U.S. Chamber of Commerce

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February 20, 2026

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on Proposed GLOBE and GUARD Rules (CMS-3448-P and CMS-3449-P)

Dear Administrator Oz:

The U.S. Chamber of Commerce ("the Chamber"), the world's largest business organization—representing the interests of more than three million businesses of all sizes—submits these comments in response to the Centers for Medicare & Medicaid Services' ("CMS's") proposed rules establishing the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (collectively, "proposals" or "proposed rules").

The Chamber urges CMS to withdraw the proposed rules. The Chamber shares the Administration's goal of ensuring that Medicare beneficiaries have access to affordable, high-quality prescription medicines. But the proposals would not achieve this goal. Instead, the proposals—which would impose foreign price controls on a sweeping array of Medicare Part B and Part D drugs through mandatory price setting—would undermine American medical innovation, reduce patient access to lifesaving therapies, and exceed CMS's legal authority. Our concerns about these impacts are particularly acute with respect to the development of medicines for rare diseases, serious mental illnesses, and other conditions with significant unmet medical needs.

Below, we further explain our concerns and the reasons why the rules should be withdrawn.

I. THE PROPOSED RULES WOULD UNDERMINE AMERICAN MEDICAL INNOVATION AND THREATEN FUTURE PATIENT ACCESS

The proposals would fundamentally alter the incentive structure that has made the United States the global leader in biopharmaceutical innovation. This leadership is driven by strong intellectual property rights, high R&D investment, and a robust startup ecosystem. The biopharmaceutical sector depends on a stable and predictable

policy environment to attract the long-term investment required to bring breakthrough medicines to patients. By tying Medicare rebates to price controls imposed by foreign governments, these proposals would import the very policies that have stifled innovation abroad and have created significant barriers to patient access in other developed nations.

A. Foreign Price Controls Reflect Non-Market Mechanisms That Undervalue Life Science Innovation

The proposals incorrectly assume that the prices of medicines set by foreign governments (which are generally *not* negotiated by manufacturers under free-market conditions) represent appropriate reference points for U.S. law and policy. Many of the 19 OECD reference countries identified in the proposed rules employ centralized price-setting mechanisms, health technology assessment frameworks that explicitly ration patient care based on Quality Adjusted Life Years (QALYs), and other unfair and non-market-based barriers that deny basic intellectual property protections and market access to U.S. innovators. Sixteen of the nineteen reference countries rely on QALYs, either directly or indirectly, to determine whether and how to reimburse innovative medicines. U.S. law significantly restricts the use of QALYs in coverage, reimbursement, and payment decisions in federal health care programs, reflecting longstanding bipartisan concern that QALY-based frameworks discriminate against people with disabilities and undervalue the older population.[1]

As a general matter, foreign pricing systems do not reflect the true value of medical innovation or the costs associated with bringing new therapies to market. Rather, foreign prices represent deliberate policy choices by foreign governments to free-ride on American investment in research and development. As the Council of Economic Advisers recognized during the first Trump Administration, foreign governments can demand prices that cover only the marginal cost of production—not the far greater sunk costs from years of research and development. That is because once a medicine is already produced, manufacturers are better off selling even at a price just above marginal cost than they are not selling at all, notwithstanding the reality that such a price does not represent a true return on investment.[2] Prices set by such governments, therefore, are neither value-based nor market-based.

In light of this reality, devising a U.S. price (whether through a rebate mechanism or other means) based on an aggregation of such foreign prices cannot

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[1] *See* 42 U.S.C. § 1320e-1 (prohibiting CMS from using a metric that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill).

[2] *See* Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* 14 (Feb. 2018), available at https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

result in a reasonable, non-arbitrary price. Prices are set in different countries for a wide variety of reasons and combining them does not result in a reasonable price under any permissible approach to government price-setting. In addition, effectively delegating governmental price-setting authority to foreign governments, who are obligated to put their own citizens' interests first in making their decisions and are not politically accountable to the American people, is predictably arbitrary.

Importing foreign price controls into Medicare would not solve the problem of international free riding. Instead, it would exacerbate the problem by eliminating the market-based pricing that currently sustains global pharmaceutical innovation. The result would be fewer new medicines, delayed access to breakthrough therapies, and diminished American leadership in a sector critical to both public health and economic competitiveness. Tying the U.S. economy to other countries with weaker and even declining economies, and importing artificially low reference prices from such countries, would undercut, rather than support, the Administration's goal of ensuring that other countries contribute their fair share to global pharmaceutical innovation, while relieving American patients, payors, and innovators of a disproportionate burden.

B. The Proposed Rules Would Reduce Access to Innovative Medicines

Experience in countries with government-imposed price controls demonstrates that such policies consistently reduce patient access to innovative medicines. Evidence shows that in markets where governments set prices for medicines, patients have access to significantly fewer innovative therapies. For example, in the United States, 85% of newly launched medicines are currently reimbursed and available to patients. In contrast, only 24% of those same medicines are available in Australia, and only 21% of those same medicines are available in Canada. Moreover, even when medicines eventually become available in price-controlled markets, patients face substantial delays and often have access to fewer indications. For some medical conditions, even a 12–18 month delay in access can mean that patients permanently lose the opportunity for effective treatment.

The proposals would import these access barriers into the U.S. Medicare program. While CMS believes that the proposals would achieve $11.9 billion in Medicare Part B net spending reductions and $14.1 billion in Medicare Part D net spending reductions, the agency provides no meaningful analysis of how these dramatic reductions in manufacturer revenue would affect the development pipeline for new therapies or the continued availability of existing treatments. That omission is not only highly problematic from the perspective of sound policy and protecting patients, but arbitrary and capricious from a legal perspective. Notably, CMS itself acknowledges that GUARD is not expected to reduce beneficiary out-of-pocket costs.

With approximately 87% of Medicare Part B beneficiaries having some form of supplemental coverage, it is unlikely that patients will see meaningful reductions in their prescription drug costs under GLOBE either.

C. The Proposed Rules Would Negatively Impact Rare Disease Innovation

The Chamber is particularly concerned about the impact of the proposals on the development of therapies for rare diseases. Currently, approximately 10,000 rare diseases exist, and 95% still have no FDA-approved treatment. For patients and families affected by rare diseases, delays or disincentives in drug development can mean having no therapeutic options at all. Because many rare diseases are progressive and a substantial share present in childhood, reduced development or delayed access can have lasting public health consequences, including irreversible disease progression during critical stages of development.

Orphan drugs—therapies developed to treat rare diseases affecting small patient populations—operate under fundamentally different market dynamics than drugs for common conditions. Utilization is constrained by disease prevalence and diagnostic rates rather than by price responsiveness. The fixed costs of research, development, and regulatory approval must be recovered from a small patient population, often with limited or no therapeutic alternatives. Reference-based pricing frameworks are therefore particularly inappropriate in the context of orphan therapies and would produce severe unintended consequences for patient access and rare disease innovation.

Small and emerging biotechnology companies are responsible for the majority of early-stage and first-in-class therapies, particularly those that address rare diseases. These companies often rely on a limited number of programs to support continued investment across multiple rare disease indications. On average, small innovative companies developing treatments for rare diseases invest 52% of their budgets annually in research and development. Moreover, many smaller companies (among other manufacturers) out-license or co-license products for commercialization outside the United States and do not control foreign pricing or net price data. Introducing substantial pricing uncertainty through mandatory participation and international reference-based benchmarks would constrain access to capital and reduce the willingness and ability of small biotech companies to initiate or sustain development programs, including follow-on indications for additional rare diseases.[3]

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[3] The proposed models would functionally eliminate incentives for orphan drug development. Many rare diseases require platform-based R&D, where investment depends on projected returns across multiple small-population indications. Because platform technologies rely on revenue from early indications to fund subsequent applications, adopting unpredictable international reference pricing would make it significantly harder to sustain multi-indication development.

The proposals are highly problematic in this regard. For example, in the GUARD proposal, the threshold of $69 million in annual Medicare Part D spending to identify products that would be subject to the rule is unrealistically low and would capture virtually any manufacturer with a commercially viable drug on the market. This threshold does not function as a meaningful screen for size, risk, or capacity to absorb the impacts of the proposed pricing requirements. Small manufacturers, particularly those commercializing orphan and other drugs developed for the treatment of rare diseases, often rely on one or a few Medicare-covered therapies for the substantial majority of their revenue, due to limited patient populations and constrained commercial diversification. The impact of the proposed rules (if finalized) on such manufacturers would materially impair their financial viability and threaten the continued availability of treatments for rare disease patients. The proposed rules do not adequately take account of these considerations, and for these reasons alone are arbitrary and capricious.

D. The Proposed Rules Would Reduce Investment in Medical Innovation and Harm American Economic Competitiveness

The biopharmaceutical sector is a cornerstone of American innovation and economic competitiveness. The proposals would undermine incentives to invest in the research and development of new medicines, threatening future progress and the myriad benefits that innovative therapies provide to patients who rely on them. Biotechnology financing relies heavily on expected future pricing, not current revenue. Most small biotechnology companies[4] have no marketed products and depend entirely on capital markets—markets that react strongly to policy risk.

Economic analyses of most-favored-nation pricing policies have estimated that such policies would reduce medicines developed by small firms by up to 90%. Over a 20-year period, MFN policies would lead to 167 to 342 fewer new drug approvals and 160 to 326 million life years lost. If expanded beyond the proposed 25% of Medicare beneficiaries to encompass all beneficiaries, GLOBE and GUARD would lead to the loss of nearly 500,000 American jobs in the biopharmaceutical industry.

The proposals also threaten American leadership in biopharmaceutical innovation at a time when strategic competitors, particularly China, are attempting to take over global leadership in this critical sector. Weakening the incentive structure that has made the United States the world leader in medical innovation would have profound implications not only for American patients (and, indeed, patients around the world), but for U.S. economic security and national security.

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[4] Unlike large, diversified manufacturers, small biotechnology companies typically rely on a single asset to fund an entire R&D pipeline. Price controls applied to even one product can therefore jeopardize several future therapies.

II. THE PROPOSED RULES WOULD EXCEED CMS'S STATUTORY AUTHORITY AND WOULD OTHERWISE BE UNLAWFUL

The proposed rules exceed CMS's statutory authority. Section 1115A authorizes the Center for Medicare and Medicaid Innovation (CMMI) to "test innovative payment and service delivery models." But the proposals do not constitute legitimate "tests" within the meaning of the law and therefore cannot be lawfully implemented as CMMI models. And the proposals are subject to other serious legal defects.

A. The Proposed Rules Are Not "Tests" of "Models" Under The Law

Section 1115A authorizes CMMI to "*test* innovative payment and service delivery *models*" to determine how new Medicare or Medicaid policies would affect "expenditures" and "the quality of care" furnished under those programs. (Emphasis added.) The statute requires the Secretary to determine that there is evidence that a model "addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(b)(2)(A). And the Secretary must "focus on models expected to reduce program costs ... while preserving or enhancing the quality of care received by individuals receiving benefits[.]"

The proposals fail to satisfy these statutory requirements in several fundamental respects.

First, the proposals are not genuine "tests" designed to evaluate whether a new approach to payment or service delivery would improve quality or reduce costs. Rather, they are mandatory price-control mechanisms designed to achieve a predetermined outcome: lower net prices for prescription drugs as the result of creating a new source of revenue for the government. The outcome—reduced program expenditures without any reason to expect a positive impact on quality of care—is known in advance. The proposed "models" are not designed to test any hypothesis; they include no process for evaluating whether the "models" are successful; and they identify no comparison group that could be used to assess the "models'" effects. The proposals are simply mandates for higher rebates from manufacturers that apply price controls across the entire market, and are not experiments bearing the foundational research design elements necessary to assess causation, effectiveness, or unintended consequences. A true test model would employ a design that allows for meaningful evaluation of whether the intervention achieves its stated objectives. The proposed rules do not do this. Put otherwise, a mandatory, nationwide price control scheme is not an experiment; it is a policy determination.

Second, the statute requires the Secretary to select only models for which the Secretary "determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(b)(2)(A). The proposals do not address any such population. Instead, CMS proposes to select beneficiaries for inclusion in the models through a random selection of zip codes throughout the nation, representing approximately 25% of Medicare Part B beneficiaries (for GLOBE) and Medicare Part D enrollees (for GUARD). By doing nothing more than selecting zip codes at random, CMS would be doing the opposite of "defining" a specific population with specific deficits in care. In other words, CMS has not proposed to select beneficiaries who are distinguishable in any way from any other Medicare beneficiaries, much less to select beneficiaries for whom there is any reason to believe that there would be deficits in care within the meaning of the statute.

CMS asserts that high costs of medicines create deficits in care for all Medicare beneficiaries, but this assertion does not satisfy the statutory requirement to identify a "defined population" with specific care deficits.[5] If CMS's interpretation were allowed, the agency could use its CMMI authority to impose any policy change it wished on any subset of Medicare beneficiaries, so long as the agency asserted that the change would reduce costs. This interpretation would render the "defined population for which there are deficits in care" requirement meaningless and would grant CMMI virtually unlimited authority to rewrite Medicare policy without congressional authorization.

Moreover, there is no reason to expect that the proposed rules would "preserv[e] or enhanc[e] the quality of care received by" Medicare beneficiaries, 42 U.S.C. § 1315a(b)(2)(A). As explained above, the proposals are bound to lower the quality of care for Medicare beneficiaries, by reducing medical innovation and reducing patient access to beneficial therapies.

Third, the scope, scale, and mandatory nature of the proposals confirm that they are not proper "models" within the meaning of Section 1115A. GLOBE would apply to drugs representing approximately 55% of annual Medicare Part B fee-for-service drug spending, and GUARD would apply to a similarly broad swath of Medicare Part D spending. CMS estimates that the proposals would reduce Medicare spending by a combined $26 *billion* over the period when the rules would be in effect. CMS itself acknowledges that GLOBE "differs substantially from most mandatory [CMMI] models."

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[5] Moreover, CMS projects that GUARD, if made final, will significantly drive up out-of-pocket costs for Medicare Part D beneficiaries, which is inconsistent with CMS's rationale for proposing GUARD. This and other aspects of the proposals indicate not only that the proposals do not meet the statutory requirements for testing models, but that the proposals, if made final, would be arbitrary and capricious in violation of the Administrative Procedure Act.

The statute's structure further shows that Phase I "tests" must be limited in scope and duration. Section 1115A expressly references rulemaking by CMS only in subsection (c), which governs the "expansion" in Phase II of models that have already been tested, and contains no parallel grant of rulemaking authority for Phase I tests. The statute also provides that expansion of a successful Phase I project may "include implementation on a nationwide basis" in Phase II. 42 U.S.C. § 1315a(c). These aspects of the statutory structure support the conclusions that Phase I tests must be more limited than Phase II expansions, and that Phase I tests cannot be developed through rulemaking that would impose mandatory obligations.

For all the reasons described above, the proposals, which would apply mandatory price controls to a substantial portion of Medicare drug spending and would affect billions of dollars in transactions, cannot qualify as Phase I "tests."[6]

B. The Proposed Rules Raise Major Questions That Require Clear Congressional Authorization

The proposed rules raise "major questions" that require clear authorization from Congress. No such authorization is present; Section 1115A contains no indication that Congress intended to grant CMMI the expansive power to impose foreign price controls on Medicare prescription medicines using a rebate mechanism or any other mechanism. Since Medicare's creation, Congress has dictated the prices at which Medicare reimburses for prescription drugs through statutory formulae set forth, often in considerable detail, in dozens of sections throughout the U.S. Code. Those provisions influence a major sector of the American economy. Against that backdrop, it would be extraordinary—and would raise serious non-delegation questions—if Congress in a single statutory provision also granted CMMI the authority to effectively displace those statutory formulae with price control mechanisms of the agency's own entirely discretionary choosing.

C. The Proposed Rules Would Violate Constitutional Protections Against Arbitrary and Confiscatory Pricing

The proposals would also violate the Fifth Amendment's Takings Clause and Due Process Clause. By requiring punishing rebates if manufacturers don't sell their products at prices tied to foreign government price controls, the proposals would impose arbitrary and confiscatory pricing that does not allow for a reasonable return on investment, which the Constitution protects from expropriation.

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[6] Relatedly, CMS may not use civil money penalties to enforce GUARD or GLOBE. CMS lacks statutory authority to create administrative penalties to enforce aspects of models established under Section 1115A.

First, the proposals would demand new rebates from manufacturers in order to effectuate prices set by foreign governments are not market-based or value-based, as noted above. Anchoring U.S. prices to these artificially suppressed foreign prices would not allow manufacturers to recover a just and reasonable return on their investments and would constitute an arbitrary and confiscatory taking of property without just compensation, and would also violate due process requirements.

Second, as noted above, many manufacturers, particularly small and emerging companies, out-license or co-license products for commercialization outside the United States and do not control, and may not have access to, foreign pricing or net price data. Tying U.S. prices to international prices that manufacturers do not control risks imposing compliance and financial consequences on those businesses that are wholly disconnected from their actual pricing decisions. This approach is fundamentally arbitrary and violates basic principles of due process.

CONCLUSION

The Chamber appreciates the opportunity to comment on the proposals. We respectfully submit that the proposals would undermine American medical innovation and competitiveness, would reduce patient access to lifesaving therapies, and would be unlawful. We urge CMS to withdraw the proposals and to work with stakeholders to develop alternative approaches that can achieve the Administration's affordability goals without undermining the innovation ecosystem that has made the United States the global leader in biopharmaceutical research and development.

Should you have any questions regarding these comments, please do not hesitate to contact us.

Sincerely,

Neil L. Bradley
Executive Vice President, Chief Policy Officer,
and Head of Strategic Advocacy
U.S. Chamber of Commerce