February 23, 2026

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-5546-P**
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS-5546-P Comments on Notice of Proposed Rulemaking for the GUARD (Guarding U.S. Medicare Against Rising Drug Costs) Model

To whom it may concern:

As health economics and policy researchers, we share the Centers for Medicare & Medicaid Services (CMS)'s concern about rising Medicare Part D drug costs and the disparity between U.S. and international drug prices. However, we have significant reservations about the GUARD Model as proposed.*

Our research demonstrates that international reference pricing approaches like GUARD face three critical challenges:

1. They cannot overcome the basic economics of the global pharmaceutical marketplace
2. They cede pricing authority to foreign governments with fundamentally different values regarding health innovation
3. They are vulnerable to gaming by foreign sovereigns

Rather than importing foreign price controls that may ultimately harm American patients and global medical innovation, we recommend pursue an "America First" pricing solution that establishes value-based benchmarks reflecting American values while encouraging foreign countries to pay their fair share for pharmaceutical innovation. To implement such an approach, we recommend CMS withdraw the GUARD Model as proposed, and replace it with an alternative, value-based pricing approach.

We note that we have submitted substantially similar comments on the concurrent proposed rule for the Global Benchmark for Efficient Drug Pricing (GLOBE) Model (CMS-5545-P). The structural and economic arguments set forth in this letter apply with equal force to the GLOBE Model, which shares the same MFN-based benchmark methodology, mandatory participation structure, and reference country basket as GUARD, differing principally in its application to Medicare Part B rather than Part D.

* The opinions expressed herein represent those of the authors and do not represent the positions of any of their affiliated organizations, including the University of Southern California or USC Schaeffer.

1. Background: The Economics of Global Pharmaceutical Pricing

1.1. The U.S. Subsidizes Global Innovation

Our research at the USC Schaeffer Center reveals that approximately 70% of global pharmaceutical profits flow from the U.S. market, despite Americans purchasing only about 20% of pharmaceuticals worldwide by volume.[1] This disproportionate contribution has enabled the United States to become the world's leading source of biomedical innovation, with American patients often gaining earlier access to breakthrough treatments for diseases like cancer, Alzheimer's, and obesity.[2]

The higher prices paid by Americans have incentivized manufacturers to invest in decades of research to develop products that address diseases prevalent in the U.S. population. Economic theory and evidence demonstrate that expected profits drive pharmaceutical innovation, [3,4] and because the U.S. market supplies such a disproportionate share of global revenues, changes there have outsized effects on global innovation decisions. Policies that reduce U.S. revenues—whether through price controls or international reference pricing—therefore pose the greatest risk to future drug development.

1.2. Foreign Countries Engage in 'Free Riding'

European and other developed nations have long benefited from American-financed pharmaceutical innovation while paying substantially lower prices through various price control mechanisms. These countries do not share U.S. views on how to value new medicines. For example, the England's NICE has considered health improvements to be as low as one-third the value of even conservative American valuations.[5,6] Other developed countries have shown ample willingness to deny access to all their consumers if offered prices they consider excessive according to their artificially low conceptions of value.[7]

This difference in preferences allows other countries to walk away from medicines that Americans expect (and ostensibly are willing to pay for). Other countries' ability to do this enables them to drive a harder bargain and to benefit from innovations funded primarily by American consumers, while refusing to pay prices that would appropriately support continued research and development.[8]

2. Fundamental Problems with the GUARD Model

2.2. Problem 1: The Model Cannot Overcome Basic Market Economics

The GUARD Model fails to address the basic economics of the global drug marketplace. Faced with a choice between accepting deep cuts in their U.S. pricing or losing weakly profitable overseas markets, many pharmaceutical manufacturers will rationally choose to pull out from overseas markets at their earliest contractual opportunity. [9]

This outcome would leave U.S. consumers paying the same prices, pharmaceutical manufacturers with lower profits, foreign patients with reduced access, and future generations worldwide with less medical innovation. In this scenario, everyone loses.[9]

Our research demonstrates that if we simply import European prices to the United States and apply them across the board, the impact on future drug development would be devastating.[10] [7]Shifting to a European pricing model in the U.S. would lead to shorter, less healthy lives for

Americans, with losses totaling trillions of dollars. Specifically, our analysis shows that lowering prices to European benchmarks would ultimately reduce innovation and cost American consumers approximately half a year of life expectancy—similar to the health loss if the U.S. suddenly "forgot" how to perform bypass surgery.[11,12]

2.2. Problem 2: The Model Cedes Pricing Decisions to Foreign Governments

By pegging U.S. prices to international benchmarks, the GUARD Model effectively allows foreign governments to determine what American Medicare beneficiaries pay for drugs. This represents a troubling delegation of domestic policy authority to foreign entities whose healthcare values and priorities differ fundamentally from those of Americans.

Many foreign countries employ quality-adjusted life year (QALY) methodologies that systematically undervalue treatments for vulnerable populations, including the elderly and disabled.[13] Research at the Schaeffer Center has demonstrated that QALY-based approaches discriminate against those who are sick by assigning lower values to health improvements for individuals with disabilities or severe diseases.[14,15] Indeed, federal law explicitly prohibits Medicare from using QALYs or similar measures as a threshold to determine coverage, reimbursement, or incentive programs. [16]

2.3. Problem 3: The Model is Vulnerable to Gaming by Foreign Sovereigns

The GUARD Model proposes to calculate rebates based on international pricing benchmarks. However, drug companies' overseas customers can circumvent this approach by maintaining high list prices while agreeing to confidential rebates—a practice already common in international markets.[11,12] European governments already employ systematic mechanisms that create a wedge between observable list prices and true net prices. The United Kingdom, Italy, and Spain, for example, maintain clawback agreements under which manufacturers must return funds to the government when pharmaceutical spending exceeds agreed budget thresholds. The UK payback rate in 2025 is 22.5%.[17] These arrangements are confidential between manufacturers and national payers, and are structured as fiscal and regulatory instruments of sovereign governments — not as pricing agreements that would be visible to GUARD's benchmarking methodology. These confidential arrangements would produce the same low net prices for foreign purchasers while creating the appearance of higher prices for GUARD benchmark calculations.

The U.S. government might attempt to compel or encourage drug companies to disclose their rebates, but such efforts would likely run afoul of foreign laws requiring confidentiality in pricing negotiations. This fundamental vulnerability undermines the model's ability to achieve its stated objectives.

3. Impacts on Medicare Beneficiaries and the Part D Program

3.1. Increased Beneficiary Out-of-Pocket Costs

CMS's own Regulatory Impact Analysis projects that the GUARD Model will increase beneficiary out-of-pocket costs by approximately $3.6 billion over the 2028–2033 period, even as the Medicare program realizes $14.1 billion in savings via rebates to the Trust Fund over the same period.[18] This structural outcome reflects the absence of any mechanism to pass Trust Fund rebates through to individual beneficiaries in the form of reduced premiums or cost-sharing. If

manufacturers maintain high list prices while providing confidential foreign rebates, the international benchmark may not decline as anticipated, resulting in limited or no rebate obligations under GUARD.

Moreover, even if rebates are collected, the indirect nature of the savings mechanism—rebates paid to the Medicare Supplementary Medical Insurance Trust Fund rather than directly to beneficiaries or Part D plans—means the benefits may not translate into meaningful premium or cost-sharing reductions for individual beneficiaries.

3.2. Potential Access Concerns

The GUARD Model could paradoxically worsen access for Medicare beneficiaries over time. Whether manufacturers respond by accepting lower U.S. prices or by withdrawing from foreign markets to avoid triggering international reference pricing, global revenues will decline.[5,9,10,19] The resulting reduction in pharmaceutical R&D would disproportionately affect older Americans, as diseases like Alzheimer's, heart failure, and age-related macular degeneration require sustained research investment that depends on adequate returns from the Medicare population.[4,20]

4. Alternative Approach: American Values-Based Pricing

Rather than importing foreign prices (and values), we recommend CMS pursue a comprehensive approach that establishes value-based pricing benchmarks reflecting American values while pressuring foreign countries to pay their fair share for innovation.

4.1. Establish American Value Assessments

For new drugs entering the Medicare Part D program, the United States should establish a system that leverages the latest advances in economic methods for computing value. This system would limit U.S. prices to rational estimates of their true value to patients while maintaining appropriate incentives for medical innovation.[21]

Research at the Schaeffer Center has shown that value-based, patient-centric pricing can account for how drugs are valued differently by patients depending on their condition. A given health improvement offers greater value for people with disabilities or severe diseases than to those in relatively better health. In such an approach, cost-effectiveness thresholds become more generous for severe illnesses such as cancer and less generous for milder conditions such as seasonal allergies—potentially differing up to a factor of ten from lowest to highest severity.[14,15] This stands in direct contrast to how foreign panels operate, where new treatments for severe illnesses are frequently valued only modestly higher than older therapies. While some foreign bodies have created special thresholds for end-of-life and rare-disease treatments, these represent ad hoc policy carve-outs rather than valuations grounded in patient preferences or empirical evidence.[22] GRACE eliminates the need for such discretionary exceptions by incorporating severity adjustments directly into its framework.

Anti-obesity medications provide an illustrative example. Research demonstrates the promise of these drugs for longer and healthier lives, but questions remain around the magnitude and durability of weight loss over time.[23] A value-based approach would incorporate outcomes-based pricing agreements where prices rise with good performance and fall when drugs fail to fulfill their promise. This could include success fees that accumulate for every period in which weight loss is sustained, with refunds to insurers and consumers if the drug fails to work.[24]

4.2. Establish an Independent Institute for Health Technology Assessment

Rather than importing valuations from foreign panels with different preferences and healthcare systems, the United States should develop its own health technology assessment (HTA) infrastructure tailored to American needs. As recommended by the USC Schaeffer Center–Aspen Institute Advisory Panel, the federal government should establish a publicly-funded Institute for Health Technology Assessment (IHTA) to coordinate and improve value assessment across the U.S. healthcare system. To maintain credibility, the IHTA must be independent of all stakeholders—healthcare payers (public or private), manufacturers, and providers of medical technologies or services. IHTA would conduct HTA for health interventions that are poorly studied in existing literature, evaluate the quality of assessments produced by private organizations, identify gaps in evidence, and advance research methods for measuring value. Critically, it would apply patient-centered methodologies—such as the Generalized Risk-Adjusted Cost-Effectiveness (GRACE) framework—that account for disease severity and avoid the discriminatory assumptions embedded in foreign approaches. [25]

Such an institute would generate actionable information to help identify wasteful spending while rewarding technologies that provide genuine value to sustain innovation. The assessments would reflect American values and aspirations for good health, particularly for severe diseases with few or no treatment options. [25]

4.3. Address Foreign Underpricing Through Trade Policy

The Office of the U.S. Trade Representative (USTR) should pursue complementary actions to confront foreign countries' discriminatory pricing practices. As we recommended in our recent comments to USTR, policy options could include:

- Initiating Section 301 investigations into countries that systematically use QALYs or similar discriminatory methodologies to suppress pharmaceutical prices below American standards of fair market value
- Negotiating bilateral agreements requiring foreign countries to abandon or modify QALY-based pricing methodologies
- Pursuing World Trade Organization dispute resolution where QALY-based practices constitute discriminatory treatment of U.S. pharmaceutical exports
- Implementing targeted tariffs or trade sanctions against countries that refuse to abandon discriminatory pricing practices [13]

These trade policy tools would complement domestic value-based pricing by incentivizing foreign countries to pay their fair share for pharmaceutical innovation, reducing the burden on American consumers without sacrificing innovation incentives.

4.4. Addressing Uncertainty through Outcomes-Based Agreements

Pricing should be contingent on effectiveness. If a drug produces promised health gains, it should be rewarded through higher payments. If it fails to deliver, its manufacturer should issue proportional refunds. Drugs should enter the market at introductory prices that reflect initial uncertainty, rise as they prove their worth and value, and decline when patents expire and generic versions become available.[26]

This approach addresses a fundamental weakness in the GUARD Model: its reliance on static international price comparisons that fail to account for the actual value delivered to patients. By

contrast, outcomes-based agreements create dynamic pricing that rewards value creation and protects both beneficiaries and the Medicare Trust Fund from paying for ineffective treatments.

5. Relationship to GLOBE Model

We wish to note for the record that the structural concerns described in Sections 2 through 4 above are not specific to the Part D program. The GLOBE Model, which applies the same MFN-based benchmark methodology to Medicare Part B drugs, presents identical economic vulnerabilities. Our recommendations below regarding the benchmark methodology, therapeutic category selection, and geographic randomization are equally applicable to GLOBE, and we have filed parallel comments in that docket.

6. Specific Comments on Proposed Regulatory Provisions

We urge CMS to withdraw the GUARD Model as proposed. The problems identified above are not technical deficiencies that can be corrected through regulatory refinement — they reflect fundamental flaws in the model's underlying design.

However, we recognize that CMS may elect to proceed with some version of this approach. In that event, the following comments identify design choices that would, at minimum, reduce the model's most serious risks. These observations should not be read as an endorsement of the model or as a conclusion that the problems identified above can be fully remediated.

6.1 Geographic Randomization

The GUARD Model proposes implementing the new rebate calculation methodology in randomly selected geographic areas representing 25% of Medicare Part D beneficiaries. This design raises several concerns:

- **Manufacturer Response Complexity:** Manufacturers must comply with different rebate calculation methodologies depending on where their Part D drugs are dispensed, creating administrative complexity without clear policy benefits.
- **Limited Learning:** Because manufacturers may or may not adjust their global pricing strategies in response to a pilot that is limited in scope, the control areas will not provide a clean counterfactual for evaluating model impacts.

6.2. International Price Benchmark Methodology

CMS proposes to calculate benchmarks using either manufacturer-reported international pricing information or available information for countries meeting certain GDP per capita and economy size thresholds. We recommend:

- **Require Net Price Reporting:** To address gaming concerns, CMS could require manufacturers report net prices after all rebates, discounts, and other price concessions in foreign markets. However, as noted earlier, because potential gaming mechanisms would likely operate through sovereign budget law, licensing surcharges, and regulatory frameworks—rather than through drug pricing agreements—the U.S. has no legal authority to compel their disclosure or prohibition.

- **Exclude Countries with Discriminatory Practices:** Countries employing QALY-based pricing or other discriminatory methodologies should be excluded from benchmark calculations until they reform such practices.
- **Adjust for National Income:** International price comparisons should account for differences in GDP per capita to reflect differing ability to pay.

6.3. Therapeutic Categories

The GUARD Model would apply to drugs in 17 specific therapeutic categories. While this focused approach has some merit, we note:

- **Arbitrary Exclusions:** The categorical approach may arbitrarily exclude important drugs that impose high costs on Medicare while including others with less fiscal impact.
- **Innovation Incentives:** Categories representing areas of active research and development should be carefully monitored for innovation impacts.

A more principled approach would prioritize drugs based on two criteria: (1) those with the highest likelihood of being priced above their true patient-centered value, and (2) those in therapeutic areas with substantial ongoing research and development activity.

Regarding the first criterion, recent research applying the GRACE framework to drugs evaluated by the Institute for Clinical and Economic Review (ICER) found that traditional cost-effectiveness methods systematically overprice treatments for milder conditions while underpricing those for severe diseases.[27] CMS could use GRACE-based assessments to identify drugs whose current prices exceed their patient-centered value—focusing negotiation efforts where the gap between price and true value is greatest.

Regarding the second criterion, prioritizing drugs in therapeutic areas with active R&D pipelines would help preserve innovation incentives. Price controls that target therapeutic areas with little ongoing research impose smaller innovation costs than those targeting areas where investment decisions are still being made.

7. Conclusion

The GUARD Model, while well-intentioned, suffers from fundamental design flaws that undermine its ability to achieve sustainable savings for Medicare beneficiaries while preserving pharmaceutical innovation. The model's reliance on international price benchmarks makes it vulnerable to gaming by foreign countries, fails to address the underlying economics of global pharmaceutical markets, and cedes pricing authority to foreign governments with different healthcare values.

We urge CMS to instead pursue a comprehensive approach centered on establishing American value-based pricing benchmarks that:

1. Reflect what drugs are truly worth to American patients based on rigorous economic analysis
2. Incorporate outcomes-based agreements that link payment to effectiveness
3. Maintain incentives for continued pharmaceutical innovation
4. Are supported by complementary trade policy actions that require foreign countries to pay their fair share

This approach would achieve the Administration's goals of making critical medications more affordable for Medicare Part D enrollees while preserving or enhancing beneficiaries' quality of care—without the unintended consequences of the GUARD Model as proposed.

We appreciate the opportunity to comment on this important proposed rule and would welcome the opportunity to discuss these recommendations further with CMS leadership.

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