CALIFORNIA LIFE SCIENCES

February 23, 2026

VIA ELECTRONIC DELIVERY

Administrator Mehmet Oz
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244-8016

Re: Global Benchmark for Efficient Drug Pricing (GLOBE) Model (CMS-5545-P) & Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (CMS-5546-P)

California Life Sciences (CLS) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services (CMS) Global Benchmark for Efficient Drug Pricing (GLOBE) Model[1] and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model[2] proposed rules (hereinafter, "proposed rules").

CLS is California's leading advocacy organization for the life sciences and is proud to represent more than 1,300 organizations, with membership spanning biotechnology, biopharmaceutical, medical device and technology, diagnostic companies, venture capital firms, and research hospitals and universities. CLS is committed to working with the administration to maintain U.S. leadership in life sciences and ensure that American citizens are getting the best access to lifesaving medications. We thank CMS for the consideration of our comments and encourage the Agency to withdraw these proposals and instead adopt policies that ensure continued innovation in life sciences and preserve patients' access to treatments and therapies. Below are our comments on the GLOBE and GUARD proposed rules. We also incorporate by reference those comments separately submitted by the Biotechnology Industry Organization (BIO) [a partner trade association serving many CLS members and the biotechnology community nationally].

MFN Policies Undermine America's Biopharmaceutical Leadership, with California the Most Affected

CLS opposes these proposed rules in their entirety, as they pose an existential threat to life sciences organizations in California and the greater U.S. Proposals that would require biopharmaceutical companies to pay the lowest global rate through foreign reference pricing, also

[1] Global Benchmark for Efficient Drug Pricing (GLOBE) Model, 90 Fed. Reg. 60,244 (Dec. 23, 2025) (proposed to be codified at 42 C.F.R. pt. 513)
[2] Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, 90 Fed. Reg. 60,338 (Dec. 23, 2025) (proposed to be codified at 42 C.F.R. pt. 514).

referred to as "Most Favored Nation" (MFN) price setting, would ultimately erode America's standing as the global leader in biopharmaceutical innovation and severely harm patient access by importing price controls from countries that routinely delay or deny access to care. As the life sciences capital of the U.S., California would by far be hit the hardest of any state.

California leads the nation in life sciences industry employment, venture capital investment, economic output, and new drug discoveries.[3] The state is home to nearly 16,000 businesses in the life sciences sector, supporting a direct workforce of more than 345,000 jobs and over 1.04 million indirect jobs statewide. California's life sciences sector generates $392 billion in annual output, $18.8 billion in state and local tax revenue, and over $18 billion in direct federal tax revenue,[4] contributing to critical public revenue streams and creating long-term economic value across the supply chain, higher education, and health care systems. Manufacturing jobs alone make up 31.2% of the state's total life sciences workforce.[5] In 2024, California's life sciences sector helped drive the development of at least 12 new therapies approved by the FDA, the highest total among all the states.

However, international reference pricing policies would dramatically undermine this innovation ecosystem by weakening incentives to develop new therapies, delaying patient access to the latest innovations, and injecting substantial uncertainty into an industry that depends on long-term, high-risk investment.

A recent study[6] examining the effects of MFN policies if they were applied across Medicare demonstrates that even if MFN policies were applied to a subset of the Medicare population in the context of the proposed models, the impact on jobs and the economy would be severe. The study found that, over a 10-year period:

- Nationally, it is estimated that the implementation of MFN policies could lead to the loss of: over 2 million jobs (40% of current U.S. jobs in the biopharmaceutical industry); $600 billion in federal tax revenue; over $450 billion in state tax revenue; and $2.4 trillion in earnings.[7] It is also estimated that there would be 230 fewer new medicines,[8] and numerous other negative spillover effects, including a substantial reduction in venture capital funding.

[3] California Life Sciences – 2025 Sector Report
[4] California Life Sciences – 2023 Sector Report
[5] Business Wire– Biocom California's 2025 Economic Impact Report Highlights Importance of the State's Life Science Industry -- One of the Top Industries in the Fourth Largest Economy in the World
[6] Vital Transformations – Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on jobs, innovation, and state budgets: The Executive Summary
[7] Vital Transformations – Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on jobs, innovation, and state budgets: The Executive Summary
[8] We Work for Health – Major Milestone: U.S. Life Sciences Investments Top $500B+

- Of these national totals, it is estimated that California will suffer the most of any state, with potential losses of: 208,969 jobs; $8,618 million in federal tax revenue; $6,387 million in state tax revenue; and $46,944 million in earnings.[9]

It is important to emphasize that the economic devastation created by such policies would greatly undercut any estimated savings that CMS expects to achieve from these proposed rules. Across losses in jobs, federal and state tax revenue, and earnings, the states that stand to lose the most are California and other states that contribute far more in federal taxes than they receive in federal funding, such as Texas and New York. In terms of net contributions, of those 19 states that contributed more in federal taxes than they received in federal spending in 2024, the largest gaps were in California ($275.6 billion), New York ($76.5 billion), and Texas ($68.1 billion).[10] The estimated losses[11] in federal tax revenue from these "donor states" greatly reduces the ability of these proposed rules to achieve any meaningful and beneficial change for Americans. Instead, these proposed rules would likely result in a net negative for state and federal governments and the patients they represent.

Conclusion

California's life sciences industry supports high-wage jobs, drives scientific discovery, and generates critical public revenue, and the state's continued success depends on strategic domestic investments in infrastructure, research, education, and access to capital. CMS's proposed rules would put all that success at risk and could allow foreign adversaries to take the lead in life sciences development. The threat of foreign adversaries outpacing the U.S. in biopharmaceutical development is particularly acute when considering U.S. competition with China. Over the last two decades, China has executed a coordinated state-driven strategy aimed at achieving global economic and military supremacy through investments in biotechnology. China has already overtaken the U.S. in the number of registered clinical drug trials, produces upwards of 120,000 PhDs annually (three times the U.S.), and is now responsible for 30% of all global drug development. China's rapid encroachment in biomedical research is a direct result of its explicit and intentional prioritization of large-scale state investments in biotechnology and biopharmaceutical development.

Protecting U.S. incentives for orphan drug development is especially vital, as China is now explicitly prioritizing rare disease innovation through coordinated national investment and newly

[9] Vital Transformations – Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on jobs, innovation, and state budgets
[10] USA Facts – Which states contribute the most and least to federal revenue?
[11] Vital Transformations – Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on jobs, innovation, and state budgets

granted market exclusivity, positioning itself to compete directly with the U.S. in a field where our country's global leadership has long been essential.

One-size-fits-all price control policies are antithetical to America's longstanding commitments to free-markets, and the proposed rules would do nothing to stop foreign freeloading on U.S. innovation.[12] These models would create substantial challenges for innovators at all levels, particularly around cutting-edge and high-risk R&D, including for rare and ultra-rare disease therapies, next-generation treatment modalities, precision and personalized medicines, and more. Rather than confronting foreign trade and pricing policies that disadvantage U.S. patients and businesses, these models would instead merely serve to penalize the very innovators pushing the frontiers of science and taking on the greatest development risks.

CLS is committed to working with the administration to find more effective solutions to lower prices and increase access to lifesaving drugs, to maintain U.S. leadership in biotechnology, and enhance both national and economic security. We strongly urge CMS to reject any policy approach that would tie U.S. drug prices to those set by foreign governments, and to fully rescind the GLOBE & GUARD proposed rules in their entirety.

CLS welcomes any questions and further discussion on the topics above, and you can contact me at schung@califesciences.org.

Sincerely,



Sam Chung

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California Life Sciences

[12] The Hill – More than 50 Conservative Leaders Sign Letter Against Trump Drug Pricing Policy Codification