plan Paid Amount; and
- Vaccine Administration Fee or Additional Dispensing Fee.

To appropriately balance transparency and efficiency, and in line with generally accepted auditing standards, the data provided to the manufacturer conducting the audit will be limited to a statistically significant random sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with labeler codes covered by the participating manufacturer's Discount Program agreement. Such data is sufficient for the

manufacturer to reach statistically valid conclusions that could be used to support a dispute under [section 100](#).

### *90.1.3 – Limitations*

To support CMS' obligation to protect the privacy of beneficiary medical information, the TPA will provide the data to the participating manufacturer on site at a location specified by the TPA, and with the exception of work papers, such data cannot be removed from the audit site. Additionally, the auditor is permitted to release only an opinion of the audit results and is prohibited from releasing any other information obtained from the audit, including its work papers, to its client, employer, or any other party. We believe these limitations on the distribution of data support beneficiary privacy, while addressing manufacturer need for access to data that are relevant to the calculation of the discounts.

### *90.2 – CMS Audits of Participating Manufacturers*

Section 1860D-14C(c)(2) of the Act requires CMS to monitor compliance by a manufacturer with the terms of a Discount Program agreement (discussed in [section 80.1](#)), and section 1860D-14C(b)(2) of the Act requires manufacturers to collect and have available appropriate data, as determined by CMS, to ensure they can demonstrate to CMS compliance with the requirements of the Discount Program. Pursuant to those requirements and our authority to provide for the administration of the Discount Program, participating manufacturers will be subject to periodic audit by CMS as specified in this section.

**Timing.** We will require participating manufacturers to undergo periodic audits by CMS, at CMS' discretion and no more often than annually, either directly or through a third party. CMS must provide the manufacturer with 60 calendar days' notice of the reasonable basis for the audit and a description of the information required for the audit.

**Data subject to audit.** CMS is permitted to audit appropriate data, including data related to labeler codes covered by the participating manufacturer's agreement and related NDC last lot expiration dates, utilization, and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines necessary to evaluate compliance with the requirements of the Discount Program and the Discount Program agreement.

## **100 – Dispute Resolution**

Section 1860D-14C(c)(1)(D) of the Act requires CMS to provide a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, Part D sponsors, and the Secretary. This section of this guidance establishes the requirements for such mechanism under the Discount Program for participating manufacturers, Part D sponsors, and CMS.

The manufacturer dispute resolution process discussed in [section 100.1](#) relates to disputes about Discount Program invoicing. For information about requesting recalculation of an eligibility

determination for phased-in discounts for specified manufacturers and specified small manufacturers, see [section 50.2.2](#) of this guidance.

### ***100.1 – Manufacturer Disputes***

This guidance establishes a 3-level manufacturer dispute resolution framework for the Discount Program. This framework is analogous to the dispute resolution process for manufacturers that CMS established for the Coverage Gap Discount Program, which is codified at [42 CFR § 423.2330\(c\)](#). We believe that aligning the new requirements, where applicable, with those of the Coverage Gap Discount Program will help to minimize any confusion at the start of the program and reduce burden on sponsors, manufacturers, and CMS. Additional operational guidance related to dispute filing and processing will be released at a later date.

**Involvement of Part D sponsors in dispute resolution process.** A determination about a manufacturer dispute at any level of the dispute resolution process described in this section cannot be appealed directly by a Part D sponsor. However, as part of the adjudication process for manufacturer disputes, sponsors will have an opportunity to confirm the accuracy of a disputed discount, when applicable.

Both in preparing Discount Program invoices to manufacturers and in the course of adjudicating manufacturer disputes, CMS relies on information provided in PDE data received by sponsors. As such, CMS may contact relevant sponsors for additional information or verification of their submitted data in response to a dispute from a manufacturer. [42 CFR § 423.505\(f\)](#) requires sponsors to submit information to CMS that is necessary for CMS to administer and evaluate the Part D program. This includes information relevant to disputes under the Discount Program.

#### ***100.1.1 – Initial Disputes***

**Time frame and method of filing.** A participating manufacturer may dispute applicable discounts invoiced to the manufacturer. Initial disputes must be filed electronically through the TPA portal no later than 60 calendar days from the date of the invoice containing the information that is the subject of the dispute (*hereafter referred to as the “dispute submission deadline”*). Initial disputes must be accompanied by supporting evidence that is material, specific, and related to the dispute, and the manufacturer must explain why they believe the invoiced discount amount is in error. This dispute resolution process can only be used to dispute data received from the TPA. The dispute resolution process described in this section cannot be used to dispute a decision by CMS to terminate a manufacturer’s participation in the Discount Program. For information about termination of a Discount Program agreement, including manufacturer appeal rights, see section 80.1.3.1.

**Time frame for making a determination.** CMS will issue a determination on an initial dispute no later than 60 calendar days from the *dispute submission deadline*.

**Notice requirements.** Written notice of the CMS determination will be issued electronically to the participating manufacturer through the TPA portal.

#### *100.1.2 – Independent Review*

A participating manufacturer that receives a timely, unfavorable determination from CMS on its initial dispute, or that has not received a determination within 60 calendar days of the *dispute submission deadline*, may request review by the independent review entity (IRE) contracted by CMS.

**Time frame and method of filing.** A request for review by the IRE must be filed no later than:

- 30 calendar days from the date of the unfavorable determination on the initial dispute; or
- If no determination was made within 60 calendar days of the *dispute submission deadline*, 90 calendar days from the *dispute submission deadline*.

All requests for IRE review must be submitted electronically through the IRE's secure online portal. CMS will issue additional operational guidance as needed, but expects to rely on the same IRE contract vehicle to conduct reviews under the Coverage Gap Discount Program to minimize any disruption in the transition to the new program.

**Time frame for making a determination.** The IRE must make and issue a determination no later than 90 calendar days from receipt of the participating manufacturer's request for independent review.

The manufacturer may receive a request for additional information as the IRE considers the appeal. Failure to comply with this request within the time frame specified may result in a denial. In addition to the information provided by the participating manufacturer, the IRE will base its decision on information received by CMS, the TPA, the Part D sponsor, and other databases compiled by CMS or other sources.

**Notice Requirements.** The IRE will issue a written decision, delivered electronically, to the participating manufacturer and to CMS no later than 90 calendar days from receipt of the request. The notice must include the following:

- A clear statement indicating whether the decision is favorable or unfavorable to the manufacturer;
- An explanation of the rationale for the IRE's decision; and
- Instructions on how to request a review by the CMS Administrator.

**Effect of IRE determination.** A decision by the IRE is binding on all parties unless the participating manufacturer or CMS files a valid request for review by the CMS Administrator under the process described below.



### *100.1.3 – Review by CMS Administrator*

**Who can request a review.** CMS or a participating manufacturer may request a final administrative review of a determination from the IRE by the CMS Administrator.

**Time frame and method of filing.** A request for review by the CMS Administrator must be filed no later than 30 calendar days from the date of the IRE decision.

**Notice requirements and effect.** The CMS Administrator will issue written notice of their decision to both parties. A decision by the CMS Administrator is final and binding.

### *100.1.4 – Adjustments to Invoiced Amounts*

CMS will adjust future invoices, or implement an alternative reimbursement process if determined necessary by CMS, if a dispute under this process is resolved in favor of the manufacturer.

### *100.2 – Disputes from Part D Plan Sponsors*

In calculating quarterly invoices billed to participating manufacturers under the Discount Program, CMS relies on information received in PDE data submitted by sponsors when applicable discounts are advanced at the POS. As such, and consistent with existing policy under the Coverage Gap Discount Program, sponsors do not have the right to directly dispute invoiced amounts under the processes described in this section.

### *100.3 – Beneficiary Disputes*

As described in [section 50](#) of this guidance, and consistent with section 1860D-14C(g)(4) of the Act, discounts are provided on the negotiated price and applicable discounts are not counted toward the enrollee's incurred costs. The IRA does not require a dispute resolution mechanism for Part D enrollees with respect to the Discount Program and, as a practical matter, an individual would likely not even be aware if a discount is provided on their claim, because in most cases, the Discount Program will not affect enrollee cost sharing. Nevertheless, any Part D enrollee who has a dispute about their plan's decision not to provide or pay for a Part D drug, including a dispute about whether a drug is excluded from Part D or about the amount of cost sharing, has the right to request a coverage determination from the plan and the right to appeal any coverage determination not fully favorable to the enrollee under the procedures specified in [Subpart M](#) of Part 423.

## **110 – Compliance Monitoring**

CMS will implement a process to monitor compliance with the requirements in this guidance, required Discount Program agreements, and any additional requirements that may be implemented through future program instruction or regulation. Such monitoring may be done directly by CMS or through a contracted entity, including the TPA.

## **120 – Civil Money Penalties**

Section 1860D-14C(e) of the Act requires that a participating manufacturer that fails to provide discounted prices for applicable drugs of the manufacturer dispensed to applicable beneficiaries, in accordance with a Discount Program agreement, be subject to a civil money penalty (CMP) for each such failure.

### ***120.1 – Amount of CMP and Required Notice***

Consistent with section 1860D-14C(e)(1) of the Act, the formula for determining the CMP amount is the sum of the amount the manufacturer would have paid with respect to the applicable discount, plus 25 percent of such amount. The statute specifies that CMS determines the amount, based on the statutory formula.

As described in [section 80.2.3](#), manufacturers are required to pay invoiced amounts to the relevant Part D sponsors within 38 calendar days of receipt of the invoice. As with existing policy under the Coverage Gap Discount Program, CMS considers a participating manufacturer to have failed to provide applicable discounts if payment is not made within the required timeframe, with limited exceptions in situations where a manufacturer demonstrates that such failure is due to technical or other reasons beyond the manufacturer's control.

When a participating manufacturer fails to make a timely payment, CMS will issue to the manufacturer a Notice of Non-Compliance with information about the violation. The manufacturer will have 5 business days to respond, during which time the manufacturer could provide additional context, evidence refuting the violation, and/or other factors that CMS will consider when determining whether to impose a CMP. It is imperative that manufacturers make timely payments under the Discount Program and a participating manufacturer's failure to establish sufficient controls to ensure compliance with this requirement will not relieve them of penalties provided under section 1860D-14C(e)(1) of the Act.

If CMS makes a determination to impose a CMP on the basis of failure to pay required discounts under the Discount Program, CMS will issue written notice of its determination to the manufacturer. The notice must include the following:

- A description of the basis for the determination;
- The basis for the penalty;
- The amount of the penalty;
- The date the penalty is due;
- The manufacturer's right to a hearing before an Administrative Law Judge (ALJ), as specified in [section 120.3](#); and
- Information about where to file the request for hearing.

CMS will impose a CMP whenever a manufacturer fails to make full payment, and the CMP will be calculated based on the outstanding invoiced amount that was not paid within the required timeframe. The amount of the CMP may be reduced by any amount the manufacturer has paid after 38 calendar days; however, late payments will not relieve a manufacturer of its obligation to pay the additional 25 percent penalty, which will be assessed on all invoiced amounts not paid within the 38-day timeframe.

### ***120.2 – CMP Appeals***

Section 1860D-14C(e)(2) of the Act makes certain provisions of section 1128A of the Act applicable to CMPs imposed on participating manufacturers under the Discount Program. Section 1128A(c)(2) specifies that CMS may not collect a CMP until the affected party has received written notice and been given an opportunity for a hearing. For the Coverage Gap Discount Program, CMS established requirements that follow existing CMP appeal procedures codified in Part 423, [Subpart T](#), which provide a manufacturer a right to a hearing before an ALJ followed by the right to a review of the ALJ decision by the Departmental Appeals Board. To maintain our consistent approach and simplify the transition between programs, as described in this section of this guidance, we will apply the requirements of [Subpart T](#) for CMP appeals under the Discount Program.

### ***120.3 – Collection of CMPs Imposed by CMS***

Consistent with CMS policy under the Coverage Gap Discount Program, if the manufacturer does not file a valid request for an ALJ hearing, CMS will initiate collection of any CMP imposed under the Discount Program following the expiration of the 60-day timeframe for requesting an ALJ hearing, as specified at [42 CFR § 423.1020](#). If the manufacturer does file a valid request for appeal, CMS will initiate collection of the penalty, as applicable, once the administrative decision is final.

## **130 – Definitions**

***Applicable beneficiary*** means an individual who, on the date of dispensing a Part D drug:

- (1) Is enrolled in a prescription drug plan or an MA-PD plan;
- (2) Is not enrolled in a qualified retiree prescription drug plan; and
- (3) Has incurred costs, as determined in accordance with section 1860D-2(b)(4)(C) of the Act, for Part D drugs in the year that exceed the annual deductible specified in section 1860D-2(b)(1) of the Act.

***Applicable discount*** has the meaning set forth in [section 50](#) of this guidance.

***Applicable drug*** means a Part D drug that is:

- (1)
  - (i) Approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FDCA); or
  - (ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act; and
- (2)
  - (i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
  - (ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or
  - (iii) Is provided to a particular applicable beneficiary through an exception or appeal for that applicable beneficiary; and
- (3) Does not include 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.

***Applicable LIS percent*** has the meaning set forth in [section 50.1.1](#) of this guidance.

***Applicable number of calendar days*** has the meaning given such term in section 1860D-14C(g)(3) of the Act.

***Applicable small manufacturer percent*** has the meaning set forth in [section 50.1.2](#) of this guidance.

***Covered Part D drug*** has the meaning set forth at [42 CFR § 423.100](#).

***Date of dispensing*** means the date of service. For long-term care and home infusion pharmacies, the date of dispensing can be interpreted as the date the pharmacy submits the discounted claim for reimbursement.

**Labeler code** means the first segment of the NDC that identifies a particular manufacturer.

**Manufacturer** means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. For purposes of the Part D Manufacturer Discount Program, such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer.

**National Drug Code (NDC)** means the unique identifying prescription drug product number that is listed with the Food and Drug Administration (FDA) identifying the product's manufacturer, product and package size and type.

**Negotiated price** has the meaning set forth at [42 CFR § 423.100](#), and with respect to an applicable drug, such negotiated price shall include any dispensing fee and, if applicable, any vaccine administration fee and sales tax.<sup>17</sup>

**Network pharmacy** has the meaning set forth at [42 CFR § 423.100](#).

**Non-applicable drug** means any Part D drug that is not an applicable drug, as described in this guidance, 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.

**Part D drug** has the meaning set forth at [42 CFR § 423.100](#).

**Primary manufacturer** has the meaning given such term pursuant to applicable regulations and guidance for the Negotiation Program.

**Selected drug** has the meaning given such term in section 1192(c) of the Act and any applicable regulations and guidance.

**Specified drug** means, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by a specified manufacturer.

**Specified small manufacturer drug** means, for 2021, any applicable drug that is produced, prepared, propagated, compounded, converted, or processed by a specified small manufacturer.

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<sup>17</sup> Refers to the regulatory definition effective January 1, 2024 ([87 FR 27704, 27902](#)).

***Third Party Administrator (TPA)*** means the CMS contractor responsible for administering certain requirements established by CMS to carry out section 1860D-14C of the Act.

***Total expenditures*** means —

- (1) With respect to Part D, the total gross covered prescription drug costs, as defined in section 1860D-15(b)(3) of the Act; and
- (2) With respect to Part B, the total Medicare allowed amount (i.e., total allowed charges), inclusive of beneficiary cost sharing, for Part B drugs and biologicals, except that expenditures for a drug or biological that are bundled or packaged into the payment for another service are excluded.