March 1, 2024

Dr. Meena Seshamani
Director, Center for Medicare
Deputy Administrator, Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies

Dear Dr. Seshamani,

Thank you for the opportunity to provide feedback on the Medicare Advantage (MA) Advanced Notice and accompanying Part D Redesign Program Instructions (Instructions). Our organizations enthusiastically support the provisions to reduce and manage beneficiary out-of-pocket (OOP) costs in the Medicare Part D program, and we appreciate our ongoing engagement with CMS to ensure that implementation allows the greatest number of beneficiaries to access and afford their prescription medications. Our comments below focus on the Instructions.

Guardrails to Prevent Utilization Management Abuse

In the press release accompanying the release of the MA Advance Notice, HHS Secretary Xavier Becerra notes that, "The Biden-Harris Administration is committed to making sure the millions of people who have managed care plans called Medicare Advantage get the best care possible, and that taxpayer dollars are used efficiently." However, our organizations are concerned that unintended consequences likely to occur as a result of the Medicare Part D redesign included in the Inflation Reduction Act (IRA) will harm beneficiary access.

The Part D redesign escalates insurers' responsibility from fifteen percent of costs in the catastrophic phase of the benefit in 2023 to sixty percent in 2025 (45 percent total increase). On top of that, the IRA limits premium growth to six percent each year through 2029. As a result, payers have limited levers in the near term to shift costs.

While Medicare beneficiaries have typically experienced fewer utilization management (UM) barriers in comparison to commercial plans, observers widely expect this to change as payers experience greater financial responsibility. Plans will find ways to compensate for these increasing costs by controlling expenses more closely, including through the potential use of utilization management (UM) techniques such as more restrictive formularies, step therapy requirements, and prior authorization processes. As a result, beneficiaries face a growing risk of potential treatment delays or loss of coverage altogether.

Additionally, if plans narrow access to certain medicines due to these dynamics, patients who are stable on a given medication may lose access and be forced to switch to an alternative medicine that is not optimal for their unique circumstances. This is because CMS allows Part D plans to switch a beneficiary's medication—sometimes called 'non-medical switching' since

the practice excludes the beneficiary's healthcare provider or is performed for reasons other than efficacy, side effects, or adherence[1]—in order to save costs.

While this series of events is extremely likely absent intervention given the underlying dynamics, so far, the Agency has indicated that it will only go so far as to "monitor" the situation. This is not a strong enough stance, as UM abuse puts patients at risk of delayed care and life-threatening adverse outcomes. Such impacts will hit Medicare beneficiaries in underserved rural communities and communities of color the hardest, despite CMS' strategic pillar commitment to health equity.

Given these considerations, it is crucial that CMS adopt a proactive approach that safeguards patient access from abusive UM tactics that are driven by plan sponsors' financial considerations rather than best practices that support the health of beneficiaries. If CMS opts for its current reactive stance—rather than placing guardrails that create clear expectations around when the use of UM is and is not appropriate—the agency is unlikely to prevent patient harm before it occurs. Instead, we encourage CMS to adopt the following:

Clear Guidelines and Standards for Appropriateness of Utilization Management

CMS must establish clear and comprehensive guidelines and standards for UM techniques used by MA and Part D plans. These guidelines should require that UM practices align with evidence-based medicine and clinical guidelines. They should also prevent the transfer of these costs to beneficiaries in the form of delayed care or reduced access, which aligns with the Congressional intent behind these provisions: improved patient access and lower patient costs. Current formulary minimum standards must also be preserved.

Further, CMS must better evaluate how MA plans are using artificial intelligence (AI) and algorithms to deny claims. It is currently unclear how CMS is monitoring and evaluating MA plans' use of such tools.[2] Our organizations encourage CMS to adopt the transparency actions recommended to CMS by House Democrats in November 2023.[3] These measures would compel MA plans to provide explanations of denials, including details about a patient's condition and the timeline of the denial itself. They would also evaluate the frequency of denials, assess the role of AI and algorithms in the denial process, examine if algorithms are self-adjusting (taking into account reversals of denials on appeal), and investigate if plans are improperly using race or other factors in algorithms.

CMS should also scrutinize the formulary design for CY 2025 to identify any potential shortcomings or disparities that may arise from IRA implementation. By conducting thorough

[1] Dolinar, Richard, et al. *The Non-Medical Switching of Prescription Medications.* Postgraduate Medicine. 29 May 2019. https://doi.org/10.1080/00325481.2019.1618195

[2] Tong, Noah. "Amid concerns about claims denials, Democrats seek greater oversight of Medicare Advantage plans' use of AI." 3 Nov 2023. https://www.fiercehealthcare.com/payers/noticing-prior-authorization-surge-democrats-demand-better-ai-oversight

[3] Chu, J., et al. "Letter to The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services." 3 Nov 2023. Retrieved from: https://chu.house.gov/sites/evo-subsites/chu.house.gov/files/evo-media-document/chu-nadler-ma-ai-oversight-letter-11.3.2023.pdf

evaluations of formulary designs, CMS can identify areas for improvement and take proactive steps to address any concerns related to access, affordability, or quality of care for Medicare beneficiaries.

Enhanced Transparency and Disclosure Requirements

It is imperative that CMS mandate increased transparency from MA and Part D plans regarding their UM practices. Annual disclosure of all new and ongoing UM techniques for every covered prescription medication should be made openly available by plans at the time of enrollment and throughout the coverage period on the MA Plan Finder platform, This should be done comprehensively and in a way that is easily understood by beneficiaries to ensure they are able to select the insurance plan that best matches their individual care needs and circumstances. This would increase competition between plans at the time of enrollment and incentivize plans to avoid abusive UM practices that would harm patients.

Increased Education and Outreach Regarding UM and Appeals Processes

CMS should prioritize education and outreach efforts to inform beneficiaries, healthcare providers, and stakeholders about abusive UM techniques and potential implications for patient access to care and negative health outcomes. Providing resources, guidance, and training materials can help empower beneficiaries to navigate UM requirements and advocate for their healthcare needs effectively. Additionally, it should be made easy for beneficiaries to access and understand what tools are available to them, including appeals processes for both beneficiaries and their providers and an expedited timeline for appeals in emergency situations.

PDP Meaningful Difference

Our organizations are concerned about CMS' proposed approach to evaluating meaningful differences among prescription drug plans (PDPs). CMS proposes using an "absolute percent" threshold method for conducting annual evaluations of meaningful differences, which will exclude consideration of differences in the use of UM. CMS notes that it will be too difficult to evaluate the impact of UM on all enrollees in PDPs. Even prior to the incentives that will exist for plans as a result of Part D redesign, the Part D market has seen a reduction in the overall number of covered Part D drugs in recent years. Since 2020, there has been a six percent decrease in the average number of branded medications covered by Part D plans.[4]

By using a metric that excludes UM, it will be very possible for two plans to score the same but lead to very different levels of access for beneficiaries. This lack of precision may also make it difficult to differentiate between standard and enhanced plans. To advance evaluations of meaningful difference, CMS should compare utilization patterns among different demographic groups, geographical regions, and health conditions to identify disparities or areas of inappropriate UM, as well as track UM trends pre- and post-IRA.

[4] Cencora analysis of Part D formularies from 2020 to 2024.

CMS's assertion that adding drugs with low utilization to formularies does not enhance benefits is also false and reflects a narrow view of the diverse needs of patients. For patients with rare or orphan diseases, formulary breadth can be of the utmost importance. This section also focuses exclusively on plans that add additional drugs to formularies without acknowledging the growing number of medications being excluded from formularies. It is alarming that CMS fails to recognize the impact of these exclusions on patient care and well-being. CMS must consider UM and other metrics such as beneficiary access, satisfaction, and convenience measures, to assess meaningful difference.

RxHCC Risk Adjustment Model

Our organizations support efforts to recalibrate the RxHCC model, which is used to predict expenditures for which Part D sponsors are responsible, using the most recent available data. Health system care and usage patterns have dramatically changed as a result of the COVID-19 pandemic. Patient behaviors, provider behaviors, and treatment modalities have all been impacted, with significant implications for risk adjustment models. We understand the need for longitudinal data for effective risk adjustment decisions but urge CMS to prioritize data accrued since the pandemic's onset, either by omitting pre-pandemic data entirely or by assigning greater weight to more recent data. By doing so, CMS can better capture the evolving landscape of healthcare delivery and ensure that risk adjustment methods align more fully with the current landscape of the healthcare system.

Implementation of the Medicare Prescription Payment Plan

As we have previously commented, the successful implementation of the Medicare Prescription Payment Plan (MP3) is critical as the new flexibility will likely be one of the most tangible impacts of the IRA felt by beneficiaries with significant out-of-pocket costs. As such, we would like to take this opportunity to reiterate our overall recommendations here and will provide additional feedback to the agency in response to the Part II guidance for the MP3.

- We are aware that CMS' Office of Communications is working on developing education materials that will be used in annual enrollment resources and in other communications MA-PDs and PDPs. CMS leadership should also create standardized communications materials targeted at pharmacists, providers and nurses, and claims professionals. Materials should be comprehensive and developed with opportunities for input from stakeholders who will utilize them to discuss MP3 with beneficiaries. Materials developed for providers and claims professionals should include complex examples to account for the more likely scenarios Medicare beneficiaries will face with respect to MP3 and these scenarios should be tailored for the various audiences interacting with the program (i.e., patient scenarios can be straightforward to illustrate program intent but more complex examples should be included for pharmacists, payors, and providers). CMS should work with stakeholder groups, including patient advocates, to capture and develop scenario examples.

- Although implementation is complex, CMS should continue to work towards implementing opt-in to MP3 at the point of sale or at the pharmacy counter, as stated

in the IRA (Section 11202(a)(1)(B)). Furthermore, the opt-in for MP3 should be available year-round, as reflected in the IRA. While point of sale opt-in was unfortunately not included in the proposed Part I guidance, we continue to strongly encourage CMS to incorporate it into the MP3 program. We also encourage CMS to continue exploring the possibility of requiring plans to pre-populate their unique MP3 BIN/PCN as part of every enrollee's prescription drug card. This would allow pharmacies to have this information readily available if, and when, an enrollee elects to opt-in to the MP3 at the POS. The enrollee could be "pre-activated" but would not be considered enrolled in the MP3 until a pharmacy submits a coordination of benefits claim to the specific MP3 BIN/PCN. Importantly, the point of sale is also a critical opportunity for education on MP3 for those most likely to benefit from opting into the program.

- CMS should ensure that resources (monetary and otherwise) for education, enrollment, and program implementation are continually available and replenished for MP3, as a one-time investment will not be enough to sustain the program long-term.

- In our ongoing conversations with CMS, we are encouraged to hear CMS state that "implementation of the MP3 program is an iterative process" and that changes will be made in subsequent years based on experience and knowledge gained in previous years. To that end, we urge CMS to keep seeking out additional stakeholders to bring to the conversation to provide a comprehensive picture of how MP3 functions in practice.

- Specific to the MA Advance Notice and discussion of plan quality measures, we encourage CMS and the agency's partners in quality measure development to evaluate the inclusion of beneficiary awareness of the annual out of pocket limited and the MP3 into current and future measures focused on member experience with Part D plans.

Thank you again for the opportunity to comment on the implementation of the IRA's Medicare Part D redesign provisions. We look forward to continuing to partner with CMS to ensure that beneficiaries can easily access and benefit from these essential policy reforms. If CMS has questions about these recommendations or to discuss further, please contact Michael Ward, Vice President of Public Policy and Government Relations at the Alliance for Aging Research, at mward@agingresearch.org.

Sincerely,

ACMCRN Arachnoiditis and Chronic Meningitis Collaborative Research Network
ADAP Advocacy
Aging Life Care Association®
AiArthritis
Alliance for Aging Research
Alliance for Patient Access
ALS Association

American Association on Health and Disability
AnCan Foundation
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Autoimmune Association
California Chronic Care Coalition
Cancer Support Community
CancerCare
Caregiver Action Network
Chronic Care Policy Alliance
Chronic Disease Coalition
CLL Society
Community Access National Network
FORCE: Facing Our Risk of Cancer Empowered
Global Coalition on Aging Alliance for Health Innovation
HealthyWomen
Healthy Men Inc.
Heart Valve Voice - US
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
International Myeloma Foundation
Lakeshore Foundation
Let My Doctors Decide Action Network
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
National Association For Continence
National Fabry Disease Foundation
National Psoriasis Foundation
Organic Acidemia Association
Partnership to Fight Chronic Disease
Patient Access Network (PAN) Foundation
Spondylitis Association of America
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