



February 23, 2026

Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services

Electronically Submitted via  
[regulations.gov](https://www.regulations.gov)

**RE: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (CMS-5546-P)**

Dear Administrator:

On behalf of the [Chronic Care Policy Alliance](https://www.chroniccarepolicyalliance.org), we appreciate the opportunity to submit comments on the proposed GUARD model for Medicare Part D. CCPA represents organizations serving people living with chronic and serious health conditions who rely on consistent access to prescription medications. From this perspective, we oppose the GUARD model and respectfully urge CMS to withdraw the rule.

**The GUARD Model Prioritizes Government Savings, Not Patient Savings**

The GUARD model is designed to reduce Medicare spending by imposing rebates on drugs that fail to meet international benchmarks. However, reductions in program spending do not necessarily result in lower costs for patients. Affordability reforms should be evaluated based on whether they reduce out-of-pocket costs and improve financial predictability for patients, not solely on whether they achieve savings for the government. By this standard, the GUARD model falls short.

**Importing QALYs Risks Limiting Access to Care**

CCPA is also concerned that the countries referenced under the GUARD model explicitly rely on quality-adjusted life years (QALYs) and similar measures to control costs and limit coverage. Adopting an MFN-style pricing approach opens the door to importing these policies into Medicare, approaches that have been soundly rejected in the United States because they prioritize cost containment over patient care.

These frameworks are associated with delayed access to new and innovative therapies and can disadvantage patients living with chronic and serious conditions, increasing the risk of poorer health outcomes when timely access to effective treatment is constrained.

**Changes to the Six Protected Classes Are Unacceptable**

We were also concerned with language in the rule that seemed to question the importance of the designated six protected classes under Medicare Part D.

These protections exist because patients with certain serious and life-threatening conditions often require access to multiple treatment options within a class. Limiting coverage options can force patients onto treatments that are less effective or inappropriate for their individual needs.

Any reduction in protected class safeguards would threaten patient access to personalized and effective care. We urge CMS and the Administration to uphold these long-standing protections.

### **A Better Path Forward**

If policymakers seek to meaningfully improve affordability for Medicare beneficiaries, they should prioritize reforms that directly reduce patient costs. This includes ensuring that discounts and rebates are negotiated and passed to patients, establishing meaningful out-of-pocket caps, and addressing misaligned incentives within the prescription drug supply chain.

For these reasons, CCPA respectfully urges CMS to withdraw the GUARD model and instead focus on reforms that lower costs for patients while preserving access to needed treatments. CCPA welcomes continued engagement with CMS to share patient perspectives and support the development of patient-centered affordability reforms.

Sincerely,



Elizabeth Helms  
President  
Chronic Care Policy Alliance