

September 20, 2023

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director, Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Seshamani,

Thank you for the opportunity for our 61 organizations to provide feedback on CMS's implementation of the Medicare Prescription Payment Plan (MP3). Our organizations supported the passage of provisions to reduce and manage beneficiary out-of-pocket (OOP) costs for enrollees in the Medicare Part D program. We appreciate the opportunity to work with the agency to ensure that implementation allows the greatest number of beneficiaries possible to benefit from the ability to pay their prescription drug costs through monthly zero-interest payment installments.

The successful implementation of the MP3 is critical. For many beneficiaries, the new flexibility will be among the most directly "felt" impacts of the *Inflation Reduction Act*. If successfully implemented, cost smoothing – in conjunction with the new annual OOP cap – will protect beneficiaries from sizeable upfront costs while reducing the OOP burden of prescription drug costs. However, significant work remains to achieve this aim, which is made more complex given the opt-in enrollment dynamic of the program.

Our organizations appreciate CMS's continued engagement with the patient advocacy community on the MP3 and the agency's commitment to an iterative process; we collectively acknowledge and commit to working with the agency to ensure those lessons inform the implementation and education process moving forward.

In the draft guidance, the agency has proposed the implementation of beneficiary protections that are critical to ensure beneficiaries benefit rather than experience unintended harms. **We support CMS's proposed beneficiary protections and ask the agency to finalize these provisions** while providing additional operational detail, where beneficial. In this letter, we also offer feedback on implementation considerations for the MP3 program.

1. Stakeholder Education (Secs. 20; 60.1, 60.2.2)

The MP3 program offers the new flexibility for beneficiaries to pay their OOP costs for prescription drugs in payment installments. However, there are a number of complexities related to the program, including the need for beneficiaries to opt-in, changing monthly maximum costs, and

the need to continue payment for previously incurred costs. As a result, a range of educational efforts will be necessary to ensure smooth introduction and implementation of the MP3, as well as ease of enrollment and use by beneficiaries.

CMS has indicated that further information on education and outreach efforts are forthcoming. We make the following recommendations for your consideration in advance of Part II of this guidance expected in early 2024:

Utilize regular points of contact with beneficiaries

CMS outlines in the guidance the Part D plans will be required to include educational material about the MP3 during Open Enrollment and in promotional materials, as well as a process to notify individuals that are likely to benefit from the program prior to and during the plan year. In addition to these requirements, CMS should outline requirements for the inclusion of information (or, at a minimum, a phone number and web link) about the MP3 on regular plan documents including the evidence of coverage notice and explanation of benefits statements. Information about the MP3 should be included on a recurring basis in the annual notice of change, as maximum potential liability under the program will change in conjunction with increases in the annual Part D beneficiary OOP cap.

In addition to materials provided by plan sponsors, CMS beneficiary and provider-facing materials such as the Medicare & You handbook should contain education about the MP3. CMS may also evaluate whether including a phone number and website for beneficiaries to learn more about the MP3 on enrollee's physical Medicare or Part D plan cards will promote beneficiary awareness.

The role of pharmacies in providing education

Pharmacists and pharmacy technicians have a central role in education, as they are required by statute to provide beneficiaries that are "likely to benefit" notification about the MP3 program. We encourage CMS to evaluate both active prompts and passive educational materials for the MP3 at the point of sale.

We also ask CMS to encourage pharmacies, on a voluntary basis, to provide information about the MP3 in Medicare beneficiary communications, such as an automated call or email when a prescription is ready. These regular communications serve as a recurring avenue to raise awareness of the payment flexibility (i.e., you may be eligible to pay your drug costs through payment installments). Further, notifying a beneficiary about the need to opt-in to the program in advance of their arrival at the pharmacy will be essential if point of sale (POS) enrollment is not mandated to coincide with the introduction of the MP3 in 2025. In the absence of advance notification, beneficiaries that are likely to benefit from the MP3 may face decisions on whether

to pay the full OOP cost of the medication or, alternatively, return to retrieve their prescription after their opt-in request has been approved by their Part D plan.

In conjunction, CMS should review concerns that arose during the implementation of the Part D program, specifically that pharmacies reported a lack of information about the low-income subsidy calculations because neither the plans nor the government provided sufficient information.¹ In advance of pharmacists and pharmacies delivering notification of likely benefit and making available a point of sale mechanism, we urge CMS to ensure that pharmacists and staff are appropriately furnished information and educational materials. This will not only make the transition to providing patient education for MP3 easier for pharmacies, but aid in ensuring patients receive the materials they need to make an informed decision on opting-in to the MP3.

Engaging prescribers in education efforts

Prescribers also have an important role in educational efforts for the MP3. As a result of the Consolidated Appropriations Act of 2021,² Part D plan sponsors are required to offer real-time benefit tools to provide prescribers with information regarding a beneficiary's financial liability for a prescribed medication. This information is valuable as care providers have discussions with their patients about their care plan and affordability.

Similarly, information and education for providers around the MP3 should be prioritized. Prescribers, case managers, and nurse navigators should be included in educational efforts for the program with the goal that providers will include information about the MP3 in their dialogue with Medicare beneficiaries. In addition to conversational prompts, providers could include information about the MP3 for Medicare beneficiaries in standard materials such as visit summaries, and when applicable, physical prescription forms. The role of the prescriber in providing this information will be even more central to beneficiary's awareness of the MP3 if point of sale enrollment is not mandated in 2025, as individuals would need to opt-in prior to reaching the pharmacy counter.

2. Flexibility in First Month Versus Subsequent Monthly Caps (Sec. 30)

CMS issued a technical memorandum³ in July 2023 on the calculation of the maximum monthly caps under the MP3, with additional details on examples included in the August guidance. We appreciate CMS's efforts to provide a direct interpretation of the statute in the IRA regarding the first month versus the calculation for subsequent months; however, we encourage the agency to

¹ Robert Pear, States Intervene After Drug Plan Hits Snags, *The New York Times*, January 8, 2006.

² Consolidated Appropriations Act of 2021. Section 119. <https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf>

³ Centers for Medicare and Medicaid Services. Technical Memorandum on the Calculation of the Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans. 17 July 2023. <https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf>

explore additional flexibility within the statute to permit beneficiaries to spread out their incurred OOP costs as evenly as possible.

Consumers and beneficiaries are used to paying expenses over a fixed period, as in a mortgage, as well as having additional incurred costs added to a previously owed principal amount, as is typical with credit cards. However, the higher maximum monthly cap calculation for the first month is novel and outside the consumer experience for other owed expenses. This complexity may make it overly difficult for beneficiaries to understand the MP3 program and their potential monthly liability.

Additionally, the higher first month cap limits the value of MP3 for beneficiaries that incur a new, relatively large OOP cost later in the year. For example, a beneficiary may start the year taking two prescriptions, each with a monthly fill cost of \$5 that the individual pays for at the time of purchase. However, in October, the same beneficiary is newly diagnosed with a condition, requiring a 90-day course of treatment with a Part D drug with an OOP cost of \$700. Under the methodology discussed in the technical memorandum, if the individual opts into MP3 at the time of their October prescription fill (consisting of \$700 for the new prescription, plus \$10 for filling the existing prescriptions), they would owe \$636.67 the first month, with a balance of \$73.33 spread out over the remaining two months of the year along with any additionally incurred costs. Under the proposed first month methodology, this beneficiary would not greatly benefit from the MP3. However, if CMS provides the flexibility to spread out costs evenly over time (*which would result in the beneficiary's opt-in month cost being less than the first month maximum monthly cap outlined in statute, fulfilling the legal requirement*), the same beneficiary could instead pay \$236.67 in October and the remaining two months of the year (along with any additional incurred costs).

As alluded to in example 1 in the guidance, beneficiaries may circumvent the higher first month cap by opting in the month prior to an incurred expense, at which point their OOP costs can be spread out evenly for months after the opt-in month. However, this may create a misaligned incentive if a beneficiary is prescribed a new costly prescription; the individual may immediately opt-in to the MP3, but delay filling the script until the following month in order to have a lesser first-month liability.

These complexities are avoidable. **We ask CMS to instead exercise regulatory authority to allow beneficiaries the option to spread out their incurred costs evenly for the opt-in month in addition to the subsequent months.** This change will lessen the complexity of determining a beneficiary's monthly liability as well as broaden the number of beneficiaries that may benefit from the MP3.

3. Payment Mechanisms (Sec. 40)

CMS encourages plans to offer a variety of payment options to beneficiaries, including manual and automated electronic fund transfers (EFT) from a financial institution, such as a checking or savings account, as well as a credit or debit card. Offering the ability to pay via manual options, such as cash or check, are also encouraged.

To the extent possible, CMS should require plans to offer the proposed payment options. The EFT options will be broadly beneficial for beneficiaries and plans, as will the ability to minimize the risk of late payment via autopay options. Additionally, manual options of paying by cash and check are important for the Medicare population, as 25% of individuals aged 65 and older report a preference for paying bills via check.⁴ Further, while credit cards should be retained as a payment option, materials should indicate this method is a non-preferred option. The use of credit cards may result in interest expenses on medical debt, thereby undermining the value of the MP3 program.

We also support CMS's direction that no minimum amount be required in order to opt-in to the MP3, as it supports the diversity of beneficiary experience and ability to select additional payment flexibility.

In addition to the included information elements for billing statements noted in the guidance, we also encourage CMS to direct plans to include a payment schedule through the end of the year based on currently invoiced amounts. The inclusion of a schedule will clarify a beneficiary's continued financial liability, as well as assist with financial budgeting and planning. This schedule should be caveated with a note indicating that the payment schedule for future months will change if additional costs are incurred.

CMS should further explore allowing beneficiaries who have opted into the program to choose to pay for selected prescriptions at the point of sale. For example, an individual that takes one medication with a relatively high OOP cost may also take two maintenance medications with a monthly fill cost of \$5 per script. The beneficiary may prefer to pay for the lower cost medications at the point of sale, rather than on a delayed basis. The costs paid for at the POS may then be applied against the maximum monthly cap amount as the plan provides the monthly invoice for costs incurred via the MP3.

We also ask CMS to provide instruction in future guidance regarding the mid-year death of a beneficiary with respect to outstanding financial liabilities under the MP3.

⁴ Federal Reserve Bank of Atlanta. U.S. Consumers' Use of Personal Checks: Evidence from a Diary Survey. January 2021. <https://www.atlantafed.org/-/media/documents/banking/consumer-payments/research-data-reports/2020/02/13/us-consumers-use-of-personal-checks-evidence-from-a-diary-survey/rdr2001.pdf>

4. Notification of Likely Benefit (Sec. 60.2)

As part of the statutory requirements of the IRA, pharmacists are required to notify beneficiaries who are “likely to benefit” about the option to utilize the MP3. However, as CMS notes, the program may not be well-suited for all beneficiaries, especially beneficiaries that only require relatively low-cost, maintenance medications.

In the proposed guidance, CMS presents the findings of a claims analysis that compares the OOP cost of a fill and the associated number of beneficiaries that are likely to benefit from enrolling in the MP3. In the table, the minimum dollar value shown is \$400, where an estimated 91% of 2.2 million beneficiaries notified would benefit. The next dollar value shown, \$500, would result in 95% of 1.1 million beneficiaries notified benefitting from enrolling in the MP3, according to CMS’s definition.

It would have been beneficial to see CMS’s analysis performed at the \$300 and/or \$350 level, as the table shown by CMS makes a clear case that the trigger for the notification should be set no higher than \$400. When the notification amount is set at \$500, by CMS’s own analysis, one million beneficiaries that would otherwise have benefited from the MP3 would not be notified. In our view, this outcome would be unacceptable.

We note that the analysis performed considers Part D costs only. Beneficiaries may have other Medicare expenses that disproportionately occur early in the year, such as deductible payments for Medicare Parts A and B.⁵ As a result, it may be advantageous for beneficiaries in some situations to backload their drug costs. Examples like the above show that CMS should err on the side of notifying more, rather than fewer, beneficiaries they are likely to benefit from the MP3. **As a result, we ask CMS to set the amount triggering notification of likely benefit at \$400 or lower. This amount should also be based on the total OOP of prescription drugs filled in a single day.** More than half of adults aged 64 and older report taking four or more prescription drugs,⁶ and the cumulative amount OOP they pay for prescription drugs is more likely to indicate benefit than their cost for a single drug.

5. Point of Sale Enrollment (Sec. 60.2.3)

Point of sale (POS) enrollment would allow beneficiaries to opt-in to the MP3 at the point they determine payment installments would help them pay for their medications. As such, **it is vital that POS enrollment be made available concurrently with the introduction of the MP3 in 2025, rather than waiting until 2026 or later.**

⁵ Medicare.gov. Costs. Accessed 11 September 2023. <https://www.medicare.gov/basics/costs/medicare-costs>

⁶ Kaiser Family Foundation. Data Note: Prescription Drugs and Older Adults. 9 Aug 2019. <https://www.kff.org/health-reform/issue-brief/data-note-prescription-drugs-and-older-adults/>

The draft guidance asks for feedback on three avenues for beneficiaries to opt-in via near real-time options: telephonic, via phone app, or through a new “opt-in” indicator on the pharmacy’s claims submission. CMS suggests that in the initial year of availability, these options would be mutually exclusive though additional options may be added in the future.

We recommend that CMS utilize a claims-based opt-in for implementation since both the telephonic and app-only approaches create potential barriers for patients. Telephonic and app-based approaches in isolation may create access restrictions for beneficiaries in areas with limited or sporadic phone reception. Specific to the telephonic option, surveys indicate that a significant percentage – 40% in a one recent study performed in the United Kingdom⁷ – of members of the “baby boomer” generation report anxiety related to talking on the telephone. Meanwhile, smartphone use is not universal among older adults. A recent AARP survey showed that 81% of individuals 60 to 69 and 62% of those 70 and older use smartphones,⁸ numbers which have been validated by other studies.⁹ Due to these access barriers, it is not appropriate to rely solely on either of these options for opting into the MP3.

In comparison, a claims-based approach would place minimal burden on the beneficiary. Ultimately, beneficiary ease of use should be the top-tier consideration, as the goal of the MP3 is to improve the ability of beneficiaries to afford their medications, thereby reducing incidence of prescription abandonment and increased risk of adverse outcomes. Such a process would also eliminate potential complexities related to “Urgent MP3 Election” outlined in Sec. 70.8.3 of the proposed guidance.

The claims-based approach is also likely to have fewer pharmacist workflow and practical shortcomings than the other proposed options. For example, pharmacy staff will be required to provide a baseline level of information about the MP3 as part of notifying the beneficiary that they are likely to benefit from the program. At that point, a claims-based approach would permit pharmacy staff to directly indicate a beneficiary would like to enroll, rather than requiring a beneficiary to get out of line and wait to the side to engage in a telephonic or app-based enrollment. Further, since beneficiaries that opt-in to the MP3 have no liability at the point of sale, no additional burden exists for pharmacy staff in terms of calculating a beneficiary’s liability.

We thank CMS for conceptualizing three options that are relatively straightforward to implement; as a result, there is no substantive reason to delay the implementation of POS enrollment to 2026 or beyond. It is important for beneficiaries to be able to opt-in to the MP3 when they need to do

⁷ Russell, Helen. Phone Call Anxiety: Simple Ways to Overcome Your Telephobia, According to Psychology. BBC Science Focus. 17 May 2023. <https://www.sciencefocus.com/the-human-body/telephobia>

⁸ Kakulla, Brittne Nelson. Older Adults Keep Pace on Tech Usage. January 2020.

<https://www.aarp.org/research/topics/technology/info-2019/2020-technology-trends-older-americans.html>

⁹ Faverio, Michelle. Share of those 65 and older who are tech users has grown in the past decade. Pew Research Center. 13 January 2022. <https://www.pewresearch.org/short-reads/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade/>

so; for beneficiaries incurring a new, relatively large OOP expense and completing their first fill, this is likely to occur at the pharmacy counter or via a mail-order service. Delaying implementation until a future year will limit the ability of beneficiaries to utilize this important option, create confusion as enrollment processes change between one year and the next, or enable or further delays in implementation that will limit the impact of the MP3 for beneficiaries. **Based on these factors, we recommend that CMS direct plans and pharmacies offer point of sale enrollment through a claims-based approach starting in 2025.** To provide maximum time for implementation, we encourage CMS to issue direction on POS enrollment prior to the issuance of Part II of this guidance through the annual Medicare Advantage rate notice or other appropriate avenues.

6. Enrollee Election and Programmatic Interactions (Sec. 70)

We laud CMS for acknowledging the importance of encouraging eligible Medicare Part D beneficiaries to apply for the Low-Income Subsidy (LIS) program. As noted, the LIS program is more advantageous than MP3 for eligible beneficiaries in that the LIS provides \$0 premiums and low-cost, fixed copayments for covered prescription drugs. It is essential that Part D sponsors inform those interested in opting into MP3 of their potential eligibility for the LIS program and how to apply. By CMS' own estimates,¹⁰ up to three million seniors and people with disabilities could benefit from LIS program but are not currently enrolled. We also support CMS' direction to Part D plan sponsors to reimburse the individual for any excess premium or OOP cost sharing when an MP3 participant is retroactively enrolled in LIS.

7. Beneficiary Protections During Termination of Election, Reinstatement, and Preclusion Processes (Sec. 80)

Our organizations thank CMS for the proposal to include key beneficiary protections in the MP3 program. The statutory language for the MP3 permits beneficiaries to be disqualified from using the payment installment flexibility in the case of a missed payment. However, a beneficiary may be late on a payment for valid reasons, including administrative error by a health plan, a hospitalization or other health event that makes the beneficiary unable to pay on time, or travel or seasonal relocation that delays receipt of an invoice.

CMS's proposals are responsive to these scenarios and provide easily-understandable protections for beneficiaries, based on precedent in the Part D program found in 45 CFR§ 423.44.¹¹ Our organizations support the creation of the proposed two-month grace period after the deadline for a payment balance has passed, the ability to switch between plans without carryover MP3

¹⁰ U.S. Department of Health and Human Services. FACT SHEET: Biden-Harris Administration Announces New Tools to Lower Prescription Drug Costs for Low-Income Seniors and People with Disabilities. 12 June 2023. <https://www.hhs.gov/about/news/2023/06/12/fact-sheet-biden-harris-administration-announces-new-tools-lower-prescription-drug-costs-low-income-seniors-people-disabilities.html>

¹¹ Code of Federal Regulations. 45 CFR§ 423.44. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423>

eligibility ramifications, and the ability for a disqualified beneficiary to have their eligibility for the MP3 reinstated by their Part D plan once overdue balances have been paid. We ask CMS to finalize these provisions in future guidance. We also ask CMS to establish a standard initial due date (such as 30 or 45 days) following issuance of a bill to beneficiaries participating in the MP3.

We support CMS’s proposal for plans to use existing Part D appeals procedures regarding election, billing, and termination-related disputes. However, given that beneficiary disputes around the MP3 may materially impact beneficiaries’ ability to pay for prescribed medications – and thus, have impacts on their health – we ask CMS to set forth definitions for “timely” review and adjudication. We also encourage the agency to consider the creation of a process measure in the Star Rating system associated with timely adjudication of beneficiary appeals. Other appeals processes (e.g., the independent dispute resolution process put in place by the No Surprises Act)¹² have faltered due to sheer volume and potential misuse; a process measure would incentivize plans to process appeals in a given timeframe.

Conclusion

We thank CMS for their responsiveness and engagement with beneficiaries on the implementation of the MP3, including through the issuance of this Part I guidance well in advance of the program’s January 1, 2025, start date. Our organizations stand ready to continue working with CMS to help ensure have consumer-friendly information needed to make informed decisions about opting into the MP3.

To discuss these recommendations in additional detail, please contact Michael Ward, the Alliance for Aging Research’s Vice President of Public Policy and Government Relations, at mward@agingresearch.org.

Sincerely,

American Academy of Allergy, Asthma & Immunology (AAAAI)
ADAP Advocacy
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
Alpha-1 Foundation
Alström Syndrome International
American Association on Health and Disability
Arthritis Foundation
Asthma and Allergy Foundation of America

Lupus Foundation of America
MET Crusaders
Miles for Migraine
Movement Disorders Policy Coalition
National Association of Nutrition and Aging Services Programs (NANASP)
National Council on Aging
National Fabry Disease Foundation
National Headache Foundation
National Health Council
National Menopause Foundation

¹² Ernst & Young. No Surprises Act: What Payers Need to Know. 26 June 2023. https://www.ey.com/en_us/health/payers-and-the-no-surprises-act

Autistic People of Color Fund
Biomarker Collaborative
Cancer Support Community
CancerCare
CaringKind, The Heart of Alzheimer's Caregiving
CLI Society
Community Access National Network
Davis Phinney Foundation for Parkinson's
Derma Care Access Network
Exon 20 Group
Genetic Alliance
Global Liver Institute
Haystack Project
HD Reach
Headache and Migraine Policy Forum
HealthyWomen
Heart Valve Voice - US
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Inflammatory Breast Cancer Research
Foundation
Lakeshore Foundation
Lupus and Allied Diseases Association, Inc.

National Organization for Rare Disorders
National Organization for Tardive Dyskinesia
Neuropathy Action Foundation
Noah Homes, Inc
Organic Acidemia Association
Partnership to Advance Cardiovascular Health
Partnership to Fight Chronic Disease
Patient Access Network (PAN) Foundation
Patients For Affordable Drugs Now
PD-L1 Amplifieds
PXE International
RASopathies Network
StopAfib.org
SYNGAP1 Foundation
The AIDS Institute
The Bonnell Foundation: living with cystic
fibrosis
The Michael J. Fox Foundation for Parkinson's
Research
Triage Cancer
TSC Alliance
U.S. Pain Foundation