NATIONAL ALLIANCE FOR CAREGIVING
Making Caregiving More Sustainable, Dignified, and Equitable

June 26, 2025

Mehmet Oz, MD, MBA Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services 7500
Security Boulevard
Baltimore, MD 21244

RE: Draft Guidance for the Medicare Drug Price Negotiation Program: Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Administrator Oz -

The National Alliance for Caregiving (NAC) welcomes the opportunity to provide input on the Centers for Medicare & Medicaid Services' (CMS) draft guidance for the Medicare Drug Price Negotiation Program for Initial Price Applicability Year (IPAY) 2028. As this landmark program advances into its third negotiation cycle under the Inflation Reduction Act (IRA), we recognize the critical importance of ensuring that implementation strategies address the needs of both Medicare beneficiaries and their family caregivers. We applaud CMS for its commitment to enhancing medication affordability and respectfully submit these recommendations to strengthen implementation through a caregiver-informed lens.

As the nation's only nonprofit organization dedicated to supporting family caregivers across all ages, conditions, and life stages, NAC has championed caregiver needs for over 25 years. Our mission centers on advancing the health and wellness of our nation’s family caregivers through research, policy, and narrative change. Through our extensive research, including the landmark Caregiving in the U.S. studies, we represent the voices and experiences of the more than fifty-three million Americans who provide unpaid care to adult family members and friends. Our membership spans caregiving organizations, healthcare providers, technology companies, and other stakeholders committed to supporting family caregivers.

NAC commends CMS’s ongoing enhancement of the Medicare Drug Price Negotiation Program, especially its broadened coverage and increased focus on operational clarity. These advances create meaningful opportunities to reduce financial burdens for individuals managing chronic conditions and disabilities, as well as their family caregivers who often coordinate care and manage healthcare expenses. Our feedback centers on critical policy elements within the guidance, emphasizing areas where enhanced stakeholder input—particularly from the caregiving community—could strengthen program outcomes. Throughout our comments, we highlight the essential role family caregivers play in medication management, healthcare navigation, and financial coordination, underscoring the need for caregiver-inclusive implementation strategies.

The recommendations outlined in this comment align with and advance the goals established in the 2022 National Strategy to Support Family Caregivers (National Strategy), which calls for healthcare systems to recognize and support the essential role of family caregivers in care delivery. The National Strategy was developed jointly by the advisory councils created by the RAISE Family Caregiving Act and the Supporting Grandparents Raising Grandchildren Act, signed into law by President Trump in 2018, with extensive input from the public, including family caregivers and the people they support.

As CMS implements the Medicare Drug Price Negotiation Program, there is a critical opportunity to operationalize the National Strategy's vision by ensuring that drug pricing decisions and program implementation systematically consider caregiver perspectives and family-centered outcomes. This alignment would demonstrate federal commitment to supporting family caregivers across all aspects of healthcare policy, from direct service delivery to the fundamental economic structures that determine medication access and affordability.

Defining Family Caregiver

For the purposes of this comment, NAC refers to family caregivers as defined in Section 2 of the RAISE Family Caregivers Act: “The term ‘‘family caregiver’’ means an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation.”[1]

Who are Family Caregivers?

According to our research project with AARP, Caregiving in the U.S., family caregivers represent a substantial portion of American society, with more than one in five Americans (21.3 percent) providing care for older adults, people with serious illnesses, or individuals with disabilities, including children. These unpaid caregivers play a critical role in navigating complex care for people with serious illness, as nearly half (45%) are caring for someone with two or more conditions—a significant jump from 37% in 2015. The complexity of their caregiving responsibilities is evident in the medical tasks they perform, with three in five caregivers (58%) performing medical and nursing tasks such as wound care and managing medications. Additionally, more family caregivers (26%) have difficulty coordinating care up from 19% in 2015, highlighting the increasing challenges they face in managing the intricate healthcare needs of their loved ones with serious illnesses.[2]

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[1] U.S. Congress. Recognize, Assist, Include, Support, and Engage Family Caregivers Act of 2017. Public Law 115-119. January 22, 2018. https://acl.gov/sites/default/files/about-acl/2018-10/PLAW-115publ119%20-%20RAISE.pdf.

[2] National Alliance for Caregiving and AARP. Caregiving in the United States 2020. Washington, DC: AARP. May 2020. https://doi.org/10.26419/ppi.00103.001

Family Caregiver Participation in Patient Listening Sessions

NAC strongly supports CMS's commitment to conducting patient-focused listening sessions as part of the Medicare Drug Price Negotiation Program. These sessions represent a vital channel for capturing the real-world experiences of both patients and their family caregivers regarding selected medications. For the caregiving community, these forums offer an essential opportunity to share insights that extend beyond clinical data to encompass the broader family impact of medication costs, access challenges, and treatment management.

Family caregivers bring a unique and comprehensive perspective to medication evaluation that is often missing from manufacturer submissions and clinical trials. Family caregivers frequently coordinate multiple aspects of care—from managing medication schedules and side effects to navigating insurance systems and coordinating with healthcare providers. They witness firsthand how medication costs affect family finances, how treatment burden impacts entire households, and how access barriers create cascading effects on family wellbeing. This perspective is crucial for determining whether a drug's pricing truly reflects its value not just to the patient, but to the family system that supports treatment success.

To ensure that listening sessions capture meaningful caregiver insights and foster inclusive participation, NAC recommends the following enhancements—in addition to patient engagement strategies outlined by NAC partners like the National Health Council—which are focused on caregiver accessibility, representation, and meaningful engagement:

1. **CMS should explicitly invite and accommodate family caregiver participation with adequate advance planning time.** A minimum 30-day notice period would allow patients and their family caregivers to arrange coverage for their caregiving responsibilities, coordinate with their care recipients, and prepare substantive input. Many caregivers manage complex care schedules and require extended lead time to participate without compromising the care they provide.

2. **CMS should offer thematic guidance and clearly defined expectations for each session.** Publishing advance notice of themes— such as "family financial impact," "caregiver burden and medication management," "coordination challenges across providers," and "impact on family employment and income" will help participants prepare more tailored and relevant input. These prompts should also include examples of narratives or data that are particularly useful in informing negotiation-related decisions.[3] Further, CMS should add clarity on the level of detail for these themes that would be most relevant in listening sessions and in any written submissions. For example, CMS should clearly state whether it is helpful to have information on financial impacts across diseases, or treatments, or stages of disease. Without clear direction on the most meaningful evidence from the caregiving community, organizations may expend scarce resources – including the time and trust of their members – on research or activities that

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[3] U.S. Food and Drug Administration, FDA Patient-Focused Drug Development Guidance Series, March 21, 2025.

may not benefit patients if CMS does not consider the information.

3. **CMS should offer multiple participation modalities that accommodate patient and caregivers' unique constraints.** In addition to live testimony, options should include written submissions, recorded video testimonials, and structured phone interviews. Many caregivers and patients cannot leave their care recipients for extended periods and need flexible participation options that work around caregiving schedules and responsibilities.

4. **CMS should ensure accessibility supports address both patient and caregiver needs.** Default accommodations should include not only interpretation and assistive services, but also virtual participation options for caregivers who cannot physically attend sessions. Recognition that caregivers may be participating while managing ongoing care responsibilities should inform session design and timing. Further, sign language interpretation, closed captioning, multilingual translation, and accommodations for cognitive or sensory impairments should be standard features, not contingent upon special requests. Establishing these supports by default reflects CMS's commitment to broad patient participation and minimizes the administrative burden on patients already navigating serious health challenges.[4]

Beyond participation logistics, CMS must enhance transparency regarding how patient and caregiver input influences pricing decisions. Currently, there is limited visibility into whether and how these perspectives are integrated into the negotiation process. Without clear demonstration of how these insights are meaningfully incorporated, CMS risks undermining future stakeholder engagement. In the patient and caregiving community, resources are already stretched very thin. If participants cannot see that their efforts are leading to information that genuinely influences decision-making, this could significantly disincentivize future participation. The ultimate consequence would be a negotiation process that lacks authentic patient and caregiver perspectives, potentially resulting in pricing decisions that fail to address the real unmet needs across diseases and patient populations.

NAC urges CMS to publish comprehensive post-session summaries that specifically highlight patient and caregiver contributions, including:

- **Caregiver and patient-reported themes** organized by impact area (e.g., family financial burden, care coordination challenges, employment effects);
- **Summaries of patient and family-level impacts** shared during sessions, including effects on household finances, family functioning, and caregiver health;
- **Documentation of how caregiver insights informed price negotiations,** particularly regarding real-world treatment burden and family-centered value assessments;
- **Explanation of patient and caregiver-reported concerns that were noted but not incorporated,** with clear rationale for these decisions.

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[4] Centers for Medicare & Medicaid Services. CMS Framework for Healthy Communities. U.S. Department of Health and Human Services. February 28, 2025. https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework.

- **Summary of key data gaps and recommendations for future research and engagement to ensure the stakeholder engagement process can improve iteratively.**

This level of transparency would demonstrate CMS's recognition that medication value extends beyond individual patient outcomes to encompass family and caregiver wellbeing—a critical factor in treatment adherence and long-term success.

Additionally, CMS should create a dedicated caregiver archive within its public listening session repository, making caregiver testimonies and insights accessible to researchers, policymakers, and other caregiver organizations. This resource would help build the evidence base around family-centered medication value assessment and inform future policy development.

Finally, NAC strongly encourages CMS to formally partner with patient and caregiver organizations, including those representing diverse communities and specific condition-focused groups. These organizations can help identify and recruit patients and caregivers whose voices might otherwise go unheard, ensuring that the full spectrum of caregiving experiences informs Medicare drug pricing decisions.

Family caregiver participation in listening sessions and through written public comments represents a fundamental opportunity to ground drug pricing decisions in the reality of how medications function within family systems. By strengthening caregiver inclusion, ensuring meaningful access for all family caregivers, and demonstrating transparent integration of caregiver insights into policy decisions, CMS can honor the comprehensive nature of healthcare delivery and improve outcomes for both Medicare beneficiaries and their families nationwide.

Implementation of MFPs for Part B Drugs: Challenges and Safeguards

NAC recognizes the significant expansion of the Medicare Drug Price Negotiation Program to include drugs reimbursed under Medicare Part B as a critical advancement for patients with serious conditions such as cancer, autoimmune diseases, and rare disorders. This extension brings into scope infused therapies, biologics, and other physician-administered treatments that are essential for many Medicare beneficiaries and their families. However, the operational complexities of implementing Maximum Fair Prices (MFPs) for Part B drugs require careful attention to the unique role family caregivers play in coordinating these treatments and managing associated billing responsibilities.

Provider Communication and Caregiver Education Needs

NAC urges CMS to establish clear, structured communication protocols that specifically address the needs of family caregivers who coordinate Part B drug treatments. While large health systems may have dedicated billing departments to manage MFP implementation, smaller practices, and rural providers—where many caregivers seek care for their family members—often lack the resources for comprehensive patient education about billing changes.

Billing Error Identification and Resolution

Family caregivers need straightforward guidance on how to identify when MFP pricing has not been correctly applied to Part B drug administration. Unlike pharmacy transactions where pricing errors may be immediately apparent, Part B billing often occurs retroactively, making it difficult for patients and caregivers to recognize discrepancies. CMS should establish clear benchmarks and provide patients and caregivers with tools to verify that MFP pricing was properly implemented.

Considerations for Future Drug Selection and Renegotiation

NAC welcomes CMS's establishment of a formal framework for renegotiating MFPs as drugs' clinical and economic value evolves over time. The ability to adjust negotiated prices in response to new FDA-approved indications, biosimilar entry, shifts in real-world utilization, or emerging clinical evidence reflects a thoughtful approach to ensuring that pricing remains aligned with therapeutic value and patient needs. However, the current renegotiation framework must be enhanced to systematically capture the family caregiver perspective, which provides essential insights into how treatment changes affect daily life and long-term care management.

Family caregivers possess a unique and comprehensive view of medication effectiveness that extends beyond clinical trial endpoints to encompass real-world treatment burden, adherence challenges, and family-wide impacts. When drugs undergo renegotiation, caregivers can provide critical insights about medication adherence patterns, side effect management, and the practical challenges of treatment implementation that may not be reflected in manufacturer submissions or clinical data. Their perspective is particularly valuable for understanding how pricing changes or treatment modifications affect family financial stability and care coordination.

Incorporating Caregiver Burden and Family Impact Assessments

CMS should expand its renegotiation criteria to explicitly include assessments of caregiver burden and family financial effects when evaluating whether a drug's value has changed sufficiently to warrant price adjustment. The current framework references "material changes" in clinical benefit or unmet need, but these determinations should encompass the broader family impact of treatment, including caregiver time, family employment effects, and household financial strain. Further, CMS should develop and publish illustrative examples—drawn from clinical, economic, and operational contexts—to clarify the types of changes that would meet the threshold for triggering renegotiation.

NAC recommends that CMS develop structured methods for collecting caregiver input during renegotiation proceedings. This should include formal opportunities for caregivers to provide testimony about changes in treatment burden, evolving care coordination requirements, or shifting family financial impacts that have occurred since the original price negotiation. Such input is particularly crucial for medications used to treat progressive conditions where caregiver responsibilities may intensify over time, or for treatments where new indications may alter the caregiving experience significantly.

Transparency and Stakeholder Engagement

NAC urges CMS to establish structured opportunities for patient and caregiver engagement that are separate from but complementary to manufacturer negotiations. This should include public comment periods specifically designed to capture these experiences, listening sessions focused on family impact, and clear communication about how patient and caregiver input influenced renegotiation decisions.

Furthermore, CMS should publish summaries of renegotiation outcomes that specifically address how patient and family and caregiver considerations were integrated into pricing decisions. This transparency will help build trust in the renegotiation process and demonstrate CMS's commitment to family-centered value assessment.

The inclusion of patient and caregiver perspectives in the renegotiation process is essential for ensuring that pricing decisions reflect the full scope of a medication's value and impact. By systematically incorporating caregiver insights, CMS can make more informed decisions that support not only individual patient outcomes but also the family systems that are crucial to treatment success.

Conclusion

The IPAY 2028 draft guidance represents a significant milestone in the evolution of the Medicare Drug Price Negotiation Program. NAC recognizes CMS's important work to broaden the program's scope to include physician-administered drugs under Part B, establish clearer enforcement and compliance frameworks, and create formal pathways for renegotiating previously selected medications. We particularly appreciate the agency's continued commitment to integrating patient experiences and real-world evidence into the negotiation process.

While these developments are encouraging, NAC urges CMS to take additional steps to systematically embed both patient and family caregiver perspectives throughout all aspects of program implementation. The success of this initiative will ultimately be measured not only by the fiscal savings it generates, but by its ability to deliver meaningful improvements in medication access, care coordination, and family wellbeing. This requires operational protocols that acknowledge caregivers' vital role in medication management, transparent communication strategies that reach and inform family caregivers, and access safeguards that protect the care coordination systems families depend upon.

Family caregivers are integral to the success of medication therapies, serving as care coordinators, medication managers, and advocates for Medicare beneficiaries. Their perspectives and experiences must be woven into the fabric of program implementation to ensure that drug pricing decisions reflect the full scope of treatment value and impact. From listening sessions that capture caregiver insights to billing processes that accommodate caregiver involvement, every aspect of the program should recognize and support the essential role family caregivers play in healthcare delivery.

NAC remains firmly committed to partnering with CMS in the successful implementation of this historic program and stands ready to collaborate in ensuring that both Medicare beneficiaries and their family caregivers are central to every decision the program encompasses. We believe that by embracing a truly family-centered approach, the Medicare Drug Price Negotiation Program can achieve its goals while strengthening the care systems that millions of American families depend upon.

Thank you for the opportunity to provide input on this critical guidance. Please do not hesitate to contact Jason Resendez, President & CEO, National Alliance for Caregiving at Jason.resendez@caregiving.org if you or your staff would like to discuss these recommendations in greater detail or explore ways to enhance caregiver integration throughout program implementation.

Sincerely,

Jason Resendez
President and CEO
National Alliance for Caregiving