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
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RE: Medicare Prescription Payment Plan Guidance

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

Haystack Project 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).

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease patient advocacy organizations to coordinate and focus efforts that address systemic reimbursement obstacles to patient access and innovation. Our core mission is to evolve health care payment and delivery systems with an eye toward spurring innovation and quality in care toward effective, accessible treatment options for all Americans. We strive to amplify the patient and caregiver voice in these disease states where unmet need is high and treatment delays and inadequacies can be catastrophic.

We are pleased to see that the draft guidance prioritizes the well-being of Medicare beneficiaries. Our feedback aims to offer CMS insights from the standpoint of rare disease patients and suggest improvements that further the Program's goal of ensuring that beneficiaries can afford the treatments they need. We look forward to supporting CMS however

we can, including bringing together the 140+ groups that participate with Haystack to review materials or provide further input on Program implementation and communication strategies.

Section 30 – Program Calculations and Examples
Implement an interactive online tool to reduce confusion on monthly payment calculations, and eliminate potential for higher payments in initial month after costs are incurred.
Section 30 of the draft guidance includes examples demonstrating how to calculate a participant's monthly payment. However, these scenarios seem to introduce a level of complexity that could confuse patients and dissuade them from participation. In light of this concern, it would be prudent for CMS to consider augmenting its explanation(s) and simplifying its approach.

One effective strategy could be to provide supplemental resources such as an interactive online tool that would be readily accessible to patients and enable them to input their specific information and receive a clearer, more personalized breakdown of their monthly obligations within the program. The resource should provide essential information, including details on how monthly payments may vary based on prescription fills, offering real-world examples for clarity. Additionally, it should offer guidance on accessing financial assistance for individuals facing challenges in affording their prescription medications, with clear instructions or convenient links for easy access. Lastly, it should reassure users that their annual out-of-pocket expenses will not surpass $2,000, offering peace of mind and financial predictability. This type of user-friendly resource would not only demystify the process but also empower individuals to make informed decisions about their participation.

Second and most importantly, CMS must understand that while the statute provides for different caps for the first month versus subsequent months, most beneficiaries expect that their expenses will be spread evenly across the remaining plan months. They expect that the Program will remove financial hardships associated with front-loaded out-of-pocket costs; CMS' implementation retains enough potential for high initial-month payments to reduce Program benefits for those needing it the most. Evenly distributed payments would comply with the statutory maximum monthly payment amounts and align with beneficiary expectations. While this approach will not significantly alter the fact that the program's value diminishes for those enrolling later in the year, it does enhance affordability during the initial month for a broader range of potential participants throughout the plan year.

Section 40 – Participant Billing Requirements
Advance warning of upcoming payments, smoothing previously unpaid amounts, and applying undesignated payments to the Program for participants paying Part D premiums through Social Security payment deductions could all improve an already well thought out set of requirements.

Section 40 provides guidance on billing and billing statements. Including the information plans must provide on monthly invoices, prioritization of payments, and the financial reconciliation process. We are grateful that CMS has thoroughly considered the needs of the Medicare

population in this section and provided multiple options for beneficiaries to meet their financial obligations to the program. We offer the following suggestions to further enhance the program and ensure beneficiaries are given appropriate access to payment information and mechanisms.

Access to Payment Information and Payment Options

Given the Medicare population's tendency to be less digitally savvy, bills should be available in paper and electronic form. Similarly, CMS should 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 as well as an option to pay in-person, via check, money order or cash. At a minimum, an address should be provided for individuals who wish to mail in their payments. Finally, beneficiaries should be well informed of the schedule of upcoming payment deadlines, especially as additional prescription drug costs are incurred.

Additional Guidance on Program Implementation

We believe beneficiaries need additional clarity regarding several elements of the Program. First, participants and plans need to understand how drug returns due to intolerable side effects or a lack of response to treatment would impact the calculation of monthly payment amounts. This issue is of particular significance within the context of rare disease patients, as the out-of-pocket costs for a single prescription could potentially reach the $2,000 annual cap. It is unclear whether participants would be issued refunds for returned products or required to continue paying for a drug they have ceased using. The practical implications of these scenarios, especially in the context of a 3-month mail order fill versus a single prescription obtained from a pharmacy, could lead to a lack of uniformity among issuers and leave some beneficiaries with financial obligations they did not expect.

The potential that the Program would offer minimal financial relief for individuals requiring high-cost treatments late in the year Is of particular concern to our patient communities. Haystack Project's patient advocacy organizations have emphasized that patients newly prescribed a treatment in the latter part of the year should not suffer financial burdens that patients filling a prescription early in the year can eliminate through Program participation. We urge CMS to enable participants to spread out-of-pocket costs over a 12-month period, rather than the remainder of the calendar year. The primary concern within our communities is that patients receiving a new prescription in, for example, October, would be unable to pay their out-of-pocket costs (with or without Program participation), and have to delay filling their prescription until January. Addressing this concern with a 12-month, rather than calendar year, approach would be an important step toward ensuring that the Program reduces the likelihood that Medicare's most vulnerable beneficiaries suffer compromised outcomes from cost-related treatment delays.

Additionally, beneficiaries express concerns about whether insurance plans can prevent individuals from opting into the payment plan for multiple subsequent years after a prior termination due to nonpayment. Similarly, participants need to understand their options during

a grace period to avoid termination. We believe that plans and participants would be well-served if CMS encourages plans to offer an opportunity distribute past-due amounts over the remaining plan months instead of requiring up-front payment of past due amounts. Since termination from the Program leaves participants with fewer financial options and plans with a debt that may be difficult to collect, we strongly encourage CMS to specifically grant participants at least one opportunity per plan year to catch up on missed payments by requesting a recalculation that evenly spreads their monthly payments over the remaining months of the plan year.

Lastly, there is a great deal of uncertainty about what constitutes "good cause" for missing a payment. Both plans and participants need guidance on the practical application of this standard. We recommend CMS provide a set of illustrative examples to shed light on the circumstances or scenarios that would qualify as "good cause" for missing one or more payments. This guidance would offer much-needed clarity in navigating the payment program.

Prioritization of Premium Payments

The guidance indicates that CMS encourages Part D sponsors, when in receipt of payments not clearly designated as a payment to either part D plan premiums or Medicare Prescription Payment Plan payments to prioritize payments towards Part D plan premiums. While we support CMS' policy decision to ensure that beneficiaries maintain Part D coverage, we have concerns that this policy may have unintended consequences.

Our understanding is that most Part D enrollees utilize direct deductions from their Social Security payments in order to pay their Part D premiums. Accordingly, these beneficiaries are unlikely to mail additional payment to the plan sponsor for the purposes of paying premiums. While their automatic social security deductions are clearly designated as a Part D premium payment, the methods of payment for Program payments are more likely to be done via personal check or EFT and therefore are much more likely to be left without a clear designation as to which account the funds should be applied. For participants paying their Part D premiums through automatic deductions from their Social Security payments, an undesignated payment would almost certainly be intended as a Program payment. may be received by the plan sponsor before the social security deduction.

In addition, participants may make payments a few days early or a few days late. This could create confusion for participants and plans on how to apply payments, e.g., toward the next month's amount due or to the balance remaining. We urge CMS to require that plans allow participants to designate how they wish to apply any payments that exceed the amount due for a particular month and (1) permit pre-payment of a subsequent month's invoice as well as (2) enable recalculation of monthly payments for participants electing to apply overpayments to the remaining balance.

Section 60 – Requirements Related to Part D Enrollee Outreach

Uniform model notices, forms, and communications from both plans and pharmacies would reduce confusion and enhance consistency and predictability; deploying patient groups like

Haystack Project as well as existing educational tools beneficiaries are familiar with will aid program awareness.

We commend CMS for recognizing the vital role of effective outreach and education in facilitating the Program's success. The creation of model notices, forms, and beneficiary communications would enhance consistency and predictability significantly. We ask that CMS release these resources in draft form, allowing stakeholders the opportunity to offer feedback and input.

In addition, we recommend that CMS utilize existing resources to maximize enrollee education. For instance, CMS could enhance program awareness by utilizing the plan finder tool as it is a critical resource for beneficiaries and their families when making decisions about their Part D plans. By incorporating a calculator tool into Medicare.gov that illustrates how the program can benefit a beneficiary based on their anticipated prescription drug needs, CMS could streamline the process for opting in. Prescribers should also have access to real-time benefit tools that offer information about the financial responsibility tied to specific prescriptions, enabling them to engage in discussions with their patients about the Program.

Similarly, CMS should develop informational materials tailored for use by pharmacies to educate beneficiaries about the program. These materials should offer clear instructions on how to opt into the program, ensuring that Part D enrollees are well-informed and prepared to make decisions regarding their participation well in advance of the 2025 plan year. Additionally, active prompts at pharmacy counters could inform Part D enrollees about the program and provide them with the opportunity to participate. This could involve incorporating statements like "have you considered opting in" within automated pharmacy notifications commonly used to alert patients that their prescription is ready for pick-up.

We also note that the IRA requires pharmacists to proactively engage beneficiaries who are “likely to benefit” from the Program, inform them on how the Program might be helpful and outline mechanisms for opting in. 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.

In addition, patient advocacy organizations like Haystack Project can play an important role in helping CMS ensure patients are not only aware of, but thoroughly understand the Program. CMS should provide FAQs and model PowerPoint presentations that patient advocacy organizations can use to inform their patient and provider communities on the Program, including how each patient can determine whether they should opt in and when/how to do so. We also encourage CMS to update the Medicare & You handbook with pertinent information on the Program and outline a clear set of requirements for plans, including that program information be included with plan documents, including the evidence of coverage notice and explanation of benefits statements.

Section 70 – Requirements Related to Part D Enrollee Election

A POS option is both feasible and critical in Plan Year 2025; Patients, pharmacies, and plans should also consider a 2025 opt-in request as same-day participation.

We believe this Program has tremendous opportunity to help beneficiaries afford and continue to afford their life saving prescriptions. Currently, a dishearteningly high number of individuals and families find themselves burdened by unaffordable out-of-pocket expenses. The prospect of spreading these costs evenly over the course of a year really is a beacon of hope for innumerable Medicare beneficiaries living on a fixed income and their families, sparing them from the agonizing reality that filling a high-cost prescription could mean getting inextricably behind on housing, utility, and transportation bills. It is critical that the first year of this Program is successful. We are concerned that confusion or unnecessary complexity in the enrollment process will either dissuade beneficiaries from participating or simply add to their existing financial stressors.

Because the IRA requires plans to make the Program available to all enrollees and does not provide for any basis upon which a participation request could be denied other than involuntary termination in the previous year, enrollment in the first year of the Program should be the easiest for plans to process. Accordingly, patients, pharmacies, and plans should consider a 2025 opt-in as participation on the day the request is made. This could be operationalized by requiring that requests for participation made via telephone or online through CMS or the plan sponsor's website are acknowledged with a tracking or confirmation number that participants can utilize at the point of sale to confirm that they have opted in.

While we understand plans may need some time to process requests, participation should be retroactively applied to the date the election was made and beneficiaries should be able to take advantage of the payment advantages the moment they elect to enroll. We are concerned that delaying participation due to processing wait times and creating an expediting mechanism for occasions when a plan agrees a prescription is “urgent” will create a burden for clinicians and patients alike. This would be an additional administrative burden in an already unfamiliar and complex Program that providers would have to navigate along with any prior authorization or step therapy hurdles plans have implemented. This issue is critically important to Haystack Project and its members. For many rare disease patients, every prescribed treatment is perceived as potentially reducing disease burden or progression and viewed as urgent. Even introducing a requirement for patients to return within 24-72 hours to access their medications would needlessly impose stress and inconvenience.

In addition, offering a point of sale (POS) opt-in process during the first year of the Program is critical to its success as most Medicare beneficiaries make important decisions about their health and finances at the pharmacy counter. A POS participation mechanism will ensure that individuals facing high out-of-pocket costs when they seek to fill their prescription can elect to participate in the Program and receive their medication without delay. **We strongly urge CMS to adopt the point-of-sale (POS) enrollment approach in the 2025 plan year, recognizing requests as equivalent to participation during the processing period stipulated by plans.**

Finally, we strongly encourage CMS to mandate that plans maintain their enrollees' participation from one year to the next, adopting a procedure akin to the auto-enrollment protocols observed in Medicare or Qualified Health Plans. Participants would be reminded of that they have the option to opt out of participation at any time. This approach would streamline the process for Medicare beneficiaries who might otherwise assume that both their plan enrollment and program participation automatically continue from year to year.

Section 80 – Procedures for Termination of Election, Reinstatement, and Preclusion
A grace period is critical and should be extended to 3 months in line with other health plans.

We support CMS' policy to implement a grace period and ask that it be three rather than two months. We also support CMS' requirement that Part D plans provide participants with continued information throughout the grace period on the impact of late payments, including that the individual faces involuntary termination from the Program. These communications should make clear that Part D benefits continue as long as premiums are paid and that the grace period for this Program is separate and distinct from enrollment in their Part D plan.

As outlined above, we urge CMS to consider adopting a mechanism that permits participants to have their missed payments spread across the remaining plan months. This measure would enhance the feasibility of ongoing participation and alleviate the necessity for terminated individuals to establish "good cause" for payment lapses. We further request 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

Haystack Project appreciates the opportunity to submit feedback 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 diseases, can receive the treatments they need without financial hardships associated with high out-of-pocket costs. If you have any questions, please contact me or our policy consultant, Kay Scanlan of Consilium Strategies at mkayscanlan@consilstrat.com.

Sincerely,

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