BEFORE THE
United States Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P, CMS-5546-P
Post Office Box 8013
Baltimore, Maryland 21244-8013

In the Matter of:	
Proposed Rules to Implement the Global Benchmark for Efficient Drug Pricing ("GLOBE") and Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Models	**File Code: CMS-5545-P** **File Code: CMS-5546-P**

COMMENT OF THE CENTER FOR INDIVIDUAL FREEDOM
URGING WITHDRAWAL OF PROPOSED GLOBAL BENCHMARK FOR EFFICIENT DRUG PRICING (GLOBE) AND GUARDING U.S. MEDICARE AGAINST RISING DRUG COSTS (GUARD) MODELS

February 23, 2026

I. Introduction

America's tradition of free market principles and unrivaled protection of intellectual property ("IP") rights account for our continuing status as the world's leading innovator and producer of lifesaving pharmaceuticals, without any close competitor.

Dangerously, however, the proposed rules to implement the Global Benchmark for Efficient Drug Pricing Model ("GLOBE Model") and the Guarding U.S. Medicare Against Rising Drug Costs ("GUARD Model") would undermine those pillars of American exceptionalism by importing foreign government price controls, and only harm the very consumers that they aim to help by reducing access to critical drugs. Although styled as separate initiatives, both GLOBE and GUARD share a common defective method: expanded federal intervention into drug pricing through so-called "Most Favored Nation" ("MFN") international

price controls and alternative rebate calculations. Both GLOBE and GUARD represent sweeping departures from market-based systems, and exceed the limited demonstration authority that Congress conferred upon the Center for Medicare & Medicaid Innovation ("CMMI").

Accordingly, the Center for Individual Freedom ("CFIF") submits this Comment to urge withdrawal of the proposed GLOBE and GUARD Models, in order to spare American consumers the harms inflicted on consumers in foreign countries that impose the drug price controls that the proposal seeks to import.

CFIF is a non-profit, non-partisan 501(c)(4) organization with over 300,000 grassroots supporters and activists across the United States, established in 1998 for the purpose of safeguarding and advancing Constitutional rights, technological innovation, free market principles and fidelity to the rule of law. As a central part of that mission, CFIF advocates for public policies that preserve the United States of America's standing as the world's most innovative nation, including in the field of pharmaceutical advances, and that ensure the American public maintains access to the safest, most effective and most comprehensive array of life-saving and life-improving pharmaceuticals possible.

The proposed models at issue here contravene that mission, and on that basis CFIF respectfully submits this Comment urging their withdrawal.

II. Discussion

1. The GLOBE and GUARD Models Would Undermine Pharmaceutical Access and Affordability

Artificial price controls imposed by governments have never worked as advertised or intended, regardless of the product or service affected, and regardless of era.

Nevertheless, some governments continue to follow the destructive siren song of price controls under the justification that they will reduce prices. In the instant matter, CMS frames both the GLOBE and GUARD models as mechanisms to reduce spending while preserving

quality of care, based upon the fundamental rationalization that blunt price control mechanisms – whether through international reference pricing under the GLOBE Model or modified inflation rebate calculations under the GUARD Model - will somehow reduce costs to Medicare and beneficiaries.

Decades and even centuries of experience and empirical evidence, however, demonstrate that price control regimes end up diminishing innovation, reducing availability and delaying access to targeted medicines, not expanding or accelerating that access.

A 2021 Congressional Budget Office (CBO) analysis, for example, showed that Most Favored Nation style price controls result in fewer pharmaceuticals coming to market and reduced innovation.[1] The CBO itself further detailed how price controls and consequent revenue reductions correlate with fewer new potential drugs entering development.

That foregone innovation isn't abstract – it translates to delayed or nonexistent cures.

As another example, research published by *Health Affairs* documented how nations that employ price controls suffer delays in patient access to newly approved therapies compared to the U.S.[2] Indeed, the U.S. leads the world in first-launch availability of new medicines, and accounts for an astounding two-thirds of all new drugs introduced to the world, which directly benefits American patients and consumers.[3]

Accordingly, the proposed models risk reversing that American preeminence.

Under the GLOBE Model, reimbursement levels for targeted drugs would become tethered to the artificially controlled prices imposed by foreign bureaucracies – many of which use health technology assessments designed to cap expenditures rather than maximize patient well-being

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1 *Congressional Budget Office, Effects of Drug Pricing Policies on Research and Development and Innovation (June 2021).*

2 *Aaron S. Kesselheim et al., "International Reference Pricing for Prescription Drugs," Health Affairs (2020).*

3 https://cfif.org/v/freedom_line_blog/25531/image-of-the-day-patent-rights-and-u-s-pharmaceutical-leadership/.

and outcomes. In response, manufacturers would be forced to delay or limit U.S. launches, withdraw products from market and curtail investment in research-intensive therapeutic areas.

Additionally, lower reimbursement levels don't automatically translate into lower out-of-pocket costs for supposed beneficiaries if provider participation is disrupted. The Government Accountability Office (GAO) previously documented cost differentials within Medicare that increase overall expenditures when care shifts to higher-cost settings, and a counterproductive drug price control regime risks precisely that outcome.[4] After all, affected drugs are typically physician-administered therapies, so if reimbursement costs plummet below acquisition and handling costs, then physicians will be forced to refer patients to hospital outpatient departments, which in turn raises overall healthcare system costs and disrupts continuity of care.

The GUARD Model would result in similar effect. By proposing to alter the calculation of Part D inflation rebates for certain drugs and biological products, GUARD effectively layers additional price suppression mechanisms atop existing statutory inflation penalties enacted under the counterproductive Inflation Reduction Act ("IRA"). Altering rebate structures would change manufacturers' pricing incentives in ways that would trigger the same reduction in revenues that the CBO warned would reduce drug research and development. The longer-term effect of rebate recalibration under the GUARD Model must therefore be assessed not in terms of short-term budget scoring, but rather in terms of foregone innovation to the detriment of patients.

2. CMS Acknowledges Systemic Model Interaction Risks Without Adequate Safeguards

The proposed rules also contravene United States Supreme Court guidance on regulations of such magnitude.

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[4] *U.S. Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (GAO-15-442).*

Specifically, both the GLOBE and GUARD proposed rules create the potential for interaction with other Medicare pricing mechanisms, including IRA drug price negotiation authority and existing inflation rebates. CMS, however, provides no clear structural exclusions preventing overlapping or cumulative application of those rules to the same covered drugs.

Consequently, that potential layering effect risks transforming what the proposal nominally labels "tests" into wholesale systemic restructuring of Medicare drug reimbursement mechanisms across Parts B and D.

Although Section 115A authorizes the testing of discrete models designed to reduce costs while preserving product quality, it does not authorize CMS to create overlapping nationwide price-control regimes that effectively avoid and substitute for Congressional legislation on the matter. As noted above, the Supreme Court has ruled that whenever federal agencies assert regulatory authority of such vast economic significance and impact, they must first possess clear Congressional authorization.[5]

Here, drug pricing overhaul for the Medicare program – affecting hundreds of billions of dollars annually – plainly qualifies as such a major question, and for that additional reason should be withdrawn.

3. Both GLOBE and GUARD Exceed the Scope of Legitimate "Model Tests"

Section 115A authorizes CMMI to test potentially innovative payment and service delivery models to reduce program costs while preserving or enhancing quality of care.[6] Historically, legitimate demonstrations pursuant to that section have involved limited geographic scope, voluntary participation or time-limited pilots.[7]

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5 *West Virginia v. EPA*, 142 S. Ct. 2587 (2022).

6 *Social Security Act § 1115A, codified at 42 U.S.C. § 1315a(a)(1)*

7 *Centers for Medicare & Medicaid Services, "Innovation Center Strategy Refresh" (2021), https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.*

In contrast, the instant proposals far exceed those constraints. For example, GLOBE would apply MFN-based pricing on a broad and mandatory basis, while GUARD would alter rebate calculations across significant segments of the Part D market. Both proposed models would also operate for multi-year durations rather than limited times, while participation would effectively be compulsory for affected manufacturers.

A nationwide, mandatory restructuring of reimbursement formulas of that magnitude simply doesn't constitute a pilot program, it constitutes a wholesale policy transformation.

With that in mind, courts have intervened to enjoin CMS when it has previously attempted to implement MFN-type rules for Part B drugs, citing both procedural and statutory objections.[8] The concerns that animated that decision – breadth, coerciveness and lack of statutory clarity – remain equally applicable in the instant matter, if not more so.

4. Importation of Foreign Price Controls Would Lead to Foreign Nations' Rationing and Unavailability

International reference pricing systems reflect harmful political choices made by foreign governments that frequently impose centralized budget caps, so-called Quality-Adjusted Life Year (QALY) limits and delayed reimbursement approvals. Those systems typically function within single-payer or much more heavily regulated markets compared to the United States, which results in rationing mechanisms fundamentally different than the more market-centered U.S. healthcare system. As even the Organization for Economic Cooperation and Development ("OECD") has documented, nations opting to benchmark drug prices with peer countries end up assuming those countries' single-payer or more heavily regulated markets characterized by rationing mechanisms. That is fundamentally incompatible with the U.S. healthcare system.[9]

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8 *Association of Community Cancer Centers v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020).

9 OECD, *Pharmaceutical Pricing Policies in a Global Market* (2019).

Similarly, the CBO has consistently warned that lower expected returns in pharmaceutical markets result in reduced research and development investment.[10] That's particularly harmful in the pharmaceutical industry, which is uniquely research-intensive. According to the National Science Foundation's Business Enterprise R&D Survey, for example, the pharmaceutical industry stands among the highest U.S. industries for R&D spending.[11]

By importing international reference pricing frameworks, the proposal would anchor U.S. reimbursement to prices artificially controlled in foreign single-payer or highly centralized healthcare systems, which would only result in fewer available drugs for American consumers, a result contrary to its stated aspirations.[12]

5. The Proposals Would Cede U.S. Pharmaceutical Leadership to Other Nations Like China

As noted above, the U.S. stands unrivaled in worldwide pharmaceutical innovation, accounting for fully two-thirds of all new drugs introduced to the world year after year. Additionally, as illustrated once again by a 2023 Information Technology and Innovation Foundation ("ITIF") analysis, the U.S. pharmaceutical sector significantly outpaces China and Europe in terms of venture capital investment.[13] That analysis warned, however, that imposing price control policies domestically would threaten that longstanding advantage.

Meanwhile, China aims to achieve global pharmaceutical leadership as a central pillar of its "Made in China 2025" industrial strategy.[14] Pursuing that strategy, China has increased state-backed investment and regulatory reform designed to capture greater global market shares.

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[10] *Congressional Budget Office, Effects of Drug Pricing Policies on Research and Development and Innovation (June 2021).*

[11] National Science Foundation, *Business Enterprise Research and Development Survey (BERD),* https://ncses.nsf.gov/surveys/business-enterprise-research-development/2023#data.

[12] https://cahc.net/wp-content/uploads/2023/10/Badger-Report-March-2019.pdf.

[13] Information Technology and Innovation Foundation, *The Case for a Robust U.S. Biopharmaceutical Sector* (2023).

[14] State Council of the People's Republic of China, *Made in China 2025* industrial policy documents.

Innovation ecosystems depend upon predictable returns on high-risk R&D investments. Government policies that systematically drive down expected returns – whether through MFN benchmarking (GLOBE) or stacked rebate recalculations (GUARD) – inevitably reduce capital investments.

Accordingly, the danger is obvious: If U.S. government policy foolishly imposes mechanisms that drive potential returns below sustainable levels, R&D capital will naturally migrate to foreign jurisdictions like China that begin to offer stronger innovation incentives.

If that occurs, the end result for American consumers won't be higher access and price relief, but rather diminished domestic R&D investment, diminished U.S. leadership and long-term risks to pharmaceutical availability and access.

That threat also implicates serious national security concerns. As the Covid pandemic illustrated, domestic biomedical capacity remains strategically important. To maintain and strengthen that capacity, we must preserve incentives for U.S.-based R&D versus foreign competitors like China. This is simply too great a risk to invite.

III. Conclusion

The proposed GLOBE and GUARD Models thus represent sweeping expansions of federal government price-control authority under the guise of model testing. They risk reduced patient access, suppressing innovation, distorting provider incentives and undermining America's global leadership in pharmaceutical research.

Furthermore, existing law and Supreme Court precedent do not authorize the implementation of nationwide, mandatory pricing transformations of this magnitude.

For these reasons, CFIF respectfully urges CMS to withdraw both the GLOBE and GUARD proposed rules, and instead pursue market-based reforms more consistent with statutory and judicial authority, as well as long-term patient and consumer welfare.

Respectfully submitted,

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