



March 15, 2024

Dr. Meena Seshamani, M.D., Ph.D  
Director, Center for Medicare  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

**Re: Medicare Prescription Payment Plan: Draft Part Two Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments**

Dear Director Seshamani,

On behalf of the more than 30 million Americans living with one of the over 10,000 known rare diseases, the National Organization for Rare Disorders (NORD) thanks the Center for Medicare for the opportunity to provide comments on the “Medicare Prescription Payment Plan: Draft Part Two Guidance,” hereafter referred to as “MPPP.” Our comments are intended to serve as a companion piece to our response to the MPPP Part One Guidance, submitted September 2023.<sup>1</sup>

NORD is a unique federation of non-profits and health organizations dedicated to improving the health and well-being of people with rare diseases by driving advances in care, research, and policy. NORD was founded 40 years ago, after the passage of the Orphan Drug Act (ODA), to formalize the coalition of patient advocacy groups that were instrumental in passing that landmark law. Since that time, NORD has been advancing rare disease research and funding to support the development of effective treatments and cures; raising awareness and addressing key knowledge gaps; and advocating for policies that support the availability of and access to safe and effective therapies.

The MPPP presents a tremendous opportunity to reduce out-of-pocket costs for rare disease patients who frequently are subject to significant financial burdens in order to obtain their medications. A 2019 NORD survey found that 76% of respondents had experienced financial challenges due to their own or their family member’s rare diagnosis.<sup>2</sup> According to data from the NIH’s National Center for Advancing Translational Sciences (NCATS), medical costs are 3-5 times greater for people with a rare disease than

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<sup>1</sup> *Part 2 of the Medicare Prescription Payment Plan Guidance*. MAPRx. (2024, March 15). <https://rarediseases.org/wp-content/uploads/2023/09/Medicare-Prescription-Payment-Plan-Sign-On-Letter-9.20.23.pdf>

<sup>2</sup> *Barriers to Rare Disease Diagnosis, Care and Treatment in the US*. National Organization for Rare Disorders. (2020, November 19). [https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report\\_FNL-2.pdf](https://rarediseases.org/wp-content/uploads/2020/11/NRD-2088-Barriers-30-Yr-Survey-Report_FNL-2.pdf)

those who do not have a rare disease.<sup>3</sup> As of 2019, the average annual cost of an orphan therapy was \$32,000 per treated patient.<sup>4</sup>

Despite the direct, positive patient impacts envisioned by the Part D redesign provisions in the Inflation Reduction Act, awareness among the general public remains limited. A July 2023 survey found that only 34% of Medicare aged respondents knew about the forthcoming annual limit on out-of-pocket drug costs for individuals with Medicare.<sup>5</sup> Without increased public awareness of the MPPP, and given the statutory requirement for patients to opt into the program, we are concerned that many patients that would otherwise benefit from participation in the MPPP may not enroll, in particular during the first year of the program. We urge CMS to work with community serving organizations, such as organizations that provide health or other services to (parts of) the Medicare population, as well as health plans, community pharmacists, health care providers, and other key stakeholders, to raise awareness. NORD is pleased to provide more detailed recommendations below and agree with comments and recommendations submitted by the MAPRx coalition on this same guidance.<sup>6</sup>

**Recommendation 1: Ensure educational materials regarding the MPPP are consistent and avoid confusion about availability of or access to the MPPP among different health plans (see Section 30.1)**

NORD strongly believes that the MPPP will benefit rare disease patients, many of whom rely on high-cost medication for treatment, but health plans will be crucial to ensuring patients are aware of and can utilize this benefit. Therefore, NORD supports mandating Part D sponsors include educational materials on MPPP throughout the course of the year and as a part of annual mailings and explanation of benefits. However, to avoid confusion and potential unintended consequences such as inadvertently steering high-cost beneficiaries to some health plans that use certain educational materials about the MPPP, we recommend a multi-pronged approach:

1. CMS should increase current agency-led education and outreach efforts regarding the MPPP, and partner with community serving organizations and other key partners to raise awareness and educate beneficiaries about the MPPP, with particular focus on engaging beneficiaries from historically underserved communities.

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<sup>3</sup> *NIH Study Suggests People with Rare Diseases Face Significantly Higher Health Care Costs*. NCATS. (2021, October 22). <https://ncats.nih.gov/news-events/news/nih-study-suggests-people-with-rare-diseases-face-significantly-higher-health-care-costs#:~:text=According%20to%20the%20Eversana%20health,those%20without%20a%20rare%20disease>

<sup>4</sup> *The Next Generation of Rare Disease Drug Policy: Ensuring Both Innovation and Affordability*. Institute for Clinical and Economic Review. (2022, April 7). [https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper\\_The-Next-Generation-of-Rare-Disease-Drug-Policy\\_040722.pdf](https://icer.org/wp-content/uploads/2022/04/ICER-White-Paper_The-Next-Generation-of-Rare-Disease-Drug-Policy_040722.pdf)

<sup>5</sup> *KFF Health Tracking Poll July 2023: The Public's Views of New Prescription Weight Loss Drugs and Prescription Drug Costs*. KFF. (2023, August 4). <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-july-2023-the-publics-views-of-new-prescription-weight-loss-drugs-and-prescription-drug-costs/>

<sup>6</sup> *Part 2 of the Medicare Prescription Payment Plan Guidance*. MAPRx. (2024, March 15). <https://rarediseases.org/wp-content/uploads/2023/09/Medicare-Prescription-Payment-Plan-Sign-On-Letter-9.20.23.pdf>

2. CMS should take deliberate steps to ensure plan sponsors use consistent language and emphasize to patients that the program is not specific to any plan. This will help ensure patients choose the plan that works best for them based on unique plan characteristics, rather than out of a mistaken belief that the MPPP is only available through certain plans. Organizations that represent the health plan community, such as AHIP and other trade organizations, can play a key role in helping to standardize the use of materials and to raise awareness more broadly.
3. Data clearly suggest that beneficiaries' health as well as socio-demographic factors are influencing plan choices, including switches between Medicare Advantage (MA) and fee-for-service (FFS) plans. Specifically, patients with increased healthcare needs are overrepresented among beneficiaries electing to switch from MA to FFS plans, a trend that may be further exacerbated by the MPPP \$2,000 out-of-pocket cap.<sup>7</sup> We encourage CMS to increase educational efforts explicitly informing beneficiaries of potential post-deductible co-insurance requirements and Medigap pre-existing condition policies to ensure all beneficiaries can make appropriately informed decisions that can best meet their healthcare needs, both at the time they first become eligible for Medicare and with each subsequent plan choice.
4. Finally, it is vital for CMS to study health plan compliance and outreach effectiveness, in particular in the first year of the program, and to learn from and revise the approaches based on these learnings moving forward.

**Recommendation 2: Consider developing additional tools and approaches to better support patients in their decision whether to participate in the MPPP (see Section 30.1.5)**

We are broadly supportive of CMS' proposed educational efforts, including adding proposed detailed examples of calculations under multiple scenarios. Specifically, we are supportive of CMS' proposal to include numerous examples of when the MPPP would or would not be likely to benefit a patient who utilizes covered part D drugs. However, we remain concerned that generalized examples will be difficult for patients to navigate and may not provide sufficient information for patients to make appropriately informed decisions about their participation in MPPP.

Choosing whether to opt-into the MPPP requires consideration of numerous factors that are frequently patient specific, including the potential for the addition of expensive products later on in the plan year. As such, we recommend developing additional educational tools, such as the creation of a tool that will allow patients to calculate their potential monthly payments with or without opting into the MPPP under different scenarios, which are tailored to be as specific to their unique situation as appropriate. We urge CMS to carefully consider the needs of the patient community and to work with external partners that serve these communities to identify these needs and find ways to improve the education process.

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<sup>7</sup> *Medicare Switching: Patterns of Enrollment Growth In Medicare Advantage, 2006-22*. Health Affairs. (2023, September). <https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00224#:~:text=Exhibit%203%20shows%20the%20characteristics,Medicare%20it%20was%201.2%20percent>.

**Recommendation 3: Limit broad distribution of ‘likely to benefit’ notices to the beginning of the plan year and tailor their distribution later in the plan year to those individuals most likely to benefit (see Section 30.2.2.3)**

We support CMS’s plans to ensure the broad distribution of “likely to benefit” notices, provided by plans at the pharmacy counter, at the beginning of the plan year as described in Section 30.2.2.3. We also share CMS’ concerns that distribution of “likely to benefit” notices late in the plan year could inadvertently result in greater harm than good for many beneficiaries who at this time in the plan year may no longer benefit from the MPPP. For this reason, we recommend a staged approach:

1. **For the first quarter of the plan year:** We recommend limiting broad distribution of the likely to benefit notices to the first quarter of the plan year. Within the likely to benefit notice, we recommend including language cautioning that MPPP participation may provide limited or no benefits when initiated later in the plan year. Moreover, we recommend time-stamping the notice and/or otherwise signaling to beneficiaries that the benefit of participation is time-limited and likely to decrease as time elapses. We further recommend reassessing participation rates in nearly real-time and engaging with community facing partners before, during, and after the first quarter of the plan year to test the language in the notice to beneficiaries and to better understand and refine the need for additional promotion efforts.
2. **Following the first quarter of the plan year,** individuals most likely to benefit from new MPPP participation are likely those with high and unexpected medical costs, such as newly diagnosed rare disease patients or oncology patients who had been in remission but whose cancer now recurred. Identification of populations most likely to benefit later on in the plan year is an area where further data collection is necessary. We encourage CMS to refine the population identification process following learnings from the first year. To most effectively educate those individuals for whom the initial targeted outreach was not as relevant given their specific circumstances, we recommend partnering with patient and provider groups serving these patients to selectively distribute likely to benefit notices and increase tailored outreach and education strategies; again, we recommend assessing the usefulness of these strategies and to identify the strategies that may be most effective in increasing expedient enrollment for future plan years.
3. **In general,** we propose a cutoff for the broad distribution of likely to benefit notifications after the first quarter of the year; while education for future years remains important, the utility of opting into the program late in the year dwindles for most beneficiaries. Likely to benefit notifications could change to forward looking documents that may help beneficiaries opt into the program at the start of successive the plan year, rather than encouraging the beneficiary to consider opting into the program for the duration of the existing plan year.

Additionally, we continue to propose amending the likely to benefit threshold trigger from one drug to the cumulative out-of-pocket costs that a beneficiary may be responsible for across all drugs they take. More

than half of Medicare aged Americans take four or more prescription drugs.<sup>8</sup> Limiting the likely to benefit notifications to situations where a single drug triggers the out-of-pocket cap leaves out a significant number of beneficiaries who would otherwise benefit from the program.

**Recommendation 4: Build upon first year learnings through data driven growth strategies (see Section 30.2.2.1)**

We applaud CMS' proposal to mandate that targeting strategies found to be effective by a plan sponsor will subsequently be applied evenly across the covered population. We recognize that equitable access and marketing across populations is a concern and believe that this proposed solution will be an important step to address this issue. To build on these successes and ensure that maximum benefit can be granted to enrollees, we encourage CMS and plan sponsors to partner to learn from the broader landscape beyond outreach and engagement initiated by plan sponsors. To achieve maximum impacts in future years, we need appropriate data; as such, we recommend CMS monitor trends in a variety of areas, including state and national lines, and plan sponsors. Following the collection of successes and failures from the first year of the program, CMS could use the collected information to require additional successful strategies in future iterations of guidance.

**Recommendation 5: Purposefully partner with healthcare providers, community-serving organizations, community pharmacists and other trusted voices to improve equitable access to the MPPP (see Section 30.2.3)**

We are supportive of CMS' proposal to encourage distribution of educational materials to in-network providers. Health care providers are trusted care partners and play a crucial role in educating patients about their conditions, the importance of medication adherence, and potential associated costs. Moreover, health care providers already often play a key role in helping patients navigate health insurance challenges from prior authorization requests to other utilization management tools. Data consistently shows that patients who have received greater levels of education from their providers have reduced hospitalizations, lower emergency room utilization, and overall health care costs.<sup>9</sup>

Lack of education can lead to negative consequences resulting from worse health outcomes and increased utilization that can be more expensive for the patient, the Part D sponsor, and the health system writ large. A 2022 survey of Medicare-aged respondents found that over 20% had not filled a prescription due to cost, with nearly 90% indicating their interest in their physician using a real time prescription benefit tool to discuss access and cost requirements.<sup>10</sup> Medication non-adherence due to cost is frequently associated

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<sup>8</sup> *Data Note: Prescription Drugs and Older Adults*. KFF. (2019, August 9). <https://www.kff.org/affordable-care-act/issue-brief/data-note-prescription-drugs-and-older-adults/>

<sup>9</sup> *Better Patient Education Can Lead to Lower Medical Costs*. Relias Media. (2020, December 1). <https://www.reliasmedia.com/articles/147129-better-patient-education-can-lead-to-lower-medical-costs>

<sup>10</sup> *Cost-Related Medication Nonadherence and Desire for Medication Cost Information Among Adults Aged 65 Years and Older in the US in 2022*. JAMA. (2023, May 18). <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012>

with worse general health status, functional limits and higher counts of total conditions.<sup>11</sup> Health care providers therefore have a vested interest in educating their patients about the MPPP.

In addition to instructing health plans to work with health care providers to distribute information about the MPPP, we encourage CMS to directly engage health care providers more broadly to distribute educational materials on the MPPP program to covered out-of-network specialists that a patient may need to see. Rare disease patients frequently must endure a diagnostic odyssey before finally receiving a correct diagnosis. The typical rare disease patient takes 5-7 years before receiving an accurate diagnosis for their condition, including an average of six physicians prior to receiving a diagnosis from the expert.<sup>12</sup> Often, there are only one or two centers across the country with the requisite knowledge to treat the patient's rare disease, which may or may not be in network with the patient's plan. Further, specialists are more likely to prescribe high-cost, specialty medications. Indeed, despite accounting for only 2% of total prescribing volume in 2021, specialty drugs accounted for over 50% of total spending on prescription drugs.<sup>13</sup>

It is crucial that all points of contact that a patient is engaged with in the health system be informed about the benefits of participation in MPPP. A patient's health care coverage can change for a variety of reasons during the plan year and not everyone in the family may have the same health coverage. Distributing information about the MPPP through health care providers more broadly will help ensure the broadest distribution to the eligible beneficiary population. Additional educational materials distributed through community pharmacists and other public facing organizations will increase outreach capacity. Through NORD's Rare Disease Centers of Excellence program, NORD has access to a national network of clinicians at major academic medical centers, and through our patient assistance, education, and community engagement programs, we regularly engage with a large and diverse cross-section of the rare disease community and would be happy to help CMS navigate the outreach to the rare disease patient and provider community.

**Recommendation 6: NORD recommends automatically re-enrolling patients who opted into the MPPP for future plan years (Section 30.3.5)**

Generally, we support CMS' efforts to generate an easy-to-understand notice of voluntary termination, as well as guidelines for ensuring that beneficiaries are not required to pay the entirety of their outstanding balance at once following termination from the program. However, we are concerned that CMS will require beneficiaries to opt into the MPPP prior to the beginning of each plan year, even if the patient remains in the same plan. Academic literature consistently shows that opt-in mechanisms result in lower

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<sup>11</sup> *Cost-Related Medication Nonadherence and its Risk Factors among Medicare Beneficiaries*. Medical Care. (2021, January). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7735208/>

<sup>12</sup> *Rare diseases: why is a rapid referral to an expert center so important?* BMC Health Services Research. (2023). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10463573/>

<sup>13</sup> *Trends in Prescription Drug Spending, 2016-2021*. Assistant Secretary for Planning and Evaluation. (2022, September). <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf>

enrollment rates compared to opt-out mechanisms.<sup>14,15</sup> Absent a submission of voluntary termination during the plan year, we strongly suggest keeping beneficiaries opted-in to the MPPP as a default during the start of a new plan year with a grace period to allow the patient to opt out shortly after the beginning of the new plan year. Around 80% of Part D beneficiaries maintain the same plan year over year.<sup>16</sup> Requiring patients to continue re-enrolling in the MPPP year after year could result in increased mid-year enrollment (with noted fewer benefits), lower overall program enrollment, and additional operational challenges for plan sponsors.

We thank CMS for the opportunity to comment on this draft guidance. We look forward to partnering with the agency to ensure that MPPP implementation is maximally effective for the rare disease community. With any questions or comments, please contact Karin Hoelzer ([khoelzer@rarediseases.org](mailto:khoelzer@rarediseases.org)) or Mason Barrett ([mbarrett@rarediseases.org](mailto:mbarrett@rarediseases.org)).

Thank you for your consideration,



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<sup>14</sup> *A Randomized Controlled Trial of Opt-in Versus Opt-Out Colorectal Cancer Screening Outreach*. American Journal of Gastroenterology. (2018, December).  
[https://journals.lww.com/ajg/Abstract/2018/12000/A\\_Randomized\\_Controlled\\_Trial\\_of\\_Opt\\_in\\_Versus.22.aspx](https://journals.lww.com/ajg/Abstract/2018/12000/A_Randomized_Controlled_Trial_of_Opt_in_Versus.22.aspx)

<sup>15</sup> *Effect of Opt-In vs Opt-Out Framing on Enrollment in a COVID-19 Surveillance Testing Program*. JAMA. (2021).  
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780574>

<sup>16</sup> *Medicare Beneficiaries Rarely Change Their Coverage During Open Enrollment*. KFF. (2022, November 1).  
<https://www.kff.org/medicare/issue-brief/medicare-beneficiaries-rarely-change-their-coverage-during-open-enrollment/>