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*Application for admission *pro hac vice* forthcoming

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

BIOTECHNOLOGY INNOVATION ORGANIZATION; CALIFORNIA LIFE SCIENCES ASSOCIATION; and BIOCOM CALIFORNIA, *Plaintiffs,* v. ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; ABE SUTTON, in his official capacity as DIRECTOR OF	Civil Case No. 3:26-cv-13372 **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

THE CENTER FOR MEDICARE AND MEDICAID INNOVATION; and CENTER FOR MEDICARE AND MEDICAID INNOVATION,

Defendants.

Plaintiffs Biotechnology Innovation Organization ("BIO"), California Life Sciences Association ("CLS"), and Biocom California ("Biocom"), on behalf of themselves and their members (together, "Plaintiffs"), bring this action against Robert F. Kennedy, Jr., in his official capacity as the Secretary of the United States Department of Health and Human Services ("HHS"); HHS; Mehmet Oz, in his official capacity as the Administrator of the Centers for Medicare & Medicaid Services ("CMS"); CMS; Abe Sutton, in his official capacity as the Director of the Center for Medicare and Medicaid Innovation ("CMMI"); and CMMI (together, "Defendants"), and allege as follows:

INTRODUCTION

1. For nearly a decade, Congress has considered—and repeatedly rejected—legislation tying American drug prices to foreign government price controls. Yet the Executive Branch now claims unilateral authority to impose the policy Congress refused to enact. Invoking an obscure 2010 provision of the Affordable Care Act that allows CMS to "test" limited "payment and service delivery models," the agency has finalized a mandatory foreign-reference price-control regime, the Global Benchmark for Efficient Drug Pricing (GLOBE) Model.

2. In what CMS itself calls "a novel application" of its statutory authority, GLOBE applies to certain highly utilized drugs under Medicare Part B and creates an obligatory, seven-year-long Medicare "rebate" system, under which drug manufacturers must pay CMS the difference between the prices they charge in the United States and the government-controlled prices charged abroad. Global Benchmark for Efficient Drug Pricing (GLOBE) Model, 91 Fed. Reg. 62,936, 62,946 (Oct. 2, 2026).

3. CMS's asserted and admittedly novel statutory hook for these rebates is 42 U.S.C. § 1315a—a "minor" and "ancillary" provision of the Affordable Care Act. *NFIB v. Sebelius*, 567 U.S. 519, 704–05 (2012) (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). Section 1315a gives CMS, through CMMI, a targeted power to "test payment and service delivery models" that "address[] a defined population for which there are deficits in care." 42 U.S.C. § 1315a(b)(1), (b)(2)(A). In conducting those tests, CMS may "waive" certain statutory requirements, but only "as

may be necessary solely for purposes of carrying out" the test. *Id.* § 1315a(d)(1). GLOBE exceeds each of these limits.

4. First, GLOBE does not "waive" statutory requirements; it rewrites them. CMS calls GLOBE's new rebates "waivers" of the Part B inflation rebate Congress enacted in the Inflation Reduction Act of 2022 ("IRA"). But CMS acknowledges the inflation rebates remain fully in force "alongside" GLOBE. 91 Fed. Reg. at 62,940. GLOBE layers on top of them an *additional* set of rebates keyed to foreign prices rather than U.S. inflation-adjusted prices. Adding foreign-pricing rebates does not "waive" the inflation rebates—any more than a phone company "waives" a bill by adding new service fees atop existing charges. These are exactly the kinds of "new and substantially different" obligations that the Supreme Court has said "waiver" authority does not permit. *Biden v. Nebraska*, 600 U.S. 477, 498 (2023).

5. Second, GLOBE does not "address" a defined population with "deficits in care." The deficit CMS identifies is cost: coinsurance high enough to deter beneficiaries from obtaining necessary medicines. But GLOBE's population is defined not by patients' cost barriers but by randomly selected ZIP codes and drug categories on which the *government* spends the most money. And the vast majority of beneficiaries in the selected ZIP codes pay no Part B coinsurance because their supplemental insurance covers it in full. Nor does GLOBE "address" the identified deficit. CMS does not dispute commenters' estimate that only about 0.3% of beneficiaries would see any change in out-of-pocket costs under GLOBE. 91 Fed. Reg. at 62,982. A model that purports to target a cost barrier most of its population never faces, and relieves it for almost no one, does not address a deficit in care.

6. Third, GLOBE is not a "test" of a "payment and service delivery model." Congress authorized CMMI to test models that change both how Medicare pays for care *and* how that care is delivered. GLOBE does neither. It does not change how care is furnished or how Medicare providers are paid, instead extracting rebates from manufacturers, which receive no Medicare payments at all. Moreover, GLOBE is not a genuine "test." GLOBE does not purport to measure any change in how

care is furnished or delivered. Its outcome is foreordained: compelled payments to CMS will reduce Medicare spending. There is nothing to test.

7. The major questions doctrine exists precisely to prevent this kind of agency circumvention of Congress. When an agency claims authority to decide a matter of "deep economic and political significance," it must identify not merely some colorable statutory basis, but "clear congressional authorization" for the power it claims. *Nebraska*, 600 U.S. at 506 (citation omitted). CMS cannot identify clear authorization here because Congress has consciously and repeatedly denied it. Bills tying U.S. drug prices to foreign prices have been introduced during every congressional session since at least 2017. Yet Congress never enacted them. When Congress *did* legislate on Medicare drug pricing in the IRA, it pointedly declined any foreign-price benchmark and chose domestic reference points instead, confirming that "'[t]he basic and consequential tradeoffs' inherent in" reshaping these drug-pricing programs "'are ones that Congress would likely have intended for itself.'" *Id.* (quoting *West Virginia v. EPA*, 597 U.S. 697, 730 (2022)).

8. CMS cannot avoid scrutiny by claiming GLOBE has only a "limited footprint." 91 Fed. Reg. at 62,953. The major questions doctrine asks whether "the breadth of the authority that [the agency] has asserted" gives the court "reason to hesitate before concluding that Congress meant to confer such authority." *West Virginia*, 597 U.S. at 721 (citation omitted). The breadth of the authority asserted here is staggering: the ability to unilaterally control the price of Medicare drugs—a multibillion-dollar market, responsible for delivering countless life-saving therapeutic advances to American patients—by importing foreign price controls and disrupting the innovation incentive for the entire sector.

9. The major questions doctrine's application is reinforced by GLOBE's intrusion into "core congressional power[s]" under Article I: those governing appropriations, patents, and foreign commerce. *Learning Res., Inc. v. Trump*, 607 U.S. 229, 243 (2026) (plurality opinion); *see* U.S. Const. art. I, § 8, cls. 3, 8; *id.* § 9, cl. 7. Congress did not hand CMS the keys to rebalance these classic legislative judgments in a provision authorizing narrow payment-and-service-delivery models.

10. Even if Section 1315a conferred the requisite authority to set a foreign-price benchmark, which it does not, CMS's actions still would violate constitutional and statutory constraints protecting Congress's power of the purse. The Appropriations Clause, and federal statutes enforcing it, reserve to Congress alone the power to set agencies' funding levels. GLOBE circumvents those structural protections by routing unauthorized rebates into the Medicare trust fund rather than the Treasury's general fund, augmenting the sums of money Congress chose to provide through appropriations.

11. The constitutional violations do not end there. The Presentment Clause prescribes a single, finely wrought procedure for enacting or amending federal law. GLOBE bypassed that procedure by creating a new foreign-reference-price rebate "in addition to" the inflation rebate scheme Congress enacted, 91 Fed. Reg. at 62,940, amending the IRA by administrative fiat. If Section 1315a truly lets CMS impose that regime—choosing the countries, benchmark, drugs, duration, and penalties with no guiding standard—it would be an unconstitutional delegation of legislative power. CMS claims power to layer on a foreign-pricing regime Congress has repeatedly rejected, with no intelligible principle to guide or confine it. To avoid these serious constitutional questions, Section 1315a should not be construed to confer the extraordinary authority CMS claims.

12. GLOBE stands as a stark example of "the Executive seizing the power of the Legislature" to "enact a program that Congress has chosen not to enact itself." *Nebraska*, 600 U.S. at 503 (citation omitted). And that power grab harms not just Plaintiffs' members—the Nation's biotechnology companies—but the entire U.S. healthcare system. By incorporating foreign price-control regimes into Medicare, GLOBE is chilling investment, curtailing research, and delaying or even preventing the development of life-saving medicines. This Court should declare GLOBE unlawful, vacate it, and permanently enjoin its enforcement.

JURISDICTION AND VENUE

13. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief and injunctive relief, and hold unlawful and set aside agency action pursuant to 28 U.S.C.

§§ 2201–02 and 5 U.S.C. §§ 705–06. GLOBE is a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Agency action is presumptively reviewable, and that presumption is "particularly strong" when a plaintiff alleges that an agency exceeded delegated authority, *Nat'l TPS All. v. Noem*, 150 F.4th 1000, 1016 (9th Cir. 2025) (citation omitted), or brings a constitutional claim, *Ctr. for Biological Diversity v. Bernhardt*, 946 F.3d 553, 561 (9th Cir. 2019). Although Section 1315a contains a limited judicial review bar, it does not preclude Plaintiffs' claims here. The statute forecloses review of six discrete design-and-implementation choices: the "selection of models" and "participants"; a model's "elements, parameters, scope, and duration"; "budget neutrality" determinations; a model's "termination or modification"; and its "expansion." 42 U.S.C. § 1315a(d)(2). Courts have accordingly recognized that the provision "merely bars judicial review of particular facets of [CMMI's] models." *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 45 (S.D.N.Y. 2020). Plaintiffs do not ask the Court to second-guess a design choice within an otherwise authorized model.

14. Plaintiffs instead contend that CMS acted outside the statutory scheme altogether because GLOBE is not within the reticulated types of models Congress authorized. Construing the closely analogous review bar governing the IRA's Medicare drug-price "negotiation" program, the D.C. Circuit recently held that a challenge going to "the scope of CMS's statutory authority"—as distinct from "the quality of the reasoning underlying any such determination"—falls outside such a bar. *Teva Pharms. USA, Inc. v. Kennedy*, 187 F.4th 587, 605 (D.C. Cir. 2026), *pet. for reh'g en banc filed* (Oct. 2, 2026); *accord AbbVie Inc. v. HHS*, 2026 WL 3263439, at *6 (D.D.C. Oct. 29, 2026) (holding claims that "CMS exceeded its authority by having an erroneous interpretation" are not barred even where interpretations were "necessary, subsidiary decisions in the lead-up to an unreviewable . . . determination"). Plaintiffs, moreover, claim that CMS violated multiple constitutional commands in addition to statutory ones. Section 1315a(d)(2) makes no mention of these claims, and absent "clear" language of "intent" to preclude them, *Webster v. Doe*, 486 U.S. 592, 603 (1988), reading the statute to "bar[] substantial statutory and constitutional claims" would be "an extreme position." *Nat'l TPS All.*, 150 F.4th at 1016 (quoting *Bowen v. Mich. Acad. of Fam.*

Physicians, 476 U.S. 667, 680–81 (1986)). Nothing about Section 1315a(d)(2) justifies such an extreme position here.

15. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because CLS resides in this district and—given California's status as the Nation's leader in life sciences—a substantial part of the events or omissions giving rise to the claims occurred in this district.

DIVISIONAL ASSIGNMENT

16. Assignment to the San Francisco Division or the Oakland Division is proper under Civil L.R. 3-2(c)–(d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in San Mateo County, where Plaintiff CLS has its principal place of business and where many of Plaintiffs' members operate and will be injured by GLOBE.

PARTIES

17. **Plaintiff Biotechnology Innovation Organization** is a nonprofit corporation organized under the laws of the District of Columbia, with its principal place of business in Washington, D.C. BIO was founded to advance the interests of the biotechnology industry. It is committed to establishing and furthering policies that foster biomedical innovation, expanding access to life-changing medicines, and securing America's position as the global leader in biotechnology.

18. BIO represents over 900 biotechnology companies and investors, academic institutions, state biotechnology centers, and related organizations. BIO's members—hundreds of which are located in California, and more than half of which are emerging small-to-mid-size biotechnology companies—are involved in the research and development of innovative healthcare and biotechnology products. They depend on a U.S. market-based system that rewards innovation and enables continued investment in the discovery and development of new medicines. As a leading policy advocate for the biotechnology industry, BIO represents its members' interests before Congress, the Executive Branch, state legislatures and agencies, and the courts.

19. Opposing the GLOBE rule and its effects on the biotechnology innovation ecosystem is central to BIO's organizational purpose. GLOBE will threaten every segment of BIO's

membership by disincentivizing investment in biotechnology innovation, reducing the funding BIO members can devote to research and development, and resulting in fewer approvals of novel treatments for patients with serious and complex diseases. Moreover, GLOBE covers products manufactured by BIO members, meaning that BIO members are subject to GLOBE's rebates and administrative burdens.

20. **Plaintiff California Life Sciences Association** is a nonprofit organization with offices in South San Francisco, Sacramento, and San Diego, California, as well as in Washington, D.C. CLS's principal place of business is in South San Francisco, California, where all of its officers work and from which they direct, control, and coordinate CLS's activities. CLS is a leading advocacy organization for the life sciences in California. Its mission is to advance California's world-leading life sciences innovation ecosystem by advocating for effective national, state, and local policies that affect entrepreneurs and life sciences businesses. To do so, it works closely with industry, government, academia, patient groups, and others to shape public policy, improve access to innovative technologies, and grow California's life sciences economy.

21. CLS represents approximately 1,300 organizations—most of which are located in California—ranging from biotechnology, pharmaceutical, medical device, and diagnostics companies; to research universities and institutes; to investors and service providers including contract manufacturing organizations and contract research organizations.

22. Challenging GLOBE is key to CLS's organizational mission. CLS exists to advocate for policies that support California's life sciences sector, and GLOBE threatens those interests by undermining the incentives that foster biomedical innovation, discouraging investment in life sciences companies, and impairing patient access to new therapies. A number of CLS members are subject to GLOBE and thus will also be harmed by its rebates and administrative burdens.

23. **Plaintiff Biocom California** is a nonprofit corporation organized under California law, with its principal place of business in San Diego, California. Biocom is an international life sciences advocacy and business organization that exists to advance, foster, and encourage the life sciences industry in the state of California. It works to advance policies that support the research,

development, and delivery of innovative products intended to improve health and quality of life for patients, including those policies that foster a competitive regulatory and investment-friendly environment that enables a fair reimbursement and pricing landscape. Biocom also works to defeat policies that would be detrimental to these objectives.

24. Biocom represents approximately 1,800 members, the vast majority of which are located in California. Its members include biotechnology, pharmaceutical, medical device, genomics, diagnostics, healthtech, and agbio companies of varying sizes, along with research universities and institutes, clinical research organizations, investors, and service providers. The companies and institutions Biocom represents span the full innovation life cycle, from early-stage research and product development to commercialization and patient access.

25. Opposing GLOBE is foundational to Biocom's organizational purpose because GLOBE will cause substantial harm to Biocom's members and the broader life sciences industry. Biocom members are currently subject to GLOBE's mandatory rebate requirements and costly compliance obligations. GLOBE will also harm Biocom members that are developing products that, if approved, would become subject to GLOBE, including early-stage research companies and the firms that seek to invest in those early-stage research companies. GLOBE severely harms Biocom's members by suppressing investment levels across the life sciences sector.

26. **Defendant Robert F. Kennedy, Jr.,** is Secretary of HHS and is sued in his official capacity.

27. **Defendant HHS** is an executive department of the federal government headquartered in Washington, D.C. HHS is responsible for CMS, CMMI, and the Medicare program.

28. **Defendant Dr. Mehmet Oz** is the Administrator of CMS and is sued in his official capacity.

29. **Defendant CMS** is an agency within HHS that is headquartered in Baltimore County, Maryland. CMS administers the Medicare program.

30. **Defendant Abe Sutton** is the Director of CMMI and the CMS Deputy Administrator and is sued in his official capacity.

31. **Defendant CMMI** is a center within CMS and is headquartered in Baltimore County, Maryland.

BACKGROUND

Investment in Research and Development Drives Pharmaceutical Innovation

32. The biotechnology industry is among the most research-intensive sectors of the U.S. economy. Biotechnology companies harness advances in biology, genomics, and molecular science to discover and develop innovative medicines for patients with serious and life-threatening conditions, including cancer, rare diseases, and chronic conditions. Plaintiffs' members manufacture many of the most innovative medicines in America—including widely used medicines that are covered under Medicare Part B.

33. Developing a new medicine is a lengthy, costly, and uncertain process that can span more than a decade and require billions of dollars of capital investment. It begins with years of preclinical research to identify and evaluate potential therapeutic candidates. Promising candidates then enter a multiphase clinical trial process designed to evaluate safety and efficacy, with each successive phase involving larger patient populations and greater costs. Only after successful completion of clinical trials can a company submit its product for regulatory review and approval.

34. The odds of success are extraordinarily low. At every stage, investigational therapies can fail. Most do. Even among compounds that appear promising enough to enter human clinical trials, approximately nine in ten fail to secure FDA approval.[1]

35. Because most drug candidates fail, the revenue from the small number of medicines that do reach the market must support more than the cost of developing those individual medicines. It must also help cover the substantial costs of unsuccessful research programs and fund the next generation of research and development. Biopharmaceutical companies reinvest approximately 33%

[1] Letter from John F. Crowley, President & CEO, BIO, to John Thune, Senate Majority Leader, Charles E. Schumer, Senate Minority Leader, Mike Johnson, Speaker of the House, & Hakeem Jeffries, House Minority Leader (Feb. 9, 2026), https://bio.org/letters-testimony-comments/letter-bio-president-ceo-john-f-crowley-senate-and-house-leadership.

of their sales revenue into research and development—nearly nine times the average for U.S. healthcare companies overall.[2]

36. Given the long odds and substantial risk, continued investment in pharmaceutical innovation is driven by a single prospect: that if a medicine successfully reaches the market and addresses a significant unmet patient need, it will have the opportunity to earn market-based returns.

37. Continued investment is critical, not just for large companies, but for the many small and mid-sized companies that drive biotechnology innovation in the United States. Those companies commonly rely on external financing from private investors willing to fund high-risk, early-stage research to sustain their research and development programs.

38. California is at the heart of this innovation ecosystem. It leads the country in life sciences industry employment, venture capital investment, economic output, and new drug discoveries.[3] California is home to nearly 16,000 life sciences businesses that produce some of the world's most important and innovative therapies.[4] Its life sciences workforce is the largest in the country (with a direct workforce of more than 345,000 jobs) and is among the most diverse and high-performing.[5] Biopharma research and development and manufacturing account for over 115,000 of those jobs.[6] Hundreds of BIO's members are located in California, as are the majority of CLS's members and Biocom's members.

39. More bioscience and biotechnology patents are issued to California companies and researchers than to those of any other state.[7] California's life sciences sector generates over $390

[2] Nam D. Pham, Sally C. Pipes, & Wayne Winegarden, *Imbalance of Financial Risks and Economic Rewards in the U.S. Healthcare Supply Chain*, at 11, Pac. Rsch. Inst. (Jan. 2026), https://pacificresearch.org/wp-content/uploads/2026/01/CMEI_HCSupplyChainFin_F_web.pdf.

[3] *See* Cal. Life Scis., 2025 Sector Report 4 (2025), https://califesciences.org/wp-content/uploads/2025/05/FINAL-2025-Sector-Report.pdf [hereinafter "CLS 2025 Rep."]; Cal. Bus. & Econ. Dev., *Biotech*, https://business.ca.gov/industries/biotech/ (last visited Nov. 5, 2026).

[4] CLS 2025 Rep., *supra* n.3, at 4.

[5] *Id.*

[6] *Id.*

[7] Cal. Bus. & Econ. Dev., *Biotech*, *supra* n.3.

billion in annual output and $18.8 billion in state and local tax revenue.[8] These contributions sustain critical public revenue streams and create long-term economic value across the supply chain, higher education, and healthcare systems.[9] Because California's life sciences sector is so large and so research-intensive, policies that suppress returns on innovative medicines have especially serious consequences in this State.

Congress Established a Statutory Framework That Encourages Innovation

40. Congress has long recognized both the public's vital interest in robust medical research and the extraordinary risks, costs, and uncertainties inherent in developing new medicines. To encourage the development of new innovative medicines, Congress has enacted and repeatedly refined a carefully calibrated statutory framework that rewards innovators with certain exclusive rights and the opportunity to earn market-based returns.

41. That framework rests on the Patent Clause, which assigns to Congress the exclusive authority "[t]o promote the Progress of Science and useful Arts" by securing to inventors exclusive rights in their discoveries for limited periods. U.S. Const. art. I, § 8, cl. 8; *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 428–29 (1984). Under federal patent laws, companies that successfully develop new medicines may obtain patent protection for their inventions. *See* 35 U.S.C. § 154. Congress has built on that foundation by establishing pharmaceutical-specific regulatory exclusivities, under which new drugs receive market exclusivity rights for a specified number of years. *See infra* ¶ 98. Taken together, these protections encourage the development of new medicines while preserving pathways for competition.

42. The value of these exclusive rights lies in the opportunity they create to earn market-based returns, which accompanies the right to sell that product at the market price that exclusivity permits. *See Biotechnology Indus. Org. v. District of Columbia* ("*BIO*"), 496 F.3d 1362, 1373 (Fed. Cir. 2007). This free-market system enables biotechnology companies to recoup some of the

[8] CLS 2025 Rep., *supra* n.3, at 5.

[9] *Id.*

substantial costs and risks associated with pharmaceutical development and incentivizes ongoing innovation.

43. Investors in the United States receive a market-based return on their investment, but only from the few products that ultimately make it to market and are successful. Those returns, in turn, drive investment in discovery, which leads to clinical trials and ultimately valuable new treatments and cures that address unmet needs. The United States has consistently ranked as the number-one intellectual-property environment in the world for more than a decade, ahead of all other top economies.[10] Price controls, by contrast, sharply curtail the potential return on investment and deny companies the funds they need to develop new medicines. Countries that impose price controls access new drugs months or years after they are available in the United States, if they become available at all.[11]

44. Congress also has repeatedly confronted the specific policy of tethering U.S. drug prices to foreign prices and has declined to enact it. Bills that tied prices of certain drugs sold in the United States to the prices of drugs sold abroad have been proposed in every Congress since 2017,[12] but Congress never enacted them.

45. When Congress did legislate on Medicare drug pricing in the IRA, Pub. L. No. 117-169, 136 Stat. 1818 (2022), it considered and rejected a proposed foreign-price benchmark and chose a fundamentally different, domestically grounded metric. The precursor to the IRA proposed

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[10] *See* Remarks by John A. Squires, Under Secretary of Commerce for Intellectual Property, U.S. Chamber of Commerce International IP Index (Mar. 16, 2026), https://uspto.gov/about-us/news-updates/remarks-director-us-chamber-commerce-international-ip-index; *see also, e.g.*, 2026 International IP Index, U.S. Chamber of Com. (Mar. 11, 2026), https://uschamber.com/intellectual-property/2026-international-ip-index; 2025 International IP Index, U.S. Chamber of Com. (Apr. 15, 2025), https://uschamber.com/intellectual-property/2025-ip-index.

[11] BIO, *Importing International Reference Pricing in the U.S. Jeopardizes Patient Access to Innovative Medicines*, https://bio.org/save-cures (last visited Nov. 5, 2026).

[12] *See, e.g.*, Medicare Drug Price Negotiation Act, H.R. 4138, 115th Cong. (2017); Medicare Drug Price Negotiation Act, S. 2011, 115th Cong. (2017); Medicare Negotiation and Competitive Licensing Act of 2018, H.R. 6505, 115th Cong. (2018); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. (2021); End Price Gouging for Medications Act, H.R. 4215, 118th Cong. (2023); Fair Prescription Drug Prices for Americans Act, S. 1218, 118th Cong. (2023); Global Fairness in Drug Pricing Act, H.R. 3493, 119th Cong. (2025); Fair Prescription Drug Prices for Americans Act, S. 1587, 119th Cong. (2025); Most Favored Patient Act of 2026, H.R. 7837, 119th Cong. (2026).

tying prices under the "Fair Price Negotiation Program" to the "average international market price."[13] However, when establishing the "Drug Price Negotiation Program" under the IRA, Congress adopted entirely domestic reference points, capping the "maximum fair price" required for drugs selected for "negotiation" under the Act at the lowest of the drug's enrollment-weighted Part D negotiated price (for Part D drugs), its U.S. average sales price (for Part B drugs), or a percentage of the drug's U.S. non-federal average manufacturer price. *See* 42 U.S.C. § 1320f-3(c).

46. Congress thus considered foreign reference pricing numerous times, understood what it entailed, and consciously rejected it, opting instead to key prices to U.S. market benchmarks.

Medicare Part B Provides Coverage for Innovative Medicines

47. Medicare is the federal health insurance program for people who are 65 years or older, as well as individuals with certain disabilities or conditions.[14] Medicare is divided into multiple "Parts," with prescription drugs covered primarily through Parts B and D. Medicare Part B covers prescription drugs a patient receives at a doctor's office or clinic, such as an infusion or injection given by a doctor or nurse. 42 U.S.C. § 1395x(s)(2)(A)–(B), (6). It also covers drugs given through medical equipment, such as an infusion pump, and certain drugs specified by statute, including certain vaccines, oral cancer drugs, and immunosuppressive therapy. *Id.* § 1395x(s)(2)(J), (Q); *id.* § 1395x(s)(10)(A)–(B). Part D, by contrast, generally covers the prescription drugs that patients have filled at pharmacies. *Id.* § 1395w-101. Medicare Part B and Part D are funded differently, and patients have different cost-sharing responsibilities under each.

48. Medicare Part B is part of the "Original Medicare" program, in which the federal government directly pays providers for covered services. It is funded by the Supplementary Medical Insurance (SMI) Trust Fund, which contains congressional appropriations and other funds as directed by statute. 42 U.S.C. §§ 1395w, 1395t, 1395s(f).

49. Drug reimbursements under Medicare Part B reflect Congress's choice to protect innovation. When a beneficiary receives a Part B drug, Medicare "reimburses"—that is, pays—the

[13] Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 117th Cong. 28–30 (2021).

[14] Paulette C. Morgan & Phoenix Voorhies, *Medicare Overview*, Cong. Rsch. Serv. (July 8, 2024), https://congress.gov/crs-product/IF10885.

provider for it according to a formula Congress has prescribed. For most drugs, Congress has long required Medicare to base that reimbursement on the drug's "average sales price" of all sales "in the United States." *See* 42 U.S.C. § 1395w-3a(b)(1)(B), (c)(1). By tying Part B payments to domestic market transactions, Congress ensured that reimbursement tracks prices formed in the U.S. market, giving manufacturers the opportunity to earn the competitive returns that encourage and fund future innovation.

50. Patients pay only a small share of that amount, if any. Once patients meet their $283 annual deductible, Medicare generally pays 80% of a Part B drug's Medicare reimbursement amount, and the patient is responsible for the remaining 20% (called a "coinsurance" payment). But approximately 90% of Part B beneficiaries have supplemental insurance that covers their coinsurance, meaning they pay little or nothing out-of-pocket for Part B drugs.[15] Many beneficiaries purchase supplemental insurance (called "Medigap") from private health insurers, and over 99% of those beneficiaries have plans that cover their Part B coinsurance costs in full.[16] Others have supplemental coverage through employer-sponsored retiree benefits,[17] while low-income beneficiaries may qualify for supplemental coverage through Medicaid,[18] a joint federal-state program that provides health insurance coverage for low-income individuals.

Congress Established CMMI as a Limited Testing Authority Under Section 1315a

51. Against this backdrop, Congress created a narrow, experimental authority to seek new and more efficient ways to finance and deliver medical services under Medicare and Medicaid. In

[15] Amanda Tripp & Kolton Gustafson, *How MFN Pricing in Part B May Affect Beneficiary OOP Costs*, Avalere Health (Jan. 21, 2026), https://avalerehealth.com/thought-leadership/how-mfn-pricing-in-part-b-may-affect-beneficiary-oop-costs/.

[16] *Compare Medigap Plan Benefits*, Medicare.gov, https://medicare.gov/health-drug-plans/medigap/basics/compare-plan-benefits (last visited Nov. 5, 2026) (showing that all but Medigap Plans K and L cover 100% of the Medicare Part B coinsurance); Meredith Freed et al., *Key Facts About Medigap Enrollment and Premiums for Medicare Beneficiaries*, KFF (Oct. 13, 2026), https://kff.org/medicare/key-facts-about-medigap-enrollment-and-premiums-for-medicare-beneficiaries/ (showing that less than 1% of Medigap enrollees are enrolled in Plans K and L).

[17] *Retiree Insurance & Medicare*, Medicare.gov, https://medicare.gov/basics/get-started-with-medicare/medicare-basics/working-past-65/retiree-insurance (last visited Nov. 5, 2026).

[18] *Beneficiaries Dually Eligible for Medicare & Medicaid*, Medicare Learning Network (June 2024), https://cms.gov/files/document/beneficiaries-dually-eligible-medicare-medicaid.pdf.

2010, as part of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3021, 124 Stat. 119, 389 (2010), Congress established within CMS a center known as CMMI.

52. A "minor" and "ancillary" provision of the Affordable Care Act, *NFIB*, 567 U.S. at 704–05 (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting), Section 1315a empowers CMS through CMMI to conduct bounded tests of new payment and service-delivery models and, where necessary to carry out such a test, to waive a specified set of otherwise applicable statutory requirements.

53. The provision's purpose is narrow and specific: "to test innovative payment and service delivery models to reduce program expenditures under [Medicare and/or Medicaid] while preserving or enhancing the quality of care furnished to individuals under such subchapters." 42 U.S.C. § 1315a(a)(1).

54. Section 1315a does not grant CMS open-ended authority to determine the price the Nation pays for prescription drugs. Rather, it requires that the Secretary "select models to be tested from models where 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." *Id.* § 1315a(b)(2)(A). Every operative word of that grant imposes a limitation:

55. **The model must identify a "defined population" characterized by "deficits in care."** CMS's discretion to select a model for testing is expressly cabined. The agency may proceed only where it "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." *Id.* § 1315a(b)(2)(A). The determination must be "evidence"-based. *Id.* The deficit must be one "in care," and it must be what "lead[s] to" poor outcomes or avoidable expenditures. *Id.* The statute requires deficits in care that lead to potentially avoidable expenditures; a desire to reduce spending, standing alone, does not suffice.

56. **The model must "address" those "deficits in care."** It is not enough to identify a population with deficits in care. The model must also "address" those deficits, meaning the model

must "deal with or give attention to" them.[19] The evaluation mandate confirms that "addressing" care deficits requires more than conjecture: by requiring an "analysis of the quality of care furnished under the model" measured against "patient-level outcomes," *id.* § 1315a(b)(4), it presupposes that the agency has a genuine, measurable theory of how the model will affect beneficiary care—a theory that can be tested against those outcomes.

57. **The Secretary may test only "payment and service delivery models," a phrase whose meaning is informed by Congress's extensive examples and selection factors.** Read in context, the conjunctive phrase describes an integrated model connecting how Medicare pays for care with how that care is organized or furnished; it does not encompass every financial obligation that an agency labels a "payment."[20] Both terms have settled meanings in the health care field. As defined by CMS in 2013, a "payment model" refers to "the manner in which a payer reimburses providers."[21] In other words, it is the system or structure by which insurers and government programs (like Medicare) pay doctors, clinics, and hospitals for the care they provide.[22] Payment models can include a traditional "fee-for-service" model, bundled payments, or value-based payment models.[23] A "service delivery model," CMS explained, "refers to the manner in which providers organize and deliver care to patients,"[24] such as who provides it, where, and how it is coordinated. So a "payment and service delivery" model must address *both* how Medicare pays providers for care and how that care is delivered to patients.

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[19] *Address*, Merriam-Webster, https://merriam-webster.com/dictionary/address (last visited Nov. 5, 2026).

[20] *See* Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 116 (2012).

[21] CMS, *Health Care Innovation Awards – Round Two: Payment Models*, at 8 (July 11, 2013), https://cms.gov/priorities/innovation/files/slides/hciatwopymtmdls.pdf.

[22] *See, e.g.*, Health Care Payment Learning & Action Network, *Alternative Payment Model (APM) Framework Fact Sheet* (2025), https://hcp-lan.org/wp-content/uploads/2025/08/APM-Framework-Factsheet.pdf; *United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018) (using the terms "payment model" and "payment structure" interchangeably to describe Medicare's traditional fee-for-service model for paying healthcare providers).

[23] *See, e.g.*, Darshak Sanghavi et al., *The Beginner's Guide to New Health Care Payment Models*, Brookings Inst. (July 23, 2014), https://brookings.edu/articles/the-beginners-guide-to-new-health-care-payment-models/.

[24] CMS, *Health Care Innovation Awards*, *supra* n.21, at 7.

58. This understanding is bolstered by the illustrations Congress listed, which, while not exhaustive, contemplate a narrowly targeted change in payment structure and service delivery with a direct connection to how care is furnished, coordinated, or delivered to patients. These examples include, among others:

a. "Promot[ing] care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment," 42 U.S.C. § 1315a(b)(2)(B)(iv);

b. "Funding home health providers who offer chronic care management services," *id.* § 1315a(b)(2)(B)(xiv); and

c. "Focusing on risk-based models for small physician practices which may involve two-sided risk and prospective patient assignment, and which examine risk-adjusted decreases in mortality rates, hospital readmissions rates," and other clinical measures, *id.* § 1315a(b)(2)(B)(xxiii).

59. Congress's list of eight "additional factors" for CMS to consider in "selecting models for testing," *id.* § 1315a(b)(2)(C), reinforces that Congress envisioned models that would focus both on payment and on how care is coordinated, organized, and delivered. Seven of the factors address practical aspects of care-delivery reform: whether a model monitors and updates patients' care plans; centers the patient and caregiver team; provides in-person contact; uses technology to coordinate care across settings; maintains close ties among care coordinators and providers; takes a team-based approach; and enables real-time information sharing. *Id.* § 1315a(b)(2)(C)(i)–(vii). The eighth is structural, addressing "effective linkage with other public sector payers, private sector payers, or statewide payment models." *Id.* § 1315a(b)(2)(C)(viii).

60. **The model must be a genuine "test."** Section 1315a directs the Secretary to "test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care" and to select, evaluate, and—only under prescribed conditions—expand them. 42 U.S.C. § 1315a(a)(1). A genuine "test" presupposes an uncertain hypothesis that the agency intends to evaluate—an identifiable research question likely to yield

useful information about whether a novel approach improves program outcomes. Indeed, Section 1315a contains an express "evaluation" requirement that presupposes an uncertain outcome: Congress required the Secretary to "*evaluate*" each model, including through "an analysis of the quality of care furnished under the model," which includes "the measurement of patient-level outcomes and patient-centeredness criteria," and an assessment of "changes in spending" attributable to the model. 42 U.S.C. § 1315a(b)(4) (emphasis added). An agency may not convert a "simple benefits cut" carrying "no research or experimental goal" into a statutory experiment merely by labeling it a "test." *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (construing a closely analogous demonstration authority under Section 1115 of the Social Security Act and holding a "simple benefits cut" is not a "test").

61. **The statute's phased structure is built around evaluation.** Section 1315a provides a two-phase process for testing and expanding models. Every model begins with Phase I testing, during which the Secretary must evaluate its effects on program spending and the quality of care, including "patient-level outcomes" and "patient-centeredness criteria." 42 U.S.C. § 1315a(b)(1), (4). That evaluation supplies the foundation for Phase II: before expanding a model's duration or scope, including nationwide, the Secretary must consider the evaluation and determine that expansion is expected to reduce spending without reducing quality or improve quality without increasing spending. *Id.* § 1315a(c)(1). The initial test must therefore generate meaningful evidence that can inform whether and how the model should be expanded.

62. Only when the statutory requirements for a "test" are met may the Secretary invoke Section 1315a's limited waiver authority. In particular, Section 1315a(d)(1) permits the Secretary to "waive such requirements" of specified provisions of the Social Security Act during a Phase I model test "as may be necessary solely for purposes of carrying out this section with respect to testing models described in [the Phase I subsection]." 42 U.S.C. § 1315a(d)(1).[25]

[25] Those include Title XI (General Provisions), Title XVIII (Medicare), and specified sections of Title XIX (Medicaid). 42 U.S.C. § 1315a(d)(1).

63. To "waive" means "to refrain from . . . enforcing."[26] Critically, waiver authority does not confer "unlimited power to rewrite" a statute. *Nebraska*, 600 U.S. at 502. An agency action, for instance, that adds "new and substantially different provisions" is not a waiver, because it "not only nullifies existing provisions, but augments and expands them dramatically." *Id.* at 498–99. In other words, agencies cannot invoke waiver authority to, in effect, draft "a new section . . . from scratch." *Id.*

64. In short, Section 1315a confers a defined and limited authority: to test—experimentally, cooperatively, and in phases—innovative changes to how care is paid for and delivered, targeted at defined populations with identifiable care deficits, and designed to preserve or enhance quality of care while reducing costs, subject to genuine evaluation and to a waiver authority that permits only forbearance, not wholesale statutory revision. Congress made its narrow intent crystal clear by specifying 27 different examples of qualifying tests and eight selection factors for evaluating additional tests.

CMS's Prior Models Confirm the Limited Scope of Section 1315a

65. CMS's prior models reflect the limited scope of the agency's testing authority under Section 1315a. As of January 2025, CMMI had tested 70 models.[27] Those models generally tested different ways of paying for and delivering care for the hospitals, physician practices, accountable care organizations, and other providers that furnish care to beneficiaries. The models have also been overwhelmingly voluntary: of the 24 models active in January 2025, 22 had voluntary participation.[28] The Oncology Care Model and its successor, the Enhancing Oncology Model, are standard examples of these voluntary models. Both tested the use of performance-based payment

[26] *Waive*, Merriam-Webster, https://merriam-webster.com/dictionary/waive (last visited Nov. 5, 2026); *see also Waive*, Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/waive (last visited Nov. 5, 2026) ("to not demand something you have a right to, or not cause a rule to be obeyed").

[27] U.S. Gov't Accountability Off., GAO-26-107953, *CMS Innovation Center: Obligations and Model Testing Progress* 13 (Mar. 2026).

[28] *Id.* at 15.

approaches instead of the standard Medicare fee-for-service reimbursement.[29] Under the Oncology Care Model, participating practices received a monthly per-beneficiary payment and could earn a retrospective performance-based payment—or, under the Enhancing Oncology Model, owe a recoupment—depending on whether their episode spending comes in below a target.[30]

66. CMS has tested only five mandatory payment and service delivery models,[31] all of which are directed at the providers that furnish care and bill Medicare for it. The same is true for another CMS model scheduled to begin in 2027, the Ambulatory Specialty Model. Each is designed to test whether changing how those providers are paid would reduce Medicare spending while improving quality of care:

a. **The Comprehensive Care for Joint Replacement (CJR) Model (2016–2024)** tested whether providing hospitals bundled payments, as opposed to fee-for-service payments, for hip and knee replacements would reduce Medicare expenditures while preserving or enhancing quality of care, such as by reducing the number of hospital readmissions.[32]

b. **The Home Health Value-Based Purchasing Model (2016–2020)** tested whether adjusting payments to home health agencies based on quality metrics would result

[29] Oncology Care Model: Request for Applications, 80 Fed. Reg. 8,323, 8,323 (Feb. 17, 2015); CMS, *Enhancing Oncology Model Request for Applications* 6 (May 30, 2024), https://cms.gov/priorities/innovation/media/document/eom-rfa-2024.

[30] 80 Fed. Reg. at 8,324; *Enhancing Oncology Model Request for Applications*, *supra* n.29, at 36.

[31] Certain other mandatory models adopted by CMS, such as the Most Favored Nation (MFN) Model and the Radiation Oncology Model, never took effect.

[32] Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Fed. Reg. 73,274, 73,276–77 (Nov. 24, 2015).

in better patient outcomes, higher functional status, and lower rates of avoidable hospitalizations.[33]

c. **The End-Stage Renal Disease Treatment Choices Model (2021–2025)** tested whether adjusting payments to dialysis facilities and clinicians based on patients' use of home dialysis and kidney transplantation would increase the use of such services while reducing Medicare expenditures and preserving or enhancing quality of care.[34]

d. **The Increasing Organ Transplant Access (IOTA) Model (2025–2031)** tests whether adjusting payments to hospitals based on the number of kidney transplants they perform and their transplant success rates increases access to kidney transplants while reducing Medicare expenditures and preserving or enhancing quality of care.[35]

e. **The Transforming Episode Accountability Model (TEAM) (2026–2030)** tests whether holding acute care hospitals financially responsible for the total cost and quality of care for certain surgeries through 30 days post-discharge will improve care coordination, lower Medicare expenditures, and reduce hospital readmissions.[36]

f. **The Ambulatory Specialty Model (ASM) (2027–2031)** will test whether adjusting payments to specialists who treat heart failure or low back pain based on quality measures and other performance metrics can improve chronic disease

[33] Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements, 80 Fed. Reg. 68,624, 68,625, 68,658 (Nov. 5, 2015).

[34] Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 Fed. Reg. 61,114, 61,115–16 (Sept. 29, 2020).

[35] Medicare Program; Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, 89 Fed. Reg. 96,280, 96,280 (Dec. 4, 2024).

[36] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates, 89 Fed. Reg. 68,986, 69,914 (Aug. 28, 2024).

management, slow disease progression, improve care coordination, and reduce avoidable hospitalizations, while decreasing Medicare expenditures.[37]

67. These models all share a defining feature not present here: each connects a change in how Medicare pays providers to a hypothesized change in how care is delivered. They test alternative payment and service delivery methods—such as bundled or performance-based reimbursement—rather than impose direct price controls.

The First Trump Administration's Efforts to Impose Foreign-Reference Pricing and the Lead-Up to GLOBE

68. In November 2020, at the tail end of President Trump's first term, CMS issued an interim final rule establishing a "Most Favored Nation" model, relying on the same CMMI authority at issue in this case, that would have tied Medicare Part B payment for certain drugs to the lowest price paid among a set of economically comparable countries. That rule was promptly challenged and enjoined by several courts—including a district court in this district—for CMS's failure to comply with the notice-and-comment requirements of the Administrative Procedure Act ("APA"). *Cal. Life Scis. Ass'n v. Ctrs. for Medicare & Medicaid Servs.*, 2020 WL 7696050, at *1–2 (N.D. Cal. Dec. 28, 2020); *Regeneron*, 510 F. Supp. 3d at 41; *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 498–99, 504–05 (D. Md. 2020). CMS ultimately rescinded the rule.[38]

69. A few months into the second Trump Administration, the President launched a government-wide policymaking effort to reimpose the foreign-reference pricing policies that courts enjoined during the first Administration.

70. On May 12, 2025, the President signed Executive Order 14297, "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients." 90 Fed. Reg. 20,749 (May 15, 2025). The Order is built on the "global freeloading" theory the Administration had advanced during

[37] Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 49,266, 49,562–63 (Nov. 5, 2025).

[38] *See* Most Favored Nation (MFN) Model, 86 Fed. Reg. 73,986 (Dec. 29, 2021) (rescinding the interim final rule).

the President's first term: that other wealthy nations use government price controls to pay far less than Americans do for the same medicines, leaving American patients to bear a disproportionate share of the cost of developing them.[39] The Order directed the Secretary of HHS to "communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations." 90 Fed. Reg. at 20,750. On May 20, 2025, HHS announced that the most-favored-nation ("MFN") "target price" would be "the lowest price in an OECD country with a GDP per capita of at least 60 percent of the U.S. GDP per capita."[40]

71. The Executive Order provided that, if "significant progress" toward MFN pricing "is not delivered," HHS "shall propose a rulemaking plan to impose most-favored-nation pricing." The White House then sent "letters to leading pharmaceutical manufacturers outlining the steps they must take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations," which "informed manufacturers that if they 'refuse to step up,' the federal government 'will deploy every tool in [its] arsenal'" against them.[41]

72. In December 2025, Secretary Kennedy announced that CMS was "answering" the President's "call,"[42] in the form of two proposed rulemakings: the Global Benchmark for Efficient Drug Pricing (GLOBE) Model, 90 Fed. Reg. 60,244 (Dec. 23, 2025), and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, 90 Fed. Reg. 60,338 (Dec. 23, 2025). GLOBE covered drugs reimbursed under Medicare Part B; GUARD covered drugs reimbursed under Medicare Part D. Both proposed rules invoked Section 1315a as their source of authority.

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[39] *See, e.g.*, Council of Econ. Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* (Feb. 2018); HHS, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May 2018); White House, *Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation* (May 12, 2025).

[40] HHS, Press Release, *HHS, CMS Set Most-Favored-Nation Pricing Targets to End Global Freeloading on American Patients* (May 20, 2025), https://hhs.gov/press-room/cms-mfn-lower-us-drug-prices.html.

[41] White House, *Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs* (July 31, 2025), https://whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-announces-actions-to-get-americans-the-best-prices-in-the-world-for-prescription-drugs.

[42] CMS, Press Release, *CMS Proposes New Mandatory GLOBE Model* (Dec. 21, 2025), https://cms.gov/newsroom/press-releases/cms-proposes-new-mandatory-globe-model.

73. The Administration's campaign of "voluntary" "lower prices or else" "got the ball rolling."[43] Beginning in September 2025 and running through August 2026, certain manufacturers—now 27 in total—entered into individual pricing agreements with the Administration that, based on public reporting, require manufacturers to provide MFN prices to Medicaid through participation in a separate, ostensibly voluntary CMMI model, called the GENErating cost Reductions fOr U.S. Medicaid (GENEROUS) Model.[44]

74. All three Plaintiffs, along with many of their members, submitted detailed comment letters to CMS on February 23, 2026, opposing the GLOBE and GUARD proposed rules and explaining, among other things, that the proposed rules exceed CMS's authority under Section 1315a, impose unauthorized penalties, and would inflict serious harm on biopharmaceutical innovation and patient access.[45]

The GLOBE Final Rule Impermissibly Rewrites Congress's Statute Under the Guise of a "Waiver"

75. On October 2, 2026, CMS issued the GLOBE final rule. GLOBE becomes effective on November 30, 2026, and requires manufacturers of certain drugs covered by Medicare Part B, including Plaintiffs' members, to pay an additional rebate to CMS calculated based on the difference

[43] Mehmet Oz, Administrator of CMS, Remarks at Deal Announcement (Oct. 1, 2025), https://rev.com/transcripts/trump-makes-drug-announcement.

[44] White House, *Fact Sheet: President Donald J. Trump Announces Deal with Regeneron to Bring Most-Favored-Nation Pricing to American Patients* (Apr. 23, 2026), https://whitehouse.gov/fact-sheets/2026/04/fact-sheet-president-donald-j-trump-announces-deal-with-regeneron-to-bring-most-favored-nation-pricing-to-american-patients/; Max Bayer, *Drugmakers with White House MFN Deals Claim Exemption from Proposed Medicare Pricing Tests*, Endpoints News (Dec. 23, 2025); White House, *Fact Sheet: President Donald J. Trump Announces Deal with Nine Additional Pharmaceutical Manufacturers to Lower Drug Prices for Americans* (Aug. 31, 2026), https://whitehouse.gov/fact-sheets/2026/08/fact-sheet-president-donald-j-trump-announces-deal-with-nine-additional-pharmaceutical-manufacturers-to-lower-drug-prices-for-americans/; Incyte Corp., Current Report (Form 8-K) 2 (Aug. 31, 2026), https://investor.incyte.com/static-files/4c5239ef-da74-4f7c-8523-f94dc482ef65.

[45] Biotechnology Innovation Org., Comment Letter on Proposed Rule for Global Benchmark for Efficient Drug Pricing (GLOBE) Model (Feb. 23, 2026), https://regulations.gov/comment/CMS-2025-1889-0152; Cal. Life Scis., Comment Letter on Proposed Rules for Global Benchmark for Efficient Drug Pricing (GLOBE) Model and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (Feb. 23, 2026), https://regulations.gov/comment/CMS-2025-1889-0081; Biocom, Comment Letter on Proposed Rule for Global Benchmark for Efficient Drug Pricing (GLOBE) Model (Feb. 23, 2026), https://regulations.gov/comment/CMS-2025-1889-0075.

between the Medicare Part B payment amount and a foreign-price "benchmark" reflecting the prices in specified reference countries. The final rule establishes GLOBE as a mandatory model under Section 1315a, meaning manufacturers of covered products are not permitted to opt out. 91 Fed. Reg. at 62,936.

GLOBE's Rebate Mechanism

76. GLOBE's core mechanism is a new rebate keyed to foreign prices. The IRA already requires manufacturers of certain Part B drugs (called "rebatable" drugs) to pay a rebate to Medicare when the drug's U.S. price rises faster than the domestic inflation rate. *See* 42 U.S.C. § 1395w-3a(i). Under the IRA, CMS calculates the inflation rebate by comparing the drug's Part B payment amount with an "inflation-adjusted payment amount," which is the drug's benchmark payment amount adjusted for domestic inflation. *See id.* § 1395w-3a(i). If the inflation-adjusted payment amount is lower than the Medicare payment amount, the manufacturer must pay the difference. Critically, the IRA rebate provisions are triggered and measured entirely by reference to *domestic* price increases over time, against a benchmark Congress itself selected and that the President signed into law, not by reference to foreign prices adopted unilaterally by the Executive Branch.

77. GLOBE invokes the IRA rebate program as its statutory launching pad—purporting to "waive" the inflation-rebate calculation—but then leaves the inflation rebate intact while imposing an entirely separate, foreign-referenced "incremental" rebate on top of it. 91 Fed. Reg. at 62,939. In CMS's own words, GLOBE operates "alongside and in addition to the Medicare Part B Drug Inflation Rebate Program." *Id.* at 62,940.

78. The GLOBE rebate is based on a foreign-price "benchmark" determined by comparing a drug's Medicare payment amount against "international drug pricing information." *Id.* at 62,938. The "international benchmark" is drawn from 19 foreign countries—Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. *Id.* at 63,106.

79. The benchmark is calculated one of two ways—and the alternatives are not evenhanded. The applicable international benchmark is based on the greater of two figures:

a. A default "Method I" benchmark equal to the *lowest* price among the reference countries. *Id.* at 63,108. CMS calculates this figure a single time, generally when a drug first enters the model, using commercially available data sources of CMS's own selection—data the agency does not disclose to the manufacturer and that, in some instances, were gathered before GLOBE was even proposed. *Id.* at 63,106–07. Once set, the default benchmark is fixed and does not change. *Id.* at 63,109.

b. An updated "Method II" benchmark equal to the *average* price across the set of reference countries, calculated by CMS on a quarterly basis, using international drug net-pricing data "voluntarily" submitted by the manufacturer. *Id.* at 63,109–10.

80. Because the default Method I benchmark is set at the *lowest* reference country price, while the updated Method II benchmark is based on the *average*, the Method II benchmark is almost certainly higher and thus yields a smaller rebate. To obtain the lower rebate under Method II, manufacturers must submit detailed pricing data from up to 19 countries within 30 days after each sales quarter. *Id.* at 63,101, 63,112. The first submissions, covering sales during the fourth quarter of 2026, are due by January 30, 2027, and apply to the model's first performance quarter beginning April 1, 2027. *Id.* Gathering these data is enormously burdensome. Manufacturers may not otherwise collect such data; foreign confidentiality obligations and competition laws could bar their disclosure; and where another company holds the rights to market the drug abroad, the U.S. manufacturer often lacks any visibility into or control over foreign pricing at all.

81. Every quarter during GLOBE's performance period, CMS will calculate a per-unit "GLOBE Model rebate amount" for each drug subject to GLOBE. That amount is the greater of (1) the Medicare payment amount[46] minus the foreign-price benchmark, or (2) the Medicare payment

[46] The GLOBE final rule refers to the "specified amount," meaning the payment amount determined under 42 U.S.C. § 1395w-3a(i)(3)(A)(ii)(I)(aa) or (bb). In most cases, the specified amount is equal to 106% of the drug's U.S. "average sales price."

amount minus the IRA's inflation-adjusted payment amount. *Id.* at 63,110–11. CMS then subtracts from the "GLOBE Model rebate amount" the IRA inflation rebate amount, which it continues to calculate and invoice under the IRA regulations it claims to waive. *Id.* at 62,942. The remainder is the "incremental" GLOBE rebate the manufacturer owes *in addition to* the inflation rebate.

82. Consider a hypothetical GLOBE Model drug with a Part B payment amount of $100 per unit. The following examples illustrate how the "incremental" rebate operates in three scenarios. *First*, if the GLOBE foreign-price benchmark is *lower* than the inflation-adjusted payment amount, then the manufacturer will owe an incremental GLOBE rebate in addition to the inflation rebate owed under the IRA.

***Scenario 1*: Foreign-Price Benchmark Lower than Inflation-Adjusted Amount**
Foreign-Price Benchmark = $60 **Inflation-Adjusted Amount** = $90 **GLOBE Model rebate** (the greater of): [Payment Amount] - [Foreign-Price Benchmark] = $100 - $60 = $40 [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $90 = $10 → The GLOBE Model rebate is **$40**. **IRA inflation rebate** (billed first): [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $90 = **$10** **Incremental GLOBE Model rebate**: [GLOBE Model rebate] - [IRA inflation rebate] = $40 - $10 = **$30**

83. *Second*, if the GLOBE foreign-price benchmark is *higher* than the inflation-adjusted payment amount, there is no incremental GLOBE rebate, and the manufacturer still must pay the full IRA rebate amount.

***Scenario 2*: Foreign-Price Benchmark Higher than Inflation-Adjusted Amount**
Foreign-Price Benchmark = $60 **Inflation-Adjusted Amount** = $40 **GLOBE Model rebate** (the greater of): [Payment Amount] - [Foreign-Price Benchmark] = $100 - $60 = $40 [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $40 = $60 → The GLOBE Model rebate is **$60**. **IRA inflation rebate** (billed first): [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $40 = **$60** **Incremental GLOBE Model rebate**: [GLOBE Model rebate] - [IRA inflation rebate] = $60 - $60 = **$0**

84. *Third*, if there is no inflation rebate, the manufacturer must nevertheless pay a GLOBE rebate if the foreign-price benchmark is lower than the Part B payment amount.

***Scenario 3*: No Inflation Rebate**
Foreign-Price Benchmark = $60 **Inflation-Adjusted Amount** = $100 **GLOBE Model rebate** (the greater of): [Payment Amount] - [Foreign-Price Benchmark] = $100 - $60 = $40 [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $100 = $0 → The GLOBE Model rebate is **$40**. **IRA inflation rebate** (billed first): [Payment Amount] - [Inflation-Adjusted Amount] = $100 - $100 = **$0** **Incremental GLOBE Model rebate**: [GLOBE Model rebate] - [IRA inflation rebate] = $40 - $0 = **$40**

85. All incremental GLOBE Model rebates are deposited into the SMI Trust Fund—*i.e.*, into the accounts containing funds Congress appropriated to CMS to spend on Medicare. 91 Fed. Reg. at 62,938.

GLOBE's Covered Population

86. GLOBE defines its covered population using two criteria: (1) ZIP code and (2) covered drugs. GLOBE applies to beneficiaries residing in randomly selected geographic areas—

defined by ZIP code areas[47]—comprising approximately 25% of the Medicare Part B population. *Id.* at 63,103.

87. GLOBE-covered drugs are Part B single-source drugs and sole-source biological products that fall within seven drug categories: cancer drugs, immunological drugs, ophthalmic agents, central nervous system agents, drugs for metabolic bone diseases, blood products, and antigout agents. *Id.* at 63,104. By its own account, CMS selected those categories because they account for roughly 91% of total Medicare Part B rebatable drug spending, reflecting costs to the *government*, not beneficiaries. *Id.* at 62,981. GLOBE excludes generics and biosimilars, orphan-only drugs, cell and gene therapies, plasma-derived products, drugs below the rule's spending threshold, and drugs subject to a maximum fair price under the IRA during a price-applicability period. *Id.* at 63,104. But within those limits, GLOBE by its terms reaches many drug categories that are widely prescribed to Medicare beneficiaries. CMS identified 19 manufacturers that would be covered under GLOBE based on 2024 data. *Id.* at 63,095. Additional products—both those existing now and those which may be approved in the future—would also become covered by GLOBE if they meet GLOBE's eligibility criteria in future years.

88. In the final rule, CMS states that it intends to waive the applicability of GLOBE to manufacturers that participate in the GENEROUS Model during a given quarter. *Id.* at 63,069–70. However, CMS expressly declined to codify the exemption in the GLOBE rule itself and "intends to use" its discretion to issue a waiver under the GENEROUS Model agreement. Under GENEROUS, which runs from January 1, 2026, through December 31, 2030, participating manufacturers provide covered drugs at MFN pricing to state Medicaid programs through supplemental rebates. *See* GENEROUS Model Request for Applications from Applicable Manufacturers (Feb. 27, 2026), https://cms.gov/priorities/innovation/files/generous-rfa.pdf [hereinafter GENEROUS RFA]. As explained above, certain manufacturers have entered into

[47] GLOBE refers to ZIP Code Tabulation Areas, which the rule defines as "approximate area representations of USPS five-digit Zonal Improvement Plan (ZIP) Code service routes that the Census Bureau creates using whole blocks to present statistical data from censuses and surveys." 91 Fed. Reg. at 63,102. For purposes of this Complaint, references to "ZIP codes" mean the ZIP Code Tabulation Areas as the phrase is used in the rule.

pricing agreements with the Administration, which reportedly require them, among other things, to participate in GENEROUS. Because of the waivers CMS will grant to GENEROUS participants, CMS projects that 15 of the 19 manufacturers whose drugs would otherwise be covered by GLOBE will not initially be required to participate. 91 Fed. Reg. at 63,093 n.227, 63,095.

89. The waiver from GLOBE applies only to quarters in which a manufacturer participates in GENEROUS. *Id.* at 63,069–70. Because GENEROUS ends on December 31, 2030, *see* GENEROUS RFA § 1.1.1, while GLOBE's performance period runs through March 31, 2032, 91 Fed. Reg. at 62,937, even manufacturers that remain in GENEROUS for its full term will be subject to GLOBE for its final five quarters unless CMS extends GENEROUS and continues the waiver.

GLOBE's Identified "Deficit in Care"

90. CMS identifies the relevant "deficit in care" as cost-related barriers to treatment: coinsurance high enough that beneficiaries may delay or forgo needed drugs. *Id.* at 62,979–81. But CMS does not find that such deficits exist in GLOBE's population. It asserts only that GLOBE addresses a population with "*likely* deficits of care due to high costs." *Id.* at 62,973 (emphasis added). For support, CMS relies on nationwide surveys about prescription drug affordability, which concern adults generally or patients who skipped refilling their prescriptions at a *pharmacy*. *See, e.g.*, *id.* at 62,936 & nn.7–15. But these surveys concern *Part D* drugs. Part *B* drugs generally are administered by a health care provider, not filled at a pharmacy. Part B and Part D drugs also have fundamentally different cost-sharing requirements. The only source CMS cites specific to Part B drugs is a single study that has "theorized"—in a single sentence—that beneficiaries without supplemental insurance may have limited access to one class of cancer drugs because of coinsurance costs. *Id.* at 62,936–37 & n.16. But, as discussed above, *see supra* ¶ 50, roughly 90% of Part B beneficiaries have supplemental insurance that covers coinsurance costs.

91. Recognizing that most beneficiaries will see no change in cost-sharing under GLOBE, CMS further claims that "all beneficiaries" may benefit through a potential reduction in Part B premiums, without explaining how GLOBE could actually deliver any decrease. 91 Fed. Reg. at

63,089. To the extent GLOBE could reduce Part B premiums, that reduction would apply to all Part B beneficiaries nationwide, not only the patients residing in the ZIP codes the model is supposed to "address[]." 42 U.S.C. § 1315a(b)(2)(A). Divided among all of the beneficiaries, the anticipated monthly premium reduction comes out to just $0.04 per month. 91 Fed. Reg. at 63,089, tbl. 14.[48] CMS thus cites no evidence that beneficiaries in the selected ZIP codes, or patients taking GLOBE drugs, experience cost-related deficits in care—let alone that GLOBE could address them.

GLOBE's Performance Period and Penalties

92. GLOBE runs for seven years: a five-year performance period followed by an additional two years of rebate invoicing and reconciliation. *Id.* at 62,937. Manufacturers must pay each incremental rebate within 30 days of receiving the applicable rebate report, subject to a reconciliation process. *Id.* at 63,115.

93. GLOBE is enforced through steep civil monetary penalties. A manufacturer that fails to pay in full and on time is subject to a civil monetary penalty equal to 125% of the unpaid rebate, *on top of* the rebate itself, which CMS purports to impose under the IRA's inflation-rebate penalty provisions and the general civil monetary penalty authority of Section 1320a-7a. *Id.* at 63,058–59. CMS also reserves the right to pursue further enforcement, including referral to the Department of Justice. *Id.* at 63,059.

The Reference Countries Are Not Comparable to the United States, and Importing Their Price Controls Harms Innovation and Patients

94. GLOBE imports prices that foreign countries set under policy choices that American law rejects. American law reflects a commitment to free markets, to the equal worth of every patient's life regardless of age or disability, and to rewarding inventors for their discoveries. The reference countries, by contrast, maintain systems fundamentally unlike our own. Many dictate drug prices, employ discriminatory practices that discount the lives of elderly and disabled patients, and afford innovators far weaker protections. The consequences of tethering Medicare rebates to those

[48] Magnolia Market Access, *Four Cents per Beneficiary a Month: Breaking Down GLOBE's Medicare Part B Premium Savings*, https://magnoliamarketaccess.com/insight/globe-model-medicare-part-b-premium-savings/ (last visited Nov. 5, 2026).

countries' prices are as predictable as they are severe: less investment, fewer new medicines, and delayed or denied access for the patients who need them most.

95. Unlike the United States, the reference countries do not price pharmaceutical products through market-based systems. Instead, most operate government-run or highly centralized healthcare systems in which government authorities set the price of drugs. Governments in these countries employ a range of mechanisms that artificially suppress prices below market levels. These include using health technology assessments that set prices for new therapies by comparison with older, less effective medicines and generics; imposing mandatory price reductions after a drug launches; and enacting statutory clawbacks that force manufacturers to return revenues to offset government budget shortfalls.

96. Most reference countries also use discriminatory metrics, like quality-adjusted life years ("QALYs"), to judge the cost-effectiveness of pharmaceutical interventions.[49] These metrics assign less value to a drug that extends the life of an elderly or disabled person, on the assumption that a year of life with a disability or chronic illness is worth less than a year lived in full health.[50] The result is that treatments for these populations are more likely to be deemed not cost-effective at any price compared to treatments for non-disabled individuals. Because these metrics systematically devalue the lives of older and disabled Americans, Congress has twice barred their use in Medicare. In the Affordable Care Act, Congress prohibited the Secretary from using QALYs or any "similar measure that discounts the value of a life because of an individual's disability" when determining Medicare "coverage, reimbursement, or incentive programs." 42 U.S.C. § 1320e-1(e). And when Congress did impose price caps in the IRA, it again forbade the use of QALYs during the drug price-setting process. *See* 42 U.S.C. § 1320f-3(e)(2) (prohibiting the Secretary from using evidence "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of

[49] Julia Wahl et al., Copenhagen Econs., QALY Use in Selected OECD Countries 2 (Feb. 2026), https://copenhageneconomics.com/publication/qaly-use-in-oecd.

[50] Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, 34 Cambridge Q. Healthcare Ethics 109, 110–13 (2025).

lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill").

97. The reference countries also provide different legal protections for innovation, which affect when competitors enter the market and what prices manufacturers can obtain. U.S. law, for example, permits restoration of up to five years of patent term for time lost during FDA's regulatory review.[51] Canada, by contrast, permits no more than two years through its Certificate of Supplementary Protection.[52] The United States also adjusts patent terms to compensate for delays during patent examination,[53] which is a protection not available in countries such as Australia, Israel, and many European nations. As a result, the same invention may remain protected in the United States years longer than in the reference countries.

98. Separate from patent protection, U.S. law confers a distinct set of FDA-administered regulatory exclusivities that themselves, independent of a patent, bar approval of competing generic or biosimilar products for fixed periods. A new chemical entity receives five years of exclusivity;[54] a drug approved on the basis of new clinical investigations receives three years;[55] and qualifying pediatric studies add six months.[56] A biological product receives twelve years of reference-product exclusivity, the first four of which are data exclusivity.[57] These periods of exclusivity afford innovators the opportunity for market-based returns before facing generic or biosimilar competition. GLOBE, by contrast, could impose foreign-reference rebates on newly approved products with no

[51] 35 U.S.C. § 156(a), (g)(6)(A).

[52] Health Canada, Guidance Document: Certificates of Supplementary Protection 8 (Aug. 19, 2024), https://canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/register-certificates/certificate-supplementary-protection-regulations.html.

[53] 35 U.S.C. § 154(b).

[54] 21 U.S.C. § 355(j)(5)(F)(ii).

[55] *Id.* § 355(j)(5)(F)(iii)–(iv).

[56] *Id.* § 355a(b)–(c).

[57] 42 U.S.C. § 262(k)(7)(A) (twelve-year exclusivity); *id.* § 262(k)(7)(B) (four-year data exclusivity).

comparable waiting period, eliminating the market-based pricing window Congress deliberately preserved.

99. GLOBE therefore does not compare like with like. It imports prices produced by foreign government price-control regimes that rely on discriminatory and prohibited valuation frameworks into the U.S. Medicare program and uses those prices to impose additional rebate liability on U.S. manufacturers. And it does so even in situations where the U.S. manufacturer does not control the marketing, reimbursement status, or price of the same or similar product in the reference countries.

100. Importing these foreign prices into Medicare not only is contrary to American law but also erodes the market-based returns that drive U.S. biomedical innovation. History confirms that where governments suppress prices, innovation goes elsewhere. This is why the United States is the global leader in pharmaceutical development. As foreign governments expanded price controls, pharmaceutical innovation migrated to the United States, and the U.S. share of newly developed medicines rose even as the shares of France, Germany, Switzerland, and the United Kingdom fell.[58]

101. The harms from importing foreign price controls fall on American patients as directly as on manufacturers. The strength of the U.S. market-based system is why biotechnology companies typically launch new medicines in the United States first, ensuring that American patients are often the first to benefit from breakthrough therapies. Examining new drugs launched from 2018 through 2022, a 2024 RAND study prepared for HHS found that "more than half of new drugs were launched first in the United States," and that, on average, new drugs reached other major OECD markets—Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom—about a year after their U.S. launch.[59] For patients with aggressive cancers, delays of twelve months can be the difference between life and death. This pattern is systemic: nearly 90% of all new medicines approved since

[58] *See* Ross C. DeVol et al., Milken Inst., *The Global Biomedical Industry: Preserving U.S. Leadership* 5 (Sept. 2011), https://pacificresearch.org/wp-content/uploads/2017/05/CASMIFullReport.pdf.

[59] Andrew W. Mulcahy, RAND Corp., *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries* v (2024), https://rand.org/t/RRA788-4.

2011 are available in the United States, compared to 50% in France, 48% in Switzerland, and 46% in Canada.[60] By importing the pricing frameworks of systems that routinely delay or deny access to new therapies, GLOBE threatens to replicate those outcomes here, with no period of market-based returns in the Medicare system.

102. GLOBE's effects on innovation extend well beyond the drugs it initially covers. Pharmaceutical investments are made years in advance, based on a product's expected returns over its commercial life, long before anyone knows whether the drug will succeed or whether it will fall within GLOBE's scope. Investors price that risk in today, not just when a product first incurs a rebate. By cutting the expected returns on successful products, GLOBE lowers the expected net present value of investments across the pipeline, from development-stage assets to established firms whose products may become subject to it later. CMS projects that GLOBE will reduce net Medicare Part B spending by $440 million, 91 Fed. Reg. at 62,940, a substantial sum on its own. But that estimate does not measure the model's broader costs to manufacturers, investors, and patients. When capital pulls back from early-stage research, the cost is measured not only in lost revenue but also in the treatments that are never developed and the patients who will never benefit from them.

103. Nor do GLOBE's exclusions and waivers limit the broader authority CMS claims. Those carve-outs reflect the agency's current self-imposed limitations about which drugs to cover, but leave intact the agency's asserted power to impose foreign-reference pricing across Medicare. CMS has already invoked that authority in its GUARD proposal for Part D drugs. The agency's decision to exempt particular products today supplies no enduring statutory limit on the power it asserts for tomorrow. The potential consequences of that broader authority are substantial. Manufacturers must make development decisions knowing that CMS could use that authority to fundamentally dismantle the pharmaceutical innovation ecosystem, reaching far beyond the covered drugs. Economic analyses project that MFN-style pricing applied across Medicare and Medicaid would reduce U.S. pharmaceutical revenues by 49% and lead to a loss of 500 new treatments over

[60] BIO, Importing International Reference Pricing in the U.S. Jeopardizes Patient Access to Innovative Medicines, https://bio.org/save-cures (last visited Nov. 5, 2026).

10 years.[61] Collectively, those forgone innovations are projected to translate into a health loss of approximately 516 million life-years, corresponding to approximately 6.6 million lives lost worldwide.[62]

CLAIMS FOR RELIEF

COUNT I

THE RULE EXCEEDS CMS'S STATUTORY AUTHORITY

104. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

105. Under the APA, courts shall "hold unlawful and set aside agency action" that is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

106. GLOBE rests on Section 1315a, which confers only a narrow, experimental authority: to test innovative payment and service delivery models that address identified deficits in care in a defined population and to "waive" certain statutory requirements, but only "as may be necessary solely for purposes of carrying out" the test. 42 U.S.C. § 1315a(d)(1).

107. **GLOBE's purported "waiver" impermissibly rewrites the Medicare statute.** Section 1315a(d)(1) permits CMS to "waive" specified statutory requirements only as necessary to carry out a Phase I model test. *Id.* § 1315a(d)(1). GLOBE purports to "waive" the IRA inflation rebates, but it does no such thing. To "waive" means to "refrain from insisting on" or to "abandon, renounce, or surrender."[63] Yet under CMS's own description, the IRA rebate program "remains operative" and GLOBE functions "alongside and in addition to" it. 91 Fed. Reg. at 62,940, 63,079. The Supreme Court's decision in *Biden v. Nebraska* forecloses this attempt. There, the Court held

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[61] Tomas J. Philipson et al., *Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs*, at 8, U. Chi. (Sept. 27, 2025), https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/09/MFN-Impact-on-Patient-Health-Final-Sep-29.pdf.

[62] *Id.*

[63] *Waive*, Black's Law Dictionary (12th ed. 2024); *see Waive*, Oxford English Dictionary (last updated June 2026) ("To relinquish (a right, claim, or contention) either by express declaration or by doing some intentional act which by law is equivalent to this"; to "refrain from insisting upon, give up (a privilege, right, claim, etc.); to forbear to claim or demand"); *Waive*, Merriam-Webster, *supra* n.26 ("to refrain from . . . enforcing").

that the Executive Branch cannot invoke statutory "waiver" authority to "augment[] and expand[]" existing provisions. 600 U.S. at 499. Just as forgiving student loan debt was not a "waiver" of repayment obligations, so too CMS's creation of a foreign-pricing rebate is not a "waiver" of the IRA's inflation rebate—it is a new obligation invented by the agency.

108. **GLOBE does not identify a defined population with "deficits in care."** Congress allowed the Secretary to test a model only if "evidence" shows that it "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). GLOBE's population is defined not by any deficit in care, but by randomly selected ZIP codes and the drugs on which the *government* spends the most. The only deficit CMS posits is cost: that high coinsurance may deter beneficiaries from obtaining covered drugs. 91 Fed. Reg. at 62,980. But CMS does not dispute that around 90% of Part B beneficiaries have supplemental coverage that pays their coinsurance. *Id.* at 63,091–92. GLOBE thus covers a population that *overwhelmingly* does not face the problem the agency claims to be targeting. And for the minority of beneficiaries without supplemental insurance, CMS offers no evidence that cost causes them to forgo physician-administered *Part B* drugs. It asserts only that covered beneficiaries "*likely* [have] deficits of care due to high costs," *id.* at 62,973 (emphasis added), and rests that guess on survey data about prescriptions that patients declined to fill at the pharmacy, which are drugs covered under *Part D*, not Part B, *see, e.g.*, *id.* at 62,936 & nn.7–15. A hunch about a deficit is not "evidence."

109. **GLOBE does not "address" any deficit in care.** To "address" a deficit is to "deal with or give attention to" it.[64] The only deficit CMS identifies is cost-related barriers that cause beneficiaries to forgo needed medicines. 91 Fed. Reg. at 62,936. But GLOBE is built in a way that does not and cannot address that problem. As described above, *see supra* ¶ 50, the vast majority of Part B beneficiaries face no out-of-pocket costs for Part B drugs. CMS does not dispute commenters' estimate that only about 0.3% of beneficiaries would see any change in what they pay under the GLOBE proposed rule, and that figure will shrink further under the final rule, which

[64] *Address*, Merriam-Webster, *supra* n.19.

covers fewer drugs. 91 Fed. Reg. at 62,982. A model that leaves beneficiaries' costs untouched does not address a cost problem.

110. **GLOBE is not a "payment and service delivery model."** Section 1315a permits CMS to test only "payment *and* service delivery models." 42 U.S.C. § 1315a(a)(1), (b)(1) (emphasis added). A qualifying model must bear a genuine connection to Medicare payment for patient care and to the delivery of that care, but GLOBE bears neither connection. CMS does not contend that GLOBE changes how care is furnished. Nor could it. CMS argues instead that "payment and service delivery" is merely a "categorical descriptor," so that a payment model alone suffices. 91 Fed. Reg. at 62,946. But GLOBE is not even that. Throughout the Medicare statute and healthcare industry, a "payment model" refers to the system or structure by which insurers and government programs pay doctors, clinics, and hospitals for the care they provide to patients. *See supra* ¶¶ 57–59. For Part B drugs, Medicare pays the providers that purchase and administer them. 42 U.S.C. § 1395u(o). GLOBE does not alter that payment structure. By CMS's own account, providers "continue to buy and bill for GLOBE Model drugs as usual." 91 Fed. Reg. at 62,938. GLOBE instead requires manufacturers, which receive no Medicare payments at all, to pay the government. Congress's 27 example models and eight selection factors illustrate what kind of model it envisioned: changes in how providers are paid and how they deliver care. Not one involves drug pricing, manufacturer-to-government rebates, or anything remotely similar.

111. **GLOBE is not a "test."** It certainly does not "test" whether compelling manufacturers to pay rebates will reduce "program expenditures." 42 U.S.C. § 1315a(b)(1). That result is assured at the outset. CMS needs no evidence to prove that point. A genuine "test," by contrast, presupposes an uncertain hypothesis that the agency intends to evaluate—an identifiable research question likely to yield useful information about whether a novel approach improves program outcomes. *See Beno*, 30 F.3d at 1069.[65] Randomizing the application of an unauthorized payment obligation does not transform it into an experiment. And there is no change in care for

[65] *See also Test*, Merriam-Webster, https://merriam-webster.com/dictionary/test (last visited Nov. 5, 2026) ("a critical examination, observation, or evaluation").

which the effect on quality could be measured, especially given that providers and patients are not even model participants. 91 Fed. Reg. at 63,064, 63,068. A guaranteed cost reduction carries "no research or experimental goal" and is therefore not a "test." *Beno*, 30 F.3d at 1069.

112. **GLOBE imposes unauthorized penalties.** An agency may impose a "penalty or fine" only "within jurisdiction delegated to the agency and as authorized by law." 5 U.S.C. §§ 551(10)(C), 558(b); *accord Carpenter v. Mineta*, 432 F.3d 1029, 1033 (9th Cir. 2005) (agencies "may not exceed their statutory power to issue sanctions"). CMS imposed GLOBE's penalties under the auspices of the IRA's inflation-rebate penalty provisions and 42 U.S.C. § 1320a-7a(a)(8). 91 Fed. Reg. at 63,058–59. But the IRA penalizes only the failure to pay the inflation rebates Congress enacted. *See* 42 U.S.C. § 1395w-3a(i)(7). And Section 1320a-7a(a)(8) reaches only knowingly "false record[s] or statement[s] material to a false or fraudulent claim for payment." Neither set of provisions empowers CMS to penalize manufacturers for failing to pay rebates the agency invented.

113. **CMS's interpretation violates the major questions doctrine.** An agency asserting the power to make decisions of "vast economic and political significance" must point to "clear congressional authorization" for the power it claims. *West Virginia*, 597 U.S. at 716, 723 (citation omitted); *see also Nebraska*, 600 U.S. at 504–06; *Learning Res.*, 607 U.S. at 242–48. Nothing in Section 1315a suggests that Congress meant to let CMS unilaterally set drug prices for a quarter of all Medicare Part B beneficiaries. The model at issue here, which involves one of the most politically contentious issues of our time, would upend Congress's carefully calibrated framework to incentivize pharmaceutical innovation. Moreover, Congress has repeatedly barred CMS from using QALYs, or any "similar measure," in Medicare coverage and reimbursement decisions, 42 U.S.C. §§ 1320e-1(e), 1320f-3(e)(2), yet GLOBE ties manufacturers' liability to foreign prices based on those prohibited metrics, *see supra* ¶ 96. As with student loan forgiveness, CMS's "assertion of administrative authority has 'conveniently enabled [it] to enact a program' that Congress has chosen not to enact itself"—despite multiple opportunities to do so. *Nebraska*, 600 U.S. at 503 (quoting *West Virginia*, 597 U.S. at 731). That asserted power is no less sweeping because CMS anticipates initially applying GLOBE to only four manufacturers, primarily because manufacturers otherwise

covered by the program will receive waivers based on their participation in GENEROUS, a *separate* CMS-created program. 91 Fed. Reg. at 63,069, 63,095. That CMS was able to leverage its asserted price-control authority underlying GLOBE to secure manufacturers' participation in the GENEROUS program—and thus reduce the current footprint of GLOBE—is proof of the asserted authority's magnitude, not its modesty.

114. "These considerations apply with particular force" where, as here, the agency reaches for "core congressional power." *Learning Res.*, 607 U.S. at 243. GLOBE intrudes on three separate congressional powers: the power of the purse, U.S. Const. art. I, § 9, cl. 7; the patent power, *id.* § 8, cl. 8, which Congress alone has authority to "re-balance" for "inventive new drugs," *BIO*, 496 F.3d at 1373–74; and the foreign commerce power, U.S. Const. art. I, § 8, cl. 3, which vests Congress with "exclusive and absolute" authority to "regulate Commerce with foreign Nations," *Japan Line, Ltd. v. County of Los Angeles*, 441 U.S. 434, 449 n.13 (1979) (citation omitted). While Congress may, in appropriate circumstances, delegate aspects of these "core" powers, a "reasonable interpreter" would expect it to do so "clearly." *Learning Res.*, 607 U.S. at 243 (quoting *Nebraska*, 600 U.S. at 514–15 (Barrett, J., concurring)). Here it did not.

115. For each of these independent reasons, GLOBE is "in excess of statutory jurisdiction, authority, or limitations" and "not in accordance with law," and must be held unlawful and set aside. 5 U.S.C. § 706(2)(A), (C). Additionally, GLOBE is *ultra vires* under the nonstatutory standard of review because CMS has plainly exceeded its authority and there would be no alternative mechanism for review of that violation.

116. The GLOBE final rule must accordingly be declared unlawful, vacated and set aside under 5 U.S.C. § 706(2), and enjoined. Because GLOBE's provisions stand or fall together, GLOBE must be vacated in its entirety. Every operative feature of GLOBE depends on the foreign-price rebate that CMS lacks authority to impose. Without the rebate, those provisions have nothing to calculate, collect, adjust, verify, or enforce. A rule that the agency would not have adopted without its invalid core cannot be partially sustained. *See, e.g.*, *Davis Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997).

COUNT II

VIOLATION OF THE APPROPRIATIONS CLAUSE AND RELATED STATUTES

117. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

118. Under the APA, courts shall "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity"; "in excess of statutory jurisdiction, authority, or limitations"; or "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A)–(C).

119. Plaintiffs' constitutional claims arise directly under the Constitution and may be brought independent of the APA. Plaintiffs may seek equitable relief against federal officers to prevent unconstitutional or *ultra vires* official action, *see Trump v. Cook*, 609 U.S. 528, 549 n.2 (2026); *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 n.2 (2010), including where, as here, they are injured by the unlawful collection of funds in violation of the Appropriations Clause and related statutes. *Scheduled Airlines Traffic Offs., Inc. v. DOD*, 87 F.3d 1356, 1361–62 (D.C. Cir. 1996).

120. The Appropriations Clause provides that "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law[.]" U.S. Const. art. I, § 9, cl. 7. This "control of the purse" is among "Congress's most important authorities." *Nebraska*, 600 U.S. at 505. Congress has protected it through statutes, including the Miscellaneous Receipts Act, which requires federal agencies "receiving money for the Government from any source" to deposit it in the Treasury—*not* in their own agency accounts—"as soon as practicable without deduction for any charge or claim." 31 U.S.C. § 3302(b). Absent specific statutory authority to keep or redirect funds, funds must be deposited in the Treasury's general fund. *Scheduled Airlines*, 87 F.3d at 1361–62.

121. GLOBE violates those constraints. It directs that rebate payments be deposited into the SMI Trust Fund rather than deposited as miscellaneous receipts in the Treasury's general fund. 91 Fed. Reg. at 62,938. Without statutory authority to retain the receipts, that routing "effectively . . . supplement[s]" the funds available for Medicare spending beyond the amounts Congress otherwise made available and is the kind of "end-run around normal appropriation channels" that the Miscellaneous Receipts Act forbids. *Scheduled Airlines*, 87 F.3d at 1362 (citation omitted).

122. No statute authorizes those deposits. The SMI Trust Fund may receive only amounts specified in Medicare Parts B and D and other enumerated categories. *See* 42 U.S.C. § 1395t(a). The novel rebates created by GLOBE are not among them.

123. An agency rule is not an "Appropriation[] made by Law," U.S. Const. art. I, § 9, cl. 7, and cannot supply the statutory authority that the Miscellaneous Receipts Act requires. GLOBE must therefore be declared unlawful, vacated and set aside, and enjoined.

COUNT III

VIOLATION OF SEPARATION OF POWERS AND NONDELEGATION PRINCIPLES

124. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

125. Under the APA, courts shall "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B). Plaintiffs may also seek equitable relief against federal officers to prevent unconstitutional official action. *See Cook*, 609 U.S. at 549 n.2; *Free Enter. Fund*, 561 U.S. at 491 n.2.

126. GLOBE implicates several structural separation-of-powers protections contained in the Constitution and is therefore contrary to constitutional rights. CMS's asserted construction of Section 1315a raises a grave Presentment Clause problem. The Clause prescribes a single, finely wrought procedure for enacting or amending federal law: passage by both Houses of Congress and presentment to the President. U.S. Const. art. I, § 7. Executive action that functionally amends or nullifies a statute bypasses this procedure. *See INS v. Chadha*, 462 U.S. 919, 946–51 (1983); *Clinton v. City of New York*, 524 U.S. 417, 438–40 (1998). Yet GLOBE, under the guise of "waiver," overlays the IRA's inflation rebate provision with an entirely new rebate regime keyed to foreign prices. If Section 1315a authorized that result, it would permit CMS to amend the Medicare statute by administrative decree rather than through bicameralism and presentment.

127. If Section 1315a were read to authorize GLOBE, it would also violate the nondelegation doctrine. "Legislative power . . . belongs to the legislative branch, and to no other." *FCC v. Consumers' Rsch.*, 606 U.S. 656, 672 (2025). Congress can delegate that authority to the Executive Branch only if it provides "an 'intelligible principle' to guide what it has given the agency

to do." *Id.* at 673 (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)). The more sweeping the power conferred, the more guidance is required. *Id.*

128. Determining the prices the Nation pays for prescription medicines and the rebates manufacturers owe is a quintessentially legislative act. Congress has repeatedly exercised precisely that power, always with domestic reference points and exclusions of its own design. *See, e.g.*, 42 U.S.C. §§ 1395w-3a, 1395w-111(i), 1395w-114b, 1320f-1. Equally legislative are the judgments GLOBE overrides about how to "re-balance" the patent system's incentives for new drugs, *BIO*, 496 F.3d at 1373–74; *see* U.S. Const. art. I, § 8, cl. 8, and how to "regulate Commerce with foreign Nations," U.S. Const. art. I, § 8, cl. 3; *accord Japan Line*, 441 U.S. at 449 n.13.

129. On CMS's reading, Section 1315a would leave to CMS's unguided discretion major legislative questions, including: whether to impose foreign-reference-pricing rebates at all; which foreign countries to select as comparators; whether to use the lowest foreign price or an average; which drugs and manufacturers the regime reaches; how large the resulting rebate liability may be; whether participation is mandatory; how long the regime remains in force; and what penalties enforce it. Congress supplied no standard to guide—much less confine—any of those determinations. Section 1315a authorizes limited, experimental tests of payment and service delivery models. Read to authorize GLOBE, it becomes a standardless grant of legislative power over nationwide drug pricing that the Constitution does not permit.

130. The separation-of-powers concerns are further exacerbated to the extent that the government attempts to shield GLOBE from judicial review. *See Am. Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946).

131. At a minimum, the canon of constitutional avoidance forecloses CMS's reading. Where a statute is susceptible of two plausible interpretations, one of which raises a serious constitutional question, a court must adopt the reading that avoids it, absent a clear statement from Congress to the contrary. *Zadvydas v. Davis*, 533 U.S. 678, 689 (2001). Section 1315a need not, and therefore should not, be read to authorize GLOBE.

132. GLOBE must accordingly be declared unlawful, vacated and set aside, and enjoined.

PRAYER FOR RELIEF

For these reasons, Plaintiffs respectfully request an order:

a) declaring, pursuant to 28 U.S.C. § 2201(a), that GLOBE is unlawful because it exceeds Defendants' statutory authority and violates the Constitution;

b) vacating and setting aside GLOBE under 5 U.S.C. § 706(2);

c) staying, or postponing the effective date of, GLOBE under 5 U.S.C. § 705;

d) permanently enjoining Defendants, their officers, agents, employees, and successors, and all persons in active concert or participation with them, from implementing, enforcing, or giving effect to GLOBE against Plaintiffs and their members;

e) awarding Plaintiffs reasonable costs and attorneys' fees as permitted by law; and

f) granting such other and further relief as the Court deems just and proper.

Dated: November 6, 2026

By: */s/ Sharon D. Mayo*

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*Application for admission *pro hac vice* forthcoming