February 23, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244
Submitted via regulations.gov

**RE: Comments on the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model**

Dear Administrator Oz,

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide comments on the proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model released on December 23, 2025.

MAPRx is a national coalition of more than 60 beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The coalition has championed policies in Part D that improve the affordability of medications and beneficiary access to those medications, including provisions of the Inflation Reduction Act (IRA) that establish an out-of-pocket cap in Part D and the Medicare Prescription Payment Plan. We are committed to ensuring that the implementation of these and other elements of the IRA are informed by the experiences and needs of beneficiaries living with chronic diseases and conditions.

MAPRx strongly opposes the GUARD Model and urges the Centers for Medicare & Medicaid Services (CMS) to abandon this proposal entirely and withdraw the model. The GUARD Model is a solution in search of a problem that no longer exists in the way CMS describes. At a time when the Medicare Part D program is beginning to achieve greater stability, introducing a new experimental pricing model threatens to undermine recent progress toward beneficiary predictability and affordability.

MAPRx urges CMS to withdraw the GUARD Model for the following reasons:

- The model is projected to increase beneficiary out-of-pocket spending, directly undermining the financial protections enacted through the Inflation Reduction Act.
- The GUARD Model creates strong incentives for plans to restrict access through prior authorization, step therapy, and other utilization management tools

- Including protected class medications undermines longstanding statutory safeguards and risks eroding access in practice.
- Inclusion of orphan drugs is inappropriate and threatens access for patients with rare and serious conditions.
- CMS has not proposed clear, enforceable beneficiary protections or a transparent framework for monitoring access and affordability impacts.
- Beneficiary and stakeholder engagement has been insufficient for a model with the potential to materially affect access to care.
- The GUARD Model is structurally misaligned with Medicare Part D, which is a plan-based benefit built on negotiated formularies, tiering, and utilization management rather than administered prices.
- The model adds operational risk and complexity at a time when CMS, plans, and beneficiaries are already navigating major Part D redesign changes.

MAPRx's specific concerns are detailed below.

**Structural Misalignment with Medicare Part D**

Medicare Part D is a plan-based benefit that relies on negotiated formularies, benefit design, and utilization management within a framework of statutory access protections. Beneficiaries experience Part D through plan decisions related to coverage, tier placement, cost sharing, and access requirements, not through administered prices set by the federal government.

The GUARD Model attempts to import an international reference pricing construct into this framework without adequately addressing how such pricing would translate through Part D's operational mechanics. International reference prices are derived from health systems with fundamentally different coverage mandates, access standards, cost-sharing structures, and patient protections. Applying those benchmarks in Part D fails to account for the central role plans play in shaping beneficiary access at the point of sale.

This misalignment is not theoretical. It directly affects beneficiary experience by shifting pressure onto plan design tools that determine whether a beneficiary can access prescribed medication without delay, administrative burden, or excessive cost sharing.

**A Massive Cost Shift onto Vulnerable Beneficiaries**

The primary justification for any Medicare demonstration should be to improve the beneficiary quality of care or affordability. The GUARD Model fails this test. CMS's own analysis projects that the model would increase beneficiary out-of-pocket spending by $3.6 billion.

This is not a marginal or abstract effect. It represents a substantial cost shift onto Medicare beneficiaries that directly undermines the financial protections Congress enacted through the IRA, including the establishment of an out-of-pocket cap. In Part D, beneficiary out-of-pocket costs are not determined by a drug's nominal price. They are driven by plan design choices, including tier placement, coinsurance rates, deductible exposure, and utilization management requirements.

When CMS imposes new pricing constraints through a model like GUARD, plans do not simply absorb the resulting financial pressure. Instead, they respond by moving drugs to higher tiers, increasing coinsurance, or imposing more restrictive access controls to manage risk. For a beneficiary living on a fixed income, retrospective payment back to the government provides no relief. Instead, it hurts them if their specific plan responds by doubling their out-of-pocket spending at the pharmacy counter. Especially as the out-of-pocket threshold jumps up hundreds of dollars each year.

This model was not built with beneficiaries in mind. It includes orphan drugs despite congressional recognition of the danger of inclusion of orphan drugs in Medicare negotiation. Orphan drugs are developed to treat rare, often life-threatening conditions for which therapeutic alternatives are frequently limited or nonexistent. For these patients, continuity of care is essential. Medicare beneficiaries with rare diseases should not be treated as a test population for a pricing experiment that could jeopardize access to the only therapies available to them.

By advancing the GUARD Model despite its projected increase in beneficiary out-of-pocket costs and threats to patient access, CMS is effectively asking the most vulnerable beneficiaries to subsidize a government experiment that provides them no tangible benefit.

**Expected Plan Responses and Resulting Access Barriers**

The GUARD Model creates strong incentives for plans to manage financial exposure through utilization management rather than through negotiated price concessions alone. These tools include prior authorization, step therapy, quantity limits, formulary narrowing, and mid-year access restrictions.

Such strategies may reduce plan liability but frequently delay treatment initiation, force non-medical switching, and increase administrative burden for beneficiaries and providers. For beneficiaries who are clinically stable on a therapy, even short disruptions can lead to adverse health outcomes and loss of disease control.

CMS has not demonstrated how it will prevent or meaningfully limit these access barriers under the GUARD Model, nor has it articulated how beneficiary harm would be identified and corrected in real time.

**Erosion of Statutory Protected Class Safeguards**

Protected class policy is not a discretionary regulatory preference. It is a statutory safeguard established by Congress to ensure that beneficiaries with serious and complex conditions, including cancer, HIV, mental health disorders, and epilepsy, are not forced to sacrifice clinical stability for plan cost containment.

By including protected class medications in the GUARD Model, CMS creates strong incentives for plans to circumvent these safeguards. Even when a medication remains technically included on a formulary, plans facing pricing pressures created by the model are likely to rely on aggressive utilization management, such as restrictive prior authorization and onerous step therapy, that renders the medication functionally inaccessible.

This approach creates a dangerous precedent in which access to life-sustaining therapy is dictated by an experimental pricing construct rather than clinical necessity. Any model that enables indirect access restrictions for protected class drugs violates both the intent and the practical function of the statutory protections Congress established.

**Interaction with Part D Redesign and Implementation Timing**

The Medicare Part D program is undergoing its most significant transformation since its inception. Plans, pharmacies, and beneficiaries are adapting to the annual out-of-pocket cap, changes in liability distribution, and the Medicare Prescription Payment Plan. Early implementation experience indicates that beneficiary awareness and understanding of these new protections remains limited, with only a small share of beneficiaries reporting that they understand how payment smoothing works.

Layering a mandatory pricing demonstration on top of this redesign adds complexity at a moment when stability is critical. It increases the risk of administrative errors, pharmacy counter confusion, and care disruptions. CMS has not sufficiently addressed how the GUARD Model would interact with Part D bidding, risk adjustment, or plan incentives under the redesigned benefit.

The necessity of introducing this additional layer of operational risk is highly questionable. CMS should prioritize successful implementation of existing reforms rather than introducing experimental variables that threaten to destabilize the benefit.

**Lack of Clear, Enforceable Beneficiary Protections**

The GUARD Model lacks clear, enforceable protections to prevent access erosion and cost shifting. CMS has not proposed limits on utilization management escalation, requirements for beneficiary impact analyses, or standardized monitoring and public reporting of access outcomes.

Without these safeguards, beneficiaries and stakeholders will have limited visibility into whether the model is improving affordability or simply shifting costs and barriers elsewhere in the system. Demonstration models that affect access to medically necessary treatments should include robust oversight and transparency mechanisms from the outset.

**Insufficient Beneficiary and Stakeholder Engagement**

Finally, MAPRx is concerned that the GUARD Model was developed without sufficient engagement with beneficiaries, patient organizations, clinicians, and other stakeholders with real-world experience in Medicare Part D.

MAPRx shares CMS's goal of improving prescription drug affordability for Medicare beneficiaries. However, the GUARD Model, as proposed, is misaligned with the structure of Medicare Part D and poses significant risks to beneficiary access, affordability, and continuity of care. These risks are especially acute for beneficiaries who rely on protected class medications, orphan drugs, and therapies for complex or chronic conditions.

For these reasons, the undersigned members of the MAPRx Coalition urge CMS not to finalize or implement the GUARD Model and instead pursue affordability strategies that strengthen Part D's existing protections while ensuring sustainable access to medically necessary medications.

For questions related to MAPRx or these comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,
AiArthritis
Alliance for Patient Access
ALS Association

American Association on Health and Disability
American Cancer Society Cancer Action Network
American Kidney Fund
American Society of Consultant Pharmacists (ASCP)
Autoimmune Association
Blood Cancer United
Eosinophilic & Rare Disease Cooperative
Epilepsy Foundation of America
Foundation for Sarcoidosis Research
GO2 for Lung Cancer
HIV+Hepatitis Policy Institute
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