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## Submitted Electronically

April 29, 2024

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

**RE: The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Prescription Payment Plan Model Documents (CMS-10882)**

Dear Administrator Brooks-LaSure,

The Protecting Innovation in Rare Cancers (PIRC) coalition appreciates the opportunity to submit feedback, including input from our patient communities, on the six model documents created as part of the Centers for Medicare & Medicaid Services' (CMS') implementation of the Part D Medicare Prescription Payment Plan (MPPP). We especially appreciate that CMS not only sought public comment on these important documents, but that it provided sufficient time for advocacy organizations like those within the PIRC coalition to collect feedback from actual patients who will need to understand the documents to fully benefit from the MPPP.

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



Protecting Innovation In Rare Cancer  
[www.rarecancerira.org](http://www.rarecancerira.org)

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 CLL Society, for example, noted that for patients with chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) targeted therapies such as BTK inhibitors and the BCL2 inhibitor known as venetoclax offer substantial efficacy and have transformed care for its patient community. These patients now have more treatment options compared to just years ago when the standard of care was chemoimmunotherapy. BTK inhibitors are covered under the Medicare Part D benefit and offer patients an effective, oral treatment that has become, for many, the standard of care in first-line therapy. Unfortunately, the historically high out-of-pocket costs have kept this option out of reach for far too many patients. The IRA's enactment of a more affordable Part D out-of-pocket cap, combined with enabling Part D enrollees to spread their out-of-pocket costs over the plan year by opting into the MPPP will make a real difference for CLL/SLL and other rare cancer patients relying on Medicare coverage in their fight against cancer.

We appreciate that CMS continues to work on ensuring smooth, timely implementation of the MPPP. The six model notices are a critical part of successful MPPP implementation as they will be disseminated to Part D enrollees considering or actively participating in the MPPP.

As noted above, we have reached out to our patient communities and asked that they review the documents to identify any language that is confusing or unclear as well as gaps between the information contained in the notices and the information patients might need. The feedback PIRC received on the model documents is outlined below:

**Document 1: Likely to Benefit Notice (“Consider Managing Your Monthly Drug Costs with the Medicare Prescription Payment Plan”)**

PIRC agrees that increased outreach and education efforts targeted toward individuals most likely to benefit from the MPPP 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 the “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.

PIRC understands that the Likely to Benefit Notice is packed with information intended to help Medicare beneficiaries decide whether the MPPP would ease the financial burden associated with their prescription drugs. Unfortunately, several patients found that the document was “densely packed” and unclear with respect to the potential benefits of participation.

- The Cutaneous Lymphoma Foundation suggested that the information be presented in bullet point format rather than as paragraphs so that individuals can easily see any steps required to opt into the MPPP.
- CLL/SLL patients noted that based on the relatively high cost of their rare cancer treatment, the \$2000 out of pocket cap would be reached in January. There was no explanation of why the \$2000 would not be divided evenly over 12 months if the individual opts in before the start of the plan year.
- For individuals likely to hit the out-of-pocket maximum more slowly, the premise that new prescriptions would lead to increased monthly payments makes sense.
- The statement that “[y]ou’ll never pay any interest or fees on the amount you owe, even if your payment is late” does not tell the full story, i.e., that individuals failing to make payments would not be eligible to participate in the MPPP with their existing plan until overdue payments are paid. That information is provided after individuals opt into participation and should also be presented during the decision process.
  - o One patient suggested that specifying that late payments do not result in additional fees or interest “just encourages folks not to make timely payments.”

- Another patient expressed concerns that the default rate under the MPPP could impact Part D premiums as well as the number of Part D sponsors continuing to offer Part D plan choices.
- The ability to make monthly payments is a good option and it would be helpful to let patients know how they would be making those payments to their plan. For example, one CLL patient noted that the Veterans Administration administers a copayment plan that allows participants to have payments automatically made each month through their bank account. Rare cancer patients, particularly those within the Medicare beneficiary population, may find it easier to have an automatic payment option so that they do not have the additional stress of looking out for and paying their MPPP bill each month.
- Patients reviewing this document were concerned that there was no clear information on whether and how an individual could exit the MPPP and go back to paying at the pharmacy counter. Again, while this information is given to individuals after they opt in, it is an important element of the MPPP that individuals should understand as they decide whether MPPP participation is right for them.
- Several patients and organizations suggested that a set of hypothetical scenarios would clarify how monthly payments are calculated. These examples should include:
  - A scenario detailing monthly payments for a patient who incurs drug expenses exceeding the out-of-pocket cap in January (or the first month of the plan year).
  - A scenario with more evenly spread costs that exceed the cap during the first three or four months of the year.
  - A scenario with high-cost drugs purchased in the last quarter of the plan year.

Without examples, Medicare beneficiaries are likely to find the MPPP confusing and even risky.

- Making an analogy between the MPPP and, for example, a consumer installment plan would help Medicare beneficiaries understand what the program is and how it works. In

simple terms, the MPPP is an installment plan without interest, and Medicare beneficiaries are likely able to understand this analogy.

- A simplified “Frequently Asked Questions” (FAQ) document, accompanying the various MPPP forms would help individuals find the information they need and reduce confusion.
- The Likely to Benefit Notice should also clarify that pharmacies, including mail order pharmacies, will be required to dispense medications to MPPP participants – several individuals were concerned that their pharmacy might delay or decline to fill prescriptions if they did not pay at the pharmacy counter.
- The model form outlined a set of scenarios that might make an individual unsuitable for MPPP participation. Several CLL/SLL patients noted that the list included the example of individuals with consistent monthly drug costs over the plan year. This could give CLL patients relying on BTK inhibitors and other rare cancer patients prescribed oral treatments the impression that they should not opt into the MPPP even though they have out-of-pocket costs exceeding \$2000 during the first month of the year. CMS should clarify or remove this example.

## **Document 2: Election Request Form (“Medicare Prescription Payment Plan participation request form”)**

Most individuals found that the Election Request Form was “straightforward and clear.” Several others expressed concerns that potential participants would need more information and greater clarity on when their participation would take effect. Additional feedback included:

- CMS should develop model language for the “terms and conditions” for plans and participants. That language should be simple and included with the Election Request Form so that Medicare beneficiaries understand their rights and responsibilities. Permitting each plan or sponsor to develop their own sets of terms and conditions would invite inconsistencies across the MPPP.

- The election form does not provide information on the timeframe required for the plan to process the election request, reasons a plan might have for denying the request, or what communications the individual should expect. This could lead to confusion and delays if, for example, the plan fails to receive and process the individual's election to participate in the MPPP.
- It is unclear whether the individual will have additional documents to execute and/or potential inquiries from the plan.
- Opting in by mailing the Election Form is not the only election mechanism plans are required to offer. The election form should provide information on alternative ways to opt in and outline the processing time associated with each mechanism.
- The phone number field should specify that the plan is requesting the phone number for which communications between the plan and participant can be made. If the plan intends to send text messages to participants, it should enable participants to opt in on text messages if they provide a mobile phone number.
- Medicare beneficiaries may be uncomfortable submitting a form with their full Medicare number through the mail or online due to privacy and identity theft concerns. We urge CMS to work with plans on alternative way of accurately identifying participants such as the last four digits of a beneficiaries Medicare number.

**Document 3: Notice of Election Approval (“Part D Sponsor Notice to Acknowledge Acceptance of Election to the Medicare Prescription Payment Plan”)**

The Notice of Election Approval lacks details individuals may need to ensure that they are able to comply with MPPP requirements. It also contains information that rare cancer patients would find helpful before opting into the MPPP (i.e., within the Notice of Likely Benefit or the Election Form).

- The Likely to Benefit document should include language similar to statements within the Notice of Election Approval reassuring individuals that plans will notify pharmacies of their participation in the MPPP. This would resolve concerns that prescription fills could

be delayed or denied if patients decline to pay their out-of-pocket costs at the pharmacy counter.

- Several rare cancer patients indicated that they were uncertain of whether plans would simply inform pharmacies that had filled previous prescriptions of their participation in the MPPP. Many individuals with CLL/SLL also mentioned that they receive their medications from multiple pharmacies and were concerned that the document seemed to indicate that their MPPP participation would not be fully linked with their plan information and available to **all** pharmacies.
- The documentation should clarify that MPPP plan participant maximum total payment would be the cost associated with the drugs they obtain during their participation minus any amounts paid during the plan year at the pharmacy counter.
- Beneficiaries reading this document might assume that if they remain in their Part D plan year after year, their participation in the MPPP will also continue until they terminate it. If that is not the case, the document should make it clear that participants must opt in each year.
- It would be helpful if plans provide a mechanism for voluntary termination from MPPP participation other than through a telephone conversation with a live customer service representative (e.g., through the plan's website). Telephone-based voluntary termination should include an option to call during or outside office hours and access a menu that would enable termination without reaching a live customer service representative. A confirmation number after verification that the participant seeks to terminate their MPPP would provide a level of comfort that the termination was effective.
- A brief sentence summarizing the information in this document on voluntary and involuntary termination should be included in the Likely to Benefit document.

**Document 4: Notice of Failure to Pay (“Part D Sponsor Notice for Failure to Make Payments under Medicare Prescription Payment Plan”)**

PIRC appreciates that the Notice of Failure to Pay clearly informs individuals that their enrollment in the Part D plan is not impacted by their failure to pay. We also appreciate that the document encourages plans to permit partial payments to enable participants to continue in the MPPP. Rare Cancer patients reviewing this document expressed that:

- The time between the payment due date and issuance of this notice is not clear. CMS should provide guidance or instructions to plans on when to notify participants that they have not made a timely payment.
- The Notice states that “[a]s of <effective date>, you’ll pay the pharmacy directly for your out-of-pocket drug costs.” This statement should be revised to clarify that responsibility will be limited to **remaining** out-of-pocket costs to reinforce beneficiary out-of-pocket is \$2000 and includes paid and unpaid balances under the MPPP even if the individual is terminated.

**Document 5: Notice of Involuntary Termination (“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”)**

While virtually all patients reviewing this document found that it was clear and understandable, several patients expressed concern that there was no stated mechanism for participants to continue working with the plan to get current and resume participation.

We urge CMS to make a revision to this document clarifying that termination does not change the beneficiary’s maximum out-of-pocket obligation and that their payments at the pharmacy counter will be limited to the amount needed to reach that \$2000 maximum. It is likely that beneficiaries who, for example, have \$1000 remaining unpaid balance under the MPPP and are terminated could believe that they will pay that \$1000 again at the pharmacy counter.

Finally, although PIRC has some concern that widespread MPPP defaults followed by defaulting individuals switching to a different plan and enrolling in that plan’s MPPP would be a destabilizing force, we believe that beneficiaries should have clear information accurately reflecting the statutory language enacting the MPPP. The section stating that participants can only resume MPPP participation after paying any amounts due should be qualified to reflect



that the “ban” on participation is for that Part D sponsor. We suggest that the question “**Can I use this payment option in the future?**” be answered with “You may enroll in a [plan/issuer] payment plan once you pay the total amount you owe.”

#### **Document 6: Notice of Voluntary Termination (“Part D Sponsor Notification of Voluntary Removal from the Medicare Prescription Payment Plan”)**

The information in the Notice of Voluntary Termination was, for rare cancer patients, generally viewed as straightforward, complete, and clear. We did receive feedback that:

- The document should reinforce, in clear, bold type, that the individual **MUST** continue to pay their Part D premium each month.
- There may be a tendency for some individuals to decline to pay remaining balances after they voluntarily terminate from the MPPP. Patients are uncertain of what, if any, impact widespread nonpayment under the MPPP might have on their future premiums and plan options (if Part D sponsors face financial risk under the MPPP).

#### **Additional Comments and Feedback**

Overall, rare cancer patients expressed appreciation for the content throughout the series of documents reiterating that there are various payment options, that not participating in the MPPP in no way impacts the patients’ Part D costs, and that there are programs that might help lower costs. This information was very clear and viewed as helpful for Medicare beneficiaries.

PIRC also appreciates that CMS intends to require that plans include MPPP 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 remain concerned that the routine nature of these mailings might increase the likelihood that enrollees will overlook important information on Program availability and opt-in mechanisms and 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 create “model” language for these information sources.

We are similarly concerned that CMS has not outlined its plan to adapt the content of the model documents to meet the needs of non-English speaking beneficiaries and those with disabilities. We urge the Agency to consider developing a set of informational videos with guidance in several languages, including American Sign Language (ASE) and to provide the model documents in Braille, large print, and in formats compatible with screen readers and other accessibility tools.

Finally, 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 support CMS' decision to require that plans use the model documents.

## **Conclusion**

Once again, the undersigned organizations appreciate the opportunity to comment on CMS' set of model documents in connection with the MPPP. 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.

If you have any questions or would like additional information, please contact Carly Boos at [cboos@cilsociety.org](mailto:cboos@cilsociety.org).

Sincerely,  
Amyloidosis Foundation  
Association of Cancer Care Centers  
Biomarker Collaborative  
*CancerCare*  
Cancer Support Community  
Chondrosarcoma CS Foundation, Inc  
Cutaneous Lymphoma Foundation  
Exon 20 Group  
Hairy Cell Leukemia Foundation

ICAN, International Cancer Advocacy Network  
International Myeloma Foundation  
International Waldenstrom's Macroglobulinemia Foundation  
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