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CENTER FOR MEDICARE

DATE: February 29, 2024

TO: Interested Parties

FROM: Meena Seshamani, M.D., Ph.D., CMS Deputy Administrator and Director of the Center for Medicare

SUBJECT: Medicare Prescription Payment Plan: Final Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Response to Relevant Comments

This memorandum provides interested parties with the final part one guidance on a select set of topics for the Medicare Prescription Payment Plan program for contract year (CY) 2025, which was established by section 11202 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) and signed into law on August 16, 2022. This 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.
- 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.

In addition to the part two guidance discussed in further detail below, CMS may supplement this final part one guidance with further program instruction as necessary to implement the program for CY 2025, including, for example, technical instructions for data submissions.

A. Introduction

Section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this final part one guidance for implementation of the Medicare Prescription Payment Plan for CY 2025, hereinafter referred to in this guidance by the full name or as the "program." In accordance with the law, on August 21, 2023, CMS issued a draft part one guidance for implementation of a select set of topics for the Medicare Prescription

Payment Plan. CMS also voluntarily solicited comments on the draft part one guidance. The 30-day comment period for the draft part one guidance began August 21, 2023 and concluded September 20, 2023. CMS received more than 100 public comments in response to the draft part one guidance, representing a wide range of views from academic experts, consumer and patient organizations, data vendors/software technology entities, Part D sponsors, health care providers, individuals, pharmaceutical and biotechnology manufacturers, pharmacies, pharmacy benefit managers (PBMs), state governments, and trade associations, among other interested parties.

CMS will post copies of the timely comment letters received on the IRA website at <https://www.cms.gov/inflation-reduction-act-and-medicare> in spring 2024. Comment letters from individuals not representing organizations will have the name, address, and contact information of the individual removed for privacy purposes. Additionally, substantively duplicative letters (e.g., submitted as part of a coordinated advocacy campaign) will be combined into a single document.

After consideration of the comments received, 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. CMS will develop its policies for CY 2026 and all subsequent years of the program through notice-and-comment rulemaking. The public will have an additional opportunity to submit comments as part of that rulemaking process and comments submitted in response to the draft part one guidance may be considered as part of that rulemaking process. CMS has also released draft part two guidance on select topics specific to the program, which is available at <https://www.cms.gov/files/document/medicare-prescription-payment-plan-draft-part-two-guidance.pdf>. Final part two guidance will be published in summer 2024.

In this memorandum, CMS provides a summary of significant comments that it received in response to the draft part one guidance, as well as the agency's response to those significant comments, which begins on page 3. CMS is not responding in this document to all comments that it received, but instead is addressing those significant comments that have prompted a revision or a clarification of its policies under the program or that otherwise raised a significant issue warranting a response that would explain to the public the agency's resolution of that issue.

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

CMS received many constructive, thoughtful, and helpful comments from consumer and patient groups, manufacturers, pharmacies, Part D sponsors, individuals, and other interested parties on the draft part one Medicare Prescription Payment Plan guidance that was released on August 21, 2023. This section provides a summary of the key changes and clarifications made to the draft part one guidance based on these comments and other feedback. Please note that we have not included an exhaustive list of the changes and clarifications made in this final part one guidance in this section. Additionally, many of the clarifications are discussed in further detail in our draft part two guidance, published on February 15, 2024 and available at <https://www.cms.gov/files/document/medicare-prescription-payment-plan-draft-part-two-guidance.pdf>. References to the relevant sections of our draft part two guidance have been included in section D below. CMS provides responses to the comments received in section C of

this final part one guidance and has made corresponding changes and clarifications to the policies described in the draft part one guidance, as summarized below.

Section 60.2.3 – Targeted Part D Enrollee Notification at Point-of-Sale (POS): In section 60.2.3 of this final part one guidance, 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

Statutory Formula for Program Calculations (Section 30)

Comment: Several commenters expressed support for the program’s maximum monthly cap calculation formulas prescribed in the IRA and discussed in the draft part one guidance, including how “months remaining in the plan year” and extended day supplies of medications were counted.

Response: CMS appreciates commenters’ support for the explanation and examples of the statutorily prescribed maximum monthly cap calculation formulas.

Importance of Education and Calculation Tools to Help Enrollees Understand the Monthly Payment Calculations (Section 30)

Comment: Many commenters expressed concern about potential enrollee confusion based on the different first and subsequent months maximum monthly cap calculations, along with increasing maximum monthly cap calculations based on additional out-of-pocket (OOP) drug costs. To address this, commenters recommended CMS develop simple, consistent beneficiary educational materials, including calculators and decision support tools. In addition, multiple commenters recommended reinforcing that in CY 2025, the annual OOP threshold will be \$2,000, as part of our education and outreach.

Response: CMS appreciates commenters’ concerns regarding potential confusion around the various aspects of the monthly payment calculation and agrees that consistent messaging and

education will help alleviate potential confusion. CMS also agrees that the CY 2025 annual OOP threshold is a key factor that should be communicated to Part D enrollees when discussing the calculation. CMS directs 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.

Request to Use Alternative Formulas for Program Calculations (Section 30)

Comment: Many commenters suggested that CMS revise the statutory formulas for the first and subsequent months maximum monthly cap calculations to ensure the same cap amount applies to each month. Some commenters recommended a flat payment of \$166.67 per month, with reconciliation at the end of the plan year, should an enrollee incur lower OOP costs. Other commenters suggested alternatives such as: the payment should always be calculated as [OOP Costs] / [number of months remaining in year]; the subsequent month payment should be the greater of that month or the prior month's maximum monthly cap; or the payments should be spread over twelve calendar months, not the remaining months in the plan year. A commenter requested that CMS clarify that the annual OOP threshold used in the first month maximum cap calculation be based on the \$2,000 annual OOP threshold for 2025, not on a lower amount if a Part D sponsor offers a benefit structure with a lower annual OOP limit. Another commenter requested that CMS not require Part D sponsors to bill the participant the lesser of the participant's actual OOP costs or the first month's maximum monthly cap, to help reduce large payments at the end of the year. Lastly, a commenter requested that very low-cost drugs be excluded from the program.

Response: As stated in section 30 of the final part one guidance, section 1860D-2(b)(2)(E)(iv) of the Social Security Act (the Act) specifies how the maximum monthly caps on OOP cost sharing payments are to be calculated. Under section 1860D-2(b)(2)(E)(iv)(I) of the Act, for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan, the maximum monthly cap is calculated using the annual OOP threshold specified at section 1860D-2(b)(4)(B), regardless of whether a participant's plan offers a benefit structure with a lower annual OOP limit. For 2025, the annual 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) of the Act 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.

Clarification Regarding Program Calculations and “Incurred Costs” and “OOP Costs” (Section 30, 50.1)

Comment: Some commenters requested additional details related to the monthly payment calculation, including clarification on the impact of the IRA’s redesign of the Part D program, which included changes to the definition of “incurred costs,” how assistance from charitable organizations and other payers is incorporated into Medicare Prescription Payment Plan calculations, and the difference between “incurred costs” and “OOP costs incurred.”

Response: CMS thanks commenters for raising these issues. Please refer to section 50.1 of the draft part two guidance for additional information regarding the treatment of supplemental payers and impacts on monthly program payment amounts. Additionally, please refer to the Draft CY 2025 Part D Redesign Program Instructions, published January 31, 2024, which provides interested parties with draft guidance regarding the implementation of section 11201 of the IRA (P.L. 117-169), including updates to the definition of “incurred costs” and which costs count toward true out-of-pocket (TrOOP) spending.¹ We have modified the definition of “OOP costs” in Appendix A of this final part one guidance 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 TrOOP. As stated in section 30 of the final part one guidance, opting into the program will not impact how a program participant moves through the Part D benefit or what counts towards their TrOOP costs; the total incurred costs and the timing of TrOOP accumulation do not change.

Request for Additional Program Calculations Examples (Section 30)

Comment: Some commenters expressed support for the program calculations outlined in the draft part one guidance, including how months remaining in the plan year and extended day supplies of medications were counted. Many commenters requested additional Medicare Prescription Payment Plan program calculation examples, especially for more complex scenarios involving claims reprocessing, retroactive changes, Low-Income Subsidy (LIS) enrollees, multiple supplemental coverages throughout the year, and Employer Group Waiver Plans (EGWPs).

Response: CMS thanks commenters for their support and recommendations. Please refer to Appendix B of this guidance, which include examples in which participants have supplemental coverage (including costs that contribute toward TrOOP) and retroactive LIS status. In this final part one guidance, CMS has added additional examples in Appendix B. CMS also directs readers to the draft part two guidance, which contains information related to specific pharmacy processes.

¹ Please see the Draft CY 2025 Part D Redesign Program Instructions: https://www.cms.gov/sites/default/files/2024-01/Draft%20CY%202025%20Part%20D%20Redesign%20Program%20Instructions_January%2031%202024_Final_Updated.pdf.

Beneficiary Protections (Prohibition on Fees, Interest Payments, and Payment Mechanism Fees) (Section 40)

Comment: Many commenters expressed support for the prohibition of participant fees, including late fees, interest payments, and payment mechanism fees.

Response: CMS thanks commenters for their support.

Comment: Several commenters expressed concern around the inability to charge participants fees, as certain fees are beyond a plan's control, such as insufficient funds fees, and stated that fees provide incentives for proper payments by program participants.

Response: 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) of the Act, and only up to the annual OOP threshold, which is \$2,000 in 2025, CMS is prohibiting plans from charging participants fees. Plan sponsors also are responsible for ensuring that any third parties they contract with do not charge participants fees. Part D sponsors should ensure participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor. CMS expects Part D sponsors to take steps to ensure that participants do not accrue any additional charges (such as an overdraft fees) as a result of errors made by the Part D sponsor and to work with participants to reconcile any of these charges, as discussed in section 40.2 of this final part one guidance. Fees that are wholly beyond a Part D sponsor's control, such as those that are no fault of the Part D sponsor, are outside the scope of this guidance.

Program Billing Requirements and Timeline (Section 40 and Section 40.2)

Comment: Many commenters expressed support for encouraging Part D sponsors to offer multiple means for participants to make their monthly program payments, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by check. In contrast, another commenter asked CMS to create a uniform standard for billing and payment under the program, rather than allowing Part D sponsors to offer multiple means of payment.

Response: CMS appreciates commenters' support. As stated in section 40 of this final part one guidance, CMS encourages Part D sponsors to offer participants multiple means of payment under the program to allow participants flexibility. A uniform standard of billing and payment may cause burden on participants and/or Part D sponsors if a participant does not have certain payment capabilities. In this final part one guidance, 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.

Comment: Many commenters expressed support for the required billing statement information detailed in the guidance and included suggestions for additional information to be required, such as information on OOP costs incurred at time of statement, notification for when the annual OOP

threshold is reached, contact information for State Health Insurance Assistance Program (SHIP) counselors, language regarding the impact of nonpayment, any prior outstanding balances, and plan mailing address for participants who choose to mail in payments. A commenter recommended that CMS clearly state that the program payments amounts will differ from the Part D prescription payment amounts shown on the Explanation of Benefits (EOB). A commenter requested clarification on what information is permitted to be included in the billing statement. They stated that plans should be allowed to include information explaining to program participants how billing amounts could change from month to month due to the participant incurring additional drug costs throughout the year.

Response: CMS appreciates the positive feedback and interest in providing program participants with comprehensive information. Many of the suggestions offered by commenters have already been listed as requirements in section 40 of this final part one guidance, including itemized OOP costs by prescription for the month billed, balances carried over from the prior month and missed payments, and plan contact information. The billing statement requirements listed in the guidance are a minimum requirement, and CMS encourages plans to include additional information that they feel is pertinent to program participants. Any additional information that plans choose to include on the billing statement must abide by Part D regulations at 42 CFR Part 423 Subpart V, which define standards for Part D required materials, content, and delivery requirements and are outlined in the Medicare Communications and Marketing Guidelines (MCMG). Our part two guidance will provide details on the language to be included in the EOB referencing the Medicare Prescription Payment Plan.

Comment: A commenter suggested that in the interest of providing a simple Part D enrollee experience with the program, CMS should require that Part D sponsors offer “patient navigators” to assist program participants in understanding their monthly bills and how to make payments. They state that this would be similar to the patient navigators established through the Patient Protection and Affordable Care Act (ACA).

Response: CMS appreciates this commenter’s feedback and desire to ensure a simple and seamless election into the program for Part D enrollees. CMS is developing resources to assist Part D enrollees interested in participating in the program, and we encourage Part D sponsors to offer support to help Part D enrollees understand the program, how their monthly bills are calculated, and how to make payments.

Comment: Several commenters expressed opposition to the list of required information detailed in section 40 regarding the monthly billing statement, stating that requiring so much information to be included in the billing statement may be confusing for program participants. A commenter specifically requested that information related to “Extra Help,” or the LIS program, be removed to avoid confusion.

Response: CMS appreciates these commenters’ feedback and interest in simplifying the billing statement. CMS believes that the list of billing statement requirements provided in section 40 of this final part one guidance offers transparency and clarity to program participants in understanding the program and their respective owed amounts. CMS has included a requirement that information about the Extra Help program be included on the billing statement in order to

ensure that all Part D enrollees are aware of the options available to make medications more affordable. The Extra Help program, for those who qualify, is more advantageous than participation in the Medicare Prescription Payment Plan.

Comment: CMS received many comments expressing support for Part D sponsors to allow program participants flexibility in choosing a date to be charged for their program costs. Several commenters requested that CMS require Part D sponsors to provide this flexibility, while a commenter requested that this not be made a requirement for Part D sponsors. Several commenters expressed opposition to allowing program participants to choose the day of the month that they would be charged for program costs, citing patient confusion and burden on plans to track individual billing and charge dates for their enrollees who are participating in the program. A commenter suggested limiting the dates program participants can choose to be charged to either the 1st or 15th of each month. Another commenter suggested aligning the charge date for the program with the charge date for the plan's monthly premium amount.

Response: CMS appreciates this feedback from commenters. In order to offer flexibility to Part D enrollees and potentially reduce operational complexities for Part D sponsors in the first year of the program, CMS is maintaining our approach to encourage Part D sponsors to work with program participants to set payment dates, as stated in section 40. Part D sponsors will have flexibility in allowing their program participants to choose the payment due date.

Comment: Several commenters expressed opposition to Dual Eligible Special Needs Plans (D-SNPs) being subject to the billing requirements listed in section 40 of the draft part one guidance, as beneficiaries of D-SNPs are primarily enrolled in the LIS program and would not benefit from the Medicare Prescription Payment Plan program.

Response: CMS appreciates the feedback received from commenters. Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible individuals.^{2 3} Due to this statutory requirement, CMS cannot waive the billing requirements for D-SNPs. While the statute requires that an LIS enrollee must have the option to become a program participant, CMS agrees that individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the program. As stated in this final part one guidance, Part D sponsors must identify Part D enrollees likely to benefit from the program and educate those enrollees on the impacts of potentially participating in the Medicare Prescription Payment Plan.

² This provision does not apply to the Limited Income Newly Eligible Transition (LI NET) coverage because participants in the LI NET program do not enroll in a PDP or MA-PD plan to receive transitional coverage under the program.

³ Under section 1894(a) of the Act, PACE organizations must provide all medically necessary services including prescription drugs, without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. While the Medicare Prescription Payment Plan is applicable to all Part D plans, it has no practical application for PACE organizations. In addition, the program has no application to those demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost sharing.

Unpaid Program Balances and Debt Collection (Section 40)

Comment: Many commenters requested additional guidance, clarity, and flexibility from CMS on debt collection procedures, specifically surrounding outstanding balances at the end of the plan year or when someone passes away mid-year. Several commenters requested that CMS prohibit aggressive debt collection practices, or debt collection in general.

Response: CMS appreciates commenters' feedback regarding debt collection procedures. CMS has consulted with the Consumer Financial Protection Bureau (CFPB) on this issue. It is CMS's intention that program participants be provided with all allowable and appropriate avenues for paying outstanding balances in a manner consistent with the requirements set forth in this final part one guidance. As stated in section 40 of this final part one guidance, plan sponsors (and any third parties Part D sponsors contract with) are expected to follow all applicable federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection, when collecting any unpaid balances related to the program.

Standalone Program Monthly Billing Statement (Section 40)

Comment: Several commenters expressed support for the billing statement to be sent monthly to program participants in order to ensure any variance in program billed amounts is understood by program participants.

Response: CMS thanks commenters for their support for a monthly billing statement.

Comment: Several commenters expressed opposition to a separate monthly bill being sent to program participants. They stated that plans should be allowed to send the program billing statement alongside or combined with the bill for the participant's plan premium to reduce confusion amongst participants and operational burden on plans.

Response: CMS appreciates the feedback from commenters on the program's monthly billing statement. The separate monthly program bill is to ensure that program participants do not confuse their payments for incurred OOP costs with their premium or other bills sent from the plan.

Prioritization of Premium Payments (Section 40.1)

Comment: Several commenters expressed support for CMS encouraging Part D plans to prioritize payments towards Part D plan premiums, rather than monthly program payments, to avoid a Part D enrollee losing their Part D coverage. A commenter requested that Part D plans be required to include in their notices that program participants should prioritize premium payments over monthly program payments.

Response: CMS appreciates commenters' support. Section 40.1 of this final part one guidance requires Part D sponsors to prioritize plan premium payment over monthly program payments when a payment is received from a program participant and it is unclear whether that payment should go towards the participant's outstanding Part D plan premium or Medicare Prescription

Payment Plan balance. Additionally, content requirements for Part D sponsor notices, which could include language encouraging program participants to prioritize premium payments, will be released as part of the model materials ICR package that CMS is issuing for comment.

Financial Reconciliation Process (Section 40.2)

Comment: Many commenters responded to CMS's request for comment on appropriate financial reconciliation standards for the program. Several commenters requested clarification on whether participants can pay more than the monthly cap. Other commenters requested clarification that manufacturers have no role in financial reconciliation and that Part D sponsors have discretion in their financial reconciliation processes.

Response: CMS appreciates the interest and feedback received from commenters. As stated in this final part one guidance, while plans may not charge more than the monthly cap, participants may pay more than the monthly cap if they choose, up to the total amount of outstanding out-of-pocket costs incurred. CMS is including in this final part one guidance that manufacturers have no role in financial reconciliation between program participants and Part D sponsors. Part D sponsors have discretion in how they manage their financial reconciliation processes, while abiding by CMS regulations and guidance.

Comment: In response to CMS's request for comment on appropriate financial reconciliation standards for the program, several commenters proposed suggestions for the standards. A commenter suggested a notification be provided by Part D sponsors to program participants who elect to pay more than the monthly cap to ensure the participants understand that this is optional. Another commenter suggested program participants be allowed to pay up to the yearly annual OOP threshold and the plan would conduct reconciliation at the end of the year to return any funds beyond the participant's incurred OOP costs. Another commenter suggested that costs incurred prior to election but processed after election, as well as adjusted costs after election, be included in the program. A commenter requested that participants not be charged penalties for billing or payment mistakes made by the Part D sponsor.

Response: CMS appreciates commenters' feedback regarding the financial reconciliation process for Part D sponsors. CMS encourages plans to engage in thoughtful and clear communication, beyond the stated requirements, with program participants, including additional notifications for participants who choose to make a payment above the monthly cap. As stated in section 1860D-2(b)(2)(E)(iii) of the Act and in section 40.2 of the guidance, a Part D sponsor is responsible for billing a participant a monthly amount that does not exceed the maximum monthly cap, as defined in section 1860D-2(b)(2)(E)(iv) of the Act. 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 readjudicated during the program period. Part D sponsors should ensure participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor, as stated in Section 40.2 of this final part one guidance. Section 40.2 requires that Part D sponsors have a financial reconciliation process in place to correct inaccuracies in billing and/or payments.

Comment: Several commenters expressed concern about collecting payments through monthly billing after a participant is no longer in the program. Some commenters suggested Part D sponsors be allowed to bill participants in full or have a shorter payment plan.

Response: CMS appreciates commenters' feedback regarding billing after a participant exits the program. To ensure that individuals are offered maximum flexibility in paying their outstanding balances after termination from the program (either voluntary or involuntary), CMS is requiring that Part D sponsors continue to bill amounts owed in monthly amounts that do not exceed the maximum monthly cap. An individual may choose, however, to pay off the outstanding balance as a lump sum amount. See section 80 of this final part one guidance for additional information.

Comment: Some commenters requested additional guidance related to claims adjustments for program participants (including out-of-cycle reversals, adjustments that occur after a participant has been billed by the Part D sponsor, and adjustments that cross calendar years).

Response: As stated in section 40.2 of this final part one guidance, section 1860D–2(b)(2)(E)(v)(III)(gg) of the Act specifies that Part D sponsors must have a financial reconciliation process in place to correct inaccuracies in billing and/or payments. Federal regulations at 42 CFR § 423.466(a) require sponsors to process the adjustment and issue refunds or recovery notices within 45 calendar days of receipt of LIS changes, Financial Information Reporting (FIR), or Information Reporting (Nx) transactions necessitating the claims adjustment.⁴ Part D sponsors must make the retroactive adjustments and promptly issue refunds or initiate recovery once complete information regarding a claim's adjustment is received. Part D sponsors bear the responsibility for timely financial reconciliation with Part D enrollees.

For instance, in Example #3 in this guidance (section 30.3.3), the maximum monthly cap and monthly participant payment for October is \$114.39. If the \$120 drug claim from October was reversed and reprocessed with a copay of \$100 (for total October OOP costs incurred of \$104, which is the sum of the \$100 copay and \$4 monthly generic), the revised maximum monthly cap for October would be \$107.72. If the participant had already been billed by the plan and paid the original \$114.39, the plan must work with the participant to determine if they should either refund the difference of \$6.67 (\$114.39-\$107.72) directly to the Part D enrollee or apply the overpayment to the remaining OOP costs owed. In either case, Part D sponsors are responsible for following normal processes for appropriately updating TrOOP accumulators and restacking

⁴ CMS contracts with a Part D Transaction Facilitator, which is responsible for activities including FIR transactions (which facilitate the timely transfer of TrOOP and drug spend accumulated between all of an enrollee's Part D plans within a calendar year) and Nx transactions (which provide Part D plans with a record of the patient pay amount after the pharmacy bills a supplemental payer).

claims. Refer to Appendix B, Examples B9 and B10, in this guidance for an example of an adjusted claim that results in a refund to the Medicare Prescription Payment Plan participant.

When reconciliation results in an increased amount owed by the participant, plans should recalculate the maximum monthly cap for the month(s) in question. As noted in section 30 of this final part one guidance, under section 1860D–2(b)(2)(E)(iv)(II) of the Act, for each subsequent month for which the Part D enrollee has opted into the program, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs incurred by the participant in the subsequent month, divided by the number of months remaining in the plan year. When Part D claims adjustments result in increased amounts owed by the participant, and these amounts have not yet been billed to the participant, they should be included in the revised remaining OOP costs owed and, thus, in the subsequent month maximum cap for the next billing period. Refer to Appendix B, Example B11, in this guidance for an example of an adjusted claim that results in additional OOP costs being owed by the Medicare Prescription Payment Plan participant.

When a covered Part D drug claim adjustment occurs after the end of a plan year, the Part D sponsor should use the above as general guidance for appropriately recalculating the amount owed to or by the participant and issue a final bill or refund, as necessary.

Pharmacy Claim Payment Obligations and Claims Processing (Section 50)

Comment: A commenter requested clarification of what is meant by “current practices for payment” as it relates to home infusion pharmacies.

Response: As stated in section 50 of this final part one guidance, Part D sponsors must reimburse network pharmacies the total of a participant’s OOP amount and the Part D sponsor portion of the payment for a covered Part D drug in accordance with existing prompt payment requirements. Part D sponsors should follow existing industry standards for prompt payment of home infusion pharmacies.

Pharmacy Claims Processing Requirements (Section 50.1)

Comment: Many commenters expressed support for the claims processing methodology set forth in the draft part one guidance, which would use a Medicare Prescription Payment Plan-specific Bank Identification Number (BIN) and/or Processor Control Number (PCN). In addition, commenters raised potential challenges of using a second BIN/PCN, including things such as additional burden on pharmacies, lack of transparency around OOP costs incurred, and retrospective/retroactive claims processing. A few commenters expressed a preference for a card-based method; however, other commenters stated that they agreed with CMS’s concerns with a card-based method.

Response: CMS thanks the commenters for their feedback and questions. CMS acknowledges that there may be challenges with the BIN/PCN approach but agrees with commenters that the BIN/PCN methodology will support a uniform implementation of the Medicare Prescription

Payment Plan in 2025. In section 50.1 of this final part one guidance, CMS sets forth the claims processing methodology for program participants using a BIN and/or PCN unique to the Medicare Prescription Payment Plan. Issues related to pharmacy costs and claims adjustments are addressed elsewhere in this section. CMS reiterates the requirement that Part D enrollees pay \$0 at the POS once their participation in the program has been effectuated. While CMS appreciates commenters' concern about a potential lack of transparency around OOP costs incurred at the POS and may consider this issue in future guidance, we also note that section 1860D-2(b)(2)(E) of the Act, as added by section 11202 of the IRA, requires Part D sponsors to calculate monthly payments and bill participants; there is no statutory requirement for pharmacies to provide financial information to Part D enrollees.

We appreciate commenters' thoughts on the use of a pre-funded card to operationalize the Medicare Prescription Payment Plan. This method would keep the pharmacy whole and could allow for coordination of benefits (COB) with other payers supplemental to Part D; however, CMS is concerned this approach does not provide the same level of Part D sponsor oversight to ensure that payments are only made for covered Part D drugs for the participant cardholder. Additionally, there are other concerns surrounding timeliness of issuing payment cards and participants needing to present a physical card at the POS, which could be forgotten, lost, or stolen, potentially causing delays in obtaining prescription drugs, elevated risk of fraud, additional costs to the Part D program and potential card processing fees for pharmacies. CMS is also aware that not all organizations have the financial capabilities established to enable a pre-funded payment card system. Moreover, interested parties have also expressed a desire to have a single, uniform method of adjudicating and managing the patient liability for the Medicare Prescription Payment Plan at the POS and CMS has determined the use of unique BIN/PCNs for the final transaction to the Medicare Prescription Payment Plan accomplishes that objective. For these reasons, CMS is not adopting the pre-funded card method for CY 2025.

CMS supports industry-wide innovation that would address potential barriers to card utilization; in future years, CMS is open to alternative claims processing strategies, provided that they meet the requirements as outlined in section 50.1 of the draft part one guidance.

Comment: Some commenters requested additional standardization with regard to pharmacy messaging, including development of additional National Council for Prescription Drug Programs (NCPDP) Approved Message Codes related to program participation and program-specific PCNs starting with "MPPP." A commenter requested that program participation be included as part of the Pharmacy Eligibility Inquiry Transaction (also referred to as an E1 transaction).

Response: The development and approval of NCPDP codes is outside of the scope of this final part one guidance; however, CMS encourages NCPDP and industry partners to assess options that help pharmacies and Part D sponsors to operationalize the program. CMS appreciates the recommendation from commenters that all Medicare Prescription Payment Plan PCNs start with "MPPP;" as stated in section 50.1 of this final part one guidance, CMS requires Part D sponsors to adopt this nomenclature. With regard to the inclusion of program participation on the E1 transaction, CMS appreciates the suggestion. While there is not currently a mechanism to include

Medicare Prescription Payment Plan information on the E1, CMS will consider this for future years of the program.

Comment: A few commenters requested CMS establish oversight processes for both plans and pharmacies to ensure claims are processed to the Medicare Prescription Payment Plan BIN/PCN appropriately and pharmacies receive timely payment. A commenter requested CMS exercise enforcement discretion related to the POS notification process in year one of the program. Commenters also requested guidance on potential situations when a pharmacy refuses to provide medication at no cost at the POS or does not appropriately process claims for program participants using the Medicare Prescription Payment Plan BIN/PCN.

Response: CMS appreciates the comments. As stated in section 50 of this final part one guidance, Part D sponsors are responsible for both notifying the pharmacy when a Part D enrollee incurs OOP costs with respect to a covered Part D drug that make it likely the Part D enrollee may benefit from the program and ensuring that pharmacies inform the enrollee of the notification. Consistent with section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, Part D sponsors must also provide for timely payment to pharmacies for covered Part D drugs. Additional information regarding monitoring and compliance is included in the draft part two guidance.

Comment: A commenter suggested program participants be provided with digital proof of election into the Medicare Prescription Payment Plan, in case of issues with pharmacy claims processing.

Response: CMS appreciates the suggestion. Section 30.3.2 of the draft part two guidance encourages Part D sponsors to provide program participants with digital evidence of their election into the Medicare Prescription Payment Plan.

Comment: A commenter requested additional guidance around FIR transactions and TrOOP accumulation in relation to participants in the Medicare Prescription Payment Plan. Another commenter requested CMS create a Medicare Prescription Payment Plan accumulator, similar to the TrOOP accumulator.

Response: As stated in section 50.1 of this final part one guidance, participation in the Medicare Prescription Payment Plan will have no impact on TrOOP accumulation, meaning Part D sponsors must calculate TrOOP balances based on the enrollee's incurred costs and not the Medicare Prescription Payment Plan payments made by the enrollee. This extends to automated TrOOP Balance Transfer (TBT) processes and FIR transactions – these will continue to reflect the TrOOP and drug spend by month using the original claim accumulators. CMS declines the request to develop a separate program-specific accumulator at this time.

Comment: Some commenters requested clarification regarding how contributions made by charitable organizations or other payers supplemental to Part D would be incorporated into the BIN/PCN payment process and counted toward TrOOP. A commenter stated that COB is the purview of the Part D sponsor, not the pharmacy, and requested this burden not be shifted to pharmacies.

Response: CMS recognizes the importance of charitable organizations and other supplemental payers in reducing OOP costs for eligible Part D enrollees. As stated in section 50.1 of this final part one guidance, the transaction processed through the Medicare Prescription Payment Plan BIN/PCN should be submitted last, in order to capture the final patient responsibility amount after all other payers have paid, so that the Part D sponsor could pay the pharmacy for the amount the participant would otherwise owe at the POS to obtain their prescription. In addition, participation in the Medicare Prescription Payment Plan must have no impact on TrOOP accumulation. If the program participant receives charitable assistance for their covered Part D drugs or has supplemental coverage, that coverage should be processed prior to submitting the final transaction to the program-specific BIN/PCN. This guidance also applies to program participants with supplemental Medicaid; while Medicaid is generally mutually exclusive to Medicare Part D, in cases where there is supplemental Medicaid coverage, the Medicare Prescription Payment Plan BIN/PCN should be submitted last. Please refer to the Medicare Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits for additional information regarding payer order.

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 provided in 42 CFR § 423.464(f), Part D sponsors must permit state pharmaceutical assistance programs (SPAPs) and entities providing other prescription drug coverage to coordinate benefits with them. CMS is aware, however, that many stakeholders are involved in the COB process, including pharmacies, and believes that this guidance will help all parties interacting with covered Part D drug claims for Medicare Prescription Payment Plan program participants.

Comment: A commenter noted that CMS referred to the NCPDP standard as “telecommunications standard” instead of using the correct term, which is “Telecommunication Standard.”

Response: CMS appreciates the clarification and has revised the guidance to reflect the correct terminology.

Comment: A commenter requested clarification on how the Medicare Prescription Payment Plan will work for Part D enrollees who are obtaining medication from a 340B program.

Response: As stated in section 30 of this final part one guidance, Part D sponsors must include all covered Part D drugs in the Medicare Prescription Payment Plan. The means by which a pharmacy purchases a covered Part D drug has no impact on its inclusion in a participant’s OOP costs under the program.

Comment: A commenter requested additional information around the interaction of participation in the Medicare Prescription Payment Plan and real-time benefit tools.

Response: As stated in section 50.1 of this final part one guidance, claims processing for the program must have no impact to prescriber or participant real-time benefit tools, meaning participant liability amounts must be represented as if the Medicare Prescription Payment Plan did not apply.

Pharmacy Transaction Costs (Section 50.2)

Comment: A few commenters requested that CMS either require Part D sponsors pay pharmacies a dispensing fee to cover the pharmacy operational costs of the Medicare Prescription Payment Plan or that CMS provide reimbursement directly to the pharmacy. Some commenters also requested CMS ensure additional protections for pharmacies from program-related costs being incorporated in retroactive fees paid by the pharmacy to Part D sponsors.

Response: CMS appreciates the commenters' feedback. 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 clarifies here that costs "otherwise related to such program" may include non-transaction costs associated with the program, such as time associated with reviewing the paid claim response for a POS likely to benefit notification or informing a Part D enrollee that they are likely to benefit from the program.

Consistent with section 1860D–11(i) of the Act, CMS may not interfere with the negotiations between Part D sponsors and pharmacies and may not institute a price structure for the reimbursement of covered Part D drugs. As such, CMS is prohibited from requiring Part D sponsors to pay pharmacies additional fees related to the Medicare Prescription Payment Plan. Further, CMS does not have the statutory authority to directly reimburse Part D sponsors' contracted pharmacies for costs associated with administering the program.

Part D sponsors' administrative costs for program implementation, including projected losses, should be accounted for in their Part D bids for CY 2025. Additional bidding guidance for CY 2025 is included in section 60.1 of the draft part two guidance. Section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act requires Part D sponsors to ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments. As a result, Part D sponsors cannot impose any fees or costs related to program implementation on pharmacies, as such fees or costs would affect the amount paid to pharmacies in violation of the statute.

As stated in section 50.2 of this guidance, participation in the Medicare Prescription Payment Plan is an arrangement between the Part D sponsor and the Part D enrollee; pharmacies cannot be held responsible for any unsettled balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

Claims Processing Requirements for Different Pharmacy Types (Section 50.3)

Comment: A few commenters expressed support for program processes applying to all pharmacy types. However, many commenters expressed concern about how the Medicare

Prescription Payment Plan will work for Part D enrollees utilizing non-retail pharmacies, including long-term care and mail order pharmacies, and what mechanism pharmacies will use to notify Part D enrollees that they are likely to benefit.

Response: CMS appreciates the feedback. Section 50.3 of the draft part two guidance details how non-retail pharmacies will be required to notify Part D enrollees that they are likely to benefit from the program.

Paper Claims Processing Exclusion (Section 50.4)

Comment: Many commenters expressed support for CMS’s exclusion of retroactive paper claims submitted to the Part D sponsor by a program participant. Some commenters requested additional clarification around the treatment of claims for direct member reimbursement (paper, telephonic, or other) and out-of-network (OON) claims.

Response: CMS appreciates the commenters’ support. CMS further states in section 50.4 of this final part one guidance that “paper claims” refer to any drug claims for which the participant submits a request for retroactive coverage by the Part D sponsor (whether the request is made via a paper form, telephonically, or electronically), including requests for direct member reimbursement for OON claims.

General Part D Enrollee Outreach Requirements for Part D Sponsors (Section 60.1)

Comment: Many commenters expressed support for a standardized, CMS-developed education and outreach plan, that includes consistent language and messaging pertaining to the program in existing model materials (e.g., ANOC, EOC, EOB, Summary of Benefits, the Medicare & You Handbook, etc.), new materials and tools (e.g., post cards, social media posts, presentations, model notices, and a monthly payment calculator tool, etc.), and associated updates to Medicare.gov, including Medicare Plan Finder.

Response: CMS appreciates commenters’ support and agrees with this comment. 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)

Additionally, to support broad education of all Part D enrollees on the availability of the program, CMS is developing new and updating existing Part D educational resources, including potential modifications to Medicare.gov and other resources, as detailed in section 40 of the draft part two guidance.

Comment: Several commenters provided feedback regarding information related to the Medicare Prescription Payment Plan program to be included specifically in the EOB. A commenter recommended to only include a high-level statement in the EOB that a beneficiary has elected to participate in the program, therefore the costs outlined in the EOB may not accurately reflect what occurred at the POS. Another commenter requested that CMS add a program participation indicator on the EOB.

Response: CMS appreciates commenters' recommendations related to the EOB. As part of the most recent Paperwork Reduction Act (PRA) renewal for the Part D EOB, given the significant changes the IRA makes to the Part D benefit design and the launch of the Medicare Prescription Payment Plan in CY 2025, CMS requested comment on what information related to the Medicare Prescription Payment Plan should be included in the EOB. On June 6, 2023, CMS published in the Federal Register (88 FR 37066) notice of a 60-day comment period regarding the Part D model EOB (CMS-10453; OMB 0938-1228). CMS considered all comments received, and on December 8, 2023, CMS issued published notice of an updated EOB with a 30-day comment period (88 FR 85622). Additional details regarding program information included in the EOB are provided in section 30.1.4 of the draft part two guidance.

Comment: Several commenters requested model materials and associated part two guidance be available as soon as possible. A few commenters specifically requested model materials be finalized no later than April 1, 2024.

Response: CMS appreciates this comment and notes that model materials will be released for comment as part of an ICR process. CMS is making every effort to provide stakeholders with program guidance and model materials as soon as possible.

Comment: Many commenters suggested that CMS develop education and outreach materials for specific audiences, including enrollees, Part D plans, pharmacies, providers, beneficiary advocates, SHIPs, and Special Needs Plans (SNPs).

Response: CMS agrees with this suggestion. As stated in section 40 of the draft part two guidance, CMS will provide an educational product on the Medicare Prescription Payment Plan that will be made publicly available for stakeholders to use and will work with stakeholders, including, but not limited to, Part D sponsors, pharmacies, providers, and beneficiary advocates, including SHIPs, to ensure they have the support needed to effectively communicate about the program.

Comment: Many commenters requested that CMS ensure all materials related to the program are culturally appropriate, easily understandable, and available in multiple languages.

Response: CMS appreciates this comment. Section 30.4 of the draft part two guidance outlines translation requirements for Part D sponsor required materials related to the Medicare Prescription Payment Plan that ensure materials are provided in a culturally competent manner.

Identification of Part D Enrollees Who Are Likely to Benefit (Section 60.2.1)

Comment: Some commenters expressed support for CMS’s likely to benefit definition, which requires that “the Part D enrollee would have to incur some level of substantial OOP costs; further, the Part D enrollee’s highest monthly OOP cost incurred would be more than the highest monthly paid amount under the Medicare Prescription Payment Plan (if the program had applied).”

Response: CMS appreciates commenters’ support.

Comment: A commenter suggested CMS reconsider using “likely to benefit” terminology as part of beneficiary outreach, out of concern that it creates the false impression that other beneficiaries are harmed.

Response: CMS appreciates the thoughtful feedback. CMS notes that the “likely to benefit” terminology is based on statutory language (see section 1860D–2(b)(2)(E)(v)(III)(dd): “when an enrollee incurs out-of-pocket costs...that make it likely the enrollee may benefit from such an election”). CMS’s use of “likely to benefit” should be interpreted to mean those Part D enrollees who both incur some level of substantial OOP costs and are unlikely to be faced with Medicare Prescription Payment Plan monthly payments that initially provide substantial financial relief but later, due to timing constraints, result in monthly payments that are higher than they would have been absent the program. As noted in section 30 of this guidance, the overall OOP costs are not changed for program participants, and Part D enrollees will have their own assessment of personal “benefit” from the program.

Targeted Part D Enrollee Outreach Requirements (Section 60.2.1, 60.2.2, 60.2.3)

Comment: Several commenters expressed general support for CMS’s targeted outreach requirements for Part D sponsors and requested clarification regarding how frequently targeted outreach should occur and which enrollees should be targeted. A few commenters requested that targeted outreach notifications should not be required during the last quarter or last two months of the plan year. Other commenters requested that certain subgroups of enrollees who are not likely to benefit (e.g., dual-eligibles, LIS enrollees, and enrollees in EGWPs) should be excluded from targeted outreach or receive notices that explicitly state they are not likely to benefit from the program. Some commenters recommended that CMS collaborate with external stakeholders on targeted outreach to enrollees likely to benefit, including health care providers, manufacturers, pharmacies, and disease-specific organizations. Another commenter specifically requested additional support for rural pharmacies. Lastly, a commenter recommended that CMS provide guidance around Part D sponsor navigation services for enrollees to help them understand which programs may be right for them.

A few commenters suggested that CMS move away from solely using criteria for targeted outreach, citing enrollees who may have not initiated high-cost treatments due to the financial burden and would thus not be identified using only prescription drug costs.

Response: CMS appreciates commenters’ support and recommendations. Additional information and requirements regarding these comments is included in section 30.2 of the draft part two guidance.

Targeted Part D Enrollee Notification at POS (60.2.3)

Comment: Some commenters expressed support for using a single day prescription total, stating that it more closely aligns with the enrollee experience at the pharmacy if they are filling multiple prescriptions and would identify a slightly larger pool of enrollees to be notified. Other commenters recommended using a single prescription to meet the threshold, citing operational concerns and potential confusion for enrollees. In addition, a few commenters suggested alternative approaches to meet the POS notification threshold, such as a combination of single prescriptions, daily or monthly prescription totals, or including additional calculations related to fill length and number of refills.

In addition, many commenters provided input on the POS threshold level. Some recommended that CMS establish a threshold at or below \$400. A commenter expressed support for the range of \$400 to \$700; another commenter recommended \$500. Other commenters recommended a \$700 threshold. Finally, some commenters suggested alternative approaches, such as setting the threshold to match the maximum monthly cap amount; varying the threshold in the first versus second halves of the year; using the specialty tier cost threshold for CY 2025; using a “recognized benchmark that reflects the average senior’s income;” including prescription information related to pattern of costs, days’ supply, or treatment of acute/chronic conditions; or providing the POS notification to all enrollees. A few commenters suggested that CMS revise the POS notification threshold annually, either indexed to inflation or based on an assessment of program performance.

Response: CMS appreciates the feedback from commenters. CMS has revised section 60.2.3 of this guidance to require that Part D sponsors and pharmacies 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 strikes the best balance between identifying Part D enrollees with a very high likelihood (~98%) of benefiting from the Medicare Prescription Payment Plan, while reducing the risk of identifying Part D enrollees for whom the program may not be as helpful.

In addition, CMS directs interested parties to the draft part two guidance, which outlines additional outreach and education requirements – both for enrollees generally and those who are likely to benefit. These requirements include targeted outreach to enrollees likely to benefit prior to the plan year and during the plan year (outside of the POS). CMS is aware that proactive notification of Part D enrollees likely to benefit (prior to their interaction at the POS) will streamline the program election process and help to prevent drug dispensing delays. With regard to potential revisions to the POS notification threshold in years after 2025, this final part one guidance is limited to CY 2025; CMS will keep these comments in mind for implementation in future years.

POS Notification Requirements (Section 60.2.4)

Comment: Some commenters raised concerns about potential burden on pharmacies from the POS notification process if action is required beyond providing the notice (such as counseling or consultations). Many commenters requested standardized POS notifications. A commenter suggested that instead of printed notifications, CMS should provide model language for plans to send in the claim response. Many commenters made recommendations or requested additional details around the pharmacy notification process itself. Some suggested that the notification be transmitted through the claims system using the NCPDP Telecommunication Standard, similar to the Medicare and Your Rights notice. A few commenters raised potential challenges for pharmacies if the notification comes through other means, such as telephone call or fax. A commenter requested that CMS clarify that pharmacies do not have to contact the enrollee upon receipt of the notification but can provide it when the prescription is picked up or delivered or via the enrollee's preferred communication method (text, email, or standard mail). Another commenter requested that pharmacies not be required to make notifications to enrollees via phone. A few commenters suggested that CMS encourage pharmacies to provide information about the program via additional avenues, such as through their automated prescription notification calls or emails. A commenter expressed concern that if CMS does not provide additional specifications for the pharmacy notification, the beneficiary interaction could be limited (such as a paper notice attached to the prescription bag) and that would make it more challenging for the beneficiary to act on the notification.

Response: CMS thanks the commenters for their feedback. We are aware of ongoing work within NCPDP to develop standardized message codes that Part D sponsors will use to notify the pharmacy when a Part D enrollee meets the POS likely to benefit criteria or is enrolled in the Medicare Prescription Payment Plan; CMS supports a standardized, consistent approach to this messaging. Additional information and requirements regarding these comments are included in the draft part two guidance.

Comment: A few commenters requested that the POS likely to benefit notifications be deactivated for those who have already opted into the program. A commenter requested that plans not be required to send the notification more than once for enrollees who meet the threshold. Another commenter requested that the POS likely to benefit notifications not be required in November and December, stating that enrollees are less likely to benefit later in the year.

Response: As stated in section 60.2.4 of this final part one guidance, participants who have already opted into the Medicare Prescription Payment Plan should not be notified about opting into the program while their participation is in effect. For enrollees who have not yet opted into the program, the pharmacy POS likely to benefit notification should be sent each time an enrollee meets the notification criteria. Some enrollees may decline to opt into the program on the first notification but change their minds with a subsequent high-cost prescription fill. CMS is also requiring in this guidance that Part D enrollees not be notified that they are likely to benefit in the last month of the plan year. CMS acknowledges that there may be a reduced opportunity to benefit from the program later in the year (given that there are fewer months available to spread out payments) but believes that Part D enrollees should be made aware of the

program and have the opportunity to opt into the program when they meet the pharmacy POS notification criteria prior to December.

Comment: A few commenters expressed support for CMS’s statement that the notification could be provided to a family member or representative if the enrollee is not physically present at the pharmacy.

Response: CMS thanks the commenters for their feedback.

Comment: A commenter requested that the POS notification requirement not apply to long-term care pharmacies or residents in long-term care facilities, because there is not a “meaningful point of sale” at which the pharmacy staff and Part D enrollee interact. Another commenter requested that mail order pharmacies be required to include program materials in the prescription packaging but not in advance of dispensing the drug. A commenter requested that the same processes apply to mail order pharmacies and that specialty pharmacies be required to discuss the Medicare Prescription Payment Plan as a component of the disease management process with all Medicare beneficiaries.

Response: CMS appreciates the commenters’ recommendations. Section 50.3 of the draft part two guidance details how non-retail pharmacies will be required to notify Part D enrollees that they are likely to benefit from the program.

Part D Enrollee Eligibility for the Program and Election (Section 70.1)

Comment: Several commenters expressed support for all Part D enrollees being eligible for the program, for the program applying to all covered Part D drugs, for Part D sponsors not being allowed to set minimum OOP thresholds for participation, and for program participation being effective upon opt in.

Response: CMS appreciates the commenters’ support.

Comment: Several commenters requested that CMS limit eligibility for the program. A few commenters requested CMS limit participation during the first three years of the program to only those Part D enrollees who met their OOP maximum in the previous plan year. Commenters also requested that CMS limit participants’ ability to elect into the program to only the first four months of the plan year. Other commenters requested that full-benefit dually eligible residents of long-term care facilities, LIS enrollees, and D-SNP enrollees be excluded from electing into the program. A few commenters recommended that CMS establish a minimum OOP threshold for eligibility. Lastly, a commenter requested that the program only apply to an individual’s future prescriptions and not to the prescription that triggered the notification of likely to benefit at the POS.

Response: Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to participate in the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible. Under section 1860D-2(b)(2)(E)(v)(II) of the Act, a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan

year or in any month during the plan year. CMS does not have authority to modify these statutory requirements. As discussed in this final part one guidance, however, CMS recognizes that while the program is open to all Part D enrollees beginning January 1, 2025, Part D enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit, as well as Part D enrollees who are not already receiving assistance to pay for their Part D prescription drugs through the LIS program or other programs. CMS is also requiring in this final part one guidance that Part D enrollees not be notified that they are likely to benefit in the last month of the plan year. As such, CMS emphasizes the importance of standardized and consistent education and outreach and directs readers to section 30 of the draft part two guidance for details on Part D sponsor requirements for both general and targeted outreach. Additionally, as stated in section 30 of this final part one guidance, once an enrollee's Medicare Prescription Payment Plan election has been effectuated, the Part D sponsors must include all covered Part D drugs in the program. This may include the prescription that triggered the likely to benefit notification, depending on whether the prescription was filled post-effectuation into the program. CMS further notes that under the \$600 POS notification threshold, the Part D prescription that triggered the likely to benefit notification at the POS would be a high-cost prescription that could pose affordability challenges, thus heightening the importance of that particular prescription being included in the program.

Comment: Several commenters requested that the application of the Medicare Prescription Payment Plan to EGWPs either be waived or delayed, noting that EGWP enrollees are not likely to benefit; EGWPs may not have reserves to front the OOP costs of medications; EGWPs should maintain discretion to manage their plans; and the Medicare Prescription Payment Plan may raise premiums and reduce enrollment and participation in EGWPs. Commenters asked that CMS use its waiver authority at 42 CFR § 423.458 to exempt EGWPs. Additionally, two plan sponsors stated that certain EGWPs may not have the authority to participate in the program because they are public trusts and are prohibited from paying private debts. Commenters also requested additional guidance on non-calendar year EGWPs and on how program election during the Part D plan enrollment process would work for EGWPs that use the Group Enrollment Mechanism.

Response: CMS appreciates commenters' concerns but disagrees with the commenters who believe that the application of the Medicare Prescription Payment Plan to EGWPs should either be waived or delayed. Section 1860D-22(b) of the Act and 42 CFR § 423.458(c) permit CMS to waive or modify any requirement that hinders the design of, offering of, or enrollment in an EGWP. Under section 1860D-2(b)(2)(E)(i) of the Act, all Part D sponsors must provide the option to participate in the Medicare Prescription Payment Plan to all Part D enrollees. Regardless of whether fewer EGWP enrollees are likely to benefit from the Medicare Prescription Payment Plan than enrollees in other types of plans, waiving the requirements of the Medicare Prescription Payment Plan would mean that some EGWP beneficiaries who would be likely to benefit would not be able to take advantage of the program. CMS believes that waiving requirements for EGWPs is not aligned with the requirement in the statute that all Part D enrollees must be provided with the option to participate in the program.

In addition, EGWPs will have sufficient time to make any financial arrangements necessary to be able to administer the program, as this final part one guidance is being released well before the start of the 2025 plan year. Finally, CMS's authority under section 1860D-22(b) of the Act and

42 CFR § 423.458(c) to waive program requirements enables CMS to waive Part D requirements for the purpose of ensuring that EGWPs are not hindered in the design and offering of Part D benefits, but does not extend to ensuring that they maintain complete discretion over the design of their plans.

CMS also disagrees that a waiver is necessary for certain EGWPs that qualify as public trusts. After consultation with the IRS, CMS does not believe that the Internal Revenue Code prohibits EGWPs from complying with the requirements of the Medicare Prescription Payment Plan and providing their enrollees with the option to participate.

CMS directs readers to the Draft CY 2025 Part D Redesign Program Instructions for guidance on how the Medicare Prescription Payment Plan applies to non-calendar year EGWPs. The program election process is the same for all types of Part D sponsors, including EGWPs who utilize the Group Enrollment Mechanism. Additionally, CMS directs readers to sections 70.1 and 70.3 of this final part one guidance and section 30.3.1 of the draft part two guidance for requirements related to program election and integration in the Part D plan enrollment process.

Interactions Between LIS and the Program (Section 70.2)

Comment: Several commenters expressed support for CMS’s recognition that LIS enrollment, for those who qualify, is more advantageous than participation in the program.

Response: CMS appreciates the commenters’ support.

Comment: A few commenters requested that CMS include language in program model materials stating that LIS-eligible enrollees are unlikely to benefit. Commenters also requested that enrollees who lose LIS eligibility should receive targeted outreach for the program, and they also noted that CMS could consider requiring sponsors to call an LIS enrollee if the person tries to elect into the program.

Response: CMS appreciates this comment and is issuing program model materials for comment through an ICR process. Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to participate in the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible individuals. CMS reiterates that LIS-eligible individuals are eligible to participate in the Medicare Prescription Payment Plan, and although the majority of LIS-eligible individuals may not benefit from participating in the program, there are nonetheless instances in which certain LIS-eligible individuals may see personal benefit from the program. As such, CMS is refraining from requiring Part D sponsors to perform targeted outreach to LIS-eligible individuals or contact LIS-eligible individuals who submit election requests, as such requirements could be seen as barring or deterring those individuals from joining. Additional information related to enrollee education and materials is included in the draft part two guidance.

Election Procedures and Format (Section 70.3.1)

Comment: A few commenters suggested that CMS should require all Part D sponsors to use the same standardized election form to promote uniformity across the program and ensure a minimum amount of information is collected.

Response: CMS appreciates the commenters' recommendation. Please refer to section 30.3.1 of the draft part two guidance for requirements on how Part D sponsors must communicate with Part D enrollees about the election process.

Medicare Plan Finder, Calculation Tool, and Election Procedure (Section 70.3.1)

Comment: A few commenters suggested that Medicare Plan Finder be modified to include a checkbox where Part D enrollees can opt into the program. Other commenters requested that MPF be updated to include a grid, similar to the existing prescription drug grid, showing OOP costs per month with and without the program, allowing individuals to see how participation in the program would impact their projected monthly costs. Some commenters noted that such a tool would minimize duplication of efforts, as sponsors would not each need to create their own tool, and it could lead to fewer calculation errors if it is standardized. A commenter noted that a CMS-developed tool should be available for use anytime. Another commenter noted that the tool could provide a comparison of OOP costs under the program versus the LIS program. Lastly, a commenter suggested that program participants should have the ability to track their spending under the program and asked that this be reflected in Medicare Plan Finder.

Response: CMS thanks commenters for these suggestions and notes that section 40 of the draft part two guidance summarizes CMS's efforts to develop and update existing Part D educational resources to provide individuals and interested stakeholders with information on the Medicare Prescription Payment Plan. These resources, paired with materials CMS is releasing as part of an ICR process, aim to provide individuals with education on the program so they can understand how the program may impact them.

Completion of Election Request (Section 70.3.2)

Comment: Many commenters expressed support for CMS's requirement that Part D sponsors offer Part D enrollees multiple election mechanisms to apply for the program. A few commenters requested clarification regarding the specific types of election mechanisms that Part D sponsors can provide to Part D enrollees, including telephonic and text message. Lastly, a few commenters recommended that fax should not be an option for applying to the program.

Response: CMS appreciates commenters' support and thanks commenters for their clarifications and recommendations. In section 70.3.1 of this final part one guidance, CMS defines the required mechanisms that Part D sponsors must have available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan. This includes an election request form provided with issuance of the member ID card, a paper option that can be mailed, a toll-free telephone number, and a website application. Note that the requirements for Part D sponsors to be able to receive election requests via fax have been removed, as there are certain Part D sponsors without this

capability and in an effort to modernize the program's election processes. Please refer to section 30.3 of the draft part two guidance for additional information regarding election mechanisms.

Processing Election Request (Sections 70.3.3 and 70.3.4 in the draft part one guidance)

Comment: A couple of commenters were opposed to the 10-day timeframe for Part D sponsors to process elections for those enrolling in a new Part D plan or remaining in the same Part D plan. A commenter noted that for prospective D-SNP enrollees, the Part D sponsor would not be able to effectuate election into the Medicare Prescription Payment Plan until after Medicaid eligibility is determined, which could be after the 10-day effectuation timeframe given state Medicaid offices' eligibility determination timeframes.

Response: To ensure Part D enrollees will have timely access to the program and information on participation, in this final part one guidance, CMS establishes in section 70.3.3 a 10-day timeframe for sponsors to process election requests for those enrolling in a new Part D plan or remaining in the same plan. CMS reiterates that the Medicare Prescription Payment Plan must be made available to all Part D enrollees. Regarding the timeframe for verifying Medicaid eligibility for prospective D-SNP enrollees, D-SNP sponsors are reminded that they must follow the procedures for verifying Medicare Advantage and Medicaid eligibility for prospective D-SNP enrollees outlined in section 20.10 of the Medicare Managed Care Manual: Chapter 2 – Medicare Advantage Enrollment and Disenrollment and section 40.2.2 of the Medicare Managed Care Manual: Chapter 16-B: Special Needs Plans. These chapters state that D-SNP sponsors must confirm Medicare Advantage and Medicaid eligibility before processing a D-SNP plan enrollment request. As such, once Medicaid eligibility is confirmed, D-SNP sponsors should process the Medicare Prescription Payment Plan election request made by a prospective D-SNP enrollee alongside the D-SNP plan enrollment request. Once the D-SNP sponsor begins processing the Medicare Prescription Payment Plan election request, they must meet the processing timeframes outlined in section 70.3.3 of this final part one guidance.

Additionally, while those who may be eligible for Medicaid are eligible to participate in the program, CMS encourages all Part D sponsors to communicate with their Part D enrollees about this program and help them understand whether the Medicare Prescription Payment Plan program is a beneficial option for them.

Comment: A few commenters requested that CMS allow Part D sponsors to give enrollees the option to decide when their Medicare Prescription Payment Plan participation becomes effective.

Response: CMS declines to offer this flexibility. Through requirements outlined in this final part one guidance and in the draft part two guidance, CMS aims to provide for a consistent Part D enrollee experience in the Medicare Prescription Payment Plan, regardless of their Part D plan. As such, CMS believes that requiring consistent standards for when participation is effectuated promotes the cleanest implementation of the program, especially in the first year. Section 70.3 of this final part one guidance outlines CMS's election effectuation requirements.

Comment: A couple of commenters expressed support for CMS's requirement that sponsors contact beneficiaries who submit incomplete election requests, noting that Part D sponsors

should be required to attempt at least two phone calls on separate days and send a letter to collect missing signatures. A commenter requested that Part D enrollees be given 30 days instead of 21 days to furnish missing information before their election request can be denied.

Response: CMS appreciates commenters' support. Consistent with the guidance on collecting missing information for incomplete Part D plan enrollment requests outlined in section 40.2.2 of the Medicare Prescription Drug Benefit Manual: Chapter 3 – Eligibility, Enrollment and Disenrollment, CMS is requiring Part D sponsors to provide Part D enrollees 21 calendar days to furnish missing information on their election requests before denying the request. Section 70.3.3 of this final part one guidance outlines this 21-day requirement, which is aligned with Part D program precedent.

Comment: A couple of commenters requested that when an election request is approved, Part D sponsors should be required to send information on the Medicare Prescription Payment Plan to the new program participant that includes examples of the first and subsequent month calculations and describes scenarios when participation in the program would not be beneficial. A couple of commenters noted that information could include a confirmation of the participant's acknowledgement of, and agreement to, the financial responsibilities and obligations associated with the program.

Response: CMS appreciates this comment. Part D sponsor requirements to furnish program participants with information on the Medicare Prescription Payment Plan once they opt into the program are included in section 30.3.2 of the draft part two guidance. Additionally, CMS is developing model materials, including a model "Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan," that Part D sponsors can distribute to new program participants. These materials will be available for comment through an ICR process (CMS-10882; OMB 0938-New).

Processing Election Request During a Plan Year (Section 70.3.5 in the draft part one guidance)

Comment: A few commenters expressed support for a 24-hour, or shorter, timeframe for Part D sponsors to process election requests during the plan year. These commenters emphasized the importance of requiring a 24-hour timeframe to ensure that Part D enrollees can access their prescriptions in a timely manner. In contrast, several commenters raised concerns regarding the 24-hour timeframe. A commenter requested an extension to ensure that Part D sponsors are compliant with requirements and are able to accurately administer the program to participants. A commenter requested an extended timeframe to ensure Part D sponsors have enough time to collect any missing information, and a commenter requested additional time to ensure Part D sponsors have enough time to send eligibility files to PBMs.

A few commenters noted that the 24-hour timeframe would require additional staffing for weekends, nights, and holidays, require coordination between plans and PBMs, and would require pharmacies to educate enrollees about the program at the POS. A commenter noted that the fact that the 24-hour timeframe is consistent with the coverage determinations timeframe is irrelevant because the election effectuation and coverage determination processes are so

different. Alternative timeframes suggested by a few commenters included 48 hours, 72 hours, 7 days, and 10 days. A commenter noted that the 24-hour timeframe should not be implemented because smaller, regional plans have operational limitations. A commenter suggested that the timing requirement be framed in business days instead of hours.

Lastly, several commenters proposed alternative procedures for processing elections. A few commenters requested timing exemptions for paper election requests and asked that CMS apply enforcement discretion for good faith efforts made by Part D sponsors to meet processing deadlines for 2025. A commenter requested that the 24-hour timeframe only be applied to electronic requests. A commenter noted that a 24-hour timeframe is feasible but asked that CMS only require Part D sponsors to process elections in 24 hours when an enrollee is identified as likely to benefit from the program or for other unique scenarios requiring fast turnaround for effectuation into the program. The commenter suggested that in all other instances, the Part D enrollee should be able to choose when they would like participation to take effect.

Response: CMS appreciates commenters' support. CMS also understands commenters' concerns regarding the 24-hour election processing requirement and appreciates the alternative approaches offered. To ensure a seamless election process for Part D enrollees and ensure they have timely access to the program and their Part D prescriptions, and to ease operational burden for Part D sponsors, CMS is requiring Part D sponsors to process election requests received during the plan year within 24 hours, as stated in section 70.3.4 of this final part one guidance. Through this requirement, CMS reiterates the importance of ensuring that Part D enrollees, once they request to participate, are able to access the benefits of the program as timely as possible. This is particularly important for those who may wait to pick up a prescription until their program participation is effectuated, especially given that a real-time/POS election option will not be required. Additionally, CMS emphasizes that Part D sponsors can encourage those who are likely to benefit from the program to opt in prior to the plan year through strong education and outreach efforts, as described in section 30.2.2 of the draft part two guidance.

In response to comments and stakeholder feedback regarding operational feasibility and staffing concerns, CMS acknowledges these concerns but reiterates the importance of ensuring that Part D enrollees gain timely access to the program and their prescriptions. As such, Part D sponsors will need to make arrangements to meet this 24-hour timeframe requirement. This includes addressing staffing needs and coordinating with PBMs or other partners to effectuate the election request. Additionally, CMS acknowledges that the expedited coverage determination and election effectuation processes are different, as commenters expressed; however, CMS believes that Part D sponsors can operationalize this 24-hour processing timeframe in 2025 and can potentially leverage some of the resources or staffing models used to meet the expedited coverage determination timeframe.

CMS recognizes that implementing this election process may pose greater challenges for smaller, regional plans than it would for larger plans; however, CMS believes that smaller plans can meet this timeframe requirement and encourages these smaller plans to begin preparing for this requirement ahead of 2025. Again, CMS reiterates that Part D sponsors should seek to ameliorate the volume of election requests made during the plan year by encouraging Part D enrollees who are likely to benefit from the program to opt in before the plan year begins.

Regarding collecting missing information, CMS reminds readers that the 24-hour timeframe only applies to complete election requests; procedures for collecting missing information are included in section 70.3.4 of this final part one guidance.

Additionally, CMS directs readers to sections 30.3.1.2, 30.3.1.3, and 30.3.1.4 of the draft part two guidance for definitions of “receipt” of election request by the Part D sponsor, which are based on the definitions included in section 10.5.2 of the Medicare Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. These definitions should provide additional clarity on the process for Part D sponsors. CMS does not intend for the 24-hour effectuation timeframe to in any way imply pharmacies are required to provide education on the program or assist Part D enrollees in requesting election, as election into the program is a process managed by the Part D sponsor. Additionally, CMS believes that the other proposed extended timeframes (48-hours, 72-hours, 7 days, and 10 days, or framing the requirement in business days) would negatively impact Part D enrollees’ timely access to the program and their prescriptions. Regarding the proposed alternative procedures for prioritizing certain elections, such as only requiring a 24-hour turnaround time for election requests made in response to receiving the likely to benefit notification from the pharmacy, CMS believes that these types of approaches would create additional complexity for Part D sponsors, as they would need to develop methods for differentiating and prioritizing election requests.

Commenters also suggested giving Part D enrollees the option to choose when their participation in the program becomes active. Through program requirements outlined in this final part one guidance and in the draft part two guidance, CMS aims to provide for a consistent Part D enrollee experience. As such, CMS believes that requiring consistent standards for when participation is effectuated promotes the cleanest implementation of the program, especially in the first year.

CMS reiterates the importance of providing Part D enrollees with timely access to the program and expects Part D sponsors to comply with the 24-hour effectuation timeframe as well as other requirements for processing election requests during the plan year, as outlined in section 70.3.4 of this final part one guidance. CMS also encourages Part D sponsors to process election requests within timeframes shorter than 24 hours, or even in real-time, if they are able to operationalize such processes; however, CMS is not requiring a processing timeframe shorter than 24 hours for 2025.

Retroactive LIS Eligibility and Election (Section 70.3.6 in the draft part one guidance)

Comment: A couple of commenters noted that program participants who become LIS-eligible should be able to choose how they are refunded from the Part D sponsor.

Response: Consistent with the guidance on reimbursement for excess cost-sharing or premiums paid by Part D enrollees who become eligible for LIS outlined in section 70.3.1 of the Medicare Prescription Drug Benefit Manual, Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals, CMS expects that Part D sponsors will develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants who become LIS-eligible.

Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours (Section 70.3.7 in the draft part one guidance)

Comment: Some commenters requested that the requirement for plans to process retroactive elections be optional. A few commenters requested additional clarification on, and examples of, reprocessing and reimbursement/billing of retroactive claims and requested that CMS clarify that if the sponsor fails to process an election request, all responsibility is with the sponsor and that the pharmacy should not be required to do additional work.

Response: CMS expects Part D sponsors to process election requests within the specified timeframes included in section 70.3.4 of the final part one guidance. If a Part D sponsor does not meet that timeframe, it must follow the process for retroactive election outlined in section 70.3.6 of the final part one guidance. Part D sponsors are ultimately responsible for managing the election request process. As stated in section 50.4 of the draft part two guidance, pharmacies are generally not required to reprocess claims under the Medicare Prescription Payment Plan that a Part D enrollee has already paid for.

Standards for Urgent Medicare Prescription Payment Plan Election (Section 70.3.8 in the draft part one guidance)

Comment: A couple of commenters requested clear standards to ensure Part D sponsors cannot deny urgent program election and requested that CMS include information on the urgent retroactive election option in educational materials so Part D enrollees will not abandon urgent prescriptions. Commenters requested clarity on how an enrollee would demonstrate or document urgent need.

Response: As stated in section 70.3.7 of the final part one guidance, Part D sponsors must have a process in place to effectuate a retroactive election into the Medicare Prescription Payment Plan when a Part D enrollee has certain urgent prescription fill(s) for which they paid the associated cost sharing before the enrollee's program election was received and processed. In section 70.3.7, CMS outlines the requirements that Part D enrollees must meet in order for the Part D sponsor to be required to process a retroactive election in an urgent situation. CMS has updated this section to require Part D sponsors, in situations where the Part D enrollee believes that any delay in filling the prescription(s) may seriously jeopardize their life, health, or ability to regain maximum function, to process an urgent retroactive election request when made by the Part D enrollee within 72 hours of the date and time the urgent claim(s) were adjudicated. Further, CMS is requiring Part D sponsors to include information on the urgent retroactive election option on their websites, as stated in section 30.1.5 of the draft part two guidance, and will consider which other materials, if any, could be updated with this information as well.

Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs Section (Section 70.3.9 in the draft part one guidance)

Comment: Many commenters voiced concern over point-of-sale (POS) election. A couple of commenters noted that pharmacies do not have a statutory requirement to facilitate election into the Medicare Prescription Payment Plan (instead, the requirement lies with the Part D sponsor).

A commenter noted that PBMs do not have the necessary information on file to process elections immediately. Several commenters noted that pharmacy burden could increase. A few commenters wrote that pharmacies do not know if the person is educated on the program. A commenter wrote that there is no mechanism for information on the program to be passed through current standards. A few commenters wrote that there are potential risks that a person other than the enrollee's legal representative could sign up for the program, and, relatedly, pharmacies could be at risk if they do not gain consent of the individual to elect into the program. A commenter noted that it is not realistic for specialty pharmacies to support election, and another commenter requested that CMS exempt long-term care pharmacies from POS election requirements. Several commenters expressed concern with the clarification code approach outlined by CMS. A few commenters stated that CMS should evaluate the need for POS election after the program launches.

Alternatively, many commenters requested that CMS enable POS election mechanisms for the 2025 plan year, noting that POS election will prevent dispensing delays and prescription abandonment. A couple of commenters wrote that program adoption and prescription affordability would increase and specifically noted that individuals with new high-cost prescriptions would benefit. Another commenter wrote that pharmacies are in a unique position to educate on the program and a commenter also raised the concern that the likely to benefit notification furnished to Part D enrollees at the POS would be confusing if they are not able to elect into the program at that time. A few commenters noted that CMS's process set forth in the draft part one guidance for retroactive elections in urgent situations would no longer be needed. A couple of commenters requested that if CMS does not implement the POS option for 2025, CMS should outline how barriers will be addressed by 2026.

Several commenters offered suggestions for enabling POS election in 2025. Several commenters expressed support for CMS's clarification code approach to POS election. A few commenters supported approaches similar to the transition fill or short supply fill processes paired with other mechanisms for opting into the program, such as via the telephone or electronically. A couple of commenters noted that providing POS election via the telephone could be a minimum offering for 2025. A couple of commenters asked that CMS consider ways in which opt-in requests can be granted upfront while pending approval with the Part D sponsor, adding that the Part D enrollee can elect over the phone or web, pay \$0 at the POS, and then if they are rejected from the program, they would pay the Part D sponsor back for their cost-sharing. A commenter suggested CMS consider how it can require POS election for 2025 in scenarios where pharmacies are owned by or affiliated with the Part D plan sponsor or only for specialty pharmacies and mail order pharmacies. A commenter suggested that CMS follow the model of real-time enrollment verification system that CMS established for Part D, which relies on a standard transaction (E1). A commenter supported enabling all three methods CMS outlined in the guidance: the telephone, a mobile/web app, and the clarification code approach.

Response: CMS appreciates these comments and agrees with many of the raised concerns. As such, CMS reiterates that a real-time/POS election option will not be required in 2025 due to several policy and operational challenges. While CMS will not require real-time/POS election, CMS does, however, encourage Part D sponsors to offer a real-time (or near-real-time) election mechanism to their Part D enrollees if they are able.

CMS would first like to clarify for readers that real-time election is meant to refer to a process that would enable a Part D enrollee to request election and be effectuated into the program in one instance from any setting (and so is not limited to only the pharmacy POS setting). POS election, rather, is limited to the pharmacy POS setting and would require immediate updates to pharmacies' claims processing systems. While these two processes are similar, they do entail different levels of effort and coordination between the Part D enrollee, Part D sponsor, PBM, and pharmacy.

CMS recognizes commenters' concerns over the impacts of not having real-time/POS election in the first year; however, CMS believes that its 24-hour effectuation timeframe for election requests made during the plan year, paired with the required process to retroactively apply the program to those meeting criteria for an urgent situation, reduces the likelihood of dispensing delays and prescription abandonment. Further, Part D sponsors will undertake activities to identify and conduct outreach to those likely to benefit from the program prior to the start of the plan year, as detailed in section 30.2.2.2 of the draft part two guidance. Through these efforts, many enrollees who are likely to benefit will be made aware of the program and can then elect into it earlier, thus avoiding the need to elect during the year. CMS disagrees that the likely to benefit notice would be confusing to the Part D enrollees who receive the notice at the pharmacy absent a POS election mechanism. As stated in the draft part two guidance, CMS is developing a standardized notice that can provide a succinct overview of the program to Part D enrollees. This notice will be made available for comment through the OMB ICR process.

Recognizing stakeholder interest in the offering, CMS has undertaken substantial outreach with a variety of stakeholders and has performed in-depth research to assess whether such offerings would be feasible for 2025. CMS identified a number of policy and operational barriers that will bar real-time/POS election requirements for 2025. As such, CMS agrees with many commenters' concerns and determined that real-time/POS election is not operationally or technologically feasible for 2025. The restricted lead-up time to the statutory implementation date of January 1, 2025, is a significant limiting factor for successful launch of a required real-time/POS election option. This is largely due to the need for several different parties, including the Part D sponsor, PBM, pharmacy (including different pharmacy types, such as specialty pharmacies, which have different processes in place), to each make operational adjustments and build up the necessary capabilities to be able to process real-time/POS elections. As commenters note, Part D sponsors and PBMs would need to establish new arrangements so that PBMs could process elections immediately, which would require additional lead time. CMS also agrees with commenters' concern that, currently, there is no mechanism for information on the program to be passed through current standards; as such, updates to current pharmacy claims processing standards, particularly for POS election, would also be needed to be approved and active by January 1, 2025. These updates would require significant lead time and coordination with industry standards committees that have existing processes and timelines outside of CMS's purview. Additionally, CMS also notes that no mechanism to support real-time/POS election between the different key stakeholders currently exists.

Commenters raised the concern that, in the case of POS election, pharmacies would not know if a Part D enrollee has been educated on the Medicare Prescription Payment Plan. CMS emphasizes the importance of educating Part D enrollees on the new program and agrees that

POS election, in particular, would not allow Part D enrollees sufficient time to understand the financial implications of participating in the Medicare Prescription Payment Plan, especially given the unique way in which monthly bills are calculated under the program and that the program is new in 2025.

Additionally, CMS agrees with commenters' concerns about pharmacies' responsibilities and is cognizant of potential additional burden pharmacies would face under a POS election option. The Medicare Prescription Payment Plan is an arrangement between the Part D sponsor, who is responsible for managing election, education, and other processes related to participation, and the Part D enrollee. Beyond providing the notification of likely to benefit to identified Part D enrollees at the POS, as detailed in section 30.2.2.3 of the draft part two guidance, pharmacies are not required to educate on the Medicare Prescription Payment Plan or facilitate election on behalf of the Part D sponsor. Additionally, commenters raised the concern that pharmacies would not know if the Part D enrollee or their legal representative opted into the program at the POS, leaving pharmacies vulnerable if they do not gain consent. CMS agrees that gaining valid consent to join is a concern and notes that gaining and verifying consent adds complexity to the POS election process.

We address the challenges presented by commenters' suggested approaches to real-time/POS election more specifically below:

- **Clarification code approach:** CMS requested comment on this potential approach for 2026. Implementing the clarification code approach for 2025, however, is not feasible, given the policy and operational concerns outlined above; the different parties (Part D sponsors, PBMs, and pharmacies) would need to make significant system updates within a limited timeframe leading up to January 1, 2025. Further, CMS is concerned that Part D enrollees will not have sufficient education on the Medicare Prescription Payment Plan to ensure that the program is appropriate for them.
- **Telephone:** Given the concerns outlined above around Part D sponsors, PBMs, and pharmacies being able to make operational and technological systems updates by January 1, 2025, POS election via the telephone is not a required option for Part D sponsors in 2025. For those Part D sponsors that are able to implement real-time telephonic election, however, CMS encourages them to do so. As noted above, real-time telephonic election is not the same as POS election.
- **Require POS election in scenarios where pharmacies are owned by or affiliated with the Part D plan sponsor:** CMS appreciates this suggestion; however, CMS seeks to promote consistency in program implementation across all Part D sponsors to ensure that all Part D enrollees, regardless of Part D plan, enjoy a seamless experience in the Medicare Prescription Payment Plan. This requirement would only apply to limited subsets of Part D sponsors and pharmacies, leading to inconsistencies in program implementation.
- **Require POS election only for specialty and mail order pharmacies:** CMS appreciates this proposal but notes that, in this scenario, the pharmacies would be the primary facilitator of the Part D enrollee's election. Additionally, as referenced above, pharmacies are not required to educate on the program or facilitate election, and so this approach is not feasible. Moreover, this approach cuts against CMS's goal to promote consistency in

program implementation to ensure all Part D enrollees, regardless of the type of pharmacy they use, have a seamless experience.

- **Real-time enrollment verification system, relying on standard transaction (E1):** CMS appreciates this proposal but notes that this process would not support real-time/POS election. The E1 transaction would only reflect an individual's program participation status and would not serve to facilitate the election and effectuation process. The Part D sponsor would need to effectuate the individual's election into the Medicare Prescription Payment Plan outside of the E1 transaction.
- **Election granted upfront:** Granting an individual the ability to pay \$0 at the POS while the Part D sponsor processes their program election request does not guarantee that the Part D enrollee or their legal representative opted into the program and could place pharmacies at risk of financial loss. This approach would also require real-time coordination between the Part D sponsor, PBM, and pharmacy, because the pharmacist would need to receive approval, in real time, from the Part D sponsor in its claims processing system that allows the Part D enrollee to pay \$0 at the POS. Updating operational and technological systems to facilitate this level of coordination, especially given the limited lead time, is not feasible for 2025. Further, as stated above, CMS is concerned that Part D enrollees would not have sufficient education on the Medicare Prescription Payment Plan to ensure the program is appropriate for them. Finally, granting participation upfront is not a standalone real-time/POS election option and would be complementary to other mechanisms, such as the telephone method. For the reasons outlined above, enabling real-time/POS election mechanisms in 2025 is not feasible.
- **Transition fill or short supply fill process:** CMS notes that the transition fill and short supply fill processes intend to bridge a gap in coverage for a Part D enrollee's existing prescriptions when they switch Part D plans or when their Part D plan removes the prescription drug from its formulary. While CMS appreciates commenters' suggestions to build on these processes to grant Part D enrollees immediate access to their prescriptions, CMS notes that it has described a process for retroactive election into the Medicare Prescription Payment Plan for Part D enrollees who need immediate access to their Part D drug (section 70.3.7 of this final part one guidance) and cannot wait for the 24-hour effectuation timeframe. CMS believes that this process addresses the concern that Part D enrollees who have an urgent need to access their prescription can immediately participate in the program. Further, the transition fill or short supply fill approaches are not real-time/POS election options in themselves but would be complementary to other mechanisms, such as the telephone method. For the reasons outlined above, enabling real-time/POS election mechanisms in 2025 is not feasible.
- **Enabling all three methods:** For the reasons outlined above, enabling all three methods for real-time/POS election—telephone, a mobile/web application, and a clarification code—in 2025 is not feasible.

Regarding commenters' concerns that specialty pharmacies and long-term care pharmacies cannot, or should not, support POS election, CMS notes that these concerns are not immediately relevant because real-time/POS election will not be required in the first year.

Although real-time/POS election will not be required in 2025, given commenters' interest in the offering, CMS is committed to exploring real-time/POS election mechanisms that can be implemented for future years. CMS agrees with commenters about the need to monitor the program and will certainly assess implementation in the first year. In the meantime, CMS again emphasizes the importance of granting Part D enrollees who wish to participate timely access to the program and is thus requiring, in section 70.3.4 of this final part one guidance, that Part D sponsors effectuate election requests made during the plan year within 24 hours. CMS believes that 24 hours is the fastest operationally feasible timeframe for Part D sponsors to effectuate election in CY 2025.

Prohibition on Part D Enrollee Discrimination (Section 70.3.10 of the draft part one guidance)

Comment: Several commenters expressed support for CMS's prohibition on Part D enrollee discrimination.

Response: CMS appreciates commenters' support.

Mid-Year Plan Election Changes (Section 70.4)

Comment: Several commenters requested additional guidance on how to address enrollees participating in the program who switch to a different plan during the plan year. Some commenters asked for additional clarity regarding what safeguards will be put in place for enrollees and what communication should occur between the former and new plan sponsors. A few commenters urged CMS to require clear communications from the former sponsor to the enrollee to articulate the responsibility for any outstanding program balances. Several commenters requested that plans be permitted to disallow enrollees from opting back into the program after switching plans if they have an outstanding balance with another Part D plan, whether within the same parent organization, or a new parent organization. A commenter requested that CMS collect and provide information on enrollees with past due balances to all plans. Another commenter expressed concern over using the plan-to-plan (P2P) process for plan switchers. Finally, some commenters expressed support for requirement in the draft part one guidance that a new sponsor cannot preclude program election when an enrollee was previously terminated from the program at a former plan due to non-payment.

Response: As discussed in section 70.4 of this final part one guidance, if a program participant switches plans during the plan year or is reassigned by CMS, the new plan sponsor will not be required to automatically sign up the individual for the Medicare Prescription Payment Plan under the individual's new plan. The Part D enrollee may choose to elect into the program with the new Part D plan, regardless of any balance owed to the prior Part D plan sponsor. Additionally, the prior Part D sponsor will continue to bill the participant monthly based on the participant's accrued OOP costs while in the program under the new plan. If an enrollee switches to a new plan but has a past due program balance with the prior plan, the prior plan may continue to collect the past due balance. Because any balance accrued under a particular Part D plan continues to be administered and billed by that plan, there is no need for coordination between plans.

As stated in section 70.4 of this final part one guidance, if a program participant switches to a new plan that is offered by a new parent organization and has a past due balance with their prior plan, the new plan cannot preclude the enrollee from opting into the program. If the new plan is offered by the same parent organization, however, the new plan is permitted to preclude an enrollee with a past-due balance from electing into the program for that year. We also note that there are no additional P2P requirements associated with the Medicare Prescription Payment Plan, and CMS will not collect and provide past due program balances to Part D sponsors. Lastly, CMS reminds Part D sponsors that sponsors (and any third parties Part D sponsors contract with) are expected to follow all applicable federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection, when collecting any unpaid balances related to the program.

Comment: Several commenters recommended that participation in the program automatically renew year-over-year, noting the process could follow auto-enrollment for Medicare or Qualified Health Plans. Commenters suggested that participants could receive a notice informing them of auto-election, and auto-election could only be for those without delinquent balances. A commenter requested CMS not enable automatic re-election.

Response: CMS thanks the commenters for their feedback. Automatic re-election into the Medicare Prescription Payment Plan will be addressed in future guidance.

Procedures for Termination of Election, Reinstatement, and Preclusion in General (Section 80)

Comment: Several commenters expressed support for the termination procedures discussed in the draft part one guidance, including the required grace period, multiple notice requirement, and beneficiary protections (e.g., good cause exemption).

Response: CMS appreciates commenters' support and has included these termination procedures in this final part one guidance.

Comment: Many commenters requested that CMS develop standardized language and model materials for program voluntary and involuntary terminations. Several commenters suggested that these model materials should include information regarding the LIS program and prioritization of Part D premium payments over program payments. A few commenters also suggested that the terminations notices be modeled after existing Part D premium non-payment notices. Lastly, a commenter asked that these notices be published no later than April 1, 2024.

Response: CMS appreciates these comments. As stated in the draft part two guidance, CMS is developing model materials, including materials specific to failure to pay and termination, that will be made available for comment through an ICR process. CMS is making every effort to provide stakeholders with program guidance and model materials as soon as possible.

Voluntary Terminations (Section 80.1)

Comment: Several commenters expressed support for allowing enrollees to voluntarily terminate their participation at any time during the plan year.

Response: CMS appreciates commenters' support.

Comment: A couple of commenters requested that CMS offer multiple mechanisms for participants to opt out of the program.

Response: CMS requires Part D sponsors have in place a process to allow a participant to opt out of the program, as stated in section 80.1 of this final part one guidance. Part D sponsors are free to offer supplemental mechanisms for participants to voluntarily opt out of the program.

Involuntary Terminations (Section 80.2)

Comment: A commenter requested that CMS establish a timeframe by which an involuntary notice of termination is provided.

Response: As discussed in Section 80.2.1 of this final part one guidance, if a participant is terminated from the program by the Part D sponsor, the Part D sponsor must send a termination notice within 3 calendar days after the end of the grace period.

Required Grace Period and Reinstatement Section (Section 80.2.2)

Comment: Several commenters asked CMS to clarify and provide examples of what constitutes "good cause" and "circumstances for which the individual has no control" for failure to pay a monthly program bill. A few commenters suggested that the lack of clarity around "good cause" could result in Part D plans refusing to reinstate individuals at will and may result in inconsistent reinstatement standards across plans. They also asked CMS to specify whether there is a difference in the meaning of "good cause" for non-payment of premiums compared to "good cause" for failure to make a monthly program payment.

Response: As discussed in Section 80.2.2. of this final part one guidance, CMS is adopting the same meaning of "good cause" outlined in section 60.2.4 of the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment and Disenrollment that applies to reinstatements when an enrollee fails to pay their Part D premiums. Additionally, section 80.2.2 also includes examples of what constitutes "good cause."

Comment: A few commenters asked for clarification regarding the timing expectations for reinstatements after an enrollee is involuntarily terminated from the program. A commenter asked CMS to clarify whether the grace period carries over into the next calendar year if non-payment occurs at the end of a calendar year.

Response: CMS appreciates these comments. As stated in section 80.2.2 of this final part one guidance, plans must reinstate enrollees who demonstrate "good cause" into the program within

a reasonable timeframe after the enrollee has repaid their past due program balance in full. When a Part D sponsor decides to reinstate a Part D enrollee into the program when they have not demonstrated “good cause” but have repaid their past due program balance, the same reasonable timeframe applies. In addition, CMS is requiring that the two-month grace period carry over into the next calendar year if non-payment occurs at the end of a prior calendar year. Further, if the program participant is within their grace period from the prior year, they must be allowed to opt into the program for the next year. This is because, as stated in section 80.2 of this final part one guidance, a participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period. As such, during the grace period, the participant cannot be terminated from the program or precluded from opting in the subsequent year due to failure to pay in situations in which the person is still in the grace period. If that participant fails to pay the amount due from the prior year during the required grace period, the Part D sponsor can then terminate their participation in the program (in the new year) following the procedures in section 80.2 of this final part one guidance.

Preclusion of Election in a Subsequent Plan Year (Section 80.3)

Comment: Several commenters expressed support for the requirement that Part D plans can only exclude enrollees from the program for a subsequent year for failure to pay their past due balance. A few commenters requested clarification regarding how many years an enrollee can be precluded from the program for failure to pay and requested this preclusion last for one year. Other commenters raised concerns around allowing Part D sponsors to have different preclusion policies by plan, but the same policy in a given plan, and recommended a standard preclusion policy requirement.

Response: CMS appreciates the commenters’ support and thanks commenters for their feedback. As stated in section 80.3 of this final part one guidance, a Part D sponsor may only preclude an individual from opting into the Medicare Prescription Payment Plan program in a subsequent year if the individual owes an overdue balance to that Part D sponsor. In addition, as stated in section 80.3, preclusion is only permitted in plans that are offered by the same parent organization but may extend beyond the immediately subsequent plan year. If an individual pays off the outstanding balance during a subsequent year, the enrollee is eligible to request to participate in the program again. Consistent with guidance on Part D disenrollment due to failure to pay premiums outlined in section 50.3.1 of the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment and Disenrollment, for each of its Part D plans (i.e., each PBP), the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan (i.e., a Part D sponsor may have different preclusion policies among its different Part D plans, but it may not have different policies within a plan).

Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed (Section 80.4)

Comment: A few commenters commended CMS’s requirement that Part D sponsors cannot disenroll enrollees from the Part D plan for failure to pay their past program balance.

Response: CMS appreciates commenters’ support.

Participant Disputes (Section 90)

Comment: Several commenters expressed support for CMS’s requirement that Part D sponsors must apply their established Part D appeals and grievance procedures to any dispute made by a Medicare Prescription Payment Plan participant related to any aspect of the Medicare Prescription Payment Plan. A few commenters requested that CMS establish a separate process for addressing enrollee disputes related to the program, in lieu of the existing Part D appeals and grievance requirements and procedures. A commenter requested that CMS create a dedicated case type specific to the program, similar to what is done for Late Enrollment Penalty (LEP) disputes.

Response: CMS appreciates commenters’ support. As stated in Section 90 of this final part one guidance, CMS will require Part D sponsors to apply their established Part D appeals and grievance procedures to any dispute made by a program participant related to any aspect of the program. CMS is not developing separate processes for disputes related to the program at this time but will monitor program implementation via data collection activities in the first year. As stated in section 100 of this final part one guidance, for monitoring purposes, CMS is requiring Part D sponsors to report information related to the program through PDE records. Part D sponsors will also be required to submit beneficiary- and contract-Plan Benefit Package (PBP)-level data related to program participation through the Medicare Advantage Prescription Drug (MARx) System and HPMS, respectively. Additionally, in section 60.3 of the draft part two guidance, CMS states that it will monitor and collect data about beneficiary complaints and grievances reported via the Medicare Complaints Tracking Module (CTM) to assess compliance with program requirements.

Comment: Several commenters expressed support for utilizing the established Part D appeals procedures which require plan sponsors to resolve disputes within a 24-hour period. A commenter requested that CMS clarify the specific timeframe for appeals.

Response: CMS appreciates commenters’ interest and support in the grievance and appeals process for Part D sponsors and program participants. Part D sponsors must meet the process and timing requirements defined in sections 30 and 40 of the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance,⁵ which, as stated in section 90 of this final part one guidance, apply to grievances and appeals related to the Medicare Prescription Payment Plan.

Data Submission Requirements (Section 100)

Comment: Many commenters provided feedback regarding the collection of information and data submission by Part D sponsors as it relates to the Medicare Prescription Payment Plan

⁵ Part D sponsors must complete a grievance investigation within 30 days of receiving the request or within 24 hours for expedited grievances. Part D sponsors must process standard coverage determination requests within 72 hours and expedited coverage determination requests within 24 hours. Please see the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for additional details on timing, processing, and notification requirements: <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

program. Several commenters requested that CMS publish de-aggregated data regarding the number of enrollees in the program, voluntary terminations, and terminations due to failure to pay. A few other commenters requested that CMS collect and publish demographic data on enrollees in the program to help identify disparities in uptake and barriers to implementation, including health equity. Another commenter requested that CMS add a program participation indicator on prescription drug event (PDE) submissions. Several commenters provided recommendations for additional collection of information related to program participation. A commenter requested that CMS develop program reporting requirements and templates in collaboration with plans to ensure effective oversight. Another commenter recommended that CMS collect the following from plans regarding the program: number of miscalculated monthly billed amounts; number of grievances related to the program and grievance outcomes (e.g., in favor or against beneficiary); number of appeals related to the program and appeal outcomes (e.g., in favor or against beneficiary); and number of election requests submitted with SHIP assistance.

A commenter requested clarity around how CMS will identify enrollees as likely to benefit and suggested adding a new field on the PDE stating a beneficiary is in the program when the claim is paid.

Response: CMS appreciates commenters' requests for program-related data. In the draft part one guidance, we stated that CMS would require Part D sponsors to report information related to the Medicare Prescription Payment Plan on PDE records and through new annual reporting requirements. Based on further consideration of data needs to support this program, we have also determined to collect some data through MARx system. To that end, CMS has developed three 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>

CMS directs commenters to submit comments related to these data submission requirements through the Office of Management and Budget (OMB) ICR process. See section 100 of this final part one guidance for additional information.

For comments related to grievances and appeals associated with the program, section 60.3 of the draft part two guidance details how CMS will monitor the Medicare Complaints Tracking Module (CTM) to assess Part D sponsor compliance with the program requirements, beneficiary protections, and program integrity.

CMS thanks the commenter for the inquiry regarding enrollees identified as likely to benefit and the suggestion of how to monitor participation in the program. Section 60.2 of this final part one guidance provides details on how Part D sponsors are to identify enrollees deemed likely to benefit.

Definitions for Medicare Prescription Payment Plan (Appendix A)

Comment: A commenter requested CMS to clarify that the program applies to drugs that are included in a Part D plan’s formulary due to determination or appeal.

Response: CMS appreciates this commenter’s clarification request. As stated in this final part one guidance, covered Part D drugs has the meaning set forth at 42 CFR § 423.100, meaning a Part D drug that is included in a Part D plan’s formulary, or treated as being included in a Part D plan’s formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, 423.600, 423.610, 423,620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

Comment: A commenter requested CMS use the term “Patient Out of Pocket (OOP) Cost” to replace the term “Patient Pay Amount” throughout the guidance, noting “Patient Pay Amount” has a specific meaning with regard to pharmacy claims and PDE data.

Response: CMS appreciates this commenter’s request. In Appendix A of this final part one guidance, CMS has modified the definitions of “OOP Costs” and “Patient Pay Amount” to better differentiate the two concepts. CMS notes that where “patient pay amount” continues to be used in section 50 of this guidance, it is in reference to the standard response pricing segment field “Patient Pay Amount” (505-F5).

Other Comments

Comment: A commenter expressed support for the program’s name, the *Medicare Prescription Payment Plan*. A couple of commenters voiced concern that the use of the word “plan” in the program’s name could confuse Part D enrollees, as they may conflate the new program with their Part D prescription drug benefit plan.

Response: CMS thanks the commenter for their support and appreciates the concerns regarding potential confusion between the new program and the Part D enrollee’s Part D prescription drug benefit plan. CMS performed multiple rounds of consumer testing fieldwork and, based on its

evaluation of the results, concluded that the name “Medicare Prescription Payment Plan” succinctly and accurately represents the program. CMS directs readers to section 10 of this final part one guidance for clarification on preferred terminology Part D sponsors should use to effectively communicate with Part D enrollees about the program and minimize confusion.

Comment: A few commenters requested that CMS provide specific guidance on how plans can project delinquencies due to the program in bids and particularly how EGWPs can do so.

Response: For guidance on Part D sponsor bids for CY 2025, please see section 60.1 of the draft part two guidance, which directs readers to the CY 2025 Bid Pricing Tool (BPT) instructions that will be made available at the following hyperlink: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions>.

Comment: Several commenters expressed concern about CMS’s timeline for publishing final part one, draft part two, and final part two guidance. A couple of commenters proposed that CMS consider phasing in certain requirements.

Response: CMS understands commenters’ concerns. Given timing limitations and the statutory implementation date of January 1, 2025, CMS is not adjusting the guidance timeline for publication in this final part one guidance. CMS is making every effort to provide interested parties with the necessary guidance and information they need to implement the program for the first year and expects Part D sponsors to comply with the requirements included in this final part one guidance and in the part two guidance. CMS will consider revised or additional requirements for future years.

Comment: A few commenters requested that CMS exercise enforcement discretion for the first and second years of program implementation.

Response: CMS appreciates this comment and expects Part D sponsors to comply with the requirements included in this final part one guidance and in the part two guidance. Information on monitoring, compliance, and audits is included in sections 60.3 and 60.4 of the draft part two guidance.

Out of Scope Comments

CMS received several comments related to deductions from participants’ Social Security checks, monitoring premium increases, claims processing limitations related to the number of other payers that can be returned on a claim response, other health insurance (OHI) returning a patient pay amount that is higher than the Part D sponsor cost sharing, and screening for LIS eligibility. While we appreciate this feedback, these comments are outside the scope of this guidance and are not addressed in this memorandum.

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

10. Introduction

The purpose of this document is to provide interested parties with final part one guidance on a select set of topics for the *Maximum Monthly Cap on Cost-Sharing Payments Program*, which was established by section 11202 of the Inflation Reduction Act of 2022 (IRA) (P.L. 117-169) and signed into law on August 16, 2022. The IRA makes Medicare stronger for current and future enrollees. It makes health care more accessible, equitable, and affordable. Section 1860D-2(b)(2)(E) of the Social Security Act (the Act), as added by section 11202 of the IRA, requires all Medicare prescription drug plans to offer their Part D enrollees the option to pay their out-of-pocket (OOP) Part D drug costs through monthly payments over the course of the plan year instead of as upfront payments at the pharmacy point of sale (POS) beginning January 1, 2025. This provision applies to all Part D sponsors,^{6, 7} including both stand-alone Medicare prescription drug plans (PDPs) and Medicare Advantage (MA) plans with prescription drug coverage (MA-PDs), as well as Employer Group Waiver Plans (EGWPs), cost plans, and demonstration plans. This final part one guidance was preceded by release of the draft part two guidance on February 15, 2024.

The Maximum Monthly Cap on Cost-Sharing Payments Program was sometimes previously referred to as “the OOP Smoothing Program.” CMS undertook beneficiary focus group testing to select a program name that would be meaningful to Medicare Part D enrollees. After multiple rounds of consumer testing fieldwork and evaluation of the results, CMS announced in the draft part one guidance that the shorthand name for the program is the “Medicare Prescription Payment Plan.” Henceforth, this document refers to the Maximum Monthly Cap on Cost-Sharing Payments Program established by section 11202 of the IRA as the Medicare Prescription Payment Plan, or the “program” as needed. Medicare Prescription Payment Plan should be used in any guidance and communications by Part D sponsors for the implementation of section 1860D-2(b)(2)(E) of the Act.

In the technical HPMS guidance titled “Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans” issued on July 17, 2023, CMS used the term “enrollee” when referring to someone using the OOP cost sharing payment options in the Medicare Prescription Payment Plan. In this guidance, CMS is replacing that term with the term “program participant,” or “participant,” for short. Medicare Prescription Payment Plan participants can voluntarily opt into the program at the time they enroll in a Part D plan or later throughout the plan year, and such an election will not have any bearing on their Part D plan enrollment. This change of terminology is important for Part D enrollees to keep the concept of their Part D plan enrollment distinct from their participation in

⁶ This provision does not apply to the Limited Income Newly Eligible Transition (LI NET) coverage because participants in the LI NET program do not enroll in a PDP or MA-PD plan to receive transitional coverage under the program.

⁷ Under section 1894(a) of the Act, PACE organizations must provide all medically necessary services including prescription drugs, without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. While the Medicare Prescription Payment Plan is applicable to all Part D plans, it has no practical application for PACE organizations. In addition, the program has no application to those demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost sharing.

the Medicare Prescription Payment Plan. CMS urges all Part D sponsors to be mindful of the language used when referring to Medicare Prescription Payment Plan participants so as not to cause confusion or alarm if, for instance, a Part D enrollee is informed that their participation in the Medicare Prescription Payment Plan has been terminated. In addition, the preferred terminology for an individual choosing to participate in the Medicare Prescription Payment Plan is “opt in,” but there may be instances in which the term “elect” into the program is acceptable. CMS discourages use of the term “enroll” when referring to an individual opting into or participating in the Medicare Prescription Payment Plan.

Section 11202(c) of the IRA directs the Secretary to implement the Medicare Prescription Payment Plan for 2025 by program instruction or other forms of program guidance. In accordance with the law, CMS is issuing this final part one guidance for implementation of the Medicare Prescription Payment Plan for 2025. This final part one guidance reflects comments received on the draft part one guidance that was published on August 21, 2023 and that had a 30-day public comment period. Additionally, on July 17, 2023 CMS issued an HPMS memo titled “Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans.” This final part one guidance describes requirements related to an initial set of topics pertaining to the implementation of the Medicare Prescription Payment Plan for CY 2025 (January 1, 2025, to December 31, 2025), specifying requirements that will be applicable to Part D sponsors. As mentioned above, CMS released a second set of draft guidance on February 15, 2024 that describes requirements related to another set of topics pertaining to program implementation for CY 2025.

This guidance is for the first year of the program, and the policies established herein will be subject to change in subsequent years.

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

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Again, this final part one guidance addresses the topics listed above, which represent a subset of topics which CMS will address via program instruction or other forms of program guidance in order to implement the Medicare Prescription Payment Plan for CY 2025. CMS released a second set of draft guidance on February 15, 2024 that describes requirements related to another set of topics, such as outreach and education, pertaining to program implementation for CY 2025. References to the draft part two guidance in this final part one guidance will be superseded by the final part two guidance once it is issued. CMS will follow the same procedures for comment solicitation before releasing the final part two guidance in summer 2024.

20. Overview

Beginning in CY 2025, the statute requires Part D sponsors to provide all Part D enrollees the option to pay their OOP prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs at the POS. As a result, Part D enrollees who opt into the Medicare Prescription Payment Plan will pay \$0 at the POS for a covered Part D drug, instead of the OOP cost sharing they would normally pay when filling a prescription. The Part D sponsor must pay the pharmacy the OOP cost sharing amount that these participants would have paid if they were not in the Medicare Prescription Payment Plan and then bill the program participants monthly for any OOP cost sharing they incurred while in the program according to the calculations described below. The amount that the Part D sponsor bills the participant for a month under the program cannot exceed a maximum monthly cap. While this program is available to anyone with Medicare Part D drug costs, Part D enrollees incurring high OOP costs earlier in the plan year are generally likely to benefit.

Under section 1860D–2(b)(2)(E) of the Act, as added by section 11202 of the IRA, Part D sponsors must, among other requirements:

- (1) provide all Part D enrollees prior to and during the plan year with the option to elect into the Medicare Prescription Payment Plan to pay their OOP cost sharing in monthly amounts that are spread throughout the plan year according to a statutory formula;
- (2) determine a maximum monthly cap for each month’s amount;
- (3) bill the program participant for an amount that must not exceed the monthly cap applicable for a month; and

- (4) have in place a mechanism to notify a pharmacy during the plan year when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the Part D enrollee may benefit from the program.

30. Program Calculations and Examples

Section 1860D–2(b)(2)(E)(iv) of the Act specifies how the monthly caps on OOP cost sharing payments are to be calculated. The formula for calculating the cap differs for the first month of participation in the program, versus the remaining months of the year. The maximum monthly cap calculations include specifics of a participant’s Part D drug costs (previously incurred costs and new OOP costs), as well as the number of months remaining in the plan year; as such, the amount can vary from person-to-person and month-to-month. Assuming a program participant remains in the Medicare Prescription Payment Plan through the end of the plan year, the total amounts billed monthly through the December payment (which would be billed and paid in the following year) will equal the total OOP costs incurred by the participant under this program during the year.

The participant will not have any monthly bills to pay under this program until opting into the program and incurring OOP costs for covered Part D drugs. Once a participant incurs an OOP Part D drug cost, all their OOP costs for all covered Part D drugs will be billed on a monthly basis as long as the participant remains in the program. Program calculations apply to all OOP Part D costs incurred, including those in the deductible phase. Part D sponsors must include all covered Part D drugs in the program. However, non-covered drugs are excluded.⁸ Part D sponsors will be responsible for correctly calculating the monthly caps based on the statutory formulas, determining the amount to be billed (not to exceed the cap), and sending monthly bills to program participants.

Opting into the program will not impact how a program participant moves through the Part D benefit or what counts towards their true out-of-pocket (TrOOP) costs.⁹ Under section 1860D–2(b)(4)(F) of the Act, a participant’s TrOOP-eligible costs under the Medicare Prescription Payment Plan will still be treated as incurred based on the date each Part D claim is adjudicated. Opting into the program only provides participants with the ability to spread OOP costs over the year—the total incurred costs and the timing of TrOOP accumulation do not change.

For participants who fill prescriptions for an extended day supply, their OOP costs for those prescriptions will be attributed to the month the prescription was filled, not pro-rated over the months covered by the prescription. For example, if a participant in the program has \$300 in OOP costs incurred for a 90-day supply dispensed in January, the full \$300 will be counted as incurred in January.

⁸ Covered Part D drugs has the meaning set forth at 42 CFR § 423.100.

⁹ For information on changes to what counts towards TrOOP in 2025, please see section 30 of the Draft CY 2025 Part D Redesign Program Instructions: https://www.cms.gov/sites/default/files/2024-01/Draft%20CY%202025%20Part%20D%20Redesign%20Program%20Instructions_January%2031%202024_Final_Updated.pdf.

The example calculations presented below are illustrative and intended to help ensure Part D sponsors program their claims and billing systems correctly for 2025. For more general audiences, CMS will develop tools to help people with Medicare Part D and their caregivers learn what monthly payments might look like under this program.

30.1 Calculation of Maximum Monthly Cap in First Month

Under section 1860D–2(b)(2)(E)(iv)(I) of the Act, for the first month for which the Part D enrollee has opted into the Medicare Prescription Payment Plan, the term “maximum monthly cap” means an amount calculated by taking the annual OOP threshold minus any Part D costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year.

Under section 1860D–2(b)(4)(B)(i)(VII) of the Act, the annual OOP cost threshold for 2025 is \$2,000. “Incurred costs” means any costs incurred or treated as incurred under section 1860D–2(b)(4)(C) of the Act. When an individual opts into the Medicare Prescription Payment Plan during the plan year, the individual’s incurred costs used to calculate the first month maximum cap are equal to the individual’s accumulated TrOOP before opting into the program. The number of months remaining in the plan year includes the month when an individual opts into the program.

When an individual opts into the Medicare Prescription Payment Plan prior to the start of the plan year (such as during open enrollment), the first month maximum monthly cap calculation applies to their first month of active coverage within the plan year. In this instance, the number of months remaining in the plan year is 12 and there is no accumulated TrOOP to subtract from the OOP threshold.

In scenarios where the OOP costs incurred in the first month of participation in the program are less than the maximum monthly cap, a Part D sponsor cannot bill the participant more than their actual incurred OOP costs. Specifically, a Part D sponsor must bill the participant the lesser of the participant’s actual OOP costs or the first month’s maximum monthly cap.

$$\text{First Month Maximum Cap} = \frac{\text{Annual OOP Threshold} - \text{Incurred Costs of the Participant}}{\text{Number of Months Remaining in the Plan Year}}$$

30.2 Calculation of Maximum Monthly Cap in Subsequent Months

Under section 1860D–2(b)(2)(E)(iv)(II) of the Act, for each subsequent month for which the Part D enrollee has opted into the program, the maximum monthly cap is determined by calculating the sum of any remaining OOP costs owed by the participant from a previous month that have not yet been billed and any additional OOP costs incurred by the participant in the subsequent month, divided by the number of months remaining in the plan year.¹⁰ The number of months

¹⁰ The maximum monthly cap calculation in subsequent months applies to newly incurred OOP costs and previous costs not yet billed. If there are unpaid balances from prior monthly bills, the total billed amount may be higher than the maximum monthly cap.

remaining includes the month for which the cap is being calculated. This calculation repeats for each month in which the participant remains in the Medicare Prescription Payment Plan. The resulting maximum monthly cap will change if additional OOP costs are incurred.

Note that “OOP costs incurred by the participant” refers only to the patient pay portion for covered Part D drugs that a program participant would have paid at the POS if they had not opted into the Medicare Prescription Payment Plan, not to all incurred costs as defined under section 1860D–2(b)(4)(C) of the Act. For these calculations, the “OOP costs incurred by the participant” do not include the covered plan paid amount or amounts paid by third parties, such as qualified State Pharmaceutical Assistance Programs (SPAPs) or charities.

Subsequent Month Maximum Cap =

$$\frac{\text{Sum of Remaining OOP Costs Not Yet Billed to Participant} + \text{Additional OOP Costs Incurred by the Participant}}{\text{Number of Months Remaining in the Plan Year}}$$

30.3 Example Calculations

Additional example calculations can be found in Appendix B.

30.3.1 Example #1: January Election; First Fill in February with No Refills

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant with no prescriptions filled in the first month of their participation in the program. The individual opts into the Medicare Prescription Payment Plan in January 2025. They have no additional prescription drug coverage through a third party. They fill no prescriptions during January.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the program is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will not bill the participant for January, since the participant has not incurred any OOP costs.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant fills a high-cost prescription at the pharmacy in February. The OOP cost sharing for this prescription is \$1,030.37.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$0 in January and thus did not receive a bill.

$$\$0 - \$0 = \$0$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant fills a single prescription with an OOP cost of \$1,030.37. Additional OOP costs incurred = \$1,030.37.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$1,030.37 + \$0)/11 = \$93.67$$

The calculation for the maximum monthly cap in subsequent months, described above, is repeated for each month remaining in the plan year and will change if there are additional OOP costs incurred by the participant. If the participant in Example #1 continued to have no new covered Part D prescription drug costs, their maximum monthly cap would be \$93.67 for all the months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$0	\$166.67	\$0
February	\$1,030.37	\$93.67	\$93.67
March	\$0	\$93.67	\$93.67
April	\$0	\$93.67	\$93.67
May	\$0	\$93.67	\$93.67
June	\$0	\$93.67	\$93.67
July	\$0	\$93.67	\$93.67
August	\$0	\$93.67	\$93.67
September	\$0	\$93.67	\$93.67
October	\$0	\$93.67	\$93.67
November	\$0	\$93.67	\$93.67
December	\$0	\$93.67	\$93.67
TOTAL	\$1,030.37		\$1,030.37

30.3.2 Example #2: Open Enrollment Election with Low-Cost Drugs in January

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant with a single low-cost drug filled in January. The individual opts into the Medicare Prescription Payment Plan during Medicare Part D open enrollment, based on their existing prescription for a high-cost maintenance drug. This participant has no additional prescription drug coverage through a third party. This participant has enough of their high-cost drug on hand for the month of January and only fills a low-cost drug during this month. The OOP cost sharing for this prescription is \$4.00.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the program is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$4 for January, since the OOP incurred amount is lower than the cap.

Note: when the amount incurred in the first month in the program is less than the maximum monthly cap, the participant cannot be billed more than their actual OOP costs in that month. Therefore, the participant would be billed \$4.00 for January.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant does not need to refill their low-cost prescription filled in January but refills their high-cost maintenance drug in February.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$4.00 in January and was billed \$4.00.

$$\$4.00 - \$4.00 = \$0$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills a high-cost prescription in February that causes them to reach the annual OOP threshold. Part D cost sharing for this drug is \$2,534.11, but the final OOP cost sharing would be \$1,996.00 (capped by the OOP threshold of \$2,000; $\$2,000 - \$4.00 = \$1,996.00$). Additional OOP costs incurred = \$1,996.00.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February). (*Note that \$0 is added to the \$1,996 because the participant was billed and paid in full the \$4 that was due for January*).

$$(\$0 + \$1,996.00)/11 = \$181.45$$

Because the participant in Example #2 has already met the annual OOP threshold, they will incur no new additional OOP costs. Their maximum monthly cap would be approximately \$181.45 for all months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$4.00	\$166.67	\$4.00
February	\$1,996.00	\$181.45	\$181.45
March	\$0	\$181.46	\$181.46
April	\$0	\$181.45	\$181.45
May	\$0	\$181.46	\$181.46
June	\$0	\$181.45	\$181.45
July	\$0	\$181.46	\$181.46
August	\$0	\$181.45	\$181.45
September	\$0	\$181.46	\$181.46
October	\$0	\$181.45	\$181.45
November	\$0	\$181.46	\$181.46
December	\$0	\$181.45	\$181.45
TOTAL	\$2,000.00		\$2,000.00

30.3.3 Example #3: April Election with 90-Day Supply of a Drug with Remaining Deductible

Calculation of Maximum Monthly Cap in First Month: The example demonstrates how the maximum monthly cap would be calculated for an individual who opts into the Medicare Prescription Payment Plan in April and fills a prescription for a 90-day supply. They have no additional prescription drug coverage through a third party. In April 2025, after opting into the program, the participant fills a new prescription for a 90-day supply. Prior to April, the participant has filled low-cost monthly maintenance drugs, so they have not yet reached their deductible. The total OOP cost sharing for the prescription in April, including the remainder of the \$545 deductible, is \$617.00.¹¹

Step 1: Determine the previously incurred costs. The participant has filled multiple, low-cost generic drugs from January through March 2025; the TrOOP Accumulator is \$12.00.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is April; months remaining in the plan year equals 9 (includes April).

$$(\$2,000 - \$12.00)/9 = \$220.89$$

The plan will bill \$220.89 for April, since the OOP incurred amount of \$617.00 is higher than the maximum monthly cap.

Calculation of Maximum Monthly Cap in Subsequent Months: In May 2025, the participant refills only their existing generic maintenance drug (OOP cost sharing: \$4.00).

¹¹ \$545 deductible is based on 2024 Part D benefit parameters; amounts subject to change with updated Part D benefit parameters for 2025.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$617.00 in April and was billed \$220.89.

$$\$617.00 - \$220.89 = \$396.11$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills only their generic maintenance drugs during this month. Additional OOP costs incurred = \$4.00.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is May; months remaining in the plan year equals 8 (includes May).

$$(\$396.11 + \$4.00)/8 = \$50.01$$

If the participant in Example #3 continued this pattern of 90-day fills (with a \$120 copay after meeting the deductible in April) and monthly generic fills (\$4 copay), their maximum monthly cap would update as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$4.00	N/A	\$4.00*
February	\$4.00	N/A	\$4.00*
March	\$4.00	N/A	\$4.00*
April	\$617.00	\$220.89	\$220.89
May	\$4.00	\$50.01	\$50.01
June	\$4.00	\$50.59	\$50.59
July	\$124.00	\$71.25	\$71.25
August	\$4.00	\$72.05	\$72.05
September	\$4.00	\$73.05	\$73.05
October	\$124.00	\$114.39	\$114.39
November	\$4.00	\$116.39	\$116.39
December	\$4.00	\$120.38	\$120.38
TOTAL	\$901.00		\$901.00

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

40. Participant Billing Rights

Section 1860D–2(b)(2)(E)(iii) of the Act requires Part D sponsors to bill participants who are in the Medicare Prescription Payment Plan and incur OOP costs an amount for each month that cannot exceed the applicable maximum monthly cap. For each billing period after an individual has opted into the program and incurred OOP costs, the Part D sponsor will calculate a monthly amount that takes into account the OOP costs in that month that were incurred on or after the date on which the individual opted into the program. Each billing period will be a calendar

month. A Part D sponsor must not bill a participant who is in the program but has not yet incurred any OOP costs during the plan year.

Note that past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap. However, the amount billed *for the month for which the maximum monthly cap is being calculated* cannot be higher than the cap for that month. For example, in Example #3 in this guidance (section 30.3.3), the maximum monthly cap and monthly participant payment for the first month in the program (April) is \$220.89. The maximum monthly cap amount for May (the participant's second month in the program) is \$50.01. If the participant paid only \$200.00 of their first month's bill, the remaining \$20.89 ($\$220.89 - \$200.00 = \20.89) could be added to the bill for May, as a separate line item from the May monthly participant payment (which would be capped by the maximum monthly cap calculation). The total billed amount for May would then be \$70.90 ($\$50.01 + \$20.89 = \70.90).¹²

CMS encourages Part D sponsors to offer multiple means of payment, such as an electronic fund transfer mechanism (including automatic charges of an account at a financial institution or credit or debit card account) and payment by check. We also encourage Part D sponsors to offer participants flexibility around requesting a specific day of the month for program charges and withdrawals from a bank account.

Because Part D sponsors may not bill a participant more than the maximum monthly cap, late fees, interest payments, or other fees, such as for different payment mechanisms, are not permitted under the program. Plan sponsors are responsible for ensuring that any third parties they contract with also comply with such requirements.

Regardless of whether they are provided by mail or electronically, billing statements must contain the following information:

- A statement that the bill is for the Medicare Prescription Payment Plan, a brief description of the program, and a reference to where additional information about the program can be found;
- The effective date of program participation;
- The last payment received, showing the date, amount of the last payment, and the means of payment made by the participant;
- Any balance carried over from the prior month, including any missed payments;
- Itemized OOP costs by prescription for the month being billed;
- The amount due from the participant for the month being billed (i.e., the amount based on the application of the monthly cap calculation);
- The remaining total OOP cost sharing balance;
- Information on the next steps if the participant fails to pay by the stated due date;
- Information on how to voluntarily opt out of the program and balances due if participation is terminated;

¹² The example outlined here assumes that the Part D sponsor has the necessary information to include the April unpaid balances in the bill for May.

- Information on the dispute processes available if the individual disputes their bill;
- General information about applying for the LIS program and how to enroll (as an additional or alternative avenue for addressing prescription drug costs), noting that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan; and
- Plan contact information for participant questions about the billing statement.

CMS reminds Part D sponsors (and any third parties Part D sponsors contract with) that actions to collect unpaid balances related to the program may be subject to other applicable federal and state laws and requirements, including those related to payment plans, credit reporting, and debt collection. For example, as such unpaid balances would be related to the provision of health care to an individual, information about such debt should be considered “medical information” under the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and treated accordingly if furnished to a consumer reporting agency. These requirements also apply in the event of a death of a program participant. Additionally, CMS reminds Part D sponsors that, under section 1860D–2(b)(2)(E)(v)(VI) of the Act, any unsettled balances with respect to amounts owed under the program will be treated as plan losses; bidding guidance for CY 2025 is included in section 60.1 of the draft part two guidance.

40.1 Prioritization of Premium Payments

While Part D sponsors may create their own billing and payment procedures for the Medicare Prescription Payment Plan, Part D sponsors are required to prioritize payments towards Part D plan premiums to avoid a Part D enrollee losing their Part D coverage when it is unclear whether a payment received from a participant is intended by the participant to cover their outstanding Part D plan premium or Medicare Prescription Payment Plan balance. Specifically, if a Part D enrollee has opted into the program and makes payments directly to the Part D sponsor, and it is unclear whether a payment should go towards the participant’s outstanding Part D plan premium or Medicare Prescription Payment Plan balance, the Part D sponsor may contact the enrollee to clarify the purpose of the payment. If the Part D sponsor does not contact the enrollee or is not able to ascertain the purpose of the payment, then the payment must be applied to the Part D premium.

Note that the above billing requirements apply only to bills for amounts due under the Medicare Prescription Payment Plan. Part D sponsors must send a separate bill for the collection of premiums, if applicable, and continue to follow existing regulations and guidance for the collection of premiums as described at 42 CFR § 423.293.

40.2 Financial Reconciliation Process

Section 1860D–2(b)(2)(E)(v)(III)(gg) of the Act specifies that Part D sponsors must have a financial reconciliation process in place to correct inaccuracies in billing and/or payments.

While a Part D sponsor may not bill a program participant an amount for a month that is more than the maximum monthly cap, a participant may pay more than the maximum monthly cap up to the annual OOP threshold. However, the participant cannot pay more than their total OOP

costs incurred. If a participant does pay more than their total OOP costs incurred, the Part D sponsor must reimburse the participant the amount that is paid above the balance owed. CMS expects that Part D sponsors will develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants. Part D sponsors should ensure participants do not incur any charges or fees as a result of overbilling or overpayment errors made by the Part D sponsor. CMS expects Part D sponsors to take steps to ensure that participants do not accrue any additional charges (such as overdraft fees) as a result of errors made by the Part D sponsor and to work with participants to reconcile any of these charges. In the event the Part D sponsor undercharges the participant, the participant is still responsible for paying the accurate payment amount; as such, Part D sponsors should work with the participant to correct the charge and collect any outstanding amount for which the participant was not correctly billed.

Sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated, voluntarily or involuntarily. The Part D sponsor may offer the participant the option to repay the full outstanding amount in a lump sum, but cannot require full immediate repayment.

50. Pharmacy Payment Obligations and Claims Processing

Consistent with 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, Part D sponsors must pay the pharmacy the enrollee’s cost-sharing amount in addition to the Part D sponsor’s portion of the payment. As program participants will pay \$0 at the POS instead of the OOP cost sharing they would normally pay at the POS when filling a prescription, Part D sponsors must pay the pharmacy the enrollee’s cost-sharing amount in addition to the Part D sponsor’s portion of the payment.

Consistent with section 1860D-12(b)(4) of the Act and 42 CFR § 423.520, Part D sponsors must reimburse a network pharmacy the total of a participant’s OOP amount and the Part D sponsor portion of the payment for a covered Part D drug no later than 14 calendar days after the date on which the claim is received for an electronic claim or no later than 30 calendar days after the date on which the claim is received for any other claim. The timing of payment of the total of a participant’s OOP amount and the Part D sponsor portion of the payment for long-term care and home infusion pharmacies should follow current practices for payment of the Part D sponsor portion to be consistent with this requirement.

50.1 Pharmacy Claims Processing Requirements

To ensure that an individual’s participation in the Medicare Prescription Payment Plan has no effect on the amount paid to pharmacies in accordance with section 1860D–2(b)(2)(E)(v)(III)(ff) of the Act, the Part D sponsor must pay the pharmacy for the final amount the individual would have otherwise paid at the POS. An individual’s OOP costs are net of any contributions made by supplemental payers to Part D that the individual may be entitled to and that reduce the OOP amount due. CMS is aware that the current coordination of benefits (COB) electronic billing process may be disrupted if a Part D sponsor initially returns an amount of \$0 in the National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard response pricing

segment field “Patient Pay Amount” (505-F5) on a Part D claim because this amount may be used by supplemental payers to determine if additional benefits are provided. Additionally, this amount may be used by Part D sponsors for other downstream reporting requirements, such as PDE records and explanation of benefits (EOB) reporting, which reflect the actual participant liability amounts as incurred.

To ensure a uniform, consistent process that satisfies all of the criteria specified in section 50.1 of the draft part one guidance and to leverage existing Part D processes to minimize operational burdens, Part D sponsors and pharmacies must use a Bank Identification Number (BIN) and/or Processor Control Number (PCN) electronic claims processing methodology for applicable Medicare Prescription Payment Plan transactions. Except for certain scenarios discussed in section 50.5 of the draft part two guidance, pharmacies and Part D sponsors must utilize an additional BIN/PCN that is unique to the Medicare Prescription Payment Plan to facilitate electronic processing of supplemental COB transactions for program participants. Part D sponsors must provide the unique Medicare Prescription Payment Plan BIN/PCN and any other pertinent billing information to the pharmacy on paid claim responses when the enrollee is also a Medicare Prescription Payment Plan participant. Part D sponsors must also assign a program-specific PCN that starts with “MPPP” and report the new BIN/PCN to CMS in a manner to be specified.

This method results in two transactions being submitted to the same Part D sponsor but using two different BIN/PCN combinations. The Part D sponsor’s primary unique BIN/PCN (as required by 42 CFR § 423.120(c)(4)) will be used for the initial Part D claim adjudication, while a second unique Medicare Prescription Payment Plan BIN/PCN will be used to process only the final OOP participant liability amount; this process will account for any other payments made by supplemental coverage to which the participant may be entitled that may reduce the participant’s OOP cost. The transaction processed through the Medicare Prescription Payment Plan BIN/PCN will be submitted after processing any applicable other payer transactions in order to capture the final patient responsibility amount after all other payers have paid. This will allow the Part D sponsor to pay the pharmacy for the amount the participant would otherwise have paid at the POS to obtain their prescription. To clarify, Medicare Prescription Payment Plan payments are not considered to be OHI, as the participant’s Part D sponsor is the source of both primary and Medicare Prescription Payment Plan payments to the pharmacy. Information Reporting (Nx) transactions will not be generated for Medicare Prescription Payment Plan COB transactions, as the Part D plan is the entity processing both the primary and Medicare Prescription Payment Plan claims and will already be aware of necessary transaction data.

This system will allow Part D sponsors to continue to adhere to Medicare Secondary Payer (MSP) laws and any other federal and state laws establishing payers of last resort (e.g., AIDS Drug Assistance Programs (ADAPs)), as discussed in the Medicare Prescription Drug Benefit Manual Chapter 14, Section 30.3.¹³ As noted above, payments made through the Medicare Prescription Payment Plan BIN/PCNs are to be processed after all other payers, including SPAPs or ADAPs.

¹³ Refer to Medicare Prescription Drug Benefit Manual; Chapter 14 – Coordination of Benefits.

When using this claims processing methodology, Part D sponsors must ensure that there is no impact to PDE cost/payment field reporting, meaning PDE financials must reflect participant and plan liability amounts as if the Medicare Prescription Payment Plan did not apply. Additionally, this approach should have no impact to prescriber or participant real-time benefit tools, meaning participant liability amounts must be represented as if the Medicare Prescription Payment Plan did not apply. If the individual has opted into the program, Part D sponsors can consider providing patient costs that reflect the program in their participant real-time benefit tool, as long as the total expected OOP liability is clearly communicated to the individual. If the individual has not opted into the program, the participant real-time benefit tool could be used to alert the individual about the program (either generally or conditionally when the participant real-time benefit tool returns a liability amount over a particular dollar amount).

Example of electronic claims processing workflow:

1. Pharmacy submits claim billing transaction using Part D plan's primary BIN/PCN.
2. Pharmacy receives paid claim response reflecting Part D plan and participant responsibility amounts.
 - a. Pharmacy receives message on paid claim that individual is enrolled in the Medicare Prescription Payment Plan and is provided with the plan's Medicare Prescription Payment Plan BIN/PCN, along with any known OHI (if applicable).
3. Pharmacy submits COB transactions to known OHI (if applicable).
 - a. If Part D copay is already \$0, then COB transaction to OHI is not necessary.
4. Pharmacy submits final COB claim billing transaction to the plan's Medicare Prescription Payment Plan BIN/PCN reflecting final participant responsibility amount after all other payers have paid.
 - a. If participant responsibility has already been reduced to \$0 by OHI, then COB transaction to the plan's Medicare Prescription Payment Plan BIN/PCN is not necessary.
5. Pharmacy receives paid claim response reflecting \$0 participant responsibility and the corresponding dollar amount indicated as plan payment.
 - a. The participant responsibility amount paid by the plan's Medicare Prescription Payment Plan BIN/PCN on this final COB transaction would be considered the OOP costs covered by the Part D sponsor to be used for subsequent participant billing purposes.

Example 1 with no OHI: \$100 negotiated price in Initial Coverage Phase of Defined Standard plan.

1. Pharmacy submits \$100 claim to Part D plan's primary BIN/PCN.
2. Pharmacy receives paid claim response reflecting \$25 Patient Pay Amount and \$75 Total Amount Paid.
 - a. Pharmacy receives paid claim response message that the individual has opted into the Medicare Prescription Payment Plan and is provided with the plan's Medicare Prescription Payment Plan BIN/PCN to bill the final participant responsibility amount as a COB transaction.

3. Pharmacy submits COB transaction for \$25 to the plan's Medicare Prescription Payment Plan BIN/PCN.
4. Pharmacy receives paid claim response on COB transaction reflecting \$0 Patient Pay Amount and \$25 Total Amount Paid.

Example 2 with OHI: \$100 negotiated price in Initial Coverage Phase of Defined Standard plan.

1. Pharmacy submits \$100 claim to Part D plan's primary BIN/PCN.
2. Pharmacy receives paid claim response reflecting \$25 Patient Pay Amount and \$75 Total Amount Paid.
 - a. Pharmacy receives paid claim response message that the individual has opted into the Medicare Prescription Payment Plan and is provided with the plan's Medicare Prescription Payment Plan BIN/PCN to bill the final participant responsibility amount as a COB transaction, along with data for another supplemental payer to Part D.
3. Pharmacy submits COB transaction to other supplemental payer (OHI).
4. Pharmacy receives paid claim response on COB transaction to OHI reflecting \$5 Patient Pay Amount and \$20 Total Amount Paid.
5. Pharmacy submits COB transaction for \$5 to the plan's Medicare Prescription Payment Plan BIN/PCN.
6. Pharmacy receives paid claim response on COB transaction reflecting \$0 Patient Pay Amount and \$5 Total Amount Paid.

CMS believes this approach would work in conjunction with existing COB processes while providing Part D sponsors the opportunity to evaluate the accuracy of the Medicare Prescription Payment Plan amount they are to pay the pharmacy on behalf of the participant.

50.2 Pharmacy Transaction Costs

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. Consistent with 42 CFR § 423.100 and sections 20.6 and 20.7 of Chapter 5 of the Medicare Prescription Drug Benefit Manual, a drug's negotiated price must include any dispensing fees, and uniform negotiated prices must be available to plan enrollees for a particular covered Part D drug when purchased from the same pharmacy.

As noted in section 40 of this final part one guidance, it is not permissible for Part D sponsors to charge program participants fees related to the Medicare Prescription Payment Plan.

Additionally, as noted in section 50 of this guidance, section 1860D-2(b)(2)(E)(v)(III)(ff) of the Act requires Part D sponsors to ensure that enrollee participation in the Medicare Prescription Payment Plan does not affect the amount paid to pharmacies or the timing of such payments. As a result, Part D sponsors cannot impose any fees or costs related to program implementation on pharmacies, as such fees or costs would affect the amount paid to pharmacies in violation of the statute. Participation in the Medicare Prescription Payment Plan is an arrangement between the Part D sponsor and the Part D enrollee; pharmacies cannot be held responsible for any unsettled

balances of a participant or for collecting unpaid balances from the participant on the Part D sponsor's behalf.

50.3 Requirements for Different Pharmacy Types

In general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including mail order, home infusion, specialty, and long-term care pharmacies. However, CMS is aware that some pharmacy types may not have direct contact with Part D enrollees and/or may lack a practical means for providing the physical standardized likely to benefit notice directly to the Part D enrollee. Therefore, we have provided additional guidance for unique pharmacy scenarios and different pharmacy types in section 50 of the draft part two guidance.

50.4 Paper Claims

Except for the election-related circumstances listed in section 70 of this guidance, Part D sponsors are not required to retroactively include under this program paper claims submitted to the Part D sponsor by a Medicare Prescription Payment Plan participant. "Paper claims" refer to any claims for which the participant submits a request to be retroactively covered by the Part D sponsor (whether the request is made via a paper form, telephonically, or electronically), including requests for direct member reimbursement for OON claims.

60. Requirements Related to Part D Enrollee Outreach

60.1 General Part D Enrollee Outreach Requirements

Under section 1860D-2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees of the option to opt into the Medicare Prescription Payment Plan in promotional materials prior to the plan year. Under section 1860D-2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also include information on the Medicare Prescription Payment Plan in Part D enrollee educational materials. As such, Part D sponsors must provide clear information about the program to Part D enrollees through communication and marketing materials during open enrollment.

Specifically, in the draft part two guidance, CMS described how Part D sponsors must use existing Part D communications materials that are required to be furnished to all Part D enrollees under § 423.2267(e) to provide information about the Medicare Prescription Payment Plan to their Part D enrollees. These materials include the membership ID card mailing that plans must provide to new Part D enrollees, the Evidence of Coverage (EOC), the Annual Notice of Change (ANOC), the Explanation of Benefits (EOB), and Part D sponsor websites. Please refer to section 30.1 of the draft part two guidance for additional communications and marketing requirements regarding general education and outreach to Part D enrollees. CMS also reminds Part D sponsors that Medicare Prescription Payment Plan materials must meet translation requirements outlined in section 30.4 of the draft part two guidance. CMS will also provide for public comment through the ICR process model materials to support Part D sponsors in meeting these requirements.

60.2 Targeted Part D Enrollee Outreach Requirements

As mentioned elsewhere in this guidance, while this program is open to all Part D enrollees, Part D enrollees incurring high OOP costs earlier in the plan year are generally more likely to benefit. Given this, in addition to the general outreach and education required under section 1860D–2(b)(2)(E)(v)(III) of the Act, Part D sponsors must also undertake targeted outreach, both prior to and during the plan year, to Part D enrollees likely to benefit from the Medicare Prescription Payment Plan. This includes the pharmacy notification process (as outlined in section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, section 60.2.4 of this final part one guidance, and section 50 of the draft part two guidance) and outreach directly to identified Part D enrollees (section 60.2.2 of this final part one guidance and section 30.2.2 of the draft part two guidance).

60.2.1 Identification of Part D Enrollees Who Are Likely to Benefit

Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program. While the statute requires this notification, it does not outline the specific criteria or define the profile of someone who is likely to benefit under the program. CMS developed a standardized framework for assessing “likely to benefit,” which will be used to inform targeted outreach both prior to and during the plan year. CMS recognizes, however, that an individual Part D enrollee may find that they would personally benefit from the program even if they would not be identified as likely to benefit under this particular standardized framework. Those individuals are certainly permitted to opt into the program. The definition and framework for “likely to benefit” presented in this section is specifically for identifying Part D enrollees for targeted outreach and communication in the absence of any information regarding an individual’s specific financial circumstances.

In retrospective modeling of PDE data, CMS found that to be “likely to benefit” from the program, the Part D enrollee would have to incur some level of substantial OOP costs; further, the Part D enrollee’s highest monthly OOP cost incurred would be more than the highest monthly paid amount under the Medicare Prescription Payment Plan (if the program had applied). CMS used this approach to identify “likely to benefit” because it focuses on addressing Part D enrollees’ potential cash-flow concerns by lowering their maximum OOP costs in a month (and limiting the potential for participants to be faced with Medicare Prescription Payment Plan monthly payments that may initially provide substantial financial relief but later, due to timing constraints, result in monthly beneficiary payments that are higher than they would have been absent the program). This approach strictly compares the monthly OOP amounts with and without the Medicare Prescription Payment Plan, and without any subjective assessments of what amount might be beneficial to an individual Part D enrollee. In addition, it is easy to explain and relatively simple to use for the first year of the program. Through program experience, CMS will gain a better understanding of which Part D enrollees are likely to opt into the program and will make modifications as appropriate and necessary in the future.

As discussed in section 30 of this guidance, the maximum monthly cap is calculated for each month a participant is in the program, and the amount billed to a participant will change each month if the participant continues to incur new OOP costs. The calculations do not change the

total amount that a participant will pay over the course of the year; instead, participants in the Medicare Prescription Payment Plan are able to spread their OOP costs over the course of the plan year in monthly amounts calculated according to the statutory formula.

Given these requirements, Part D enrollees with high OOP costs earlier in the plan year, in particular, are more likely to benefit from participating. For example, in 2025, an individual with no previously incurred costs who opts into the program in January will have a maximum monthly cap for the first month of \$166.67 and a full 12 months of billing periods over which to spread costs. If that same individual were to opt into the program in September (assuming no previously incurred costs), their maximum monthly cap for the first month would be \$500; newly incurred OOP costs would be spread over four billing periods (September through December). The table below provides an example of a Part D enrollee who is likely to benefit from the program. In this example, the individual opts into the Medicare Prescription Payment Plan and begins filling a high-cost prescription in January 2025. Because they reach the annual OOP threshold in April, they incur no new OOP costs over the remainder of the year and have the ability to spread costs incurred early in the year over the entire 12 months of the plan year. In alignment with the standardized “likely to benefit” concept discussed above, the highest monthly OOP payment amount without the Medicare Prescription Payment Plan is \$500.00, which is greater than the highest monthly payment amount under the Medicare Prescription Payment Plan of \$181.32.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$500.00	\$166.67	\$166.67	\$333.33
February	\$500.00	\$75.76	\$75.76	\$757.57
March	\$500.00	\$125.76	\$125.76	\$1,131.81
April	\$500.00	\$181.31	\$181.31	\$1,450.50
May	\$0.00	\$181.31	\$181.31	\$1,269.19
June	\$0.00	\$181.31	\$181.31	\$1,087.88
July	\$0.00	\$181.31	\$181.31	\$906.57
August	\$0.00	\$181.31	\$181.31	\$725.26
September	\$0.00	\$181.32	\$181.32	\$543.94
October	\$0.00	\$181.31	\$181.31	\$362.63
November	\$0.00	\$181.32	\$181.32	\$181.31
December	\$0.00	\$181.31	\$181.31	\$0.00
TOTAL	\$2,000.00		\$2,000.00	

In comparison to the example above, if an individual incurs a similar amount of OOP costs but they opt into the Medicare Prescription Payment Plan and begin filling prescriptions in September as opposed to January, the individual would not hit the annual OOP threshold until December and would have no remaining time in the plan year to spread their costs. Because the monthly maximum cap calculation updates each month to include newly incurred OOP costs in that month, participation in the Medicare Prescription Payment Plan results in early payments that provide substantial financial relief (e.g., \$166.67 compared to \$500.00 in October) but later, due to timing constraints, results in monthly payments that are higher than they would have been

absent the program (e.g., \$916.66 compared to \$500.00 in December). In the table below, the highest monthly OOP payment amount without the Medicare Prescription Payment Plan is \$500.00, which is lower than the highest monthly payment amount under the Medicare Prescription Payment Plan of \$916.66; this participant is thus not likely to benefit from the program.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$0.00	N/A	\$0.00	\$0.00
February	\$0.00	N/A	\$0.00	\$0.00
March	\$0.00	N/A	\$0.00	\$0.00
April	\$0.00	N/A	\$0.00	\$0.00
May	\$0.00	N/A	\$0.00	\$0.00
June	\$0.00	N/A	\$0.00	\$0.00
July	\$0.00	N/A	\$0.00	\$0.00
August	\$0.00	N/A	\$0.00	\$0.00
September	\$500.00	\$500.00	\$500.00	\$0.00
October	\$500.00	\$166.67	\$166.67	\$333.33
November	\$500.00	\$416.67	\$416.67	\$416.66
December	\$500.00	\$916.66	\$916.66	\$0.00
TOTAL	\$2,000.00		\$2,000.00	

Part D enrollees with low-to-moderate recurring OOP drug costs (e.g., maintenance drugs whose annual costs are not expected to exceed the OOP threshold) are also not likely to benefit from the Medicare Prescription Payment Plan because their costs are already distributed evenly throughout the year.

The table below provides an example of an individual who is not likely to benefit from the program. The participant opts into the Medicare Prescription Payment Plan and begins filling multiple monthly maintenance drugs in January 2025. They do not reach the annual OOP threshold in 2025. Because the monthly maximum cap calculation updates each month to include newly incurred OOP costs in that month, participation in the Medicare Prescription Payment Plan results in early payments that provide substantial financial relief (e.g., \$5 compared to \$55 in February) but later, due to timing constraints, results in monthly payments that are higher than they would have been absent the program (e.g., \$166.09 compared to \$55 in December). The highest monthly OOP payment amount without the Medicare Prescription Payment Plan was \$55.00, which is lower than the highest monthly payment amount under the Medicare Prescription Payment Plan of \$166.09; this participant is thus not likely to benefit from the program.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$55.00	\$166.67	\$55.00	\$0.00
February	\$55.00	\$5.00	\$5.00	\$50.00
March	\$55.00	\$10.50	\$10.50	\$94.50
April	\$55.00	\$16.61	\$16.61	\$132.89
May	\$55.00	\$23.49	\$23.49	\$164.40
June	\$55.00	\$31.34	\$31.34	\$188.06
July	\$55.00	\$40.51	\$40.51	\$202.55
August	\$55.00	\$51.51	\$51.51	\$206.04
September	\$55.00	\$65.26	\$65.26	\$195.78
October	\$55.00	\$83.59	\$83.59	\$167.19
November	\$55.00	\$111.10	\$111.10	\$111.09
December	\$55.00	\$166.09	\$166.09	\$0.00
TOTAL	\$660.00		\$660.00	

In comparison to the example above, if an individual had similar total OOP costs, but they were incurred as a single acute event instead of recurring monthly fills, the individual would have an opportunity to spread those costs over the remaining months in the year. This participant would be considered likely to benefit from the program; the highest monthly OOP payment amount without the Medicare Prescription Payment Plan was \$660.00, which is greater than the highest monthly payment amount under the Medicare Prescription Payment Plan of \$200.00.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$0	N/A	\$0	\$0.00
February	\$0	N/A	\$0	\$0.00
March	\$660.00	\$200.00	\$200.00	\$460.00
April	\$0.00	\$51.11	\$51.11	\$408.89
May	\$0.00	\$51.11	\$51.11	\$357.78
June	\$0.00	\$51.11	\$51.11	\$306.67
July	\$0.00	\$51.11	\$51.11	\$255.56
August	\$0.00	\$51.11	\$51.11	\$204.45
September	\$0.00	\$51.11	\$51.11	\$153.34
October	\$0.00	\$51.11	\$51.11	\$102.23
November	\$0.00	\$51.12	\$51.12	\$51.11
December	\$0.00	\$51.11	\$51.11	\$0.00
TOTAL	\$660.00		\$660.00	

While unique individual financial situations may make participation in the program beneficial at any point in the plan year (with the possible exception of December, as OOP costs incurred in December cannot be spread over multiple months), generally, those with high OOP drug costs

early in the year (including recurring costs) are likely to benefit from the Medicare Prescription Payment Plan.

60.2.2 Targeted Part D Enrollee Notification Prior to POS

In addition to notifying all prospective Part D enrollees about the option to opt into the Medicare Prescription Payment Plan, Part D sponsors must also conduct outreach directly to individuals who are likely to benefit from the program, both prior to and during the plan year.

Please refer to section 30.2 of the draft part two guidance for specific requirements that Part D sponsors must follow in identifying and conducting outreach to enrollees that are likely to benefit.

60.2.3 Targeted Part D Enrollee Notification at POS

Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs with respect to covered Part D drugs that make it likely the enrollee may benefit from participating in the program.

Furthermore, section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such a notification from the plan sponsor, informs the Part D enrollee that it is likely that the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

Using the concept of “likely to benefit” discussed in section 60.2.1, CMS modeled how various potential POS notification thresholds performed in identifying Part D enrollees who would meet the above definition of “likely to benefit” based on 2021 PDE data. As guided by the statute’s reference to OOP costs, CMS analyzed 2021 PDE records for patterns in drug spend and patient pay that would make a Part D enrollee likely to benefit from the Medicare Prescription Payment Plan. The analysis used only OOP costs that would be known at the POS, not historical costs, to align with what the Part D sponsor and pharmacy would be communicating at a point in time. In the analysis, CMS excluded Part D enrollees who first met the POS notification threshold in December, as OOP costs incurred in December cannot be spread over multiple months. In this final part one guidance, these analyses have been updated from the draft part one guidance to reflect 2022 PDE data.

Our modeling and approach in this guidance is based on the OOP costs for any single prescription counting toward a potential threshold. As a sensitivity analysis, CMS also examined the performance of various potential threshold amounts by counting OOP costs for prescriptions filled on the same day toward a single POS total, assuming that those prescriptions would have been paid for during the same pharmacy visit. While counting OOP costs for all prescriptions filled on the same day results in more Part D enrollees being notified, the differential is less than 200,000 Part D enrollees at the lower threshold and even smaller at the highest threshold. Since the results were similar in scale and relative counts for each possible threshold, our current guidance is to use the OOP cost of any single prescription as a trigger for the POS notification for simplicity of operations with minimal impact on Part D enrollees.

Whether the pharmacy notification process is based on OOP costs for a single prescription or all prescriptions within a single day, there is limited visibility into possible future prescription costs, and therefore almost any threshold has the potential to identify Part D enrollees whose subsequent cost patterns will cause them to no longer meet the definition of likely to benefit. Higher POS thresholds identify a smaller pool of Part D enrollees but increase the probability that those who would receive the notification would continue to meet the definition of likely to benefit. The table below summarizes key findings from CMS’s analyses of POS thresholds based on a single prescription.

Single Prescription OOP Cost Threshold	Part D Enrollees Identified as Likely to Benefit*	Part D Enrollees Who Actually Would Have Benefited (%)
\$400	2.9 million	2.6 million (90%)
\$500	1.7 million	1.6 million (95%)
\$600	1.0 million	982k (98%)
\$700	580k	574k (99%)
\$800	430k	429k (99.6%)
\$900	374k	374k (99.8%)
\$1,000	334k	334k (99.98%)

*Number of Part D enrollees identified in retrospective analyses using 2022 PDE data

The table below displays the results from the sensitivity analysis, which counts OOP costs for all prescriptions filled on the same day toward a single POS total.

Single Day OOP Cost Threshold	Part D Enrollees Identified as Likely to Benefit*	Part D Enrollees Who Actually Would Have Benefited (%)
\$400	3.1 million	2.8 million (90%)
\$500	1.9 million	1.8 million (95%)
\$600	1.1 million	1.1 million (97%)
\$700	662k	654k (99%)
\$800	483k	480k (99.5%)
\$900	409k	108k (99.8%)
\$1,000	357k	357k (99.98%)

*Number of Part D enrollees identified in retrospective analyses using 2022 PDE data

In our draft part one guidance, we sought comment on whether to establish a single or daily OOP cost prescription drug accumulation. Based on the comments received and our internal analyses, CMS is establishing in this final part one guidance that Part D sponsors and pharmacies must use a \$600, single prescription threshold to identify enrollees likely to benefit. CMS chose a \$600, single prescription drug cost threshold because this approach strikes the best balance between identifying 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 who will not meet the likely to benefit definition.

In setting the POS threshold, CMS strives to balance the desire to identify individuals with potential cash-flow concerns at the pharmacy and provide them key information about a program that may benefit them while ensuring precision in the notification (i.e., limiting the potential for participants to be faced with Medicare Prescription Payment Plan monthly payments that initially provide substantial financial relief but later, due to timing constraints, result in monthly payments that are higher than they would have been absent the program).

60.2.4 POS Notification Requirements

Under section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors are required to have in place a mechanism to notify the pharmacy when a Part D enrollee who has not already opted into the Medicare Prescription Payment Plan incurs OOP costs with respect to a covered Part D drug that make it likely the Part D enrollee may benefit from the program. As articulated above, for the pharmacy notification requirement, the determination of whether an enrollee is likely to benefit from participating in the program is based on when they incur OOP costs for a single prescription that equal or exceed the POS threshold.

Part D sponsors must notify pharmacies when a Part D enrollee’s OOP costs meet these criteria at the POS and require the pharmacy to inform the Part D enrollee that they may benefit from the program and how to opt in if the Part D enrollee would like to participate in the program. Please refer to sections 50.2 and 50.3 of the draft part two guidance for additional information regarding POS notifications. Please also refer to sections 30 and 40 of the draft part two guidance for additional guidance on the contents of notifications as well as model language for educational materials.

A Part D enrollee is unlikely to benefit from opting in during December, the last month of the plan year, because OOP costs incurred in that month cannot be spread over more than one month.¹⁴ As such, a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year. Additionally, participants who have already opted into the Medicare Prescription Payment Plan should not be notified about opting into the program while their participation is in effect. If a prescription is picked up by another person who is not the Part D enrollee, the Part D sponsor must require the pharmacy to provide the person who is picking up the prescription with information about the program when the pharmacy would have been required to provide such information if the Part D enrollee had picked up the prescription. However, only the Part D enrollee or their legal representative may opt into the program. Nothing in this guidance precludes a pharmacy from educating a Part D enrollee about this program, regardless of whether the enrollee’s cost-sharing reaches the POS threshold for required notification.

Part D sponsors must notify a pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed the POS threshold of \$600, regardless of whether the Part D enrollee receives prescriptions through a retail pharmacy or through a mail order, home infusion, specialty, or long-term care pharmacy. CMS is aware that claims processing and billing practices may differ for certain unique pharmacy scenarios. We have provided additional guidance for unique pharmacy scenarios and different pharmacy types (e.g., long-term care pharmacies, mail

¹⁴ Except for non-calendar year EGWPs, which would apply the last month of their specific plan year.

order pharmacies, Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies) in section 50 of the draft part two guidance.

70. Requirements Related to Part D Enrollee Election

70.1 Part D Enrollee Eligibility

Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible individuals.

The program is voluntary for any Part D enrollee to opt into. In addition, Part D sponsors cannot set a minimum OOP cost sharing amount that Part D enrollees must incur to participate. As described above, Part D sponsors must identify Part D enrollees likely to benefit and educate those enrollees on the impacts of potentially participating in the Medicare Prescription Payment Plan.

Under section 1860D–2(b)(2)(E)(v)(II) of the Act, a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. In addition, under section 1860D–2(b)(2)(E)(v)(III)(aa) of the Act, Part D sponsors may not restrict the application of the Medicare Prescription Payment Plan benefit to specific covered Part D drugs. To minimize potential confusion and operational challenges, for a given plan year, once an individual has opted into the program, OOP cost sharing for all covered Part D drugs must be included until the participant reaches the OOP threshold or opts out of the Medicare Prescription Payment Plan.

70.2 Interactions Between Low-Income Subsidy (LIS) and Medicare Prescription Payment Plan

The IRA expanded the LIS program so that, beginning in 2024, beneficiaries with incomes up to 150% of the federal poverty line and who meet the resource standard at either of sections 1860D–14(a)(3)(D) or (E) of the Act will be eligible for the full LIS benefit. Prior to 2024, the full LIS benefit was available only to enrollees earning less than 135% of the federal poverty line. This subsidy provides for \$0 premiums and low-cost, fixed copayments for covered prescription drugs.

Considering this change, and the potential reductions in OOP costs from enrolling in LIS, it is critical that Part D enrollees eligible for the LIS program are encouraged to apply. While the statute requires that an LIS enrollee must have the option to become a Medicare Prescription Payment Plan participant, individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the program. (Please refer to section 60.2.1 of this final part one guidance and section 30.2 of the draft part two guidance for additional detail around identification of Part D enrollees who are likely to benefit.). Further, LIS enrollment, for those who qualify, is more advantageous than participation in the Medicare Prescription Payment Plan. There may be limited circumstances in which an LIS enrollee would benefit from remaining in the Medicare Prescription Payment Plan, such as when a participant incurs high OOP costs early in the year

and later becomes LIS-eligible with an effective date that is not retroactive to include the high-cost drugs. In this scenario, the participant may wish to continue to pay the balance from the early, high-cost drugs in monthly payments through the Medicare Prescription Payment Plan. However, in general, participation in the Medicare Prescription Payment Plan is unlikely to benefit LIS enrollees.

It is important that Part D sponsors inform any individual interested in the Medicare Prescription Payment Plan of potential eligibility for the LIS program. As a result, throughout this final part one guidance and the draft part two guidance, CMS is requiring Part D sponsors to provide individuals with information about both the Medicare Prescription Payment Plan and the LIS program prior to the plan year and upon opting into the Medicare Prescription Payment Plan (see sections 60 and 70 of this final part one guidance and sections 30 and 40 of the draft part two guidance). In addition, section 70.3.5 contains special requirements under the Medicare Prescription Payment Plan when there is retroactive LIS eligibility and enrollment and encourages Part D sponsors to provide additional education at the time of the LIS status change. Finally, section 80.2.1 states that when a Part D sponsor sends an initial notice that a participant has failed to pay the billed amount under the Medicare Prescription Payment Plan, the notice must provide information and encouragement to apply for the LIS program.

In sections 30 and 40 of the draft part two guidance, CMS provides additional requirements about the Medicare Prescription Payment Plan, enrollees' rights, and Part D sponsor responsibilities related to Part D enrollees participating in the LIS program. Specifically, CMS has provided requirements in the draft part two guidance about how Part D sponsors must perform general and targeted education and outreach to Part D enrollees, and how they must provide communications to program participants, including instructions on using CMS-provided model materials that will be issued through the ICR process.

70.3 Election Procedures

70.3.1 Format of Election Requests

Although participation in the Medicare Prescription Payment Plan has no bearing on an individual's enrollment in a Part D plan, program election requirements are guided by the requirements in the Eligibility, Enrollment, and Disenrollment chapter of the Medicare Prescription Drug Benefit Manual, as applicable.¹⁵ Specifically, the Part D enrollee or their legal representative must complete an election request to opt into the Medicare Prescription Payment Plan. Part D sponsors must consider Medicare Prescription Payment Plan election requests, regardless of the election mechanism.

Part D sponsors must have the following mechanisms available to Part D enrollees who wish to opt into the Medicare Prescription Payment Plan:

- An election request form as part of the Part D (or MA-PD) member ID card issuance when an individual enrolls in an MA-PD or PDP;
- A paper option that can be mailed;

¹⁵ Refer to Medicare Prescription Drug Benefit Manual; Chapter 3 - Eligibility, Enrollment and Disenrollment.

- A toll-free telephone number, that must provide the individual with evidence the election request was received (e.g., a confirmation number); and
- A website application that must provide the individual with evidence the election request was received (e.g., a confirmation number).

Each telephonic election request must be recorded and include statements of the Part D enrollee's agreement and a verbal attestation of the intent to opt into the Medicare Prescription Payment Plan. If the request is made by an individual other than the Part D enrollee, the recording must include an attestation regarding the individual's authority to complete the request, in addition to the required information. All telephonic election recordings must be reproducible and maintained consistent with CMS requirements in the Eligibility, Enrollment, and Disenrollment chapter of the Medicare Prescription Drug Benefit Manual.

Paper election requests can either be filled out electronically and printed or filled out by hand by a Part D enrollee or their representative. There will be the option for either a pen-and-ink or electronic signature. A telephone request is satisfied with a verbal attestation of intent to opt in, and an electronic request is satisfied with an electronic signature or a clear and distinct step that requires the applicant to activate an "Opt In Now," or "I Agree," type of button or tool.

The electronic election mechanism must capture an accurate time and date stamp at the time the applicant executes the electronic signature. If a legal representative is completing this request, they must attest that they have authority to make the request and that proof of this authority is available upon request.

If an election request is submitted and a signature is not included, the Part D sponsor must verify with the Part D enrollee or their legal representative, through the mail (if the enrollee has opted out of phone or electronic communications), otherwise through a phone call or electronic communication, and document the contact within 10 calendar days rather than return the request as incomplete. Part D sponsors are expected to keep a copy of the election request and provide a copy upon request by the Part D enrollee. The Part D sponsor is responsible for the security and privacy of the information provided by the applicant and for the timely disclosure of any breaches in accordance with applicable law.

CMS is developing a "Medicare Prescription Payment Plan participation request form" model material for Part D sponsors that Part D enrollees can use to initiate the request to opt into the program. The specific model language for the "Medicare Prescription Payment Plan participation request form" will be issued for public comment in the Federal Register and approved through the OMB ICR process.

70.3.2 Completion of Election Request

Consistent with section 1860D-2(b)(2)(E)(v)(II) of the Act, a Part D enrollee may opt into the Medicare Prescription Payment Plan prior to the beginning of the plan year or in any month during the plan year. The Part D enrollee, or their legal representative, must complete an election request, provide the required information to the Part D sponsor, and be approved by the Part D sponsor to opt into the Medicare Prescription Payment Plan.

70.3.3 Processing Election Request Prior to Plan Year (or New Plan Effective Date)

Part D sponsors must allow Part D enrollees to opt into the Medicare Prescription Payment Plan during Part D plan annual enrollment periods, initial Part D enrollment periods, and special Part D enrollment periods. This includes individuals who enroll in a new Part D plan, choose to remain in their current Part D plan, or have not yet made a decision for the upcoming plan year. As stated in section 30 of the draft part two guidance, information regarding the Medicare Prescription Payment Plan and how to opt in must be integrated into the EOC, ANOC, membership ID card issuance for the upcoming plan year, and Part D websites.

It is important for the Part D sponsor to process Medicare Prescription Payment Plan requests promptly. When a Part D sponsor receives a program election request for the next, upcoming plan year (or in advance of a new plan enrollment effective date during a plan year) through either an election request form or through other means (as outlined in section 70.3.1 of this final part one guidance), the Part D sponsor must process the request within 10 calendar days of receipt, or the number of calendar days before the plan enrollment starts, whichever is shorter.

The Medicare Prescription Payment Plan application date is the date the Part D sponsor initially receives the election request. See sections 30.3.1.2, 30.3.1.3, and 30.3.1.4 of the draft part two guidance for details on when an election request is considered received by the Part D sponsor. Upon receiving a Medicare Prescription Payment Plan election request, a Part D sponsor must acknowledge receipt of the request electronically or by mail within 10 calendar days of receipt and provide:

- An approval of the request and effective date when the individual starts in the Medicare Prescription Payment Plan;
- A request for additional information; or
- A denial of the request through a written notice of denial.

When a request to participate in the Medicare Prescription Payment Plan is approved, the Part D sponsor must provide the participant with a notice of acceptance of election. As stated in section 30.3.2 of the draft part two guidance, CMS is developing a “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan” to support Part D sponsors in meeting this notice requirement. This model material will be made available for public comment through the ICR process.

If a Part D sponsor receives an election request that does not have all necessary elements required to consider it complete, the sponsor must not immediately deny the request. The Part D sponsor must contact the individual to request the additional documentation necessary to process the request within 10 calendar days of receipt of the incomplete election request.

Additional documentation to make the program election request complete must be received by the Part D sponsor within 21 calendar days of the request for additional information. The Part D sponsor may deny the election request if the requisite information is not received from the individual in that timeframe.

If an individual's request to participate in the Medicare Prescription Payment Plan is denied, the Part D sponsor must notify the individual and explain the reason for denial (such as failing to submit the information requested within the timeframe listed on the request) and a description of the grievance process available to the individual within 10 calendar days of the denial or the expiration of the timeframe for submission of additional information. See section 90 for additional information on participant dispute requirements.

For prospective D-SNP enrollees who wish to opt into the Medicare Prescription Payment Plan, D-SNP sponsors must first follow the procedures for verifying Medicare Advantage and Medicaid eligibility for prospective D-SNP enrollees outlined in section 20.10 of the Medicare Managed Care Manual: Chapter 2 – Medicare Advantage Enrollment and Disenrollment and section 40.2.2 of the Medicare Managed Care Manual: Chapter 16-B: Special Needs Plans. These chapters state that D-SNP sponsors must confirm Medicare Advantage and Medicaid eligibility before processing a D-SNP plan enrollment request. As such, once Medicaid eligibility is confirmed, D-SNP sponsors should process the Medicare Prescription Payment Plan election request made by a prospective D-SNP enrollee alongside the D-SNP plan enrollment request. Once the D-SNP sponsor begins processing the Medicare Prescription Payment Plan election request, they must meet the processing timeframes as outlined previously in this section.

70.3.4 Processing Election Request During a Plan Year

When a current Part D enrollee requests to opt into the Medicare Prescription Payment Plan during the plan year, Part D sponsors must process the election request within 24 hours to prevent delays in dispensing drugs to individuals when they opt into the program. Requiring an efficient election request processing timeframe during the plan year will ensure that individuals who may benefit from the program do not face unnecessary barriers to accessing their prescriptions.

The Medicare Prescription Payment Plan application date and time is the date and time the Part D sponsor initially receives the election request. See sections 30.3.1.2, 30.3.1.3, and 30.3.1.4 of the draft part two guidance for details on when an election request is considered received by the Part D sponsor. Upon receiving a Medicare Prescription Payment Plan election request, a Part D sponsor must communicate within 24 hours:

- An approval of the request and effective date when the individual starts in the Medicare Prescription Payment Plan;
- A request for additional information; or
- A denial of the request through a written notice of denial.

When an individual's election into the Medicare Prescription Payment Plan has been approved, the Part D sponsor must provide the new program participant a notice of acceptance of election. As stated in section 30.3.2 of the draft part two guidance, CMS is developing a "Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan" to support Part D sponsors in meeting this notice requirement. This model material will be made available for public comment through the ICR process.

Part D sponsors must make reasonable efforts to collect additional information and process the election request within 24 hours of receiving the necessary information.

If an individual's request to participate in the Medicare Prescription Payment Plan is denied, the Part D sponsor must notify the individual and explain the reason for denial (such as failing to submit the information requested within the timeframe listed on the request) and a description of the grievance process available to the individual within 24 hours of the denial or the expiration of the timeframe for requested additional information. See section 90 for additional information on participant dispute requirements.

70.3.5 Retroactive LIS Eligibility and Election

As LIS applicant status is usually effective retroactively, CMS regulations at 42 CFR § 423.800(c) apply if a subsidy-eligible individual opts into the Medicare Prescription Payment Plan. These regulations require Part D sponsors to reimburse subsidy-eligible individuals, and any organizations paying cost sharing on behalf of such individuals, any excess premium or OOP cost sharing paid by the individual or organization for Medicare Prescription Payment Plan amounts as appropriate under § 423.800(c).

Under the timeframes specified at 42 CFR §§ 423.800(e) and 423.466(a), Part D sponsors must process retroactive claims and premium adjustments for LIS-eligible individuals and make any resulting refunds and recoveries within 45 calendar days of the Part D sponsor's receipt of complete information regarding these adjustments.¹⁶ Part D sponsors and pharmacy benefit managers (PBMs) should coordinate, as necessary, to determine appropriate reimbursement amounts within the 45-day timeframe after taking into consideration the participant's Medicare Prescription Payment Plan payments already made and remaining Medicare Prescription Payment Plan outstanding balances. Specifically, if the participant paid more than what they should have paid as an LIS-eligible individual, the Part D sponsor must reimburse the participant for any excess payments and spread-out future participant costs consistent with their LIS eligibility if they remain in the program. Consistent with the guidance on reimbursement for excess cost-sharing or premiums paid by Part D enrollees who become eligible for LIS outlined in section 70.3.1 of the Medicare Prescription Drug Benefit Manual: Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals, CMS expects that Part D sponsors will develop standardized procedures for determining and processing reimbursements for excess Medicare Prescription Payment Plan payments made by program participants who become LIS-eligible.

Part D sponsors are also encouraged to provide additional consultation and education to Medicare Prescription Payment Plan participants at the time of an LIS status change, given that such a status change can significantly modify a participant's OOP obligations and thus the likelihood of them benefiting from the Medicare Prescription Payment Plan.

¹⁶ Refer to Medicare Prescription Drug Benefit Manual; Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals.

70.3.6 Retroactive Election in the Event the Part D Sponsor Fails to Process an Election within 24 Hours

If a Part D enrollee has fulfilled all program election requirements, but the Part D sponsor is unable to process the election into the program in the required amount of time due to no fault of the individual, the Part D sponsor must process a retroactive election back to the original date when the individual should have been admitted into the Medicare Prescription Payment Plan (i.e., within 24 hours of the individual providing the requisite information for election into the program). In addition, the Part D sponsor must reimburse the participant for any OOP cost sharing paid on or after that date and include those amounts, as appropriate, in a monthly bill under the program within 45 calendar days.

70.3.7 Standards for Urgent Medicare Prescription Payment Plan Election

Part D sponsors must have a process to effectuate a retroactive election into the Medicare Prescription Payment Plan when an enrollee has certain urgent prescription fill(s) for which they paid the associated cost sharing before the enrollee's program election was received and processed.

Under this policy, a retroactive election must be processed if all the following conditions are met:

- The Part D enrollee believes that any delay in filling the prescription(s) due to the 24 hours timeframe required to process their request to opt in may seriously jeopardize their life, health, or ability to regain maximum function; and
- The Part D enrollee requests retroactive election within 72 hours of the date and time the urgent claim(s) were adjudicated.

Once the enrollee's Medicare Prescription Payment Plan election has been effectuated, the Part D sponsor must process the reimbursement for all cost sharing paid by the enrollee for the urgent prescription and any covered Part D prescription filled between the date of adjudication of the urgent claim and the date that the enrollee's election is effectuated within 45 calendar days of the election date.

If the Part D sponsor determines that an enrollee failed to request retroactive election within the required timeframe, it must promptly notify the individual of its determination and provide instructions on how the individual may file a grievance (see section 90).

70.3.8 Prohibition on Part D Enrollee Discrimination

Part D sponsors are not allowed to design their Medicare Prescription Payment Plan to discriminate against any person based on race, color, national origin, disability, sex, or age in admission to or participation in the program, whether carried out directly by the Part D sponsor or through a contractor.¹⁷

¹⁷ Refer to CMS Accessibility & Nondiscrimination Notice.

In addition, under 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the opportunity to opt into the Medicare Prescription Payment Plan to any Part D enrollee, including a Part D enrollee who is an LIS-eligible individual. Part D sponsors cannot discriminate against or otherwise inhibit access to the Medicare Prescription Payment Plan by any Part D enrollee. This includes a prohibition on Part D sponsors seeking to obtain a Part D enrollee’s credit report from a consumer reporting agency. Part D sponsors may not require a Part D enrollee to answer questions about or provide documentation demonstrating their ability to pay their Medicare Prescription Payment Plan balance as a condition of accepting an election into the Medicare Prescription Payment Plan.

70.4 Mid-Year Plan Election Changes

Section 1860D–2(b)(2)(E)(v)(II) of the Act requires Part D sponsors to offer the Medicare Prescription Payment Plan to all Part D enrollees in any month during the year. If an individual who opted into the Medicare Prescription Payment Plan switches plans during the plan year or is reassigned by CMS, the new plan sponsor will not be required to automatically sign up the individual for the Medicare Prescription Payment Plan under the individual’s new plan. However, an individual must be able to opt into the program regardless of whether they had participated in the program under the prior plan. The prior Part D sponsor will continue to bill the participant monthly based on the participant’s accrued OOP costs while in the program under that plan. The prior Part D sponsor may also offer the participant the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment.

When an individual opts into the Medicare Prescription Payment Plan after switching plans mid-year, the new Part D sponsor must calculate the individual’s monthly cap for the first month of participation under the new plan using the formula for the calculation of the maximum monthly cap in the first month, as discussed in section 30.1 of this guidance. Part D sponsors may not prevent an individual who has switched plans from opting into the Medicare Prescription Payment Plan because the individual was terminated from the program for non-payment by a different Part D sponsor or had voluntarily opted out of the program under the original plan.

Under 42 CFR § 423.464, Part D sponsors have an obligation to coordinate benefits with entities providing other prescription drug coverage to Part D eligible individuals. This obligation includes other Part D sponsors. CMS requires that all contracts participate in the P2P process. The P2P process provides a means to coordinate correction of claims payments made by a Part D sponsor other than the Contract of Record.¹⁸

Part D sponsors should follow the P2P transition timeline and process outlined in the PDE guidance to implement the Medicare Prescription Payment Plan benefit for individuals that switch their plan in any month during the plan year.¹⁹ Each plan should report and utilize the PDE data consistent with the PDE guidelines for P2P transition periods to implement the

¹⁸ Refer to CSSC Operations PDE Plan-to-Plan (P2P) Reconciliation Training. P2P reconciliation is a financial settlement process between two Part D Sponsors in which the Contract of Record compensates the Submitting Contract for all Covered D Plan Paid (CPP) and low-income cost sharing subsidy (LICS) amounts paid by the Submitting Contract for a beneficiary enrolled in the Contract of Record.

¹⁹ Refer to Medicare Prescription Drug Benefit Manual; Chapter 14 - Coordination of Benefits.

Medicare Prescription Payment Plan when an individual switches plans during the plan benefit year. It should not be necessary for the plans to exchange any new data related to the program or billing to implement the program for individuals that switch plans and opt into the program under their new plan in addition to the PDE data they access and report under the current P2P transition process. This is because, under the Medicare Prescription Payment Plan, a participant's TrOOP-eligible costs will still be treated as incurred once the relevant prescription drug claim has been adjudicated. As such, the PDE data accessed under the current P2P transition process will contain all the data necessary to administer the program in the event of a mid-year plan change.

80. Procedures for Termination of Election, Reinstatement, and Preclusion

80.1 Voluntary Terminations

Part D sponsors must have a process to allow a participant who has opted into the Medicare Prescription Payment Plan to opt out during the plan year. Sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated. The Part D sponsor may also offer the participant the option to repay the full outstanding amount in a lump sum but may not require full immediate repayment. After opting out, the individual will pay any new OOP costs directly to the pharmacy.

After the individual notifies the Part D sponsor that they intend to opt out under the Part D sponsor's established process, the Part D sponsor must provide the individual with a notice of termination. Once the termination is processed, the Part D sponsor must maintain appropriate records of the termination.

As stated in section 30.3 of the draft part two guidance, CMS is developing model materials to support Part D sponsors in meeting these requirements. The specific model language for the "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" will be issued for public comment in the Federal Register and approved through the OMB ICR process.

80.2 Involuntary Terminations

Section 1860D-2(b)(2)(E)(v)(IV)(aa) of the Act requires a Part D sponsor to terminate an individual's Medicare Prescription Payment Plan participation if that individual fails to pay their monthly billed amount. A participant will be considered to have failed to pay their monthly billed amount only after the conclusion of the required grace period, as described in section 80.2.2.

Nothing in the Act or in this guidance prohibits Part D sponsors from billing an individual for an outstanding amount owed. Sponsors must continue to bill amounts owed under the program in monthly amounts not to exceed the maximum monthly cap according to the statutory formula for the duration of the plan year after an individual has been terminated. The Part D sponsor may also offer the participant the option to repay the full outstanding amount in a lump sum, but cannot require full immediate repayment. See Section 40 of this guidance regarding collection of

unpaid balances. Once an individual leaves the program, they must resume paying OOP cost sharing to the pharmacy for any covered Part D drugs subsequently dispensed up to the annual OOP threshold.

80.2.1 Notice Requirement

If a Part D sponsor determines that a Medicare Prescription Payment Plan participant has failed to pay a monthly billed amount, the Part D sponsor must send the individual:

- An initial notice explaining that the individual has failed to pay the billed amount within 15 calendar days of the payment due date; and
- A termination notice explaining that the individual has been terminated from the Medicare Prescription Payment Plan if the individual has failed to pay the amount due by the end of the grace period (see below). This notice must be sent within 3 business days following the last day of the end of the grace period.

If either notice is returned to the Part D sponsor as undeliverable, the Part D sponsor should immediately implement its existing procedure for researching a potential change of address.

As stated in section 30.3 of the draft part two guidance, CMS is developing model materials to support Part D sponsors in meeting these requirements. The specific model language for the “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” and for the “Part D Sponsor Notice for Failure to Make Payments under the Medicare Prescription Payment Plan - Notification of Termination of Participation in the Medicare Prescription Payment Plan” will be issued for public comment in the Federal Register and approved through the OMB ICR process.

80.2.2 Required Grace Period and Reinstatement

The Part D sponsor must provide individuals with a grace period of at least two months when an individual has failed to pay the billed amount by the payment due date. The grace period must begin on the first day of the month for which the balance is unpaid or the first day of the month following the date on which the payment is requested, whichever is later. Individuals must be allowed to pay the overdue balance during the grace period to remain in the program.

The two-month grace period must carry over into the next calendar year if non-payment occurs at the end of a prior calendar year. If the program participant is within their grace period from the prior year, they must be allowed to opt into the program for the next year. If that participant fails to pay the amount due from the prior year during the required grace period, the Part D sponsor can terminate their participation in the program (in the new year) following the procedures outlined in this guidance.

Part D sponsors must also reinstate an individual who has been terminated from the Medicare Prescription Payment Plan if the individual demonstrates good cause for failure to pay the program billed amount within the grace period and pays all overdue amounts billed. Part D sponsors are expected to reinstate individuals into the program within a reasonable timeframe

after the individual has repaid their past due program balance in full. To demonstrate good cause, the individual must establish by a credible statement that failure to pay the monthly amount billed within the grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

Based on the “good cause” criteria discussed in section 60.2.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual,²⁰ CMS is stating in this final part one guidance that, in general, the following circumstances constitute good cause:

- A serious illness, institutionalization and/or hospitalization of the program participant or their authorized representative (i.e., the individual responsible for the participant’s financial affairs), that lasted for a significant portion of the grace period for Medicare Prescription Payment Plan payment;
- Prolonged illness that is not chronic in nature, a serious (unexpected) complication to a chronic condition or rapid deterioration of the health of the participant, a spouse, another person living in the same household, a person providing caregiver services to the participant, or the participant’s authorized representative (i.e., the individual responsible for the participant’s financial affairs) that occurs during the grace period for the Medicare Prescription Payment Plan payment;
- Recent death of a spouse, immediate family member, person living in the same household, or person providing caregiver services to the participant, or the participant’s authorized representative (i.e., the individual responsible for the participant’s financial affairs);
- Home was severely damaged by a fire, natural disaster or other unexpected event, such that the participant or the participant’s authorized representative was prevented from making arrangement for payment during the grace period for the Medicare Prescription Payment Plan;
- An extreme weather-related, public safety or other unforeseen event declared as a Federal or state level of emergency prevented premium payment at any point during the Medicare Prescription Payment Plan grace period. For example, the participant’s bank or U.S. Post Office closes for a significant portion of the grace period; or
- For Part D plan disenrollments effectuated by CMS for failure to pay Part D Income-Related Monthly Adjustment Amount (IRMAA), Federal government error (i.e., CMS, SSA or RRB) caused the Medicare Prescription Payment Plan payment to be incorrect or late, and the participant was unaware of the error or unable to take action prior to the disenrollment effective date.

There may be situations in addition to those listed above that result in favorable good cause determinations. If an individual presents a circumstance which is not captured in the listed

²⁰ <https://www.cms.gov/files/document/cy-2024-pdp-enrollment-and-disenrollment-guidance.pdf>.

examples, it must meet the regulatory standards of being outside of the participant's control or unexpected such that the participant could not have reasonably foreseen its occurrence, and this circumstance must be the cause for the non-payment of past due program balances.

Part D sponsors may also reinstate, at the sponsor's discretion and within a reasonable timeframe, an individual who has been terminated from the Medicare Prescription Payment Plan if the individual pays all overdue amounts billed, even if the individual does not demonstrate good cause.

80.3 Preclusion of Election in a Subsequent Plan Year

Under section 1860D-2(b)(2)(E)(v)(IV)(bb) of the Act, Part D sponsors may preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual fails to pay the amount billed for a month as required under the program.

A Part D sponsor may only preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual owes an overdue balance to that Part D sponsor. Preclusion is only permitted in plans that are offered by the same parent organization. In other words, an individual who owes an overdue balance under the program cannot be precluded from opting into the Medicare Prescription Payment Plan in a subsequent year by a different Part D sponsor that does not have the same parent organization.

Preclusion may extend beyond the immediately subsequent plan year, if a Part D enrollee remains in a plan offered by the same parent organization and continues to owe an overdue balance. If an individual pays off the outstanding balance during a subsequent year, the Part D sponsor must promptly permit them to opt in after that point.

A Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plans. However, consistent with guidance on Part D disenrollment due to failure to pay premiums outlined in section 50.3.1 of the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment and Disenrollment, for each of its Part D plans (i.e., each PBP), the Part D sponsor must apply its preclusion policy consistently among all enrollees of the same Part D plan (i.e., a Part D sponsor may have different preclusion policies among its different Part D plans, but it may not have different policies within a plan).

80.4 Prohibition on Part D Plan Enrollment Penalties for Failure to Pay Medicare Prescription Payment Plan Amount Billed

Consistent with section 1860D-1(b)(1)(B) of the Act and 42 CFR § 423.44(b), Part D sponsors may only involuntarily disenroll a Part D enrollee from a Part D plan if the Part D enrollee fails to pay any monthly premium in a timely manner or if CMS grants a disenrollment request when a Part D enrollee engages in disruptive behavior that substantially impairs the Part D sponsor's ability to arrange or provide for services to the individual or to other plan enrollees. A Part D plan sponsor is prohibited from disenrolling a Part D enrollee from a Part D plan for failure to pay any amount billed under the Medicare Prescription Payment Plan.

In addition, a Part D sponsor cannot decline future enrollment into a Part D plan based on an individual's failure to pay a monthly amount billed under the Medicare Prescription Payment Plan.

80.5 Disenrollment

If a participant in the Medicare Prescription Payment Plan is disenrolled voluntarily or involuntarily from their Part D plan under the provisions at 42 CFR § 423.44(b), the participant is also terminated from the Medicare Prescription Payment Plan in that plan. If they enroll in a different plan, they may opt into the Medicare Prescription Payment Plan under their new plan. Nothing in the Act or in this guidance prohibits Part D sponsors from billing an individual for an outstanding Medicare Prescription Payment Plan amount owed.

90. Participant Disputes

Consistent with sections 1860D-4(g) and (h) of the Act and 42 CFR § 423.566(a), each Part D sponsor must have procedures for making timely coverage determinations and redeterminations regarding the prescription drug benefits an individual is entitled to under the Part D plan. Part D sponsors must apply their established Part D coverage determination and appeals procedures, as appropriate, to any dispute made by a Medicare Prescription Payment Plan participant about the amount of Part D cost sharing owed by that participant for a covered Part D drug.

Consistent with section 1860D-4(f) of the Act and 42 CFR § 423.562, each Part D sponsor must provide meaningful procedures for the timely hearing and resolution of grievances between Part D enrollees and Part D sponsors or any entity or individual through which the Part D sponsor provides covered benefits. Part D sponsors must apply their established Part D grievance procedures to any dispute made by a Medicare Prescription Payment Plan participant related to any aspect of the Medicare Prescription Payment Plan, including election requests, billing requirements, and termination-related issues other than disputes related to the amount of Part D cost sharing owed by that participant for a drug. A decision on the amount of cost sharing for a drug is a coverage determination. See 42 CFR § 423.566(b)(5).

Please refer to the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for requirements related to grievances, coverage determinations, and redeterminations.²¹

100. Data Submission Requirements

42 CFR § 423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, its Part D enrollees, and the public, at the times and in the manner that CMS requires, statistics indicating the following:

- 1) The cost of its operations.
- 2) The patterns of utilization of its services.

²¹ <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>

- 3) The availability, accessibility, and acceptability of its services.
- 4) Information demonstrating that the Part D sponsor has a fiscally sound operation.
- 5) Pharmacy performance measures.
- 6) Other matters that CMS may require.

To that end, CMS will require Part D sponsors to report information related to the Medicare Prescription Payment Plan on Prescription Drug Event (PDE) records and through new annual reporting requirements, as is described in the ICR package titled “Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982),” which appeared in the Federal Register on December 18, 2023 for a 60-day public comment period, and the ICR package titled “Medicare Part D Reporting Requirements (CMS-10185; OMB: 0938-0992),” which appeared in the Federal Register on February 2, 2024 for a 60-day public comment period.^{22,23}

As described in section 50.1 of this guidance, there should be no impact to PDE cost/payment field reporting, meaning PDE financials should reflect individual and plan liability amounts as if the Medicare Prescription Payment Plan did not apply. Additional guidance on PDE reporting will be forthcoming.

For monitoring purposes, Part D sponsors will also be responsible for reporting data elements related to their Medicare Prescription Payment Plan, both at the beneficiary-level and contract-Plan Benefit Package (PBP) levels. Part D sponsors will report beneficiary-level data on a monthly basis through the MARx System, and contract-level data on an annual basis through HPMS. For 2025, CMS will not require independent data validation for these new reporting requirements.

The data elements were formally issued for public comment in the **Federal Register** through the Office of Management and Budget (OMB) Information Collection Request (ICR) process.

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) which appeared in the Federal Register on January 26, 2024 for a 60-day public comment period, with comments due by March 26, 2024 and can be accessed here: <https://www.federalregister.gov/documents/2024/01/26/2024-01582/agency-information-collection-activities-proposed-collection-comment-request>.

The Medicare Part D Reporting Requirements (CMS-10185; OMB 0938-0992) ICR 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>.

²² <https://www.federalregister.gov/documents/2023/12/18/2023-27684/agency-information-collection-activities-proposed-collection-comment-request>

²³ <https://www.federalregister.gov/documents/2024/02/02/2024-02095/agency-information-collection-activities-proposed-collection-comment-request>

Data elements for the Medicare Prescription Payment Plan may include, but are not limited to:

Beneficiary-level Data Elements:

- 1) Contract Number
- 2) PBP Number
- 3) Medicare Beneficiary Identifier (MBI) Number
- 4) Beneficiary first name
- 5) Beneficiary last name
- 6) Beneficiary date of birth (DOB)
- 7) Date of election into the Medicare Prescription Payment Plan
- 8) Date of election termination from the Medicare Prescription Payment Plan
- 9) Election termination reason code (voluntary versus involuntary)

Contract-PBP-level Data Elements:

- 1) Contract Number
- 2) PBP Number
- 3) Total number of individuals identified during the reporting period as likely to benefit from the Medicare Prescription Payment Plan based on POS criteria (unique beneficiaries, including those who did not elect to participate in the Medicare Prescription Payment Plan)
- 4) Total uncollected Medicare Prescription Payment Plan balances from the reporting period
- 5) Number of program participants with uncollected Medicare Prescription Payment Plan balances from the reporting period
- 6) Number of individuals precluded from opting into the Medicare Prescription Payment Plan (in the subsequent year)

CMS will provide more information about data collection requirements through the ICR process and invites feedback on the data elements through the requisite public comment periods.

Appendix A – Definitions for Medicare Prescription Payment Plan

Covered Part D Drug has the meaning set forth at 42 CFR § 423.100.

Supplemental Drug: A drug that would be a covered Part D drug, but which is specifically excluded under 42 CFR § 423.100.

Annual OOP Threshold: The annual OOP cost threshold is \$2,000 for 2025. For subsequent years, the annual OOP threshold will be calculated in accordance with section 1860D–2(b)(4)(B)(i)(VIII) of the Act.

Billing Period: The calendar month, or the portion of a calendar month, in which OOP costs were incurred, beginning either on the effective date of a Part D enrollee’s participation in the Medicare Prescription Payment Plan (for the first month a participant elects into the program during the plan year) or the first day of the month (for each subsequent month or for the first

month of a participant who elects into the program prior to the start of the plan year), and ending on the last date of that month.

Incurred Costs (as used in the description of the first month’s maximum cap calculation):

Incurred costs has the meaning set forth at section 1860D–2(b)(4)(C) of the Act. For the first month’s maximum cap calculation of the Part D cost sharing incurred by the Part D enrollee within the plan year, it includes those Part D cost sharing amounts that are incurred prior to effectuation of an election into the Medicare Prescription Payment Plan, including all TrOOP-eligible costs, regardless of payer. If election into the program occurs mid-month, this would include Part D costs incurred within the calendar month of election but prior to election.

Number of Months Remaining in the Plan Year: The count of calendar months remaining in the plan year, including the current reference month (e.g., for a calendar year plan, the months remaining in the calculation for the January maximum cap would be 12).

OOP Costs: For the Medicare Prescription Payment Plan, out-of-pocket costs refers to the amount the Part D enrollee is directly responsible for paying. For the subsequent month calculation of the Part D cost sharing incurred by the Part D enrollee, it includes those Part D cost sharing amounts that the enrollee is responsible for paying after taking into account amounts paid by third-party payers. Specifically, this does not include the covered plan pay amount or other TrOOP-eligible amount(s), such as any amount paid by potential third-party payers, such as State Pharmaceutical Assistance Programs or charities.

Remaining OOP Costs Owed by the Participant: In subsequent months in which the participant is active in the Medicare Prescription Payment Plan, the remaining OOP costs owed by the participant are the sum of OOP costs incurred under the Medicare Prescription Payment Plan, but not yet billed to the program participant. For example, if a Medicare Prescription Payment Plan participant incurs \$2,000 in January and is billed \$166.67, the remaining OOP costs are $\$2,000 - \$166.67 = \$1,833.33$.

Patient Pay Amount: Patient Pay Amount refers to the NCPDP Telecommunication Standard response pricing segment field “Patient Pay Amount” (505-F5).

TrOOP Accumulator: The TrOOP Accumulator is a value Part D sponsors maintain in real time in order to adjudicate a Part D enrollee’s claim in the correct benefit phase. The TrOOP Accumulator is the sum of the enrollee’s incurred costs for the benefit year known immediately before the Part D sponsor begins adjudication of an individual claim.

Appendix B – Additional Medicare Prescription Payment Plan Calculation Examples

The examples presented below are illustrative and intended to help ensure Part D sponsors program their claims and billing systems correctly for 2025. These examples are not necessarily indicative of situations in which an individual would “benefit” (applying our definition in section 60.2.1) from participation in the Medicare Prescription Payment Plan. The individual described in Example B2, for instance, has a highest monthly OOP cost of \$154, but under the program has a highest monthly payment of \$313.67; this individual would neither have met the POS

notification threshold nor have met the definition of “likely to benefit” described in section 60.2.1.

In addition, Part D sponsors should refer to the Draft CY 2025 Part D Redesign Program Instructions, published January 30, 2024. This document provides interested parties with draft guidance regarding the implementation of section 11201 of the IRA (P.L. 117-169), including updates to the definition of incurred costs and which costs count toward TrOOP spending.²⁴ Please note that IRA-related changes to the definition of incurred costs and which costs count toward TrOOP are not reflected in the examples provided in this final part one guidance for the Medicare Prescription Payment Plan.

Example B1: January Election with ADAP

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant with additional prescription drug coverage through an ADAP. The individual has already opted into the Medicare Prescription Payment Plan. The participant presents to the pharmacy in January to fill two prescriptions. The first prescription processed has Part D enrollee cost sharing of \$1,390.28 and is included on the ADAP formulary. The second prescription has Part D enrollee cost sharing of \$665.46 and is not included on the ADAP formulary. After following standard COB processes, the participant’s OOP cost sharing for the ADAP-covered drug is reduced to \$0. The final OOP cost sharing for the second drug, which is not covered by ADAP, would be \$609.72 (capped by the annual OOP threshold of \$2,000; $\$2,000 - \$1,390.28 = \$609.72$).

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$609.72 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: In February 2025, the participant refills their existing prescriptions.

²⁴ Please see the Draft CY 2025 Part D Redesign Program Instructions: https://www.cms.gov/sites/default/files/2024-01/Draft%20CY%202025%20Part%20D%20Redesign%20Program%20Instructions_January%2031%202024_Final_Updated.pdf.

Step 1: Determine the remaining costs owed by the participant. Under the Medicare Prescription Payment Plan, the participant incurred \$609.72 in January and was billed \$166.67.

$$\$609.72 - \$166.67 = \$443.05$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant has already reached the annual OOP threshold of \$2,000, so they incur no new OOP costs at this visit. Additional OOP costs incurred = \$0

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$443.05 + \$0)/11 = \$40.28$$

Because the participant in Example B1 has already met the annual OOP threshold (which includes the payments made by the ADAP on behalf of the participant), they will incur no new additional OOP costs. Their maximum monthly cap would be approximately \$40.28 for all months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$609.72	\$166.67	\$166.67
February	\$0	\$40.28	\$40.28
March	\$0	\$40.28	\$40.28
April	\$0	\$40.28	\$40.28
May	\$0	\$40.28	\$40.28
June	\$0	\$40.28	\$40.28
July	\$0	\$40.28	\$40.28
August	\$0	\$40.27	\$40.27
September	\$0	\$40.28	\$40.28
October	\$0	\$40.27	\$40.27
November	\$0	\$40.28	\$40.28
December	\$0	\$40.27	\$40.27
TOTAL	\$609.72		\$609.72

Example B2: March Election with Supplemental Drugs

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant in an enhanced alternative plan who is also filling prescriptions for supplemental drugs. The individual opts into the Medicare Prescription Payment Plan at the beginning of March. They have no additional prescription drug coverage through a third party. In January, prior to opting into the program, they filled a single 90-day prescription for a covered Part D drug with a co-pay of \$55. In March 2025, the participant fills two prescriptions, one of which is a supplemental drug. According to the plan’s benefit design, the covered Part D drug has a \$99 copay; the supplemental drug has a \$47 copay.

The total OOP cost sharing is \$146; however, because supplemental drugs are not included in the Medicare Prescription Payment Plan, the participant would be responsible for the \$47 copay to the pharmacy. The costs for the \$99 copay would be billed through the normal plan processes for the Medicare Prescription Payment Plan.

Step 1: Determine the previously incurred costs. The individual filled a 90-day supply in January; the TrOOP Accumulator is \$55.00.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is March; months remaining in the plan year equals 10 (includes March).

$$(\$2,000 - \$55)/10 = \$194.50$$

The plan will bill \$99.00 for March, since the OOP incurred amount is lower than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills their existing prescriptions in April 2025, including the 90-day prescription previously filled in January.

Step 1: Determine the remaining costs owed by the participant. Under the Medicare Prescription Payment Plan, the participant incurred \$99 in March and was billed \$99.

$$\$99 - \$99 = \$0$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills their 90-day maintenance drug (\$55 copay) and refills the \$99 drug and the \$47 supplemental drug. Additional OOP costs incurred (which do not include the supplemental drug): $\$99 + \$55 = \$154$

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is April; months remaining in the plan year equals 9 (includes April).

$$(\$0 + \$154)/9 = \$17.11$$

If the participant in Example B2 continued to have the same recurring OOP prescription costs for the remainder of the year (\$99 copay each month and \$55 every third month), their maximum monthly cap would update each month, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$55.00	N/A	\$55.00*
February	\$0.00	N/A	\$0.00
March	\$99.00	\$194.50	\$99.00
April	\$154.00	\$17.11	\$17.11
May	\$99.00	\$29.49	\$29.49
June	\$99.00	\$43.63	\$43.63
July	\$154.00	\$69.30	\$69.30
August	\$99.00	\$89.09	\$89.09
September	\$99.00	\$113.85	\$113.85
October	\$154.00	\$165.18	\$165.18
November	\$99.00	\$214.68	\$214.68
December	\$99.00	\$313.67	\$313.67
TOTAL	\$1,210.00		\$1,210.00

*This payment was made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

Example B3: August Election with Part B and D Drugs

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant who is filling both Part B- and Part D-covered drugs. They have already opted into the Medicare Prescription Payment Plan. The participant has no additional prescription drug coverage through a third party. They present to the pharmacy in August 2025 with two new prescriptions – one for a Part B-covered drug and one for a Part D-covered drug. They have previously filled multiple Part D-covered drugs with a total incurred cost of \$234.63. According to the plan’s benefit design, the OOP cost sharing for the Part D-covered drug would be \$846.68. The cost sharing for the Part B-covered drug would be \$354.77. Because Part B-covered drugs are not included in the Medicare Prescription Payment Plan, the participant would be responsible for the \$354.77 coinsurance to the pharmacy; the \$846.68 would be billed through the normal plan processes for the Medicare Prescription Payment Plan.

Step 1: Determine the previously incurred costs. The individual has previously filled multiple Part D-covered drugs; the TrOOP Accumulator is \$234.63.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is August; months remaining in the plan year equals 5 (includes August).

$$(\$2,000 - \$234.63)/5 = \$353.07$$

The plan will bill \$353.07 for August, since the OOP incurred amount of \$846.68 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: In September 2025, the participant refills their existing prescriptions.

Step 1: Determine the remaining costs owed by the participant. Under the Medicare Prescription Payment Plan, the participant incurred \$846.68 in August and was billed \$353.07.

$$\$846.68 - \$353.07 = \$493.61$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills their multiple maintenance drugs (\$64.02) and both the new Part D- and Part B-covered drugs (\$846.68 and \$354.77, respectively). Additional OOP costs incurred (which do not include the Part B-covered drug): $\$64.02 + \$846.68 = \$910.70$

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is September; months remaining in the plan year equals 4 (includes September).

$$(\$493.61 + \$910.70)/4 = \$351.08$$

If the participant in Example B3 refills their Part D-covered drugs in October, they would reach the annual OOP threshold of \$2,000 at that time. Their maximum monthly cap for October would change to \$353.74, as shown below, and would remain at that amount for the rest of the year.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$100.00	N/A	\$100.00*
February	\$34.63	N/A	\$34.63*
March	\$0	N/A	\$0
April	\$100.00	N/A	\$100.00*
May	\$0	N/A	\$0
June	\$0	N/A	\$0
July	\$0	N/A	\$0
August	\$846.68	\$353.07	\$353.07
September	\$910.70	\$351.08	\$351.08
October	\$7.99	\$353.74	\$353.74
November	\$0	\$353.74	\$353.74
December	\$0	\$353.74	\$353.74
TOTAL	\$2,000.00		\$2,000.00

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

Example B4: January Election Mid-Month

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how to calculate the maximum monthly cap for an individual who opts into the Medicare Prescription Payment Plan mid-month and had incurred costs earlier in the month, prior to opting into the

program. The individual presents to the pharmacy in mid-January 2025 to fill a prescription for a new, high-cost drug. They have no additional prescription drug coverage through a third party. The OOP cost sharing is \$1,157.63. Earlier in January, prior to opting into the Medicare Prescription Payment Plan, the individual filled two prescriptions with a total incurred cost of \$57.

Step 1: Determine the previously incurred costs. The individual filled two prescriptions in early January; the TrOOP Accumulator is \$57.00.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$57)/12 = \$161.92$$

The plan will bill \$161.92 for January, since the OOP incurred amount of \$1,157.63 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills all three of their prescriptions in the month of February.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$1,157.63 in January (while in the Medicare Prescription Payment Plan) and was billed \$161.92.

$$\$1,157.63 - \$161.92 = \$995.71$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills all three prescriptions in February and reaches the annual OOP threshold of \$2,000. Additional OOP costs incurred = \$785.37.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$995.71 + \$785.37)/11 = \$161.92$$

Because the participant in Example B4 has already met the annual OOP threshold, they will incur no additional OOP costs. Their maximum monthly cap would be approximately \$161.92 for all months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$1,214.63*	\$161.92	\$161.92
February	\$785.37	\$161.92	\$161.92
March	\$0	\$161.92	\$161.92
April	\$0	\$161.92	\$161.92
May	\$0	\$161.92	\$161.92
June	\$0	\$161.91	\$161.91
July	\$0	\$161.92	\$161.92
August	\$0	\$161.91	\$161.91
September	\$0	\$161.92	\$161.92
October	\$0	\$161.91	\$161.91
November	\$0	\$161.92	\$161.92
December	\$0	\$161.91	\$161.91
TOTAL	\$2,000.00		\$2,000.00

*This amount reflects the total OOP costs incurred in January (\$57 prior to opting into the Medicare Prescription Payment Plan and \$1,157.63 after opting into the Medicare Prescription Payment Plan). The calculation for the first month maximum cap includes the costs incurred prior to the Medicare Prescription Payment Plan election (\$57).

Example B5: January Election with Drug Discontinuation

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant who fills a prescription for a high-cost drug and then subsequently discontinues it. They have already opted into the Medicare Prescription Payment Plan, anticipating that they would fill multiple months of a high-cost drug. The participant has no additional prescription drug coverage through a third party. The participant presents to the pharmacy in January 2025 to fill their prescription; the OOP cost sharing for the first month is \$642.39.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$642.39 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant has an adverse reaction to the drug started in January, and their provider discontinues the drug. They have no prescription claims in February.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$642.39 in January and was billed \$166.67.

$$\$642.39 - \$166.67 = \$475.72$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant has no new prescription claims in February. Additional OOP costs incurred = \$0.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$475.72 + \$0)/11 = \$43.25$$

Even though the participant's high-cost prescription has been discontinued, they will continue to receive monthly bills from the Part D sponsor related to their January fill. If the participant in Example B5 continued to have no new covered Part D prescription drug costs, their maximum monthly cap would be approximately \$43.25 for all the months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$642.39	\$166.67	\$166.67
February	\$0.00	\$43.25	\$43.25
March	\$0.00	\$43.25	\$43.25
April	\$0.00	\$43.25	\$43.25
May	\$0.00	\$43.25	\$43.25
June	\$0.00	\$43.25	\$43.25
July	\$0.00	\$43.25	\$43.25
August	\$0.00	\$43.24	\$43.24
September	\$0.00	\$43.25	\$43.25
October	\$0.00	\$43.24	\$43.24
November	\$0.00	\$43.25	\$43.25
December	\$0.00	\$43.24	\$43.24
TOTAL	\$642.39		\$642.39

Example B6: January Election with Mid-Year Plan Switch

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant who initially opts into the Medicare Prescription Payment Plan in January under his original plan (Plan A), then switches to a new plan (Plan B) in March. The participant has already elected into the Medicare Prescription Payment Plan for Plan A prior to filling any prescriptions. The participant has no additional prescription drug coverage through a third party. In mid-January, the participant fills three prescriptions, with a total OOP cost sharing of \$498.80.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$498.80 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills all three of their existing prescriptions in February; the total OOP cost sharing is \$498.80.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$498.80 in January and was billed \$166.67.

$$\$498.80 - \$166.67 = \$332.13$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills all three prescriptions in February; the total OOP cost sharing is \$498.80. Additional OOP costs incurred = \$498.80.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$332.13 + \$498.80)/11 = \$75.54$$

If the participant in Example B6 switches from their original Part D plan (Plan A) to a new Part D plan (Plan B) in March, they would need to opt into the Medicare Prescription Payment Plan again if they intend to continue spreading their new OOP prescription drug costs over the remainder of the plan year. The maximum monthly cap for their initial month enrolled with Plan B (March) would again use the calculation for the maximum monthly cap in the first month ((Annual OOP Threshold – Incurred Costs)/Number of Months Remaining in the Plan Year).²⁵ Following the steps outlined above, the participant’s maximum monthly cap for the first month with Plan B would be \$100.24 ((\\$2,000 - \$498.80 - \$498.80)/10).

Assuming the participant continues to refill their existing prescriptions with a monthly total OOP cost sharing of \$498.80, they would reach the annual OOP threshold of \$2,000 in May.

²⁵ Part D sponsors must follow the standard processes for FIR transactions and automated TBT to ensure that the receiving plan has accurate information related to the participant’s progression through the Part D benefit.

Month	OOP Costs Incurred (Plan A)	Maximum Monthly Cap (Plan A)	Monthly Participant Payment (Plan A)*	OOP Costs Incurred (Plan B)	Maximum Monthly Cap (Plan B)	Monthly Participant Payment (Plan B)
January	\$498.80	\$166.67	\$166.67	N/A	N/A	N/A
February	\$498.80	\$75.54	\$75.54	N/A	N/A	N/A
March	N/A	N/A	\$75.54	\$498.80	\$100.24	\$100.24
April	N/A	N/A	\$75.54	\$498.80	\$99.71	\$99.71
May	N/A	N/A	\$75.54	\$4.80	\$100.31	\$100.31
June	N/A	N/A	\$75.54	\$0	\$100.31	\$100.31
July	N/A	N/A	\$75.54	\$0	\$100.31	\$100.31
August	N/A	N/A	\$75.54	\$0	\$100.30	\$100.30
September	N/A	N/A	\$75.54	\$0	\$100.31	\$100.31
October	N/A	N/A	\$75.54	\$0	\$100.30	\$100.30
November	N/A	N/A	\$75.54	\$0	\$100.31	\$100.31
December	N/A	N/A	\$75.53	\$0	\$100.30	\$100.30
TOTAL	\$997.60		\$997.60	\$1,002.40		\$1,002.40

*This example assumes the participant does not pay off the remaining balance to Plan A in a single lump sum and continues to receive monthly bills from Plan A.

Example B7: January Election with LIS

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant who receives a LIS.²⁶ They have already opted into the Medicare Prescription Payment Plan. The participant is LIS-eligible (category code 1) and has no additional prescription drug coverage through a third party. The participant presents to the pharmacy in January 2025 to fill four generic prescriptions with copays of \$4.50 each²⁷ (\$18.00 total). Because these are low-cost generic drugs, the individual does not reach the annual OOP threshold in 2025.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$18.00 for January, since the OOP incurred amount is lower than the cap.

²⁶ Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to opt into the Medicare Prescription Payment Plan to all Part D enrollees, including enrollees who are LIS-eligible individuals. However, CMS notes individuals with low, stable drug costs (such as LIS enrollees) are not likely to benefit from the program.

²⁷ Copay amounts subject to change with updated Part D benefit parameters for 2025.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills all four of their existing prescriptions in February.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$18.00 in January and was billed \$18.00.

$$\$18.00 - \$18.00 = \$0$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills four prescriptions with copays of \$4.50 each, for a total OOP cost sharing of \$18.00. Additional OOP costs incurred = \$18.00.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$0 + \$18.00)/11 = \$1.64$$

If the participant in Example B7 remains LIS-eligible and continues to fill their four prescriptions each month through the remainder of the year, their maximum monthly cap would update as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$18.00	\$166.67	\$18.00
February	\$18.00	\$1.64	\$1.64
March	\$18.00	\$3.44	\$3.44
April	\$18.00	\$5.44	\$5.44
May	\$18.00	\$7.69	\$7.69
June	\$18.00	\$10.26	\$10.26
July	\$18.00	\$13.26	\$13.26
August	\$18.00	\$16.85	\$16.85
September	\$18.00	\$21.36	\$21.36
October	\$18.00	\$27.35	\$27.35
November	\$18.00	\$36.36	\$36.36
December	\$18.00	\$54.35	\$54.35
TOTAL	\$216.00		\$216.00

Example B8: January Election with Retroactive LIS

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for an individual who initially opts into Medicare Prescription Payment Plan and incurs OOP costs while in the program, then becomes LIS-eligible in March, with an effective date retroactive to January 1, 2025. The individual initially opts into the Medicare Prescription Payment Plan in early January and has no additional prescription drug coverage through a third party. In January 2025, the participant fills a single prescription for a brand drug; the total OOP cost sharing is \$341.91.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$341.91 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills their prescription in February.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$341.91 in January and was billed \$166.67.

$$\$341.91 - \$166.67 = \$175.24$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills their prescription in February; the OOP cost sharing is \$341.91. Additional OOP costs incurred = \$341.91.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$175.24 + \$341.91)/11 = \$47.01$$

If the participant in Example B8 becomes LIS-eligible in early March, with an effective date retroactive to January 1, 2025, their claims from January and February will need to be reprocessed. The amount the participant has already paid the Part D plan while in the Medicare Prescription Payment Plan will need to be reconciled with the revised OOP cost sharing amounts (see section 70.3.5 of this guidance for additional information). If the participant had already paid their January (\$166.67) and February (\$47.01) bills in full, the plan would owe the participant \$208.66 ($\$166.67 + \$47.01 - \$4.60 - \$0.42 = \208.66).

The participant in Example B8 is now LIS-eligible (category code 2). If they remain LIS-eligible and continue to fill their single prescription (now with a cost share of \$4.60²⁸) through the remainder of the year, their maximum monthly cap will update as shown below. Because payments by the LIS program count toward the individual's TrOOP, they would reach the annual OOP threshold in June.

²⁸ Copay amounts subject to change with updated Part D benefit parameters for 2025.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	<i>(\$341.91)</i> \$4.60*	\$166.67	<i>(\$166.67)</i> \$4.60*
February	<i>(\$341.91)</i> \$4.60*	<i>(\$47.01)</i> \$0.42*	<i>(\$47.01)</i> \$0.42*
March	\$4.60	\$0.88	\$0.88
April	\$4.60	\$1.39	\$1.39
May	\$4.60	\$1.96	\$1.96
June	\$4.60	\$2.62	\$2.62
July	\$0	\$2.62	\$2.62
August	\$0	\$2.62	\$2.62
September	\$0	\$2.62	\$2.62
October	\$0	\$2.62	\$2.62
November	\$0	\$2.63	\$2.63
December	\$0	\$2.62	\$2.62
TOTAL	\$27.60		\$27.60

*Values shown in parentheses and italics are the original OOP costs, maximum monthly cap, and monthly participant payments, calculated prior to the participant receiving LIS status. The revised values show how the amounts would be updated, given the individual's LIS eligibility (the maximum monthly cap for the first month (January) did not change).

Example B9: April Election with 90-Day Supply of a Drug with Subsequent Adjustment

This example builds upon Example #3 in section 30.3.3 of this guidance. Please refer to that section for the calculations of the first month and subsequent month maximum caps.

This example (B9) demonstrates how the maximum monthly cap and remaining amounts owed would be adjusted if a prescription is reprocessed with a lower OOP cost after the participant has paid their monthly bill and the participant chooses to receive a refund for the overpayment. In the original example (#3), October OOP costs incurred totaled \$124 for a combination of brand (\$120) and generic (\$4) prescriptions; the maximum monthly cap for October was \$114.39. In November, the Part D sponsor billed the participant \$114.39, and the participant paid their monthly bill in full. If, later in November, the Part D claim for the brand medication was adjusted to now have an OOP cost of \$100 (for revised total October OOP costs incurred of \$104), the revised maximum monthly cap for October would be \$107.72 ($(\$219.16 + \$104.00)/3 = \107.72). The participant's October payment was thus an overpayment of \$6.67 ($\$114.39 - \$107.72 = \6.67).

If the participant requests a refund for that amount, the Part D sponsor must then issue a refund for the October overpayment of \$6.67 (bringing the total participant payment for October OOP costs to \$107.72). The Part D sponsor must also revise the remaining costs owed by the participant to reflect the lower OOP cost for October. As such, the maximum monthly cap calculations for November and December would incorporate a slightly lower remaining balance than in the original Example #3.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$4.00	N/A	\$4.00*	\$0
February	\$4.00	N/A	\$4.00*	\$0
March	\$4.00	N/A	\$4.00*	\$0
April	\$617.00	\$220.89	\$220.89	\$396.11
May	\$4.00	\$50.01	\$50.01	\$350.10
June	\$4.00	\$50.59	\$50.59	\$303.51
July	\$124.00	\$71.25	\$71.25	\$356.26
August	\$4.00	\$72.05	\$72.05	\$288.21
September	\$4.00	\$73.05	\$73.05	\$219.16
October	<i>(\$124.00)</i> \$104**	<i>(\$114.39)</i> \$107.72**	<i>(\$114.39)</i> \$107.72**	<i>(\$228.77)</i> \$215.44**
November	\$4.00	\$109.72	\$109.72	\$109.72
December	\$4.00	\$113.72	\$113.72	\$0
TOTAL	\$881.00		\$881.00	

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

**Values shown in parentheses and italics are the original OOP costs, maximum monthly cap, monthly participant payment, and remaining balance for October, calculated prior to the October prescription drug claim being adjusted.

Example B10: April Election with 90-Day Supply of a Drug with Subsequent Adjustment

This example builds upon Example #3 in section 30.3.3 of this guidance. Please refer to that section for the calculations of the first month and subsequent month maximum caps.

This example (B10) demonstrates how the maximum monthly cap and remaining amounts owed would be adjusted if a prescription is reprocessed with a lower OOP cost after the participant has paid their monthly bill and the participant chooses to apply the overpayment to the remaining balance. In the original example (#3), October OOP costs incurred totaled \$124 for a combination of brand (\$120) and generic (\$4) prescriptions; the maximum monthly cap for October was \$114.39. In November, the Part D sponsor billed the participant for that amount, and the participant paid their monthly bill in full. If, later in November, the Part D claim for the brand medication was adjusted to now have an OOP cost of \$100 (for revised total October OOP costs incurred of \$104), the revised maximum monthly cap for October would be \$107.72. The participant's October payment was thus an overpayment of \$6.67 ($\$114.39 - \$107.72 = \6.67). If the participant requests that the October overpayment of \$6.67 be applied to their remaining program balance, the Part D sponsor would revise the remaining balance appropriately (September remaining balance of \$219.16 + October OOP costs incurred of \$104.00 – October payment of \$114.39 = \$208.77) and use that amount to calculate the maximum monthly cap for subsequent months. As such, the maximum monthly cap calculations for November and December would incorporate a slightly lower remaining balance than in the original Example #3.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$4.00	N/A	\$4.00*	\$0
February	\$4.00	N/A	\$4.00*	\$0
March	\$4.00	N/A	\$4.00*	\$0
April	\$617.00	\$220.89	\$220.89	\$396.11
May	\$4.00	\$50.01	\$50.01	\$350.10
June	\$4.00	\$50.59	\$50.59	\$303.51
July	\$124.00	\$71.25	\$71.25	\$356.26
August	\$4.00	\$72.05	\$72.05	\$288.21
September	\$4.00	\$73.05	\$73.05	\$219.16
October	<i>(\$124.00)</i> \$104**	<i>(\$114.39)</i> \$107.72**	\$114.39	<i>(\$228.77)</i> \$208.77**
November	\$4.00	\$106.39	\$106.39	\$106.38
December	\$4.00	\$110.38	\$110.38	\$0
TOTAL	\$881.00		\$881.00	

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

**Values shown in parentheses and italics are the original OOP costs, maximum monthly cap, and remaining balance for October, calculated prior to the October prescription drug claim being adjusted.

Example B11: April Election with 90-Day Supply of a Drug with Subsequent Adjustment

This example builds upon Example #3 in section 30.3.3 of this guidance. Please refer to that section for the calculations of the first month and subsequent month maximum caps.

This example demonstrates how the maximum monthly cap and remaining amounts owed would be adjusted if a prescription is reprocessed with a higher OOP cost after the participant has paid their monthly bill. In the original example (#3), October OOP costs incurred totaled \$124 for a combination of brand (\$120) and generic (\$4) prescriptions; the maximum monthly cap for October was \$114.39. In November, the Part D sponsor billed the participant for that amount, and the participant paid their monthly bill in full. If, later in November, the Part D claim for the brand medication was adjusted to now have an OOP cost of \$140 (for revised total October OOP costs incurred of \$144), the revised maximum monthly cap for October would be \$121.05 $((\$219.16 + \$144.00)/3 = \$121.05)$. The participant's October payment was thus an underpayment of \$6.66 $(\$121.05 - \$114.39 = \$6.66)$.

The plan would update the remaining balance from October to reflect the revised OOP total for October and what was actually billed.

September remaining balance of \$219.16 + revised October OOP costs incurred of \$144.00 – October billed amount of \$114.39 = \$248.77

This revised remaining amount of \$248.77 would be used to calculate the maximum monthly cap for the November billing statement ($(\$248.77 + \$4.00)/2 = \$126.39$). The November bill would now be \$126.39.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment	Remaining Balance
January	\$4.00	N/A	\$4.00*	\$0
February	\$4.00	N/A	\$4.00*	\$0
March	\$4.00	N/A	\$4.00*	\$0
April	\$617.00	\$220.89	\$220.89	\$396.11
May	\$4.00	\$50.01	\$50.01	\$350.10
June	\$4.00	\$50.59	\$50.59	\$303.51
July	\$124.00	\$71.25	\$71.25	\$356.26
August	\$4.00	\$72.05	\$72.05	\$288.21
September	\$4.00	\$73.05	\$73.05	\$219.16
October	<i>(\$124.00)</i> \$144**	<i>(\$114.39)</i> \$121.05**	\$114.39	<i>(\$228.77)</i> \$248.77**
November	\$4.00	\$126.39	\$126.39	\$126.38
December	\$4.00	\$130.38	\$130.38	\$0
TOTAL	\$921.00		\$921.00	

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

**Values shown in parentheses and italics are the original OOP costs, maximum monthly cap, and remaining balance for October, calculated prior to the October prescription drug claim being adjusted.

Example B12: January Election; First Fill in February with Reversal

This example (B12) builds upon Example #1 in section 30.3.1 of this guidance. Please refer to that section for the calculations of the first month and subsequent month maximum caps.

This example demonstrates how the maximum monthly cap and remaining amounts owed would be adjusted if a prescription that is processed for a Medicare Prescription Payment Plan participant is not picked up and returned to stock by the pharmacy. The individual opts into the Medicare Prescription Payment Plan in January 2025. They have no additional prescription drug coverage through a third party. They fill no prescriptions during January. The participant is prescribed a new high-cost prescription on the final day of February 2025. In March 2025, their Part D sponsor generates the monthly bill for the participant, based on the subsequent month maximum cap calculation outlined below. (As a reminder, this individual opted into the program in January but had no OOP costs for that month. Therefore, the Part D sponsor did not bill the participant for January and applied the subsequent month calculation for OOP costs incurred in February.)

Calculation of Maximum Monthly Cap in Subsequent Months: The participant's provider prescribes a new, high-cost drug in February. The OOP cost sharing for this prescription is \$1,030.37.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$0 in January and thus did not receive a bill.

$$\$0 - \$0 = \$0$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant fills a single prescription with an OOP cost of \$1,030.37. Additional OOP costs incurred = \$1,030.37.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$1,030.37 + \$0)/11 = \$93.67$$

The Part D sponsor thus bills the participant \$93.67 for the month of February. If the participant does not go to the pharmacy to pick up the prescription, the pharmacy will reverse the claim and return the medication to stock. Depending on timing, this could occur after the bill for February is generated and sent to the participant. In such cases, the Part D sponsor will be responsible for taking prompt action to prevent participants from paying a bill for medication not received. As stated in section 40.2 of this final part one guidance, Section 1860D-2(b)(2)(E)(v)(III)(gg) of the Act specifies that Part D sponsors must have a financial reconciliation process in place to correct inaccuracies in billing and/or payments. When possible, CMS strongly encourages Part D sponsors to contact participants and address any billing errors in advance of receiving payment from the participant.

If the individual had their provider re-submit the original high-cost claim in March, the maximum monthly cap calculation for that month would be $(\$0 + \$1,030.37)/10 = \$103.04$. If the participant in Example B12 continued to have no new covered Part D prescription drug costs, their maximum monthly cap would be approximately \$103.04 for all the months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$0	\$166.67	\$0
February	<i>(\$1,030.37)</i> \$0*	<i>(\$93.67)</i> \$0*	<i>(\$93.67)</i> \$0*
March	\$1,030.37	\$103.04	\$103.04
April	\$0	\$103.04	\$103.04
May	\$0	\$103.04	\$103.04
June	\$0	\$103.04	\$103.04
July	\$0	\$103.04	\$103.04
August	\$0	\$103.03	\$103.03
September	\$0	\$103.04	\$103.04
October	\$0	\$103.03	\$103.03
November	\$0	\$103.04	\$103.04
December	\$0	\$103.03	\$103.03
TOTAL	\$1,030.37		\$1,030.37

*Values shown in parentheses and italics are the original OOP costs, maximum monthly cap, and monthly participant payment, calculated prior to the reversal of the late February claim.

Example B13: January Election with Drug Discontinuation and Overdue Amounts

This example builds upon Example B5 in this guidance. Please refer to that section for a more detailed calculation of the first month maximum cap.

This example demonstrates how the maximum monthly cap would be calculated for a participant who fills a prescription for a high-cost drug and then subsequently discontinues it. They have already opted into the Medicare Prescription Payment Plan, anticipating that they would fill multiple months of a high-cost drug. The participant has no additional prescription drug coverage through a third party. The participant presents to the pharmacy in January 2025 to fill their prescription; the OOP cost sharing for the first month is \$642.39. The first month maximum cap is calculated as $(\$2,000 - \$0)/12 = \$166.67$; the plan will bill \$166.67 for January, since the OOP incurred amount of \$642.39 is higher than the cap.

However, by the time the participant receives their January bill in late February 2025, they have discontinued the medication and do not pay their January amount owed of \$166.67. As stated in section 40 of this final part one guidance, past due balances from prior monthly bills may also be included in a billing statement, which could result in the total amount on the billing statement exceeding the maximum monthly cap. However, the amount billed *for the month for which the maximum monthly cap is being calculated* cannot be higher than the cap for that month.

As such, if the participant did not pay their billed amount for January of \$166.67 and had no new OOP costs in February, the February billed amount would be calculated as the sum of:

1. the amount not yet billed to the participant $(\$642.39 - \$166.67 = \$475.72)$ plus additional OOP costs incurred (\$0), divided by the remaining months in the plan year (11), and
2. the remaining amount owed from the January bill (\$166.67)

$$((\$475.72+\$0)/11) + \$166.67 = \$209.92$$

If the participant then voluntarily opted out of the program and paid their entire OOP costs incurred in a lump sum (\$642.39), they would receive no further bills from the Part D sponsor. After opting out, the individual will pay any new OOP costs directly to the pharmacy.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Billed Amount	Monthly Participant Payment
January	\$642.39	\$166.67	\$166.67	\$0
February	\$0.00	\$43.25	\$209.92	\$642.39
March	\$0.00	N/A	N/A	N/A
April	\$0.00	N/A	N/A	N/A
May	\$0.00	N/A	N/A	N/A
June	\$0.00	N/A	N/A	N/A
July	\$0.00	N/A	N/A	N/A
August	\$0.00	N/A	N/A	N/A
September	\$0.00	N/A	N/A	N/A
October	\$0.00	N/A	N/A	N/A
November	\$0.00	N/A	N/A	N/A
December	\$0.00	N/A	N/A	N/A
TOTAL	\$642.39			\$642.39

Example B14: January Election with Mid-Year Plan Switch

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant who initially opts into the Medicare Prescription Payment Plan in January under their original plan (Plan A), then switches to a new plan (Plan B) in June. The participant has already elected into the Medicare Prescription Payment Plan for Plan A prior to filling any prescriptions. The participant has no additional prescription drug coverage through a third party. In mid-January, the participant fills three prescriptions, with a total OOP cost sharing of \$302.13.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan election is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$302.13 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: The participant refills all three of their existing prescriptions in February; the total OOP cost sharing is \$302.13.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$878.12 in January and was billed \$166.67.

$$\$302.13 - \$166.67 = \$135.46$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills all three prescriptions in February; the total OOP cost sharing is \$302.13.

Additional OOP costs incurred = \$302.13.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$135.46 + \$302.13)/11 = \$39.78$$

The participant in Example B14 continues to fill the same prescriptions each month, incurring \$302.13 in OOP costs. In June 2025, they switch from their original Part D plan (Plan A) to a new Part D plan (Plan B). At that time, they opt to pay off the remaining program balance owed to Plan A as a lump sum (OOP costs incurred of $(\$302.13 * 5)$ minus payments of \$166.67, \$39.78, \$69.99, and \$103.56 = \$1,130.65). They opt not to elect into the Medicare Prescription Payment Plan in their new plan (Plan B), and instead pay their OOP costs directly to the pharmacy for the rest of the year. Assuming the participant continues to refill their existing prescriptions with a monthly total OOP cost sharing of \$302.13, they would reach the annual OOP threshold of \$2,000 in July.

Month	OOP Costs Incurred (Plan A)	Maximum Monthly Cap (Plan A)	Monthly Participant Payment (Plan A)	OOP Costs Incurred (Plan B)	Maximum Monthly Cap (Plan B)	Monthly Participant Payment (Plan B)
January	\$302.13	\$166.67	\$166.67	N/A	N/A	N/A
February	\$302.13	\$39.78	\$39.78	N/A	N/A	N/A
March	\$302.13	\$69.99	\$69.99	N/A	N/A	N/A
April	\$302.13	\$103.56	\$103.56	N/A	N/A	N/A
May	\$302.13	\$141.33	\$1,130.65	N/A	N/A	N/A
June	N/A	N/A	N/A	\$302.13	N/A	\$302.13*
July	N/A	N/A	N/A	\$187.22	N/A	\$187.22*
August	N/A	N/A	N/A	\$0	N/A	N/A
September	N/A	N/A	N/A	\$0	N/A	N/A
October	N/A	N/A	N/A	\$0	N/A	N/A
November	N/A	N/A	N/A	\$0	N/A	N/A
December	N/A	N/A	N/A	\$0	N/A	N/A
TOTAL	\$1,510.65		\$1,510.65	\$489.35		\$489.35

*These payments were made directly to the pharmacy, outside of the Medicare Prescription Payment Plan.

Example B15: Open Enrollment Election with Voluntary Termination and Re-election

This example builds upon Example #1 in section 30.3.1 of this guidance. Please refer to that section for the calculations of the first month and subsequent month maximum caps.

In this example (B15), after opting into the program in January and incurring high OOP costs in February, the individual chooses to voluntarily opt out of the program in March. They continue to be billed monthly (\$93.67) for their OOP costs incurred while in the Medicare Prescription Payment Plan. In July, the enrollee chooses to opt into the program again and remains a participant in the program for the remainder of the year. Note that the individual remains in the same Part D plan throughout the year.

When the Part D enrollee makes a new election into the Medicare Prescription Payment Plan starting in July, the maximum monthly cap for July is calculated using the formula for the calculation of maximum monthly cap in subsequent months.

Calculation of Maximum Monthly Cap in Subsequent Months (re-election in July): The individual opted into the Medicare Prescription Payment Plan in January 2025. After incurring OOP costs of \$1,030.37 in February, they choose to voluntarily opt out of the program and continue to be billed \$93.67 monthly by the Part D sponsor. The individual re-elects into the Medicare Prescription Payment Plan in July, in advance of a new high-cost prescription.

Step 1: Determine the remaining costs owed by the participant. The participant incurred \$1,030.37 in February and has paid \$93.67 per month for five months ($\$93.67 * 5 = \468.35).

$$\$1,030.37 - \$468.35 = \$562.02$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant fills a single prescription in July with an OOP cost of \$451.26. Additional OOP costs incurred = \$451.26.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is July; months remaining in the plan year equals 6 (includes July).

$$(\$562.02 + \$451.26)/6 = \$168.88$$

The plan will bill the participant \$168.88 for July.

In August, the participant incurs OOP costs of \$518.37 and reaches the annual OOP threshold for 2025. Their maximum monthly cap for August would be calculated using the same subsequent month formula (remaining balance of \$844.40 + new OOP costs incurred of \$518.37 divided by the months remaining $(\$844.40 + \$518.37)/5 = \$272.55$). Because the participant has now met

the annual OOP threshold, they will incur no new additional OOP costs. Their maximum monthly cap would be approximately \$272.55 for all months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$0	\$166.67	\$0
February	\$1,030.37	\$93.67	\$93.67
March	\$0	\$93.67	\$93.67
April	\$0	N/A*	\$93.67
May	\$0	N/A*	\$93.67
June	\$0	N/A*	\$93.67
July	\$451.26	\$168.88	\$168.88
August	\$518.37	\$272.55	\$272.55
September	\$0	\$272.56	\$272.56
October	\$0	\$272.55	\$272.55
November	\$0	\$272.56	\$272.56
December	\$0	\$272.55	\$272.55
TOTAL	\$2,000.00		\$2,000.00

*The individual is not participating in the Medicare Prescription Payment Plan during these months.

Example B16: January Election with SPAP

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant with additional prescription drug coverage through a qualified SPAP. The individual has already opted into the Medicare Prescription Payment Plan. The participant presents to the pharmacy in January to fill a new prescription with a Part D enrollee cost sharing of \$781.94. The individual’s SPAP pays 50% of the OOP costs for covered Part D drugs. After submitting the primary Medicare Part D claim, the pharmacist submits the claim to the SPAP and receives a final OOP cost sharing for the participant of \$390.97 ($\$781.94 * 0.50 = \390.97).

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$390.97 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: In February 2025, the participant refills their existing prescription.

Step 1: Determine the remaining costs owed by the participant. Under the Medicare Prescription Payment Plan, the participant incurred \$390.97 in January and was billed \$166.67.

$$\$390.97 - \$166.67 = \$224.30$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills their single prescription, with Part D cost sharing of \$781.94 and 50% SPAP coverage. Additional OOP costs incurred = $\$781.94 * 0.50 = \390.97

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$224.30 + \$390.97)/11 = \$55.93$$

If the participant in Example B16 continues to fill their single prescription with secondary SPAP coverage, they will meet the annual OOP threshold in March. The OOP costs incurred in the table below reflect only the costs the participant is directly responsible for paying; however, the payments made by the SPAP also count toward the individual's TrOOP.

In March, the participant refills the same medication; prior to the claim being processed, the participant's TrOOP Accumulator is \$1,563.88 (two prescription fills, each with participant OOP costs of \$390.97 and SPAP payments of \$390.97; $\$390.97 * 4 = \$1,563.88$). Because of the \$2,000 annual OOP threshold, the Part D sponsor returns an OOP cost sharing of \$436.12 ($\$2,000 - \$1,563.88 = \436.12). After submitting this amount to the SPAP, the final March OOP cost sharing for the participant is \$218.06. Because the participant has now reached the annual OOP threshold, they incur no new OOP costs and their maximum monthly cap would be approximately \$77.74 for all months remaining in the plan year, as shown below.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$390.97	\$166.67	\$166.67
February	\$390.97	\$55.93	\$55.93
March	\$218.06	\$77.74	\$77.74
April	\$0.00	\$77.74	\$77.74
May	\$0.00	\$77.74	\$77.74
June	\$0.00	\$77.74	\$77.74
July	\$0.00	\$77.74	\$77.74
August	\$0.00	\$77.74	\$77.74
September	\$0.00	\$77.74	\$77.74
October	\$0.00	\$77.74	\$77.74
November	\$0.00	\$77.74	\$77.74
December	\$0.00	\$77.74	\$77.74
TOTAL	\$1,000.00		\$1,000.00

Example B17: January Election with Manufacturer Patient Assistance Program (PAP)

Calculation of Maximum Monthly Cap in First Month: This example demonstrates how the maximum monthly cap would be calculated for a participant with additional prescription drug coverage through a manufacturer patient assistance program (PAP). The individual has already opted into the Medicare Prescription Payment Plan. They also apply for assistance with drug costs through a PAP that operates outside of the Part D benefit. The individual is on two high-cost prescription medications – one that is covered fully by the PAP (prescription A) and one that is not (prescription B). The participant presents to the pharmacy in January to fill both prescriptions. The pharmacist processes prescription A directly through the PAP, without submitting it to the participants Part D sponsor. The payments for this prescription do not count toward the participant’s TrOOP and are not reflected in the OOP costs incurred for the Medicare Prescription Payment Plan. The pharmacist then submits the claim for prescription B to the Part D sponsor, which returns an OOP cost sharing of \$601.35.

Step 1: Determine the previously incurred costs. The participant has had no prior pharmacy expenditures in January 2025; the TrOOP Accumulator is \$0.

Step 2: Calculate the maximum monthly cap for the first month in which the Medicare Prescription Payment Plan is effective for the participant. The annual OOP threshold for 2025 is \$2,000. The month is January; months remaining in the plan year equals 12 (includes January).

$$(\$2,000 - \$0)/12 = \$166.67$$

The plan will bill \$166.67 for January, since the OOP incurred amount of \$601.35 is higher than the cap.

Calculation of Maximum Monthly Cap in Subsequent Months: In February 2025, the participant refills their existing prescriptions.

Step 1: Determine the remaining costs owed by the participant. Under the Medicare Prescription Payment Plan, the participant incurred \$601.35 in January and was billed \$166.67.

$$\$601.35 - \$166.67 = \$434.68$$

Step 2: Determine the additional OOP costs incurred by the participant. The participant refills their two prescriptions, one covered by the PAP and one through their Part D sponsor. The Part D cost sharing for prescription B is again \$601.35.

Step 3: Calculate the maximum monthly cap for the subsequent month. The month is February; months remaining in the plan year equals 11 (includes February).

$$(\$434.68 + \$601.35)/11 = \$94.18$$

If the participant in Example B17 continues to fill their prescriptions each month, they will meet the annual OOP threshold in April. The OOP costs incurred in the table below reflect only the costs the participant is directly responsible for paying; the payments made by the PAP are outside of the Part D benefit and do not count toward the individual's TrOOP.

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Participant Payment
January	\$601.35	\$166.67	\$166.67
February	\$601.35	\$94.18	\$94.18
March	\$601.35	\$154.32	\$154.32
April	\$195.95	\$176.09	\$176.09
May	\$0.00	\$176.09	\$176.09
June	\$0.00	\$176.09	\$176.09
July	\$0.00	\$176.09	\$176.09
August	\$0.00	\$176.09	\$176.09
September	\$0.00	\$176.10	\$176.10
October	\$0.00	\$176.09	\$176.09
November	\$0.00	\$176.10	\$176.10
December	\$0.00	\$176.09	\$176.09
TOTAL	\$2,000.00		\$2,000.00