Issue Brief

FEDERAL ISSUE BRIEF

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CMS Issues Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments

The Centers for Medicare & Medicaid Services (CMS) have released a memorandum that provides the final part one guidance on a select set of topics for the Medicare Prescription Payment Plan program for contract year (CY) 2025.

A copy of the 108-page memorandum is available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf

The memorandum includes four sections:

A. An introduction, which begins on page 1.

B. A summary of key changes and clarifications to the draft part one guidance released on August 21, 2023, which begins on page 2.

C. A summary of the public comments received in response to the draft part one guidance, and the Centers for Medicare & Medicaid Services' (CMS's) responses to those public comments, which begins on page 3.

Comments

CMS is addressing many comments. However, we are only providing "snippets" of many, but not all, items.

D. Final part one guidance that establishes final policies for CY 2025 on the topics discussed for the Medicare Prescription Payment Plan program, which begins on page 43.

A. Introduction

Section 11202(c) of the ***Inflation Reduction Act*** of 2022 (IRA) directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance.

CMS is making certain changes to the policies described in the draft part one guidance in this final part one guidance for the first year of the program, which begins on January 1, 2025.

Beginning in 2025, the prescription drug law requires all Medicare prescription drug plans (Medicare Part D plans) — including both standalone Medicare prescription drug plans and Medicare Advantage plans with prescription drug coverage — to offer Part D enrollees the option to pay out-of-pocket prescription drug costs in the form of capped monthly payments instead of all at once at the pharmacy.

This program does not reduce the amount of money that an individual pays in out-of-pocket costs; it helps individuals with high costs spread those costs out throughout the plan year.

The final part one guidance focuses on Part D plan sponsor operational requirements and contains:

- Program calculations for the monthly payment amounts and detailed examples demonstrating the calculations.
- Instructions for Part D sponsors on how to handle monthly billing, including specific information that must be included in the monthly bill.
- Requirements for Part D sponsors to promptly reimburse pharmacies the cost sharing amount that would otherwise have been collected from program participants.
- Requirements for claims processing under the program that ensure program participants are charged $0 at the pharmacy.
- Requirements for identification of Part D enrollees who are likely to benefit from the program based on out-of-pocket costs at the point-of-sale (POS).
- Requirements related to Part D enrollee election into the program.
- Procedures for termination, reinstatement, and preclusion of program participation.
- Participant protections under the program, including notice and grace period requirements, if a monthly bill has not been paid on time.
- Participant dispute resolution process requirements.
- Data submission requirements.

B. Summary of Key Changes and Clarifications in Final Part One Medicare Prescription Payment Plan Program Guidance

Section 60.2.3 – Targeted Part D Enrollee Notification at Point-of-Sale (POS): CMS has made changes and clarifications to policies detailed in section 60.2.3 of the draft part one guidance, including:

POS Threshold for Out-of-Pocket Costs: CMS has revised section 60.2.3 to state that Part D sponsors and pharmacies must use a $600, single prescription POS threshold to identify enrollees likely to benefit. CMS chose a single prescription drug cost POS threshold of $600 because this approach identifies Part D enrollees with a very high likelihood (~98%) of benefiting from the Medicare Prescription Payment Plan program, while reducing the risk of identifying Part D enrollees for whom the program may not be as helpful.

Sections 70.3.3 and 70.3.4 – Processing Election Request at the Time of Enrollment in a New Plan and Processing Election Request Before a Plan Year Begins While Remaining in Same Plan: These sections have been combined into a new section, Section 70.3.3 – Processing Election Request Prior to Plan Year (or New Plan Effective Date), to streamline the guidance. As such, the subsequent section numbers were updated accordingly.

C. Summary of Public Comments on the Draft Part One Medicare Prescription Payment Plan Program Guidance and CMS's Responses

CMS is directing readers to the draft part two guidance, which discusses CMS and Part D sponsor education, outreach, and communications requirements regarding the program in more detail. CMS will also publish model materials specific to the Medicare Prescription Payment Plan for Part D sponsors to use through an Office of Management and Budget (OMB) Information Clearance Request (ICR) process.

For 2025, the annual Out-Of-Pocket (OOP) cost threshold is $2,000. For subsequent years, the annual OOP threshold will be calculated in accordance with section 1860D–2(b)(4)(B)(i)(VIII). In addition, section 1860D–2(b)(2)(E)(v)(III)(aa) requires all covered Part D drugs to be included in the Medicare Prescription Payment Plan, regardless of whether, for example, they are low-cost drugs. CMS notes that it does not have the authority to change the statutory formula for the maximum monthly cap, nor limit the covered Part D drugs that are included in the program. As stated in section 30.1 of this final part one guidance, when OOP costs incurred in the first month under the program are less than the maximum monthly cap, a Part D sponsor cannot bill the participant more than their actual incurred OOP costs.

CMS has modified the definition of "OOP costs" in Appendix A to more clearly refer to the OOP costs that would be directly payable by the Part D enrollee to the pharmacy for covered Part D drugs if the enrollee does not participate in the Medicare Prescription Payment Plan.

Once a Part D enrollee has opted into the Medicare Prescription Payment Plan and is paying $0 at the POS, these OOP costs continue to count as incurred costs when calculating true out-of-pocket spending (TrOOP).

As stated in section 40 of the guidance, in order to ensure program participants are billed no more than the maximum monthly cap, as required by section 1860D–2(b)(2)(E)(iii), and only up to the annual OOP threshold, which is $2,000 in 2025, CMS is prohibiting plans from charging participants fees.

CMS is removing the requirement for Part D sponsors to offer a cash payment option due to concerns around mail theft and to stay consistent with forms of acceptable payment for Part D premiums, as certain Part D sponsors may not accept cash payment for premiums.

While a participant is permitted to pay more than the maximum monthly cap up to their remaining balance of total OOP costs incurred, a Part D sponsor is not allowed to retain any additional funds from the participant that exceed the participant's incurred costs and apply them to future incurred costs. As such, plans may not accept or retain payments from participants that exceed their remaining balance for incurred Part D drug costs, up to the annual OOP threshold, and then reconcile any overpayments at the end of the year, as suggested by a commenter. If a program participant pays more than their remaining balance for incurred Part D drug costs, the Part D sponsor must reimburse the participant the amount that is above the balance owed in a timely manner. CMS is not allowing OOP costs for covered Part D drugs incurred prior to a Part D enrollee opting into the program to be included in the program's calculated amount and billing, even if the claims are subsequently re-adjudicated during the program period.

When reconciliation results in an increased amount owed by the participant, plans should recalculate the maximum monthly cap for the month(s) in question.

To ensure that Part D enrollees receive the benefit of charitable contributions for their covered Part D drugs, charitable organizations may want to consider registering and file sharing through CMS's Benefits Coordination & Recovery Center (BCRC). This will ensure that Part D sponsors adjust the payer order such that these payments are processed before the final transaction to the Medicare Prescription Payment Plan BIN/PCN.

As stated in section 50.2 of this guidance, any additional transaction fees or other costs pharmacies incur from processing claims under the Medicare Prescription Payment Plan or otherwise related to such program are considered allowable pharmacy costs associated with the dispensing of a covered Part D drug that may be paid through applicable dispensing fees.

CMS has provided additional guidance on general education and outreach requirements in section 30 of the draft part two guidance. Below are the ICR packages referenced in that section:

- Medicare Advantage and Prescription Drug Programs: Part C and Part D Explanation of Benefits (CMS-10453; OMB 0938-1228)
- Medicare Advantage and Prescription Drug Program: Final Communications and Marketing Provisions in 42 CFR 422.111(a)(3) and 423.128(a)(3) (CMS-10260; OMB 0938-1051)
- Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-New)

CMS has developed three Information Clearance Requests (ICRs) that introduce new reporting requirements specific to the Medicare Prescription Payment Plan. These include:

- The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Advantage Prescription Drug (MARx) System Updates for the Medicare Prescription Payment Plan Program (CMS-10887; OMB 0938-New) ICR, which appeared in the ***Federal Register*** on January 26, 2024 for a 60-day public comment period, with comments due by March 26, 2024. It can be accessed here: https://www.federalregister.gov/documents/2024/01/26/2024-01582/agency-information-collection-activities-proposed-collection-comment-request; and

- The Medicare Part D Reporting Requirements (CMS-10185; OMB 0938-0992) ICR, which appeared in the ***Federal Register*** on February 2, 2024 for a 60-day public comment period, with comments due by April 2, 2024. It can be accessed here: https://www.federalregister.gov/documents/2024/02/02/2024-02095/agency-information-collection-activities-proposed-collection-comment-request

- Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982) ICR, which appeared in the ***Federal Register*** on December 18, 2023 for a 60-day public comment period, with comments due by February 16, 2024. It can be accessed here: https://www.federalregister.gov/documents/2023/12/18/2023-27684/agency-information-collection-activities-proposed-collection-comment-request

D. Final Part One Guidance on the Medicare Prescription Payment Plan

The table of contents for this section is as follows:

Final Comments

This guidance memorandum is difficult to locate. The announcement of the memorandum was sent as an email notice containing the following websites for additional material;

- For the fact sheet on the final part one guidance for the Medicare Prescription Payment Plan: https://www.cms.gov/files/document/fact-sheet-medicare-prescription-payment-plan-final-part-one-guidance.pdf.
- For the Information Collection Request (ICR) for the Medicare Prescription Payment Plan model plan materials: https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10882.
- For the draft part two guidance fact sheet: https://www.cms.gov/files/document/fact-sheet-medicare-prescription-payment-plan-draft-two-guidance.pdf.
- For an updated implementation timeline for the Medicare Prescription Payment Plan: https://www.cms.gov/files/document/medicare-prescription-payment-plan-timeline.pdf.

The last bulleted item above will take you to the plan timeframe. You need to scroll down to the first February 29 date to find the link to the 108-page document.

Our analysis of the document is extremely brief trying to identify the more important aspect of the changes being made. Those involved in this program need to review the material in-depth.

It continues to amaze this reader that CMS continues to acknowledge commenters suggestions by saying "CMS appreciates" more than 61 times.