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By Electronic Transmission to: PartDPaymentPolicy@cms.hhs.gov

March 16, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1771-P
P.O. Box 8013
Baltimore, MD 21244-1850

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:

Haystack Project is pleased to contribute feedback and recommendations on Part Two of the Centers for Medicare & Medicaid Services' (CMS') Guidance implementing the Medicare Prescription Payment Plan (MPPP).

Haystack Project is a 501(c)(3) non-profit organization enabling rare and ultra-rare disease advocacy organizations to highlight and address systemic access barriers to the therapies they desperately need. We strive to amplify the patient and caregiver voice in disease states where unmet need is high, and treatment delays and inadequacies can be catastrophic. Our core mission is to evolve health care payment and delivery systems, spurring innovation and quality in care toward effective, accessible treatment options for Americans living with rare or ultra-rare conditions. Haystack Project is committed to educating policymakers and other

stakeholders about the unique circumstances of extremely rare conditions with respect to product development and fair access to care.

For members of our patient communities relying on Medicare Part D to access medications, the MPPP offers tangible relief from the financial burdens associated with high or unexpected out-of-pocket costs. Medications for rare and ultra-rare conditions tend to be placed on the highest tiers of Part D plan formularies. Patients have frequently found that the cost of filling their prescriptions, particularly at the beginning of the plan year, is too high to be absorbed within a single month.

Our comments focus on ensuring that patients, especially those with rare and ultra-rare conditions, have access to the financial relief the MPPP was intended to convey. 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.

General Comments and Recommendations

Haystack understands that CMS has had an extremely narrow timeline for implementing the prescription drug provisions of the Inflation Reduction Act (IRA). We agree that publishing and soliciting stakeholder comments on draft program instructions and guidance in a piecemeal manner has helped CMS ensure that it can move efficiently in implementing program changes. Unfortunately, in reviewing this Part Two guidance, we found that reference to the Part One draft guidance (which was only recently finalized) in the Part Two Guidance and reference to the draft Part Two Guidance in the finalized Part One Guidance creates uncertainties and gaps in our understanding of how the MPPP will work in the real world.

We strongly urge CMS to afford an opportunity for stakeholders to provide feedback on the two parts of the Guidance as a whole.

In addition, our comments to Part One of the MPPP Guidance included several aspects of the MPPP on which our patient communities expressed a need for greater clarity. As these issues were not discussed in the draft Part Two Guidance or the finalized Part One Guidance, we reiterate our request that CMS clarify the following:

- 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. Since out-of-pocket costs for a single rare disease treatment could potentially reach the \$2,000 annual cap in a single month, this issue is particularly important to our communities. It is unclear whether participants would be issued refunds for returned products or be required to continue paying for doses they have not used. We expect that the same could be true for individuals receiving a 3-month mail

order fill and that the lack of CMS clarification could create variability among Part D sponsors and leave some beneficiaries with financial obligations they did not expect.

- Patients have also expressed concerns about whether plans can prevent individuals from opting into the payment plan for multiple subsequent years after a prior termination due to nonpayment.
 - o We appreciate clarification that individuals would be eligible to participate if they pay amounts due from prior years or enroll in a different sponsor's plan.
 - o We continue to 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 a single up-front payment. CMS could, for example, require (or encourage) plans to provide at least one opportunity per plan year for participants to catch up on missed payments with a recalculation that evenly spreads their monthly payments over the remaining months.

- Although there is detailed information on enrollment processes, timeframes for processing requests, and standards for urgent enrollment processing and retroactive applicability, we are unable to ascertain:
 - o What information will plans require from enrollees requesting to opt into the MPPP that is not already within records maintained by plans and would, if missing, delay processing?
 - o Are there any justifications for plans to decline an opt-in request in 2025?
 - o Can plan participants who have received a confirmation number after opting into the MPPP (online or by telephone) present their member ID and the confirmation number to a pharmacy when filling a prescription with high out-of-pocket costs?

Section 30. Outreach, Education, and Communications Requirements for Part D Sponsors

General outreach

Effective beneficiary outreach and education are crucial to facilitating the MPPP's success. We agree with CMS that model notices, forms, and beneficiary communications would significantly enhance consistency and predictability. We urge CMS to release these resources in draft form so that patients and advocacy organizations have an opportunity to offer feedback and input.

We appreciate that CMS will require plans to use existing Part D materials furnished to their enrollees and include information about the MPPP. We support CMS' proposed requirements that plans:

- Include MPPP information and an enrollment form when sending Part D enrollee membership ID cards.
- Utilize CMS' revised Explanation of Benefits (EOB) that includes MPPP information and explains that enrollees participating in the program will receive a separate monthly MPPP billing statement.
- Send the Annual Notice of Change (ANOC) with educational language describing the MPPP and instructing plan enrollees on how to opt into the program. This document must be sent to Part D enrollees by September 30 of each year.
- Include educational information on the MPPP within the Evidence of Coverage (EOC) document detailing covered benefits and enrollee cost-sharing responsibilities.
- Provide MPPP information on their websites, including election request mechanisms that enrollees can use to opt into the MPPP.

Haystack urges CMS to require that plans ensure that the required MPPP information is conspicuously displayed on the various documents so that enrollees do not overlook this important information due to its inclusion in documents routinely receive from their plans.

We also expect that the online election request mechanism will be particularly helpful to individuals wishing to have real-time confirmation that their opt-in request was received and appreciate that the Agency is encouraging plans to provide a confirmation number. We have previously urged CMS to create a calculator tool that could be included on plan websites so that individuals can see how the MPPP might benefit them based on their anticipated prescription drug needs. This would be more helpful to beneficiaries than the set of examples CMS would require plans to develop and include on their websites.

Similarly, Haystack believes that CMS' efforts to inform Medicare beneficiaries of this new program would be greatly enhanced with informational materials tailored for use by pharmacies to educate beneficiaries about the program. These materials should be distributed in advance of the 2025 plan year and offer clear instructions on how to opt into the program. In addition, active prompts at pharmacy counters could be used to augment targeted outreach and inform Part D enrollees about the program.

Finally, 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-developed FAQs and model PowerPoint presentations would be helpful to patient advocacy organizations wishing to inform their patient and provider communities on the Program, including how each patient can calculate whether they would benefit from opting in.

Targeted outreach

Haystack appreciates CMS' efforts to ensure that beneficiaries most likely to benefit from the MPPP have multiple opportunities to review and evaluate program information and opt-in if the program will likely benefit them. We agree that:

- Requiring plans to notify enrollees with high out-of-pocket costs in 2024 and previously years will reduce the number of Medicare beneficiaries delaying prescription fills due to the time required to opt-in and receive confirmation of MPPP participation.
- Targeted outreach during the plan year for enrollees with pending prior authorization requests for high-cost drugs would enhance other ongoing efforts to identify individuals likely to benefit from the MPPP. We believe that this mechanism would be more helpful if:
 - o Plans identifying these enrollees too late in the plan year to convey an MPPP participation benefit notified these individuals about the program and offered an opportunity to opt-in for the upcoming plan year.
 - o Plans used a notification mechanism (e.g., telephone contact or text messaging) more likely to provide a real opportunity for the individual to opt-in to the MPPP and benefit from the program. It is unlikely that mailing the notification the day after the prior authorization request is flagged would be provide MPPP information in time for opt-in election prior to prescription pick-up.
- Pharmacies are an important contact point for patients likely to benefit from the MPPP and plan notification to pharmacies of an individual likely to benefit from the program can enable pharmacies to convey that information to patients. We believe this targeted outreach will be most effective if it reduces the possibility that a Medicare beneficiary would decline to pick up their prescription due to high out-of-pocket costs. We recommend:
 - o The information on MPPP should be conveyed to the patient **before** the patient picks up their prescription.
 - o The patient should have an opportunity to opt-in by telephone or online and can pick up their prescription with \$0 cost at the pharmacy counter by providing their member ID and election confirmation number.

Overview of Election Requirements

Haystack believes the MPPP offers a tremendous opportunity to help beneficiaries afford their life saving prescriptions. The ability to spread out-of-pocket costs evenly over the course of a year can, for many Medicare beneficiaries, reduce the possibility that a patient will have to choose between receiving their medication and paying their housing, utility, and transportation bills. We are concerned that confusion or unnecessary complexity in the enrollment process will either dissuade beneficiaries from participating, add to their existing financial stressors, or deter participation in future years.

Because the IRA requires plans to make the Program available to all enrollees and does not provide for any denial mechanism other than involuntary termination in the previous year, enrollment in the first year of the Program should be a ministerial task, not a determination. While we understand plans may need some time to process requests, we urge CMS to enable a mechanism through which participants could present their opt-in confirmation number when picking up their prescription. We believe this would reduce the need for retroactive participation and ensure that individuals unable to pay at the pharmacy counter and wait for a “refund” do not walk away without necessary medication. This issue is

critically important to Haystack Project and its members. For many rare disease patients, every prescribed treatment that can reduce disease burden or progression should be viewed as urgent.

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 used in Medicare or Qualified Health Plans. Participants would be reminded 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.

Conclusion

Haystack Project appreciates the opportunity to submit feedback on CMS' draft Part Two Guidance implementing 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 at Kara.berasi@haystackproject.org or our policy consultant, Kay Scanlan of Consilium Strategies at mkayscanlan@consilstrat.com.



