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CENTER FOR MEDICARE

DATE: July 16, 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 Two 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 two guidance on a select set of topics for the Medicare Prescription Payment Plan 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 2.
- B. A summary of key changes and clarifications to the draft part two guidance released on February 15, 2024, which begins on page 3.
- C. A summary of the public comments received in response to the draft part two guidance, and the Centers for Medicare & Medicaid Services' (CMS') responses to those public comments, which begins on page 5.
- D. Final part two guidance that establishes final policies for CY 2025 on the topics discussed for the Medicare Prescription Payment Plan, which begins on page 64.

CMS may supplement this final part two 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 two 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 February 29, 2024, CMS issued a final 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 two guidance. The 30-day comment period for the draft part two guidance began February 15, 2024 and concluded March 16, 2024. CMS received more than 100 public comments in response to the draft part two 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>. 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 two guidance in this final part two 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 two guidance may be considered as part of that rulemaking process. CMS has also released final part one guidance on select topics specific to the program, which is available at <https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf>.

Additionally, CMS developed six model and standardized materials to support Part D sponsors in meeting their education, outreach, and communications requirements for the Medicare Prescription Payment Plan. CMS issued the materials through an Information Collection Request (ICR) process with two opportunities for public comment. After considering comments received, CMS finalized and published the materials on July 16, 2024. The materials are available through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package and on the CMS.gov website at <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

In this memorandum, CMS provides a summary of significant comments that it received in response to the draft part two guidance, as well as the agency's response to those significant comments, which begins on page 5. CMS is not responding in this document to all comments that it received but instead is addressing those 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 Two Medicare Prescription Payment Plan Guidance

CMS received many comments from consumer and patient groups, manufacturers, pharmacies, Part D sponsors, individuals, and other interested parties on the draft part two Medicare Prescription Payment Plan guidance that was released on February 15, 2024. This section provides a summary of the key changes and clarifications made to the draft part two 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 two guidance in this section.

CMS provides responses to the comments received in section C of this final part two guidance and has made corresponding changes and clarifications to the policies described in the draft part two guidance, as summarized below.

Section 10 Introduction: In response to comments received on the applicability of the Medicare Prescription Payment Plan to certain types of Part D plans, CMS has modified section 10 of this final part two guidance to clarify that CMS does not expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the final part one guidance or this final part two guidance.

Section 30.1.1 Required Mailings with Membership ID Card Issuance: In response to comments on the requirement for Part D sponsors to send a program election request form with the membership ID card mailing, CMS updated section 30.1.1 of this final part two guidance. CMS is no longer requiring Part D sponsors to send an election request card with the membership ID card mailing; instead, Part D sponsors may choose to either send an election request form with the membership ID card mailing or separately in a different mailing sent out within the same timeframe as the membership ID Card mailing.

Section 30.2.2.2 Identifying Part D Enrollees Likely to Benefit During the Plan Year: In response to comments received on requirements for Part D sponsors to identify Part D enrollees likely to benefit from the program throughout the plan year, CMS has modified section 30.2.2.2 of this final part two guidance. The updated section still

requires Part D sponsors to put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year but has been modified to no longer specifically require targeted outreach based on prior authorization or other utilization management edits in place for a drug with out-of-pocket (OOP) costs at or above the pharmacy point of sale (POS) notification threshold. Instead, Part D sponsors must develop their own strategies for ongoing outreach during the plan year to enrollees who are likely to benefit from the program.

Section 30.3 Communications with Program Participants and Model Materials

Requirements for Part D Sponsors: In response to comments on the communications requirements for Part D sponsors, CMS updated the subsections throughout section 30.3 of this final part two guidance to include specific content requirements for communications materials Part D sponsors must send to Part D enrollees regarding election into, participation in, and termination from the program. If Part D sponsors choose not to use CMS-developed model materials and instead develop their own notices, they must meet these content requirements.

Section 50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount:

In response to comments requesting additional clarification on situations where a supplemental payer to Part D returns a higher final patient pay amount to the pharmacy, CMS has modified section 50.1 of this final part two guidance. The modified language states that, in these cases, Part D sponsors may only include in the Medicare Prescription Payment Plan the participant's original Part D cost sharing, as determined by their plan-specific benefit structure.

Section 50.3.1 Long-Term Care Pharmacies: In response to comments requesting clarity on whether Part D sponsors have discretion in ensuring that long-term care pharmacies provide the "Medicare Prescription Payment Plan Likely to Benefit Notice" prior to dispensing a medication, CMS has modified section 50.3.1 of this final part two guidance. In this section, CMS explains that Part D sponsors should not require that the long-term care pharmacy provide the notice prior to dispensing. Instead, the Part D plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process.

Section 50.4 Readjudication of Prescription Drug Claims for New Program

Participants: In response to comments expressing concern regarding requirements to readjudicate claims for prescriptions that have not yet been picked up by a new program participant, CMS has modified the requirements outlined in section 50.4 of this final part two guidance. CMS is no longer requiring all prescription drug claims to be readjudicated for new Medicare Prescription Payment Plan participants; rather, pharmacies are only required to reverse and reprocess the claim for the prescription that triggered the likely to benefit notification for the new participant, so the date of service on the claim falls within

the Part D enrollee's dates of participation in the program. If the enrollee has other prescriptions with earlier dates of service that have not yet been paid for and picked up, the pharmacy is only required to reverse and reprocess claims for those prescriptions at the request of the participant.

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

Introduction (Section 10)

Comment: A commenter asked whether the Medicare Prescription Payment Plan applies to both Medicare Advantage (MA) plans and MA plans offering prescription drug coverage (MA-PDs). The commenter noted that footnote 2 states that the program has no practical application to Programs for All-Inclusive Care for the Elderly (PACE) organizations or Medicare-Medicaid Plans (MMPs). The commenter asked whether that means that MMPs and PACE organizations do not have to comply with any portion of the Medicare Prescription Payment Plan guidance, including notification requirements, website requirements, enrollee outreach, and reporting.

Response: CMS thanks the commenter for their questions. As noted in the draft part two guidance, section 1860D-2(b)(2)(E)(i) of the Social Security Act (the Act) requires that Part D sponsors offering stand-alone prescription drug plans (PDPs) and MA organizations offering MA-PDs shall provide to any enrollee of such plan the option to participate in the Medicare Prescription Payment Plan. However, CMS understands that the Medicare Prescription Payment Plan has no practical application for PACE participants or enrollees in plans that exclusively charge \$0 cost sharing for covered Part D drugs. Because enrollees in such plans never have any cost sharing for covered Part D drugs, there are no OOP Part D drug costs that could be paid through monthly payments over the course of the plan year. Therefore, opting into the Medicare Prescription Payment Plan would have no practical benefit or effect for an enrollee of such a plan. Moreover, the provision of information about the Medicare Prescription Payment Plan in plan promotional and educational materials could cause confusion among enrollees of such plans by informing them of a program that has no practical benefit or effect. As such, CMS does not expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or to otherwise comply with the final part one guidance or this final part two guidance. As noted above, this clarification is limited to Part D plans that *exclusively* charge \$0 cost-sharing for covered Part D drugs to all plan enrollees. If a Part D plan has any enrollees that could pay any cost sharing, even a nominal amount, under the Part D plan at any point during the year, then this clarification would not be applicable to such a plan.

Overview of the Medicare Prescription Payment Plan (Section 20)

Comment: A commenter stated that the final part one guidance includes references to policies proposed in the draft part two guidance and stated that the final part one guidance seems to assume that policies proposed in the draft part two guidance will be finalized before considering feedback by interested parties.

Response: CMS thanks the commenter for their concerns. CMS disagrees that its broad references to the content of the draft part two guidance in the final part one guidance indicate that CMS intended to finalize the policies proposed in the draft part two guidance without considering feedback by interested parties. CMS has sought to provide interested parties with as much information as possible as soon as possible about the Medicare Prescription Payment Plan out of recognition of the short timeframe provided under the statute for interested parties to operationalize the program. As such, in the final part one guidance, CMS included references to the content of the part two guidance to be clear about what policies would be covered in the part two guidance. Those references were not intended to suggest that CMS would not adjust its policies in response to feedback from interested parties. As stated in section B of this memorandum, CMS has adjusted policies announced in the draft part two guidance based on interested party feedback where appropriate. In addition to directly integrating feedback from interested parties received through the public comment periods, CMS has held numerous interviews and ad hoc meetings with a range of interested parties to inform the development of the Medicare Prescription Payment Plan part one guidance and part two guidance.

Outreach, Education, and Communications Requirements for Part D Sponsors (Section 30)

Comment: Many commenters expressed support for CMS' proposals for outreach, education, and communications requirements.

Response: CMS thanks commenters for their support.

Comment: Many commenters urged CMS to require Part D sponsors to use standardized materials to perform education and outreach to enrollees. They voiced concerns that the part two guidance grants Part D sponsors too much flexibility in modifying or developing materials, which, they wrote, can create inconsistencies and confusion among Part D enrollees and stakeholders. These commenters requested that if CMS does not require sponsors to use a specific educational product or use the model materials verbatim, CMS should develop a process to review and confirm the accuracy of sponsor-developed materials.

Response: CMS appreciates commenters' concerns. We believe that the education, outreach, and communications requirements outlined in section 30 of this final part two guidance, paired with CMS' education and outreach efforts, outlined in section 40 this final part two guidance, will

ensure that all Part D enrollees will receive a uniform and consistent level of information and education on the program, regardless of their Part D plan.

Regarding the use of the CMS-developed educational product (referred to as the “CMS-developed fact sheet” in this final part two guidance) to satisfy education requirements, while Part D sponsors do have flexibility to develop their own educational materials, CMS does encourage sponsors to use the CMS-developed fact sheet, which has been consumer tested, with the aim of ensuring that the information provided and language used is accessible, appropriate, and easy to understand for Medicare Part D enrollees. As stated throughout this guidance, however, CMS does remind Part D sponsors that if they choose to develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy requirements, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the Medicare Communications and Marketing Guidelines (MCMG), which provide guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through the Health Plan Management System (HPMS), and use of marketing materials.

Regarding the use of CMS’ newly-developed model materials for the program, Part D sponsors can choose to use the models to satisfy the requirements for communications with prospective and current program participants (with the exception of the “Medicare Prescription Payment Plan Likely to Benefit Notice,” which is a standardized material that Part D sponsors are required to use verbatim). If Part D sponsors choose to develop their own materials, they must ensure that the required content is included in their materials. CMS has added specific content requirements for each model notice throughout section 30.3 of this final part two guidance.

Finally, CMS appreciates commenters’ request for information on how CMS will review and confirm the accuracy of sponsor-developed materials. CMS expects all Part D sponsors to comply with the education, outreach, and communication requirements included in this final part two guidance. Additionally, CMS reminds Part D sponsors that existing Part D regulations regarding Part D sponsors’ communications and marketing materials, specified at 42 CFR Part 423 subpart V, apply to any required materials, including model and standardized materials, developed and used for the Medicare Prescription Payment Plan. As stated above and in section 60.3 of this final part two guidance, CMS will monitor sponsors’ performance, including beneficiary complaints in the Medicare Complaints Tracking Module (CTM), to assess compliance with all Medicare Prescription Payment Plan requirements, including those related to education, outreach, and communications.

Comment: A few commenters requested that CMS release the model documents and educational materials as soon as possible because plans are already beginning to prepare products for the CY 2025 Annual Enrollment Period (AEP). A commenter recommended that CMS grant plans the flexibility to use draft models and/or have the flexibility to modify the materials without CMS

review and approval or non-standardized language. The commenter also suggested that CMS exercise enforcement discretion for good faith efforts to update the materials and not impose penalties for non-standardized language or if the sponsors issue supplemental mailings to beneficiaries.

Response: As stated above in the introduction section of this final part two guidance, newly-developed model materials for the Medicare Prescription Payment Plan were released following an ICR process and are available online. CMS notes that the Evidence of Coverage (EOC), Annual Notice of Change (ANOC), and Explanation of Benefits (EOB)¹ were released in spring 2024 as part of the general issuance of CY 2025 model materials. This publication timeline follows the standard timeline for release of existing Part D models and, as such, Part D sponsors are accustomed to this timing and have been able to make necessary updates to their materials and processes ahead of the date on which Part D sponsors may begin marketing their plans for next year and ahead of the AEP each year.

CMS is making every effort to release materials timely and believes these timelines provide Part D sponsors with sufficient lead time to implement necessary changes, prepare materials, and comply with the education and outreach requirements outlined in this final part two guidance. Part D sponsors are required to use the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” in the format and manner provided by CMS. If Part D sponsors use the other newly developed model materials, they are required to follow instructions provided in the model documents. As stated in section 30 of this final part two guidance, Part D sponsors may choose to develop their own notices to meet communications requirements in lieu of using CMS-developed models; however, these materials must include the elements outlined throughout section 30.3 of this final part two guidance.

Comment: Several commenters requested that CMS integrate feedback from stakeholders and from diverse populations of Medicare beneficiaries, such as Chronic Condition Special Needs Plans (C-SNP) enrollees, to ensure the education and outreach materials meet enrollees’ needs.

Response: CMS agrees with commenters that engagement of interested parties and diverse populations of Medicare beneficiaries, including C-SNP members, is essential for ensuring that education and outreach materials meet Part D enrollees’ needs. As such, in addition to directly integrating feedback from interested parties received through the public comment periods, CMS has held numerous interviews and ad hoc meetings with a range of interested parties to inform the development of the Medicare Prescription Payment Plan part one guidance and part two guidance. Further, CMS performed multiple rounds of research on its materials and products newly developed for the Medicare Prescription Payment Plan. The rounds of research included

¹ The 2025 model EOC and ANOC are available at <https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials>. The 2025 model Part D EOB is available at <https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-model-materials>.

Medicare Part D enrollees who would and would not benefit from the program, and CMS was responsive to feedback raised by participants when finalizing the materials.

Comment: Several commenters requested that CMS develop standardized educational materials that plans can share with providers and pharmacies and that can be used by all stakeholders—particularly by caregivers, patient advocates, and brokers—to educate beneficiaries.

Response: CMS agrees that providers and pharmacies serve as trusted sources of information for Part D enrollees and will play a key role in making Part D enrollees aware of the program. As such, as stated in section 40.3 of the final part two guidance, CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have the necessary support and resources to educate Part D enrollees on the program and help them determine whether the program would be beneficial for them. Additionally, in section 30.2.3 of this final part two guidance, CMS encourages Part D sponsors to include information about the Medicare Prescription Payment Plan in their communications with contracted providers and network pharmacies.

Comment: A few commenters warned of potential information fatigue from adding information on the Medicare Prescription Payment Plan to too many materials and advised that CMS focus on “high-value touches.” A commenter recommended that CMS prioritize direct mail over websites when transmitting information on the program, though another commenter encouraged the use of technology wherever possible. A couple of commenters voiced support for Part D sponsors sending communications through the enrollee’s preferred method.

Response: CMS appreciates the concerns raised by commenters and believes that the level of information and breadth of materials being provided is appropriate to fulfill CMS’ and Part D sponsors’ statutory obligations under sections 1860D–2(b)(2)(E)(v)(I) and 1860D–2(b)(2)(E)(v)(III) of the Act to inform all Part D enrollees of the option to participate in the Medicare Prescription Payment Plan. Further, as described in section 30.1 of this final part two guidance, CMS is leveraging existing Part D materials, such as the ANOC, EOC, and EOB, to educate Part D enrollees on the program. In utilizing materials Part D enrollees are already accustomed to receiving, CMS is minimizing the number of additional documents they receive for the new program. Regarding the method of communication, CMS appreciates commenters’ support for allowing Part D enrollees to receive communications through their preferred method and believes that this flexibility, where possible, is important to ensure that individuals who have varying levels of access or comfort with digital platforms are able to successfully receive information on the program.

Comment: Many commenters stated that a robust education and outreach campaign coordinated by CMS is important for broad awareness, and these commenters offered suggestions for content to be included in resources: an explanation of the terms and conditions of the program; how and

when to opt in; clarification that the Medicare Prescription Payment Plan is a government-mandated program offered by all Part D plans; clarification that the Medicare Prescription Payment Plan does not replace Part D; clarification that participants do not receive discounts under the program; and clear explanations of who may and may not benefit. A few commenters asked that CMS broaden education and outreach requirements to ensure as many beneficiaries as possible understand the program. A commenter stated that plans should be required to send a document separate from the ANOC, EOC, and EOB that only explains the Medicare Prescription Payment Plan, that is clear and easy to understand, and that is printed on colored paper.

Response: CMS appreciates these comments and agrees that a robust education and outreach campaign is essential for ensuring broad awareness of the program. Section 40 of this final part two guidance includes a high-level overview of CMS' education and outreach efforts, and this section is not comprehensive of the various activities CMS is undertaking to effectively educate on and promote the program. Supporting broad awareness of the Medicare Prescription Payment Plan is, however, a shared responsibility between CMS and Part D sponsors, who are required under statute to broadly educate on the program and ensure all Part D enrollees are made aware of the option. CMS thanks commenters for the suggestions regarding specific information to be included in materials and will take these suggestions under advisement while developing beneficiary-facing materials and products. Additionally, CMS considered comments received on the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package when developing the model materials for the program.

CMS believes that the scope of education and outreach requirements for Part D sponsors included in section 30 of this final part two guidance is appropriate and satisfies Part D sponsors' statutory obligations under section 1860D-2(b)(2)(E)(v)(III) of the Act to inform all Part D enrollees of the option to participate in the program while also ensuring that Part D enrollees understand the nuances of the program and who may and may not benefit. CMS appreciates the request to require Part D sponsors to distribute a document on the program that is separate from other existing Part D documents but believes that Part D sponsors' obligations to send other standalone program-specific documents, such as the election request form, "Medicare Prescription Payment Plan Likely to Benefit Notice," and educational information, among others, serves this purpose.

Comment: Several commenters recommended that CMS' materials include information on other programs to help beneficiaries lower costs, such as the Low-Income Subsidy (LIS) program (also known as Extra Help), and on other changes under the IRA, such as the \$0 cost sharing for Advisory Committee on Immunization Practices (ACIP) recommended Part D vaccines, the \$35 monthly cap for each covered insulin product, and the recent expansion of LIS eligibility.

Response: CMS agrees that raising awareness of other financial assistance programs, such as the LIS program, is paramount to ensuring that eligible Medicare beneficiaries are aware of and able

to enroll in the program. CMS also recognizes the importance of educating beneficiaries on the recent changes to the Part D benefit under the IRA, particularly those that increase affordability for beneficiaries. In section 30.1.5 of this final part two guidance, CMS requires Part D sponsors to include on their websites general information about the LIS program, including information on the recent LIS expansion of eligibility and how to enroll in the program, with a note that LIS enrollment, for those who qualify, is likely to be more advantageous than participation in the Medicare Prescription Payment Plan. Additionally, CMS encourages Part D sponsors to include information on the new \$2,000 annual OOP cap on Part D covered drugs in 2025. Part D sponsors are encouraged to educate their beneficiaries on other important changes to the Part D benefit under the IRA, and CMS is undertaking efforts to strengthen beneficiaries' awareness of the changes.

General Outreach and Education (Section 30.1)

Comment: Many commenters supported CMS' requirements to use both existing and new model materials to provide education and outreach on the program.

Response: CMS thanks commenters for their support.

Comment: A commenter noted that updating model materials will increase administrative costs for plans, as they will need to reconfigure existing systems and pay to disseminate the information, and the commenter noted that the Medicare Prescription Payment Plan education and outreach will drive traffic to plans' call centers, further increasing costs for plans.

Response: CMS appreciates this commenter's concern. By updating existing Part D materials that Part D sponsors are already required to disseminate, such as the ANOC, EOC, and EOB, with information on the Medicare Prescription Payment Plan, CMS aimed to minimize burden and integrate the new, statutorily mandated program into Part D sponsors' existing processes. Part D sponsors are encouraged to provide their enrollees with education and information on the program in ways that go beyond the requirements stated in the final part one and final part two guidance documents; in doing so, Part D sponsors may be able to meet the needs of their members early on and reduce call center volume.

Comment: A couple of commenters requested that CMS issue a model summary of benefits and model formulary materials reflecting the Medicare Prescription Payment Plan.

Response: CMS thanks commenters for their request. CMS has carefully considered which existing Part D materials to update with information on the Medicare Prescription Payment Plan and determined that updates to the ANOC, EOC, and EOB are appropriate to reach Part D enrollees regardless of their membership status (i.e., currently enrolled in, new to, or staying in their current Part D plan). The summary of benefits is no longer a model provided by CMS, and

updating model formulary materials to reflect the Medicare Prescription Payment Plan could cause confusion because the program does not impact formularies. CMS will consider the need for modifications to additional documents in the future.

Comment: A commenter appreciated how CMS granted Part D sponsors the flexibility to include information about the Medicare Prescription Payment Plan in their marketing materials. Another commenter stated that CMS should require plans to use standard terminology in marketing materials. Another commenter did not support the “proposal to require all Part D sponsors to advertise [the program]” and requested that CMS require a CMS-developed script that makes it clear that the Medicare Prescription Payment Plan is offered by all Part D plans.

Response: CMS thanks commenters for their support. CMS does not believe required, standard terminology for Part D sponsors’ marketing materials is necessary given the scope of existing Part D marketing requirements and parameters; as described in section 30 of this final part two guidance, 42 CFR Part 423 subpart V sets forth requirements for Part D sponsors’ marketing materials. Additionally, the MCMG offers CMS’ interpretation and examples of select subpart V provisions, as well as HPMS submission rules and processes for marketing materials. Taken together, these regulations and requirements outline specific requirements and prohibited practices for Part D sponsors’ marketing materials and activities, such as a prohibition on providing inaccurate or misleading information and parameters around the timing of when Part D sponsors can market their plan offerings. In addition, CMS must prospectively review marketing radio and television advertisements submitted via HPMS, and may retrospectively review other marketing materials in HPMS as well. As such, CMS believes these requirements and the agency’s review provide sufficient safeguards for ensuring marketing materials—and any references to the Medicare Prescription Payment Plan included in these materials—are accurate, transparent, and accessible. Further, CMS reminds interested parties that section 1860D–2(b)(2)(E)(v)(III) of the Act requires Part D sponsors to engage in this level of outreach and education. CMS also encourages Part D sponsors to refer to language in the CMS-developed fact sheet and in CMS-developed model materials when drafting language for their documents. The language included in CMS’ materials has undergone consumer testing to ensure it effectively conveys vital information on the program.

Required Mailings with Membership ID Card Issuance (Section 30.1.1)

Comment: A few commenters expressed support for CMS’ proposed requirement to send the election request form with the membership ID card mailing.

Response: CMS thanks commenters for their support.

Comment: Many commenters requested that CMS retract or reconsider the proposed requirement to send the election request form with the membership ID card mailing, largely

stating that sending an election request form to enrollees who are unlikely to benefit, such as LIS, Employer Group Waiver Plan (EGWP), certain dual-eligible, or dual-eligible special needs plan (D-SNP) enrollees, would cause significant confusion and lead them to think the Medicare Prescription Payment Plan is the right choice. A couple of commenters also stated that enrollees may think they need to fill out the election form to use their Part D benefit, and two sponsors said an enrollee who opted in earlier in the AEP may be confused upon receipt of the paper form and submit the form again. A few commenters cited operational concerns for Part D sponsors, stating that adjusting their automated systems and processes to accommodate the new requirement to include additional documents and making arrangements with their vendors would lead to increased burden and administrative cost and could potentially result in printing delays and errors. A few commenters also stated that Part D plan sponsors do not send membership ID cards to every member every year, only to new enrollees, so if CMS would like all enrollees to receive the paper election form, perhaps it should be sent in a separate mailing within the same timeframe as the membership ID card mailing, such as, for example, the confirmation of enrollment. Additional recommendations include deferring the requirement to 2026; providing flexibility to plans to send a separate mailing with the election form; and allowing plans to exclude an enrollee from the mailing if they are unlikely to benefit or if they have already elected into the program.

Finally, a few commenters requested that sponsors be required to include standardized materials with the membership ID card, requesting CMS be prescriptive and require—not simply encourage—sponsors to use the CMS-developed educational product, or, in the least, require sponsors to submit their materials to CMS for review prior to use.

Response: CMS appreciates commenters' concerns regarding sending a Medicare Prescription Payment Plan paper election request form and information on the program with the membership ID card mailing. Under section 1860D–2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D–2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also provide educational materials to Part D enrollees. These statutory obligations apply regardless of the extent to which the beneficiary is expected to benefit from the program.

CMS understands commenters' concerns and therefore has amended the membership ID card mailing requirement. CMS updated section 30.1.1 of this final part two guidance to allow Part D sponsors to send the election request form and program information either with the membership ID card or in a separate mailing to new Part D plan enrollees. If using a separate mailing, it must be sent out within the same timeframe as the membership ID card mailing. As a reminder, under § 423.2267(e)(32)(i), the hard copy of the membership ID card must be provided to new enrollees within ten calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. Additionally, Part D sponsors may choose to send the paper election request and program

information to all Part D plan enrollees of the plan or to only those new Part D plan enrollees who are receiving the membership ID card mailing.

In addition, in response to comments requesting CMS require the use of standardized material or at least review Part D sponsor materials regarding the program before their use, CMS is aiming to balance Part D sponsor operational burden with the need to provide consistent language regarding the program to Part D enrollees and believes that requiring specific educational and communications materials at every touch point may be overly burdensome. Rather than requiring a standardized material to be sent with the membership ID card mailing, CMS is encouraging Part D sponsors to use the CMS-developed fact sheet to satisfy the requirement to provide information on the Medicare Prescription Payment Plan. As stated above and in section 60.3 of this final part two guidance, CMS will monitor sponsors' performance, including data on grievances and beneficiary complaints entered in the CTM, to assess compliance with all Medicare Prescription Payment Plan requirements, including those related to education, outreach, and communications.

Comment: A commenter requested that Part D sponsors have the flexibility to include in the membership ID card mailing and other materials discussing the program a website address where Part D enrollees can complete the electronic election request. A commenter stated that program materials should explain to new Part D plan enrollees that they must complete the program election request form to participate in the program and that the new Part D plan will provide the program election request form to them once it receives confirmation from CMS that their Part D plan enrollment has been accepted. Another commenter asked if the membership ID card will have the "4RX information" needed to process the coordinated benefit.

Response: Section 30.3.1.1 of this final part two guidance has been updated to specify that Part D sponsors must include a link to their online election request form on the paper election request form that will be mailed with other program information. Additionally, Part D sponsors may include a link to the online election form in other program materials. Comments related to the content of the CMS-developed model "Medicare Prescription Payment Plan Participation Request Form" were considered through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR process. CMS is not making updates to the membership ID card itself in relation to the Medicare Prescription Payment Plan. Part D sponsors will communicate Part D enrollees' participation status with pharmacies via the required National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard.

Evidence of Coverage (EOC) and Annual Notice of Change (ANOC) (Sections 30.1.2 and 30.1.3, respectively)

Comment: A couple of commenters supported the proposal to add information to the EOC and ANOC and supported the timing of release of the document. A couple of other commenters

requested that CMS incorporate beneficiary feedback and pilot testing into content added to the EOC and ANOC and confirm language is accessible and accommodates varied health literacy levels to ensure beneficiaries understand their coverage.

Response: CMS thanks commenters for their support. As stated in sections 30.1.2 and 30.1.3 of this final part two guidance, the model EOC and model ANOC were released in spring 2024 as part of the general issuance of CY 2025 Model Materials for the Part D program (CMS-10260; OMB 0938-1051). CMS considered feedback received from multiple rounds of research on CMS-developed program materials when making updates to the model ANOC and EOC to reflect the Medicare Prescription Payment Plan. The rounds of research included Medicare Part D enrollees who would and would not benefit from the program, and CMS was responsive to feedback raised by participants when finalizing the materials.

Part D Explanation of Benefits (EOB) (Section 30.1.4)

Comment: Though a commenter supported adding information to the Part D EOB, a few commenters stated that the language included in the EOB would cause confusion on whether the enrollee is in the program or not, and because the EOB could be sent late in the year, it could lead enrollees to opt in during the later months when they are less likely to benefit. Further, commenters stated that all enrollees, including those unlikely to benefit, receive the EOB, which could increase confusion, and adding language to the EOB could lead to information overload or fatigue. A commenter recommended not adding information to the EOB and instead allowing Part D sponsors to refer Part D enrollees to a more robust source of information, and another recommended not including language in the EOB and instead adding language to the Medicare Prescription Payment Plan election approval notice stating that the EOB will not reflect participation in the program.

A commenter suggested modifying the high-level information about the Medicare Prescription Payment Plan that was added to the 2025 Part D EOB that directs members to where they can learn more. Several commenters suggested updating the EOB with visual aids and examples to clarify the program's impact on cost sharing.

Response: CMS thanks commenters for their feedback regarding the information on the Medicare Prescription Payment Plan included in the model 2025 Part D EOB. CMS believes that inclusion of high-level information in the EOB is appropriate and will help Part D sponsors fulfill their statutory requirements under section 1860D-2(b)(2)(E)(v)(III)(cc) of the Act to broadly provide information about the Medicare Prescription Payment Plan in enrollee educational materials.

Regarding specific comments on the content of the EOB, as stated in section 30.1.4 of this final part two guidance, CMS issued the EOB for two separate public comment periods as part of the

most recent OMB ICR renewal for the Part D EOB (CMS-10453; OMB 0938-1228). CMS thoughtfully considered comments received during both comment periods when updating the model EOB with information on the Medicare Prescription Payment Plan and included references to other resources Part D enrollees can use to obtain more detailed information on the program.

Part D Sponsor Websites (Section 30.1.5)

Comment: Several commenters supported the website requirements, though a commenter requested that CMS waive EGWPs from the requirements to put Medicare Prescription Payment Plan information on their websites because, the commenter stated, EGWP enrollees are unlikely to benefit.

Response: CMS thanks commenters for their support. Regarding the request to exempt EGWPs from the website requirements, while CMS recognizes that Part D enrollees with low cost sharing may be less likely to benefit from the Medicare Prescription Payment Plan, these enrollees must nonetheless be made aware of and given the option to participate in the program as required by statute. As such, CMS is not exempting EGWPs from website requirements outlined in section 30.1.5 of this final part two guidance. CMS reminds commenters that all Part D sponsors have a statutory obligation to broadly educate all Part D enrollees about the program. CMS believes that including program information on Part D sponsors' websites is an appropriate avenue for providing education to all Part D enrollees. Further, in section 30.1.5 of this final part two guidance, CMS requires Part D sponsors to include on their websites examples of cost-sharing scenarios that demonstrate when the program would and would not benefit a Part D enrollee and a description of who is likely to benefit. CMS encourages Part D sponsors to use the example calculations included in the CMS-developed fact sheet, final part one guidance, or technical memoranda to satisfy this requirement.² Additionally, CMS encourages all Part D sponsors to directly communicate with their Part D enrollees about this program and help them understand whether the Medicare Prescription Payment Plan is a beneficial option for them given their unique situation.

Comment: Many commenters requested that CMS provide and require standardized language for Part D sponsors to use on their websites, and some encouraged CMS to be prescriptive about the placement and display of information to ensure the information is prominent and easily accessible. A few commenters also suggested that CMS release additional guidelines to ensure online content is user-friendly and accessible to all beneficiaries.

Many commenters had suggestions for additional content requirements. A few commenters advocated for a calculator tool to be included on the website, and a commenter recommended

² To access the final part one guidance and technical memoranda, see: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

that CMS create standardized example calculations for use on websites. A few other commenters stated that CMS should require sponsors to include a disclaimer on their websites stating that the Medicare Prescription Payment Plan is a new, free, voluntary Medicare program required to be offered by all Part D plans. A few commenters also requested that websites include a description of someone who is not likely to benefit, a description of the beneficiary protections, appeals, and reinstatement processes, information on the LIS program, and information on the \$2,000 OOP cap in 2025.

Response: CMS appreciates commenters' feedback. As stated above, CMS is aiming to balance Part D sponsor operational burden with the need to provide consistent language on the program to Part D enrollees and believes that requiring specific, standardized educational and communications materials and language at every touch point may be overly burdensome. As stated in section 30.1.5 of this final part two guidance, however, CMS encourages Part D sponsors to use language from the CMS-developed fact sheet and other CMS-provided resources to meet website requirements. Additionally, CMS states in section 30.1.5 of this final part two guidance that Part D sponsors' websites must comply with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, with regard to providing access to websites and other materials, so that individuals can read sites and materials with screen reader technology. Further, as stated in section 30.4 of this final part two guidance, websites must comply with Medicare Part D language access and accessibility requirements.

Regarding commenters' suggestions for additional content requirements, CMS notes that the list of required information that Part D sponsors must include on their websites serves as minimum information requirements. Part D sponsors may, and are encouraged to, provide additional information, tools, and resources to best serve their Part D enrollees and ensure they properly understand the program and how it may benefit them. Further, as stated in section 30.1.5 of this final part two guidance, Part D sponsors are required to include examples of how the program calculation works with easy-to-understand explanations and may provide a calculator tool as well. CMS encourages Part D sponsors to use the example calculations included in the CMS-developed fact sheet, final part one guidance, or technical memoranda to satisfy this requirement.³ CMS agrees that Part D sponsors should include language stating that the program is new, free to join, and voluntary. While the draft part two guidance required Part D sponsors to include language stating that the program is free to join, section 30.1.5 of this final part two guidance has added requirements for Part D sponsors to also state the program is new, voluntary, and offered by all Part D plans.

Comment: Though a commenter supported the requirement for the website election mechanism to provide a confirmation number confirming the Part D enrollee has successfully submitted a request to participate in the program, a couple of commenters expressed concern about the

³ To access the final part one guidance and technical memoranda, see: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

requirement and requested CMS not require or delay the requirement for plans to offer a confirmation number due to operational complexities.

Response: CMS thanks commenters for their feedback and clarifies that a confirmation number is not required for the online election mechanism. Section 70.3.1 of the final part one guidance and section 30.1.5 of this final part two guidance state that the website mechanism must provide the individual with “evidence the election request was received” (e.g., a confirmation number). Providing a confirmation number is one way a Part D sponsor can satisfy the requirement to provide evidence that the online election request was received by the Part D sponsor. Part D sponsors may choose to provide evidence that the online election request was received in other ways.

Targeted Outreach and Education Requirements for Part D Sponsors (Section 30.2)

Comment: Many commenters expressed general support for CMS’ requirements for targeted outreach; however, a commenter expressed concern that the focus on targeted outreach would limit efforts for general educational efforts to all Part D enrollees. Some commenters also expressed support for CMS’ statement that the targeted outreach requirements are a minimum and the requirement that any supplemental identification strategies be applied consistently across a plan’s population.

Response: CMS thanks the commenters for their feedback. We recognize the importance of general outreach and education related to the Medicare Prescription Payment Plan and, as described elsewhere in this document, have outlined both requirements for Part D sponsors and planned actions by CMS to provide general education. However, given that not all Part D enrollees are likely to benefit from the program and the importance of proactive notification of those Part D enrollees likely to benefit to streamline the election process, CMS is establishing the targeted outreach requirements in section 30.2 of this final part two guidance.

Comment: Many commenters expressed support for CMS developing a standardized notice for enrollees likely to benefit from the Medicare Prescription Payment Plan. Some commenters also highlighted the importance of providing additional program-related education along with the “Medicare Prescription Payment Plan Likely to Benefit Notice,” either to be included in the notice language itself or separately available resources. Another commenter requested that the notice include enrollee-specific information as to why they are receiving the notice, next steps for opting into the program, and how to learn more about the program. A few commenters requested flexibility with regard to distributing the “Medicare Prescription Payment Plan Likely to Benefit Notice,” both in terms of the timing of providing the notice to identified enrollees and the method (such as incorporating the notice language into other plan materials).

Response: CMS thanks the commenters for their suggestions. Regarding specific content included in “Medicare Prescription Payment Plan Likely to Benefit Notice,” CMS considered comments received on the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package when finalizing updates to the materials. CMS agrees that enrollees receiving the notice will need additional details about the program and the implications of participation. CMS refers readers to section 30.2.2 of this final part two guidance for requirements related to timing of distribution of the notice and when educational materials must be provided with the notice. In addition to those requirements, interested enrollees are encouraged to seek out additional program-related information from their Part D sponsor, Medicare.gov, or SHIP counselors. Section 30.2.2 of this final part two guidance also contains the timing requirements for distribution of the notice.

Comment: A few commenters suggested that CMS provide additional examples of circumstances when it does not make sense for individuals to opt into the Medicare Prescription Payment Plan; a commenter requested that these examples be included in educational materials and the “Medicare Prescription Payment Plan Likely to Benefit Notice,” so enrollees understand when it would not be to their financial benefit to participate in the program.

Response: CMS agrees that it is important for enrollees to understand the implications of program participation and how it may impact their payments over the course of the plan year. The CMS-developed fact sheet contains examples of scenarios where enrollees do and do not meet the standardized “likely to benefit” definition. However, as noted elsewhere in this document, CMS recognizes 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 the standardized framework, and these individuals are certainly permitted to opt into the program.

Comment: A commenter requested that the election request form be sent alongside the “Medicare Prescription Payment Plan Likely to Benefit Notice” to every enrollee identified as likely to benefit.

Response: CMS thanks the commenter for this suggestion. In this final part two guidance, we have revised section 30.2.2.1 of this final part two guidance to require Part D sponsors to include the election request form when they notify Part D enrollees prior to the plan year that they are likely to benefit from the Medicare Prescription Payment Plan.

Comment: Some commenters requested clarifications related to the notice, including language translation requirements, if and how enrollees could opt out of receiving the notice, and confirmation that it is a CMS-provided standardized notice, not branded by plan.

Response: As described in section 30.2.1 of this final part two guidance, the “Medicare Prescription Payment Plan Likely to Benefit Notice” is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS. Part D enrollees are not able to opt out of receiving this notice. When the notice is provided by the Part D sponsor directly to the enrollee (such as in the prior to plan year outreach described in section 30.2.2.1 of this final part two guidance), the Part D sponsor should adhere to the language access and accessibility requirements at § 423.2267, as described in section 30.4 of this final part two guidance. The Part D sponsor may also include the plan name and logo on the notice, in accordance with § 423.2267(b).

When the notice is provided by a pharmacy directly to the enrollee (pursuant to section 30.2.2.3 of this final part two guidance), the pharmacy shall provide the standardized notice without any plan-specific branding. Identified enrollees who receive the notice from the pharmacy and need the notice in another format or language are instructed in the notice to call their Part D sponsor for assistance. In those instances, in accordance with § 423.2267, the Part D sponsor must provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in the non-English language or accessible format, as requested. Additionally, CMS has provided a Spanish translation of the “Medicare Prescription Payment Plan Likely to Benefit Notice,” which was available for public comment through the ICR process. Pharmacies should make available the CMS-developed Spanish-language version of the notice, in lieu of the English-language version, to their patients upon request. CMS will consider making available translations in other languages in the future.

Comment: Many commenters expressed support for the requirements that Part D sponsors provide targeted outreach to enrollees likely to benefit prior to the plan year based on the accumulation of \$2,000 in OOP costs in the first three quarters of the year.

Response: CMS thanks the commenters for their support.

Comment: Some commenters expressed opposition to the requirements for targeted outreach based on the accumulation of \$2,000 in OOP costs in the first three quarters of the year. Most of these commenters stated that the criteria would result in the identification of too limited a pool of Part D enrollees and that CMS should modify the criteria to include lower dollar thresholds and/or modified lookback periods. A commenter who was opposed to the prior to plan year targeted outreach criteria requested that CMS exclude enhanced alternative (EA) plans from the requirements for CY 2025, given the other Inflation Reduction Act-related changes for EA plans in CY 2025.

Response: CMS thanks the commenters for their feedback. The prior to plan year notification criteria described in section 30.2.2.1 of this final part two guidance seeks to identify Part D enrollees with persistently high costs who have a high likelihood of benefiting from the program and reduce the risk of identifying Part D enrollees for whom the program may not be as helpful.

Part D enrollees who do not meet these criteria but feel that they would benefit from the program are still able to opt into the program, both prior to and during the plan year. With regard to the comment about exclusion of EA plans from the notification criteria, CMS reiterates that the requirements outlined in section 30.2 of this final part two guidance apply to all Part D sponsors, regardless of benefit design, in accordance with section 1860D-2(b)(2)(E)(i) of the Act. Additionally, CMS reminds Part D sponsors that they have a statutory obligation under sections 1860D-2(b)(2)(E)(v)(III)(bb) and 1860D-2(b)(2)(E)(v)(III)(cc) to broadly educate Part D enrollees about the program.

Comment: Many commenters expressed support for the requirement in the draft part two guidance for outreach during the plan year based on prior authorization requests or utilization management edits for high-cost drugs; however, many other commenters expressed opposition to these requirements. Commenters opposing the requirements noted operational challenges with linking OOP drug costs to the plan's prior authorization or utilization management systems, stating that the coverage determination process is a clinical review that does not take into account financial costs. These commenters stated that coverage determination systems often do not incorporate dosage or day supply and thus would not be able to calculate an anticipated drug cost for the request. Some of these commenters also noted that outreach based on a prior authorization request may be unlikely to reach Part D enrollees prior to their receipt of the notice from the pharmacy. Some commenters requested CMS clarify that these requirements would only apply to approved (and not denied) prior authorization requests and are not an expectation for plans to implement new utilization management edits on high-cost drugs.

Response: CMS appreciates these comments and acknowledges the identified operational challenges with the approach outlined in the draft part two guidance. As such, section 30.2.2.2 of this final part two guidance requires Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit during the plan year, but has been modified to no longer specifically require targeted outreach based on prior authorization or other utilization management edits in place for a drug with OOP costs at or above the pharmacy POS notification. Instead, Part D sponsors must develop their own strategies for ongoing outreach during the plan year to enrollees who are likely to benefit from the program. Such approaches could include, but are not limited to, outreach based on prior authorization requests for high-cost drugs. CMS may revisit this requirement in the future.

CMS appreciates commenters' feedback related to tying outreach to approved prior authorization requests (as opposed to any prior authorization request received). While the requirements in section 30.2.2.2 of this final part two guidance have been modified, should Part D sponsors undertake targeted outreach based on prior authorization processes, CMS supports limiting that outreach to approved requests only. The approach described above for targeted outreach during the plan year is in no way a recommendation for plans to implement additional utilization management edits on high-cost drugs.

Comment: Some commenters requested clarifications or made additional suggestions related to during the plan year targeted outreach, including requesting that notices not be required to be sent in the fourth quarter of the year, or, if sent late in the year, include information on how an enrollee could opt into the program for the subsequent year; requesting additional details on how during the plan year targeted notifications would apply to formulary or tiering exceptions processes; suggesting a lower threshold than \$600 or a threshold based on all Part D-related requests within a set timeframe, instead of a single drug; and suggesting that Part D sponsors be required to use real-time notification methods instead of mail for targeted notifications during the plan year, out of concern for potential mail delays.

Response: Part D sponsors must develop standardized processes for implementing their criteria for identification of enrollees likely to benefit from the program during the plan year. CMS expects Part D sponsors to develop criteria that provide for ongoing identification of enrollees likely to benefit from the program throughout the plan year. For enrollees identified late in the plan year, Part D sponsors may choose to provide information about how to opt into the program for the upcoming year in addition to how to opt in for the remainder of the current year. For enrollees identified as likely to benefit in December, Part D sponsors should not notify enrollees that they are likely to benefit in the current year; however, Part D sponsors may choose to provide them with information on how to opt into the program for the upcoming year. CMS recognizes that there may be a slight delay in written communications reaching the enrollee; as described in section 30.2.2.2 of this final part two guidance, if a Part D sponsor provides a telephonic notice, CMS requires that the written “Medicare Prescription Payment Plan Likely to Benefit Notice” and additional program information be sent within three calendar days of the telephonic notice. If Part D sponsors develop outreach criteria linked to drug tier or cost, they should also have standardized processes for handling formulary or tiering exceptions as part of the ongoing identification of enrollees likely to benefit from the program. Any identification approach designed by a Part D sponsor must be applied to their Part D enrollee population uniformly. Finally, Part D sponsors should continue to follow their standard processes for discussing options to lower OOP costs with enrollees, such as financial assistance programs or tiering exception requests.

As noted in section 30.2 of this final part two guidance, early notification of enrollees likely to benefit from the program (prior to the enrollee reaching the POS) will streamline the election process and prevent drug dispensing delays; as such, CMS expects Part D sponsors to develop rigorous approaches for ongoing identification of enrollees likely to benefit during the plan year.

Comment: Some commenters expressed concern that receiving multiple notifications within a short period of time (such as directly from the health plan and then from the pharmacy during the plan year) may cause enrollee confusion.

Response: CMS thanks the commenters for the feedback. While there may be the potential for enrollee confusion if they receive multiple notices in a short period of time or a notice soon after

opting into the Medicare Prescription Payment Plan, CMS believes that, especially in the first year of the program, it is important that enrollees who are likely to benefit from the program have the opportunity to be notified through multiple mechanisms, such as directly from their plan and at the pharmacy POS. Part D sponsors should be aware of the potential for multiple notifications when contacted by an enrollee to discuss participation in the program and should counsel enrollees accordingly.

Comment: A commenter requested requiring targeted outreach to enrollees who recently lost LIS status.

Response: CMS thanks the commenter for this suggestion and notes that the existing notice sent to enrollees who no longer qualify for LIS (CMS Product No. 11198) directs enrollees to resources, such as Medicare.gov, the Medicare & You handbook, or their State Health Insurance Assistance Program, all of which will provide information on the Medicare Prescription Payment Plan. In addition, Part D sponsors are encouraged to conduct targeted outreach to enrollees who recently lost LIS status and discuss if the Medicare Prescription Payment Plan may benefit them.

Comment: A commenter expressed concern about telephonic outreach to enrollees who are likely to benefit from the Medicare Prescription Payment Plan, citing concerns about fraud. The commenter requested that telephone calls be restricted to information only and direct enrollees to reputable sources of information, such as Medicare.gov or their Part D sponsor's website.

Response: CMS thanks the commenter for sharing their concerns and agrees that Part D enrollees should be vigilant about potential Medicare fraud. CMS encourages Part D sponsors to help protect their enrollees from Medicare fraud by educating enrollees on how to verify legitimate requests for information from their Part D sponsor. In addition, CMS reminds Part D sponsors that they must adhere to the regulations and requirements referenced in section 30 of this final part two guidance with regard to Part D sponsors' communications and marketing materials and activities; specifically, that while the initial notice may be provided via telephone, the written "Medicare Prescription Payment Plan Likely to Benefit Notice" and additional information should be sent within three calendar days of the telephone notification. Such requirements will help validate the telephone call from the Part D sponsor.

Comment: Some commenters expressed support for the requirements related to targeted outreach at POS, including CMS' statements that providing the notice at POS does not require pharmacy staff to provide additional education or counseling and CMS' requirement that the Part D sponsor clearly outline next steps for an enrollee when they opt in after a POS notification. A commenter requested that pharmacy staff be required to provide education on the Medicare Prescription Payment Plan at the POS.

Response: CMS thanks the commenters for their feedback. Section 1860D-2(b)(2)(E)(v)(III)(ee) of the Act requires that the Part D plan sponsor provide that a pharmacy, after receiving 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. As described in section 30.2.2.3 of this final part two guidance, this requirement for pharmacies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in no way obligates pharmacy staff to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. CMS encourages pharmacies to make additional educational resources available to Part D enrollees identified as likely to benefit from the program at POS; however, ultimately, the Medicare Prescription Payment Plan is an arrangement between the Part D sponsor and the Part D enrollee, and, as such, the Part D sponsor bears the responsibility for managing election, education, and other processes related to program participation.

Comment: A few commenters expressed concern about the potential burden of operationalizing POS messaging, particularly for smaller Part D plans and rural pharmacies. A commenter requested that CMS clarify the mechanism that Part D sponsors must have to notify a pharmacy 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 participating in the program.

Response: CMS appreciates the commenters’ concerns. As noted in the final part one guidance, there is 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. In addition, all covered entities such as health insurers and pharmacies, including those participating in the Part D program, are required to use the NCPDP Telecommunication Standard consistent with 45 CFR 162.920. As such, all Part D sponsors must use the Approved Message Codes developed by NCPDP for communication with network pharmacies about enrollees’ Medicare Prescription Payment Plan status as appropriate.

Comment: Many commenters requested clarifications from CMS regarding targeted notifications, including how frequently an enrollee must be notified, examples of supplemental targeted outreach criteria, whether plans can exclude certain enrollees from notification requirements (such as LIS enrollees, when the Part D sponsor is aware of a change in clinical status for an enrollee, or when an enrollee has multiple high cost prescriptions within a short time frame). Commenters also asked for guidance on whether true out-of-pocket (TrOOP) or OOP costs should be used to identify enrollees for targeted outreach prior to the plan year, how to handle tiering and formulary exceptions and Medicare Prescription Payment Plan notices, and how to handle precluded enrollees. A commenter asked if Part D sponsors must notify enrollees prior to the plan year if the Part D sponsor is aware that the enrollee is switching to a new plan in the upcoming year. Finally, a commenter requested that CMS require Part D sponsors to provide information to Part D enrollees identified as likely to benefit from the program late in the plan year about how they can opt into the program for the subsequent year.

Response: For the targeted outreach processes required in section 60.2.3 of the final part one guidance and section 30.2.2.3 of this final part two guidance, Part D sponsors must notify the pharmacy each time an eligible enrollee incurs OOP costs that meet or exceed the POS threshold (\$600 for CY 2025), even if the enrollee has previously declined to participate in the program. This applies to covered Part D drugs approved through the formulary or tiering exceptions process. Part D sponsors are not required to notify the pharmacy during the month of December, when an individual is already a participant in the Medicare Prescription Payment Plan, or when an enrollee is not eligible for participation in the program such as if the enrollee is precluded from participating in the program.⁴ For all targeted outreach requirements set forth in the final part one and final part two guidance documents, Part D sponsors are not allowed to exclude enrollees who are otherwise eligible and meet the notification criteria; however, as stated in section 30.2.2.1 of this final part two guidance, Part D sponsors should be aware that potential changes to a Part D enrollee’s clinical condition, medication status, or cost sharing (e.g., discontinuation of therapy or addition of supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the program and should counsel enrollees accordingly.

The prior to plan year targeted outreach described in section 30.2.2.1 of this final part two guidance is based on OOP costs for CY 2024, not TrOOP; for example, if an LIS-eligible enrollee incurred \$3,000 in TrOOP costs in the first three quarters of 2024 but had only \$10 in OOP costs, the Part D sponsor should not send that enrollee a notice prior to the plan year. Part D sponsors are required to send the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to the plan year to identified enrollees even when an individual enrollee is switching plans for the upcoming year. At the start of program operation in CY 2025, no enrollees will be precluded from participating, so the prior to plan year notifications should be sent to all identified enrollees. Prior to plan year notification policies for subsequent years of the program will be addressed in the future.

Finally, regarding late in the year notifications, CMS appreciates the suggestion and will take that into consideration in the future.

Comment: Some commenters made suggestions for targeted outreach enhancements in future years, including adjusting the dollar thresholds based on program performance or inflation, revisiting the use of OOP costs incurred versus TrOOP, and reassessing the timeframes and lookback for notifications. A commenter urged CMS to monitor any emerging technologies, like

⁴ Additional requirements related to enrollee preclusion from the Medicare Prescription Payment Plan are included in the final part one guidance. As stated in section 80.3 of the 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 and 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 enrollee is eligible to request to participate in the program again.

artificial intelligence, used to identify enrollees for targeted outreach, to ensure that such practices do not reinforce existing biases and disparities in the health care system.

Response: CMS thanks the commenters for their suggestions. For CY 2025, Part D sponsors are required to adhere to the targeted outreach requirements outlined in section 60.2 of the final part one guidance and section 30.2 of this final part two guidance. CMS will consider revised or additional requirements for targeted outreach for future years.

Communications with Contracted Providers and Pharmacies (Section 30.2.3)

Comment: A few commenters expressed appreciation for CMS' recognition of the importance of providers and pharmacists in cost-of-care conversations. A commenter stated that communications with providers and pharmacies would be challenging due to competing priorities and time limitations. Some commenters requested that CMS require, as opposed to encourage, Part D sponsors to communicate with contracted providers and pharmacies about the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their support and reiterates the importance of providers and pharmacists in engaging enrollees in cost-of-care discussions. Section 30.2.3 of this final part two guidance encourages Part D sponsors to provide Medicare Prescription Payment Plan-related information to their contracted providers and network pharmacies, and we also direct readers to sections 40.2 and 40.3 of this final part two guidance, which outline CMS efforts to provide tools and resources for a wide variety of interested parties, including providers and pharmacists.

Comment: Some commenters suggested that CMS develop standardized educational products for Part D sponsors to use with pharmacies and providers. Commenters also noted the importance of CMS providing additional educational resources for providers and pharmacies, including trainings, videos, case studies, and frequently asked questions documents (FAQs), as well as updates to Medicare.gov, Medicare Plan Finder, and online calculators. A commenter encouraged CMS to consider other sections of the health care system that could be engaged in Medicare Prescription Payment Plan educational efforts, such as community health workers.

Response: CMS appreciates the comments and agrees that a variety of resources will be helpful in educating enrollees and key interested parties about the program. We direct readers to section 40 of this final part two guidance for additional information on CMS-developed resources including a fact sheet that can be used with both pharmacies and providers. In addition, changes to the Medicare Plan Finder for CY 2025 were announced in the May 31, 2024 HPMS memo

“Medicare Plan Finder Enhancements for Contract Year 2025.”⁵ The memo includes a summary of changes made to reflect the Medicare Prescription Payment Plan.

Communications with Program Participants and Model Materials Requirements for Part D Sponsors (Section 30.3)

Comment: A few commenters requested that CMS issue guidance to sponsors on employing various communications methods beyond required telephonic and written notices, which could include informational videos, interactive online Q&A sessions, and community outreach events. A commenter stated that sponsors should be required to use more than one method of communication, and another requested that sponsors be required to transmit all notices electronically.

Response: CMS thanks commenters for their feedback. Education and outreach requirements described in section 30 of this final part two guidance, including those around the use of telephonic and written notices, are minimum requirements for Part D sponsors. Part D sponsors are certainly encouraged to employ other communication methods, such as online information sessions or community outreach events. CMS reminds Part D sponsors that any additional communications with Part D enrollees must comply with existing Part D regulations at 42 CFR Part 423 subpart V, which set forth standards for Part D required materials, content, and delivery requirements. Part D sponsors should also refer to the MCMG for CMS interpretation and examples of select subpart V provisions, as well as HPMS submission rules and processes for marketing materials. Regarding Part D sponsors’ use of multiple communications methods or requiring all communications to be sent electronically, unless specifically specified for a certain notice throughout section 30.3 of this final part two guidance, Part D sponsors should transmit Medicare Prescription Payment Plan notices in the participant’s preferred and authorized contact method.

Overview of Election Requirements (Section 30.3.1)

Comment: A few commenters expressed general support for election requirements and the availability of paper, phone, and web election options, with a commenter also requesting that Part D enrollees be able to opt into the program via their Medicare.gov account. A couple of commenters urged CMS to require Part D sponsors to include a clear explanation of opt-in mechanisms by mail, telephone, or on the website, with step-by-step instructions and information regarding the timeline for receipt, processing, and confirmation of their request. Other commenters asked that CMS establish a robust support system for Part D enrollees, particularly

⁵ The May 31, 2024 HPMS memo titled “Medicare Plan Finder Enhancements for Contract Year 2025” can be found by downloading the attachments available at this link: <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-may-27-31>.

through use of a monthly cost calculator or other decision aids that can help beneficiaries understand how the program would impact their costs.

One commenter requested that CMS limit the ways in which enrollees can opt into the program in the first year to simplify the process. Relatedly, a commenter recommended that the election request form not be required to be accepted via email, consistent with Part D plan enrollment guidance. A commenter asked whether CMS would need to confirm Part D plan enrollment prior to the person opting into the Medicare Prescription Payment Plan. Additionally, several commenters asked CMS to confirm whether the option to elect into the Medicare Prescription Payment Plan will also be included on the Part D plan enrollment form and said that doing so would add operational burden and complexity, and a commenter urged CMS to reconsider adding the option for Part D enrollees to elect during the time of enrollment in a new plan, as enrollees may misunderstand the program and confuse the program with how their premiums will be billed.

Response: CMS thanks commenters for their support of the election requirements. CMS notes that Part D sponsors are required to include a description of how to opt into and out of the program, including timing requirements around election effectuation, on their websites. Additionally, as described in section 40.2 of this final part two guidance, CMS is making appropriate modifications to existing Part D resources to ensure Part D enrollees will be able to learn about the program and understand how it may benefit them. These resources will include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder,⁶ among others.

Regarding the suggestion that Part D enrollees be able to elect into the program through their Medicare.gov account, CMS reminds readers that the Medicare Prescription Payment Plan is an arrangement between the Part D sponsor and the Part D enrollee. As such, Part D sponsors are responsible for managing election, education, and other processes related to participation in the program. While Medicare.gov may be a useful educational resource for Part D enrollees, as described in section 40 of this final part two guidance, Part D sponsors must ultimately be responsible for processing election requests. CMS declines to limit the number of required election mechanisms Part D sponsors must offer to Part D enrollees or bar other election request formats (i.e., email or handwritten letter), as outlined in section 70.3.1 of the final part one guidance. CMS believes that allowing Part D enrollees to opt in via a paper form, a telephonic request, an electronic mechanism, or other mechanisms, will ensure that Part D enrollees will be able to effectively opt into the program regardless of potential limiting factors, such as their accessibility to or level of comfort with technology.

In response to comments on how election into the Medicare Prescription Payment Plan interacts with enrollment in a new Part D plan, CMS reiterates its requirement in section 70.3.3 of the

⁶ Changes to the Medicare Plan Finder for CY 2025 were announced in the May 31, 2024 HPMS memo “Medicare Plan Finder Enhancements for Contract Year 2025.” The memo includes a summary of changes made to reflect the Medicare Prescription Payment Plan.

final part one guidance, which states that 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. CMS notes that Part D sponsors are responsible for managing election into the program and all aspects of participation. When an individual enrolls in a new Part D plan during a Part D enrollment period and also submits an election request form for the Medicare Prescription Payment Plan, the Part D sponsor must process the election request form within ten calendar days of receipt of the request. The 10 calendar day window grants Part D sponsors sufficient time to process the Part D plan enrollment request and receive confirmation of enrollment from CMS before the Part D sponsor must notify the individual of the status of their Medicare Prescription Payment Plan election request. The Part D sponsor must not deny a Medicare Prescription Payment Plan election request due to delays in the Part D plan enrollment process that are the fault of the Part D sponsor or CMS. Instead, if system issues or delays in the Part D plan enrollment process that result in the Part D sponsor not receiving confirmation of Part D plan enrollment within ten calendar days of receiving the Medicare Prescription Payment Plan election request, the Part D sponsor may wait to receive confirmation of Part D plan enrollment from CMS before notifying the individual of their program election request status. In these cases, the Part D sponsor must notify the individual as quickly as possible. Additionally, the model Part D plan enrollment form will not be updated to include a field for Medicare Prescription Payment Plan election.

Comment: Regarding paper requests, a couple of commenters stated that the date of receipt should not be the day the sponsor receives the mailed form; instead, it should be the postmarked date. Additionally, one of the commenters requested that CMS standardize the form and not allow sponsors to develop their own.

Response: CMS thanks commenters for their feedback but declines to change the definition of the election request date for requests sent by mail, which, as described in section 30.3.1.2 of this final part two guidance, is the date the mailed election request is received by the Part D sponsor (i.e., arrives in the Part D sponsor’s mailbox or mailroom), regardless of the date of the postmark. This definition is consistent with the definition of receipt of a mailed Part D enrollment request, as described in section 10 of the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment, and Disenrollment. CMS declines to standardize the election request form but certainly encourages Part D sponsors to use the CMS-developed model “Medicare Prescription Payment Plan Participation Request Form” included in the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package. Additionally, section 30.3.1.1 of this final part two guidance has been updated to list elements that are required for the election request form, should a Part D sponsor choose to develop its own.

Comment: Regarding phone requests, a couple of commenters requested that CMS draft a model call script for sponsors to standardize how the information on the model election form is

conveyed during the call. A couple of commenters recommended that CMS remind sponsors to try to obtain all needed information during one phone call.

Response: As stated in section 30.3.1.3 of this final part two guidance, for requests made by telephone, the call must be based on a script previously approved by the Part D sponsor that includes the required elements for the election request form, outlined in section 30.3.1.1 of this final part two guidance, and that is based on the content of the model “Medicare Prescription Payment Plan Participation Request Form.” CMS expects Part D sponsors to comply with this requirement and convey all necessary information. Additionally, section 30.3.1.3 of this final part two guidance states that CMS expects Part D sponsors to complete the entirety of the program election request process in that single phone call. Section 30.3.1.1 of this final part two guidance has been updated to include what elements of information are required for a program election request to be considered “complete.”

Comment: Regarding website requests, a couple of commenters requested that CMS allow plans to host their electronic application behind a sign-in page on their member portals, which would allow them to confirm that the person is an active plan enrollee. Alternatively, a couple of commenters requested that the election request be displayed on the sponsor’s Medicare homepage and requested that a “pop-up” for the Medicare Prescription Payment Plan election appear when someone is enrolling in a Part D plan. Some commenters specifically requested that the online election mechanism be user friendly, prominently displayed, and truly “online” and not a link to a PDF form, and some commenters also suggesting that the tool allow an enrollee to verify if they are a program participant.

A commenter urged CMS to include a sponsor’s relevant mobile application as another mechanism for the request.

Response: CMS appreciates these comments. Part D sponsors may choose to require Part D enrollees to log into their member portal to access the online election request mechanism. CMS is not requiring any changes to Part D sponsors’ online Part D plan enrollment mechanisms to reflect the Medicare Prescription Payment Plan. In developing their Medicare Prescription Payment Plan website election request mechanisms, Part D sponsors are encouraged to make the process as user-friendly as possible. Further, they must design their website election request mechanism in such a way that satisfies the requirements described in section 70.3.1 of the final part one guidance and in sections 30.1.5 and 30.3.1.4 of this final part two guidance. Namely, the website application mechanism must provide evidence the election request was received and include a distinct step that requires Part D enrollees to click an “Opt-In Now” or “I Agree” type of button or tool. To meet these requirements, it is unlikely that a Part D sponsor could simply link to a PDF format of the election request form. Part D sponsors are encouraged, however, to include the election request form in a printable format on their website, should a Part D enrollee prefer to submit a paper election request form. Additionally, Part D sponsors may offer a mechanism through which Part D enrollees can verify if they are an active program participant,

and Part D sponsors may also offer election request mechanisms through their mobile application, in addition to required website mechanism.

Comment: A few commenters requested that CMS not require education and outreach, specifically using the election form, to enrollees with minimal cost sharing, such as LIS, D-SNP, or MMP enrollees, as sending materials to those who are unlikely to benefit can cause confusion and will result in additional administrative burden for plans. If CMS keeps the requirements to send materials to all enrollees, a couple of commenters asked that CMS allow separate but consistent materials targeted to particular members.

Response: CMS thanks commenters for their feedback but notes that 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. Further, under section 1860D–2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D–2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also provide educational materials to all Part D enrollees. These statutory obligations apply regardless of whether Part D enrollees typically have low cost sharing amounts.⁷ CMS appreciates the request for separate but consistent materials targeted at particular members with low cost sharing; however, in an effort to maintain consistency across Part D plan sponsors so all Part D enrollees have a similar and seamless experience with the new program, CMS is declining to offer separate materials. CMS does, however, encourage all Part D sponsors to directly communicate with their Part D enrollees about this program and help them understand whether the Medicare Prescription Payment Plan is a beneficial option for them given their unique situation.

Comment: A few commenters urged CMS to require sponsors to provide interested enrollees with information tailored to their specific needs and asked for clarification on what constitutes a “review” of an enrollee’s expected monthly payments, as described in the guidance. A commenter asked that CMS provide model language for the review.

Response: CMS strongly encourages all Part D sponsors to communicate with interested Part D enrollees about this program, offer them additional information about the program, and help them understand whether the Medicare Prescription Payment Plan may be a beneficial option for them. Requiring Part D sponsors to provide all interested enrollees with individually tailored

⁷ CMS, however, understands that the Medicare Prescription Payment Plan has no practical application for PACE participants or enrollees in plans that exclusively charge \$0 cost sharing for covered Part D drugs. As such, as stated above and in section 10 of this final part two guidance, CMS does not expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the final part one guidance or this final part two guidance.

information may be overly burdensome. CMS declines to require this type of outreach. A “review” of a Part D enrollee’s expected estimated monthly payments under the program could take different forms, including asking the Part D enrollee about their expected Part D drug costs, the timing of such costs, and then explaining how the program calculation may spread those costs over the remaining months in the plan year. CMS expects Part D sponsors to tailor these conversations to the unique situations, questions, and needs of the Part D enrollee and does not believe model language is applicable for these reviews.

Comment: A couple of commenters requested that CMS require sponsors to submit enrollment data to pharmacies.

Response: Part D sponsors will transmit Medicare Prescription Payment Plan participation data to pharmacies using the NCPDP Telecommunication Standard. Part D sponsors must do so in order to ensure that program participants will pay \$0 to the pharmacy for Part D covered drugs under the program.

Notice of Acceptance of Election (30.3.2)

Comment: A few commenters expressed support for the election approval notice. Some commenters requested that CMS give sponsors the flexibility to omit the telephone notification for election requests made during the plan year because written and telephonic notification is redundant. A few commenters specifically requested the notice of acceptance of election be omitted when someone opts in over the phone and completes the entire process on that single call, when additional information is needed to complete the election request, and when a confirmation of acceptance into the program is received from CMS within 24 hours. A commenter also asked CMS to confirm whether a voicemail would satisfy the telephone requirement. A couple of commenters requested that the method of communication be left to member preference. Further, another commenter requested clarification on whether the notice must include a list of requirements included in section 70.3 of the draft part one guidance, as the final part one guidance does not include this list.

Response: CMS thanks commenters for their support. Providing the Part D enrollee with prompt notice that their participation in the Medicare Prescription Payment Plan is effective is important for ensuring they are aware of their participation status as soon as possible. CMS is requiring Part D sponsors to deliver the notice first with a telephone call that is then followed by a written notice, as specified in section 30.3.2 of this final part two guidance. In cases where a Part D sponsor processes an election request over the phone in one single phone call and is able to confirm the request is approved and the Part D enrollee’s participation is active immediately, that same, single phone call can serve to meet the telephone notification requirement. In this case, however, the written notice requirement still applies and must be delivered within the specified timeframe in section 70.3.4 of the final part one guidance. Section 30.3.2 of this final part two guidance has been updated to reflect this situation.

When additional information is needed for a Part D sponsor to complete the election request, the Part D sponsor must follow the procedures and timing requirements in section 70.3.4 of the final part one guidance. Additionally, CMS notes that Medicare Prescription Payment Plan election request statuses will not be required to be submitted to CMS via a Daily Transaction Reply Report (DTRR). Therefore, Part D sponsors will not need to wait for a confirmation of program election from CMS when processing program election requests. Further, CMS is clarifying in section 30.3 of this final part two guidance that the telephonic notice of acceptance of election for election requests made during the plan year is considered delivered by the plan on the date (and time, if applicable) a plan speaks directly to or leaves a voicemail for a Part D enrollee or their representative. This is consistent with the definition of delivery outlined in section 10.5.3 of the Medicare Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.

Lastly, section 30.3.2 of this final part two guidance has been updated to include a description of the required elements for the notice of acceptance of election. Part D sponsors are also encouraged to use the CMS-developed “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan” included in the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package to meet the notice requirement.

Comment: A few commenters recommended that CMS allow three business days rather than calendar days to send the notice, citing staffing concerns for weekends and holidays, with one specifically asking CMS to consider a 10-calendar day timeframe. A commenter requested that CMS clarify what actions Part D sponsors are required to take in the event an acceptance transaction is received from CMS more than 24 hours after a submission, as sponsors often receive responses from submitted transactions three to four days after the submission date. The commenter recommended that CMS count the 24-hour timeframe from the date the plan receives the acceptance of program opt-in from CMS via the DTRR.

Response: CMS appreciates these comments and, as noted above, reiterates that providing the Part D enrollee with prompt notice that their participation in the Medicare Prescription Payment Plan is effective is important for ensuring they are aware of their participation status as soon as possible. As such, CMS is maintaining the requirement for Part D sponsors to deliver the notice of acceptance of election within three calendar days. Additionally, as stated above, Medicare Prescription Payment Plan election request statuses will not be required to be submitted to CMS via a DTRR, and Part D sponsors will not need to wait for an “acceptance transaction” when processing program election requests. Part D sponsors are responsible for all aspects of Part D enrollees’ participation in the program, including processing program election requests. CMS is requiring Part D sponsors to submit participant-level data on program election separately to CMS through MARx. This data collection effort is separate from Part D sponsors’ responsibility to manage program election for Part D enrollees and process election requests timely. Please see the

MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (CMS-10887; OMB 0938-1468) ICR for more information.

Notice of Failure to Pay (Section 30.3.3)

Comment: A few commenters recommended that CMS require additional notices to be sent during the grace period.

Response: CMS thanks commenters for their feedback and agrees that sending additional notices to program participants who have failed to pay their program balance would be beneficial. As such, CMS has revised section 30.3.3 of this final part two guidance to state that Part D sponsors may send interim notices after the initial notice, which is consistent with the notice requirements for failure to pay Part D premiums, outlined in the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment, and Disenrollment.

Notice of Termination of Election Following the End of Grace Period (Section 30.3.4)

Comment: Some commenters supported the requirement to send a notice of involuntary termination. A commenter asked whether the requirement to send the notice after the end of the grace period is three business days or calendar days, and a commenter recommended that sponsors have at least seven calendar days to generate the notice of termination following the end of the grace period. A commenter recommended that the notice should be considered mailed when it leaves the sponsor's possession, consistent with the enrollment/disenrollment guidance, and a commenter also asked whether there are any requirements on the mode in which the notice is delivered.

Response: CMS appreciates commenters' support and is clarifying that the requirement to send the notice of termination of election following the end of the grace period is three calendar days, not business days. This requirement is included in section 30.3.4 of this final part two guidance and is incorrectly stated as business days in the final part one guidance. The requirement to send this notice within three calendar days is based on the notice requirement for involuntary termination from a Part D plan due to failure to pay premiums, as outlined in section 50.3.1 of the Medicare Prescription Drug Benefit Manual, Chapter 3 – Eligibility, Enrollment, and Disenrollment, and, as such, CMS declines to extend the requirement to seven calendar days. CMS agrees that notices outlined in this final part two guidance are considered delivered on the date (and time, if applicable) the notice has left the possession of the plan or delegated entity, as is consistent with guidance on when notifications are considered delivered by the plan, outlined in section 10.5.3 of the Medicare Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Section 30.3 of this final part two guidance has been revised to include the definition of delivered. Further, section 30.3 of this final part two guidance has been updated to state that unless otherwise specified, Part D sponsors should deliver notices

summarized in section 30.3 of this final part two guidance according to the Part D enrollee's preferred and authorized contact method.

Language Access and Accessibility Requirements (Section 30.4)

Comment: Many commenters voiced support for CMS' proposed language access and accessibility requirements. A commenter requested that CMS provide translated materials, as it routinely does for other Part D model documents, and another commenter recommended CMS clarify that any materials Part D sponsors tailor must also meet these requirements.

Response: CMS thanks commenters for their support. CMS has provided a Spanish translation of the "Medicare Prescription Payment Plan Likely to Benefit Notice," which was available for public comment through the ICR process. CMS will consider making available translations in other languages in the future. Additionally, CMS directs commenters to section 30.4 of this final part two guidance, which states that Part D sponsors must meet existing Part D regulations for translating materials required under Part D at § 423.2267 and in the CY 2025 MA and Part D Final Rule. These regulations apply to all required materials, including standardized and model materials, Part D sponsors use, tailor, or develop for the Medicare Prescription Payment Plan.

Comment: A few commenters recommended that CMS explore using visual aids, videos, and other electronic formats to further strengthen accessibility of materials and program information, and a couple other commenters recommended that CMS encourage Part D sponsors to invest in meaningful efforts to reach underserved populations.

Response: CMS thanks commenters for their recommendations and agrees that accessibility of materials and engagement of a wide range of Medicare beneficiaries is vital for ensuring program information is easily and effectively understood by Part D enrollees. For resources provided by CMS directly to Part D enrollees, CMS will ensure compliance with Section 504 and Section 508 of the Rehabilitation Act of 1973, which address availability of auxiliary aids and accessibility of electronic information technology for individuals with disabilities. Further, Part D sponsors must ensure that all required materials, including standardized and model materials, related to the Medicare Prescription Payment Plan meet language access and accessibility requirements at § 423.2267, as outlined in section 30.4 of this final part two guidance. Section 30.4 of this final part two guidance has also been updated to state that Part D sponsors must ensure compliance with all applicable protections and requirements under section 1557 of the Affordable Care Act, including those related to language access, language assistance services, and auxiliary aids and services to protect individuals with limited English proficiency (LEP) and individuals with disabilities.⁸ Additionally, Part D sponsors have a statutory

⁸ The final rule regarding section 1557 of the Affordable Care Act is available at this link: <https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities>. A fact sheet is available at this link: <https://www.hhs.gov/civil-rights/for-individuals/section-1557/faqs/index.html>.

requirement to provide education on the program to all Part D enrollees, and CMS expects Part D sponsors to apply their education efforts equally among all enrollees.

Comment: A couple commenters requested clarity on whether and how pharmacies must meet translation requirements for the Medicare Prescription Payment Plan materials, and a commenter requested that CMS provide pharmacies with required translations. Another commenter reiterated that pharmacies are not responsible for providing materials to beneficiaries.

Response: CMS reminds commenters that Part D sponsors are responsible for meeting translation requirements outlined in section 30.4 of this final part two guidance and notes that CMS does not specifically obligate pharmacies to provide translated materials to Part D enrollees. The Part D sponsor must ensure compliance with the language access and accessibility requirements at § 423.2267, as outlined in section 30.4 of this final part two guidance.

As stated above, CMS is providing a Spanish translation of the “Medicare Prescription Payment Plan Likely to Benefit Notice” through the ICR process to support sponsors in meeting their requirements. Pharmacies should make available the CMS-developed Spanish-language version of the notice, in lieu of the English-language version, to their patients upon request.

CMS Part D Enrollee Education and Outreach (Section 40)

We note that commenters made similar recommendations in terms of the content and outreach strategy of the CMS-provided educational materials and CMS outreach strategy discussed in this section and communications requirements for Part D sponsors discussed in Section 30. As such, there is overlap between the comments and responses in this section and the comments and responses for Section 30.

Comment: A commenter stated that surveys suggest that a plurality of Medicare beneficiaries prefer to get information about the Medicare program via mail and suggested that CMS prioritize the use of direct mail rather than a website as a communication tool. The commenter also emphasized that a reliance on the internet as a communication tool could expose Medicare beneficiaries to fraudulent information.

Response: CMS appreciates the commenter’s feedback. CMS made modifications to a variety of existing Part D resources to ensure that individuals have the tools they need to learn about the availability of the program, including resources delivered by mail, such as the Medicare & You handbook.

Comment: Several commenters suggested that CMS develop additional resources to those described in the draft part two guidance, including online educational videos. Several commenters suggested that CMS develop information resources and tools for physicians and

other prescribers as well as pharmacies to provide additional opportunities for beneficiaries to learn about the program and enroll.

Several commenters suggested that CMS consider broadcasting Program Public Service Announcements, similar to those used to inform individuals about Affordable Care Act coverage and enrollment deadlines. A commenter suggested that CMS continue to explore additional options for providing information on LIS and the Medicare Prescription Payment Plan and build tools for understanding how the Medicare Prescription Payment Plan applies to LIS-eligible beneficiaries. Several commenters suggested that CMS deploy a television advertising campaign during the summer of 2024. Several commenters also suggested that CMS create a new letter with Medicare Prescription Payment Plan details outside of the ANOC process and with a different color. A commenter suggested that CMS convey to beneficiaries that the Medicare Prescription Payment Plan is not a new Medicare or Part D benefit. Rather, they suggest CMS inform beneficiaries that Medicare Prescription Payment Plan is a new Medicare program that will help patients.

Response: CMS thanks the commenters for their suggestions and will take them into consideration. Additional information related to available CMS-provided resources will be available ahead of the CY 2025 Annual Election Period.

Comment: Several commenters emphasized the importance of a CMS-led outreach strategy, stating that CMS should not rely on plan sponsor efforts and will need to ensure that its own education and outreach efforts are highly successful. Some commenters also expressed concern that the approach described in the draft part two guidance is insufficient to effectively educate beneficiaries.

Response: CMS appreciates the commenters' input. CMS is committed to ensuring that beneficiaries have the information they need to make informed decisions about participation in the Medicare Prescription Payment Plan and believe that the approach described in this final guidance will achieve that goal. As described in section 40 of this final guidance, CMS is developing new educational resources for the Medicare Prescription Payment Plan and is updating existing Part D resources to include information on this program. Both new and updated resources will include beneficiary-facing materials. CMS will continue to release these resources and additional information about outreach and training opportunities in the coming months.

Comment: Several commenters made specific recommendations for the content of the CMS-developed educational product. Several commenters recommended that the educational product developed by CMS contain a description of the beneficiaries that are likely to benefit from joining the Medicare Prescription Payment Plan. Some commenters also recommended that the educational product should reference participants' obligations to timely repay Part D sponsors

monthly despite not incurring any costs at the point of sale. A commenter expressed that it is important to consider education for beneficiaries who opt in late in the year.

Response: CMS appreciates the commenters' feedback. The fact sheet includes general information about which beneficiaries are likely to benefit from the Medicare Prescription Payment Plan as well as links to additional resources that beneficiaries may consult. The fact sheet also describes the billing process and consequences of non-payment. Finally, the fact sheet indicates that beneficiaries are more likely to benefit from the Medicare Prescription Payment Plan if they opt in earlier rather than later in the year.

Comment: Several commenters expressed support for a CMS-developed educational product. A commenter expressed support for CMS' encouragement of plan sponsors, pharmacies, healthcare providers, beneficiary advocates, and others to use this product for education. Several commenters also expressed support for CMS' proposal to modify existing Part D resources. Additionally, several commenters expressed support for CMS' intention to work with interested parties to ensure they have the support and materials needed to effectively communicate about the Medicare Prescription Payment Plan. Finally, several commenters expressed support for CMS providing messaging that communicates information that beneficiaries should consider when opting into the Medicare Prescription Payment Plan.

Response: CMS appreciates commenters' support.

Comment: Several commenters expressed concern that CMS is merely encouraging plan sponsors to use CMS-developed resources and recommended that CMS require plans to use these resources.

Response: CMS thanks the commenters for their input. CMS believes that plan sponsors have sufficient incentive to ensure that beneficiaries are well informed about the Medicare Prescription Payment Plan. Under section 1860D-2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D-2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also provide educational materials to all Part D enrollees. As such, we do not believe it is necessary to require rather than encourage use of CMS-developed resources.

Comment: Several commenters recommended that CMS prioritize updating Medicare Plan Finder to include educational information on the Medicare Prescription Payment Plan. Several commenters also suggested that CMS prioritize the Medicare & You handbook.

Response: CMS appreciates the commenters' input. CMS intends to update all relevant materials in advance of the CY 2025 Annual Election Period. In addition, changes to the Medicare Plan

Finder for CY 2025 were announced in the May 31, 2024 HPMS memo “Medicare Plan Finder Enhancements for Contract Year 2025.” The memo includes a summary of changes made to reflect the Medicare Prescription Payment Plan.

Comment: A commenter emphasized that it is important to ensure that the larger public is aware of the Medicare Prescription Payment Plan given the role that caregivers often play in assisting with Part D plan selection and enrollment. Several commenters stated that CMS should be proactive in reaching out to other interested parties, including providers, pharmacists, agents and brokers, and patient advocacy groups.

Response: CMS agrees that it is important to ensure that caregivers and others are adequately informed about the Medicare Prescription Payment Plan. CMS has had discussions with a diverse array of interested parties throughout the development of the Medicare Prescription Payment Plan and continues to be open to input from all interested parties to ensure they have the resources they need to assist beneficiaries in making informed decisions about the Medicare Prescription Payment Plan.

Comment: A commenter recommended that CMS provide more information about ways that the agency will work with providers and beneficiary advocates. A commenter asked whether CMS plans to release any training or hold a webinar on the Medicare Prescription Payment Plan.

Response: As stated in section 40.3 of this final part two guidance, CMS is engaging interested parties through national outreach efforts and will release additional information about outreach and training opportunities in coming months.

Pharmacy Processes (Section 50)

Comment: Some commenters expressed appreciation for CMS’ acknowledgement of the important role pharmacies will play in operationalizing the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their support.

Comment: A few commenters expressed concerns about difficulties with contract negotiations between Part D sponsors and network pharmacies to include the provision of the likely to benefit notification in pharmacy contracts. Some commenters noted that Part D sponsors will have limited visibility into when and how the notices are distributed at POS; these commenters requested that a contract provision to provide the likely to benefit notice suffice and that pharmacies not be required to track and report additional information to Part D sponsors. Some commenters also requested the guidance be updated around this point from “Part D sponsors must ensure” that a pharmacy informs to the enrollee to “Part D sponsors must encourage.” A commenter stated that Part D plans should establish mechanisms to monitor and enforce the POS

notifications at network pharmacies; however, another commenter requested that CMS confirm that Part D sponsors are not required to verify that pharmacies provide the notice.

Response: CMS thanks the commenters for their feedback. As noted in section 50 of this final part two guidance, 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 Part D 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 notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees. This provision is sufficient to meet the requirements outlined in section 50 of this final part two guidance for Part D sponsors to ensure that a pharmacy, after receiving such a notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Additional tracking or documentation by the pharmacy or on behalf of the pharmacy by the Part D sponsor that the notice has been delivered to the identified enrollee is not required.

Comment: A few commenters requested that CMS create best practices and/or comprehensive guidelines for pharmacy requirements to drive adherence. Another commenter requested enforcement discretion for pharmacy processes early in the implementation of the Medicare Prescription Payment Plan. Finally, a commenter requested that CMS prohibit Part D sponsors and their PBMs from using contract terms to force pharmacies to distribute additional educational material or using additional educational material to steer patients to vertically integrated or preferred pharmacies.

Response: CMS thanks the commenters for their input and will consider requests for additional guidance and supporting documents for future years of the program. For CY 2025, CMS expects Part D sponsors to comply with the requirements included in both the final part one and final part two guidance. The statute does not impose requirements on pharmacies to either distribute program educational materials or provide counseling to enrollees about the program, beyond providing the likely to benefit notification. Finally, CMS appreciates the commenter’s suggestions about additional educational material and will take them into consideration in the future.

Comment: A few commenters expressed concern about the additional burden being placed on pharmacies to operationalize the Medicare Prescription Payment Plan without any required additional pharmacy reimbursement. These commenters requested CMS mandate reimbursement to pharmacies for the time and materials required to implement the program. Some commenters also expressed concern about potential price concession fees levied by Part D sponsors related to Medicare Prescription Payment Plan quality measures. A commenter requested that CMS

prohibit Part D sponsors from implementing new auditing requirements and potential price concessions related to pharmacy distribution of the “Medicare Prescription Payment Plan Likely to Benefit Notice.”

Response: CMS appreciates the commenters’ concerns and thanks the commenters for their feedback. Consistent with section 1860D–11(i) of the Act, CMS may not interfere with the negotiations between Part D sponsors and pharmacies and generally may not institute a price structure for the reimbursement of covered Part D drugs. Further, CMS does not have the statutory authority to directly reimburse Part D sponsors’ contracted pharmacies for costs associated with administering the program. That said, CMS recognizes the important role that pharmacies will play in the implementation of this program and strongly encourages Part D sponsors to ensure that pharmacies receive adequate reimbursement for services provided to Part D enrollees related to participation in the Medicare Prescription Payment Plan.

As stated in section 50.2 of the final part one 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. Should Part D sponsors and pharmacies come to contractual arrangements that reimburse pharmacies for program operations through a non-dispensing fee mechanism (e.g., remuneration for administrative services), these arrangements must be reported appropriately via the bid pricing tool and direct and indirect remuneration (DIR) reporting, as necessary.

Finally, CMS appreciates commenters’ concerns related to auditing, quality measures, and associated fees and will take them into consideration in the future.

Comment: A few commenters requested additional information related to the standardized processes for Part D sponsors and their PBMs to provide likely to benefit and program participation information to pharmacies. Some commenters requested that CMS outline the specific NCPDP codes used to communicate an enrollee’s status with pharmacies. A commenter requested that CMS require that Part D sponsors and their PBMs create a process to notify pharmacies if an enrollee declines participation in the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their feedback. As noted elsewhere in this document, NCPDP is developing values for Approved Message Code (548-6F) responses that provide a standardized way for Part D sponsors and their PBMs to communicate an enrollee’s Medicare Prescription Payment Plan status to pharmacies. CMS supports this work and requires that Part D sponsors utilize the NCPDP Telecommunication Standard for notifications to the pharmacy.

Some enrollees may decline to opt into the Medicare Prescription Payment Plan on an earlier notification but change their minds with a subsequent high-cost prescription fill. As such, Part D

sponsors may not exclude eligible enrollees from their notifications to the pharmacy when they incur OOP costs that otherwise meet the POS notification requirements. CMS notes, however, that if an enrollee has already been a participant in the Medicare Prescription Payment Plan during the current calendar year and is now no longer participating (whether voluntarily or involuntarily removed from the program), then the Part D sponsor is not required to send the Approved Message Code indicating that the enrollee is likely to benefit from the program.

Comment: A few commenters expressed concern that once an enrollee opts into the Medicare Prescription Payment Plan, they will no longer have visibility into the OOP costs they are incurring for Part D drugs. A commenter requested that CMS provide instructions for pharmacy staff on how to estimate when and how much a participant will be billed for the medications they are picking up.

Response: CMS appreciates commenters' concern about a potential lack of transparency around OOP costs incurred at the POS and may consider this issue in the future. However, we also note that section 1860D-2(b)(2)(E) of the Act, as added by section 11202 of the IRA, requires the Part D sponsor to calculate monthly payments and bill participants. CMS strongly encourages Part D sponsors to educate program participants on the options for assessing OOP costs prior to the pharmacy POS (such as utilizing interactive prescription drug cost tools available on the Part D sponsor's website or calling the plan's customer service line).

Comment: A commenter requested that CMS make available to pharmacies an enrollee's program participation status and claim billing identified data via the Pharmacy Eligibility Inquiry Transaction (also referred to as an E1 transaction). The commenter stated that inclusion on the E1 transaction would prevent inconsistencies in applying all claims for the participant to the monthly billing process.

Response: 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 commenter requested that CMS explicitly explain what it expects from Part D sponsors when it states the requirements are the same for all pharmacy settings except as "otherwise required in this guidance or under other applicable requirements."

Response: As noted in section 50 of this final part two guidance, in general, Medicare Prescription Payment Plan requirements apply to all pharmacy types; however, CMS recognizes that there may be operational differences by pharmacy type. For example, as noted in section 50.3.2 of this final part two guidance, while a Part D sponsor is, in general, required to notify the pharmacy when an enrollee incurs OOP costs at or above the POS threshold, CMS is not requiring that Part D sponsors return the POS notification when the claim is received from an

Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) pharmacy, given that I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. Please refer to section 50 of this final part two guidance for information related to pharmacy processes and where requirements for Part D sponsors and/or pharmacies may vary by pharmacy type.

Comment: A few commenters requested that CMS remove the term “primary” from references to the “primary Part D claim response” in the final part two guidance.

Response: CMS thanks the commenters for the suggestion. This final part two guidance has been updated to remove “primary” and instead refer to the Part D claim response.

Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount (Section 50.1)

Comment: Some commenters supported CMS’ statement that Part D sponsors should ensure their customer service representatives are aware of enrollees’ supplemental coverage. Some commenters requested that CMS provide additional instructions for pharmacies and Part D sponsors on how to counsel enrollees identified as likely to benefit who have supplemental coverage. A commenter stated that Part D sponsor customer service representatives may not have insight into a specific enrollee’s supplemental coverage, so may not be able to provide guidance regarding Medicare Prescription Payment Plan election. Another commenter expressed concern that directing enrollees who have supplemental coverage to seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan puts undue burden on enrollees.

Response: CMS thanks the commenters for their feedback. As noted in section 50.1 of this final part two guidance, Part D sponsors should prepare their customer service representatives for discussing program election with potential participants. This may include reviewing records for indicating supplemental coverage or other health insurance (OHI) but could also involve a discussion with the enrollee about how they pay for covered Part D drugs and what other benefits or charities they may have available. CMS strives to make the program election process straightforward for enrollees; however, it is also important to ensure that all potential participants understand the financial implications of participation in this program and have the necessary information to make an informed decision. Regarding the request for additional instructions for pharmacies on how to counsel enrollees, CMS reiterates that the distribution of the “Medicare Prescription Payment Plan Likely to Benefit Notice” by pharmacies in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee.

Comment: Many commenters requested clarifications related to supplemental coverage and the Medicare Prescription Payment Plan, including how to handle billing for participants with supplemental coverage such as state pharmaceutical assistance programs (SPAPs), if notifications could be suppressed for enrollees with supplemental coverage, and how the program works with Medicare Secondary Payers (MSP). A few commenters expressed concern that the pharmacy claims process for the program will inhibit the use of charitable assistance.

Response: CMS thanks the commenters for their questions and refers readers to the final part one guidance for additional information related to pharmacy claims processing requirements for the Medicare Prescription Payment Plan. As stated in section 50.1 of the final part one guidance, the transaction processed through the Medicare Prescription Payment Plan Bank Identification Number (BIN) and Processor Control Number (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. 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. In situations where Medicare is the secondary payer, only the enrollee cost sharing under the Part D plan (after the primary payment) would be attributable to the Medicare Prescription Payment Plan. The requirements outlined in section 50.1 of the final part one guidance will allow Part D sponsors to continue to process claims in the established payer order discussed in the Medicare Prescription Drug Benefit Manual Chapter 14, Section 30.3.⁹ As a reminder, the Medicare Prescription Payment Plan BIN/PCN transaction is not considered to be OHI or a separate payer; this process does not change any existing rules for determining payer order when an enrollee has other coverage in addition to Part D.

CMS is aware of concerns that the return of a \$0 claim response at the POS may inhibit pharmacies from offering suggestions for their patients to explore other mechanisms to reduce OOP costs, like charitable organizations. CMS recognizes the importance of charitable organizations and other supplemental payers in reducing OOP costs for eligible Part D enrollees; nothing in this guidance prohibits pharmacies from continuing their current practices with regard to recommending charitable support to patients.

When Part D sponsors are generating billing statements, only the OOP costs the participant is directly responsible for paying should be included (see example B16 in the final part one guidance for a scenario in which the participant also has SPAP coverage). 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. Readers may also refer to the April 25, 2024, HPMS memo titled “Technical Memorandum on the Changes to True Out-of-Pocket

⁹ Refer to Medicare Prescription Drug Benefit Manual; Chapter 14 – Coordination of Benefits.

(TrOOP) Costs and the Calculation of the Maximum Monthly Cap for the Medicare Prescription Payment Plan” for additional examples that illustrate the Medicare Prescription Payment Plan calculations alongside TrOOP-accumulation calculations under the CY 2025 Part D benefit redesign.

Comment: A few commenters requested that CMS provide clear language in educational materials and notices regarding supplemental coverage. A commenter also requested that CMS include similar language stating that supplemental drugs (not covered by Part D) are not included in the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their feedback. The specific contents of CMS-developed educational materials and the model documents are outside of the scope of this document; however, as noted in section 50.1 of this final part two guidance, CMS has provided language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan.

As noted in section 30 of the final part one guidance, drugs that are excluded from Part D coverage are also excluded from the Medicare Prescription Payment Plan.¹⁰ Additionally, drugs covered under Medicare Parts A or B are excluded from the program. CMS has provided language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” and the CMS-developed fact sheet noting that this program only applies to covered Part D drugs.

Comment: A few commenters requested additional guidance related to situations in which a supplemental payer to Part D returns a higher final patient pay amount.

Response: As discussed in the final part one guidance, for participants in the Medicare Prescription Payment Plan, transactions processed through the program-specific BIN/PCN should be submitted last, in order to capture the final patient responsibility amount after all other payers have paid. This ensures that the Part D sponsor then pays the pharmacy for the amount the participant would otherwise owe at the POS to obtain their prescription. CMS is aware that occasionally, the final patient pay amount returned to the pharmacy by a supplemental payer for a covered Part D drug is higher than the original Part D patient pay amount. CMS has modified section 50.1 of this final part two guidance to note that in these cases, for the program participant’s portion of the claim (what they would have paid directly to the pharmacy), the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant’s original Part D cost sharing, as determined by their plan-specific benefit structure.

¹⁰ Covered Part D drug has the meaning set forth at § 423.100.

Pharmacy POS Notifications Late in the Plan Year (Section 50.2)

Comment: A few commenters supported Part D sponsors ensuring their customer service representatives are aware of late-in-year enrollment and how this may impact the likelihood of benefit from the program. A few commenters expressed concern that this could be confusing to enrollees; some of those commenters suggested alternative calculations to adjust payments in those situations. Some commenters requested additional clarifications and education for enrollees on this topic, including examples and calculators.

Response: CMS thanks the commenters for their feedback and acknowledges that specific enrollee circumstances (such as receiving “Medicare Prescription Payment Plan Likely to Benefit Notice” based on high prescription drug costs late in the year) may make it less likely that an enrollee who opts into the program will meet the standardized definition of likely to benefit.¹¹ As noted in section 30.3.1 of this final part two guidance, Part D sponsors are encouraged to provide support tailored to the potential participant’s unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program, which could include late in year elections with high first month maximum monthly cap values. Finally, CMS notes that it does not have the authority to change the statutory formula for the maximum monthly cap calculations.

Comment: A few commenters requested reinforcement from CMS that notices do not need to be distributed in December. Some commenters requested that notices be stopped earlier in the year, such as before November or before the fourth quarter, instead of December.

Response: As stated in the final part one guidance and in section 30.2.2.2 of this final part two guidance, CMS is requesting 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.

Pharmacy POS Notifications in Retail and Non-Retail Pharmacies (Section 50.3)

Comment: Some commenters expressed support for the POS notification requirement, including the requirement for distribution of hard copies of the “Medicare Prescription Payment Plan Likely to Benefit Notice” in settings with direct contact with enrollees, the application of the

¹¹ Refer to section 60.2.1 of the final part one guidance for additional details.

requirements to all pharmacy types, and the option for pharmacies to leverage additional notification strategies.

Response: CMS thanks the commenters for their support.

Comment: Many commenters requested flexibility and/or exceptions in how the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided. Some of these commenters requested that the notice be able to be provided in manners other than hard copy (such as text, web pop-up, email, or QR code), either based on pharmacy practices or the enrollee’s preferred mode of communication. A few commenters requested additional restrictions on when the “Medicare Prescription Payment Plan Likely to Benefit Notice” must be distributed by the pharmacy, such as limiting the requirement to initial fills and new prescription transfers or allowing certain drug tier exemptions.

Response: CMS thanks the commenters for their feedback. As described in section 50.3 of this final part two guidance, in pharmacy settings with direct contact with Part D enrollees, the Part D sponsor must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. These notification strategies are a minimum requirement; pharmacies are encouraged to leverage additional notification strategies (such as those mentioned by the commenters above).

Comment: A few commenters expressed concern about the requirements outlined in section 50.3 of the draft part two guidance, noting that it may be difficult to notify enrollees who choose not to pick up their prescription. A commenter expressed support for the Part D sponsor ensuring that the pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” if they are in contact with the Part D enrollee identified as likely to benefit, even if the enrollee declines to complete the prescription filling process.

Response: CMS thanks the commenters for their feedback and recognizes the challenge in reaching identified Part D enrollees who do not pick up their prescriptions. The requirement outlined in section 50.3 of this final part two guidance for the pharmacy to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee even if the enrollee declines to fill the prescription only applies to situations in which a pharmacy is in contact with the identified enrollee (e.g., the enrollee presents to the pharmacy and then declines the prescription or, in a mail order setting, the pharmacy is on the phone with the enrollee). As noted elsewhere in this document, pharmacies are encouraged to develop additional notification strategies, but CMS does not expect pharmacies to take measures beyond their typical notification strategy to contact enrollees who chose not to pick up their prescription.

Comment: A few commenters requested that CMS provide additional detail related to expectations for pharmacy practices when a person picks up the prescription on behalf of the Part D enrollee.

Response: As noted in section 50.3 of this final part two guidance, in pharmacy settings in which there is direct contact with enrollees (e.g., community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. If a prescription is picked up by a person acting on behalf of the Part D enrollee, the Part D sponsor must require the pharmacy to provide the person who is picking up the prescription with the “Medicare Prescription Payment Plan Likely to Benefit Notice.” This applies whether or not the person picking up the prescription is the Part D enrollee’s authorized representative. However, only the Part D enrollee or their authorized representative may opt into the Medicare Prescription Payment Plan.

Comment: A commenter expressed concern about the ability of pharmacy staff to have detailed conversations about the Medicare Prescription Payment Plan with an enrollee at the pharmacy counter. Another commenter expressed appreciation for CMS noting that pharmacies are not obligated to provide Medicare Prescription Payment Plan counseling or consultation to Part D enrollees when receiving the “Medicare Prescription Payment Plan Likely to Benefit Notice,” stating that doing so would divert time and resources from other patient care activities. A commenter also requested that CMS clarify that enrollees should seek advice and information about the program from their plan, PBM, or insurance agent, not the pharmacy.

Response: As noted in section 30.2.2.3 of this final part two guidance, the requirement to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. Pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan at the time they provide an enrollee with the notice. While Part D enrollees will have access to Medicare Prescription Payment Plan information from CMS and other resources (such as SHIP counselors), ultimately, the Part D sponsor is responsible for managing election, education, and other processes related to participation.

Comment: Some commenters requested that CMS or Part D sponsors provide pharmacies with additional educational materials related to the Medicare Prescription Payment Plan (such as brochures or videos) to share with enrollees identified as likely to benefit at the POS.

Response: CMS thanks the commenters for their suggestions and directs readers to sections 40.2 and 40.3 of this final part two guidance. Additional information related to available CMS-provided resources will be available ahead of the CY 2025 Annual Election Period.

Comment: Another commenter recommended CMS clarify that the Medicare Prescription Payment Plan only applies through the initial coverage phase, up to the \$2,000 annual OOP threshold.

Response: CMS thanks the commenter for their suggestion. As the commenter noted, in CY 2025, the annual OOP threshold will be \$2,000. Once an enrollee reaches the annual OOP threshold and enters the catastrophic phase of the benefit, the enrollee will pay no cost sharing for Part D drugs. This applies regardless of whether the enrollee is participating in the Medicare Prescription Payment Plan.

Comment: A commenter requested that CMS provide all pharmacies with program materials in either the five most common non-English languages or any additional non-English language that is the primary language of at least five percent of the individuals in a service area.

Response: CMS thanks the commenter for their suggestion. Part D sponsors are required to adhere to the language access and accessibility requirements at § 423.2267, as outlined in section 30.4 of this final part two guidance. CMS has provided a Spanish translation of the “Medicare Prescription Payment Plan Likely to Benefit Notice,” which was available for public comment through the ICR process; pharmacies should make this available for identified enrollees. CMS will consider making available translations in other languages in the future.

Comment: Some commenters stated appreciation for CMS’ acknowledgment of the unique operations of long-term care pharmacies. Other commenters, however, expressed concern that CMS’ guidance did not go far enough in addressing the complexities of long-term care and requested the exclusion of long-term care pharmacies (or other groups, such as all dual-eligible residents of long-term care facilities) from the likely to benefit notification requirements. Another commenter stated that many older adults in nursing homes or institutional settings may have cognitive impairments that would make it difficult to understand the Medicare Prescription Payment Plan requirements.

Response: CMS appreciates the commenters’ concerns and thanks them for their feedback. We agree that there are unique challenges with regard to long-term care pharmacies. However, 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. Additionally, section 1860D–2(b)(2)(E)(v)(III)(dd) of the Act requires Part D sponsors to have a mechanism to notify a pharmacy when a Part D enrollee incurs OOP costs that make it likely the Part D enrollee may benefit from participating in the program and section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires Part D sponsors to ensure that a pharmacy, after receiving such notification from the Part D sponsor, informs the Part D enrollee that they are likely to benefit from the program. The statute does not provide for exclusion of long-term care pharmacies or certain groups of Part D enrollees, such as dual-eligible residents of long-term care facilities. CMS notes that the requirement for provision of the “Medicare Prescription

Payment Plan Likely to Benefit Notice” is based on OOP costs incurred, so enrollees who are dual-eligible would be unlikely to incur such OOP costs as to warrant distribution of the notice. In addition, for enrollees with cognitive impairments, their authorized representative may be engaged in reviewing pharmacy and health plan documents and could choose to opt into the Medicare Prescription Payment Plan on behalf of the enrollee.

Comment: Some commenters requested clarification regarding the long-term care pharmacy notification requirements, including if the requirements applied to all patients using a long-term care pharmacy (assisted living, skilled nursing facility, group homes, community living, etc.). A commenter requested that CMS confirm that the “Medicare Prescription Payment Plan Likely to Benefit Notice” requirements do not apply to residents covered by Medicare Part A, as their medications are subject to the Consolidated Billing requirement. Some commenters noted the language in section 50.3.1 of the draft part two guidance stating that the plan sponsor “can require” long-term care pharmacies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” and requested clarification on whether provision of the likely to benefit notice was at the Part D sponsor’s discretion. Other commenters requested clarification on whether “the typical billing process” referenced in section 50.3.1 was referring to the pharmacy billing the plan or the pharmacy billing the Part D enrollee.

Response: CMS thanks the commenters for their feedback. Section 50.3.1 of this final part two guidance applies to long-term care pharmacies generally, regardless of setting type (e.g., nursing home, assisted living, etc.) or if the pharmacy utilizes retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). The Medicare Prescription Payment Plan only applies to Part D enrollees and covered Part D drugs; medications covered under Medicare Part A as part of a qualifying nursing facility stay are not included in the program.

Section 1860D–2(b)(2)(E)(v)(III)(ee) of the Act requires that Part D sponsors shall provide that a pharmacy, after receiving the notification that an enrollee is likely to benefit from the Medicare Prescription Payment Plan, informs the Part D enrollee of the notification. As such, the provision of the “Medicare Prescription Payment Plan Likely to Benefit Notice” through the pharmacy is a requirement that CMS places on Part D sponsors. In the long-term care pharmacy setting, the requirement for the Part D sponsor to ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit at the time the prescription is picked up does not apply, given that there is typically no POS encounter. Instead, Part D sponsors should ensure that the notice is provided to the Part D enrollee or their authorized representative at the time of the long-term care’s typical billing of cost sharing to the enrollee. CMS has made minor modifications to the language in section 50.3.1 of this final part two guidance to describe these requirements more clearly.

Comment: Some commenters stated appreciation for CMS’ acknowledgment of the unique operations of I/T/U pharmacies. A commenter noted that Part D sponsors do not have visibility

into IHS-eligibility and instead requested that CMS clarify that plans are not required to send the pharmacy notification to any I/T/U pharmacy.

Response: CMS thanks the commenters for their feedback. CMS has modified section 50.3.2 of this final part two guidance to clarify that Part D sponsors are not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program to any I/T/U pharmacy.

Comment: Many commenters requested modifications to the requirements for notification for pharmacies without an in-person interaction. Suggested changes included removing all notification requirements for mail-order or online/digital pharmacies, allowing other notification methods (such as text messages, website pop-ups, etc.), or only requiring paper notices with the prescription shipment. A few commenters requested that CMS require the prescription shipment be delayed until the notification is delivered.

Response: CMS thanks the commenters for their input. As noted in section 50.3.3 of this final part two guidance, Part D sponsors must require that pharmacies without an in-person encounter (such as mail order pharmacies) convey the content of the “Medicare Prescription Payment Plan Likely to Benefit Notice” to identified enrollees either via telephone or their preferred contact method. This is similar to the current requirements for Part D sponsors to arrange with network mail order pharmacies to provide enrollees with the “Medicare Prescription Drug Coverage and Your Rights” notice (Form CMS-10147) via the enrollee’s preferred method of communication. While CMS encourages pharmacies without in-person encounters to leverage existing touchpoints to provide the notice prior to processing payment and shipping the prescription, we decline to require delaying prescription shipment.

Comment: Commenters requested clarifications around mail-order and other pharmacies without in-person interactions, including whether scripting will be provided, if hard copies need to be provided in addition to a verbal notification, number and mode of outreach attempts required, and if the pharmacy needs to document the notice was provided. A commenter expressed concern about allowing Part D sponsors to establish pharmacy outreach procedures and suggested that CMS establish maximum thresholds.

Response: CMS thanks the commenters for their questions. In settings in which the notice is provided telephonically, pharmacies are expected to provide an abbreviated overview of the “Medicare Prescription Payment Plan Likely to Benefit Notice” and direct identified enrollees to their Part D sponsor for more information. CMS declines to provide specific scripting for the telephonic notice at this time, and pharmacies are not required to provide a hard copy of the notice after telephonic outreach. CMS may consider requiring specific “Medicare Prescription Payment Plan Likely to Benefit Notice” scripting for pharmacies in future rulemaking. As noted elsewhere in this document, Part D sponsors are not required to have pharmacies document the successful delivery of the “Medicare Prescription Payment Plan Likely to Benefit Notice.”

However, as noted in section 50.3.3 of this final part two guidance, CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees. CMS declines to require the mode or number of outreach attempts but expects expeditious notification of Part D enrollees identified as likely to benefit.

Readjudication of Prescription Drug Claims for New Program Participants (Section 50.4)

Comment: A few commenters expressed support for the requirement that pharmacies readjudicate prescriptions that have not yet been picked up and paid for once an enrollee has opted into the Medicare Prescription Payment Plan. Commenters also noted the importance of educating enrollees about this process. Many commenters requested that CMS retract or revise its requirement that outstanding prescriptions be readjudicated after an enrollee opts into the Medicare Prescription Payment Plan. They cited a variety of reasons for opposing this policy, including lack of plan visibility into what has not yet been paid for, burden (in time and cost) for pharmacies, challenges readjudicating claims if there are multiple pharmacies involved, difficulties differentiating covered Part D drugs from Part B or supplemental drugs, and issues with modifying the original date of service on the claim (including issues with TrOOP accumulation, billing, secondary payer reimbursement, provider abrasion, potential formulary change, impacts to drug utilization review, and impacts to refill timing and adherence metrics). A commenter suggested that the program effectuation date be the first of the next month to avoid these issues. Commenters suggested that, should CMS choose to maintain the readjudication requirement, it be limited to the prescription and pharmacy that triggered the likely to benefit notice and be enrollee choice instead of a mandate. A few commenters requested clarification on how this requirement would apply in long-term care pharmacies, online/digital pharmacies, and settings in which a pharmacy ships drugs before receipt of payment and before participation in the Medicare Prescription Payment Plan is effective. Additionally, a few commenters requested that CMS prohibit plans and PBMs from requiring pharmacies to reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for and picked up by the Part D enrollee.

Response: CMS thanks the commenters for their feedback. In section 50.4 of this final part two guidance, CMS has modified the requirements for readjudication of prescription drug claims for new Medicare Prescription Payment Plan participants. Only the prescription that triggered the likely to benefit notification must be reversed and reprocessed, so the date of service on the claim falls within the enrollee's dates of participation in the Medicare Prescription Payment Plan. If the enrollee has other prescriptions with earlier dates of service that have not yet been paid for and picked up, the pharmacy is only required to reverse and reprocess at the request of the participant. These requirements apply to all pharmacy types, including online/digital pharmacies and long-term care pharmacies – if an enrollee has not yet paid for a prescription and requests that it be reversed and reprocessed so as to be included under the Medicare Prescription Payment Plan, the pharmacy must do so.

These requirements only apply to covered Part D prescriptions for which the enrollee has not yet paid the pharmacy. If an enrollee has already paid the pharmacy for a prescription and meets the criteria to make an urgent election into the Medicare Prescription Payment Plan, the Part D sponsor, not the pharmacy, is responsible for reimbursing the enrollee's cost sharing, as described in section 70.3.7 of the final part one guidance.

Comment: A commenter requested that CMS provide examples illustrating the statement that the pharmacy is not required to reverse and resubmit the Part D claim, provided that the pharmacy otherwise obtains the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

Response: As noted in section 50.4 of this final part two guidance, when the Part D claim date of service is the same as the date of program effectuation (such as when the Part D sponsor is able to effectuate program participation the same day the request is received), the pharmacy is not required to reverse and resubmit the Part D claim, as long as the participant's OOP cost sharing is appropriately processed through the Medicare Prescription Payment Plan-specific BIN/PCN. For example, an enrollee receives a new high-cost prescription from their provider. When the enrollee goes to the pharmacy to pick up the prescription that same day, they receive the printed "Medicare Prescription Payment Plan Likely to Benefit Notice" and choose to hold off paying for that prescription while they step away to call their Part D sponsor. If the sponsor is able to effectuate their program participation immediately and provides digital verification of program participation via their health plan app, including the program-specific BIN/PCN, the pharmacist could process the secondary transaction to that BIN/PCN without having to reverse and reprocess the Part D claim.

Processing of Covered Part D Claims for Program Participants in Special Settings (Section 50.5)

Comment: A few commenters expressed support for CMS' discussion of processing claims for Medicare Prescription Payment Plan participants in special pharmacy settings.

Response: CMS thanks these commenters for their support.

Comment: Some commenters expressed concern that the guidance for long-term care pharmacies lacks clarity and would necessitate an individual, high-touch approach that would be burdensome to pharmacies. Another commenter requested that the program requirements not apply to dually eligible enrollees in long-term care settings. A commenter suggested that CMS monitor uncollected balances related to long-term care settings and consider future program modifications.

Response: CMS appreciates these commenters' feedback. As noted above, we agree that there are unique challenges for long-term care pharmacies, such as variation in payment arrangements between long-term care pharmacies and long-term care facilities and/or Part D enrollees. As such, this necessitates that Part D sponsors work with long-term care pharmacies to take a more nuanced approach to Medicare Prescription Payment Plan billing, so as to avoid any undue financial burden on the Part D enrollee.

Additionally, 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 (emphasis added); dual-eligible individuals may not be excluded from the program, but Part D sponsors are strongly encouraged to be aware of an enrollee's dual-eligible status when contacted by an enrollee to discuss participation in the program and should counsel enrollees (and/or their authorized representative) accordingly.

Comment: A few commenters requested clarification on I/T/U pharmacies and noted that Part D sponsors do not have visibility into which enrollees are IHS-eligible and should instead reject any Medicare Prescription Payment Plan BIN/PCN submitted from an I/T/U pharmacy.

Response: CMS thanks the commenters for their feedback and has modified section 50.5.2 of this final part two guidance to state that if a Part D sponsor receives a claim from an I/T/U pharmacy that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim.

Part D Bidding Guidance for CY 2025 (Section 60.1)

Comment: Many commenters expressed concern that uncertainty and lack of historical experience will make it difficult for health plans to accurately predict risk associated with the Medicare Prescription Payment Plan for bid purposes, with potentially disruptive impacts to plan premiums. Commenters urged CMS to provide more detailed guidance in developing assumptions for bid calculations related to the impacts of the Medicare Prescription Payment Plan for the initial program year. One commenter suggested that CMS create a standard loss estimate per patient per month, or other standardized calculation, that could be applied consistently across all sponsors, and issue guidance during the 2026 bidding process that allows sponsors to account for any true ups in loss estimates based on actuals from 2025. Another commenter encouraged CMS to publish information related to bad debt in CY 2025 to inform CY 2026 plan bids.

Response: CMS appreciates the commenters' concerns and thanks them for their suggestions, which CMS will consider for future bidding cycles. CMS will not provide estimates for utilization or bad debt associated with the Medicare Prescription Payment Plan for CY 2025 plan bids but requests that plan sponsors' estimates be reasonable and fully supported in

documentation. Additionally, CMS notes that the premium stabilization provision of the IRA functions to phase in the effects of the IRA on the average basic Part D premium and prevent unaffordable increases in premiums owed by Part D beneficiaries associated with implementation of the IRA.

Comment: Several commenters recommended that CMS explore the use of mitigation mechanisms, such as using demonstration authority to narrow risk corridors, to stabilize the Part D program and keep plan sponsors whole from program losses associated with the Medicare Prescription Payment Plan.

Response: CMS appreciates the concerns raised by the commenters. As noted in the CY 2025 Advance Notice, under section 1860D-15(e)(3)(C) of the Act and § 423.336(a)(2)(ii), CMS may establish a risk corridor with higher threshold risk percentages for Part D risk sharing. However, the statute does not permit CMS to narrow the corridors relative to the CY 2011 thresholds. While CMS acknowledges commenters' suggestions to use demonstration authority under section 402 of the Social Security Amendments of 1967, 42 U.S.C. § 1395b-1, to narrow the risk corridors, we note that doing so is outside of the authority of this document.

Comment: Several commenters expressed support for the modification of the Bid Pricing Tool (BPT) to reflect projected losses associated with the Medicare Prescription Payment Plan and urged CMS to finalize and post the modified BPT as soon as possible.

Response: CMS thanks the commenters for their support. The CY 2025 Bid Pricing Tool was released on April 5, 2024.

Comment: One commenter expressed concern that EGWPs will be disadvantaged because they do not submit bids and therefore cannot assume plan losses in their bids.

Response: CMS thanks the commenter for their feedback. In lieu of a plan-specific standardized bid amount, CMS uses the national average monthly bid amount (NAMBA) to determine the direct subsidy amount for Part D EGWPs. The NAMBA is the average of the standardized bid amount for each PDP and MA-PD plan, weighted by enrollment in these Part D plans. Consequently, payments to EGWPs in 2025 will reflect the average losses associated with the Medicare Prescription Payment Plan assumed in PDP and MA-PD bids.

Medical Loss Ratio (MLR) Instructions (Section 60.2)

Comment: Many commenters requested that CMS treat unsettled balances as claims included in the numerator of the MLR calculation. Commenters expressed concern that CMS' proposal to exclude unsettled balances from the numerator of the MLR calculation would penalize Part D sponsors despite the fact that they pay pharmacies the full negotiated price for a drug, including

enrollee cost sharing subject to the Medicare Prescription Payment Plan, and may have less control over Medicare Prescription Payment Plan unsettled balances compared to other administrative costs. Several commenters noted that Congress did not modify the MLR provisions of the statute directly or include any cross reference to the MLR provisions when enacting the provisions that establish the Medicare Prescription Payment Plan at section 1860D-2(b)(2)(E)(v)(VI) of the Act. Commenters stated that the IRA does not dictate that unsettled balances be treated as administrative expenses for purposes of MLR reporting and noted that treating unsettled balances as losses for government subsidy purposes is not inconsistent with treating them as claim payments for MLR purposes.

Response: CMS thanks the commenters for their feedback. CMS declines to include unsettled balances in the numerator of the MLR. Section 1860D-2(b)(2)(E)(v)(VI) of the Act requires Part D sponsors to treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses; CMS considers these unsettled balances as part of the plan's administrative costs. MLR is the share of revenue used for incurred claims and quality improvement activities, rather than the share of revenue used for administrative costs and profit. Therefore, excluding unsettled balances from the numerator of the MLR calculation is consistent with the statutory direction to treat unsettled balances as plan losses and CMS' approach to other administrative expenses incurred by Part D sponsors.

As stated in Section 40 of the final part one guidance, Part D sponsors are not prohibited from collecting any unpaid balances related to the program, but must comply with all applicable federal and state laws and requirements.

Comment: Several commenters requested that CMS treat unsettled balances similarly to unpaid premium bad debt for the purposes of the MLR calculation and exclude unsettled balances from both the MLR numerator and denominator.

Response: CMS thanks the commenters for their feedback. CMS declines to exclude unsettled balances from the denominator of the MLR calculation. Section 1860D-2(b)(2)(E)(v)(VI) of the Act requires Part D sponsors to treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses and allows Part D sponsors to include unsettled balances assumed as losses in their bids. Consequently, Part D sponsors will receive revenue covering these assumed losses through their direct subsidy and premium payments, which should be included in the denominator of the MLR. This is different from unpaid premiums for which the Part D sponsor can demonstrate to CMS that it made a reasonable effort to collect, which are not actually received as revenue and excluded from the denominator.

Monitoring and Compliance (Section 60.3)

Comment: A couple of commenters expressed support for the incorporation of the Medicare Prescription Payment Plan into Part D sponsors' compliance programs. One commenter suggested that CMS require plans to submit information on their Medicare Prescription Payment Plan program and compliance approach for CMS review as part of their annual plan bid submissions. A couple of commenters requested that CMS clarify how it will oversee compliance with education and outreach requirements. Commenters were particularly interested in how CMS will monitor sponsors' compliance with targeted outreach requirements and confirm that the information needs of beneficiaries, particularly those facing language and accessibility barriers, are met.

Response: CMS thanks the commenters for their support and suggestions. CMS expects Part D sponsors to comply with the requirements outlined in the final part one guidance and final part two guidance. As stated in section 60.3 of this final part two guidance, CMS will monitor sponsors' performance, including through collecting data on Part D sponsors' implementation of the program through data reporting requirements and beneficiary complaints entered into the CTM, to assess compliance with all Medicare Prescription Payment Plan requirements, including those related to education, outreach, and communications.

Comment: Some commenters expressed concern with the complexity of the program and the tight timelines to finalize model documents, operationalize new processes, and implement technology solutions. The commenters requested that CMS exercise enforcement discretion and provide a good faith safe harbor for plan sponsors in the first year of the program. A couple of commenters requested that CMS hold additional user group calls with plans and share lessons learned or best practices over the course of year one.

Response: CMS thanks the commenters for their feedback and acknowledges the challenges associated with rapidly operationalizing a new program. CMS does not intend to conduct any audits of plan sponsors' Medicare Prescription Payment Plan programs in CY 2025, and will engage with plan sponsors throughout the first year of the program to identify educational opportunities and potential compliance issues, with the goal of supporting all plan sponsors in offering compliant programs.

Comment: Several commenters expressed support for CMS' plans to monitor beneficiary complaints entered into the CTM. A commenter suggested that Medicare Prescription Payment Plan-related metrics be incorporated into Star Ratings for Part D plan sponsors.

Response: CMS thanks the commenters for their support. CMS does not currently have plans to incorporate specific Medicare Prescription Payment Plan-related metrics into Star Ratings but may consider ways to assess plan performance in the future based on program experience. CMS

notes that there is an existing Star Ratings measure for Part D plans (“Complaints about the Drug Plan”) assessing the rate of complaints about the drug plan using CTM data. To the extent that complaints related to the Medicare Prescription Payment Plan are entered in the CTM, they may be captured in the existing measure as applicable, following the specifications for included subcategories.

Comment: Several commenters expressed concern about potential increases in plan grievances and beneficiary complaints in the CTM due to implementation of the Medicare Prescription Payment Plan. Commenters suggested that CMS establish a CTM category to help CMS and plans track these types of complaints and evaluate their frequency rates and impacts; one commenter suggested CMS establish subcategories for complaints associated with pharmacy interactions and complaints against MA-PDs or PDPs. A commenter requested additional guidance regarding how and when to submit CTM complaints related to the Medicare Prescription Payment Plan prior to its implementation. Another commenter requested that CMS allow for a grace period when addressing Medicare Prescription Payment Plan-related complaints and grievances.

Response: As stated in section 60.3 of this final part two guidance, CMS will monitor sponsors’ performance, including through assessing beneficiary complaints in the CTM, to assess compliance with all Medicare Prescription Payment Plan requirements, including those related to education, outreach, and communications. Beneficiaries may follow existing processes to submit CTM complaints related to the Medicare Prescription Payment Plan prior to and after implementation. With respect to beneficiary complaints in the CTM, CMS will assess whether an additional CTM category or subcategory is needed for the Medicare Prescription Payment Plan in future years.

Plan sponsors are expected to follow the plan grievance requirements and timeframes at § 423.564 and the requirements for the timeliness of complaint resolution in the CTM at § 423.129 for all plan grievances and beneficiary complaints, including those related to the Medicare Prescription Payment Plan.

Comment: Several commenters expressed concern that increases in complaints and grievances related to the Medicare Prescription Payment Plan could impact Star Ratings and Display measures or Part D CAHPS measures and recommended that CMS apply a hold harmless policy to ensure summary and overall Star Ratings for individual plans do not go down if lower performance results are likely due to Medicare Prescription Payment Plan impacts.

Response: CMS appreciates the commenters’ concerns. This program will create new opportunities for Part D sponsors to support their enrollees and provide customer service. CMS will monitor complaints related to the Medicare Prescription Payment Plan in CY 2025 to identify educational opportunities or potential compliance issues. As codified at §§ 422.164(d)(2), and 423.184(d)(2), substantive updates (that is, changes) to Star Rating measure

specifications must be updated through rulemaking, and CMS uses the Advance Notice and Rate Announcement process to announce non-substantive specification changes as described at §§ 422.164(d)(1) and 423.184(d)(1).

Comment: Several commenters requested additional guidance related to Medicare Prescription Payment Plan appeals and grievances processes. Commenters asked CMS to clarify how appeals would differ from good cause for re-entry or participation in the program, and which beneficiary notifications will generate appeal rights. Another commenter asked how Medicare Prescription Payment Plan-related appeals and grievances should be presented in the Parts C & D annual reporting and CMS program audit universe.

Response: As stated in Section 90 of the 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.

Comment: Many commenters requested that CMS implement proactive monitoring mechanisms to learn from the first years of the program and make timely adaptations as necessary. Several commenters suggested that CMS monitor the program's impact on health equity by tracking data on demographics, median costs, or the most commonly used drugs. Other commenters encouraged CMS to use data to better calibrate the likely to benefit threshold and strike the right balance between inclusivity in outreach efforts and limiting unnecessary exposure for beneficiaries unlikely to benefit. Some commenters suggested that CMS use data to track uptake and identify barriers to enrollment to address in future years. A commenter suggested that CMS proactively reach out to beneficiaries via surveys and focus groups to identify areas for improvement; the commenter also requested that CMS include a field on Prescription Drug Event (PDE) reports indicating if a prescription was processed under the Medicare Prescription Payment Plan to support future evaluation of the program.

Response: CMS thanks the commenters for their suggestion. As outlined in Section 100 of final part one guidance, Part D sponsors will be responsible for reporting data elements related to the Medicare Prescription Payment Plan, both at the beneficiary level and contract-Plan Benefit Package (PBP) levels. Part D sponsors will report beneficiary-level data through the MARx System, contract-level data through HPMS, and claim-level data through PDE records. CMS has added an indicator to PDE records that will indicate if a prescription was processed under the Medicare Prescription Payment Plan. The data elements were formally issued for public comment in the Federal Register through the Office of Management and Budget (OMB) ICR process. Additional details related to these requirements can be found in the following ICR packages:

- The MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (OMB Control Number 0938-1468), which can be accessed here: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202404-0938-007.
- The Medicare Part D Reporting Requirements (CMS-10185; OMB 0938-0992), which can be accessed here: <https://www.federalregister.gov/documents/2024/05/24/2024-11397/agency-information-collection-activities-submission-for-omb-review-comment-request>.
- The Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982), which can be accessed here: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202403-0938-002.

Additionally, CMS will monitor sponsors' performance, including through assessing data on plan grievances and beneficiary complaints entered into the CTM, to assess compliance with all Medicare Prescription Payment Plan requirements, including those related to election. Data reported by Part D sponsors and obtained via the CTM will assist CMS in monitoring outreach and enrollment efforts and program participation, and assessing the efficacy of the \$600 single prescription POS threshold to identify enrollees likely to benefit. CMS will consider whether additional data collection is necessary to adequately monitor sponsor compliance with program requirements in future years.

Comment: A commenter requested that CMS exercise enforcement discretion for pharmacies as they work through point-of-sale notification challenges within the pharmacy workflow. Commenters also requested that CMS broaden the scope of the CTM or provide another pathway to allow pharmacy submissions of complaints and grievances to CMS about Medicare Prescription Payment Plan operational challenges or missing Part D sponsor reimbursements.

Response: CMS thanks the commenters for their feedback and acknowledges the challenges associated with rapidly operationalizing a new program. CMS intends to engage with interested parties, including pharmacies and Part D plan sponsors, throughout the first year of the program to identify educational opportunities and disseminate best practices.

Audits (Section 60.4)

Comment: Several commenters expressed support for audits as a critical element of compliance efforts and requested that CMS publicly release audit results at the sponsor and plan level. A couple of commenters requested additional clarification on the types of audit activities CMS is considering, including the nature, timing, and frequency of planned audits. A commenter asked CMS to provide an audit protocol in draft form for public comment through the PRA process; another commenter suggested CMS adopt a standardized auditing process, to promote consistency of reviews and provide Part D sponsors with a blueprint for administering an effective Medicare Prescription Payment Plan. Finally, several commenters requested that CMS

forego audits in 2025 except in cases of material deficiencies. They suggested that CMS should pursue more informal monitoring processes, focused on disseminating best practices, for the first year of the program to allow plans to refine their internal processes.

Response: CMS thanks the commenters for their feedback and acknowledges the challenges associated with rapidly operationalizing a new program. CMS does not intend to conduct any audits of plan sponsors' Medicare Prescription Payment Plan programs in CY 2025. CMS will monitor the program using the data sources outlined in Section 60.3 of the final part two guidance to inform audit and oversight methods and processes in future years. CMS intends to engage with plan sponsors throughout the first year of the program to identify educational opportunities and disseminate best practices, with the goal of supporting all plan sponsors in offering compliant programs, and will provide advanced notice to plan sponsors regarding any future audit activities.

Other Comments

Comment: A commenter expressed appreciation that CMS has declined to adopt recommendations by interested parties to delay or limit the program. Another commenter stated that they agree with CMS' position that the Medicare Prescription Payment Plan benefits a relatively small portion of the larger Part D population and agrees that it is essential to identify those members prior to the start of the plan year whenever possible. Several commenters expressed general support for the Medicare Prescription Payment Plan and the proposals in the draft part two guidance, including CMS' proposals to ensure that sponsors fulfill their outreach, education, and communication obligations to enrollees and CMS' outreach strategy.

Response: CMS thanks the commenters for their support.

Comment: Several commenters expressed general opposition to the Medicare Prescription Payment Plan. A commenter observed that there are many beneficiaries who will not benefit from this program. Another commenter stated that the draft guidance could cause significant upheaval and confusion at the pharmacy counter. Several commenters expressed concern regarding the operational burden of implementing the requirements of the Medicare Prescription Payment Plan.

Response: CMS thanks the commenters for their input. CMS notes that we have consistently stated that the Medicare Prescription Payment Plan is likely to benefit a specific subset of the Medicare population and have provided specific guidance to plan sponsors on proactively identifying those likely to benefit. We appreciate that the complexities of the program could create a potential for beneficiary confusion at the pharmacy counter and believe that robust efforts to educate beneficiaries about the Medicare Prescription Payment Plan by CMS, plan sponsors, and other interested parties will be important to ensuring that beneficiaries are

appropriately informed about the program. We also appreciate the potential for increased operational burden resulting from the Medicare Prescription Payment Plan. We note that plan sponsors are required to offer the Medicare Prescription Payment Plan by statute and that CMS has engaged with interested parties throughout the development of the Medicare Prescription Payment Plan to engage with and address concerns about any operational challenges that may arise.

Comment: Several commenters recommended that CMS should reconsider the current naming convention of the Medicare Prescription Payment Plan. The commenter stated that referring to a voluntary smoothing option as a “plan” could confuse beneficiaries. The commenter also stated that the name fails to emphasize the monthly nature of the Medicare Prescription Payment Plan.

Response: CMS 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 and, based on its evaluation of the results, concluded that the name “Medicare Prescription Payment Plan” succinctly and accurately represents the program.

Out of Scope Comments

CMS received several comments related to the contents and formats of model and educational materials, how drug manufacturers should advertise the program, timeframes for processing election requests during the plan year, processes for election, including real-time/POS election, termination, and reinstatement, billing procedures, the \$600 single prescription POS notification threshold, the BIN/PCN claims processing methodology, consumer debt protections, and the LIS program, among other topics.

While we appreciate this feedback, these comments are outside the scope of this final part two guidance and are not addressed in this memorandum.

Many of the concerns raised in these comments were addressed through the final part one guidance published on February 29, 2024.¹²

Regarding comments related to the contents and format of the newly developed model documents for the Medicare Prescription Payment Plan, CMS considered comments received on the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare

¹² For Medicare Prescription Payment Plan final part one guidance, see: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package when updating those materials.

Further, CMS is aware of questions related to consumer financial protections. As noted in Section 40 of the 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. Additionally, section 40 of the final part one guidance states that unpaid program balances would be related to the provision of health care to an individual, and, as such, information about such debt should be considered “medical information” under the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq.

Additionally, the Consumer Financial Protection Bureau (CFPB) has an Advisory Opinion Program. The program provides written guidance to assist regulated entities to better understand their legal and regulatory obligations. Parties may submit requests for advisory opinions regarding any issue under the Bureau’s purview that can be resolved through an interpretive rule. The information about this program can be found at <https://www.consumerfinance.gov/compliance/advisory-opinion-program/>.¹³

¹³ In addition, the CFPB has published a [proposed rule](#) that would, if finalized, generally stop credit reporting companies from sharing medical debt information with lenders and prohibit lenders from making lending decisions based on medical debt information.

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

10. Introduction

The purpose of this document is to provide interested parties with final part two guidance on a select set of topics for the Medicare Prescription Payment Plan, 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,^{14,15} 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.

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 two guidance for implementation of the Medicare Prescription Payment Plan (also referred to in this guidance as the “program”) for 2025. This final part two guidance follows the final part one guidance that was issued on

¹⁴ CMS does not expect the Limited Income Newly Eligible Transition (LI NET) Program to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or to comply with the final part one guidance or this final part two guidance. In footnotes 2 and 6 in the final part one guidance and footnote 1 of the draft part two guidance, we stated that section 1860D-2(b)(2)(E) of the Act does not apply to the LI NET Program “because participants in the LI NET program do not enroll in a PDP or MA-PD plan to receive transitional coverage under the program.” These footnotes inadvertently suggest that Part D-eligible individuals enrolled in the LI NET Program are not enrolled in a Part D prescription drug plan. We wish to clarify that, consistent with the agency’s longstanding interpretation and implementation of the LI NET Program, participants in the LI NET Program are considered to be enrolled in a PDP. However, because the LI NET Program is limited to offering Part D-eligible individuals with temporary coverage during a limited, transitional period, CMS does not expect the LI NET Program to comply with the requirements of the final part one guidance or this final part two guidance in connection with the offering of such transitional coverage.

¹⁵ Under section 1894(a) of the Act, Programs for All-Inclusive Care for the Elderly (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 participants or enrollees in plans that exclusively charge \$0 cost sharing for Part D covered drugs. As such, CMS does not expect Part D plans that exclusively charge \$0 cost sharing for covered Part D drugs to all plan enrollees to offer enrollees the option to pay their OOP costs through monthly payments over the course of the plan year or otherwise comply with the final part one guidance or this final part two guidance. If a Part D plan has any enrollees that could pay any cost sharing, even a nominal amount, under the Part D plan at any point during the year, then this clarification would not be applicable to such a plan.

February 29, 2024 through a Health Plan Management System (HPMS) memo titled “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.” 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,” and on April 25, 2024, CMS issued a second HPMS memo titled “Technical Memorandum on the Changes to True Out-of-Pocket (TrOOP) Costs and the Calculation of the Maximum Monthly Cap for the Medicare Prescription Payment Plan.”¹⁶ These memos provide additional instructions for and examples of program calculations for the Medicare Prescription Payment Plan.

Additionally, CMS developed six model materials to support Part D sponsors in meeting their education, outreach, and communications requirements for the Medicare Prescription Payment Plan. CMS issued the materials through an Information Collection Request (ICR) process with two opportunities for public comment. After considering comments received, CMS finalized and published the materials on July 16, 2024. The materials are available through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package and on the CMS.gov website at <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

In this final part two guidance, CMS describes requirements for Part D sponsor obligations related to outreach and education, pharmacy processes, and operational considerations for the program. 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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¹⁶ Medicare Prescription Payment Plan publications can be accessed at: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements>.

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20. Overview of the Medicare Prescription Payment Plan

Beginning in contract year (CY) 2025, the statute requires Part D sponsors to provide all Part D enrollees the option to pay their OOP Part D prescription drug costs in monthly amounts over the course of the plan year, instead of paying OOP costs in full 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 at the POS when

filling a prescription. The Part D sponsor must pay the pharmacy the OOP cost-sharing amount that 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 calculations described in the final part one guidance). 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 costs¹⁷ earlier in the plan year are generally more likely to benefit, as discussed in the final part one guidance.

In the final part one guidance, CMS explained how Part D sponsors can satisfy statutory requirements for the Medicare Prescription Payment Plan, including how they must: provide all Part D enrollees with the option to elect into the Medicare Prescription Payment Plan prior to, and during, the plan year; determine a maximum monthly cap for each month's amount; bill the program participant for an amount that must not exceed the applicable monthly cap; and 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.

This final part two guidance builds on the final part one guidance by primarily focusing on Part D sponsors' obligations for Part D enrollee education, outreach, and communications related to the Medicare Prescription Payment Plan. This includes how Part D sponsors must perform general and targeted education and outreach to Part D enrollees and provide communications to program participants, including instructions on using CMS-provided model materials that were issued through the OMB ICR process. This guidance also includes a summary of how CMS is supporting Part D enrollee education and outreach, provides additional details related to pharmacy processes for operationalizing the program, and instructs Part D sponsors on how to prepare for CY 2025 program implementation.

30. Outreach, Education, and Communications Requirements for Part D Sponsors

Under section 1860D-2(b)(2)(E)(v)(III) of the Act, Part D sponsors are required to provide Part D enrollees with promotional and educational materials on the Medicare Prescription Payment Plan both prior to, and during, the plan year. Specifically, section 1860D-2(b)(2)(E)(v)(III)(bb) of the Act requires Part D sponsors to notify prospective Part D enrollees of the option to make such an election in promotional materials prior to the plan year, and section 1860D-2(b)(2)(E)(v)(III)(cc) of the Act requires Part D sponsors to include information on the Medicare Prescription Payment Plan in Part D enrollee educational materials. Additionally, under section 1860D-2(b)(2)(E)(v)(III)(dd) of the Act, Part D sponsors must have a mechanism in place to notify a pharmacy when an enrollee incurs OOP costs for covered Part D drugs that make it

¹⁷ For the definition of OOP costs used for the Medicare Prescription Payment Plan, see Appendix A of the final part one guidance.

likely the Part D enrollee may benefit from participating in the Medicare Prescription Payment Plan. Finally, under section 1860D-2(b)(2)(E)(v)(III)(ee) of the Act, Part D sponsors must also ensure that a pharmacy, after receiving such notification, informs the Part D enrollee about the program.

This section of the guidance outlines a list of materials that satisfy the requirements for Part D sponsors to provide enrollees with information about this program, including an overview of language access and accessibility requirements. In addition, this section includes guidance on how Part D sponsors can fulfill their statutory pharmacy notification requirements.

In this final part two guidance, CMS describes how it has modified existing Part D materials to reflect implementation of the Medicare Prescription Payment Plan (see section 30.1). Additionally, CMS developed model materials that have been made available for public comment through the OMB ICR process. Part D sponsors can use the model materials to communicate with Part D enrollees and program participants about the Medicare Prescription Payment Plan. As stated in the introduction section, the model materials can be accessed through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package and on the CMS.gov website at <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements/medicare-prescription-payment-plan>.

For all materials provided to Part D enrollees, whether newly created or updated for this program, Part D sponsors should also reference existing Part D regulations at 42 CFR Part 423 subpart V, which set forth standards for Part D required materials, content, and delivery requirements. Part D sponsors should also refer to the Medicare Communications and Marketing Guidelines (MCMG) for CMS interpretation and examples of select subpart V provisions, as well as HPMS submission rules and processes for marketing materials.¹⁸ Finally, sponsors should also reference the Medicare Prescription Drug Benefit Manual and HPMS memoranda to ensure compliance with other Part D communications requirements.¹⁹ Part D sponsors are also encouraged to review their plan materials including, but not limited to, those described in this

¹⁸ The model and standardized materials developed for the Medicare Prescription Payment Plan are considered communications materials per the definition at § 423.2260. Under § 423.2261(c), communications materials are not required to be submitted through HPMS for CMS review.

¹⁹ These regulations and requirements outline specific requirements and prohibited practices, such as providing inaccurate or misleading information, for Part D sponsors' communications and marketing materials and activities. They also state specific requirements for submission, review, and distribution of materials, among other parameters for how Part D sponsors can contact Part D enrollees. Please note this summary is not exhaustive of the different requirements outlined in 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission through HPMS, and use of marketing materials. References to these regulations, requirements, and guidelines are meant to remind Part D sponsors that any materials used under the Medicare Prescription Payment Plan are subject to existing Part D requirements.

guidance, and update these materials to include information about the Medicare Prescription Payment Plan, as appropriate.

Taken together, the education and outreach requirements included in this section aim to integrate the new Medicare Prescription Payment Plan into current Part D education, outreach, and enrollment processes to create a seamless experience for Part D enrollees.

30.1 General Outreach and Education

Under section 1860D–2(b)(2)(E)(v)(III)(bb) of the Act, Part D sponsors must notify prospective Part D enrollees prior to the plan year through promotional materials of the option to participate in the Medicare Prescription Payment Plan. Additionally, under section 1860D–2(b)(2)(E)(v)(III)(cc) of the Act, Part D sponsors must also provide educational materials to Part D enrollees. Because general outreach to and education of Part D enrollees are central to ensuring that all prospective and current Part D enrollees are aware of this program, CMS will require plans to use existing Part D materials that are required to be furnished to Part D enrollees under § 423.2267(e), as updated accordingly to include information about the program.

Further, Part D sponsors may include information on the Medicare Prescription Payment Plan in their marketing materials, so long as their marketing materials comply with existing Part D regulations at 42 CFR Part 423 subpart V, which sets forth standards for Part D required materials, content, and delivery requirements. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing materials.

30.1.1 Required Mailings with Membership ID Card Issuance

Under § 423.2267(e)(32), the membership ID card is a model communications material that Part D plans must provide to Part D plan enrollees. It must be provided to new enrollees within ten calendar days from receipt of CMS confirmation of enrollment in the Part D plan or by the last day of the month prior to the plan effective date, whichever is later. The membership ID card must be provided in hard copy, and Part D plans may also provide a digital version, in accordance with § 423.2267(d).

For CY 2025, when an individual signs up for a Part D plan, Part D sponsors will be required to include with the membership ID card hard copy mailing or in a separate mailing:

- a Medicare Prescription Payment Plan election request form; and
- information on the Medicare Prescription Payment Plan.

If a Part D sponsor chooses to include information on the program and an election request form in a separate mailing, the Part D sponsor must provide this mailing to Part D enrollees within the same timeframe as the membership ID card mailing, described above. Additionally, Part D sponsors may provide the separate mailing to all Part D enrollees of the plan or to only those new Part D plan enrollees who are receiving the membership ID card mailing.

Requirements related to the election request form are outlined in section 30.3.1.1 of this guidance.

Part D sponsors are encouraged to provide the CMS-developed fact sheet, described in section 40.1 of this guidance, to satisfy the requirement to furnish information regarding the Medicare Prescription Payment Plan alongside the election request form in the membership ID card issuance packet. If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of those marketing materials using HPMS, and use of marketing materials.

30.1.2 Evidence of Coverage (EOC)

As required under § 423.2267(e)(1), the EOC is a standardized communications material that must be provided annually by Part D sponsors to all current Part D enrollees of a plan by October 15th prior to the year to which the EOC applies or, for new Part D enrollees, within ten calendar days of the date the Part D sponsor receives confirmation of Medicare Part D enrollment from CMS or by the last day of the month prior to the Part D enrollment effective date, whichever is later. The EOC is a legal document that contains a detailed description of a Part D enrollee's plan benefits and rights, as required under § 423.128(b), and that explains the plan's rules for covered services and prescription drugs.²⁰

CMS updated the model EOC to include educational information about the Medicare Prescription Payment Plan, given the program's relevance to Part D plans' descriptions of their covered benefits and related cost-sharing responsibilities.

The updated model EOC was released on June 12, 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).²¹

²⁰ <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

²¹ CY 2025 Model Materials are posted at: <https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials>.

30.1.3 Annual Notice of Change (ANOC)

As required under § 423.2267(e)(3), the ANOC is a standardized marketing material that must be provided by Part D sponsors to current Part D enrollees annually and outlines changes in plan costs, coverage, and benefits that take effect on January 1 of the next plan year to help Part D enrollees decide whether to remain in their plan or choose a different plan.²² In general, the document must be sent to Part D enrollees by September 30 of each year, and posted on the Part D sponsor's website by October 15, prior to the plan year.²³

CMS has added educational language to the ANOC that describes the Medicare Prescription Payment Plan and provides instructions on how to opt into the program.

The updated model ANOC was released on June 12, 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).

30.1.4 Explanation of Benefits (EOB)

Under section 1860D-4(a)(4) of the Act, Part D sponsors are required to furnish Part D enrollees with a written EOB when Part D benefits are provided. The EOB informs Part D enrollees about their prescription drug costs in relation to the Part D annual deductible, initial coverage limit, and annual OOP threshold. Part D EOB requirements are codified at § 423.128(e). Section 423.128(e)(7) requires that the EOB is furnished no later than the end of the month following any month when Part D benefits are utilized. Part D EOBs must be written in the manner specified by CMS and in a form easily understandable to Part D enrollees.

As part of the most recent OMB ICR renewal for the Part D EOB (CMS-10453; OMB 0938-1228), 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.²⁴

CMS considered comments received through the ICR process and issued a final Part D EOB for CY 2025 on May 23, 2024.²⁵ The EOB includes information about the Medicare Prescription Payment Plan and explains that enrollees who participate in the Medicare Prescription Payment Plan will receive a separate monthly Medicare Prescription Payment Plan billing statement. The

²² <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-V/section-423.2267>.

²³ <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

²⁴ See <https://www.federalregister.gov/documents/2023/06/06/2023-11996/agency-information-collection-activities-proposed-collection-comment-request> and <https://www.federalregister.gov/documents/2023/12/08/2023-27033/agency-information-collection-activities-submission-for-omb-review-comment-request>.

²⁵ <https://www.cms.gov/files/zip/cy-2025-part-d-eob-instructions-and-exhibits.zip>.

EOB also explains that costs included in the EOB might differ from what a Medicare Prescription Payment Plan participant paid at POS.

30.1.5 Part D Sponsor Websites

Under § 423.128(d)(2), Part D sponsors are required to have a publicly available website that includes a description of the Part D plan's coverage details, including information on the benefits offered, such as applicable conditions and limitations, premiums, and cost sharing (including for subsidy-eligible individuals), and any other information associated with receipt or use of benefits. Websites must comply with anti-discrimination provisions, such as Section 508 of the Rehabilitation Act, with regard to providing access to websites and other materials, so that individuals can read sites and materials with screen reader technology.²⁶ Additionally, as stated in section 30.4 of this final part two guidance, websites must comply with Medicare Part D language access and accessibility requirements.

As such, in addition to the required content under § 423.2265(b), Part D sponsors will be required to include information on the Medicare Prescription Payment Plan on their websites. Section 70.3.1 of the Medicare Prescription Payment Plan final part one guidance outlines the requirement for Part D sponsors to have available on their websites a Medicare Prescription Payment Plan election request mechanism that Part D enrollees can use to opt into the program and that provides the individual with evidence the election request was received (e.g., a confirmation number). Section 30.3.1.4 of this final part two guidance outlines requirements for this website election request mechanism.

In addition to offering an election request mechanism, Part D sponsors must provide on their websites:

- An overview of the program, including that it is a new program offered by all Part D plans and that it is voluntary to join;
- Examples of how the program calculation works with easy-to-understand explanations. CMS encourages Part D sponsors to include a few examples of cost-sharing scenarios that demonstrate when the program would and would not benefit a Part D enrollee;
- A description of who is likely to benefit;
- The financial implications for the enrollee of participating in the program, including that the program is free to join, there are no fees or interest charged under the program, and the program does not reduce the amount of cost sharing a participant owes for their Part D prescriptions. Part D sponsors are also encouraged to include information about the \$2,000 Medicare Part D OOP cap in 2025;
- The importance of paying monthly bills, including the implications of not paying monthly bills;

²⁶ For more specific website requirements, see § 423.2265. Part D sponsors should also reference the MCMG.

- A description of how to opt into and out of the program, including timing requirements around election effectuation;
- A description of the standards for urgent Medicare Prescription Payment Plan Election, as described in section 70.3.7 of the final part one guidance;
- A description of how Part D enrollees can file complaints and grievances related to the program;
- Contact information that Part D enrollees can use to obtain further information; and
- General information about the Low-Income Subsidy (LIS) program, including information on the recent LIS expansion of eligibility, and how to apply and enroll in the LIS program (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.

Part D sponsors are encouraged to use language from the CMS-developed fact sheet on the Medicare Prescription Payment Plan and other CMS-provided resources to meet these requirements. CMS-provided resources are discussed in more detail in section 40 below. Additionally, CMS encourages Part D sponsors to link to the CMS-developed fact sheet or CMS-developed resources, where applicable, to ensure the content is up to date.

30.2 Targeted Outreach and Education Requirements for Part D Sponsors

Under sections 1860D–2(b)(2)(E)(v)(III)(dd) and 1860D–2(b)(2)(E)(v)(III)(ee) 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 and must provide that the pharmacy, after receiving such a notification, informs the enrollee about the program.²⁷ CMS recognizes, however, that notification of Part D enrollees likely to benefit from the Medicare Prescription Payment Plan *prior* to reaching the pharmacy POS will be a critical component to program success. Early notification will streamline the election process and prevent drug dispensing delays, especially because, as discussed in the final part one guidance, a POS election option is not planned for 2025. As such, CMS is also requiring Part D sponsors to undertake targeted outreach, both prior to and during the plan year, directly to Part D enrollees likely to benefit from the program.

30.2.1 Notice for Part D Enrollees Likely to Benefit

To support Part D sponsors in meeting this requirement, CMS has developed a standardized notice for Part D enrollees identified as likely to benefit from the Medicare Prescription Payment Plan, the “Medicare Prescription Payment Plan Likely to Benefit Notice.” Part D sponsors are

²⁷ Additional information related to the notification of Part D enrollees who are likely to benefit at the POS is included in section 60.2.3 of the final part one guidance. For information on the framework used to define “likely to benefit,” see section 60.2.1 of the final part one guidance.

required to use this standardized notice to satisfy their obligation to perform targeted outreach to Part D enrollees who are identified as likely to benefit prior to and during the plan year, including those identified through the pharmacy notification process. This outreach, when performed outside of the pharmacy POS notification process, may be done via mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). If the enrollee is identified through the pharmacy notification process, this outreach must be completed at the pharmacy POS (see section 30.2.2.3 below).

30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year

Section 60.2.1 of the final part one guidance presented the CMS standardized framework for assessing “likely to benefit.” Specifically, we stated 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). In that final guidance, CMS built upon the likely to benefit definition to define thresholds for targeted Part D enrollee notification at the pharmacy POS. The pharmacy POS notification, as required under sections 1860D–2(b)(2)(E)(v)(III)(dd) and (ee) of the Act, is a key component of the Medicare Prescription Payment Plan. However, as noted above, CMS is aware that proactive notification of Part D enrollees likely to benefit (prior to their interaction at the pharmacy POS) will streamline the program election process and help to prevent drug dispensing delays.

To address this, CMS is requiring that Part D sponsors, prior to and during the plan year, identify Part D enrollees likely to benefit from the program and undertake targeted outreach to inform those Part D enrollees of the program. CMS recognizes 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 the final part one guidance are specifically for identifying Part D enrollees for targeted outreach and communication in the absence of any information regarding an individual’s specific financial circumstances.

30.2.2.1 Identifying Part D Enrollees Likely to Benefit Prior to the Plan Year

As discussed in the final part one guidance, while the Medicare Prescription Payment Plan 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. In setting criteria to identify Part D enrollees likely to benefit prior to the plan year, CMS strives to identify individuals who have persistently high costs for covered Part D prescription drugs. That is balanced, however, by a desire to limit notifications to Part D enrollees who are not likely to benefit from participation in the program

(such as Part D enrollees for whom the program would initially provide substantial financial relief but later, due to timing constraints, would result in monthly payments that are higher than they would have been absent the program).²⁸

With the goal of assessing the persistence of high OOP costs, and thus, the likelihood of a prior year's OOP costs predicting future OOP burden, CMS analyzed historic Prescription Drug Event (PDE) records. CMS first identified Part D enrollees who had incurred total OOP costs of at least \$2,000²⁹ in the first three quarters of 2021, then examined their total OOP costs in the subsequent year, 2022. Of the 929,000 enrollees identified who reached \$2,000 in OOP costs in the first three quarters of 2021, 82 to 89 percent met CMS' quantitative definition of "likely to benefit" in the subsequent year.³⁰ In addition, the majority (66 percent) of those 929,000 enrollees again had annual OOP costs of at least \$2,000 in the first three quarters of 2022.

CMS' analysis was based on the patient payment amount for covered Part D claims only, reflecting the actual OOP financial burden for Part D enrollees.

To identify Part D enrollees likely to benefit in advance of the plan year, Part D sponsors are required to assess their current Part D enrollees' prescription drug costs from the current year and conduct outreach to Part D enrollees who incurred \$2,000 in OOP costs for covered drugs through September of that year. (More details on the process for conducting this analysis and outreach are below.)

Part D sponsors may develop supplemental strategies for identification of additional Part D enrollees likely to benefit prior to the plan year. The approach outlined in this section is a minimum requirement. If supplemental strategies are implemented, then Part D sponsors must apply any additional identification criteria to every enrollee of each plan uniformly.

Prior to the plan year, when a Part D sponsor identifies current Part D enrollees as likely to benefit using the above methods, it is then required to notify each such Part D enrollee in writing that they are likely to benefit from the Medicare Prescription Payment Plan, using the standardized "Medicare Prescription Payment Plan Likely to Benefit Notice" (as discussed above in section 30.2.1). This outreach may be done via mail or electronically (based on the Part D enrollee's preferred and authorized communication methods) and must include a Medicare Prescription Payment Plan election request form. The outreach must also include additional information about the Medicare Prescription Payment Plan; this additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about

²⁸ Please refer to section 60.2.1 of the final part one guidance for additional information related to identifying Part D enrollees likely to benefit from the Medicare Prescription Payment Plan.

²⁹ \$2,000 was used in this analysis because it is the Part D annual OOP threshold for CY 2025.

³⁰ The range of participants meeting the "likely to benefit" definition is based on two calculations—one using the full denominator of enrollees identified based on 2021 PDE data and the other using a denominator only including those who remained Part D enrollees in 2022.

the program (see section 40.1 for additional information about the product). If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing material. Additionally, the initial notice may be provided via telephone, so long as the written notice and additional information are sent within three calendar days of the telephone notification.

To fulfill the requirements above, during the fourth quarter of the year, Part D sponsors must review their Part D claims history from the first three quarters of the year to identify Part D enrollees likely to benefit in the upcoming year. Based on this analysis and any additional analysis plan sponsors conduct to identify enrollees who may be likely to benefit from this program, the plan sponsor must send the “Medicare Prescription Payment Plan Likely to Benefit Notice” to identified enrollees no later than the end of the Annual Election Period (open enrollment), which is December 7 of each year. For CY 2025, Part D sponsors must assess claims for covered Part D drugs with dates of services from January through September 2024 and send the “Medicare Prescription Payment Plan Likely to Benefit Notice” in October, November, or early December 2024 (no later than December 7, 2024). If Part D sponsors develop supplemental strategies for identification of Part D enrollees likely to benefit prior to the plan year, these notifications must be provided during the same time frame.

While Part D sponsors are required to notify all Part D enrollees who meet the criteria outlined above, Part D sponsors should be aware that potential changes to a Part D enrollee’s clinical condition, medication status, or cost sharing (e.g., discontinuation of therapy or addition of supplemental payers) could affect the likelihood that a Part D enrollee may benefit from the Medicare Prescription Payment Plan. Part D sponsors should be aware of potential status changes when contacted by an enrollee to discuss participation in the program and should counsel enrollees accordingly.

30.2.2.2 Identifying Part D Enrollees Likely to Benefit During the Plan Year

In addition to the criteria outlined above for identification of Part D enrollees likely to benefit from the program *in advance of* an upcoming plan year, CMS is also requiring Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. For example, Part D sponsors may undertake targeted outreach to Part D enrollees if they become aware in advance of a new high-cost prescription for a Part D enrollee that would trigger the pharmacy POS notification process.³¹ If Part D sponsors have prior

³¹ As discussed in section 60.2.4 of the final part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed the POS threshold of \$600.

authorization or other utilization management edits in place for a drug that, based on their benefit structure, would result in OOP costs above the pharmacy POS notification threshold, then the Part D sponsor could initiate outreach to the Part D enrollee based on approved prior authorization requests, informing them of the Medicare Prescription Payment Plan and of the opportunity to opt into the program. (More details on this process are below.) A Part D enrollee is less likely to benefit from opting in during the last quarter of a year. For example, in December, the last month of the plan year, because OOP costs incurred in that month cannot be spread over more than one month. As such, a Part D enrollee should not be notified that they are likely to benefit in the last month of the plan year for that 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.

Part D sponsors may develop strategies other than the approach outlined above for identification of additional Part D enrollees likely to benefit during the plan year. However, Part D sponsors must develop standardized processes for implementing their criteria for identification of enrollees likely to benefit from the program during the plan year, including outreach timeframe and mode of communication, and must apply any identification criteria to every Part D enrollee uniformly.

During the plan year, when a Part D sponsor identifies current Part D enrollees as likely to benefit from the program, it is required to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” (as discussed above in section 30.2.1) to the identified Part D enrollee along with a Medicare Prescription Payment Plan election request form and additional information about the Medicare Prescription Payment Plan. This additional information requirement may be fulfilled by including with the notice the CMS-developed fact sheet about the program (see section 40.1 for additional information about the product). If Part D sponsors develop and use alternative informational materials in lieu of the CMS-developed fact sheet to satisfy this requirement, they must ensure that these alternative materials accurately convey program information and are compliant with existing Part D requirements specified at 42 CFR Part 423 subpart V. Part D sponsors should also refer to the MCMG, which provides guidance and examples regarding what constitutes a marketing material, the rules and processes for sponsor submission of marketing materials through HPMS, and use of marketing materials. This outreach may be done via mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). Additionally, the initial notice may be provided via telephone, so long as the written “Medicare Prescription Payment Plan Likely to Benefit Notice,” election request form, and additional information are sent within three calendar days of the telephone notification. Part D sponsors are encouraged to inform the Part D enrollee that they are likely to benefit when contacting the Part D enrollee for other reasons, such as while communicating a prior authorization coverage determination.

30.2.2.3 Requirements for Identifying Part D Enrollees Likely to Benefit 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 Part D 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 Part D sponsor, informs the Part D enrollee that it is likely the Part D enrollee may benefit from the Medicare Prescription Payment Plan.

As discussed in section 60.2.4 of the final part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs for a single prescription that equal or exceed the POS threshold of \$600. To fulfill the requirement for pharmacies to then inform the Part D enrollee, the Part D sponsor must require the pharmacy to provide the English-language version of the “Medicare Prescription Payment Plan Likely to Benefit Notice” (discussed above in section 30.2.1) to the Part D enrollee. Pharmacies should make available the CMS-developed Spanish-language version of the notice, in lieu of the English-language version, to their patients upon request. Identified enrollees who receive the notice from the pharmacy and need the notice in another format or language are instructed to call their Part D sponsor for assistance. The Part D sponsor should ensure compliance with the language access and accessibility requirements at § 423.2267, as outlined in section 30.4, in the delivery of the “Medicare Prescription Payment Plan Likely to Benefit Notice.” CMS encourages Part D sponsors to provide pharmacies with additional educational material on the Medicare Prescription Payment Plan, such as the CMS-developed fact sheet described in section 40.1, which could also be distributed to Part D enrollees along with the notice.

This requirement to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” in no way obligates the pharmacy to provide additional Medicare Prescription Payment Plan counseling or consultation to the Part D enrollee. Pharmacies are encouraged, but not required, to provide educational material related to the Medicare Prescription Payment Plan at the time they provide an enrollee with the notice.

When a Part D enrollee opts into the Medicare Prescription Payment Plan after receiving the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, in addition to providing the notice of acceptance of election, as described in section 30.3.2 of this guidance, the Part D sponsor is responsible for clearly communicating additional necessary next steps to the Part D enrollee. Next steps may include, but are not limited to, how to proceed with filling any outstanding prescriptions.

30.2.3 Communications with Contracted Providers and Pharmacies

CMS is aware that health care providers and pharmacists play a key role in cost-of-care conversations with their patients that can include discussions about potential prescription drug costs. CMS encourages Part D sponsors to include information about the Medicare Prescription Payment Plan in their communications with contracted providers and network pharmacies. More specifically for contracted providers, CMS encourages Part D sponsors to target these communications to subgroups of providers based on provider specialty and likelihood of prescribing high-cost covered Part D drugs.

With regard to network pharmacies, CMS encourages Part D sponsors to provide pharmacies with education and resources related to the Medicare Prescription Payment Plan. While some pharmacies, such as specialty pharmacies, may be more likely to dispense high-cost drugs that trigger the POS notification, all pharmacy types would benefit from program resources and a thorough understanding of how the Medicare Prescription Payment Plan works and how it can benefit participants.

The CMS-developed fact sheet described in section 40.1 of this guidance may serve as a useful tool for Part D sponsors to communicate information on the Medicare Prescription Payment Plan with both contracted providers and pharmacies.

30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors

This section provides an overview of the Medicare Prescription Payment Plan election and termination requirements. Additionally, this section introduces new model materials that CMS developed to support Part D sponsors in meeting Part D enrollee communications requirements. These model materials and their content serve as an example of how to convey information on the Medicare Prescription Payment Plan to Part D enrollees and program participants, as applicable. Though Part D sponsors are not required to use the model materials and content verbatim, use of the model materials will satisfy the communications requirements included throughout this section. If a Part D sponsor chooses not to use a model material, they must meet the content requirements included throughout this section for the alternate notices they develop. CMS notes that the “Medicare Prescription Payment Plan Likely to Benefit Notice,” discussed above, is a standardized material that Part D sponsors are required to use in the form and manner provided by CMS. Part D sponsors can refer to §§ 423.2267(b) and 423.2267(c) for requirements related to the use of model and standardized materials.

The specific model materials that CMS developed for the Medicare Prescription Payment Plan and that are outlined in this section were issued through the Medicare Advantage and

Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

Unless otherwise specified throughout this section, Part D sponsors may deliver the notices included in this section in hard copy or electronically, if the enrollee has opted into receiving electronic versions as permitted in § 423.2267(d).

For delivery of the notices included in this section, notification is considered delivered by the plan when:

- For written, hard copy notices, unless otherwise specified, notification is considered delivered on the date (and time, if applicable) the notice has left the possession of the plan or delegated entity. Generally, this occurs when the notice has been deposited into the courier drop box or external outgoing mail receptacle (e.g., U.S. Postal Service or FedEx bin). Placement into the plan or delegated entity's internal outgoing mail receptacle is not considered delivered;
- For electronic notices, notification is considered delivered on the date the plan sends the materials to the Part D enrollee; or
- For verbal notices, notification is considered delivered on the date (and time, if applicable) a plan speaks directly to or leaves a voicemail for an enrollee or enrollee's representative.

Part D sponsors must address notifications to the Part D enrollee's last known mailing address, email address, or phone number on record.

30.3.1 Overview of Election Requirements

Under section 1860D–2(b)(2)(E)(i) of the Act, Part D sponsors must provide the option to elect into the Medicare Prescription Payment Plan to all Part D enrollees, including Part D 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. Additionally, Part D sponsors must allow Part D enrollees to opt into the Medicare Prescription Payment Plan during the annual Part D election period, Part D initial enrollment periods, and Part D special enrollment periods. Further, as noted in section 70.3.1 of the final part one guidance, Part D sponsors must offer paper, telephone, and website program election options.

Part D sponsors are strongly encouraged to provide interested Part D enrollees with additional information about the Medicare Prescription Payment Plan, including offering a review of what their estimated monthly payments under the program may be, to ensure that potential participants understand the financial implications of participation. Part D sponsors are also encouraged to

provide support tailored to the potential participant's unique situation and clearly communicate to enrollees when it appears that they are less likely to benefit from the program (e.g., enrollees with low-to-moderate recurring OOP drug costs).

In addition to the requirements outlined below for requests made via different election mechanisms, Part D sponsors should also reference section 70.3 of the final part one guidance for requirements related to election into the Medicare Prescription Payment Plan, including procedures for collecting missing information. In communications about the program with current and prospective program participants, Part D sponsors are also reminded that they must provide 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 more advantageous than participation in the Medicare Prescription Payment Plan.

30.3.1.1 Request to Participate in the Medicare Prescription Payment Plan

CMS issued a model "Medicare Prescription Payment Plan Participation Request Form" for Part D sponsors that Part D enrollees can use to initiate the request to opt into the program through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

If a Part D sponsor chooses to develop its own program election request form, the form must include all fillable fields included in the CMS-provided model "Medicare Prescription Payment Plan Participation Request Form." The form must include instructions on how the form can be sent back to the Part D plan via mail, fax, or email and must indicate that all fields should be completed unless marked optional. Additionally, the form must include a website link to the Part D sponsor's online election request form. Further, the form must include information that allows the individual to attest that they understand:

- That the form is a request to participate in the Medicare Prescription Payment Plan, and the Part D plan will contact them if more information is needed to complete the request;
- That by signing the form, they have read and understood the form and the Part D plan's terms and conditions (if the Part D plan chooses to include terms and conditions on or with the form); and
- That the Part D plan will inform the individual when their participation in the program is active, and, until the individual receives that notification, that they are not a participant in the program.

For paper and electronic requests, Part D sponsors may choose to include their program terms and conditions on the election request form, on an attachment provided with the election request form, or separately, such as through a follow-up electronic communication or phone call. For

telephone requests, Part D sponsors must provide an overview of the terms and conditions during the election request phone call.

For an election request to be considered “complete,” the Part D enrollee must submit their first and last name, Medicare number, and their signature (or verbal attestation, in the case of telephonic requests) to attest that they understand the form and the Part D plan’s terms and conditions. A Part D enrollee must attest that they understand the Part D sponsor’s terms and conditions for the request to be considered “complete,” whether the terms and conditions are included on the election request form or provided separately.

As detailed above in section 30.1.1, an election request form, along with information on the Medicare Prescription Payment Plan, must be sent either with the membership ID card issuance materials that are provided to new Part D enrollees upon enrollment in the Part D plan or in a separate mailing sent to new Part D enrollees within the same timeframe.

Part D sponsors must process election requests they receive regardless of the format of the request (e.g., a letter or email). When a Part D sponsor receives an election request in an alternate format and required information is missing, they must contact the Part D enrollee telephonically or electronically to collect all necessary information and document the Part D enrollee’s and/or their legal representative’s agreement to the Part D sponsor’s terms and conditions. Part D sponsors must follow the requirements and procedures related to collecting missing information outlined in sections 70.3.3 and 70.3.4 of the final part one guidance.

30.3.1.2 Paper Election Requests

When a paper election request is received (e.g., via mail) by the Part D sponsor, the Part D sponsor should ensure the request is complete, the information provided is accurate, and the Part D enrollee and/or their legal representative has agreed to the Part D sponsor’s terms and conditions for the program. To expedite the election request process and streamline it for all parties, CMS encourages Part D sponsors to include their terms and conditions for participation in the election request form. This applies whether they use CMS’ model “Medicare Prescription Payment Plan Participation Request Form” or develop their own election request form. If the election request is incomplete or inaccurate, or if the terms and conditions are not included in the election request form, then, upon receipt of a paper request, the Part D sponsor must promptly contact the Part D enrollee telephonically or electronically to finalize the election process and document the individual’s and/or their legal representative’s agreement to the Part D sponsor’s terms and conditions (see sections 30.3.1.3 and 30.3.1.4 below for telephonic and electronic requirements and sections 70.3.3 and 70.3.4 of the final part one guidance for procedures related to collecting missing or incomplete information).

For requests sent to the Part D sponsor by mail, the election request date is the date the request is received by the Part D sponsor, regardless of the date of the postmark. Paper election requests are considered received on the date and time:

- The Part D sponsor initially stamps a document received by regular mail (i.e., U.S. Postal Service); or
- A delivery service that has the ability to track when a shipment is delivered (e.g., U.S. Postal Service, UPS, FedEx, or DHL) delivers the document.

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 an option for either a pen-and-ink or electronic signature.

30.3.1.3 Telephonic Election Requests

For requests made by telephone, the election request date is the date of the call. A telephonic election request is considered received on the date and time:

- The verbal request is made by telephone with a customer service representative; or
- A message is left on the Part D sponsor's voicemail system if the Part D sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

The call must be recorded and follow a script previously approved by the Part D sponsor that includes the required elements for the election request form listed above in section 30.3.1.1 and that is based on the content of the model "Medicare Prescription Payment Plan Participation Request Form." The script must also include a clear statement that the individual is requesting to participate in the Medicare Prescription Payment Plan, and record a confirmation that the individual understands the Part D sponsor's terms and conditions. CMS expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election process in that single telephone interaction if the Part D enrollee wishes to participate in the program. As such, Part D sponsors must include an overview of their program terms and conditions during the phone call.

30.3.1.4 Website Election Requests

For electronic election requests made using the Part D sponsor's website, the election request date is the date the Part D enrollee completes the request through the Part D sponsor's secure electronic portal. An electronic election request is considered received on the date and time a request is received through the plan's website, provided the website and/or portal meets all applicable regulatory requirements. This is true regardless of when a Part D sponsor ultimately retrieves or downloads the request.

CMS expects Part D sponsors to complete the entirety of the Medicare Prescription Payment Plan election request process, including documenting the individual’s agreement to the Part D sponsor’s terms and conditions, in that single electronic election request. Election request systems must be based on the model “Medicare Prescription Payment Plan Participation Request Form” and include a distinct step that requires the Part D enrollee to activate an “Opt-In Now” or “I Agree” type of button or tool, along with documentation that the Part D enrollee understands the Part D sponsor’s terms and conditions.

30.3.2 Notice of Election Approval

Once the program election request is accepted by the Part D sponsor, the Part D sponsor must communicate that the request to participate in the Medicare Prescription Payment Plan has been accepted and effectuated via written notice. For Part D sponsor requirements related to response times for election requests, please reference the final part one guidance.

For requests received prior to the plan year, Part D sponsors are required to send a written notice of acceptance of election within the timeframes specified in the final part one guidance.

For requests received during the plan year, regardless of how the Part D enrollee submitted the election request (paper, telephone, or electronic), the Part D sponsor must deliver the notice of acceptance of election within the specified timeframe first telephonically and then via a written notice. The call must include the required elements for the notice of acceptance of election outlined below, and Part D sponsors are encouraged to base the script used for the telephone notice on the language included in the “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan.” The Part D sponsor must then deliver a written notice of acceptance of election to the program participant either via mail or electronically, depending on the participant’s preferred and authorized communication method, within three calendar days of delivering the initial telephone notice.

If a Part D sponsor is processing an election request over the phone and is able to confirm the election request is approved and the Part D enrollee’s participation is active immediately, the same, single phone call can serve to meet the acceptance of election telephone notification requirement. In this case, the Part D sponsor must still deliver the written notice as well.

CMS also encourages Part D sponsors to provide program participants with digital evidence of their election into the Medicare Prescription Payment Plan.

The notice of acceptance of election must include:

- The effective date of the individual’s participation;

- A description of how payments for covered Part D drugs under the program will work, including that the individual will pay \$0 to the pharmacy for covered Part D drugs and the Part D plan will bill the individual each month;
- An overview of how the monthly bill is calculated, including a statement on how monthly bills may change each month, and a statement outlining that under the program, the individual will not pay more for covered Part D drugs than they would have paid without the program or more than the Medicare Part D annual out-of-pocket maximum;
- Information about procedures for involuntary termination due to failure to pay and how to submit an inquiry or file a grievance, as well as a statement informing the individual that they can voluntarily leave the program at any time;
- A statement describing that leaving the Medicare Prescription Payment Plan, either involuntarily or voluntarily, will not affect the individual's Medicare Part D coverage with the Part D plan;
- A description of how if an individual leaves the program, they may still owe a program balance, they can pay the balance all at once or be billed monthly, and that they will resume paying the pharmacy directly for their Part D prescriptions after leaving the program; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer's Pharmaceutical Assistance Program, and how to learn more about these programs.

CMS issued a model “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 through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

30.3.3 Notice of Failure to Pay

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. As discussed in section 80.2.1 of the final part one guidance, 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 fifteen calendar days of the payment due date. After sending this notice, Part D sponsors may send interim notices during the following grace period.

The notice of failure to pay must include:

- Pertinent dates and key pieces of information, including the date the missed monthly payment was due, the amount the individual must pay to remain in the program, and the date by when payment must be received, which is the date of the end of the grace period;
- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual’s Part D drug coverage will not be impacted;
- Instructions for how to submit payment;
- Information about procedures for involuntary termination due to failure to pay, including the date on which the participant would be removed if payment is not received, and how to submit an inquiry or file a grievance;
- A statement on how individuals should pay their Part D plan premium first if they cannot afford both their premium and their program balance; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer’s Pharmaceutical Assistance Program, and how to learn more about these programs.

CMS issued a model “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” to support sponsors in meeting this notice requirement through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

30.3.4 Notice of Involuntary Termination Following End of Grace Period

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 of the final part one guidance.

Part D sponsors must provide a notice of termination of participation to Part D enrollees who have failed to pay their outstanding balance within the required grace period. This notice must be sent within three calendar days after the end of the grace period.

The notice of termination of participation must include:

- Pertinent dates, including the date the individual was originally notified of the missed monthly payment and the due date for that payment, as well as the date on which the individual’s participation in the program ends, which should be the same date as the notice;

- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual’s Part D drug coverage will not be impacted;
- Instructions for how to submit payment and the amount owed;
- How to submit an inquiry or file a grievance;
- A statement clarifying that the individual can join the Medicare Prescription Payment Plan again if they pay the amount owed; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer’s Pharmaceutical Assistance Program, and how to learn more about these programs.

CMS issued a model “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan - Notification of Termination of Participation in the Medicare Prescription Payment Plan” to support sponsors in meeting this notice requirement through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

30.3.5 Notice of Voluntary Termination

Part D sponsors must have a process in place to allow Part D enrollees participating in the Medicare Prescription Payment Plan to voluntarily terminate their participation in the program. After a participant voluntarily terminates their participation in the program, Part D sponsors must work with the enrollee to determine how they will pay their outstanding balance, which may include a lump sum payment; however, Part D sponsors cannot require full immediate repayment. If the enrollee chooses to continue paying in monthly amounts, Part D 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 opting out, the individual will pay any new OOP costs directly to the pharmacy. The Part D sponsor must process the participant’s voluntary termination request and send the individual a notification confirming the termination within ten calendar days of receipt of the request. The Part D sponsor must also maintain a record of individuals who have been terminated from the program.

Additionally, as stated in section 80.5 of the final part one guidance, when a Part D enrollee disenrolls from the Part D plan, such as when switching plans during the coverage year or for a subsequent coverage year, their participation in the Medicare Prescription Payment Plan, as administered by the Part D plan losing the enrollee, effectively ends. Part D sponsors must notify these individuals that they have been voluntarily removed from the Medicare Prescription Payment Plan.

The notice of voluntary termination must include:

- Pertinent dates, including the date on which the individual’s participation in the program ends;
- An explanation that the individual is receiving the notice either because they requested a voluntary termination or because they changed Part D plans;
- A statement clarifying that the notice only applies to participation in the Medicare Prescription Payment Plan, and that the individual’s Part D drug coverage will not be impacted;
- A statement clarifying that the individual will continue to be billed monthly or can choose to pay the amount owed all at once, and that the individual will not pay interest or fees on the amount owed;
- A statement clarifying that the individual can join the Medicare Prescription Payment Plan again and instructions for how to do so, which may differ depending on whether the voluntary termination was requested by the individual or if it was because the individual changed Part D plans; and
- An overview of other Medicare programs that can help lower costs, including Extra Help, the Medicare Savings Program, the State Pharmaceutical Assistance Program, and the Manufacturer’s Pharmaceutical Assistance Program, and how to learn more about these programs.

CMS issued a model “Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan” to support Part D sponsors in meeting this notice requirement through the Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882; OMB 0938-1475) ICR package.

30.4 Language Access and Accessibility Requirements

Under section 1860D–2(b)(2)(E)(v) of the Act, both CMS and Part D sponsors are required to provide Medicare Prescription Payment Plan information and educational materials to Part D enrollees. Under § 423.2267, CMS requires outreach materials and communications be provided in a culturally competent manner to all Part D enrollees, including those with limited English proficiency (LEP) or reading skills and diverse cultural and ethnic backgrounds.

As required by § 423.2267(a)(2) for all materials that CMS deems vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form to be translated and made available in markets with a significant population of persons with limited English proficiency. In addition, for markets with a significant population of persons with limited English proficiency, the requirements finalized in the CY 2024 MA and Part D Final Rule (CMS–4201–F) apply to all Medicare Prescription Payment Plan required model and

standardized materials.³² These requirements stipulate that Part D sponsors must provide translated materials to Part D enrollees on a standing basis in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area.

In addition, under § 423.2267(a)(3), required model and standardized materials must be provided in a non-English language and an accessible format using auxiliary aids and services upon request or otherwise learning of the Part D enrollee's primary language and/or need for an accessible format. As stated above in section 30.1.5, Part D sponsors' websites must comply with anti-discrimination provisions, such as Section 504 and Section 508 of the Rehabilitation Act, with regard to providing access to websites and other materials, so that individuals who are blind or have low vision, for example, can read sites and materials with screen reader technology.

The Part D regulation at § 423.2267(e)(33) also requires that Part D sponsors use a multi-language insert (MLI) that informs the reader, in several commonly spoken non-English languages used in the United States, as well as in any additional non-English language that is the primary language of at least five percent of the individuals in a PBP service area, that interpreter services are available for free.³³ Plans are required to include the MLI whenever a Medicare beneficiary is provided a CMS-required material.

Further, Part D sponsors must ensure compliance with all applicable protections and requirements under section 1557 of the Affordable Care Act, including those related to language access and language assistance services to protect individuals with LEP, and related to auxiliary aids and services to protect individuals with disabilities.³⁴

The above requirements apply to information about the Medicare Prescription Payment Plan that is included in the following modified or newly created documents that Part D sponsors must use to educate on, or communicate about, the Medicare Prescription Payment Plan:³⁵

- ANOC;
- EOC;
- EOB;
- Part D sponsor websites;

³² <https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf>.

³³ Under the 2023 MA and Part D Final Rule, the MLI must state, "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service." <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>.

³⁴ The final rule regarding section 1557 of the Affordable Care Act is available at this link: <https://www.federalregister.gov/documents/2024/05/06/2024-08711/nondiscrimination-in-health-programs-and-activities>. A fact sheet is available at this link: <https://www.hhs.gov/civil-rights/for-individuals/section-1557/faqs/index.html>.

³⁵ <https://www.cms.gov/medicare/health-plans/managedcaremarketing/finalpartcmarketingguidelines>.

- Election request form;
- Notice of election approval;
- Notice of failure to pay;
- Notice of involuntary termination;
- Notice of voluntary termination; and
- The “Medicare Prescription Payment Plan Likely to Benefit Notice.”

CMS has provided a Spanish translation of the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” through the ICR process. Pharmacies should make the Spanish-language version of the notice available, in lieu of the English-language version, to their patients upon request. Part D sponsors must provide the standardized notice in additional languages upon request.

40. CMS Part D Enrollee Education and Outreach

Section 1860D-2(b)(2)(E)(v)(I) of the Act requires CMS to provide educational materials to Part D enrollees on the option to participate in the Medicare Prescription Payment Plan. To support broad education of all Part D enrollees on the availability of the program, CMS is developing new Part D educational resources and is updating existing Part D resources that provide individuals with information on Medicare Part D.

40.1 Information on the Medicare Prescription Payment Plan

CMS is issuing a fact sheet for Part D enrollees on the Medicare.gov website and through other communication channels. Additionally, interested parties, such as Part D sponsors, pharmacies, providers, beneficiary advocates, and others, are encouraged to use this fact sheet to educate Part D enrollees.

Part D sponsors’ use of this fact sheet will satisfy the Part D sponsor requirement to provide information on the Medicare Prescription Payment Plan:

- on their website (section 30.1.5);
- alongside the election request form included in the membership ID Card mailing or in a separate mailing (section 30.1.1); and
- alongside the “Medicare Prescription Payment Plan Likely to Benefit Notice” when sent prior to or during the plan year (section 30.2.2).

Additionally, Part D sponsors are encouraged to use this fact sheet to:

- provide additional information to pharmacies that pharmacists can furnish to Part D enrollees identified as likely to benefit at the POS alongside the “Medicare Prescription Payment Plan Likely to Benefit Notice” (section 30.2.2.3);
- communicate with contracted providers (section 30.2.3) and other interested parties; and
- describe the Medicare Prescription Payment Plan in other Part D enrollee education, communications, and marketing materials.

40.2 Modifications to Existing Part D Resources

CMS will make appropriate modifications to CMS-provided Medicare Part D documents, web content, and tools to ensure that individuals have the resources needed to learn about the availability of the program before the plan year begins and understand how the program may benefit them based on their needs. Resources that CMS will modify include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder,³⁶ among others.

40.3 National Outreach and Education Efforts

CMS will work with interested parties to ensure that Part D sponsors, pharmacies, providers, and beneficiary advocates—including State Health Insurance Assistance Program (SHIP) counselors—have sufficient support and materials needed to effectively communicate the availability and nuances of this program to individuals. CMS will release additional information about these outreach and training opportunities in the coming months.

50. Pharmacy Processes

Pharmacies play an important role in operationalizing the Medicare Prescription Payment Plan. 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 Part D 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 Part D sponsor, informs the Part D enrollee that they are likely to benefit from the Medicare Prescription Payment Plan. Given this statutory requirement, Part D sponsors must ensure that their pharmacy network contracts include a provision requiring pharmacies to provide this notification to Part D enrollees.

In this section, CMS provides additional information around pharmacy processes related to the Medicare Prescription Payment Plan. Except as otherwise required in this guidance or under other applicable requirements, all Medicare Prescription Payment Plan requirements are the same

³⁶ Changes to the Medicare Plan Finder for CY 2025 were announced in the May 31, 2024 HPMS memo “Medicare Plan Finder Enhancements for Contract Year 2025.” The memo includes a summary of changes made to reflect the Medicare Prescription Payment Plan.

for every pharmacy type, including but not limited to, mail order, home infusion, specialty, and long-term care pharmacies.

50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount

In the final part one guidance for the Medicare Prescription Payment Plan, CMS stated that the likely to benefit notification required at the pharmacy POS will be based on the OOP costs incurred for a single prescription. Part D sponsors will be responsible for notifying the pharmacy when OOP prescription costs equal or exceed the \$600 threshold, as finalized in the final part one guidance. This notification will be returned to the pharmacy on the Part D claim response from the Part D sponsor or pharmacy benefit manager (PBM). CMS is aware, however, that a small portion of Part D enrollees will have supplemental coverage, such as through a State Pharmaceutical Assistance Program (SPAP), charity, or other health insurance (OHI). In these cases, the final patient pay amount on a covered Part D prescription drug claim may then be reduced below the required notification threshold because of the contributions of a supplemental payer. CMS intends to provide language in the “Medicare Prescription Payment Plan Likely to Benefit Notice” that recommends enrollees with supplemental coverage seek advice related to their specific situation prior to opting into the Medicare Prescription Payment Plan.

Part D sponsors should ensure that their customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election. When discussing a Part D enrollee’s prescription drug costs, customer service representatives may need to review records for Information Reporting (Nx) transactions, indicating supplemental coverage or OHI. As discussed in more detail in the final part one guidance, all Part D enrollees are eligible for the Medicare Prescription Payment Plan, but those with low OOP costs are less likely to benefit.

CMS is aware that occasionally, the final patient pay amount returned to the pharmacy by a supplemental payer for a covered Part D drug is higher than the original Part D patient pay amount. In these cases, for the program participant’s portion of the claim (what they would have paid directly to the pharmacy), the Part D sponsor may only include in the Medicare Prescription Payment Plan the participant’s original Part D cost sharing, as determined by their plan-specific benefit structure.

50.2 Pharmacy POS Notifications Late in the Plan Year

As specified by section 1860D–2(b)(2)(E)(iv) of the Act, the number of months remaining in the plan year is an important component of the maximum monthly cap calculation.³⁷ As described in section 30.1 of the final part one guidance, the maximum monthly cap in the first month of program participation is determined by calculating the annual OOP threshold minus any Part D

³⁷ See section 30 of the final part one guidance for additional details on program calculations.

costs the Part D enrollee incurred during the year before opting in, divided by the number of months remaining in the plan year. Given that the pharmacy POS threshold will be a static amount, this may result in scenarios late in the plan year in which Part D enrollees who receive the “Medicare Prescription Payment Plan Likely to Benefit Notice” at the pharmacy based on their OOP costs, but whose costs are below the maximum monthly cap, are then required to pay the full amount as part of their first month’s bill. For example, if a Part D enrollee has not yet opted into the Medicare Prescription Payment Plan and fills a new prescription with an OOP cost of \$650 in October 2025, their maximum monthly cap in the first month could be as high as \$666.67 (assuming \$0 in prior TrOOP accumulation). In this scenario, a Part D enrollee could receive the POS notification based on their OOP costs exceeding the threshold, but if they opted into the Medicare Prescription Payment Plan, because their OOP costs are below the maximum monthly cap, the Part D sponsor would bill them for the entire \$650 as part of their first month’s bill.³⁸ Part D sponsors should ensure that customer service representatives are aware of this possibility when receiving inquiries from Part D enrollees regarding program election.

50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies

As noted above, in general, all Medicare Prescription Payment Plan requirements are the same for every pharmacy type, including, but not limited to, mail order, home infusion, specialty, and long-term care pharmacies. In pharmacy settings in which there is direct contact with enrollees (e.g., community pharmacies where enrollees present in person to pick up prescriptions), the Part D sponsor must ensure that a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” is provided to enrollees identified as likely to benefit (or the person acting on their behalf) at the time the prescription is picked up. This includes pharmacies with a drive-through or curbside pick-up option. 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 a hard copy of the “Medicare Prescription Payment Plan Likely to Benefit Notice” directly to the Part D enrollee. CMS is providing additional guidance below related to these settings.

In addition, CMS notes that regardless of the setting, if the pharmacy is in contact with a Part D enrollee identified as likely to benefit and the enrollee declines to complete the prescription purchase, the Part D sponsor must ensure that the pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. For example, if a Part D enrollee visits a retail pharmacy to pick up their prescription but then declines to complete the transaction because of the cost, the Part D sponsor must still ensure that the pharmacy provides the standardized “Medicare Prescription Payment Plan Likely to Benefit Notice” to that Part D enrollee.

³⁸ In comparison to the example described here, if a Part D enrollee had a prescription with OOP costs of \$650 in February instead of October (with no prior TrOOP accumulation), their maximum monthly cap in the first month would be \$181.82.

Pharmacies may also choose to develop additional strategies to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to enrollees identified as likely to benefit. For example, pharmacies with disease management or medication management programs may choose to include Medicare Prescription Payment Plan information as a component of those processes. In addition to providing a hard copy, CMS encourages pharmacies to consider providing the “Medicare Prescription Payment Plan Likely to Benefit Notice” in other modes of communication with enrollees identified as likely to benefit, such as through a patient portal or secure email.

50.3.1 Long-Term Care Pharmacies

Long-term care pharmacies typically do not have a POS encounter between the pharmacy and the enrollee (long-term care resident). In these cases, the pharmacy may deliver medications that are kept in the custody of long-term care facilities until time of administration. In addition, long-term care pharmacies often use retrospective or post-consumption billing (i.e., billing after the drug is dispensed to the facility for an enrollee). As such, when the POS notification is received by a long-term care pharmacy, the plan sponsor should not require that the long-term care pharmacy provides the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to dispensing the medication. Instead, the plan sponsor should require the long-term care pharmacy to provide the notice to the Part D enrollee (or their authorized representative) at the time of its typical enrollee cost-sharing billing process.

50.3.2 Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies

I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan’s benefit structure, is not collected at the POS. As such, if a high-cost prescription drug claim for a Part D enrollee is submitted to a Part D sponsor from an I/T/U pharmacy, the Part D sponsor is not required to return the pharmacy notification indicating the enrollee is likely to benefit from the program.

50.3.3 Other Pharmacy Types

For other pharmacy types without in-person encounters (such as mail order pharmacies), Part D sponsors must require the pharmacy to notify the Part D enrollee via a telephone call or their preferred contact method. This requirement should not, however, be interpreted as a requirement to delay dispensing the medication. Pharmacies are encouraged to utilize existing touchpoints with Part D enrollees, such as outreach to review medication instructions or collect a method of payment, to convey the content of the “Medicare Prescription Payment Plan Likely to Benefit Notice” prior to processing payment for the prescription that triggered the notice. As with retail

pharmacies, CMS encourages other pharmacy types to consider providing the “Medicare Prescription Payment Plan Likely to Benefit Notice” via additional modes of communication beyond the requirements in this section, such as through a patient portal or secure email.

CMS encourages Part D sponsors to work with pharmacies to establish and maintain reasonable procedures related to the timing and number of attempts for prompt notification of identified Part D enrollees.

50.4 Readjudication of Prescription Drug Claims for New Program Participants

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. For claims to be processed appropriately using the Medicare Prescription Payment Plan Bank Identification Number (BIN) and Processor Control Number (PCN) methodology, the date of service on the Part D claim and the additional program-specific transaction must be on or after the date of program effectuation.

When a Part D enrollee receives the “Medicare Prescription Payment Plan Likely to Benefit Notice” from the pharmacy, they may choose to take time to consider opting into the program and leave the pharmacy without the prescription that triggered the notification. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription after successfully opting into the program, the prescription claim that triggered the notification must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. Should a Part D enrollee have other unpaid claims at the same pharmacy for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification, they may also request that those claims be readjudicated, so as to be included in the Medicare Prescription Payment Plan. CMS encourages Part D sponsors to provide their enrollees with education and information on how to proceed with readjudication of other unpaid claims for covered Part D drugs.

For example, a Part D enrollee is prescribed a new medication with an OOP cost that is above the POS notification threshold. The plan would notify the pharmacy that the enrollee is likely to benefit from the Medicare Prescription Payment Plan. The pharmacy would then provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee. The enrollee decides to leave the pharmacy without paying for their high-cost prescription, so they can contact their plan and opt into the program. However, the pharmacy also has two other covered Part D prescriptions filled for the Part D enrollee from prior dates of service, for which the Part D enrollee also decided to leave the pharmacy without picking up and paying. When the Part D enrollee returns to the pharmacy after their election into the Medicare Prescription Payment Plan has been effectuated, the plan sponsor must require the pharmacy to reverse and reprocess the high-cost claim that triggered the likely to benefit notification. The program participant would then pay \$0 at the pharmacy for the high-cost claim and pay their typical plan-

defined cost sharing for the other claims with prior dates of service. Alternatively, the Part D enrollee could request that the pharmacy reverse and reprocess all three claims, so the program participant pays \$0 at the pharmacy for all three drugs.

In the case of same-day program effectuation (when the Part D claim date of service is the same as the date of program effectuation), the pharmacy is not required to reverse and resubmit the Part D claim, provided that it otherwise obtains the necessary Medicare Prescription Payment Plan BIN/PCN for the program-specific transaction.

CMS notes that, in general, plan sponsors are not required to provide that pharmacies reverse and reprocess claims under the Medicare Prescription Payment Plan that have already been paid for by the Part D enrollee. As noted in section 70.3.7 of the final part one guidance, Part D sponsors must have processes in place to reimburse enrollee cost sharing for urgent prescriptions when an enrollee has met the conditions for a retroactive election into the Medicare Prescription Payment Plan.

50.5 Processing of Covered Part D Claims for Program Participants in Special Settings

50.5.1 Long-Term Care Pharmacies

CMS is aware that there are multiple types of payment arrangements between long-term care pharmacies and long-term care facilities and/or Part D enrollees. In some situations, long-term care pharmacies do not collect Part D cost sharing from the enrollee but instead bill the long-term care facility for the final patient OOP responsibility. When such an arrangement is in place between a long-term care pharmacy and a long-term care facility, and an enrollee in a long-term care facility is participating in the Medicare Prescription Payment Plan, billing the participant's Part D plan's Medicare Prescription Payment Plan BIN/PCN for the participant's OOP costs (when the pharmacy would not have otherwise directly billed the enrollee) may result in additional financial burden on that participant. In such cases, CMS encourages Part D sponsors to take the participant's particular circumstances into account when considering Medicare Prescription Payment Plan billing practices and to work with the participant, their authorized representative, and the long-term care pharmacy to understand the best billing approach for the participant.

50.5.2 I/T/U Pharmacies

As noted in section 50.3.2, I/T/U pharmacies provide no-cost prescription drugs to eligible IHS enrollees. When IHS-eligible Part D enrollees fill a prescription at an I/T/U pharmacy, their covered Part D prescription drug cost sharing, as defined by their plan's benefit structure, is not collected at the POS. Given that, if an IHS-eligible Part D enrollee is also participating in the Medicare Prescription Payment Plan, the I/T/U pharmacy cannot bill the Part D plan's Medicare

Prescription Payment Plan BIN/PCN. Instead, the I/T/U pharmacy must process the claim as if the IHS-eligible enrollee were not participating in the Medicare Prescription Payment Plan. If a Part D sponsor receives a claim from an I/T/U pharmacy that was submitted to the Medicare Prescription Payment Plan-specific BIN/PCN, the Part D sponsor must reject the claim. To help prevent this situation from occurring, Part D sponsors must also put in place processes to prevent Medicare Prescription Payment Plan BIN/PCNs from being returned on paid claim responses to I/T/U pharmacies.

These requirements apply only with respect to I/T/U pharmacies that dispense prescriptions at no cost to the IHS enrollee. The plan sponsor must ensure other network pharmacies providing services to Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements, as outlined in the final part one guidance and elsewhere in this final part two guidance.

Part D sponsors should also ensure that their customer service representatives are aware of this situation regarding I/T/U pharmacies when receiving inquiries from Part D enrollees regarding program election. In discussing a Part D enrollee's prescription drug costs, customer service representatives may need to review the primary pharmacy type used by the Part D enrollee. Part D enrollees who solely use I/T/U pharmacies, and thus have \$0 in OOP costs for covered Part D drugs, may not benefit from participation in the Medicare Prescription Payment Plan.

60. Part D Sponsor Operational Requirements

This section builds on the final part one guidance and discusses the various operational requirements that Part D sponsors should be aware of and must comply with in implementing the program.

60.1 Part D Bidding Guidance for CY 2025

Section 1860D-2(b)(2)(E)(v)(VI) of the Act requires Part D sponsors to treat any unsettled balances with respect to amounts owed by participants under the Medicare Prescription Payment Plan as plan losses. In addition, the statute requires that the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids. If a Part D sponsor is compensated by or on behalf of the participant for an unsettled balance or sells an unsettled balance as a debt, it cannot treat the amount as a loss and cannot include it in its bid. Only uncompensated unsettled balances can be included in the bid.

Given these changes, the Part D bid pricing tool (BPT) has been modified to reflect projected losses associated with the Medicare Prescription Payment Plan. Specifically, these losses must be reflected as administrative costs in the Part D BPT. The CY 2025 Part D BPT must be completed by following the applicable guidance for CY 2025 bidding, which is available at the following

hyperlink: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Bid-Forms-Instructions>.

60.2 Medical Loss Ratio (MLR) Instructions

Sections 1857(e)(4) and 1860D-12(b)(3)(D) of the Act require that MA organizations and Part D sponsors be subject to financial and other penalties for a failure to have an MLR of at least 85 percent. The MLR is computed at the contract level and is expressed as a percentage that represents the portion of the revenue received under the contract that is used for patient care (for example, incurred claims for clinical services and prescription drug costs and quality improvement activities) rather than for such other items as administrative expenses or profit. The sanctions for failure to meet the 85 percent minimum MLR requirement include remittance of funds to the Secretary, a prohibition on enrolling new members, and ultimately contract termination. To monitor this requirement and implement sanctions as required by the statute for failure to meet the MLR requirement for multiple consecutive contract years, CMS requires MA organizations and Part D sponsors to report MLR data to CMS on an annual basis, pursuant to the regulations at §§ 422.2460 and 423.2460.

Section 1860D-2(b)(2)(E)(v)(VI) of the Act specifies that any unsettled balances with respect to amounts owed under the Medicare Prescription Payment Plan “shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.” Consistent with the inclusion of plan losses in the administrative expense portion of the Part D bid, unsettled balances from the Medicare Prescription Payment Plan will be considered administrative costs for purposes of the MLR calculation and therefore be excluded from the MLR numerator.

60.3 Monitoring and Compliance

As discussed in section 100 of the final part one guidance for the Medicare Prescription Payment Plan, CMS will require Part D sponsors to report information related to the program through PDE records and new reporting requirements.³⁹ Additional guidance on PDE reporting was issued as part of the PDE reporting instructions published on April 15, 2024. Additional details related to other reporting requirements can be found in the final part one guidance and associated OMB ICR packages:

- The MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (OMB Control Number 0938-1468) ICR, approved through May 31, 2027. It can be accessed here: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202404-0938-007.

³⁹ Please see section 100 of the final part one guidance for additional information.

- The Medicare Part D Reporting Requirements (CMS-10185; OMB 0938-0992) ICR, which concluded its 30-day comment period on June 24, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2024/05/24/2024-11397/agency-information-collection-activities-submission-for-omb-review-comment-request>.
- The Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments (CMS-10174; OMB: 0938-0982) ICR, approved through April 30, 2027, 2024. It can be accessed here: https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202403-0938-002.

CMS will also monitor sponsors' performance, including collecting data about plan grievances and beneficiary complaints entered in the Medicare Complaints Tracking Module (CTM) to assess compliance with all Medicare Prescription Payment Plan requirements, beneficiary protections, and program integrity. With respect to beneficiary complaints entered into the CTM, CMS will assess whether an additional CTM category or subcategory is needed for the Medicare Prescription Payment Plan in future years. Please refer to section 30 of the latest Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for details on grievance process requirements and section 40 for details on appeals requirements.⁴⁰ Additionally, plan sponsors may refer to the CY 2025 MA and Part D Final Rule (89 FR 30506) for timeliness requirements for Part D sponsor resolution of complaints received via the CTM, which are codified in § 423.129. In addition, CMS expects Part D sponsors to incorporate the Medicare Prescription Payment Plan into their compliance programs to ensure that they are meeting program requirements.⁴¹ Part D sponsors are reminded that they must comply with the reporting requirements at §§ 423.505(f) and 423.514, and applicable final Medicare Part D Reporting Requirements⁴² with respect to the Medicare Prescription Payment Plan.

60.4 Audits

CMS and/or its contractors may conduct specific audits of Part D sponsors' implementation of the Medicare Prescription Payment Plan and may initiate audit activity that requires additional data collection or site visits.⁴³

⁴⁰ <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

⁴¹ § 423.504(b)(4)(vi) requires Part D sponsors to adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. Please refer to Chapter 9 of the Prescription Drug Benefit Manual for additional information regarding compliance program requirements.

⁴² For the most recent Medicare Part D Reporting Requirements, see:

<https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/part-d-reporting-requirements>.

⁴³ §§ 422.504(e) and 423.505(e).

60.5 Direct and Indirect Remuneration (DIR) Reporting Guidance

Section 1860D-15(f)(1)(A) of the Act requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of section 1860D-15 of the Act, including the calculation of reinsurance and risk-sharing. Therefore, each year, Part D sponsors are required to report to CMS drug costs and DIR associated with the Medicare Part D benefit.

CMS anticipates no changes to DIR calculations or reporting due to the Medicare Prescription Payment Plan. Part D sponsors should continue to report DIR in accordance with the explanatory guidance and instructions issued annually by CMS.