



Stakeholder Roundtable

# IMPLEMENTING MEDICARE PART D AFFORDABILITY REFORMS



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### Overview

Millions of seniors and people with disabilities across the United States depend on Medicare Part D to help cover the cost of their prescription medications to manage serious, life-threatening, disabling, and chronic conditions. Yet growing out-of-pocket (OOP) drug costs have led to 23 million Americans reporting an inability to pay for a prescription within the past year<sup>1</sup>.

Congress addressed many of these affordability issues with the inclusion of several provisions in the Inflation Reduction Act (IRA), including impactful changes to the Medicare Part D program. Key among those changes are: 1) a cost “smoothing” mechanism that allows beneficiaries to pay their OOP drug costs via zero-interest monthly payment installments within the course of a calendar year, scheduled to be implemented in 2025, and 2) capping annual OOP drug costs at \$2,000, also commencing in 2025.

These provisions are intended to have a profoundly positive impact on the health and well-being of millions of people, and on the country’s healthcare system overall. However, they also have the potential to create new market dynamics and disruption. The ultimate success of these essential beneficiary affordability provisions depends largely upon the implementation of the law and development of patient protections.

On May 2, 2023, the Alliance for Aging Research and the National Health Council convened a roundtable discussion – attended by organizations representing insurers, pharmacies, pharmaceutical companies, and patient advocacy groups, among others – to discuss the implementation of these affordability reforms and their impact on stakeholders in the healthcare ecosystem.

The goal of the roundtable was to identify barriers to and potential unintended consequences of implementation, and explore ways to advance patient protections, patient awareness, and patient education. Participants also sought to develop consensus principles that emerged from the discussion.

*Following is a summary of highlights, discussion points, and key takeaways from the event.*

<sup>1</sup>Project LOOP, How Congress Can Ensure Affordability for Patients in Medicare Part D

## IMPLEMENTATION RECOMMENDATIONS

The stakeholders participating in the roundtable reached general agreement on the following areas for CMS to consider as the implementation process moves forward:



**CMS should work with the community to develop a better way to refer to the smoothing flexibility.**

An explanatory term that beneficiaries can understand should be established by CMS and universally adopted by plans and other stakeholders to minimize confusion.



**CMS leadership should create standardized communications materials for insurance plans, pharmacies, pharmacists, and other providers.**

Materials should be developed with opportunities for input from multiple stakeholder types. Information about the option to smooth costs should be available at multiple points so that beneficiaries are aware of and understand their ability to opt-in to the smoothing option.



**The ability of beneficiaries to opt-in to smoothing at the point-of-sale and/or at the pharmacy is included in the IRA (Sec. 11202(a)(1)(B)). However, implementation is incredibly complex and challenging.**

Further conversation among stakeholders and with CMS is warranted to determine if accommodations may be necessary during the initial years of the program.



**Resources – monetary and otherwise – must be made available to support implementation.**

Allocation should also include providers who will have additional educational responsibilities and are crucial to success.



**CMS should monitor implementation actively and intentionally, both to gauge successes and to identify problems.**



**Representation from additional stakeholders would bring value to additional conversations.**

Perspectives from physicians, nurses, care navigators, employers, retiree benefit plans, brokers, and others may help identify additional considerations.



**Utilization management can be an important tool, but it also has implications for patient access.**

As utilization management is used, care must be taken to ensure it is used in a clinically appropriate fashion and that potential harmful patient impacts are avoided. CMS must monitor and address increased utilization management as a result of Part D changes.



**The opt-in for smoothing should be available year-round, as reflected in the statute.**

Beneficiaries will have the option to smooth costs not just in January or when signing up for a Part D plan, but over the course of the plan year.



**Beneficiaries should have the option to autopay costs they opt to smooth.**

This will reduce burden on beneficiaries and reduce the likelihood of missed payments.



**Additional conversations and dialogue are necessary to identify and address the potential unintended consequences of the OOP cap such as utilization management and formulary restrictions.**



**Implementation timelines are short, given technical, operational, and educational needs.**

Close collaboration between stakeholders can help facilitate the rate of implementation, as well as help develop consensus-driven input to CMS.



## MODERATED DISCUSSION

### Implementing the Smoothing Mechanism for Medicare Part D Beneficiaries

#### DISCUSSION HIGHLIGHTS

Opportunities | Issues of concern | Collaboration among and between stakeholder groups and CMS

**Communication throughout the Medicare Part D ecosystem** is perhaps both the biggest opportunity and, simultaneously, the biggest challenge to effective implementation of the smoothing flexibility.

- *If beneficiaries aren't aware of and/or don't understand the benefits available to them, they can't take advantage of them.* Everyone will need assistance in understanding the changes to Part D, but how, when, and in what form will they get that assistance? The need for a rigorous communications process and consistent, continuous messaging is paramount.
- *Different communities and patients groups may require different messages.* How can a balance be reached between the development and distribution of consistent messaging by CMS and the ability of each patient community to customize and personalize that information?
- *Patients trust what their providers tell them; education of doctors, nurses, and pharmacy staff is critical.* How will the information that pharmacy benefit managers and pharmacies share be consistent with the information distributed by CMS?
- *Patients do not always see the same pharmacist or pharmacy; interfaces need to be built to address this concern.* How will information be shared between and among various pharmacists? How can that information be made available at all pharmacy counters – not just specialty and retail pharmacies but long-term care facilities as well?

**Collaboration among and between CMS and the stakeholder community is essential.**

- *Data collection and evaluation are key.* How can the stakeholder community come together to share data to identify who is enrolling, where the pain points are, what policies are and are not working, and what are the population trends?
- *Providing CMS with real world examples of how various patient communities are impacted in disparate ways will also be important.* Many patients suffering from chronic illness and diseases are prescribed numerous medications at different times throughout the year. Patient advocacy groups can start to make a list of disease states that are most impacted or who may experience additional barriers, as these will look different based on race, geography, age, and other factors.

## **Enrollment success requires effort and input from all stakeholders to provide all enrollees with information and tools to make informed decisions.**

- *Because beneficiaries must opt-in to smoothing, Medicare Part D enrollees must have access to knowledgeable experts to help them understand and navigate the enrollment process.* Providers, insurers, and hospitals must have the infrastructure and resources available to facilitate education and enrollment in smoothing.
- *Special consideration must be paid to patients with special needs who enter Medicare before the age of 65.* Individuals with a disability or that have end-stage renal disease may have unique educational or accessibility needs that should be incorporated into enrollment mechanisms.
- *Point-of-sale enrollment requires further discussion.* How can this option be implemented in ways that allow patients to take advantage of it? What technology and information exchange capabilities are necessary, and how quickly can they be implemented? Patient navigator groups and integrated systems and practices must be included in implementation discussions.

## **The structure and operationalization of copayments/coinsurance need to be explained.**

*There is little clarification around the structure of the copayment/coinsurance process, pharmacy workflow, and the payment cycle.* Pharmacists play a critical role in this process but will need time and manpower to facilitate the ability to serve as a front-line educator. Currently, there is not money appropriated for education or assistance with navigation of cost smoothing enrollment, and pharmacists do not have reimbursement codes for time that will be required for additional education.

## **Timing is a collective and real concern.**

- *CMS should work to issue sub-regulatory guidance as soon as is reasonably possible.* If the agency does not issue guidance prior to November 2023, there may not be adequate time for effective communication and successful implementation.
- *Careful attention must be given to set reasonable expectations.* Typically, communication that occurs early and often in the process is beneficial. Given the opt-in nature and potential complexities surrounding the implementation of smoothing, stakeholders agreed that starting public-facing education about smoothing in 2023 would be beneficial. However, given that the option to smooth and the full implementation of the annual OOP limit will not occur until 2025, there may be confusion about the ability of beneficiaries to have access to the new policies in the 2024 plan year.

## MODERATED DISCUSSION

### Implementing the Annual OOP Cap for Medicare Part D Beneficiaries

#### DISCUSSION HIGHLIGHTS

Opportunities | Issues of concern | Collaboration among and between stakeholder groups and CMS

#### Implementation will be provisionally complex.

*The OOP cap will alleviate financial hardship, improve access to care, adherence to medications, and could reduce costs as well.* However, implementation will be provisionally complex and interact with other provisions of Medicare Part D redesign. These interactions could create unintended outcomes.

#### Unintended consequences must be monitored and addressed.

- *There are significant concerns around utilization management and more restrictive formularies.* It is expected that beneficiaries we will see more utilization management, narrower formularies, and increased generic drug utilization as a way for insurers to manage plan drug costs. This pressure on payers results from other changes included in the IRA regarding insurer liability for spending in the catastrophic phase of the Part D benefit (payers are currently responsible for 20% of costs in the catastrophic phase; the IRA changes this percentage to 60% in 2025).
- *There are sensitivities around application of utilization management.* There is an understanding that utilization management can serve a purpose, and it should be a tool that helps patients access appropriate treatment. However, patient groups have concerns about the use of techniques such as step therapy, which may delay access to physician-prescribed treatments. Providers must be part of the feedback loop to ensure that utilization management is only applied in situations where it is clinically appropriate.

#### Cost, benefit, and medication management skepticism exists.

- *Patients are grateful for the OOP cap, but \$2,000 may still be too expensive for many. Patients need to understand their liability when they are paying at the pharmacy counter.*
- *Changes in formularies, premiums, and utilization management could hinder access.* CMS should monitor for access problems as well as for improvements in beneficiaries' ability to adhere to prescribed medication regimens.
- *There must be a focus on addressing equity and disparities of access.*

**Once full implementation occurs and there is lived experience, issues may be identified that will require either regulatory or statutory changes.**



## ROUNDTABLE SPONSORS

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## PARTICIPATING ORGANIZATIONS

AARP	National Health Council
AbbVie	PAN Foundation
Alliance for Aging Research	Patients for Affordable Drugs
American Cancer Society Cancer Action Network	National Association of Specialty Pharmacy
AHIP	Sanofi
Better Medicare Alliance	The ALS Association
Blue Cross Blue Shield Association	The American Society of Consultant Pharmacists
Bristol Myers Squibb	The Leukemia & Lymphoma Society
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