

June 5, 2023

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

Dear Dr. Seshamani,

Thank you for the opportunity to provide feedback on the upcoming implementation of the *Inflation Reduction Act's* (IRA) provisions related to Medicare Part D redesign. Our organizations supported the passage of IRA provisions that created the Part D annual \$2,000 out-of-pocket (OOP) cap and the beneficiary option to "smooth" out OOP prescription drug costs over the plan year. These policies will help address financial barriers to access that can result in the abandonment of prescribed medications vital to individuals' health and wellness.

The successful implementation of these two provisions is critical. For many beneficiaries, cap and smoothing will be among the most directly "felt" impacts of the IRA. Ensuring the development of consumer-friendly processes and effectively communicating how beneficiaries will interact with these provisions should be one of CMS's top priorities. The opt-in enrollment dynamic of smoothing increases the difficulty and the essential need for day one operational readiness.

Simultaneously, CMS will implement a broader redesign of the Part D benefit, including eliminating beneficiary coinsurance and reallocating financial liability in the catastrophic phase. While these changes will result in savings for the Medicare program, participating prescription drug plans will likely expand utilization management (UM) efforts to limit the impact of increased cost exposure. While UM can help ensure cost-effective care in some cases, deference to patient well-being and direct practitioners' expertise and knowledge of each beneficiary's unique medical needs is necessary. CMS must put in place protections to ensure that UM is used only in situations where it is clinically appropriate, does not create undue delays or changes in care that may harm patient outcomes, and that UM requirements do not reset when switching insurance providers. Further, CMS should clarify coverage requirements outlined in its March 15, 2023, guidance for drugs and biologics subject to negotiation.

Implementation of the Annual Out-of-Pocket Cap and Cost "Smoothing" Flexibilities

The patient community is deeply invested in the implementation of the OOP cap and cost smoothing provisions. It is vital to ensure these policies operate as intended, that is, to reduce financial hardship and enable greater treatment adherence. If successfully implemented, cost

smoothing and the OOP cap will protect beneficiaries from sizeable upfront costs at the beginning of each plan year and reduce the burden of medical payments. However, CMS must proactively address complexities related to implementation and stakeholder education to achieve this aim.

Congress did not define specific patient protections in association with the cost smoothing provision; however, the statute does expressly enable Medicare Prescription Drug Plans (PDP) and Medicare Advantage Prescription Drug Plans (MA-PD) to disqualify beneficiaries from future use of smoothing due to nonpayment. However, plans should not be tasked with defining the criteria for disqualification. Further, standards should be consistent across PDP and MA-PD plans.

Our organizations ask CMS to include the following patient protections in the cost smoothing guidance that are consistent with, or build upon, provisions already present in regulations for the Part D program in 45 CFR§ 423.44:¹

- **Consistent guidelines and criteria for beneficiary disqualification, as well as defined categories or specific instances that merit permanent exclusion from the use of cost smoothing.**
- **Requirements for plans to develop a beneficiary appeals process related to disqualification from payment smoothing.** Such a process should be transparent and allow for beneficiary relief in cases where payments are missed due to proven financial hardship or inability to pay for other reasons – including a family or medical emergency, billing disputes, or clerical/mailing errors.
- **Require a minimum grace period for late payments, analogous to the grace period for Medicare premium nonpayment;**
- **Finally, CMS should refrain from requiring beneficiaries to exceed a minimum OOP threshold amount (or specify only a de minimis amount) to trigger the enrollee’s eligibility or notice of likely benefit from election of smoothing.**

Education will be vital to ensure awareness of the phased implementation of the annual cap and equitable access to and uptake of the smoothing flexibility. CMS should work with a broad base of stakeholders to create standardized beneficiary and provider-facing educational resources that clearly explain the smoothing benefit, enrollment process, and payment expectations. While physicians and nurses were not directly referenced in the smoothing statute, they also have an important role in raising awareness of the benefit. The recent implementation of Medicare requirements related to real-time benefit tools (RTBTs) allows prescribers to have a line of sight into beneficiaries’ OOP costs when prescribing. With multiple audiences, educational materials should elucidate the roles and responsibilities of respective stakeholders. Information should also be available via multiple forums. For beneficiaries, CMS and participating plans should

¹ Code of Federal Regulations. 45 CFR§ 423.44. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423>

provide details on smoothing through avenues such as annual enrollment materials, the Medicare & You handbook, explanation of benefits documents, electronic portals, and the PDP and MA-PD plan card.

Clear and consistent terminology is necessary for beneficiary-facing communications on smoothing. For example, the term smoothing and the statutory language of a maximum monthly cap are not consumer-friendly. Therefore, **CMS should work with stakeholders to develop improved verbiage to refer to smoothing and then require standardized terminology across communications from CMS, payers, and providers.**

We acknowledge the technical complexities facing insurers and providers as they implement the cost smoothing flexibility. However, it is clear in the statute that beneficiaries shall be able to opt in throughout the plan year and receive notification at the point of sale if they are likely to benefit from opting in to smoothing.² In order for smoothing to operate as intended and for this notification to be meaningful in combating medication abandonment, beneficiaries must be able to decide to activate the flexibility at the time they are facing substantial costs for Part D-covered items. In discussions with stakeholders, concerns around the pharmacists' ability to provide education in a time-effective manner at the point of sale, especially given demands and the current lack of a billing code for the time associated with education, have been raised as a concern. Similarly, ensuring consistent technical standards and informational exchange capability to provide real-time information on smoothing liability at the point-of-sale are paramount.

To develop recommendations around these potential barriers, **we recommend that CMS convene expert groups – including patient advocacy leaders – to provide feedback to the agency at each stage of proposed regulation development and to issue additional Information Collection Requests as needed through widely-available distribution channels.** Alternatively, patient advocacy leaders stand ready to convene multistakeholder efforts and coordinate with CMS to ensure that the most relevant topics around implementation are addressed throughout and following initial implementation.

CMS should also encourage various payment options via beneficiary election, including automated deduction from Social Security checks or through automated clearing house transfer. These options will help ensure regular payment; however, some beneficiaries may prefer standard notification and cash/check payment options that CMS should preserve.

Implementation will be a complex task requiring thoughtful discourse and a commitment of resources. CMS should monitor implementation, have clear indicators of success, and remain flexible to correct any problems that might arise. Implementation timelines are brief given

² Inflation Reduction Act of 2022 (Sec. 11202(a)(1)(B))s

technical, operational, and educational needs. Close collaboration between stakeholders can facilitate the rate of implementation and aid in developing consensus-driven input to CMS.

Intersection of Part D Redesign and Utilization Management

As a result of the changes that the IRA made to the Part D benefit, insurers' liability will increase from 15 percent of costs during the catastrophic phase in 2023 up to sixty percent in 2025.³ Payers will find ways to compensate for these increasing costs by more closely managing expenses, including through the use of UM techniques such as step therapy.

While UM is an important tool, it can have significant implications for patient access to care and, in extreme cases, can lead to worse patient outcomes. To prevent potential harm, **CMS should prevent plans from implementing UM practices that run counter to consensus clinical guidelines or lack clear and enforceable guidelines for appeals processes.** CMS must measure and monitor how the expansion of UM techniques impacts beneficiaries and be prepared to quickly utilize regulatory flexibilities to remedy potential harms related to restricted access.

In CMS's March 2023 proposed guidance for implementing the IRA's price negotiation provisions, CMS outlined principles for establishing a "maximum fair price" (MFP) for prescription drugs subject to price negotiation. In the guidance, CMS noted that drugs subject to negotiation must be included on plan formularies but did not provide additional information on whether plans can apply UM to these drugs. However, CMS and Part D plan providers will, by statutory definition, pay a "fair price" for the clinical benefit conferred by negotiated drugs and the use of additional UM may result in unintended consequences for beneficiaries.

For example, while the establishment of the MFP will lower list prices for selected drugs, counterintuitive market incentives may be created because of the rebate system. In establishing prescription drug formularies and products' placement within tiers on those formularies, pharmacy benefit managers (PBMs) and insurers often receive rebates based on a drug's list price.⁴ In 2021, rebates, discounts, and other payments made by manufacturers of prescription drugs to PBMs reached \$236 billion.⁵ A portion of these rebates are retained by PBMs and payers, which can create incentives to give favorable tier placement on formularies for drugs offering greater rebates.

³ Kaiser Family Foundation. Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit. 20 Apr 2023. <https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/#:~:text=Part%20D%20plans%20and%20drug%20manufacturers%20will%20pay%20a%20larger,generic%20drugs%20beginning%20in%202025.>

⁴ Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy (Chapter 13). 15 Mar 2021. https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch13_sec.pdf

⁵ Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers. March 2022

Drugs selected for negotiation and subject to the MFP will in some cases have less ability to offer sizeable rebates, which may result in the placement of these drugs on a less preferred tier. At the same time, drugs not subject to MFP and thus with potentially higher list prices may continue to offer greater rebates and receive preferred tier placement. If this does occur, several undesirable effects could occur, including the realization of fewer savings than projected related to the negotiation program, greater cost sharing for beneficiaries if drugs selected for negotiation are placed on a non-preferred tier, and potential year-over-year medication changes related to formulary placement rather than medical need.

We encourage CMS to clarify and expand upon the March 2023 guidance by:

- **Evaluating whether the use of UM is appropriate for drugs selected for negotiation, and**
- **Mitigating potentially misaligned market incentives that may undermine the IRA's statutory intent.**

Conclusion

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,

ADAP Advocacy Association
Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association of Kidney Patients
American Cancer Society Cancer Action Network
American Kidney Fund
Autistic People of Color Fund
Autistic People of Color Fund
Autistic Women & Nonbinary Network
Autoimmune Association
Cancer Support Community
CancerCare
CLL Society

JDRF
LUNGeivity Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
National Health Council
National Organization for Rare Disorders
National Psoriasis Foundation
Neuropathy Action Foundation
Noah Homes
Organic Acidemia Association
Partnership to Advance Cardiovascular Health
Partnership to Fight Chronic Disease
PlusInc
RASopathies Network
Red Hot Mamas North America Inc

Coalition of Wisconsin Aging and Health
Groups
Community Access National Network
Derma Care Access Network
Global Healthy Living Foundation
Global Liver Institute
Hawai'i Parkinson Association
Haystack Project
Headache & Migraine Policy Forum
HealthyWomen
ICAN, International Cancer Advocacy Network
International Pemphigus Pemphigoid
Foundation

RetireSafe
Second Wind Dreams
StopAfib.org, American Foundation for
Women's Health
The Asthma and Allergy Foundation of
America
The Headache and Migraine Policy Forum
The Mended Hearts, Inc.
Triage Cancer
TSC Alliance
U.S. Pain Foundation