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## CENTER FOR MEDICARE

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**DATE:** February 15, 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: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments

### 10. Introduction

The purpose of this document is to provide interested parties with draft 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,<sup>1,2</sup> 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

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<sup>1</sup> This provision does not apply to the Limited Income Newly Eligible Transition (LI NET) coverage because participants in the LI NET program do not enroll in a PDP or MA-PD plan to receive transitional coverage under the program.

<sup>2</sup> Under section 1894(a) of the Act, PACE organizations must provide all medically necessary services including prescription drugs, without application of deductibles, copayments, coinsurance, or other cost-sharing that would otherwise apply under Medicare or Medicaid. While the Medicare Prescription Payment Plan is applicable to all Part D plans, it has no practical application for PACE organizations. In addition, the program has no application to those demonstration Medicare-Medicaid Plans (MMPs) that have no Part D cost-sharing.

accordance with the law, CMS is issuing this draft part two guidance for implementation of the Medicare Prescription Payment Plan (also referred to in this guidance as the “program”) for 2025. This draft part two guidance builds on the draft part one guidance that was issued on August 21, 2023 through a Health Plan Management System (HPMS) memo titled “Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments,” and the July 17, 2023, HPMS memo titled “Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans.”<sup>3</sup> In this draft part two guidance, CMS describes requirements for Part D sponsor obligations related to outreach and education, pharmacy processes, and operational considerations for the program.

CMS is voluntarily soliciting comment on this draft part two guidance. Please send comments pertaining to this draft guidance to [PartDPaymentPolicy@cms.hhs.gov](mailto:PartDPaymentPolicy@cms.hhs.gov) with the subject line “Medicare Prescription Payment Plan Guidance – Part Two.” Comments received by March 16, 2024 will be considered. CMS will issue final part two guidance in summer 2024 after considering the public comments received in response to this draft part two guidance. In the final guidance, CMS may make changes to any policies described in this draft guidance, including policies on which CMS has not expressly solicited comment, based on the agency’s further consideration of the relevant issues. This guidance, paired with the part one guidance, pertains to the first year of the program, contract year (CY) 2025, and the policies established in the final guidance will be subject to change in subsequent years. Additionally, CMS will issue model materials specific to the program in summer 2024 following an Information Collection Request (ICR) through the Office of Management and Budget (OMB).

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.

The table of contents for this memorandum is as follows:

<b>10. Introduction</b>	1
<b>20. Overview of the Medicare Prescription Payment Plan</b>	3
<b>30. Outreach, Education, and Communications Requirements for Part D Sponsors</b>	4
30.1 General Outreach and Education	6
30.1.1 <i>Required Mailings with Membership ID Card Issuance</i>	6
30.1.2 <i>Evidence of Coverage (EOC)</i>	7
30.1.3 <i>Annual Notice of Change (ANOC)</i>	7
30.1.4 <i>Explanation of Benefits (EOB)</i>	7
30.1.5 <i>Part D Sponsor Websites</i>	8
30.2 Targeted Outreach and Education Requirements for Part D Sponsors	9
30.2.1 <i>Notice for Part D Enrollees Likely to Benefit</i>	10

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<sup>3</sup> Medicare Prescription Payment Plan publications, including the draft part one guidance and technical memorandum, can be accessed at: <https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements>

30.2.2 Requirements for Identifying Part D Enrollees Likely to Benefit Prior to and During the Plan Year	10
30.2.3 Communications with Contracted Providers and Pharmacies	15
30.3 Communications with Program Participants and Model Materials Requirements for Part D Sponsors	15
30.3.1 Overview of Election Requirements	16
30.3.2 Notice of Acceptance of Election	18
30.3.3 Notice of Failure to Pay	19
30.3.4 Notice of Termination of Election Following End of Grace Period	19
30.3.5 Notice of Voluntary Termination	20
30.4 Language Access and Accessibility Requirements	20
<b>40. CMS Part D Enrollee Education and Outreach</b>	21
40.1 Information on the Medicare Prescription Payment Plan	22
40.2 Modifications to Existing Part D Resources	22
40.3 National Outreach and Education Efforts	22
<b>50. Pharmacy Processes</b>	23
50.1 Part D Enrollees with Supplemental Coverage that Modifies the Final Patient Pay Amount	23
50.2 Pharmacy POS Notifications Late in the Plan Year	24
50.3 Pharmacy POS Notifications in Retail and Non-Retail Pharmacies	24
50.3.1 Long-Term Care Pharmacies	25
50.3.2 Indian Health Service (IHS), Tribe and Tribal Organization, and Urban Indian Organization (I/T/U) Pharmacies	25
50.3.3 Other Pharmacy Types	25
50.4 Readjudication of Prescription Drug Claims for New Program Participants	26
50.5 Processing of Covered Part D Claims for Program Participants in Special Settings	27
50.5.1 Long-Term Care Pharmacies	27
50.5.2 I/T/U Pharmacies	27
<b>60. Part D Sponsor Operational Requirements</b>	28
60.1 Part D Bidding Guidance for CY 2025	28
60.2 Medical Loss Ratio (MLR) Instructions	28
60.3 Monitoring and Compliance	29
60.4 Audits	30
60.5 Direct and Indirect Remuneration (DIR) Reporting Guidance	30

## **20. Overview of the Medicare Prescription Payment Plan**

Beginning in 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 draft 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 costs<sup>4</sup> earlier in the plan year are generally more likely to benefit, as discussed in the draft part one guidance.

In the draft 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 draft part two guidance builds on the draft 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 will be 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 contract year (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 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.

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<sup>4</sup> For the definition of OOP costs used for the Medicare Prescription Payment Plan, see Appendix A of the draft part one guidance.

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 section 30.4. In addition, this section includes guidance on how Part D sponsors can fulfill their statutory pharmacy notification requirements.

In this draft part two guidance, CMS describes how it will modify existing Part D materials to reflect implementation of the Medicare Prescription Payment Plan (see section 30.1). Additionally, CMS is developing model materials that will be 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. Once the model materials are approved through the OMB ICR process, they will be released in summer 2024, ahead of the CY 2025 Annual Election Period.

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. Finally, sponsors should also reference the Medicare Prescription Drug Benefit Manual and HPMS memoranda to ensure compliance with other Part D communications requirements.<sup>5</sup> Part D sponsors are also encouraged to review their plan materials including, but not limited to, those described in this 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. CMS requests public comment on the scope of included materials, including updated existing Part D materials and newly developed resources; their use, content, and distribution; ways to ensure all Part D enrollees receive information in an easy-to-understand manner, including at an appropriate literacy level and using language that allows all Part D enrollees, particularly those who may have language and accessibility barriers, to make an informed decision; and other potential materials that may be appropriate to modify or develop that are not currently included in this section.

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<sup>5</sup> 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.

### 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), 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 10 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 plan, Part D sponsors will be required to include with the membership ID card hard copy mailing:

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

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 educational product, 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 educational product 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 15<sup>th</sup> prior to the year to which the EOC applies or, for new Part D enrollees, within 10 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.<sup>6</sup>

CMS is updating 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 will be released in spring 2024 as part of the general issuance of CY 2025 Model Materials (CMS-10260; OMB 0938-1051).<sup>7</sup>

### *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.<sup>8</sup> 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.<sup>9</sup>

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 will be released in spring 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

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<sup>6</sup> <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

<sup>7</sup> CY 2025 Model Materials will be posted at: <https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/models-standard-documents-educational-materials>.

<sup>8</sup> <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-V/section-423.2267>.

<sup>9</sup> <https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf>.

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, given the significant changes the IRA makes to the Part D benefit design and the launch of the Medicare Prescription Payment Plan in CY 2025, CMS requested comment on what information related to the Medicare Prescription Payment Plan should be included in the EOB. On June 6, 2023, CMS published in the Federal Register (88 FR 37066) notice of a 60-day comment period regarding the Part D model EOB (CMS-10453; OMB 0938-1228).<sup>10</sup>

CMS received a wide range of public comment regarding the EOB, including comments about inclusion of Medicare Prescription Payment Plan language.<sup>11</sup> Some commenters recommended CMS indicate whether the individual is participating in the program and include general education and the individual's previously paid and future costs under the program, as well as information as to whether the individual has met the annual OOP cap. CMS considered all comments received, and on December 8, 2023, published notice of an updated EOB with a 30-day comment period (88 FR 85622).<sup>12</sup> The revised 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 EOB also explains that costs included in the EOB might differ from what a Medicare Prescription Payment Plan participant paid at POS. After considering comments received during the 30-day comment period, CMS expects to issue a final EOB for CY 2025 in spring 2024 as part of the general issuance of CY 2025 model materials.

### *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.<sup>13</sup> Additionally, as stated in section 30.4 of this draft 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 draft part one guidance outlines the requirement for Part D sponsors to have available on their websites a Medicare Prescription

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<sup>10</sup> <https://www.federalregister.gov/documents/2023/06/06/2023-11996/agency-information-collection-activities-proposed-collection-comment-request>.

<sup>11</sup> [https://www.reginfo.gov/public/do/PRAViewDocument?ref\\_nbr=202312-0938-004](https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202312-0938-004).

<sup>12</sup> <https://www.federalregister.gov/documents/2023/12/08/2023-27033/agency-information-collection-activities-submission-for-omb-review-comment-request>.

<sup>13</sup> For more specific website requirements, see 42 CFR 423.2265. Part D sponsors should also reference the MCMG.



Payment Plan election request mechanism that Part D enrollees can use to opt into the program and that provides the individual with evidence that the election request was received (e.g., a confirmation number). Section 30.3.1.4 of this draft 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;
- 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;
- 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 70.3.8 of the draft 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 recent the 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 educational product on the Medicare Prescription Payment Plan and other CMS-provided resources to meet these requirements. The CMS-developed educational product and other resources will be released at a later date and are discussed in more detail in section 40 below. Additionally, CMS encourages Part D sponsors to link to the CMS-developed educational products 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.<sup>14</sup> 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 section 70.3.9 of the draft 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 is developing 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 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).

Specific parameters around how and when Part D sponsors must use the “Medicare Prescription Payment Plan Likely to Benefit Notice” to meet the targeted outreach requirements are outlined below. The “Medicare Prescription Payment Plan Likely to Benefit Notice” will be issued through the OMB ICR process, and once approved, will be released in summer 2024 ahead of the CY 2025 Annual Election Period. Additionally, CMS notes that 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 sponsors can refer to 42 CR 423.2267(b) for requirements related to the use of standardized materials.

### *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 draft 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 draft 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

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<sup>14</sup> 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 draft part one guidance. For information on the framework used to define “likely to benefit,” see section 60.2.1 of the draft part one guidance.

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 draft 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 draft 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).<sup>15</sup>

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 \$2,000<sup>16</sup> 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’s quantitative definition of “likely to benefit” in the subsequent year.<sup>17</sup> 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’s analysis was based on the patient payment amount for covered Part D claims only, reflecting the actual OOP financial burden for Part D enrollees.

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<sup>15</sup> Please refer to section 60.2.1 of the draft part one guidance for additional information related to identifying Part D enrollees likely to benefit from the Medicare Prescription Payment Plan.

<sup>16</sup> \$2,000 was used in this analysis because it is the Part D annual OOP threshold for CY 2025.

<sup>17</sup> 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.

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 equally.

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). 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 a CMS-developed educational product 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 educational product 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 that Part D sponsors put in place reasonable guidelines for ongoing identification of Part D enrollees likely to benefit *during* the plan year. At minimum, Part D sponsors must 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.<sup>18</sup> Specifically, if Part D sponsors have prior 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 must undertake outreach to the Part D enrollee, 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. 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 supplemental strategies for identification of additional Part D enrollees likely to benefit during 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 Part D enrollee equally.

During the plan year, when a Part D sponsor identifies current Part D enrollees using the above methods, 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 within the same timeframe that applies to the coverage determination for the associated utilization management requirement.<sup>19</sup> For example, if the Part D sponsor receives a request for an expedited coverage determination for a covered Part D drug with OOP costs above the pharmacy POS notification threshold, they must provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” to the Part D enrollee within 24 hours of receiving the request. This outreach must be performed in writing either by mail or electronically (based on the Part D enrollee’s preferred and authorized communication methods). The outreach must also include additional information about the Medicare Prescription Payment Plan, and this additional information requirement may

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<sup>18</sup> As discussed in section 60.2.4 of the draft part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold. The specific threshold amount will be published in the final part one guidance.

<sup>19</sup> Please refer to the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for coverage determination processing requirements. <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

be fulfilled by including with the notice a CMS-developed educational product 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 educational product 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. Additionally, the initial notice may be provided via telephone, so long as the written “Medicare Prescription Payment Plan Likely to Benefit Notice” 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 draft part one guidance, CMS is requiring that Part D sponsors notify the pharmacy when a Part D enrollee incurs OOP costs that exceed a set threshold. The specific threshold amount will be published in the final part one guidance. To fulfill the requirement for pharmacies to then inform the Part D enrollee, the Part D sponsor must require the pharmacy to provide the “Medicare Prescription Payment Plan Likely to Benefit Notice” (discussed above in section 30.2.1) to the Part D enrollee. The Part D sponsor must ensure compliance with the language access and accessibility requirements 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 educational product 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 program works and how it can benefit participants.

The CMS-developed educational product 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 will develop 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, they must base their developed materials on CMS's model materials and must include the elements and information included in CMS's model materials in their developed materials. 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 is developing for the Medicare Prescription Payment Plan and that are outlined in this section will be issued through the OMB ICR process as one package. Once approved, the materials will be finalized by summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

### *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 Part D plan annual enrollment periods, initial Part D enrollment periods, and special Part D enrollment periods. Further, as noted in section 70.3.1 of the draft 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 draft 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 is developing 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. As discussed above, the specific model language for the “Medicare Prescription Payment Plan Participation Request Form” will be published for public comment in the Federal Register and approved through the OMB ICR process.

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

Part D sponsors must accept 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 section 70.3.3, 70.3.4, and 70.3.5 of the draft 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's 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 section 70.3.3 of the draft 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, follow a script previously approved by the Part D sponsor based on the content of the model "Medicare Prescription Payment Plan Participation Request Form," 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.

#### *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 Acceptance of Election*

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, to be issued in early 2024.

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. 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.

For all requests, in addition to the written notification of acceptance of election and effectuation, Part D sponsors must provide the new program participant with the information required in section 70.3 of the draft part one guidance. CMS also encourages Part D sponsors to provide

program participants with digital evidence of their election into the Medicare Prescription Payment Plan.

CMS is developing 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. As discussed above, the specific model language for the “Part D Sponsor Notice to Acknowledge Acceptance of Election into the Medicare Prescription Payment Plan” will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be finalized by summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

### *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 draft 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 15 calendar days of the payment due date.

CMS is developing a model “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” to support sponsors in meeting this notice requirement. The specific model language for the “Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan” will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

### *30.3.4 Notice of Termination of Election 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 draft 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.

CMS is developing 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. The specific model language for the “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” will be published for public comment in the Federal

Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the CY 2025 Annual Election Period.

### *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 10 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.

CMS is developing 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. The specific model language for the "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" will be published for public comment in the Federal Register and approved through the OMB ICR process. Once approved, the model notice will be released in summer 2024 ahead of the Annual Election Period for CY 2025 enrollment.

As stated in section 80.5 of the draft 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 are encouraged to use language from the "Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan" to communicate with these Part D enrollees, as well.

### 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. 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 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 educational and communications materials.<sup>20</sup> 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, 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 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.

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.<sup>21</sup> Plans are required to include the MLI whenever a Medicare beneficiary is provided a CMS-required material.

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:<sup>22</sup>

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

#### **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

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<sup>20</sup> <https://www.govinfo.gov/content/pkg/FR-2023-04-12/pdf/2023-07115.pdf>.

<sup>21</sup> 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>.

<sup>22</sup> <https://www.cms.gov/medicare/health-plans/managedcaremarketing/finalpartcmarketingguidelines>.

broad education of all Part D enrollees on the availability of the program, CMS will develop new Part D educational resources and will update existing Part D resources that provide individuals with information on Medicare Part D.

#### 40.1 Information on the Medicare Prescription Payment Plan

CMS will develop and provide an educational product 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 product to educate Part D enrollees.

Part D sponsors' use of this educational product 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 (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 educational product 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 may modify include the Medicare & You Handbook, Medicare.gov, and the Medicare Plan Finder, 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.

## **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 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 draft 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 determined threshold that will be finalized in the final part one guidance. This notification will be returned to the pharmacy on the primary 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 draft 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.

## 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.<sup>23</sup> As described in section 30.1 of the draft 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 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 true out-of-pocket (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.<sup>24</sup> 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 filling process, 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

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<sup>23</sup> See section 30 of the draft part one guidance for additional details on program calculations. The values there are illustrative; the POS threshold will be published as part of the final part one guidance.

<sup>24</sup> 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.



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.

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, pharmacies may also choose to provide 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 delivers 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 is not required to ensure 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 can require the long-term care pharmacy to provide the notice to the Part D enrollee at the time of its typical 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 an IHS-eligible 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. 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 BIN/PCN methodology, the date of service on the primary 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. As such, when the Part D enrollee returns to the pharmacy to pick up their prescription(s) after successfully opting into the program, all claims for covered Part D drugs from prior dates of service that have not yet been paid for and picked up by the beneficiary must be readjudicated to allow for appropriate processing by the Part D sponsor and/or PBM. This includes unpaid claims for covered Part D drugs from prior dates of service, in addition to the prescription that may have triggered the likely to benefit notification.

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 all three claims, so the program participant pays \$0 at the pharmacy for all three drugs. Alternatively, the Part D enrollee could choose to pick up and pay for the two other covered Part D prescriptions at the initial pharmacy visit and only return for the high-cost prescription that triggered the notification once their election into the Medicare Prescription Payment Plan has been effectuated. The pharmacy must then reverse and reprocess only the claim for the high-cost prescription that is being billed under the program, so that the program participant pays \$0 at the pharmacy for that prescription. This same process applies when the Part D enrollee has prescriptions that have not yet been picked up and paid for at multiple pharmacies.

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 they otherwise obtain 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 70.3.8 of the draft 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 for an IHS-eligible enrollee 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 IHS-eligible Part D enrollees process claims in accordance with the Medicare Prescription Payment Plan requirements, as outlined in the draft part one guidance and elsewhere in this draft 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 use solely 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 draft 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) will be 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 will be made 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 of revenue 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 levels of 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 administer any of the penalties, 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.” As 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 draft 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.<sup>25</sup> Additional guidance on PDE reporting will be issued as part of the PDE reporting instructions, which will be published in spring 2024. Additional details related to other reporting requirements can be found in the draft part one guidance and associated OMB ICR packages:

- The MARx Medicare Prescription Payment Plan Beneficiary-Level Data Elements (CMS-10887; OMB 0938-New) ICR, which was published on January 26, 2024 for a 60-day public comment period, with comments due by March 26, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2024/01/26/2024-01582/agency-information-collection-activities-proposed-collection-comment-request>
- The Medicare Part D Reporting Requirements (CMS-10185; (OMB 0938-0992) ICR, which was published on February 2, 2024 for a 60-day public comment period, with comments due by April 2, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2024/02/02/2024-02095/agency-information-collection-activities-proposed-collection-comment-request>
- 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, which was published on December 18, 2023 for a 60-day public comment period, with comments due by February 16, 2024. It can be accessed here: <https://www.federalregister.gov/documents/2023/12/18/2023-27684/agency-information-collection-activities-proposed-collection-comment-request>

CMS will also monitor and collect data about beneficiary complaints and grievances reported via 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 and grievances reported via 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.<sup>26</sup>

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<sup>25</sup> Please see section 100 of the draft part one guidance for additional information: <https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf>.

<sup>26</sup> <https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev>.

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.<sup>27</sup> 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 Requirements<sup>28</sup> 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.<sup>29</sup>

#### 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.

CMS encourages interested parties to submit comments on this draft part two guidance no later than March 16, 2024, as per the instruction in the Introduction section of this document.

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<sup>27</sup> 42 CFR § 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's 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.

<sup>28</sup> For the most recent Medicare Part D Reporting Requirements, see:

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

<sup>29</sup> 42 CFR §§ 422.504(e) and 423.505(e).