



Submitted Electronically to PartDPaymentPolicy@cms.hhs.gov

September 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Meena Seshamani, M.D., Ph.D.
Deputy Administrator
Director, Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Prescription Payment Plan Guidance

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') draft part one guidance outlining its proposed implementation of the Medicare Prescription Payment Plan program created under Section 11202 of the Inflation Reduction Act (Social Security Act Section 1860D-2(b)(2)(E) (the Program).

PIRC is a collaborative, multi-stakeholder, patient advocacy coalition focused on improving access to and affordability of existing treatments while preserving the incentives required to advance future innovations in rare cancers. The coalition seeks to fulfill an important role in exchanging information and collaborating toward educating our own rare cancer communities as well as policymakers on the positive impact the Inflation Reduction Act (IRA) might have on access to existing Part D drugs and the challenges the law presents to continuing innovation.



Protecting Innovation In Rare Cancer
www.rarecancerira.org

While cancer patients can face significant challenges in affording their treatments, *rare* patients typically face even higher costs, fewer treatment options, and a limited set of clinicians and facilities with expertise in treating their cancer. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with enabling Part D enrollees to participate in a payment plan will make a real difference for

Medicare beneficiaries fighting cancer and their families. We look forward to working with the Agency in educating our rare cancer communities about these changes.

We appreciate that CMS' draft guidance focuses first and foremost on the needs of Medicare beneficiaries. Our comments are intended to provide CMS with the rare cancer patient perspective and recommend refinements that align with the Program's over-arching goal of ensuring that all Medicare patients and their families can base treatment decisions on their needs rather than their financial resources.

Program Calculations and Examples (Section 30) – A “calculator tool” on CMS and plan websites and lower initial-month payments will significantly aid participants

The scenarios presented in the draft guidance to illustrate how a participant's monthly payment amount is calculated tend to reflect a complexity that will likely confuse patients as they determine whether the program will be of benefit. Most participants will find that monthly payments are most affordable if their expenses can be distributed evenly over the remaining plan months rather than set at a higher, and potentially unaffordable, initial month's payment followed by evenly distributed amounts due for subsequent months. Although evenly distributed payments will not substantially change the fact that the program's utility diminishes for individuals who opt in late in the year, it will enable greater initial-month affordability for more potential participants throughout the plan year.

In addition, patients and providers would be best equipped to make an informed decision on whether to participate if CMS provides a “calculator” tool on CMS' and plan websites. There should also be language informing beneficiaries that:

- Monthly payments may vary from month to month, with examples showing how each filled prescription might impact the monthly payment due.
- Assistance is available for individuals unable to afford their prescription drug costs (with specific links and/or instructions on accessing additional financial help).
- Out-of-pocket costs will never exceed \$2,000 for the calendar year.

Participant Billing Requirements (Section 40) – Participants may not benefit from assigning unidentified payments to premiums; Several clarifications would aid participation

We appreciate that CMS wishes to ensure participants have multiple options for viewing their bills and making monthly payments. We urge the Agency to require that plans:

- Send paper bills **and** enable access to e-bills.
- Offer a variety of payment options, including manual and automated electronic fund transfers (EFT) from a checking or savings account, credit card, or debit card. (with no service or convenience fee charged by the plan for use of these payment methods)
- Enable individuals to pay in person with a check, money order, or cash.
- Provide a mailing address for individuals wishing to manually send a check or money order.
- Permit participants to designate how they wish to apply any payments that exceed the amount due for a particular month (e.g., apply funds to the balance due or to the next month's payment).
- Include a payment schedule outlining amounts due for future months, noting (if applicable) that the payment schedule for future months may change as additional prescription drug costs are incurred.

We are concerned that CMS' well-intentioned proposal to have plans apply payments that are not clearly designated as payment program payments to premiums may have unintended consequences. Although we agree that retaining enrollment in Part D and avoiding unintended instances of unpaid premiums is extremely important, most Part D enrollees pay their premiums through direct deductions from their Social Security payments. These enrollees do not submit checks or make electronic payments to their plans now, and plans should assume that any "additional" payments made by these participants are intended to be applied to the payment plan.

In addition, our rare cancer communities have expressed an interest in having greater clarity from CMS on:

- How drug "returns" due to intolerable side effects or lack of response to treatment would impact the monthly payment amount. This is particularly important within the context of rare cancer patients since the out-of-pocket costs associated with a single prescription could quickly reach the \$2,000 cap, and treatment alternatives may be limited to Part B drugs.
 - o Would participants be issued a refund for returned product?
 - o Could patients be required to continue paying for a drug they stopped using?
 - o How would this work within the context of a 3-month mail order fill, versus a single prescription purchased at the pharmacy counter?
- Whether plans can preclude individuals from opting-into the payment plan for multiple subsequent years after termination due to nonpayment.
- How participants can avoid termination during the grace period if they become current on payments.

- Will CMS encourage plans to spread the past-due amount(s) over remaining plan months rather than allow them to require a larger lump sum payment?
- We urge CMS to provide participants with at least one opportunity per plan year to catch up on missed payments by requesting a recalculation that evenly distributes their missed monthly payments over the remaining months of the plan year.
- What does it mean to have “good cause” for missing a payment? Both plans and participants need granularity and predictability on how this standard will be applied. We urge CMS to provide a set of examples to illustrate, but not limit, the sets of circumstances or scenarios that would be good cause for missing a payment.

Requirements Related to Part D Enrollee Outreach (Section 60) – Uniformity, clarity, and multiple messaging channels will be critical in aiding participation.

We applaud CMS for acknowledging that effective outreach and education are crucial to ensuring the success of the program. Model notices, forms, and beneficiary communications would facilitate greater uniformity and predictability, and should be published in draft so that stakeholders can provide feedback. In addition, we recommend that CMS:

- Leverage the plan finder as a tool for increasing awareness of the program. Beneficiaries and their families rely on Medicare.gov to make important decisions regarding their Part D plan. Participation election could be streamlined if CMS included a calculator tool illustrating how the program may benefit a beneficiary based on their likely prescription drug needs.
- Provide sets of FAQs and model PowerPoint presentations that patient advocacy organizations can use to inform their patient communities about the program, including how each patient can determine whether they should opt in and when/how to do so.
- Develop informational materials that can be utilized by pharmacies to inform beneficiaries of the program. This should include clear information on how to opt in so that Part D enrollees are prepared to make decisions on participation in advance of the 2025 plan year.
- Outline a clear set of requirements for plans, ensuring that program information be included prominently with plan documents, as well as the evidence of coverage notice and explanation of benefits statements.
- Append the “Medicare & You” handbook to include educational content related to the program and provide a phone number and website that beneficiaries can use to learn more about the program.
- Explore the use of active prompts at the pharmacy counter to ensure that Part D enrollees are aware of and have the opportunity to participate in the program. This might include a “you may wish to consider opting in” statement within automated pharmacy calls informing patients that their prescription is ready for pick-up. Similar messaging tools have been used for flu and covid vaccination reminders.

- Provide real-time benefit tools to inform prescribers on the financial liability associated with a particular prescription so they can discuss the program with their patients.

The IRA also requires pharmacists to proactively engage beneficiaries who are “likely to benefit” from the program, inform them on how the program might be helpful, and review their options for participating. We strongly urge CMS to set the single-fill dollar threshold at or below \$400. This is particularly important in the initial year since beneficiaries may be unaware that they have the option to make monthly payments to their plan and avoid paying at the pharmacy counter. Rare cancer patients may fill multiple prescriptions each month – some to treat their cancer and others to manage side effects or address non-cancer acute (e.g., infection) and chronic conditions – and reach their out-of-pocket maximum in the first quarter of the calendar year without incurring over \$400 in costs attributable to a single prescription.

Requirements Related to Part D Enrollee Election, Including a Request for Information on Real-Time POS Election (Section 70) – CMS should implement a POS enrollment strategy in the 2025 plan year, deem requests as equivalent to participation during the time period plans require to process opt in requests, and implement auto-enrollment in future years

For our rare cancer patient communities, access to prescribed medications is critical. Today, too many individuals are unable to afford the out-of-pocket cost of the treatment that best suits their needs. The opportunity to spread costs over the year will help countless Medicare beneficiaries living with rare cancers and their families avoid having to choose between life-extending treatments and maintaining adequate food and housing. Unfortunately, any uncertainties in the opt-in process that result in delayed access to treatment re-inject the financial stressors the program seeks to avoid.

The IRA clearly requires plans to make the program available to all their enrollees and does not provide for any basis upon which a participation request could be denied other than involuntary termination from the program in the previous year. The patient experience during the first year will set the stage for program success in future years. Unless there is a basis for a plan to decline a participation request in 2025, patients, pharmacies, and plans should consider a 2025 opt in as participation on the day the request is made. Plans may require a period of time to process requests, but the processing time should not impact the patient or their ability to receive their medications at the pharmacy counter and be billed on a monthly basis for their out-of-pocket costs. Participants should not be asked to make an up-front payment at the point of sale if they have opted into the program.

We similarly believe that offering a point of sale (POS) opt in process is critical to the program. This will ensure that a patient facing high OOP costs when filling their prescription can immediately elect to participate in the program and take home the medication they came for without delay. Adding a process for plans to determine whether a particular prescription is “urgent” will create a burden for clinicians. Clinicians already have burdensome prior authorization and step therapy hurdles to navigate. It also

creates the very real possibility of the pharmacy suggesting the prescriber can avoid having to demonstrate that the patient's need is urgent by substituting the prescribed treatment with a less costly alternative. Cancer patients perceive all of their prescribed treatments as urgently needed and requiring that they return in 24-72 hours to receive their medication would create unnecessary stress and inconvenience. The Administration is well aware of transportation insecurities in the Medicare population, and this requirement could result in delays much longer than 24-72 hours if the patient cannot easily return to the pharmacy. We strongly urge CMS to implement the POS enrollment strategy in the 2025 plan year and make participation effective on the opt-in date.

In addition, participation requests received by telephone or online through CMS' or the plan sponsors website should be acknowledged with a tracking/confirmation number that participants could use at the point of sale to verify that they have opted in for program participation.

Finally, we urge CMS to require plans to continue their enrollees' participation from year to year in a manner similar to auto-enrollment in Medicare or Qualified Health Plans. Participants would be reminded that they have the ability to opt out of participation at any time. This would streamline the process for Medicare beneficiaries who may assume that both their plan enrollment and program participation continue from year-to-year.

Procedures for Termination of Election, Reinstatement, and Preclusion (Section 80) – Inclusion of a Grace Period is Critical and Should be Extended to 3-mos as in other health care plans

We support CMS' guidance providing participants with a grace period but recommend a three-month period akin to the one applied to Qualified Health Plans under the Affordable Care Act (ACA). We ask that the Agency clarify whether the additional 3-day notice at the end of the grace period is calculated in calendar days or business days. We similarly support CMS' plans to require that Part D plans communicate with participants throughout the grace period on the impact of late payments, including that the individual faces involuntary termination from the program. These communications should focus on the payment plan as separate and distinct from the Part D plan with respect to termination so that individuals understand that their Part D benefits continue as long as premiums are paid.

As outlined above, we also urge CMS to consider adopting a mechanism that permits participants to have their missed payments spread across the remaining plan months. This would increase the affordability of continuing participation and reduce the need for individuals terminated from the program to demonstrate "good cause" for missing payments. We also ask that CMS provide illustrative examples of "circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee."

Conclusion

Once again, the undersigned organizations appreciate the opportunity to comment on CMS' part one guidance on implementation of the Medicare Prescription Payment Plan. We look forward to continuing to work with you in ensuring that all Medicare beneficiaries, including those with rare cancers, can receive the treatments they need without financial hardships associated with high out-of-pocket costs.

Sincerely,

A Cure In Sight
Association of Oncology Social Work
Biomarker Collaborative
CancerCare
Cancer Support Community
Cholangiocarcinoma Foundation
CLL Society
Cutaneous Lymphoma Foundation
Exon 20 Group
Haystack Project
HealthTree
Histiocytosis Association
Hope for Stomach Cancer
ICAN, International Cancer Advocacy Network
International Waldenstrom's Macroglobulinemia Foundation
MET Crusaders
Ovarian Cancer Research Alliance
PD-L1 Amplifieds
The Life Raft Group
The Patient Story