

Department of Health & Human Services  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850



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**DATE:** November 14, 2024

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

**FROM:** Vanessa S. Duran  
Director, Medicare Drug Benefit and C & D Data Group

Jennifer R. Shapiro  
Director, Medicare Plan Payment Group

**SUBJECT:** Medicare Part D Manufacturer Discount Program: Draft Revisions to Sections 100.1.1 and 100.1.2 of the Final Guidance

The purpose of this memorandum is to announce draft changes to sections 100.1.1 and 100.1.2 of the Medicare Part D Manufacturer Discount Program Final Guidance<sup>1</sup> and to solicit input on these changes via a 30-day public comment period.

Section 11201 of the Inflation Reduction Act of 2022, Public L. 117-169 (IRA) establishes the Medicare Part D Manufacturer Discount Program (Discount Program), effective January 1, 2025. As codified in sections 1860D-14C and 1860D-43 of the Social Security Act, under the Discount Program, Part D coverage is available only for applicable drugs for which the labeler code is covered by a Discount Program agreement with CMS, and participating manufacturers must provide discounts on their applicable drugs in the initial and catastrophic coverage phases of the Part D benefit. Section 11201 of the IRA also eliminates the coverage gap phase of the Part D benefit and sunsets the Coverage Gap Discount Program (CGDP) on January 1, 2025. CGDP requirements are codified in Subpart W of 42 CFR Part 423.

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 CMS published the Medicare Part D Manufacturer Discount Program Draft Guidance on May 12, 2023 and voluntarily solicited comment with a 30-day public comment period. After consideration of the comments received, CMS released the Medicare Part D Manufacturer Discount Program Final Guidance (Final Guidance) on November 17, 2023.

Since releasing the Final Guidance, CMS has identified a need for revisions to sections 100.1.1 and 100.1.2, regarding manufacturer initial disputes and independent review. Specifically, based on program experience under the CGDP, we have identified that the time frame for CMS to make a determination on an initial dispute in section 100.1.1 would be prohibitively complex to operationalize. We have further identified a need for corresponding revisions to the time frame within which a manufacturer can request independent review under section 100.1.2. The draft

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<sup>1</sup> <https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf-0>

changes and voluntary comment solicitation are discussed in more detail below.

### **Section 100.1.1 Initial Disputes**

Section 100.1.1 of the Final Guidance provides the time frame and method by which participating manufacturers can file an initial dispute about applicable discounts they are invoiced. A manufacturer must file an initial dispute electronically through the third party administrator (TPA) portal no later than 60 calendar days from the date of the invoice containing the information that is the subject of the dispute. The section also provides the time frame for CMS to make a determination on a manufacturer's initial dispute, which is 60 calendar days from the date the dispute was filed. Under the CGDP, there is no adjudication time frame for initial disputes specified in regulation. Operationally, in order for CMS to timely adjudicate the volume of initial disputes we receive, CMS collectively processes all disputes received for a given quarterly invoicing cycle immediately following the dispute submission deadline. This process allows CMS to gather necessary prescription drug event data from Part D sponsors, and other information needed for adjudication, as efficiently as possible. Accordingly, all initial disputes for a given quarterly invoicing cycle must be received and the time frame during which a manufacturer can file an initial dispute must close prior to CMS starting the adjudication process. For this reason, CMS is issuing a draft revision regarding the initial dispute adjudication time frame in section 100.1.1 of the Final Guidance to align with longstanding initial dispute adjudication processes under the CGDP. Specifically, CMS is changing the time frame for adjudicating an initial dispute from "no later than 60 calendar days from the date the dispute was filed" to "no later than 60 calendar days from the dispute submission deadline." For readability, we are also clarifying that "dispute submission deadline" refers to the date by which the initial dispute must be filed by the participating manufacturer. Section 100.1.1 appears below with the draft changes shown in red italic text.

#### *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.

## Section 100.1.2 Independent Review

Section 100.1.2 provides the time frame and method by which participating manufacturers can request review by the independent review entity (IRE) contracted by CMS. Specifically, under section 100.1.2, manufacturers may request review by the IRE no later than 30 calendar days from the date of an unfavorable initial dispute determination or, if no determination was made within 60 calendar days of the filing date of the initial dispute, 90 calendar days from the filing date of the participating manufacturer's initial dispute. CMS has learned that this time frame allows for the possibility of a manufacturer being able to file with the IRE prior to receiving an initial dispute determination from CMS, depending on when the manufacturer filed an initial dispute, though the independent review process is not designed to adjudicate initial disputes. To address this, and to maintain consistent terminology within the Final Guidance, CMS is issuing draft revisions to section 100.1.2 to reflect the dispute submission deadline draft revisions in section 100.1.1. Specifically, in section 100.1.2, CMS is replacing the text "date the initial dispute was filed," "filing date of the initial dispute," and "filing date of the participating manufacturer's initial dispute" with "dispute submission deadline." Section 100.1.2 appears below with the draft changes shown in red italic text.

### *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.

### **Comment Solicitation**

CMS is committed to engaging with interested parties for the successful implementation of the Discount Program. For this reason, CMS is voluntarily seeking comment on the draft revisions to sections 100.1.1 and 100.1.2 of the Final Guidance, as described in this memorandum. Comments should be sent to [PartDManufacturerDiscountProgram@cms.hhs.gov](mailto:PartDManufacturerDiscountProgram@cms.hhs.gov) with the subject line “Manufacturer Discount Program Final Guidance, Draft Revisions to Sections 100.1.1 and 100.1.2” no later than 5:00PM EST, December 16, 2024.

Any questions about this memorandum or the Discount Program, generally, may be sent to [PartDManufacturerDiscountProgram@cms.hhs.gov](mailto:PartDManufacturerDiscountProgram@cms.hhs.gov).