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April 29, 2024

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

**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:

Haystack Project is pleased to contribute feedback and recommendations on the six model documents the Centers for Medicare & Medicaid Services (CMS) released as part of its implementation of 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, denials 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.

Medications for rare and ultra-rare conditions tend to be placed on the highest tiers of Part D

plan formularies. Since most rare and ultra-rare patients lack an FDA-approved, disease-specific treatment, our patients must rely on off-label treatments and often require multiple medications to manage disease symptoms and/or slow disease progression. 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. The MPPP, therefore, offers tangible relief from the financial burdens associated with high or unexpected out-of-pocket costs for our patient communities relying on Medicare Part D to access medications,

In Haystack Project's comments to CMS' MPPP Part Two Guidance, we emphasized the critical role effective beneficiary outreach and education will play in facilitating the MPPP's success. We fully supported CMS' proposal to create model notices, forms, and beneficiary communications and urged the Agency to release these resources in draft form so that patients and advocacy organizations have an opportunity to offer feedback and input. We applaud CMS for not only soliciting feedback on the six model documents but providing sufficient time for Haystack Project to collect input from actual patients and caregivers.

We distributed the six model documents to our member organizations, asking that they reach out to patients and caregivers within their communities with the inquiry below:

Tell us YOUR FIRST IMPRESSIONS (as if you'd just received them in the mail) -- what makes sense in each one, and what doesn't?

- What do you think each document is telling you?
- What questions does each leave you wanting to ask?

Even if you understood it, would you have said something differently? If you didn't understand it, that's very helpful too!

Our comments reflect input gathered from patients, caregivers, and our patient advocacy organization members, including initial impressions as well as any questions or confusion on the MPPP and "next steps" patients receiving the document should take.

### **General Feedback on the MPPP and Model Documents**

Haystack Project's patients were generally enthusiastic about the MPPP as it offers an opportunity to help beneficiaries ineligible for other forms of assistance to afford their life saving prescriptions. By spreading out-of-pocket (OOP) costs evenly over the course of a year, many Medicare beneficiaries can minimize the possibility that they will have to choose between receiving their medication and paying their housing, utility, and transportation bills.

Patients reviewing the model documents appreciated that CMS reiterated that there are a variety of ways to pay MPPP bills, that not participating in the MPPP would have no impact on Medicare Coverage or their Part D plan, and that other programs exist that might reduce OOP costs for eligible patients. They conveyed that this information, included throughout the series of documents, was clear and helpful.

Much of the feedback centered on information *not* provided in the model documents. For example, 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. Haystack Project's member community includes patients with progressive conditions impacting both vision and hearing as well as families with limited proficiency reading technical information presented in English. 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.

In addition, neither the model documents nor CMS' Guidance to date provides any clarity on whether and how a plan could decline to accept an individual's request to participate in the MPPP during the initial program year. Since the IRA requires that plans make the Program available to all enrollees and does not provide for any denial mechanism other than involuntary termination in the previous year, initial year acceptance of participation requests appears to be a ministerial task, rather than a determination requiring review and a decision. We once again urge CMS to create a real-time opt-in mechanism. This could be as simple as enabling participants to present their opt-in confirmation number as evidence of MPPP participation 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 patient communities and appropriate resolution could eliminate patient frustration with the MPPP that could carry over into subsequent years.

Finally, patients and caregivers reviewing the documents were unable to determine whether participants have to submit an election request every year, only when they have switched plans, or just once (with participation continuing until terminated). We strongly encourage CMS to mandate that plans maintain their enrollees' participation from one year to the next if they are currently auto-enrolling beneficiaries into their plans. Participants would then 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. Information on whether and when a new election request must be submitted should be included in Documents 1-3.

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

Haystack Project understands that individuals encountering high OOP costs later in the plan year may be less likely to benefit from MPPP participation. These patients may, however, benefit from receiving MPPP information when they encounter high OOP costs so they can consider opting in for the next plan year. We urge CMS to ensure that when patients meet cost thresholds meeting the “likely to benefit” criteria in the fourth quarter, plans give these individuals an opportunity to opt in for either/both the current and next plan year.

With respect to the Likely to Benefit Notice, patients noted that it was packed with information, yet did not clearly convey the potential benefits of participation. Individuals suggested presenting information in bullet-point format and providing example calculations so that Medicare beneficiaries have a better understanding of how the MPPP works.

In addition, individuals reviewing the documents expressed both concerns and questions, including:

- Will individuals receive more than one bill per month from their plan?
- Ultra-rare disease patients might “shy away” from “any complications and insurance company fights when I first hear about the program. I would be concerned (just from the info in Document #1) that there might be confusion with the pharmacy/mail order provider about giving me the medication without payment at point of service.”
- The information on Document #3 explaining that pharmacies will be notified should be included in Document 1, and there should be clear information on what a patient can and should do if a pharmacy asks for payment at the pharmacy counter.
- Document 1 looks like it was written by a lawyer and not someone who understands how people read documents. Breaking it up into sections/sidebars/text boxes may help make it more understandable as would a hypothetical and a separate

“frequently asked questions” document that could accompany each of the six model documents.

- The use of the term “payment option” was a bit confusing and CMS and Part D plans should refer to it at the beginning of Document 1 as an “optional payment plan” called the “Medicare Prescription Payment Plan.”
- There was also confusion on whether the MPPP would bill participants based on the OOP maximum of \$2000. A patient specifically asked, “will a participant be responsible for paying \$2000 even if they don’t have a prescription cost that adds up to \$2000?”
- Although Document 1 includes the statement “[y]ou’ll never pay any interest or fees on the amount you owe, even if your payment is late," it should also notify potential participants that individuals failing to make payments would not be eligible to participate in the MPPP with their existing plan until overdue payments are paid.
- Document 1 should also let individuals know that they can voluntarily exit the MPPP and go back to paying at the pharmacy counter.
- Although it was helpful to outline a set of scenarios that might make the MPPP less helpful for potential participants, including the example of patients with consistent monthly drug costs over the plan year might discourage individuals with extremely high, but even OOP costs throughout the year. CMS should clarify this example to ensure that, for example, individuals with predictable monthly costs of \$1000 each month do not conclude that they would not benefit from MPPP participation.

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

Although patients and caregivers within Haystack Project’s communities generally found the Election Request Form easy to understand, we received feedback that::

- Participants need to know when their participation will take effect and when/how their plan will notify them that their request was received, processed, and approved.

- There does not appear to be enough space in the form for individuals with long last names.
- The terms and conditions should be consistent across plans and individuals should be able to read that information and agree to it when they submit their opt-in request. It will be difficult for patients to opt in if they have extra steps that need to be completed later and do not know how they will be informed of what to do and when.
- The Election Form should include information on other ways to opt in to the MPPP and let potential participants decide what opt in mechanism they are most comfortable with.
- It is unclear what types of communications might be made to the participant's phone. If, for example, plans wish to communicate by text message, the form should enable individuals to specify whether the number provided is a mobile number or landline.

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

As mentioned above, Document 3 contains information on voluntary termination and impact of failure to make payments under the MPPP that would be helpful to Medicare beneficiaries as they determine whether to participate in the MPPP. Although most individuals found the notice to be understandable and clear, others conveyed that they remained somewhat confused and uncertain of what next steps an individual should take after receiving this notice. Feedback included:

- Uncertainty on what a participant can/should do if their pharmacy requires that they pay at the pharmacy counter before taking their medication home.
- As in Document 1, patients would appreciate having an example in Document 3 illustrating how each monthly payment is calculated and what if any impact OOP costs paid prior to participation would have on calculations of monthly maximum payment. This would be especially important for individuals who, for example, paid

\$1,000 or more in the first month of the plan year but had not received their MPPP participation approval until the second (or subsequent) month.

- Several individuals voiced confusion over whether ALL pharmacies within their plan would know that they participate in the MPPP or only those that had previously filled a prescription for the patient. Is there a mechanism needed to make the information more broadly available so that if, for example, a particular drug out of stock at the individual's usual pharmacy, they can go to any pharmacy carrying the medication without worrying that they will be asked to pay at the pharmacy.
- Although patients appreciate the ability to terminate their participation in the MPPP at any time, it would be helpful to require that plans give voluntary termination options in addition to communicating by telephone. In addition, patients are concerned that they will not know that their termination request was processed.

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

Haystack Project's patient community was pleased that CMS reiterated in the Notice of Failure to Pay that Part D enrollment is not connected to or impacted by the MPPP. Patients and caregivers appreciated that individuals falling behind on their MPPP payments might have the option of spreading their past-due amounts over the remainder of the year or making a partial payment. In addition, patients and caregivers:

- Expressed that it is “so nice to have optional programs spelled out on where to get help. Love the statement that many people qualify and do not realize it.”
- Suggested simplified wording and presentation of information to make it easier to read and understand. Specifically, one individually suggested the following wording:

*"We didn't get your monthly payment for the Medicare Prescription Payment Plan that was due <insert payment due date>.*

*To stay in the Medicare Prescription Payment Plan, you must:*

- *Pay <insert the full amount past*
- *Pay > by <insert date for the end of the grace period.*

- *Contact us at [insert phone number or other contact information] if you are unable to pay [insert amount] by [insert date] and wish to set up a partial payment [or other arrangement] to continue your MPPP participation.*
- Were concerned that there was no mention of extenuating circumstances that might justify a delinquent payment. If participant hardships are taken into consideration when a plan determines to involuntarily terminate MPPP participation, the document should spell this out and let individuals know how to communicate this to the plan.
- The Notice does not let patients know whether they have reached their OOP maximum. Individuals were also uncertain of whether any unpaid amounts under the MPPP would count toward their OOP maximum. The Notice will misinform beneficiaries who have met their OOP maximum if it conveys that after termination from the MPPP the beneficiary will be required to pay OOP costs at the pharmacy.

**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. Several individuals suggested that CMS clarify any impact termination might have on the total amount needed to reach their OOP maximum. Patients were also unsure of what they might expect if they are involuntarily terminated from the MPPP, including whether the debt would be turned over to a collection agency, and even whether their pharmacy might try to collect the debt before filling their future prescriptions.

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

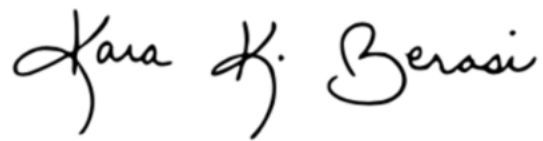
The information in the Notice of Voluntary Termination was viewed as clear and understandable for Haystack Project’s patient communities.



## Conclusion

Once again, we appreciate that CMS has sought feedback on the six model documents and 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](mailto:Kara.berasi@haystackproject.org) or our policy consultant, M Kay Scanlan of Consilium Strategies at [mkayscanlan@consilstrat.com](mailto:mkayscanlan@consilstrat.com).

Sincerely,

A handwritten signature in black ink that reads "Kara K. Berasi". The signature is written in a cursive style with a large, stylized 'K' and 'B'.

Kera Berasi, PharmD, MS  
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