IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, *et al.*,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 1:20-cv-03531-CCB

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION

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INTRODUCTION

Urgent action by this Court is needed to stop a legally deficient, wholesale transformation of the Medicare program via interim final regulation that will cause immense, irreparable harm to patients, healthcare providers, and pharmaceutical manufacturers starting on January 1, 2021.

For years, the Trump Administration urged major revisions to the Medicare Part B reimbursement system that would substitute foreign price controls for the market-based approach adopted by Congress. The Administration recognized that such a fundamental change could be undertaken only by new legislation, and while it urged Congress to act, Congress declined. So this summer, the President decided to proceed on his own initiative. "We've been waiting for Congress to take action for many decades to reduce drug prices," he announced. "I'm unwilling to wait any longer." *Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices* (July 24, 2020), https://bit.ly/37zwGJt [July 2020 Remarks]. Lacking "any meaningful legislative support," the Administration implemented administratively—without going through notice-and-comment procedures—what it calls a "historic" and "transformative" effort to "completely restructure the prescription drug market, in terms of pricing and everything else." *Id.*; *Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans* (Nov. 20, 2020), https://bit.ly/3ophZzI [Nov. 2020 Remarks].

This motion seeks a temporary restraining order (TRO) and a preliminary injunction against this executive overreach, which is unauthorized by statute and inconsistent with our constitutional system of government. Under the Medicare statute enacted by Congress, reimbursement for a drug covered under Medicare Part B is based on the drug's average domestic price. But the new regulation by the Centers for Medicare and Medicaid Services (CMS), known as the Most Favored Nation Rule (MFN Rule), implements an entirely new, untested payment scheme for 50 critical medicines, which are administered to Part B patients for serious conditions like

autoimmune disorders and cancer. In contrast to Congress's market-based approach, the MFN Rule bases reimbursement on the lowest price available in almost two dozen other countries—regardless of how those countries structure their healthcare systems, the (dis)incentives they provide for innovation, or the limitations they place on patients' ability to access medications.

CMS claims authority to supersede Congress's work from Section 1115A of the Social Security Act, as added by the Affordable Care Act. Yet Section 1115A does not authorize anything close to the MFN Rule. Described by four Supreme Court Justices as a "minor," "ancillary" provision, *NFIB v. Sebelius*, 567 U.S. 519, 704–05 (2012) (joint dissent), Section 1115A creates the "Center for Medicare and Medicaid Innovation" (CMMI), which is charged with "test[ing] innovative payment and service delivery models," 42 U.S.C. § 1315a(a)(1). By law, CMMI may test models that address "a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." *Id.* § 1315a(b)(2)(A). During model tests, CMMI may waive parts of the Medicare statute and certain other parts of the Social Security Act, but only "as may be necessary" for the "sole[]" purpose of testing the model. *Id.* § 1315a(d)(1). If—and only if—an initial pilot test proves successful based on statutory criteria and a certification from the CMS Chief Actuary, then CMMI may follow prescribed procedures to "expand ... the duration and the scope of [the] model" to a second phase, including potentially "expand[ing] ... the scope of a model" "on a nationwide basis." *Id.* § 1315a(c).

Or that is how the law is supposed to work. But CMS is now attempting to use this modest "test" authority to "transform drug pricing forever." Nov. 2020 Remarks. The MFN Rule is not a "test" of a "model," nor does it "address a defined population" with identified "deficits in care." The Rule also skips the two-step statutory process—*first* to "test" and *then* to "expand," 42 U.S.C. § 1315a(c)—in favor of an immediate rollout in all U.S. states and territories. With no control

group, mandatory participation nationwide, and massive fiscal effects, the MFN Rule is nothing like the sort of limited "test" of a "model" that Section 1115A authorizes.

CMS's reading of Section 1115A would arrogate to the agency unbridled power to revise Medicare in its sole discretion. If CMS can launch mandatory, nationwide models of its own design while waiving much of the Medicare statute, nothing stops it from replacing the program entirely. The damage to the separation of powers is manifest. CMS is claiming authority to use the Medicare statute as a suggestion, which it may keep, revise, or discard on its way to a healthcare system designed, implemented, and enforced in-house by the Executive Branch.

The MFN Rule will irreparably harm every part of the Medicare Part B ecosystem. CMS *expects* the Rule to impede patients' access to medications, forcing them to accept less-effective treatments or forgo necessary care. It will shortchange healthcare providers, reimbursing them a fraction of what they pay for critical medicines, forcing some to close and casting patients adrift. And it will slash incentives for research and development, resulting in fewer innovative medicines. Plaintiffs attach declarations from providers, provider groups, patient groups, and pharmaceutical companies, as well as a report from a prominent health economist, attesting to these real and imminent harms. One neurologist who treats patients with multiple sclerosis, for example, and "ha[s] devoted [his] career to protecting [his] patients' neurological function," attests that, "[t]o me, implementation of the MFN Rule on January 1 is unthinkable and places my patients at an unnecessary risk of relapse and permanent neurological damage." Ex. N, ¶ 12.

Moreover, CMS has denied the public *any* say in this overhaul. CMS jettisoned the notice-and-comment process ordinarily required for rulemaking and instead issued the MFN Rule as an "interim final rule," effective immediately. Although the Administration has been considering reference pricing proposals for almost three years, CMS attempts to justify this procedural violation

by reference to COVID-19, even though the pandemic did not stir CMS to action at any point during the ten months since it was declared a public health emergency; and the MFN Rule's seven-year term is in no way correlated to the pandemic. By short-circuiting the notice-and-comment process, CMS deprived the public of the opportunity to point out the many shortcomings of the Rule before it became effective, including how it will harm patients in both the short and long term by reducing drug availability and development.

For these reasons, the Court should enter a TRO and a preliminary injunction stopping the implementation of this *ultra vires* rulemaking before it begins irreparable harming patients, healthcare providers, and manufacturers on January 1, 2021. At minimum, Plaintiffs request that the Court enter an order preliminarily enjoining the interim final rulemaking from going into effect until Defendants have complied with notice-and-comment requirements.

BACKGROUND

A. Medicare Part B and the U.S. Drug Pricing System

"Medicare is a federal program providing subsidized health insurance for the aged and disabled." *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012). While "Medicare Part A provides coverage for inpatient care," *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020), Medicare Part B "is a supplemental voluntary insurance program," whereby individuals "may purchase supplementary insurance for hospital out-patient services, physician services, and other medical services." *Rehab. Ass'n of Va., Inc. v. Kozlowski*, 42 F.3d 1444, 1446 (4th Cir. 1994). Enrollees "pay a monthly premium and an annual deductible," plus 20% of providers' reasonable charges "as a copayment or coinsurance." *Id.* Enrollees also may purchase private "Medigap" insurance to help cover their copays. *See* 42 U.S.C. § 1395ss(g)(1). Relevant here, Part B provides coverage for certain drugs and biologicals administered by providers on an outpatient basis. *Id.* § 1395x(s)(2).

Healthcare providers are reimbursed for Part B drugs under a so-called "buy and bill" system, whereby providers purchase drugs from manufacturers or other suppliers and then submit claims to Medicare for reimbursement. 83 Fed. Reg. 54,546, 54,548 n.4 (Oct. 30, 2018). By statute, covered drugs are reimbursed at rates approximating "the actual price paid by purchasers" in "real market transaction[s]." H.R. Rep. 108-178, pt. 2, at 194, 197–98 (2003). In most cases, Medicare Part B reimbursement rates are based on the "average sales price"—a market-based price reflecting the volume-weighted quarterly average of all manufacturer sales prices to U.S. customers (with limited exceptions). Providers also receive an add-on of 6% (or 4.3% under sequestration), which serves as a handling fee and helps ensure that all providers (including small and rural providers that may pay higher-than-average drug prices) at least break even. *See* 42 U.S.C. § 1395w-3a.

Strong, market-based incentives are necessary to encourage investment in pharmaceutical innovation because new life-saving and life-enhancing drugs come at enormous cost. On average, a manufacturer will spend nearly $3 billion developing one new medicine. *See* DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/30UAIdg. Some pharmaceutical companies have invested an average of over $10 billion per new drug. Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, 2016, at 3–4, https://bit.ly/2PWRKRC. These investments are a gamble—only one in 5,000 compounds that enter preclinical testing will be approved by the FDA to treat patients. Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://bit.ly/2Y2gwEK. And of the therapies that are approved and sold on the commercial market, only one-third manage to even cover their development costs, much less turn a significant profit. *See* CEA, *Funding the Global Benefits to Biopharmaceutical Innovation* 7 fig.3 (Feb. 2020), https://bit.ly/3qtwLHc [2020 CEA

Report]. Pharmaceutical companies sustain these investments on a key prospect: A product that reaches market and fills a medical need will earn market-based returns.

B. Foreign Drug Pricing Systems

Other countries, especially in Europe and Asia, structure their systems differently. "[N]ormal returns" to recoup up-front costs generally are not available in these countries, where price controls and other interventions push drug prices below market prices—often as low as the marginal cost of production. *Id.* at 8. Many of these interventions rely on "external reference pricing," in which the price of a drug in one country is pegged to its price in other countries. U.S. Dep't of Health & Human Servs., *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* 15 (May 2018), https://bit.ly/3lGap1O [HHS Blueprint]. As HHS has recognized, these interventions are constantly increasing. *Id.* at 14.

External reference pricing and other price controls stymie innovation and harm patients. In the mid-1980s, for example, Europe outspent the United States on drug research and development by 24%, but by 2004, after price controls obstructed investment, Europe trailed by 15%. *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation* 4 (2008). Price controls lead to "a slower pace of innovation" and "fewer potential new life-saving therapies for patients in all countries," with staggering economic and human costs. 2020 CEA Report at 20. Price controls also prevent patients from accessing new medications in a timely fashion—or sometimes at all. Today, nearly 90% of new medicines launched since 2011 are available in the United States, but availability in countries with price control regimes lags far behind—Germany, for example, comes in a distant second at 63%, and in Ireland, the number is just 41%. PhRMA, *The United States vs. Other Countries: Availability of New Medicines Varies* (July 2020), https://onphr.ma/30XsuBl; *see* Ex. C, ¶¶ 37-40; Ex. D, ¶¶ 52-61.

C. The Challenged Rulemaking

1. The IPI Advanced Notice of Proposed Rulemaking

On October 30, 2018, CMS published an advance notice of proposed rulemaking that proposed external reference pricing. 83 Fed. Reg. at 54,546. Citing concerns about the high prices for drugs under Medicare Part B relative to other countries, CMS's advance notice offered so-called "International Pricing Index" (IPI) as a potential solution. Rather than reimbursing providers for drugs based on their average U.S. sales prices, providers would obtain drugs through a vendor, which Medicare would pay based on an index of prices from around the world. *See id.* at 54,555-56. In effect, the IPI concept would have imported foreign price controls into the United States.

CMS announced the IPI concept as an advance notice, not a notice of proposed rulemaking. *Id.* at 54,546. Yet for months, CMS neither proposed nor implemented the IPI concept. Instead, the President urged legislative action. In his 2019 State of the Union Address, President Trump "ask[ed] the Congress to pass legislation that finally takes on the problem of global freeloading" on U.S. pharmaceutical investment and innovation. *President Donald J. Trump's State of the Union Address* (Feb. 5, 2019), https://bit.ly/3mIWRUh. But by December 2019, when the House of Representatives was debating a reference-pricing bill, the Administration reversed course. It lauded the bill's "goal of lowering prices" but warned that "the threat it poses to continued medical innovation will harm American patients in ways that far outweigh any benefits." CEA, *House Drug Pricing Bill Could Keep 100 Lifesaving Drugs from American Patients* (Dec. 3, 2019), https://bit.ly/36FH2rW [2019 CEA Analysis].

2. The Executive Orders

On July 24, 2020, the Administration changed course again. With great fanfare, President Trump signed four Executive Orders to "massively lower prescription drug costs." White House Fact Sheet, *President Donald J. Trump Is Taking Action to Lower Drug Costs and Ensure That*

Americans Have Access to Life-Saving Medications (July 24, 2020), https://bit.ly/2UJJd7i [White House Fact Sheet]. One order was entitled "Lowering Drug Prices by Putting America First"—or so it appeared, as the Administration refused to make the order publicly available. The President explained that he planned to hold "talks" with pharmaceutical companies to reduce drug prices and obviate the perceived need for the order, predicting that companies would negotiate because the order would be "very tough" for them. July 2020 Remarks.

On its website, the White House stated that the withheld order would institute a scheme even more aggressive than the IPI concept by "ensur[ing] that the United States pays the lowest price available in economically comparable countries for Medicare Part B drugs." White House Fact Sheet. While President Trump described all four of executive orders as "sweeping," he singled out the MFN order as "transformative." July 2020 Remarks. He described it as "bold," "sweeping," "historic," "very big," and "very dramatic"—"the granddaddy" of "the most far-reaching prescription drug reforms ever issued." *Id.* Together, the four orders would "completely restructure the prescription drug market, in terms of pricing and everything else." *Id.*

While President Trump warned that he would release the withheld order in one month if talks with pharmaceutical companies did not prove fruitful, the Administration in fact withheld it for nearly two months, releasing it on September 13, 2020. The order announced: "It is the policy of the United States that the Medicare program should not pay more for costly Part B … prescription drugs or biological products than the most-favored-nation price." Exec. Order No. 13948 of September 13, 2020, 85 Fed. Reg. 59,649, 59,649 (Sept. 23, 2020). Based on that policy, the President directed Secretary Azar to take "steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." *Id.*

3. The Interim Final Rule

On November 20, 2020, CMS announced the promulgation of a regulation (MFN Rule or Rule) "[i]n response to the September 13, 2020 Executive Order." 85 Fed. Reg. at 76,182. As an "interim final rule with comment period," the Rule went into effect immediately on November 27, the day it was published in the Federal Register, but CMS will accept comments for 60 days—until January 26, 2021. *Id.* at 76,180. Even though the Administration had been considering a different international reference pricing scheme for years, CMS claimed to "find that there is good cause to waive the notice and comment requirements under section[] 553(b)(B) of the APA and section 1871(b)(2)(C) [of the Social Security Act] because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic." *Id.* at 76,249.

By any measure, the MFN Rule is far-reaching. Starting on January 1, 2021, the Rule rewrites the reimbursement rules for 50 drugs and biologicals with the highest Part B spending, with narrow exclusions. *Id.* at 76,189. Those 50 drugs currently "account[] for approximately 75 percent of annual Medicare Part B drug allowed charges." *Id.* at 76,193. And CMS has said that every year it will add new drugs that rise into the top 50, but likely will not remove drugs that drop out of the top 50. *Id.* at 76,192. As a prominent health economist explains in an attached report, the Rule thus "target[s] the very drugs that are successful: those that help many people, and can command a high price because of the therapeutic value they offer patients." Ex. J, ¶ 66. The Rule also takes direct aim at manufacturers' patents by excluding drugs that are subject to competition from generic drugs. 85 Fed. Reg. at 76,188-89.

For selected drugs, CMS ultimately will reimburse an amount equal to the so-called "MFN Price" (or the statutory market-based amount, in the unlikely event it is lower). *Id.* at 76,196. CMS will calculate each selected drug's MFN Price on a quarterly basis based not on an average of international prices, as in the IPI plan, but on the *lowest* GDP-per-capita-adjusted price of that drug

in any OECD country with a purchasing-power-parity-adjusted GDP per capita that is at least 60% of that of the United States. *Id.* Currently, that list includes almost two dozen countries, including countries with government-run, single-payor healthcare systems like the U.K. and Sweden. *Id.* at 76,200. The Rule shifts reimbursement from the statutory rate to the MFN Price over a four-year phase-in period. *Id.* at 76,235. And CMS will further lower the reimbursement rate if the price of a selected drug rises faster than both inflation and the MFN Price. *Id.* at 76,213-15. In full, the MFN Rule will run for seven years. *Id.* at 76,181.

The MFN Rule's new reimbursement rates will drastically cut the amounts that providers are paid for drugs they purchase and administer to patients. The MFN Rule "require[s] mandatory participation" across "all states and U.S. territories," from "all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN drug," subject to "limited exclusions." *Id.* at 76,181, 76,185. And unlike the IPI plan, the MFN Rule maintains the "buy and bill" system, such that providers shoulder the risk that reimbursement at the MFN price will not cover their costs of purchasing medicines at market prices, undercutting their ability to continue treating patients. *Id.* at 76,236; *see* Ex. H, ¶¶ 10-15; Ex. I, ¶¶ 10-15; Ex. M, ¶¶ 11-15.

The MFN Rule also changes the add-on amount providers receive as a handling fee. In place of the statutory 6% add-on, the MFN Rule sets a flat per-dose add-on payment that is uniform across all drugs. 85 Fed. Reg. at 76,216-17. While the new add-on scheme is projected to increase providers' add-on revenue in the aggregate, it will reduce add-on revenue for nine major medical specialties, including neurology, infectious disease, and several types of oncology. *Id.* at 76,218-20. The US Oncology Network attests that the harm to oncologists will be "immediate and profound." Ex. M, ¶ 19.

As authority for this administrative revolution, CMS relies on Section 1115A of the Social Security Act, which establishes CMMI and charges it with "test[ing] innovative payment and service delivery models" through a two-phase process. 42 U.S.C. § 1315a(a)(1). In "phase I," the Secretary "select[s] models to be tested … where … 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 Secretary then "test[s]" selected models "to determine the[ir] effect … on program expenditures … and the quality of care," and "conduct[s] an evaluation of each model tested," *Id.* § 1315a(b)(1), (b)(4)(A). Based on that evaluation—and only if certain prerequisites are met—the Secretary may move to "phase II," in which the Secretary "may, through rulemaking, expand … the duration and the scope of a model that is being tested," including "implementation on a nationwide basis." *Id.* § 1315a(c). While the Secretary may waive certain statutory provisions "as may be necessary solely for purposes of" a phase I test, the Secretary has no waiver authority for a phase II expansion. *Id.* § 1315a(d)(1).

Though purporting to rely on Section 1115A, 85 Fed. Reg. at 76,231, CMS fails to identify any "defined population" with "deficits in care," as the statute requires, 42 U.S.C. § 1315a(b)(2)(A). And the Administration's public statements confirm that the Rule is not a "test[]" of a "model." *Id.* It is a new national drug-pricing "policy" at odds with that of Congress, 85 Fed Reg. at 59,649, undertaken to "transform drug pricing forever" "in the absence of meaningful legislative support." Nov. 2020 Remarks. Secretary Azar declared the MFN Rule "the most significant single action any administration has ever taken to lower American drug costs." CMS Press Release, *Trump Administration Announces Prescription Drug Payment Model To Put American Patients First* (Nov. 20, 2020), https://go.cms.gov/3ofX8hS [CMS Press Release].

ARGUMENT

A movant seeking a TRO or a preliminary injunction must show: (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm absent relief, (3) that the balance of equities tips in its favor, and (4) that an injunction is in the public interest. *See Roe v. Dep't of Def.*, 947 F.3d 207, 219 (4th Cir. 2020). Here, all four factors strongly support relief.

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

The MFN Rule flouts applicable notice-and-comment requirements, exceeds CMS's limited statutory authority under Section 1115A, and violates the constitutional separation of powers.

A. The MFN Rule Was Unlawfully Promulgated Without Notice and Comment

Under the APA, before promulgating a final rule, an agency must publish a "[g]eneral notice of proposed rulemaking … in the Federal Register" and then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b), (c). The Social Security Act likewise provides that, "before issuing in final form any regulation …, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1). These requirements "are not mere formalities" but rather "are basic to our system of administrative law." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). Notice and comment is especially important for Medicare, "the largest federal program after Social Security," since "even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808, 1816 (2019); *see* Ex. T, ¶ 13.

For legislative rules like the MFN Rule, the APA and the Social Security Act provide only one exception to this requirement: an agency may dispense with notice and comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor

in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b); *see* 42 U.S.C. § 1395hh(b)(2)(C) (incorporating this exception into the Social Security Act). This good cause exception, however, is to be "narrowly construed and only reluctantly countenanced." *N.C. Growers's Ass'n v. United Farm Workers*, 702 F.3d 755, 767 (4th Cir. 2012) (citation omitted). "The circumstances justifying reliance on the good cause exception are rare, and will be accepted only after a reviewing court examines closely proffered reason for an agency's deviation from notice and comment." *Id.* (cleaned up). "The good cause exception applies only in emergency situations, or in cases when delay could result in serious harm," *id.* (quotation marks omitted)—for example, where a "delay would imminently threaten life or physical property" or risk "fiscal calamity," *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706-07 (D.C. Cir. 2014).

CMS's own dilatory conduct alone precludes any "good cause" to dispense with notice and comment here. "Good cause cannot arise as a result of the agency's own delay," *Nat. Res. Def. Council*, 894 F.3d at 114, and courts "have repeatedly rejected good cause when the agency delays implementing its decision," *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 16 (D.D.C. 2017). Delays of as little as six months "have precluded reliance on the good cause exception." *Chamber of Commerce v. DHS*, 2020 WL 7043877, at *8 (N.D. Cal. Dec. 1, 2020). Here, CMS's delay is far more egregious. The Administration first discussed the concept of an external reference pricing model in January 2018—almost *three years* ago. *See* Nov. 2020 Remarks. CMS then solicited comments on the IPI plan through an advance notice of proposed rulemaking over two years ago. In July 2019, President Trump stated that his Administration "very shortly" would be announcing a "favored nations" drug-pricing scheme "in the form of an executive order." White House Remarks, *Remarks by President Trump Before Marine One Departure* (July 5, 2019),

https://bit.ly/39GqSjV. On July 24, 2020, President Trump announced an executive order requiring the Secretary to implement the MFN Rule. But it was not until November 27 that the Administration finally promulgated the MFN Rule as an interim final rule, without notice and comment.

CMS claimed to find "good cause" because the problem of "[h]igh drug prices" has been "rapidly exacerbated" by "[t]he COVID-19 pandemic." 85 Fed. Reg. at 76,249. But the COVID-19 pandemic was declared a public health emergency—by Secretary Azar—over ten months ago. HHS Press Release, *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (January 31, 2020), https://bit.ly/2VBc91v. Since then, CMS has issued multiple proposed rules on other subjects that have "expressly requested input on the impact of the COVID-19 pandemic." *Chamber of Commerce*, 2020 WL 7043877, at *9; *see, e.g.*, 85 Fed. Reg. 39,408, 39,428 (June 30, 2020); 85 Fed. Reg. 22,065, 22,087 (Apr. 21, 2020).

CMS's invocation of the good cause exception also lacks credibility for other reasons. The MFN Rule relies on CMS's "test[ing]" authority under Section 1115A, but it makes no sense that there could be an immediate need to begin a *seven-year* "test" of a new payment "model," with a *four-year* phase-in—far longer than any emergency connected with the pandemic. The MFN Rule thus bears no resemblance to "temporary" regulations, where "an emergency situation has been eased by the promulgation of interim rules." *Block*, 655 F.2d at 1157-58.

CMS also asserts that "[t]he economic disruptions caused by the COVID-19 pandemic have increased the burdens placed on America's seniors and other Medicare Part B beneficiaries" and that "[i]mplementation will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs." 85 Fed. Reg. at 76,249. But that "largely conclusory statement that … immediate promulgation is necessary in order to benefit the greatest number of [beneficiaries]" is "not enough." *Zhang v. Slattery*, 55 F.3d 732, 747 (2d Cir. 1995). "Presumably, agencies deem

all their rules beneficial; the notice and comment requirement would be a dead letter if compliance could be excused whenever the beneficial effect would thereby be accelerated." *Id.* In any event, most Medicare beneficiaries are retired, and the vast majority have Medigap and other supplemental coverage for out-of-pocket expenses. 85 Fed. Reg. at 76,183 n.22; Ex. J, ¶ 51. And again, the MFN purported "test" is set to last seven years, well beyond the pandemic. If CMS's real goal were to reduce copays, it easily could have done so more directly and effectively. In fact, the MFN Rule will *exacerbate* the problems posed by the pandemic by slashing reimbursements, obstructing patients' access to medications, and forcing patients out of local treatment centers into distant, crowded, COVID-19-affected hospitals. Ex. I, ¶¶ 20-22; Ex. J, ¶ 62; Ex. M, ¶ 24; Ex. S, ¶ 13.

CMS's pandemic-related justification falls especially flat because the MFN Rule categorically *exempts* drugs used "to treat patients with suspected or confirmed COVID-19." 85 Fed. Reg. at 76,191. CMS deems that exemption necessary because including COVID-19 treatments would undermine their "rapid, widespread availability." *Id.* In other words, because the MFN Rule threatens access to *any* included drug, CMS has exempted COVID-19 drugs, while simultaneously rushing the Rule through on grounds of improving patient access during the COVID-19 emergency.

This is not the first time a court has confronted a strained invocation of COVID-19 to justify jamming through a long-term change by interim final rule. Last week, a district court struck down new visa rules promulgated without notice and comment, purportedly to ease pandemic-related economic hardship. *Chamber of Commerce*, 2020 WL 7043877, at *1-*2. The court rejected the agencies' invocation of "good cause" because "even if the problems Defendants purport to solve with the Rules may have been exacerbated by the COVID-19 pandemic, Defendants do not suggest they are new problems." *Id.* at *8. While "[t]he COVID-19 pandemic is an event beyond Defendants' control, … it was within Defendants' control to take action earlier than they

did." *Id.* at *9. So too here. This Court should "[]not countenance—reluctantly or otherwise—Defendants' reliance on the COVID-19 pandemic to invoke the good cause exception." *Id.* at *1.

B. The MFN Rule Exceeds CMS's Statutory Authority

CMS's disregard for notice-and-comment rulemaking alone justifies a TRO and a preliminary injunction. But beyond that, the MFN Rule is a complete overhaul of Medicare Part B, not the limited "test" that the law envisions. Section 1115A authorizes CMMI "to test innovative payment and service delivery models." 42 U.S.C. § 1314a(a)(1). To do so, the Secretary "select[s] models to be tested" where "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," and then "conduc[t]s an evaluation of each model tested." *Id.* § 1315a(b)(2)(a).

The MFN Rule is flatly inconsistent with that statutory text. The ordinary meaning of the verb "test" denotes an effort to "try" something on a limited basis to evaluate its performance. *See* Oxford English Dictionary (2d ed. 1989), https://bit.ly/3as6yRV ("to try, put to the proof; to ascertain the existence, genuineness, or quality of"); *Test*, Black's Law Dictionary (11th ed. 2019) ("A procedure designed to discover whether equipment or a product works correctly, or else to discover more about it."). Similarly, the word "model" refers to a demonstration "on a small scale," to be followed and potentially adopted more widely later. Oxford English Dictionary (2d ed. 1989), https://tinyurl.com/y33ajme9. This narrow reading is reinforced by the requirement of a "defined population" with "deficits in care"—logically, a "defined population" with "deficits in care" must be distinct from and narrower than the general population of Medicare beneficiaries, whose level of care sets the baseline against which any "deficit" would be measured.

The MFN Rule does not resemble a "test" of a "model" for a "defined population" with "deficits in care." As President Trump and Secretary Azar have acknowledged—indeed, boasted—the MFN Rule is "the most significant single action any administration has ever taken to lower

American drug prices" and "the granddaddy" of "the most far-reaching prescription drug reforms ever issued," which will "completely restructure the prescription drug market." 2020 CMS Press Release; July 2020 Remarks. By its own terms, the MFN Rule "will require mandatory participation" from "a broad set of providers" across "all states and U.S. territories." 85 Fed. Reg. at 76,181, 76,184. It will run for seven years—spanning three presidential terms and four Congresses. *Id.* at 76,181. It will rewrite the reimbursement rules for the top 50 drugs by Part B expenditures, accounting for 75% of annual Part B spending, just in year one. *Id.* at 76,193. CMS never even attempts to identify any "defined population" with "deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." 42 U.S.C. § 1315a(b)(2)(A). Rather, the Rule is designed to "reduce Medicare program expenditures" *generally*. 85 Fed. Reg. at 76,181.

The MFN Rule is unprecedented in Section 1115A's ten-year history. Out of more than 50 models CMMI has tested, only four have been mandatory, and *none* of those was nationwide like the MFN rule. The Joint Replacement model, for example, ran only in acute care hospitals in selected geographic areas, and had *less than 0.5%* the projected fiscal impact of the MFN Model. *Id.*; 80 Fed. Reg. 73,274, 73,282 (Nov. 24, 2015). Even then, CMS scaled back mandatory participation while also cancelling two other planned mandatory models, citing concerns about "provider burden" that mandatory participation imposed. 82 Fed. Reg. 57,066, 57,069 (Dec. 1, 2017).

The MFN Rule is also inconsistent with Section 1115A's structure and the process it creates. The statute prescribes a two-phase process: In "phase I," the Secretary selects models and evaluates them, waiving certain statutory requirements if necessary, and in "phase II," he may expand tested models, but may not waive statutory requirements. 42 U.S.C. § 1315a(b)-(d). Phase II may involve "implementation on a nationwide basis"—but only "through rulemaking,"

and only "if" data from Phase I shows that expansion would meet prescribed requirements regarding expenditures, quality of care, and coverage and provision of benefits. *Id.* § 1315a(c).

The MFN Rule steamrolls this two-phase process. While the statute contemplates "implementation on a nationwide basis" in phase II—and even then, only if statutory prerequisites are met—the MFN Rule effects a mandatory, nationwide rollout in phase I. The sole statutory purpose of phase I, moreover, is to generate information for "evaluation." Yet the MFN Rule is so broad—with no "independent comparison group to establish the counterfactual (what would have happened in the absence of the model)," 85 Fed. Reg. at 76,232—that it defies meaningful evaluation. In moments of candor, CMS admits the real reason for the Rule's design: not to gather information for evaluation, but to "realize its full potential spending reductions" and supposedly "allow[] all eligible beneficiaries … to benefit from … cost-sharing reductions." *Id.* at 76,188, 76,205.

CMS's interpretation also conflicts with the Secretary's duty to include "recommendations … for legislative action to facilitate the development and expansion of successful payment models" in annual reports to Congress. *Id.* § 1315a(g). If CMS can adopt new payment models on a mandatory, nationwide basis in phase I, then the agency can "facilitate the development and expansion of successful payment models" without *any* congressional involvement. In fact, on CMS's reading, nothing would stop the agency from simply replacing the entire Medicare program wholesale, forever. That flouts the maxim that "Congress … does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

CMS's interpretation of Section 1115A also conflicts with the market-based drug-pricing system Congress designed to promote innovation. *See supra* pp. 5-6. The MFN Rule instead rewrites the Part B system, viewing Congress's market-based "methodology in section 1847A," 85

Fed. Reg. at 76,180, as a problem for the executive branch to solve. And CMS's interpretation of Section 1115A would arrogate to the agency Congress's exclusive power over the patent system. The MFN Rule attempts to do so by singling out drugs protected by patents and exempting those subject to competition from generic drugs. *Id.* at 76,188-89. "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—[CMS] has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

The MFN Rule also treads on Congress's "exclusive and plenary" authority to regulate foreign commerce. *Bd. of Trs. of Univ. of Ill. v. United States*, 289 U.S. 48, 56 (1933); *see* U.S. Const. art.1, § 8, cl. 3. The MFN Rule is expressly designed to "end foreign freeloading," 85 Fed. Reg. at 76,181, by forcing "foreign socialist systems … to bear their fair share" of research and development costs, July 2020 Remarks. CMS fully expects manufacturers to change their prices abroad, *see id.* at 76,236—as President Trump put it, "their number will go up, our number will come very substantially down, and we'll all agree" on a price in the middle. July 2020 Remarks. But just as states within the union "may not adopt legislation that has the practical effect of establishing a scale of prices for use in other states," *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (quotation marks omitted), CMS may not, without clear legislative authorization, prescribe drug prices abroad. At minimum, courts should not presume Congress has delegated its exclusiveauthority over foreign commerce to an executive agency unless it has clearly said so. *See Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014). Yet nothing in Section 1115A suggests that Congress delegated any part of its Foreign Commerce Clause authority to CMS.

C. As Interpreted in the MFN Rule, Section 1115A Is Unconstitutional

Read properly, Section 1115A does not authorize anything like the transformation of Part B that the MFN Rule attempts. But if the statute permitted this overhaul, it would be

unconstitutional twice over: as interpreted by CMS, Section 1115A offends the requirements of bicameralism and presentment and reflects an improper delegation of legislative power to the executive. At minimum, CMS's expansive claim of authority raises "serious constitutional doubts" and should be rejected. *Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018).

1. The MFN Rule Violates Bicameralism and Presentment Requirements

The Presentment Clause provides: "Every Bill which shall have passed the House of Representatives and the Senate, shall, before it become a Law, be presented to the President of the United States; If he approve he shall sign it, but if not he shall return it …." U.S. Const., Art. I, § 7, cl. 2. "There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes." *Clinton v. City of N.Y.*, 524 U.S. 417, 438 (1998). The Presentment Clause thus bars "unilateral … action that … repeals or amends parts of duly enacted statutes." *Id.* at 439.

Courts determine whether the Executive Branch has enacted, repealed, or amended a statute by looking to the executive action's "legal and practical effect." *Id.* at 438. In *Clinton v. City of New York*, the Supreme Court concluded that the President's cancellations of two budgetary provisions under the Line Item Veto Act had the impermissible "legal effect" of amending the relevant statutes because the cancellations rendered the provisions without "legal force or effect" and "entirely inoperative as to [the challengers]." *Id.* at 438, 441 (citation omitted). The cancellations had a similar "practical effect" because the President had "reject[ed] the policy judgment made by Congress and rel[ied] on his own policy judgment" instead. *Id.* at 438, 444. Rather than "executing [a] policy that Congress had embodied in the statute"—as might have occurred if the President had made a required determination in response to a statutorily specified event—the cancellations effectuated "the functional equivalent of partial repeals of Acts of Congress." *Id.*

Here too, the MFN Rule has the "legal and practical effect" of repealing duly enacted statutes governing Part B. As noted, Section 1115A allows the Secretary to waive provisions of the

Medicare statute, as well as other provisions of the Social Security Act, to implement models for phase I testing; the MFN Rule purports to use that authority to repeal Congress's reimbursement scheme and replace it with one of CMS's own making. Those waivers have the "legal effect" of amending the "finely wrought" Part B reimbursement system Congress established. *Id.* at 438-39 (citation omitted). Together, the waivers substitute the MFN regime for the statutory average sales price reimbursement methodology for top 50 products. Nor is the MFN Rule a mere implementation action taken in response to a statutorily prescribed triggering event—the Administration "reject[ed] the policy judgment made by Congress" and "rel[ied] on [its] own policy judgment." *Id.* And it is no answer that the provisions remain operative outside the MFN Rule; whatever "continuing … effect" they have elsewhere, the waived provisions are "entirely inoperative" as to drugs included in the Rule, which represent 75% of Part B spending. *City of N.Y.*, 524 U.S. at 441.

Nor does it matter that Section 1115A's waiver authority was itself granted in a law passed in accordance with the bicameralism and presentment requirements. Even if Congress could have anticipated that CMS would use this waiver authority to override its laws, "Congress cannot alter the procedures set out in Article I, § 7, without amending the Constitution." *Id.* at 446.

2. The MFN Rule Violates the Non-Delegation Doctrine

Article I of the Constitution vests "[a]ll legislative Powers" in Congress, and the Supreme Court has held that Congress may not "abdicate or transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935). Congress runs afoul of this prohibition if it delegates significant policymaking authority to an administrative agency without "an intelligible principle" to guide the agency's exercise of authority. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality op.) (quoting *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928)). Exactly how "intelligible" the principle must be depends on the delegation; "the degree of agency discretion that is acceptable

varies according to the scope of the power congressionally conferred." *Whitman*, 531 U.S. at 475. Ultimately, delegations are permissible only "if Congress had made clear to the delegee 'the general policy' he must pursue and the 'boundaries of [his] authority.'" *Gundy*, 139 S. Ct. at 2123 (plurality op.) (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

As interpreted by CMS in the MFN Rule, Section 1115A reflects an unconstitutional delegation of legislative power. Far from following any congressionally enacted "intelligible principle," *Gundy*, 139 S. Ct. at 2123 (plurality op.), CMS has seized upon Section 1115A as a vehicle to *repudiate* Congress's market-based approach to drug pricing. CMS blames Congress's "methodology in section 1847A" for purportedly higher drug costs, 85 Fed. Reg. at 76,180, and the Administration has admitted that it is using Section 1115A not to execute Congress's scheme, but to implement its own chosen "policy." 85 Fed. Reg. at 59,649. If Section 1115A authorizes the MFN Rule, the provision contains no "intelligible principle" whatsoever.

This is exactly the kind of executive aggrandizement that has prompted judicial concern about delegating to the Executive Branch "major policy questions of great economic and policy importance." *See, e.g. Gundy*, 139 S. Ct. at 2131 (Alito, J., concurring in the judgment); *id.* at 2138–39 (Gorsuch, J., dissenting). The MFN Rule undoubtedly falls in that category. At a minimum, Congress must "speak clearly"—far more clearly than in Section 1115A—"if it wishes to assign to an agency decisions of vast economic and political significance," *Util. Air Regulatory Grp.*, 573 U.S. at 324 (quotation marks omitted).

D. This Court Has Jurisdiction

This Court has jurisdiction over this case. There is "a strong presumption that Congress intends to allow for judicial review of final agency actions," which can be overcome only by "clear and convincing evidence that Congress intended to restrict judicial review." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 637 F.3d 259, 267 (4th Cir. 2011) (quotation marks omitted).

While Section 1115A bars judicial review of some administrative determinations related to CMMI's testing authority, it does not preclude jurisdiction over Plaintiffs' claims here.

First, nothing in Section 1115A bars Plaintiffs' challenge to CMS's failure to follow the applicable notice-and-comment requirements. Section 1115A(d)(2) provides in relevant part that "[t]here shall be no administrative or judicial review … of (A) the selection of models for testing or expansion …; (B) the selection of organizations, sites, or participants to test those models selected; [or] (C) the elements, parameters, scope, and duration of such models for testing or dissemination." None of those has anything to do with CMS's improper failure to follow notice-and-comment procedures, as the APA and the Social Security Act require. CMS agrees: In the MFN Rule, CMS "interpret[ed]" Section 1115A(d)(2) to bar review only of CMS's selection of participants, drugs, geographic areas, and relevant international pricing data, as well as CMS's methodology for determining MFN Prices, drug payment amounts, add-on payments, and financial hardship payments. 85 Fed. Reg. at 76,234-35. *Cf. CASA de Maryland, Inc. v. Trump*, 355 F.Supp.3d 307, 320 (D. Md. 2018) (jurisdictional bar provision did not bar "APA claims").

Second, Section 1115A(d)(2) likewise does not foreclose review of Plaintiffs' *ultra vires* claims that the MFN Rule falls outside the authority to "test" a "model" for a "defined population" with "deficits in care." "If a no-review provision shields particular types of administrative action, a court … must determine whether the challenged agency action is of the sort shielded from review." *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). And "the case law … is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003); *see Ancient Coin Collectors Guild v. U.S. Customs & Border Prot.*, 801 F. Supp. 2d 383, 405 (D. Md. 2011) (exercising *ultra vires* review), *aff'd*, 698 F.3d 171 (4th Cir. 2012). Even HHS itself has "acknowledge[d] that judicial review may

be available when the actions charged are claimed to be *ultra vires*." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1132 (D.C. Cir. 2017).

The D.C. Circuit's decision in *Amgen* is instructive. That case involved a similar provision stating that "[t]here shall be no administrative or judicial review … of," among other things, "other adjustments" to certain Medicare Part B payments. 357 F.3d at 111 (quoting 42 U.S.C. § 1395*l*(t)(2)(E)). The court "construe[d] [that provision] to prevent review only of those 'other adjustments' that the Medicare Act authorizes the Secretary to make; in other words, the preclusion on review of 'other adjustments' extends no further than the Secretary's statutory authority to make them." *Id.* at 112. Thus, the question "whether the challenged agency action [fell] within the scope of the preclusion on judicial review" "merge[d]" with the question "whether the agency ha[d] authority for the challenged action"; if "such authority [was] lacking," the bar on review did not apply. *Id.* at 113-14; *see Fischer v. Berwick*, 503 F. App'x 210, 213 (4th Cir. 2013). So too here.

Finally, Section 1115A(d)(2) also does not bar Plaintiffs' constitutional challenges. "[W]here Congress intends to preclude judicial review of constitutional claims[,] its intent to do so must be clear." *Webster v. Doe*, 486 U.S. 592, 603 (1988). The Supreme Court has even applied that principle to allow review of "constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 680-81 & n.12 (1986). Here, Section 1115A(d)(2) never mentions constitutional claims, let alone clearly precludes them. Plaintiffs' claims are therefore within this Court's jurisdiction.

II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM ABSENT RELIEF

To obtain a TRO or preliminary injunction, a movant must demonstrate irreparable harm that "cannot be fully rectified by the final judgment after trial." *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 216 (4th Cir. 2019) (citation omitted). A movant also "must make a clear showing that it will suffer harm that is neither remote

nor speculative, but actual and imminent." *Id.* (quotation marks omitted). Here, Plaintiffs have made the required showing in *five* ways. Absent relief entered by January 1, 2021: (1) patients' health will suffer due to lost access to needed medications, (2) healthcare providers' practices and provision of patient care will be gravely harmed, (3) pharmaceutical manufacturers will suffer unrecoverable economic losses and lost research and development opportunities, (4) all Plaintiffs will lose their right to comment upon the MFN Rule before it becomes effective, and (5) all Plaintiffs will suffer irreparable constitutional injuries.

A. Patients Will Suffer Irreparable Harm to their Health

First and foremost, the MFN Rule will irreparably harm patients' health by obstructing their access to needed medications. "[P]atients … suffer irreparable injury" when they "stand to be denied appropriate medical care either because physicians will choose not to treat them at all, or because the physicians will be forced to resort to less safe medical procedures which expose the patients to a greater degree of risk." *Richmond Med. Ctr. for Women v. Gilmore*, 11 F. Supp. 2d 795, 809 (E.D. Va. 1998). "The Fourth Circuit has held that irreparable injury occurs when the public loses medical services." *Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602, 618 (D. Md. 2019) (citing *Pashby v. Delia*, 709 F.3d 307, 329 (4th Cir. 2013)).

This harm is not mere speculation. CMS *acknowledges* that the MFN Rule will impede patients' ability to access their medications. CMS admits that the MFN Rule will cause some providers to "choose not to provide MFN Model drugs or prescribe alternative therapies instead." 85 Fed. Reg. at 76,244. As a result, "beneficiaries may experience access to care impacts by having to find alternative care providers locally, having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." *Id.* Indeed, "a portion of the savings" CMS projects the MFN Rule to realize "is attributable to beneficiaries not accessing their drugs through the Medicare benefit, along with

the associated lost utilization." *Id.* at 76,237. That means lost medical care for patients. In 2021 alone, CMS projects a 9% increase in the rate at which patients at non-safety-net providers have "No Access" to covered medications. *Id.* By 2023, CMS projects that rate to jump by 19%—nearly one fifth. *Id.* As made clear by the attached declarations—from a prominent economist, an oncology network, and multiple infusion providers—many providers, especially for oncological care, will be unable to keep their doors open, particularly in rural and underserved areas, reducing the availability of critical treatments. *See* Ex. H, ¶¶ 15-24; Ex. I, ¶¶ 15-24; Ex. J, ¶ 62; Ex. K, ¶¶ 6-10: Ex. M, ¶¶ 14-20; Ex. N, ¶ 6; Ex. S, ¶ 7; Ex. T, ¶ 10. Others, faced with shuttering clinics or only treating patients with commercial insurance, will have to discontinue treatment of patients reliant on Part B. Ex. H, ¶¶ 17-18; Ex. I, ¶¶ 16-17; Ex. K, ¶ 6; Ex. O, ¶¶ 10-11; Ex. P, ¶ 16.

The aggregate adverse health effects from patients' lost access to critical medicines are staggering. Last year, President Trump's Council of Economic Advisers scored a legislative reference-pricing proposal and concluded that it would cost the country "from $375 billion to $1 trillion per year" in worsened health outcomes. 2019 CEA Analysis. There is no reason to believe the ill effects of the MFN Rule will be any less devastating. *See* Ex. J, ¶ 65. Many of the drugs included in the MFN Rule for 2021 treat complex, rare, and chronic diseases like autoimmune disorders, rheumatoid arthritis, and cancer. Ex. J, ¶ 71. Delayed or forgone treatment for these diseases risks further health problems and flare-ups that can quickly become medical emergencies, with lifelong repercussions and higher long-term medical costs. *See* Ex. H, ¶ 21; Ex. I, ¶ 24; Ex. L, ¶¶ 8-17; Ex. M, ¶¶ 19-22; Ex. N, ¶¶ 6-12; Ex. O, ¶¶ 12-14; Ex. P, ¶ 17; Ex. S, ¶¶ 8-9; Ex. R, ¶ 16.

Plaintiffs have standing to represent patients whose health will suffer. Providers may assert the irreparable injuries of their patients, *Richmond Med. Ctr.*, 11 F. Supp. at 809-10, and organizations may assert the irreparable injuries of their members, *Kravitz v. U.S. Dep't of Commerce*,

366 F. Supp. 3d 681, 741, 755 (D. Md. 2019). For example, members of Plaintiff the Association of Community Cancer Centers (ACCC), including Maryland Oncology and Hematology and Virginia Cancer Institute, will be forced "to immediately cut services to Medicare cancer patients." Ex. K, ¶ 6; *see* Ex. U. Five of the 50 drugs initially included in the MFN Rule are FDA-approved for treating colorectal cancers, harming patients for whom Plaintiff the Global Colon Cancer Association advocates. Ex. L, ¶¶ 8-9. The MFN Rule will make it "economically impossible" for members of Plaintiff the National Infusion Center Association (NICA) "to offer patients the listed medications," leading to "treatment disruption or discontinuation." Ex. N, ¶¶ 6-7. Within weeks, NICA member patients with multiple sclerosis, for example, will experience "permanent neurological damage" and "rebound disease activity" involving "acute inflammation that is worse than the disease itself." *Id.* ¶¶ 7-8, 11. One rheumatologist states that the MFN Rule "will work irreparable harms on nearly half of my infusion patients, who may never be able to recover." Ex. O, ¶ 14.

B. Healthcare Providers Will Suffer Irreparable Harm to their Practices

As explained, the MFN Rule operates by slashing the reimbursement amounts Medicare pays to healthcare providers. In 2021 alone, CMS projects that the MFN Rule will reduce Medicare Part B drug expenditures—and thus revenues for providers—by almost $5 billion. 85 Fed. Reg. at 76,238. The MFN Rule will accordingly injure the professional practices of providers irreparably.

CMS acknowledges that, come January 1, providers "will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs." 85 Fed. Reg. at 76,236. Where providers cannot purchase drugs for a price at or below MFN rates—as will be the case for many selected drugs—providers will have no choice but to (1) incur losses on every dose, or (2) "prescribe alternative therapies instead." 85 Fed. Reg. at 76,244; *see id.* at 76,237 (9% increase in the rate at which patients at non-safety-net providers cannot access covered medications in 2021).

Either way, providers will suffer irreparable harm. To the extent providers incur losses, "economic damages may constitute irreparable harm where no remedy is available at the conclusion of litigation." *Mountain Valley Pipeline, LLC v. W. Pocahontas Properties Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019); *see Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (Scalia, J., in chambers) ("If expenditures cannot be recouped, the resulting loss may be irreparable."); *SH Franchising, LLC v. Newlands Homecare, LLC*, 2019 WL 356658, at *5 (D. Md. Jan. 29, 2019) (harm that "can be remedied at a later time with money damages" is not "truly irreparable" (citation omitted)). It follows that "where a plaintiff cannot recover damages due to the defendant's sovereign immunity, any loss of income suffered by a plaintiff is irreparable per se." *Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672, 690 (E.D. Va. 2017) (quotation marks omitted), *vacated in part on other grounds*, 896 F.3d 615 (4th Cir. 2018). Multiple courts of appeals, as well as district courts within the Fourth Circuit and elsewhere, have recognized that economic losses are irreparable when caused by the actions of a governmental defendant that is protected from damages claims by sovereign immunity.[1] At least one district court has applied this principle in the context of Medicare reimbursements. *Lawrence & Mem'l Hosp. v. Sebelius*, 986 F. Supp. 2d 124, 133 n.3 (D. Conn. 2013). Here, the APA's waiver of federal sovereign immunity extends only to actions "seeking relief other than money damages." 5 U.S.C. § 702. So if the Rule is not enjoined before January 1 and Plaintiffs ultimately prevail, there will be no way for providers to recover the economic losses they will suffer in the meantime.

[1] *See, e.g., E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1280 (9th Cir. 2020); *Pennsylvania v. Trump*, 930 F.3d 543, 574 (3d Cir. 2019), *rev'd on other grounds*, 140 S. Ct. 2367 (2020); *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 733 F.3d 393, 423 (2d Cir. 2013); *N.C. Growers' Ass'n, Inc. v. Solis*, 644 F. Supp. 2d 664, 670 (M.D.N.C. 2009); *Synagro-WWT, Inc. v. Louisa Cty., VA*, 2001 WL 868638, at *4 (W.D. Va. July 17, 2001); *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 2020 WL 5232076, at *40 (D.D.C. Sept. 2, 2020).

To the extent providers try to avoid losses by altering the drugs they prescribe, providers suffer "irreparable injury" when they are "constrained to alter their medical advice to, and their medical care of, their patients contrary to their best judgments." *Mayor & City Council of Baltimore*, 392 F. Supp. 3d at 618 (citation omitted). No provider should be forced to give its patients an alternative therapy that is less safe or effective because of a CMMI "test." But losing money on every dose is not sustainable. Community-based care centers, for example, are often small businesses reliant on Part B drug reimbursements to break even. *See* Ex. J, ¶¶ 60-62; Ex. P, ¶ 14; Ex. Q, ¶¶ 9-11. And oncology practices "will incur staggering losses within days after the Rule's January 1, 2021 effective date." Ex. O, ¶ 19. The MFN Rule threatens providers' very "ability to provide medical treatment," which "cannot be likened to interrupting a typical business's ability to turn a profit." *Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 689. "The typical business can catch up on lost profits in the future, but a [provider] cannot retroactively treat its patients." *Id.* ACCC and NICA members are among those that will be irreparably harmed. *Supra* pp. 26-27.

For providers in some specialties, it gets worse. As noted, the MFN Rule also changes the add-on amount providers receive as a handling fee, replacing the 6% (4.3% post-sequestration) add-on with a flat per-dose payment. CMS estimates that this new add-on payment will substantially reduce average add-on revenue for nine major specialties. *See supra* p. 10. For these specialties, the MFN Rule strikes a double blow—reduced reimbursements *and* reduced add-on payments. Ex. J, ¶ 60. Recognizing the harm to providers, the Rule includes a "financial hardship exemption," but it includes thresholds that many affected providers will not meet. *See* 85 Fed. Reg. at 76,222-24. The exemption also operates through post-hoc "reconciliation payment[s]," *id.* at 76,223, which will often come too late to help, Ex. M, ¶¶ 19-20; Ex. N, ¶¶ 5-12; Ex. O, ¶¶ 9-12.

To be sure, CMS assumes that manufacturers will respond to the MFN Rule with some combination of cutting domestic prices and raising foreign prices. But even if manufacturers will *eventually* adjust their domestic or foreign prices, there is no way they can do so by January 1, 2021. Manufacturers sell to providers under pre-negotiated contracts, which cannot possibly be renegotiated within the next three weeks. *See* Ex. G, ¶¶ 26-28; Ex. H, ¶¶ 10-14; Ex. I, ¶¶ 10-15; Ex. J, ¶¶ 59, 84; Ex. K, ¶ 6: Ex. M, ¶¶ 12-13; Ex. N, ¶¶ 5-6; Ex. T, ¶¶ 12. Provider harm will thus start on January 1: US Oncology Network, for instance, attests that its losses will begin immediately, because its network oncology practices "have binding contracts that set prices for oncology drugs affected by the MFN Rule, and the contracts extend for months at a time and even for a year or more." Ex. M, ¶ 12. And even in the long term, manufacturers may not adjust their prices for all selected drugs; providers' purchase prices may *never* fall below the new MFN reimbursement rates. Indeed, while CMS "expect[s]" manufacturers "to devote considerable resources to" "altering the availability and terms of their international prices," *id.* at 76,236, the reason prices are lower in many other OECD countries is government price controls, which are not subject to negotiation by manufacturers. *See* Ex. D, ¶¶ 27-29; Ex. G, ¶¶ 23-24; Ex. J, ¶ 56. Some manufacturers only have the right to sell MFN-selected drugs in the United States, and thus have no control over prices abroad. *See* Ex. E, ¶¶ 6-10, 18, 31-32. And CMS acknowledges that manufacturers may respond to the MFN Rule by "refusing to adjust their price[s]." 85 Fed. Reg. at 76,236.

C. Pharmaceutical Manufacturers Will Suffer Unrecoverable Economic Harms and Lost Research and Development Opportunities

The MFN Rule also will inflict devastating, unrecoverable economic losses on pharmaceutical manufacturers, including members of PhRMA, which make 35 of the 50 drugs initially included in the MFN regime. As detailed in the attached declarations, PhRMA members project massive revenue losses as a result of the MFN Rule—for some companies, hundreds of millions

of dollars in 2021 alone and a substantial share of total revenue. *See* Ex. A, ¶¶ 26-47; Ex. B, ¶ 13; Ex. C, ¶¶ 20-31; Ex. D, ¶¶ 44-55; Ex. E, ¶¶ 26-41; Ex. F, ¶¶ 13-18; Ex. G, ¶¶ 21-22. These figures should come as no surprise to the MFN Rule's architects. The Rule's stated goal is to force "manufacturers to address the large difference between prices in the U.S. and in other countries." 85 Fed. Reg. at 76,213. As explained, these losses are "irreparable per se" due to sovereign immunity. *Children's Hosp. of the King's Daughters*, 258 F. Supp. 3d at 690.

Indeed, the economic harms from the MFN Rule are such that they would support injunctive relief even if sovereign immunity were waived. Manufacturers will directly lose revenue through multiple interacting mechanisms—including lower prices, lost market share, and lower overall utilization—making "monetary damages … difficult to ascertain" and manufacturers' losses "[i]rreparable." *SH Franchising*, 2019 WL 356658, at *5 (citation omitted). Similarly, a "loss of current or future market share," *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 67 (2d Cir. 2007), or "the possibility of permanent loss of customers to a competitor," *Corp. Healthcare Fin., Inc. v. BCI Holdings Co.*, 2006 WL 1997126, at *4 (D. Md. July 13, 2006) (citation omitted), also qualify as irreparable. Multiple PhRMA members anticipate significant losses of market share to competitor products based on the simple fact that their product is in the top 50 and a competitor product is not. Ex. A, ¶¶ 43-48; Ex. D, ¶¶ 21-43; Ex. E, ¶¶ 37-42; *see Par Pharm., Inc. v. TWI Pharm., Inc.*, 2014 WL 3956024, at *4 (D. Md. Aug. 12, 2014).

Massive revenue reductions will in turn necessitate reducing investment in research and development. *See* Ex. A, ¶¶ 49-66; Ex. B, ¶¶ 16-18; Ex. C, ¶¶ 32-36; Ex. D, ¶¶ 54-61; Ex. F, ¶¶ 17-18; Ex. J, ¶¶ 11, 66. As an economist explains, because "R&D decisions … depend[] on the expected net present value of the investment, which in turn depends on factors such as future prices," *id.*, ¶ 66, a "change in willingness to invest will manifest itself immediately upon implementation

of the MFN Rule," *id.* at ¶11. And "decelerat[ing] [a pharmaceutical company's] investment in research and development" is "precisely the type[] of irreparable harm that an injunction is designed to remedy." *Endo Pharm. Inc. v. Amneal Pharm., LLC*, 2016 WL 1732751, at *6 (S.D.N.Y. Apr. 29, 2016). Manufacturers also will have to reallocate resources away from Part B drugs and toward other areas, resulting in lost innovation opportunities that can never be quantified or recovered. *See* Ex. A, ¶¶ 65-66; Ex. B, ¶¶ 16-17; Ex. C, ¶ 34; Ex. D, ¶¶ 56-60; Ex. F, ¶ 18; Ex. J, ¶¶ 66-67. The MFN Rule will result in lower capital investment, loss and reallocation of manufacturer personnel, the attempted renegotiation of numerous contracts, and other significant financial and operational changes. *See* Ex. B, ¶ 14; Ex. D, ¶¶ 62-64; Ex. E, ¶¶ 34-35; Ex. G, ¶¶ 26-31; Ex. J, ¶¶ 11, 62. All of those harms are imminent and irreparable.

D. Plaintiffs Will Suffer Irreparable Harm to Their Notice-and-Comment Rights

It is well settled that an agency's violation of a procedural protection, like the right to notice and comment, causes a cognizable injury where "the government act performed without the procedure in question will cause a distinct risk to a particularized interest of the plaintiff." *Nat'l Fed'n of the Blind v. U.S. Abilityone Comm'n*, 421 F. Supp. 3d 102, 116 (D. Md. 2019). Affected parties thus are injured by the "[d]eprivation of a procedural right—in this case, the right … to submit comments on the [MFN Rule] prior to its adoption." *Nat'l Fed'n of the Blind v. U.S. Dep't of Educ.*, 407 F. Supp. 3d 524, 533 (D. Md. 2019). "Importantly, when a plaintiff seeks to enforce procedural … rights, the plaintiff need not demonstrate that but for the procedural violation the agency action would have been different.'" *U.S. Abilityone*, 421 F. Supp. 3d at 117 (cleaned up).

Applying this settled standing principle to the context of preliminary injunctions, courts have held that the "depriv[ation] of the opportunity to offer comments" on a rule "may constitute irreparable injury while a rule promulgated in violation of [the APA] is in effect, provided that plaintiffs suffer some additional concrete harm as well." *E. Bay Sanctuary Covenant v. Trump*,

349 F. Supp. 3d 838, 865 (N.D. Cal. 2018), *aff'd*, 950 F.3d 1242 (9th Cir. 2020). In other words, so long as a prospective commenter has an "immediate" interest "at stake," such as "fiscal interests" that are "ongoing," the "procedural injury" stemming from a notice-and-comment violation "may serve as the basis for a finding of irreparable harm." *California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 829 (N.D. Cal. 2017), *aff'd in part, vac'd in part on other grounds*, 911 F.3d 558 (9th Cir. 2018). At minimum, an affected party suffers irreparable harm where a rule improperly promulgated without notice and comment "will dramatically alter" a "complex and far-reaching regulatory regime," and the affected party has articulated "meaningful concerns." *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009).

It would be an understatement to say that the MFN Rule "will dramatically alter" a "complex and far-reaching regulatory regime." *Id.* The Rule's own architects have described the Rule in sweeping terms as "transform[ing] drug pricing forever." Nov. 2020 Remarks. To say that Plaintiffs have "meaningful concerns" about the MFN Rule would be even more of an understatement. The Administration is attempting to ram the Rule through in its final days in office, usurping Congress's prerogatives while obstructing patients' access to essential medications, undermining healthcare providers in the midst of a pandemic, and decimating incentives to innovate.

It is no answer that Plaintiffs may offer comments *after* the MFN Rule goes into effect. The harms here will begin on January 1—before comments are even due on January 26, and long before CMS can meaningfully consider them. *See* Ex. B, ¶ 12; Ex. H, ¶¶ 10-14; Ex. I, ¶¶ 10-12; Ex. J, ¶ 13; Ex. M, ¶¶ 19-20; Ex. N, ¶¶ 5-12; Ex. O, ¶¶ 9-12; Ex. 2, ¶ 12. Post-implementation comment is always possible when an agency proceeds by interim final rule, moreover, but at that point, CMS "is far less likely to be receptive to comments." *N. Mariana Islands*, 686 F. Supp. 2d at 18. "The notice and comment procedure … is designed to encourage public participation in the

administrative process" and to "ensure that the agency maintains a flexible and open-minded attitude towards its own rules." *N.C. Growers' Ass'n*, 702 F.3d 755, 763 (quotation marks omitted). "[T]he opportunity to comment must be a meaningful opportunity," *id.* (quotation marks omitted), and "permitting the submission of views after the effective date of a regulation is no substitute," *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1158 (D.C. Cir. 1981). "If the [MFN] Rule is not enjoined prior to its effective date, [Plaintiffs] will never have an equivalent opportunity to influence the Rule's contents." *N. Mariana Islands*, 686 F. Supp. 2d at 18-19. "Every day the [Rule] stand[s] is another day Defendants may enforce regulations likely promulgated in violation of the [applicable] notice and comment provision[s], without Plaintiffs' advance input." *California*, 281 F. Supp. 3d at 830.

E. Plaintiffs Will Suffer Irreparable Constitutional Injury

Finally, "the denial of a constitutional right ... constitutes irreparable harm for purposes of equitable jurisdiction." *Ross v. Meese*, 818 F.2d 1132, 1135 (4th Cir. 1987). Indeed, "[w]hen an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary." IIA Wright & Miller, *Federal Practice & Procedure* § 2948.1 (2005). Here, as explained, the MFN Rule is unconstitutional on multiple levels. *See supra* pp. 19-22. The Rule's unconstitutionality establishes irreparable harm on its own, but it also reinforces the unrecoverable injuries the Rule will inflict on patients, providers, and manufacturers.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR RELIEF

The final two factors in the analysis—the balance of equities and the public interest—"merge" where "the government is a party." *CASA de Md., Inc. v. Trump*, 971 F.3d 220, 255 (4th Cir. 2020). Here, the equities and the public interest both plainly favor preliminary relief.

To begin with, a TRO and a preliminary injunction will prevent irreparable harm to patients, healthcare providers, and pharmaceutical manufacturers. *Supra* pp. 24-34. There is "a robust

public interest in safeguarding access to health care," *Texas Children's Hosp.*, 76 F. Supp. 3d at 246, and "in . . . patients obtaining needed medications in a timely manner." *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 230 (D.D.C. 2012). There can be no serious dispute that protecting healthcare providers' ability to care for patients is in the public interest. And "[t]he public interest" favors "promoting industry incentives to research and develop new drug treatments." *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 124 (D.D.C. 2007). More broadly, "there is a substantial public interest in having Defendants abide by the federal laws that govern their operations," including "the rule-making processes in the APA." *Guilford Coll. v. McAleenan*, 389 F. Supp. 3d 377, 395 (M.D.N.C. 2019) (cleaned up). And "upholding constitutional rights surely serves the public interest." *Centro Tepeyac v. Montgomery Cty.*, 722 F.3d 184, 191 (4th Cir. 2013) (citation omitted).

On the other side, the government will suffer no harm from an injunction. At worst, "[i]f Defendants ultimately prevail, then a [TRO and a] preliminary injunction will have merely delayed their preferred regulatory outcome." *Pennsylvania v. Trump*, 281 F. Supp. 3d 553, 585 (E.D. Pa. 2017), *rev'd on other grounds*, 816 F. App'x 632 (3d Cir. 2020). CMS's own lengthy delays, *supra* pp. 13-17, belie any notion that implementation must be immediate. Allowing the Rule to take effect on January 1, moreover, would force the incoming Administration to confront immediate, cascading harms from an ill-considered policy with significant consequences for patient health, while delaying it will allow it to receive a considered evaluation. And litigating this case to final judgment should not take long—the merits issues are purely legal, and review will be based on the administrative record. In the meantime, a TRO and a preliminary injunction will "protect the status quo and prevent irreparable harm." *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017).

CONCLUSION

Accordingly, Plaintiffs' Motion for a Temporary Restraining Order and a Preliminary Injunction should be granted, and the MFN Rule should be temporarily and preliminarily enjoined.

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Respectfully submitted,

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* *Pro hac vice*
** *Pro hac vice* application forthcoming
*** Application for admission forthcoming
**** Application for admission pending

CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 5. I further certify that a courtesy copy of this Memorandum of Law in Support of Plaintiffs' Motion for a Temporary Restraining Order and a Preliminary Injunction and accompanying exhibits will be sent to the Court via third-party commercial carrier.

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