



September 20, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dr. Meena Seshamani
Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Draft Part One Guidance on Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the first draft guidance related to the maximum monthly cap on cost-sharing payments under prescription drug plans. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN strongly advocated for inclusion in the *Inflation Reduction Act* of both an annual cap on total Part D out-of-pocket costs and a mechanism that would allow an enrollee the option to pay the required cost-sharing in capped monthly installments because we know from research that high out-of-pocket costs can decrease medication adherence, which results in negative health outcomes.¹ We appreciate CMS' release of the draft guidance, which is instructive for the first year of implementation of the Medicare Prescription Payment Plan. We strongly encourage CMS to actively monitor implementation of the Medicare Prescription Payment Plan in real time and use the lessons learned to revise the guidance accordingly in future years. We offer the following comments on the draft guidance:

20. Overview

We appreciate that CMS has conducted extensive consumer testing regarding the appropriate naming of the "maximum monthly cap" or "smoothing" program. This testing has resulted in CMS referring to the program as the "Medicare Prescription Payment Plan." We believe this title accurately provides a description of the program and will be easily understood by beneficiaries. We would encourage CMS to retain this name.

40. Participant Billing Requirements

We appreciate CMS' clarifying that Part D sponsors must offer participants multiple methods of payment, including an electronic funds transfer mechanisms (such as automatic charges of an account at a financial institution or credit or debit card account) and payment by cash or check. CMS is also encouraging Part D sponsors to offer participants flexibility to choose a specific day of the month for program charges. We support

¹ Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *K Clin Oncol*. 2014; 32:302-311; Nekhlyudov L, Madden J, Graves A, Zhang F, Soumerai S, Ross-Degnan D. Cost-related medication nonadherence and cost-sharing strategies used by elderly Medicare cancer survivors. *J Cancer Surviv*. 2011;5:395-404.

these clarifications – particularly as they relate to allowing individuals the opportunity to choose a specific day of the month for which program charges will be deducted from the individual’s account. We also encourage CMS to permit individuals the option to have their Medicare Prescription Payment Plan cost sharing obligations deducted from their Social Security checks (which is also an option for Part D premiums)

CMS also provided a list of information that Part D sponsors need to include on billing statements, which are to be provided to individuals. We strongly support the list of required elements. We would also encourage CMS to require the inclusion of some additional information:

- Information on Medicare.gov and 1-800-MEDICARE, which can provide individuals with non-biased information about the Medicare Prescription Payment Plan and information on how to contact a Medicare State Health Insurance Assistance Program (SHIP) counselor who can provide one-on-one information.
- Information on how the participant can change their method of payment. Individuals may initially choose to pay via credit card and may later opt for a different method of payment.
- For individuals who have met their annual out-of-pocket cap, clear information noting that the individual’s monthly out-of-pocket costs will not increase over the course of the year.
- For individuals who have not met their annual out-of-pocket cap, clear information noting that the individual’s monthly out-of-pocket costs may increase if the individual takes additional prescription drugs, but in no case will their out-of-pocket costs exceed the value of the annual cap (which is \$2,000 in 2025).

60. Requirements Related to Part D Enrollee Outreach

The draft guidance notes that “CMS will develop tools (e.g., model documents and training materials) to help Part D enrollees decide whether the program is right for them.”² We very much appreciate CMS’ efforts and welcome the opportunity to work with CMS to better educate enrollees, their families, and other stakeholders about the Medicare Prescription Payment Plan option. As CMS conducts outreach and education, we strongly encourage the Agency to use the Medicare Plan Finder tool as one means to educate individuals. Just as the Plan Finder currently estimates an individual’s monthly out-of-pocket costs for selected drugs under a given plan, the Plan Finder could provide an estimate of the individual’s monthly out-of-pocket costs if the individual were to select to enroll in the Medicare Prescription Payment Plan.

60.2.3 Targeted Part D Enrollee Notification at POS

The statute requires Part D sponsors to have a mechanism to notify a pharmacy when a Part D enrollee is likely to benefit from participating in the Medicare Prescription Payment Plan. We appreciate the modeling CMS has conducted to help determine which individuals are “likely to benefit” but we caution that the trigger should not be based on a single prescription counting towards a potential threshold. Enrollees in the Part D program are a diverse group and have different financial situations which vary considerably from individual to individual.

70. Requirements Related to Part D Enrollee Election

70.3.5 Processing Election Request During a Plan Year

We strongly support CMS’ proposal to establish a 24-hour requirement for processing election requests during the plan year. We agree this timeframe is operationally feasible for plans given that it is consistent with existing

² Draft guidance, page 19.

requirements for the processing of expedited coverage requests.

70.3.8 Standards for Urgent Medicare Prescription Payment Plan Election

CMS is requiring Part D plans to have a process to allow individuals to retroactively elect to enroll in the Medicare Prescription Payment Plan when they have urgent prescription drug fills for which they paid the corresponding cost-sharing before the individual's election was received and processed. Under the process, individuals must request retroactive election within 72-hours of the adjudication of the claim.

We are concerned that under the proposal, individuals are still required to pay at the point of sale the cost sharing corresponding to their prescription drugs and would not be assessed cost-sharing provided under the Medicare Prescription Payment Plan option. While individuals would be permitted to retroactively seek reimbursement from their Part D plan, this policy would still require individuals to incur large up-front costs, which can create a financial hardship for many individuals and cause them to decline filling prescriptions. We are also concerned that under the proposal, Part D sponsors have 45 days to reimburse the individual. We believe this timeframe is too long and imposes an undue burden on individuals. We would recommend that CMS consider a timeframe of 14 days in which the Part D plan has to process reimbursement to the individual.

We encourage CMS to allow individuals to enroll in the Medicare Prescription Payment Plan at the point of sale. This would obviate the need for an urgent election process.

70.3.9 Request for Information on Real-Time or Near-Real-Time POS Election and Other POS Needs

We are disappointed that CMS is not allowing individuals to enroll in the Medicare Prescription Payment Plan option at the point of sale, regardless of whether an enrollee chooses to fill their prescription via mail order or a brick-and-mortar pharmacy. We believe that allowing individuals to enroll at the point of sale is the best option for individuals to benefit from this program. We strongly encourage CMS to reevaluate the feasibility of a point-of-sale enrollment process beginning in 2025.

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

We seek clarification in cases where an individual is enrolled in the Medicare Prescription Payment Plan but dies in the middle of the plan year. We are not aware of an instance within the Medicare program where the individual's estate would bear responsibility for cost-sharing obligations. We therefore assume that in cases where an individual dies in the middle of the plan year (or owing any cost-sharing obligation under the Medicare Prescription Payment Plan) that the plan sponsor and/or the Medicare program bear responsibility for those costs. We urge CMS to provide clarification.

80.2 Involuntary Terminations

CMS is requiring plan sponsors to provide specific notices to individuals who fail to pay a monthly billed amount. CMS requires Part D sponsors to provide a grace period of at least 2 months before the individual can be terminated from the Medicare Prescription Payment Plan.

We appreciate CMS modeling the involuntary termination requirements of the Medicare Prescription Payment Plan program after those of non-payment of Part D premiums. As noted above, we urge CMS to allow individuals the option to have their cost sharing deducted from their Social Security checks. Current CMS regulations³ prohibit Part D plans from disenrolling individuals who elect to have their Part D premiums directly deducted from their Social Security check and we encourage CMS to adopt a similar prohibition for individuals who elect to have their cost sharing obligations under the Medicare Prescription Payment Plan deducted from their Social

³ 45 C.F.R. § 423.44(d)(v).

Security check.

80.3 Preclusion of Election in a Subsequent Plan Year

The statute provides that Part D sponsors may preclude an individual from opting into the Medicare Prescription Payment Plan in a subsequent year if the individual fails to pay the amount billed as required under the program. We urge CMS to clarify this prohibition lasts for a single year and that an individual would be permitted to enroll in the Medicare Prescription Payment Plan in subsequent years.

CMS is proposing that a Part D sponsor that offers more than one Part D plan may have different preclusion policies for its different plan but must apply the same policy to every participant in the same plan. We are concerned that this could lead to confusion among individuals. We urge CMS to encourage Part D sponsors maintain standard preclusion policies.

90. Participant Disputes

CMS is requiring that each Part D sponsor must provide meaningful procedures for the timely hearing and resolution of grievances between Part D enrollees and Part D plan sponsors. However, CMS fails to articulate specific timeframes associated with disputes related to the Medicare Prescription Payment Plan program. The Medicare appeals process is complicated.⁴ We urge CMS to clarify specific timeframes and amend sections 30 and 40 of the Parts C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance accordingly.

Conclusion

We thank CMS for offering the opportunity to comment on the Medicare Prescription Payment Plan draft guidance. We stand ready to work with CMS to develop materials that will help to educate enrollees about the option and what the enrollees' responsibilities are when they make that election. If you have any questions, please feel free to contact me or have your staff contact Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at anna.howard@cancer.org.

Sincerely,



Lisa A. Lacasse, MBA
President

American Cancer Society Cancer Action Network

⁴ See American Cancer Society Cancer Action Network. The Medicare Appeals Process: Reforms Needed to Ensure Beneficiary Access. Nov. 17, 2020. Available from: <https://www.fightcancer.org/sites/default/files/Medicare%20Appeals%20Paper%20FINAL.pdf>.