



February 23, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Submitted electronically to: <http://www.regulations.gov>

Re: The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model [Docket Number CMS-5546-P]

Dear Administrator Oz:

On behalf of WellLink Health Alliance, we appreciate the opportunity to submit comments on The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (CMS-5546-P), as published in the December 23, 2025 Federal Register. WellLink shares the Centers for Medicare & Medicaid Services' (CMS) commitment to ensuring Medicare beneficiaries can access and afford necessary therapies and values the agency's efforts to explore new strategies to address rising drug costs.

WellLink Health Alliance is a regional healthcare collaborative committed to advancing access, affordability, and quality across the continuum of care. We work with healthcare providers, community partners, and other stakeholders to strengthen care delivery systems and improve health outcomes. Our focus includes supporting coordinated care, addressing behavioral and physical health integration, and ensuring that policy decisions promote patient-centered, sustainable healthcare solutions. Through collaboration and data-informed strategies, WellLink seeks to support reforms that enhance patient access while maintaining the stability of the broader healthcare system.

Given the scope and mandatory nature of the GUARD Model, we believe it is critical that CMS carefully assess potential operational, access, and system-wide impacts prior to implementation.

Potential Unintended Consequences That Must Be Addressed to Minimize Negative Impact On Patients and the Healthcare System

The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model is a proposed mandatory model designed to reduce Medicare Part D drug costs by benchmarking U.S. drug prices against those paid in economically comparable countries. Under the model, if a drug's price exceeds the international benchmark, manufacturers would be required to pay additional rebates to Medicare. The model would operate in randomly selected geographic areas representing 25 percent of Medicare Part D enrollees and is proposed to run for five years beginning January 1, 2027.

As outlined in the proposed rule, several operational and policy questions remain regarding how the GUARD Model would function and its broader impact across the healthcare delivery system. WellLink respectfully urges CMS to address the following concerns prior to implementation to avoid unintended consequences that could affect patient access and system stability.



Manufacturer Impact and Innovation

CMS proposes to apply the model primarily to single-source drugs, biologics, and biosimilars. Aligning Part D payment rates with international pricing benchmarks may prompt manufacturers to adjust pricing strategies in other markets, potentially affecting global pricing structures and distorting the benchmark itself. Additionally, there are concerns about potential effects on innovation, particularly if manufacturers alter product launch strategies or research investments in response to international pricing alignment.

We encourage CMS to clarify what safeguards will be in place to prevent unintended pricing shifts internationally or within other segments of manufacturers' portfolios. It will also be important to understand how the GUARD Model may interact with other federal drug pricing initiatives.

Impact on Other Drug Pricing Benchmarks

The introduction of a new international benchmarking methodology may have downstream implications for other drug pricing benchmarks, including those used in Medicare Part B payment calculations and programs that rely on established pricing methodologies. Healthcare providers depend on predictable and transparent pricing benchmarks to maintain financial stability and ensure patient access.

We urge CMS to assess and clearly communicate any potential ripple effects the GUARD Model may have on other Medicare payment systems and federally supported drug pricing programs.

Implementation Timeline and Supply Chain Stability

CMS proposes implementation beginning January 2027. Given the complexity of the healthcare supply chain, including manufacturers, distributors, pharmacies, health plans, and providers, this timeline may present operational challenges. Rapid or insufficiently coordinated changes could lead to administrative burdens, contract renegotiations, or unintended supply disruptions that ultimately impact patients.

We recommend CMS consider whether additional time, phased implementation, or pilot testing would allow for more careful evaluation and minimize risk to patient access and care continuity.

WellLink Health Alliance appreciates the opportunity to provide comments on the proposed GUARD Model (CMS-5546-P). We support efforts to improve affordability for Medicare beneficiaries and encourage CMS to carefully evaluate potential system-wide impacts before finalizing the model.

We look forward to continued collaboration with CMS and other stakeholders to advance thoughtful reforms that strengthen patient access, promote innovation, and ensure the long-term sustainability of our healthcare system.

Sincerely,

Daniel Lettenberger Klein
Executive Director
WellLink Health Alliance