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CENTER FOR MEDICARE

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TO: Pharmaceutical Manufacturers; All Part D Plan Sponsors

FROM: Amy Larrick Chavez-Valdez, Director
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SUBJECT: Medicare Part D Manufacturer Discount Program Draft Guidance and Request for Comment

This memorandum provides draft guidance to pharmaceutical manufacturers and Part D plan sponsors for implementing the Medicare Part D Manufacturer Discount Program (Discount Program), enacted into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. CMS voluntarily solicits comment on this draft guidance. Comments should be sent to PartDManufacturerDiscountProgram@cms.hhs.gov with the subject line "Manufacturer Discount Program Draft Guidance Comments." CMS will issue final guidance after considering all comments received by 5:00PM EDT, June 12, 2023. In the revised guidance, CMS may make changes to any policies, including policies on which CMS has not expressly solicited comment, based on the agency's further consideration of the relevant issues.

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 guidance is divided into the following major sections:

10 – Introduction

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50 – Applicable Discounts

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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 without modification 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 intends to implement 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.

20 – Overview

The Coverage Gap Discount Program makes manufacturer discounts available at the point-of-sale (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 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 manufacturer has a signed 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. 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 to 20 percent for all covered Part D drugs, with plans continuing to receive an 80 percent federal reinsurance subsidy. Beginning in 2025, the IRA eliminates the coverage gap benefit phase, introduces manufacturer discounts in the initial and catastrophic coverage phases, changes enrollee and plan liability in the initial coverage phase, 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[1]) is met.
2. **Initial coverage.** The enrollee pays 25 percent coinsurance for covered Part D drugs. The sponsor pays 65 percent for applicable drugs (as defined in section 1860D-14C(g)(2) of the Act) and selected drugs [2], and 75 percent for all other covered Part D drugs. 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 updated enrollee out-of-pocket cap ($2,000 for 2025).
3. **Catastrophic.** Enrollees pay no cost sharing. Plan sponsors pay 60 percent for all covered Part D drugs. CMS pays a 40 percent federal reinsurance subsidy for selected drugs and all other covered Part D drugs that are not applicable drugs, and a 20 percent federal reinsurance subsidy for applicable drugs. Manufacturers pay a discount through the Discount Program, typically 20 percent, for applicable drugs.

[1] Amount to be determined based on Annual Percentage Increase.
[2] Price applicability periods for selected drugs, as described in section 1191 of the Act, do not begin until 2026.

Under the Discount Program, participating manufacturers will be required to provide discounts on their applicable drugs (as defined 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 intends to implement 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 those applicable drugs of manufacturers that participate in the Discount Program by entering into and having in effect a Discount Program agreement with CMS, as described in section 1860D-14C(b) of the Act.

CMS requires participating manufacturers to submit a complete list of their labeler codes for applicable drugs. 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 labeler codes that are subject to 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 preliminary January 2025 labeler code list in Spring 2024 and a final January 2025 labeler code list by August 2024.

40.1 – Applicable Drugs

Consistent with section 1860D-14C(g)(2) of the Act, applicable drugs under the Discount Program are all Part D drugs approved under a new drug application (NDA) or biologics license application (BLA), including biosimilar products licensed under section 351(k) of the Public Health Service Act, other than a selected drug dispensed during a price applicability period, even

if a Part D sponsor treats the product as a generic under its benefit. Conversely, Part D drugs that are marketed under trade names and generally thought of as brand name products but are not approved under an NDA or BLA are not applicable drugs and, therefore, not subject to the requirements of the Discount Program. Applicable drugs are identified by their NDC. Drugs excluded from Part D under 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.

Selected Drugs. Any Part D drug that is a selected drug (as defined in section 1192(c) of the Act) is excluded from the definition of applicable drug during a price applicability period (as defined in section 1191(b)(2) of the Act) with respect to such drug and, therefore, is not subject to applicable discounts under the Discount Program when it is dispensed during a price applicability period. Beginning January 1, 2025, for any time period prior to the start of a price applicability period in 2026 or later, and upon the end of a price applicability period, the manufacturer must have a Discount Program agreement in place, i.e., executed and in effect (see section 80.1.2), for these drugs to be covered under Part D.

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 of a manufacturer that does not participate in, and has not entered into and have in effect an agreement under, the Discount Program. Non-applicable drugs (as defined in 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. We believe that the plainest reading of section 1860D-43(a), which contemplates that all manufacturers of Part D drugs must sign Discount Program agreements for any such drugs, including non-applicable drugs, is inappropriate and infeasible for the same reasons we found such a reading inappropriate and infeasible for purposes of the Coverage Gap Discount Program (77 FR 22082).

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) 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), this exception to the exclusion from Part D coverage does not apply to any applicable 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.

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(b)(5), to affected enrollees (as defined in 42 CFR § 423.100) and others if a covered Part D drug will no longer be covered because the manufacturer has failed to sign a Discount Program agreement or their agreement is terminated as described in section 80.1.3 of this guidance. In addition, because applicable drugs that are not covered under 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.

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 50.2, with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary (as defined 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 that individual is entitled to an income-related subsidy under section 1860D-14(a), and discounts do not count toward an 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 defined 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) 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 LIS beneficiaries and one for certain applicable drugs of specified small manufacturers dispensed to applicable beneficiaries. Each of these phase-ins is discussed in this section.

CMS will identify which participating manufacturers qualify for these phase-ins by analyzing Medicare Parts B and D claims data and ownership information submitted by participating manufacturers. All manufacturers that enter into a Discount Program agreement in time to participate in any year of the phase-in will be considered for the phase-ins, and do not need to submit a separate application. For the first year of the Discount Program, CMS intends to provide manufacturers that submit and attest to the required ownership information by a certain date (to be announced later this year) with information regarding their eligibility for the phase-ins prior to the statutory deadline of March 1, 2024 to enter into a Discount Program agreement for 2025. See section 80.5.1 of this guidance for additional information about submission of manufacturer ownership information in HPMS.

Prior to releasing the revised HPMS Discount Program module, which we expect to do in late 2023, CMS will release additional information explaining the methodology CMS will use to identify manufacturers eligible for phase-ins. To assist Part D sponsors in accurately calculating

applicable discounts, CMS will publish a list of manufacturers eligible for the phase-ins prior to the start of the Discount Program.

50.1.1 – Phase-In for Certain Applicable Drugs Dispensed to LIS Beneficiaries

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;[3]
- Total expenditures for all of its specified drugs covered by such Coverage Gap Discount Program agreement(s) for 2021 and covered under Part D in 2021 represented less than

[3] 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.

1.0 percent of total gross covered prescription drug costs (as defined in section 1860D-15(b)(3) of the Act) for all Part D drugs in 2021; and

- Total expenditures for all of its specified drugs (as defined in section 130 of this guidance) 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.

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 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

- 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 defined 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 gross covered prescription drug costs for all its specified small manufacturer drugs covered under Part D in 2021.

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 manufacturer) is not included in the definition, effective at the beginning of the plan year immediately following the acquisition or, for an acquisition before 2025, effective January 1, 2025.

50.2 – 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 point of sale (POS), just as is 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 defined 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 who 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.

60.1.2 – 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.

60.1.3 – 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 dispensing.

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 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 dispensing an applicable drug. 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.

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 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, 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 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) 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, manufacturers will also be required to enter into an agreement directly with the TPA in order to participate in the Discount Program.

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

80.1 – Part D Manufacturer Discount Program Agreement

Section 1860D-14C(a) of the Act requires CMS to enter into agreements with manufacturers under the Discount Program.

80.1.1 – Requirements of Agreement

Pursuant to section 1860D-14C(b), the Discount Program agreement will at a minimum require participating manufacturers to:

- Collect and have available appropriate data to ensure the manufacturer can demonstrate compliance with the requirements of the Discount Program;
- Reimburse all applicable discounts provided by Part D sponsors on behalf of the manufacturer to applicable beneficiaries for applicable drugs that are dispensed on or after January 1, 2025 and invoiced to the manufacturer as specified in section 80.2 of this guidance;
- Comply with requirements imposed by CMS for purposes of administering the Discount Program, including:
    - the determination of the amount of the discounted price of an applicable drug of a manufacturer, or
    - procedures established pursuant to section 1860D-14C(c)(1).

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, unless terminated as described in this section.

For calendar year 2025, a 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.

For calendar year 2026 and subsequent years, an agreement will become effective on the first day of a calendar quarter. A 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 quarter. If a manufacturer enters into the agreement after the last day of the first month of a particular quarter, the initial term will begin on the first day of the second quarter after the quarter in which the manufacturer entered into the agreement.

The initial term will end on December 31 of the first calendar year which ends not less than 12 months from the effective date of the agreement.

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

Pursuant to section 1860D-14C(b)(4)(B)(i), CMS will 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. The termination 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 if requested. 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 accordance with section 1860D-14C(b)(4)(B)(ii), a manufacturer may terminate its Discount Program agreement for any reason. If the termination occurs before January 31 of a calendar year, the termination will be effective as of January 1 of the succeeding calendar year. If the termination occurs 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.

Consistent with section 1860D-14C(b)(4)(B)(iii), the termination of a Discount Program agreement will not affect the manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with the manufacturer's labeler code(s)

that were incurred under the agreement before the effective date of termination.

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 the manufacturer's FDA-assigned labeler code(s) that are 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.

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 that do not have labeler codes corresponding to the manufacturer. If payment is withheld in such an instance, the manufacturer must notify the TPA and any affected Part D sponsors within 38 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 in the process of modifying the existing 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 and ownership information;
- 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; and
- Execute new Manufacturer Discount Program agreements.

More information about changes to HPMS is provided in the proposed information collection requirements for the Part D Manufacturer Discount Program. The information collection, CMS-10846 (OMB control no. 0938-New), was posted in the Federal Register on February 7, 2023 (88 FR 7976). Prior to the release of the updated HPMS Discount Program module in late 2023, CMS will issue additional operational guidance related to the submission of required information 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

Manufacturers will be required to enter into an agreement with the TPA in order to participate in the Discount Program and to establish and maintain accounts on the TPA's electronic portal for invoicing, payment, and initial dispute filing. Additional operational instructions related to the TPA agreement, TPA portal access, invoicing, payment and related processes applicable under the MDP will be issued at a later date.

80.5 – Reporting and Maintenance of Required Information

Participating manufacturers are required to collect, have available, and maintain appropriate data, including data related to manufacturer's labeler codes, 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 data CMS determines necessary to carry out the Discount Program, 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 proposed Part D Manufacturer Discount Program collection of information referred to in section 80.3.

80.5.1 – Corporate Ownership

As discussed in section 50.1, CMS will identify which participating manufacturers are specified manufacturers and specified small manufacturers for purposes of applying the phased-in discounts. For 2025, in order to make an accurate determination, CMS will rely on ownership information provided in HPMS by manufacturers that submit the required information in HPMS and enter into a Discount Program agreement for 2025 by the statutory deadline of March 1, 2024. As discussed in section 50.1 of this guidance, for the first year of the Discount Program, CMS intends to provide manufacturers that submit and attest to the required ownership information by a certain date (to be announced later this year) with information regarding their eligibility for the phase-ins prior to the statutory deadline of March 1, 2024 to enter into a Discount Program agreement for 2025. The required manufacturer ownership information is discussed in more detail in the proposed information collection for the Part D Manufacturer Discount Program, CMS-10846 (OMB control no. 0938-New), which was posted in the Federal Register on February 7, 2023 (88 FR 7976). The information collection, with any revisions, will be posted this summer for a 30-day public comment period. Prior to the expected release of the revised HPMS Discount Program module in late 2023, CMS will issue additional operational guidance related to the submission of required information in HPMS for the Discount Program.

Manufacturers are required to notify CMS of a change in ownership within 30 days after the manufacturers execute a legal obligation for such an arrangement and no later than 45 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 pursuant to the timeframe specified, 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

Participating manufacturers are required to provide CMS with labeler codes for all of the manufacturer's applicable drugs, and are responsible for keeping the list of its labeler codes

current on an ongoing basis. A manufacturer's failure to update its labeler codes in with this guidance does not change the manufacturer's responsibility to pay the amounts invoiced.

Newly assigned labeler codes. Through HPMS, participating manufacturers must submit new labeler code(s) 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.

Transfer of existing labeler codes. If two manufacturers participating in the Discount Program wish to transfer existing labeler code(s) from one to the other, CMS requires both manufacturers to take part in the transfer process. The labeler code owner of record and the assuming manufacturer must submit a request through HPMS indicating the company that will assume ownership of the labeler code(s), and the proposed effective date for the transfer. If both manufacturers are in agreement, CMS will confirm the labeler code transfer. If the request is received at least 45 days prior to the next invoice, the transfer will become effective at beginning of the next quarter. Transfer requests received less than 45 days prior to the next invoice will be effectuated in the following quarter. The labeler code owner of record remains liable for payment of all discounts until the transfer is complete. Once the transfer is complete, the new owner assumes responsibility for all Discount Program requirements with respect to the transferred labeler code(s). The transfer of labeler codes must include all NDCs associated with that labeler code; CMS will not transfer individual NDCs.

Removal of obsolete labeler codes. Participating manufacturers will have an opportunity to remove obsolete labeler codes from their listings of approved codes during an annual confirmation process.

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 of their applicable drug products 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 manufacturer's 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.

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 intends to use its authority to provide for implementation of the Discount 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 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 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 manufacturer's applicable drugs. 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 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 sample of data held by the TPA that were used to determine applicable discounts for applicable drugs having NDCs with the manufacturer's FDA-assigned labeler codes. 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 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 intend to 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 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 a manufacturer's FDA-assigned labeler codes, 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, prescription drug plans and MA-PD plans, and the Secretary." This section of this guidance establishes the requirements for such mechanism under the Discount Program for manufacturers, Part D sponsors, and CMS.

100.1 – Manufacturer Disputes

We intend to establish 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 stakeholder confusion at the start of the program and 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 days from the date of the invoice containing the information that is the subject of the dispute. 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 or as a result of a manufacturer's audit (see section 90.1). 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.

Time frame for making a determination. CMS will make a determination on an initial dispute no later than 120 calendar days from the date of the relevant invoice.

Notice requirements. Written notice of the CMS determination will be issued electronically to the disputant through the TPA.

100.1.2 – Independent Review

A participating manufacturer that receives an unfavorable determination from CMS on its initial dispute, or that has not received a determination within 120 days of the date of the relevant invoice, 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 days from the date of the unfavorable determination on the initial dispute; or
- If no determination was made within 60 days of the dispute deadline, 90 days from the filing date of the manufacturer's initial dispute.

All requests for IRE review must be submitted electronically through the process established on 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 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 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 manufacturer and to CMS no later than 90 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 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 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 days from the date of the IRE decision.

Notice requirements and effect. The Administrator will issue written notice of their decision to both parties. A decision by the 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 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. As such, we do not expect enrollees to dispute issues related to the Discount Program. However, 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.

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.

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.

As described in section 80.2.2, manufacturers are required to pay invoiced amounts to the relevant Part D sponsors within 38 days of receipt of the invoice. As with existing policy under the Coverage Gap Discount Program, CMS considers a manufacturer to have failed to provide applicable discounts if payment is not made within the required timeframe, unless such failure is due to technical or other reasons beyond the control of the manufacturer. Consequently, 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 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 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

  (i) 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 means —

(1) with respect to claims for reimbursement submitted electronically, 14 days; and

(2) with respect to claims for reimbursement submitted otherwise, 30 days.

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 product 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 given such term in section 1860D-2(d)(1)(B) of the Act, 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.

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 defined in this guidance, including 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.

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.

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.