Submitted Electronically to PartDPaymentPolicy@cms.hhs.gov

March 16, 2024

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 Part Two

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to provide feedback and recommendations on the Centers for Medicare & Medicaid Services' (CMS') draft part two guidance proposing policies and mechanisms for implementing 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 both our rare cancer communities

and policymakers on the impact the Inflation Reduction Act (IRA) might have on access to existing Part D drugs and development of new therapeutic options.

Cancer patients can face significant challenges in affording their prescribed treatments. Since rare cancer patients typically have fewer effective therapeutic options, unaffordable out-of-pocket costs can be catastrophic. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with an available option for Part D enrollees to participate in a payment plan will make a real difference for Medicare beneficiaries and their families as they fight cancer. We look forward to working with the Agency in educating our rare cancer communities about these changes.

We appreciate that CMS' draft guidance seeks to strike a balance between timely outreach and participation election for beneficiaries and manageable implementation of this new Program for Part D plans and sponsors. We focus our comments and recommendations on refinements that align with the real-world experience of rare cancer patients and the Program's intended goal of ensuring that all Medicare patients and their families can base treatment decisions on their needs rather than their financial resources.

We look forward to working with CMS to ensure that all rare cancer patients who might benefit from the Program have the information they need to decide whether and when to opt in.

General Outreach, Education, and Communication Requirements for Part D Sponsors

PIRC appreciates that CMS has emphasized the need for informational uniformity and clarity through multiple messaging channels in crafting Part D plan outreach and education requirements. We agree that CMS-created model notices, forms, and beneficiary communications will be crucial to effective outreach and urge CMS to publish these resources in draft to enable stakeholder feedback.

We also support CMS' requirement that plans provide their enrollees with Program information on their websites as well as within the Part D materials currently furnished to enrollees, including mailings of membership ID cards, explanation of benefits (EOB), Annual Notice of Change (ANOC), and Evidence of Coverage (EOC) documents. We are concerned, however, that the routine nature of these mailings might increase the likelihood that enrollees will overlook important information on Program availability and opt-in mechanisms. We strongly recommend that CMS require plans to make this "new" information conspicuous by including notification

language on the envelope where it can easily be seen as well as on the first page of any document(s).

We also urge CMS to require plans to include:

- A clear explanation of each mechanism for opting into the Program, with steps clearly outlined. Potential participants should, for example, be informed of the timeline for receipt and processing of their request when submitted online, by telephone, or by mail.

- Availability of a real-time opt-in mechanism through which participants can fully complete all participation requirements and receive a unique confirmation number that can be used at the pharmacy counter or in communications with their plan.

- A calculator tool in addition to examples of how the Program works so that Medicare beneficiaries can have an estimate of their monthly costs under the Program based on their prescribed medications.

We similarly urge CMS to:

- Include Program information on the plan finder tool that beneficiaries and their families are accustomed to using when selecting their Part D plan.

- 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.

- Consider broadcasting Public Service Announcements similar to those used to inform individuals about availability of Affordable Care Act coverage and enrollment deadlines.

- Include prescribers within outreach and education initiatives so that physician offices have the resources they need to discuss the program with their patients.

- Develop a set of informational materials tailored for use by pharmacies to educate beneficiaries about the program in advance of the 2025 plan year so that beneficiaries can make a timely decision on whether to opt-in and initiate their participation at the start of the plan year when it is of greatest benefit.

Requirements for Targeted Outreach

PIRC agrees that increased outreach and education efforts targeted toward individuals most likely to benefit from the Program will be essential to Program success, especially in its initial years. We appreciate that CMS seeks to provide these individuals with multiple, meaningful opportunities to review Program materials and opt into participation. We support CMS' requirement that plans review enrollee prescription drug expenditures for previous plan years and target outreach to their enrollees with historically high out-of-pocket costs.

We also agree that the later a beneficiary opts into the Program, the less likely they are to benefit from participation. These individuals may, however, benefit from opting in for the next plan year and, for beneficiaries meeting "likely to benefit" criteria in the fourth quarter, we urge CMS to require that plans give these individuals an opportunity to opt in for either/both the current and next plan year.

Similarly, we support targeted outreach during the plan year based on prior authorization requests for costly treatments. Unfortunately, Program information and participation forms delivered by mail are unlikely to reach the enrollee by the time their prescription is ready for pickup. We believe these individuals need to understand that there is an alternative to paying the full out-of-pocket costs or declining to pick up the prescription. While the ability to pay at the pharmacy counter and ask for a refund based on retroactive participation in the Program may be helpful for some individuals, far too many patients will be unable to do so. We strongly urge CMS to require that plans use a notification mechanism such as telephone contact to provide Program information and enable a real-time opt-in mechanism.

We also urge CMS to require that plan efforts to identify enrollees likely to benefit from the program focus beyond costs associated with a single prescription. Medicare beneficiaries with rare cancers often fill multiple prescriptions each month – to treat their cancer, manage side effects or treat other chronic conditions. It is common for a patient to reach their out-of-pocket maximum during the first quarter of a plan year without receiving any medications that have exceptionally high out-of-pocket costs. We were disappointed that CMS' final Part One Guidance contained a single-fill threshold of $600 and ask that that plans calculate the costs of all prescriptions presented or filled on a single day toward the single-fill threshold.

PIRC similarly believes that pharmacies may be the most critical point of contact for Medicare beneficiaries as they can provide real-time information on the out-of-pocket costs associated with a pending prescription and give patients the information they need to opt into the Program when participation is likely to convey a meaningful benefit. Ideally, a beneficiary would

have an opportunity to opt in through online or telephone participation mechanisms, receive a confirmation number from their plan, and pick up their prescription(s) without paying at the pharmacy counter.

Election Requirements

PIRC understands that the recently finalized Part One guidance contains election process requirements that intersect with the draft Part Two guidance. We strongly urge CMS to reconsider its decision to delay implementation of a point of service (pharmacy counter) election mechanism and, at a minimum, enable real-time 2025 plan year elections with participation effective as of the date and time the election is made. As you know, access to prescribed medications is particularly critical for cancer patients and too many individuals with rare cancers have been unable to afford the treatment that best suits their needs. For our patients, the ability to spread costs over the year can make the difference between knowing that they can start and stay on their prescribed treatment and having to choose between paying for life-extending treatments and being able to afford their housing, transportation, and food. Any uncertainties, delays, or requirements for multiple interactions within the opt-in process that result in delayed access to treatment will perpetuate the financial stressors the program seeks to avoid. We expect that these delays, requirements that beneficiaries pay at the pharmacy counter after opting in, and uncertainties in when enrollment is effective will reduce confidence in the benefits of participation in future years.

We understand that the IRA requires plans to make the program available to all their enrollees and appreciate that CMS has declined to adopt stakeholder recommendations to delay or limit the Program. With the exception of nonpayment of a prior year's monthly payment obligations, there is no clear statutory basis for any plan to decline any enrollee's opt-in request. This does not apply during the 2025 plan year. Although plans may require a period of time to process requests and update their systems, the time to perform these ministerial tasks 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. We applaud CMS' for the proposal that plans issue a confirmation number to enrollees completing their Program election and urge the Agency to outline a simple mechanism through which beneficiaries can present their member ID and Program election confirmation number to the pharmacy counter when they pick up their medications.

We similarly believe that offering a point of sale (POS) opt-in process will ensure that patients facing prohibitive costs when filling their prescription can immediately elect to participate in

the program and fill their prescriptions without delays related to financial burdens. The processes outlined in CMS' Part One guidance for plans to determine whether a prescription is urgent create additional layers of Program complexity and will burden clinicians with additional paperwork beyond the prior authorization documentation hurdles they currently navigate. Rare cancer patients urgently need all of their prescribed treatments and a streamlined election process with real-time effect would alleviate the burden on clinicians and plans associated with determining whether a particular treatment is "urgent" for a particular patient.

Finally, we expect that a POS election option would be particularly helpful in streamlining elections for future years. For example, a pharmacy filling a prescription for a Program participant during the last quarter of the plan year could prompt the patient on whether they intend to opt into the Program for the next calendar year and offer real-time election to opt-in or terminate participation as well as information on the election process if the beneficiary has not yet decided. This would streamline the process for Medicare beneficiaries who may assume that both their plan enrollment and program participation continue from year-to-year.

Program details on which our patient communities have requested additional information.

PIRC's 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.
    - Would participants be issued a refund for returned product?
    - Could patients be required to continue paying for a drug they stopped using?
    - How would this work within the context of a 3-month mail order fill, versus a single prescription purchased at the pharmacy counter?
- 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 encourage that plans 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.

Conclusion

Once again, the undersigned organizations appreciate the opportunity to comment on CMS' part two guidance outlining CMS intended 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. Please contact us at info@rarecancerira.org or our policy advisor, Saira Sultan, JD, at ssultan@cllsociety.org with any questions.

Sincerely,

Biomarker Collaborative
Cancer*Care*
Cancer Support Community
Chondrosarcoma Foundation
CLL Society
Cutaneous Lymphoma Foundation
Desmoid Tumor Research Foundation
Exon 20 Group
Hope For Stomach Cancer
ICAN, International Cancer Advocacy Network
MET Crusaders
No Stomach for Cancer
Ovarian Cancer Research Alliance (OCRA)
PD-L1 Amplifieds
PTEN Foundation (Hamartoma Tumor Syndrome Foundation)
The Healing NET Foundation
The Life Raft Group