IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMUNITY ONCOLOGY ALLIANCE, INC., Plaintiff, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II, Secretary of the U.S. Department of Health and Human Services, in his representative capacity, CENTERS FOR MEDICARE AND MEDICAID SERVICES, and SEEMA VERMA, Administrator of the Centers for Medicare and Medicaid Services, in her representative capacity, Defendants.	Civil Action No. 20-3604

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

COA, the country's only nonprofit organization dedicated solely to representing, supporting, and recognizing independent community oncology practices and the patients they serve, moves this Court to remedy the unauthorized, improper, and otherwise unconstitutional conduct of Defendants in drastically transforming how doctors are reimbursed under Medicare Part B for administering certain life-saving prescription drugs to patients. Defendants—the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his representative capacity ("Secretary Azar"), the Centers for Medicare and Medicaid Services ("CMS"), and Seema Verma, in her representative capacity ("Administrator Verma") (collectively, "Defendants")—have unilaterally replaced (initially for 50 drugs) the existing Medicare Part B drug pricing scheme approved by Congress with a flawed, untested, and hastily assembled scheme reliant on international drug prices that will harm patients. To prevent this abuse, Plaintiff Community Oncology Alliance, Inc. ("COA") respectfully asks this Court to declare unlawful and enjoin Defendant's implementation of an "Interim Final Rule" enacted without notice-and-comment.

COA seeks a temporary restraining order ("TRO") and preliminary injunction against this overreach, which both exceeds Defendants' statutory/regulatory authority and flies in the face of constitutional separation of powers protections. Absent such relief, patients and providers, including COA's more than 5,000 healthcare provider members, will suffer imminent, unrecoverable, and irreparable harm. Indeed, the lives of vulnerable seniors suffering from cancer—as well other patients with potentially life-threatening diseases—hang in the balance.

After years of failing to change drug prices through legislative or administrate action, on or about September 13, 2020, President Trump signed an Executive Order designed purely to lower drug prices without proper consideration to provider or patient care by creating a "most favored nation" drug pricing system for Medicare Part B prescription drugs. This Executive Order directed

Secretary Azar to "immediately" implement a 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." Exec. Order No. 13948 of September 13, 2020, 85 Fed. Reg. 59,649 (Sept. 23, 2020) ("Executive Order 13948"). The "most-favored-nation price" is based on drug prices in a collection of foreign countries.

On November 27, 2020, just weeks after the presidential election, CMS issued the "Most Favored Nation (MFN) Model" Interim Final Rule (the "MFN Interim Final Rule"). 85 Fed. Reg. 76,180, (Nov. 27, 2020). Purportedly issued under Section 1115A of the Social Security Act, 42 U.S.C. § 1315a, the MFN Interim Final Rule purports to be a "new Medicare payment model . . . [to] test whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as 'drugs') with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries." *See* 85 Fed. Reg. at 76,180.

The MFN Interim Final Rule requires CMS to reduce the pertinent Medicare Part B drug statutory reimbursement formula for about 50 drugs initially, with the potential to expand the list of covered drugs. It shifts the current reimbursement scheme —referred to as "Average Sales Price" ("ASP") plus 6% (excluding the effect of sequestration, discussed below)—to an amount based upon on the lowest international pricing for countries with a gross domestic product ("GDP") per capita that is at least 60% of the U.S. GDP per capita, plus a flat add-on amount, rather than a percentage increase.

The MFN Interim Final Rule is neither a "model" nor a "test," as permitted by Section 1115A; instead, without addressing "deficits in care," it implements a *mandatory*, *seven-year*, *nationwide* program whereby healthcare providers will be reimbursed initially for 50 designated

drugs in accordance with an entirely new international pricing scheme. These 50 drugs account for nearly 80% of Part B drug spending, and 38 of these drugs are used by oncologists and hematologists to treat cancer and blood disorders. CMS intends to add new drugs each year, subjecting these drugs to the same novel and untenable pricing scheme.

CMS acknowledges healthcare providers may suffer extreme financial hardship, *see id.* at 76,222, and some Medicare seniors may receive inferior therapies with "lower efficacy or greater risks," or end up "postponing or forgoing treatment" altogether, *id.* at 76,244. CMS's own estimates show that, during the first year (2021) when the MFN Interim Final Rule is implemented, nearly 10% of Medicare Part B seniors will "forgo access" to covered drugs, *id.* at 76,237-38, and that by 2023, nearly one in five Medicare Part B seniors will forgo such treatment. Critically, half of the projected savings to Medicare "would be due to lost utilization" of these drugs. *Id.* at 76,239. All while CMS's own actuaries concede their "assumptions reflect that some manufacturers will adhere to their current pricing instead of lowering sales prices in response to" the Rule. *Id.* at 76,237.

The MFN Interim Final Rule is unlawful in three broad respects:

First, in issuing the MFN Interim Final Rule, CMS ignored the notice-and-comment requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553.

Second, the MFN Interim Final Rule fails to meet the requirements of Section 1115A in several critical ways, including by: (a) failing to comply with the two-phase structure of the statute whereby an initial sample model is to be tested in the first phase ("Phase I") and the "testing" of the "model" may be expanded (including nationwide), only if certain requirements are met in the second phase ("Phase II"); (b) selecting a "model" in the absence of any "evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes

or potentially avoidable expenditures," 42 U.S.C. § 1315a(b)(2)(A); and (c) imposing a mandatory, nationwide regime through the MFN Interim Final Rule that will result in the denial of, or limitation on access to, life-sustaining care to cancer patients and other seniors. *Id.* § 1315a(c). Moreover, CMS's waiver of certain statutory provisions under Section 1115A contravenes the mandate that such waiver is permitted "solely for purposes of" testing the model during the Phase I. *Id.* § 1315a(d)(1). As the MFN Interim Final Rule is neither a "test" nor a "model" under Section 1115A, CMS has no authority to waive any of the cited provisions.

Third, in rewriting the Medicare Modernization Act of 2003 ("MMA") and bypassing Congress altogether, Defendants violated, and are continuing to violate, the separation-of-powers doctrine. The MMA, enacted by Congress, provides an express statutory formula by which Medicare Part B outpatient providers or suppliers (not including hospitals) are paid or reimbursed for Part B drugs. By adopting the MFN Interim Final Rule and thereby amending the MMA, Defendants have unconstitutionally intruded upon the Legislative Branch's authority in violation of the Presentment Clause, the separation of powers, and the Non-Delegation Doctrine.

If not enjoined, the MFN Interim Final Rule will force community oncology clinics to administer therapies reimbursed at rates less than the cost thereof. Oncologists will thus be left with the untenable choice of suffering business-threatening losses by either: (1) accepting below-cost reimbursement; or (2) having to transition the care of seniors who comprise a significant volume of their existing practices to other providers (such as 340B hospitals).

At its core, the MFN Interim Final Rule is a dangerous and unlawful gamble with the lives of some of America's sickest and oldest cancer patients who require chemotherapy, immunotherapies, and other potentially life-saving drugs. Defendants' wrongful acts compromise access to care for seniors who will be unable to be treated by their oncologists. A significant

number of seniors will have to forgo treatment altogether or be unable to find or afford treatment when their local community oncology practice is forced to absorb losses, causing it to shut down or join a more expensive hospital. Unless this unlawful program is stopped, community oncology practices will close and cancer patients will suffer and, in some cases, die.

BACKGROUND

I. THE LONGSTANDING MEDICARE PART B DRUG REIMBURSEMENT FORMULA AND SECTION 1115A.

Medicare is the program through which the government provides health insurance to seniors and the disabled. It is administered by Defendants HHS and CMS. Medicare Part B governs reimbursement or payment for certain physician services, drugs, and supplies considered medically necessary to treat a disease or condition. Relevant here, under the Medicare Part B program, seniors are entitled to receive certain prescription drugs as a covered benefit pursuant to 42 U.S.C. § 1395k, and participating providers are entitled to bill for these drugs pursuant to 42 U.S.C. § 1395u(o)(1). In the community-based oncology setting in which COA's members practice, covered prescription drugs typically include infusible treatment drugs, like chemotherapy and immunotherapies, and other drugs administered in a physician-office setting to treat patients.

The reimbursement method for Medicare Part B drugs currently is fixed by an express formula. Under § 1395u(o)(1), the amount payable for such drugs furnished on or after January 1, 2005, is determined by a statutory formula whereby payment for Medicare Part B drugs, such as oncological drugs, equals the ASP for the drugs plus 6%. 42 U.S.C. § 1395w-3a(b). Effective April 1, 2013, this reimbursement formula was reduced to ASP plus 4.3% due to sequestration cuts resulting from Congress's inability to reach a budget agreement. Compl. ¶ 26.

The MFN Interim Final Rule states that it was promulgated pursuant to Section 1115A of the Social Security Act, 42 U.S.C. § 1315a (added by the Patient Protection and Affordable Care

Act ("ACA")). Section 1115A created the Center for Medicare & Medicaid Innovation ("CMMI") as a sub-agency within CMS and permits CMS, through CMMI, to "test innovative payment and service delivery models to reduce program expenditures under [Medicare] while preserving or enhancing the quality of care furnished to individuals under such subchapters." 42 U.S.C. § 1315a(a)(1). It also gives CMS limited authority to waive certain statutory provisions within Medicare, including ASP, "solely" for the purpose of conducting such "tests." *Id.* § 1315a(b)(1), (d)(1). However, Section 1115A only permits CMS to "test" a "model" if "there is evidence that [it] addresses a defined population for which there are deficits in care." *Id.* § 1315a(b)(2)(A). In doing so, CMS must "focus on models expected to reduce program costs under the applicable subchapter *while preserving or enhancing the quality of care received by individuals receiving benefits* under such subchapter." *Id.* (emphasis added). Tests must proceed in two phases (referred to *infra* as Phase I and Phase II), and nationwide implementation is permitted only in Phase II and only after evaluation of Phase 1. *Id.* § 1315a(c). *See infra* § VI(B).

II. MEDICARE PART B PRICING CONCERNS PRECEDING THE MFN INTERIM FINAL RULE.

The MFN Interim Final Rule purports to respond to the economic impact that the COVID-19 pandemic and resulting public health emergency (the "COVID-19 PHE")[2] has had on Medicare beneficiaries by reducing Medicare Part B drug costs. But CMS has been working to reduce those costs for more than two years, including looking to international pricing models. On October 30, 2018, CMS published an advance notice of proposed rulemaking to solicit comments on an "International Pricing Index Model for Medicare Part B Drugs," which differs from the approach

[2] This emergency was declared by Secretary Azar under Section 319 of the Public Health Service Act. 42 U.S.C. § 247d.

under the MFN Interim Final Rule. 83 Fed. Reg. 54,546 (Oct. 30, 2018) ("ANPRM"). While CMS solicited comments, it never moved forward with the rulemaking.

Subsequent to the ANPRM, the Trump Administration began to lobby Congress to pass legislation that finally takes on the problem of global freeloading.[3] Apparently disappointed by Congress's lack of action, President Trump signed four executive orders on July 24, 2020. The President's objective in issuing these executive orders purportedly was to "massively lower prescription drug costs and increase Americans' access to life-saving medications."[4] President Trump stated that these executive orders reflected the "most far-reaching prescription drug reforms ever issued by a President. Nothing even close."[5] One of the four executive orders, entitled "Lowering Drug Prices by Putting America First," was not issued in August 2020 with the other three orders, but rather was withheld by President Trump pending discussions with the pharmaceutical industry. The White House press claimed that this order would go beyond the pricing proposal in the ANPRM by "ensur[ing] that the United States pays the lowest price available in economically comparable countries for Medicare Part B drugs," a scheme known as "most-favored-nation pricing."[6]

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[3] *President Donald J. Trump's State of the Union Address* (Feb. 5, 2019), https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-state-union-address-2/.

[4] 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://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-lower-drug-costs-ensure-americans-access-life-saving-medications/ ("White House Fact Sheet").

[5] *Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices* (July 24, 2020),https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices (emphasis added) (hereinafter "July 2020 White House Remarks"). *See also* Press Release, *Congress Didn't Act on Prescription Drug Prices. So President Trump Did* (July 2020), https://www.whitehouse.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did ("July 2020 Press Release").

[6] White House Fact Sheet, *supra*.

On September 13, 2020, President Trump released the fourth executive order. In it, he announced "[i]t 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." Executive Order 13948. 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.* The Executive Order revealed the focus of the Administration's policy was to reduce drug costs—not to address "deficits in care," as required under the statute.

On November 20, 2020, President Trump held a press conference and Secretary Azar issued a press release to announce a forthcoming rule on Medicare Part B drug pricing. [7]

III. CMS ISSUES THE MFN INTERIM FINAL RULE WITHOUT A FORMAL NOTICE-AND-COMMENT PROCESS.

On November 27, 2020, Defendants issued the MFN Interim Final Rule. Rather than proceeding through publication as a notice of proposed rulemaking for public comment as required under the APA, the MFN Final Interim Rule became *effective immediately* upon publication in the Federal Register, but allowed for the submission of comments for 60 days *post-promulgation*.[8] *See* 85 Fed. Reg. at 76,180. CMS invoked the APA's "good cause" exception to justify its circumvention of procedural requirements, claiming that the economic disruption caused by the COVID-19 PHE exacerbated the already severe impact that high drug prices have on Medicare beneficiaries and thus required remedial action on an emergency basis. *Id.* at 76,249.

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[7] *See Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans* (Nov. 20, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans/ ("Nov. 2020 White House Remarks"); Press Release, CMS, (Nov. 20, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-announces-prescription-drug-payment-model-put-american-patients-first ("2020 CMS Press Release").

[8] COA has submitted a preliminary comment, as have numerous other interested parties.

IV. THE SWEEPING SCOPE OF THE MFN INTERIM FINAL RULE.

The MFN Interim Final Rule reduces Medicare Part B drug reimbursement even further than it was already reduced after sequestration to the detriment of both patients and providers. Practically speaking, the MFN Interim Final Rule operates by reducing the rate of reimbursement for drugs purchased and administered by Medicare providers in the outpatient setting. Because providers like COA's members typically purchase and store on site the drugs they administer to seniors *before receiving reimbursement*, the MFN Interim Final Rule's steeper reimbursement reduction heightens the significant financial risks that providers already incur to treat their patients.

By its terms, the MFN Interim Final Rule will remain in place for an initial period of seven years ending December 31, 2027, *see id.* at 76, 181, subject to the requirements of 42 U.S.C § 1395hh(a)(3). Over that time period, CMS will calculate a drug's price under the MFN Interim Final Rule ("MFN Price") quarterly, based on the lowest per capita, GDP-adjusted price of that drug in any OECD country with a purchasing power parity-adjusted GDP per capita of at least 60% of the United States, and then add on a flat amount rather than a percentage. *See* 85 Fed. Reg. at 76,196; *see also* 85 Fed. Reg. 76,181. Currently, this encompasses over 20 countries, including those with government-run, single-payer healthcare systems. *Id.* at 76,200.

CMS will phase in the new MFN Prices during the first three years of the MFN Interim Final Rule. Over the first year, CMS will set reimbursement rates for each covered Medicare Part B drug at a weighted average of 25% of the MFN Price and 75% of ASP. *Id.* at 76,205, Table. 5. CMS will then transition to a blended rate at 50-50% in the second year and, in the third year, to 75% of the MFN Price and 25% of ASP. *Id.* The phase-in will end after three years; in years four through seven, reimbursement rates will be set at 100% of the MFN Price. *Id.*

CMS will further lower drug reimbursement rates if either the wholesale acquisition cost or the ASP of a drug covered by the MFN Interim Final Rule rises faster than both inflation and

the MFN Price. *Id.* at 76,254. Thus, reimbursement could decline even more precipitously than the stated percentage for a given year. It also means the MFN Interim Final Rule effectively regulates reimbursed drugs prices *outside* Medicare Part B, as certain commercial plans and Medicare Advantage Organizations ("MAO") base their reimbursement on the Medicare rates.

The MFN Interim Final Rule initially applies to 50 single-source drugs and biologicals with the highest Part B spending, subject to certain narrow exclusions. *Id.* at 76,181. COA's members use 38 of these drugs to treat cancer and blood disorders, including the latest cutting-edge immunotherapies that have had dramatic results in improving cancer survival. CMS estimates in the first year, those 50 drugs will account for nearly 80% of the Part B drug spending.[9] And CMS plans to extend the Rule every year to cover new drugs that enter the top 50 drugs based on updated annual Medicare Part B spending. *Id.* at 76,192. Because nearly all drugs covered by the Rule will remain covered, the number of covered drugs will only increase over time. *Id.*

Finally, the MFN Interim Final Rule requires mandatory participation from "a broad set of providers," *id.* at 76,187, including "all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN [Rule] drug," subject only to limited exceptions, *id.* at 76,181. The MFN Interim Final Rule also applies across "all states and U.S. territories," with no geographic exceptions. *Id.* CMS explained it did not believe the MFN Interim Final Rule could "realize its full potential in spending reductions . . . without broad participation of Medicare participating providers and suppliers through a nationwide scope." *Id.* at 76,188.

[9] *See* Issue Brief, Dep't of Health & Hum. Servs., *Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs* (Nov. 20, 2020), *available at* https://aspe.hhs.gov/system/files/pdf/264421/Part-B Drugs-International-Issue-Brief.pdf.

V. THE MFN INTERIM FINAL RULE'S DEVASTATING IMPACT ON PATIENTS AND PROVIDERS, INCLUDING COA MEMBERS.

If the MFN Interim Final Rule is not enjoined, the nation's most vulnerable seniors and cancer patients will suffer extreme and irreparable harm. According to CMS's own analysis, Medicare patients may receive inferior therapies with "lower efficacy or greater risks" and may end up "postponing or forgoing treatment" altogether. *See id.* at 76,244. CMS further projects that nearly one in five Medicare Part B seniors may forgo access to drugs covered by the MFN Interim Final Rule within three years. *Id*. at 76,237–38. CMS admits that the MFN Interim Final Rule will impair patients' access to lifesaving drugs—delays that will force patients "to travel to seek care from an excluded provider, receiv[e] an alternative therapy that may have lower efficacy or greater risks, or postpone[] or forgo[] treatment" altogether. *Id*. at 76,244. Moreover, CMS estimates that 9% of Medicare patients who are treated with one of the 50 drugs subject to the MFN Interim Final Rule will lose access to care in *year one* of the program. *Id*. at 76,237, Table. 11. That number will increase to 14% in year two and 19% in years three through seven. *Id*. The threats that the MFN Interim Final Rule poses to access and availability are particularly harmful to oncology patients, as even a short delay in obtaining the Part B drugs necessary to treat conditions like cancer can meaningfully affect their health or even reduce the chance for survival. Details about the particularized harm likely to be suffered by COA's members and their patients are provided *infra* § VI.E, as well as in the attached declarations, at Exhibits 1-9.

ARGUMENT

A plaintiff seeking injunctive relief "must establish '(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction were not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.'" *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224,

235 (D.D.C. 2014) (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006)). "The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Id*. (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)). "In this Circuit, the four factors have typically been evaluated on a 'sliding scale,' such that if 'the movant makes an unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor.'" *NAACP v. U.S. Postal Serv*., 2020 WL 5995032, at *3 (D.D.C. Oct. 10, 2020), *enforcement granted*, 2020 WL 6441317 (D.D.C. Oct. 27, 2020) (quoting *Davis v. Pension Benefit Guar. Corp*., 571 F.3d 1288, 1291-92 (D.C. Cir. 2009)).[10]

I. COA IS LIKELY TO SUCCEED ON THE MERITS BECAUSE THE MFN INTERIM FINAL RULE IS UNLAWFUL.

A. The MFN Interim Final Rule Violated the APA Because CMS Lacked "Good Cause" to Bypass Notice-and-Comment Requirements and to Make the Rule Immediately Effective.

The MFN Interim Final Rule constitutes final agency action reviewable under the APA, 5 U.S.C. § 704, because (a) it "marks the consummation of [CMS's] decision making process [and is not] merely tentative or interlocutory in nature;" and (b) the Rule determines "rights [and] obligations" and "legal consequences [that] will flow" from it. *See Tex. Children's Hosp.*, 76 F. Supp. 2d at 240 (citing *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). As a final agency action with legal effect, the MFN Interim Final Rule required compliance with the APA.

The APA requires federal agencies to publish notice of proposed rulemakings in the Federal Register and provide the public with an opportunity to comment on such proposed

[10] While the D.C. Circuit Court of Appeals "has suggested that a positive showing on all four preliminary injunction factors may be required," courts undertake "a balancing approach . . . given that the Circuit has had no occasion to decide this question[.]" *Holmes v. Fed. Election Comm'n*, 71 F. Supp. 3d 178, 183 n.4 (D.D.C. 2014) (citations omitted); *NAACP*, 2020 WL 5995032, at *3.

rulemakings. 5 U.S.C. § 553(b)–(c); *see also* 42 U.S.C. § 1395hh(a)(3), (b). It further demands that a substantive rule be published "not less than 30 days before its effective date." 5 U.S.C. § 553(d)(3); *see also* 42 U.S.C. § 1395hh(e)(1)(B). These rulemaking requirements exist to permit the public to be heard and ensure that agency decisionmakers are informed and consider all aspects and potential consequences of regulatory changes *before* they become effective. *See, e.g.*, *UPMC Mercy v. Sebelius*, 793 F. Supp. 2d 62, 69 (D.D.C. 2011); *Chamber of Com. v. U.S. Dep't of Health & Hum. Servs*., 2020 WL 7043877, at *6 (N.D. Cal. Dec. 1, 2020).

Compliance with the APA's procedural requirements is critical where Medicare regulations are concerned. Changes to Medicare programs have a sweeping and substantial impact on interested parties. For this reason, Congress has even heightened the notice-and-comment and delayed effectiveness requirements for Medicare regulations. 42 U.S.C. § 1395hh(a)(3), (b), (e)(1)(B); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808-09 (2019) (describing changes to procedural requirements applicable to Medicare regulations from inception to present). Indeed, "Congress . . . decided that, with the growing scope of Medicare, notice-and-comment should become a matter not merely of administrative grace, but of statutory duty." *Id.* at 1809.

There are few lawful excuses for the government's non-compliance with the APA's procedural protections. The APA's "good cause" exception excuses non-compliance with notice-and-comment requirements only if 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)(B). *See also* 42 U.S.C. § 1395hh(b)(2)(c). A similar but separate exception permits agencies to publish a substantive rule less than 30 days before its effective date if there is good cause to do so. *Id*. § 553(d)(3). *See also* 42 U.S.C. § 1395hh(e)(1)(B).

In evaluating an agency's invocation of good cause, courts consider "the 'totality of the factors at play' and must ensure the exception does not swallow the rule." *Chamber of Com.*, 2020 WL 7043877, at *6. This Circuit has long held the good cause exception is to be "narrowly construed and only reluctantly countenanced." *New Jersey v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980) (collecting cases). It is "is not an 'escape clause;' its use 'should be limited to emergency situations.'" *Util. Solid Waste Activities Grp. v. E.P.A.*, 236 F.3d 749, 754 (D.C. Cir. 2001) (citation omitted). Emergency situations are those where delay would cause "real harm to life, property, or public safety." *Chamber of Com.*, 2020 WL 7043877, at *7 (citation omitted). An agency's delay in acting is *not* an emergency that justifies rushing regulatory changes under the guise of good cause. *Nat'l Venture Ass'n v. Duke*, 291 F. Supp. 3d 5, 16 (D.D.C. 2017) (quoting *Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 202 F. Supp. 3d 20, 26 (D.D.C. 2016), *aff'd*, 857 F.3d 907 (D.C. Cir. 2017)). "Otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait until the eve of a statutory, judicial, or administrative deadline [(or a lame duck administration)], then raise up the 'good cause' banner and promulgate rules without following APA procedures." *Chamber of Com.*, 2020 WL 7043877, at 7-8 (collecting cases where agency delay precluded good cause exception).

Here, CMS promulgated the MFN Interim Final Rule as an *immediately effective* Interim Final Rule with Comment rather than through a full and proper notice-and-comment rulemaking process and with a delayed effective date. 85 Fed. Reg. 76,180 *et seq.* CMS invoked the good cause exception to justify this circumvention, claiming that it had good cause for depriving interested parties of their procedural rights because the COVID-19 PHE "exacerbated" the "serious economic and health consequences" caused by "high drug prices." *See id. at* 76,248–50. To bolster CMS's claim of good cause, the MFN Interim Final Rule asserts that prior "increases in

Part B premiums and deductibles" were caused by "rising spending on physician-administered drugs," which in turn could cause "improper medication adherence or skipped treatment." *Id*. at 76,249. The Rule then reasons the economic effects caused by the COVID-19 PHE—including "historic levels of unemployment," "an increase in food prices," and "strained budgets for many of America's seniors"—further "exacerbate" these problems. *Id.* The Rule also claims the "general financial instability" of Medicare beneficiaries was worsened by the COVID-19 PHE, particularly "in communities of color[.]" *Id.* It then articulates the same facts as "good cause" for CMS's decision to dispense with the 30-day delay required under § 553(d)(3) of the APA. *Id.*

CMS's reliance on the good cause exception fails in every respect. The MFN Interim Final Rule is not a response to a newly developed emergency situation: Congress has recognized the need to address Medicare Part B reimbursements for years, and CMS had been evaluating its reimbursement methods for at least two years before the COVID-19 PHE even arose, *see supra* Background § II (discussing the ANPRM). Instead, the MFN Interim Final Rule is mere pretext; the build-up to the rule ensured that the public knew that executive action was being taken on Medicare drug pricing in advance of the 2020 election. *Id*. This is highlighted by the lack of any mention of the COVID-19 PHE in Executive Order 13948 or in statements made by President Trump or Secretary Azar regarding the shift to a most-favored-nation approach. *Id*. And, the MFN Interim Final Rule was not promulgated until November 2020, more than eight months after COVID-19 spread to the United States.

Nor does the MFN Interim Final Rule remedy the "serious economic and health consequences" caused by "high drug prices" that purportedly were "exacerbated" by the COVID-19 PHE. The MFN Interim Final Rule is itself internally contradictory with respect to its ability to address the economic impacts of the COVID-19 PHE and it ignores the harmful effects to be

felt by beneficiaries and providers alike. While the MFN Interim Final Rule states that it "will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments and no beneficiary cost-sharing on the alternative add-on payment," 85 Fed. Reg. 76,249, it elsewhere admits that it will *reduce* beneficiaries' access to drugs and may cause them to *pay more* for the medical care they desperately need. *See id.* at 76,237 & 76,247. Indeed, the Rule itself recognizes that: (a) shifting to an MFN model for Medicare Part B drugs may cause *nearly 10%* of Medicare beneficiaries to have "no access" to their Part B drugs in the first year of implementation alone, and *nearly 20%* of beneficiaries to have "no access" by the third year; (b) projected savings to Medicare under the MFN Interim Final Rule are "attributable to beneficiaries *not accessing their drugs through the Medicare benefit;*" and (c) the "*potential loss of access to certain drugs*" may cause seniors to incur "*additional medical expenses.*" *Id*. at 76,237 (including Table 11) & 76,247 (emphasis added). These impacts are inconsistent with CMS's alleged good cause, *i.e.*, addressing both economic and health consequences of drug pricing.[11]

The MFN Interim Final Rule also threatens to cause serious financial harm and business disruptions to providers, undermining CMS's stated basis for invoking the good cause exception. As described in the declarations, Exhibits 1-9, the MFN Interim Final Rule will force oncologists and hematologists in community practices to administer therapies that will be reimbursed at significantly less than their cost. By lowering reimbursement for the leading cancer drugs to below the actual cost of these drugs to oncologists, local community oncology practices will be faced

[11] CMS also ignores the potential compounding effect of reducing payment under commercial payor/MAO contracts, as payors may base their respective payment rates to providers on the MFN Interim Final Rule's pricing methodology. While the Rule is intended to apply to Medicare fee-for-service payments, MAO plans negotiate rates under provider contracts. CMS has said the non-interference provisions of "Section 1854(a)(6)(B)(iii) of the Social Security Act prohibit[] CMS from interfering in the payment arrangements between MAOs and contract providers."

with crippling losses. *See supra* Background § V. Ironically, the harm to providers will be felt at a time where the COVID-19 PHE has placed unprecedented pressure on community oncology practices, particularly as hospitals are already stretched to the breaking point. Exhibits 1-9.[12]

For these reasons, the MFN Interim Final Rule fails to establish a connection between the "economic disruptions" caused as a result of the COVID-19 PHE and an alleged exacerbation of "economic and health consequences" for Medicare beneficiaries or an inability of Medicare beneficiaries to obtain Medicare Part B medications under the current reimbursement scheme. Tellingly, this is not the first time a federal agency has tried, unconvincingly, to rely on "economic disruptions" caused by the COVID-19 PHE as a justification for not abiding by the APA. In *Chamber of Commerce*, the U.S. District Court for the Northern District of California invalidated a Department of Homeland Security rule, finding that "the emergent nature of the COVID-19 pandemic writ large" could not justify non-compliance with the APA without a showing "that the impact of the COVID-19 pandemic on domestic [economic conditions] justified dispensing with the 'due deliberation' that normally accompanies rulemaking to make changes to [an agency] program that even Defendants acknowledge are significant." *Chamber of Com.*, 2020 WL 7043877, at *6 (citing 85 Fed. Reg. 63,901 & 63,908). The same is true here.

CMS may claim that its violation of the APA nevertheless is justified because the MFN Interim Final Rule permits interested parties to submit comments until January 26, 2021. But this post-promulgation comment period does not cure CMS's errors. Nor is the MFN Interim Final

[12] The MFN Interim Final Rule imposes other burdens on providers, including potentially forcing them to inventory Medicare Part B drug products supplied to seniors under the Medicare fee-for-service program or outside of the program. To permit manufactures to properly track sales of Medicare Part B drugs outside the MNF Interim Final Rule, the Rule requires drug manufacturers "to exclude from their calculation of ASP all units of MFN Model drugs that are furnished to MFN beneficiaries and for which payment under § 513.210 is allowed." 85 Fed. Reg. 76,188.

Rule easily undone once set in motion. The Rule will apply nationwide and CMS intends to "test the model" for years. Starting January 1, 2021, Medicare Part B reimbursement rates will be affected before CMS has even considered critical input from interested parties, let alone adjusted the Rule in response to that input. For example, the MFN Interim Final Rule indicates CMS relied on two behavioral studies on which the public has not had a chance to comment, one of which assumes that providers will simply: (a) accept a reduction in their revenue *even though that may not be financially feasible*; or (b) seek out alternative treatments covered under Medicare Part B *even though that might not be possible. See* 85 Fed. Reg. at 76,240-43.[13]

In sum, CMS's effort to use the COVID-19 PHE as a basis for circumventing the APA's procedural protections falls short. While lowering Part B drug costs is a laudable goal, and while it also may well be true that the COVID-19 PHE has negatively affected the financial situation of certain Medicare beneficiaries, CMS's reliance on the COVID-19 PHE fails to satisfy the good cause exception or to justify prejudicing interested parties by failing to abide by the APA's requirements. 5 U.S.C. § 553(b)(3)(B), (d)(3); *see also* 42 U.S.C. § 1395hh(b)(2)(C). Thus, the MFN Interim Final Rule is invalid and should be vacated and set aside.

B. The MFN Interim Final Rule Exceeds CMS's Statutory Authority.

"'[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.'" *U.S. Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1921 (2020) (Sotomayor, J., concurring) (citation omitted). The APA requires courts to "hold unlawful

[13] Industry experts are already discovering l flaws in CMS's pronouncements. At least one study has examined the alleged reduced copays promised under the MFN Interim Final Rule and found that less than 1% of Medicare beneficiaries will experience reduced out-of-pocket costs. *See* M. Sullivan et al., *Most Favored Nation Rule's Impact on Medicare Beneficiaries OOP Costs*, Avalere (Dec. 2020), https://avalere.com/insights/most-favored-nation-rules-impact-on-medicare-beneficiaries-oop-costs (hereinafter "Avalere Study").

and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

The issuance of the MFN Interim Final Rule exceeded CMS's authority under Section 1115A to "test innovative payment and service delivery models" for Medicare Part B drug pricing. *See* 42 U.S.C. § 1314a(a)(1). The Rule is not a limited "test"—instead, it is an effort to completely revamp drug pricing for the top 50 physician-administered Medicare Part B drugs on a nationwide basis. CMS claims that it has authority to do so under 42 U.S.C. § 1315a(d)(1), which authorizes the Secretary to waive certain provisions of the Social Security Act "as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)." *See* 85 Fed. Reg. at 76,230. This justification fails, however, because the MFN Interim Final Rule does not constitute a "test" of a "model" as permitted under Section 1115A(b). Instead, the MFN Interim Final Rule ignores the specific requirements of Section 1115A, including the two-step statutory process for initial "test[ing]" under Section 1115A(b) (*i.e.*, Phase I) and subsequent "expan[sion]" under Section 1115A(c) (*i.e.*, Phase II).

During Phase I, CMS may only select a "model" for a "test" under Section 1115A(b)(2) if CMS determines *there is evidence* that the model addresses *both* of the following criteria: (i) "a defined population" and (ii) such population has "deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." *Id.* § 1315a(b)(2)(A) (the "Selection Criteria"). CMS is then required to "conduct an evaluation of each model tested under this subsection" and the evaluation "shall include an analysis of: (i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and (ii) the changes in spending under the applicable titles by reason of the model." *Id.* § 1315a(b)(4)(A)(i)–(ii).

CMS may only move to Phase II if certain conditions are met. That is, CMS must consider "the evaluation under subsection (b)(4)" of Phase I. *Id.* § 1315a(c). Then, CMS must promulgate a rulemaking proposing to "expand (*including implementation on a nationwide basis*) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under Section 1395cc-4, to the extent determined appropriate by the Secretary[.]" *Id*. (emphasis added).

While the terms "test" and "model" are not specifically defined in Section 1115A, a plain reading of the statute makes clear that a test of a model is initially to be selected in accordance with the Selection Criteria under Phase I and then, only after CMS has complied with the requirements of Phase I, can the testing be expanded nationwide under Phase II. Here, however, CMS has not followed the Selection Criteria for Phase I, as has no "evidence that the model addresses either: (i) a defined population; or (ii) deficits in care leading to poor clinical outcomes or potentially avoidable expenditure." *Id.* § 1315a(b)(2)(A). First, the Rule automatically applies nationwide, not to any specific or defined population. Indeed, CMS admits that its purported nationwide "model" has no control group against which to measure sample results. 85 Fed. Reg. at 76,232. The Rule's mandatory nature further suggests that its "test" is not targeted to a defined population. *Id.* at 76,181 (rule applies to nearly all providers who bill Medicare for separately payable Part B medicines and to products that account for approximately 80% of the Part B drug spending on separately payable drugs and biologicals).

Second, the MFN Interim Final Rule provides no evidence of existing deficits in care leading to poor clinical outcomes or potentially avoidable expenditures that must be remedied. Instead, the Rule emphasizes that its intent is to ensure a *continuation* of access to care, not to describe or address *deficits* in such access. *See id.* at 76,224 (emphasis added). Worse yet, the MFN Interim Final Rule will actually *create deficits of care*. *See infra* § II(B).

Beyond this, CMS was wholly without authority to apply the MFN Interim Final Rule on a nationwide basis. Only upon completing Phase I testing, and "[t]aking into account the evaluation" required under Section 1115A(b), may the Secretary, in Phase II, "expand" a model's "duration" and "scope"—including by "implement[ing] [it] on a nationwide basis" through "rulemaking." 42 U.S.C. § 1315a(c). Any other interpretation of the statute would essentially give CMS unfettered authority to depart from or ignore the text of Section 1115A or itself effectively amend Medicare broadly.

In sum, the MFN Interim Final Rule's requirements go well beyond CMS's statutory authority. The MFN Interim Final Rule contravenes the language and the purpose of Section 1115A, which was intended to address deficits of care, not to save the government money on the backs of the country's seniors and cancer patients. CMS simply has no lawful basis for imposing a seven-year, mandatory, nationwide reimbursement regime based on no permitted sample testing.

C. The MFN Interim Final Rule Is Unconstitutional.

Federalism and the separation of powers protect our liberties. *See Shelby County v. Holder*, 570 U.S. 529, 543 (2013). They "divide[] power among sovereigns and among branches of government precisely so that we may resist the temptation to concentrate power in one location as an expedient solution to the crisis of the day." *New York v. United States*, 505 U.S. 144, 187 (1992). Here, CMS's efforts to unilaterally substitute Congress's ASP approach to Medicare Part B drug pricing with an entirely new international pricing scheme of CMS's own creation—even if purportedly done to solve the so-called "crisis of the day," which it was not—flies in the face of the separation of powers. As a result, the misguided MFN Interim Final Rule cannot stand.

The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or "contrary to constitutional right, power, privilege, or immunity." *See* 5 U.S.C. § 706(2)(A)–(B). Even apart from the APA, courts must set aside agency action that

violates the Constitution. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 n.2 (2010). In implementing the MFN Interim Final Rule, Defendants violated, and are continuing to violate, the Presentment Clause, Non-Delegation Doctrine, and the separation of powers crucial to our government's constitutional structure. On this basis alone, an injunction should issue.

1. The MFN Interim Final Rule Violates the Presentment Clause.

The Presentment Clause requires that "[e]very 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. Conversely, "[t]here is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes." *Clinton v. City of New York*, 524 U.S. 417, 438 (1998).

This presentment requirement was considered so important to the Founders they took effort to prevent its circumvention. Such requirements "were intended to erect enduring checks on each Branch and to protect the people from the improvident exercise of power by mandating certain prescribed steps." *INS v. Chadha*, 462 U.S. 919, 957 (1983). As a result, the President is entrusted with only the limited authority in the lawmaking process to nullify *proposed* legislation. Accordingly, the Supreme Court has interpreted the Presentment Clause to bar "unilateral [Executive] action that either repeals or amends parts of duly enacted statutes." *Id.* at 439. Courts look to the "legal and practical effect" of an executive action to determine whether the Executive Branch has enacted, repealed, or amended a statute. *Id.* at 438.

The seminal case of *Clinton v. City of New York* is instructive. There, the Supreme Court held the President's annulments 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). Further, the cancellations also had a comparable "practical

effect"—because the President had "reject[ed] the policy judgment made by Congress," and instead "rel[ied] on his own policy judgment. *Id.* at 438 & 444. Thus, rather than "executing [a] policy that Congress had embodied in the statute"—as would have happened if the President had made a required determination in response to a statutorily specified event—the cancellations were "the functional equivalent of partial repeals of Acts of Congress." *Id.* Such conduct, the Court held, was improper. Here, as in *Clinton*, CMS has interpreted its waiver authority under Section 1115A to allow it to repeal part of the congressionally enacted Medicare statute and to replace that repealed portion with a new and complex statutory regime of its own making.

Section 1115A permits the Secretary to waive any provision of the Medicare statute—as well as other important provisions of the Social Security Act—"*as may be necessary*" and "*solely*" for the purpose of testing under Phase I. *See* 42 U.S.C. § 1315a(d)(1) (emphasis added). Said differently, when the Secretary excises his wavier authority under Section 1115A, he must do so to "test" a "model" designed to address a "deficit in patient care." *Id.* § 1315a(a)(1)). Because CMS ignored the requirements of Phase I and improperly enacted a nationwide, most-favored-nation replacement for Congress's ASP reimbursement formula, CMS exceeded its authority.

CMS's waivers regarding, among other things, reimbursement pricing provisions in the MFN Interim Final Rule have the "legal . . . effect" of amending the Medicare statutes in significant ways, including by repealing and replacing the ASP methodology. CMS's waivers also have the "practical effect" of amending statutes duly enacted under the Presentment Clause; each of the MFN Interim Final Rule's waivers erases a cornerstone of the "finely wrought" congressional Medicare Part B drug pricing system. *Clinton*, 524 U.S. at 440.

In sum, the MFN Interim Final Rule effectively repeals Congress's statutory scheme, which CMS criticizes for allegedly "incentivizing avoidable costs and causing greater utilization

of higher priced drugs." 85 Fed. Reg. at 76,235; *see also id.* at 76,180. What has emerged from CMS's use of Section 1115A's waiver authority in the MFN Interim Final Rule is not just a "truncated" version of the Medicare reimbursement program, *Clinton*, 524 U.S. at 440, but an entirely different program altogether.[14] Indeed, CMS has not only suspended enforcement of certain provisions, it superseded these statutory provisions with entirely new requirements reflecting its "own policy judgment." *Id*. at 438 & 444. By creating a new Medicare drug pricing system with a new reimbursement formula, CMS is impermissibly usurping the lawmaking process to itself. If the MFN Interim Final Rule is authorized by statute, then the Rule violates the Presentment Clause at Article I, Section 7, of the U.S. Constitution.

2. The MFN Interim Final Rule Violates the Non-Delegation Doctrine.

Article I, Section 1, of the U.S. Constitution provides "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States." U.S. CONST., art. I, § 1. The Supreme Court has interpreted this language to hold that Congress may not "abdicate or transfer to others the essential legislative functions with which it is thus vested." *See A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935); *cf. Chadha*, 462 U.S. at 951 ("The Constitution sought to divide the delegated powers of the new federal government [and] assure, as nearly as possible," that each Branch "would confine itself to its assigned responsibility.").

Congress violates this Non-Delegation Doctrine if it delegates significant and/or expansive policymaking authority to an administrative agency by statute without providing appropriately clear guidelines for the agency to follow. Courts have historically looked for "an intelligible principle" to guide the agency's exercise of authority. *Gundy v. United States*, 139 S. Ct. 2116,

[14] Ironically, CMS asserted its authority to rewrite the Medicare statute via Section 1115A derives from the ACA. Yet the Administration is asking the Supreme Court strike the ACA in its entirety. Br. for the Federal Resp'ts at 13, 47, in *California v. Texas*, Nos. 19-840, 19-1019 (June 25, 2020).

2123 (2019) (plurality op.) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). Just how "intelligible" such a "principle" must be depends on the nature of the delegation at issue. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475 (2001) ("[T]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred."). Delegations are permissible only "if Congress has made clear to the delegee 'the general policy' he must pursue and the 'boundaries of his authority.'" *Gundy*, 139 S. Ct. at 2129 (plurality op.) (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)) (brackets omitted).

Here, the MFN Interim Final Rule conflicts with Article I, Section 1, of the U.S. Constitution in violation of APA, 5 U.S.C. § 706(2)(B). Although cloaked as a "test," the MFN Interim Final Rule purports to discard Medicare's statutory reimbursement formula nationwide with CMS using its own judgment to adopt a drastically different system for nearly 80% of Medicare Part B's drug expenditures for the better part of a decade. *See supra* Argument § I(B). If the MFN Interim Final Rule is not *ultra vires* (which it is), and instead reflects a legitimate use of the Secretary's authority to "test" a "payment and service delivery model[]" that "addresses a defined population," then the statute violates the Non-Delegation Doctrine as the statute contrains CMS's discretion, and there is no "intelligible principle" to which the Agency is directed to conform. *See Gundy*, 139 S. Ct. at 2123 (citation omitted). On the contrary, CMS used its ostensible authority to unilaterally renounce Congress's ASP approach to Medicare Part B drug pricing. The MFN Interim Final Rule acknowledges as much. *See* 85 Fed. Reg. at 76,180 (blaming ASP "methodology in section 1847A" for ostensible higher drug costs). Rather than execute Congress's "intelligible principle," the Administration *admits* it is using the waiver authority in Section 1115A to supplant Congress's ASP approach with its own "policy."[15]

[15] *See* Executive Order 13948.

So, too, has the President made no secret of his intention to usurp Congress's constitutionally-protected role, proclaiming during the signing of the MFN Executive Order that: "[W]e've been waiting for Congress to take action for many decades to reduce drug prices . . . [but] *I'm unwilling to wait any longer*."[16] And once the MFN Executive Order was signed, the White House compounded this concession with a press release entitled "Congress Didn't Act on Prescription Drug Prices. So President Trump Did."[17] That such a "historic," "transformative," and "revolutionary" effort to "completely restructure the prescription drug market, in terms of pricing and everything else,"[18] is being planned, modified, and enacted within the administrative offices of the Executive Branch—as opposed to Congress—is both telling and constitutionally incurable.[19] Therefore, if the MFN Interim Final Rule is authorized by statute, then Section 1115A separately violates Article I, Section 1 of the U.S. Constitution and the Non-delegation Doctrine.

D. Judicial Review is Not Barred and this Court Has Jurisdiction to Consider COA's Challenge to the Interim Final Rule.[20]

Section 1115A(d)(2) contains a preclusion of review clause providing: "There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or

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[16] July 2020 White House Remarks, *supra*.

[17] July 2020 Press Release; Nov. 2020 White House Remarks ("[I]n the absence of any meaningful legislative support, this administration has delivered real, tangible results.").

[18] July 2020 White House Remarks, *supra*; *Remarks by President Trump on Prescription Drug Prices* (Oct. 25, 2018), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trumpprescription-drug-prices (hereinafter "2018 White House Remarks").

[19] Relatedly, COA's separation-of-powers claim also requires consideration of the Constitution's Take Care Clause, U.S. CONST. art. II, § 3, because such analysis focuses specifically on the President's authority in relation to Congress's. *See Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 587 (1952). The Framers made clear that, far from *creating* laws that bind the people of the United States, the President "shall take care that the laws be faithfully *executed*." U.S. CONST. art. II, § 3 (emphasis added); *Myers v. United States*, 272 U.S. 52, 117 (1926) (Take Care Clause applies to entire Executive Branch, rather than the President alone). Here, the President's conduct violates the Take Care Clause for the same reasons it runs afoul of the Non-Delegation Doctrine.

[20] To the extent Defendants assert that the Court lacks jurisdiction under 42 U.S.C. § 405 and 42 U.S.C. § 1395ff, and/or because COA did not present a "claim" for reimbursement, such arguments fail. Neither of those sections is applicable here. Nor is this case an appeal from a determination

otherwise of" several enumerated agency actions, including the "selection of models for testing or expansion;" "selection of organizations, sites, or participants to test those models selected;" and "the elements, parameters, scope, and duration of such models for testing or dissemination." Despite the apparent broad scope of this clause, none of COA's claims is barred thereby.

There is a "strong presumption that Congress intends judicial review of administrative action" and "statutory provisions expressly prohibiting judicial review must be read narrowly." *Am. Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1204 (D.C. Cir. 2019); *Am. Hosp. Assoc. v. Azar*, 964 F.3d 1230, 1238-39 (D.C. Cir. 2020); *Am. Hosp. Assoc. v. Azar*, 967 F.3d 818, 823-24 (D.C. Cir. 2020). The presumption that "Congress intends judicial review of agency action in excess of delegated authority" is "particularly strong," and it "can only be overcome by a 'clear and convincing evidence' that Congress intended to preclude the suit." *Amgen Inc. v. Smith*, 357 F.3d 103, 111-12 (D.C. Cir. 2004).

Courts look first to the plain language of a preclusion-of-review provision to determine whether Congress, in fact, intended to bar review of the plaintiff's claims. *Id.* at 112. If a plaintiff's challenge falls squarely within the categories of agency action precluded from review, the court is without jurisdiction. *See, e.g.*, *Texas Alliance for Home Care Servs. v. Sebelius*, 681 F.3d 402, (D.C. Cir. 2012) (statute expressly precluded review). The inverse necessarily is true for actions that fall squarely outside of the preclusion statute. If a plaintiff's claims require the court to determine whether the challenged action even qualifies as one of the categories of agency action precluded from review, the court may exercise jurisdiction because the provision "merges" the preclusion and merits analyses. *See Am. Hosp. Assoc.*, 964 F.3d at 1238 (describing similar

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of benefits. Instead, COA is exercising its rights under the APA to ask the Court to block the enforcement and implementation of an unlawful regulation. *See* 5 U.S.C. §§ 705-706.

preclusion provision as one that "merges consideration of the legality of [agency] action with consideration of the court's jurisdiction in cases in which the challenge to the [agency's] action raises the question of the [agency's statutory] authority") (quoting *Amgen*, 357 F.3d at 113-14). "In such cases, if the court find[s] that [the agency] has acted outside the scope of its statutory mandate," the court has jurisdiction. *Id.* (internal quotation marks and citations omitted).

Count I of COA's Complaint is not barred from review because it challenges the procedures through which the MFN Interim Final Rule was promulgated, which falls squarely beyond the scope of Section 111A(d)(2). *See, e.g.*, *Yale New Haven Hosp. v. Azar,* 409 F. Supp. 3d 3, 15 (D. Conn. 2019) (judicial review bar does not preclude challenges that "seek[] review of the promulgation of . . . rules and policies . . . separate from the substance of any such rules or policies"). The same is true for Count III of the Complaint, which asserts Constitutional claims. "[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). *See also Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 680-81 & n.12 (1986) (allowing review of "constitutional challenges to the Secretary's administration of Part B of the Medicare program"). Here, Section 1115A(d)(2) never mentions, let alone clearly precludes, constitutional claims.

Count II in COA's Complaint, however, requires a "merged" analysis because the Court must determine whether the MFN Interim Final Rule even qualifies as a type of action precluded by Section 1115A(d)(2). In other words, the Court must answer whether the Rule constitutes a permitted "test" of a "model" before it can even address the selection of models or other specific details about how CMS exercises its authority to test models. *See* § 1315a(d)(2). Thus, the Court is not barred from reviewing Count II of the Complaint, but must, instead, evaluate it co-extensively with the merits question. *Am. Hosp. Assoc.*, 964 F.3d at 1238-39.

Were the Court to find that Count II of COA's Complaint falls within the ambit of section 1115A(d)(2), this Court could still review the claims under the *ultra vires* doctrine. *See, e.g.*, *id.* The Court has an independent duty to set aside agency action that is *ultra vires*, even if such action were otherwise not subject to judicial review. *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1208 ("If an agency exceeds 'its statutory bounds, judicial review remains available' to curb the rogue action.") (quoting *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018)); *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) ("When an executive acts *ultra vires,* courts are normally available to reestablish the limits on his authority.") (citation omitted). As shown above, CMS clearly exceeded its authority in issuing the MFN Interim Final Rule. Thus, judicial review is not barred, and the Court has jurisdiction over COA's claims.

II. COA IS LIKELY TO SUFFER IRREPARABLE HARM IF THE GOVERNMENT IS NOT ENJOINED FROM IMPLEMENTING THE MFN RULE.

To obtain a TRO/preliminary injunction, a movant must show that unless the challenged rule is enjoined, the movant will suffer "irreparable harm that cannot be cured by ultimate success on the merits in [the instant] case." *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009) (citation omitted). The alleged harm must be "both certain and great; it must be actual and not theoretical, and of a nature of such imminence that there is a clear and present need for equitable relief to prevent irreparable harm." *Texas Children's Hosp.*, 76 F. Supp. 3d at 242.

If the MFN Interim Final Rule is not enjoined, COA's and its members will suffer immediate and irreparable harm in the form of: (1) massive significant financial losses to oncology clinics nationwide if they are forced to administer cancer drugs purchased at prices in excess of reimbursement rates, which will force them to stop treating Medicare patients or shut down altogether; (2) substantial delays in (or a complete lack of) access to treatment for the country's most vulnerable seniors and cancer patients; (3) the deprivation of procedural rights to notice-and-

comment under the APA; and (4) the deprivation of constitutional rights.

A. COA's Members Will Suffer Irreparable Harm to their Community Oncology Practices.

Of the 50 drugs covered by the MFN Interim Final Rule, 38 of them—*i.e.*, 76% of *all drugs* implicated by the Rule—are cancer drugs. For each of these 38 drugs, the MFN Interim Final Rule will pay oncology clinics a reimbursement rate that is substantially lower than the cost that oncology clinics currently pay to administer the drugs to patients. *See* Declaration of Michael Seiden, M.D., Ph.D. ("Seiden Declaration"), attached hereto as **Exhibit 1,** ¶ 15. The consequences are as straightforward as they are dire: If a cancer clinic is forced to administer cancer drugs to Medicare patients at a steady and significant loss, it will be forced to (a) stop administering those drugs or (b) shut down its operations altogether. Either way, the harm is irreparable. Injunctive relief, therefore, is required. *See D.C. v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 34 (D.D.C. 2020) (stating that economic damages constitute irreparable harm where, as here, plaintiff cannot otherwise "recover monetary damages").

Since its founding 16 years ago, COA has built a national grassroots network of more than 5,000 community oncology practices. *See* Declaration of Ted Okon ("Okon Declaration"), attached hereto as **Exhibit 2**, ¶ 3. These practices—which include "individuals from all levels of the cancer care delivery team: oncologists, hematologists, pharmacists, mid-level providers, oncology nurses, patients and survivors"—are incredibly diverse. *Id*. Some facilities serve patients in extremely rural communities; others serve patients in major metropolitan areas. Some are run by a single doctor; others employ dozens of doctors. Despite their differences, COA and its members share one common mission: provide the best possible treatment to those suffering with life-threatening diseases.

The declaration submitted by Dr. Barbara McAneny, former President of the American Medical Association and current President and CEO of New Mexico Oncology Hematology Consultants Ltd. ("NMOHC"), illustrates the harm caused by the MFN Interim Final Rule. *See* Declaration of Barbara McAneny, M.D. ("McAneny Decl."), attached hereto as **Exhibit 3**. NMOHC is a small, multi-disciplinary practice providing care to roughly 20,000 patients per year in two locations in rural New Mexico. *Id*. ¶ 2. Many of its patients live on the frontier and travel several hours to get their treatment. *Id*. ¶ 3. Each year, NMOHC faces the challenge of whether it will bring in enough revenue to stay open and it "rel[ies] heavily" on a charity foundation to provide its patients with care. *Id*. ¶ 4.

According to NMOHC's calculations, if the MFN Interim Final Rule is not enjoined, its practice would lose $3.36 million in *2021 alone*, a figure that amounts to 75% of NMOHC's current anticipated annual profit (assuming no further reduction in revenue or increases in costs due to COVID-19). *Id*. ¶ 7. These reductions would seriously affect its ability to hire physicians and other professionals, "many of whom are in high demand," and may prevent it from meeting its lease obligations, which would cause "defaults and involuntary closure of [its] business." *Id*. Equally distressing, NMOHC would be "unable to make payroll or pay other operating expenses" at one of its two locations, while it would have to "stop treating Medicare patients" altogether "in order to try and keep [the] doors open" at its other clinic. *Id*. ¶¶ 7–8. As a result, more than 1,000 of its current Medicare patients would "*immediately*" lose access to care, *id.* ¶ 8 (emphasis added), and it would no longer have the resources necessary to provide its Medicare Advantage and Medicaid Managed patients with chemotherapy, *id*. ¶ 9.

The New York Cancer and Blood Specialists ("NYCBS"), which treats 275,000 patients across 55 clinics in metropolitan New York, calculates $17.1 million in losses in 2021 due to the

MFN Interim Final Rule—losses that "will grow progressively worse" each year. *See* Declaration of Jeff Vacirca, M.D. ("Vacirca Declaration"), attached hereto as **Exhibit 4,** ¶ 7. The Hematology-Oncology Associates of CNY ("HOAC"), which operates clinics covering 75% of the Central New York oncology market, stands to lose $6.2 million in the first year alone, which will "severely affect the longevity" of its oncology practice. *See* Declaration of Maryann Roefaro, M.S. ("Roefaro Declaration"), attached hereto as **Exhibit 5**, ¶¶ 4 & 7. In Illinois, five clinics operated by Northwest Oncology & Hematology ("NWOH") are projected to lose $3.8 million in the first year alone, a development that will "force [them] out of business." *See* Declaration of Gary E. Kay, M.D. ("Kay Declaration"), attached hereto as **Exhibit 6**, ¶ 4. The Pontchartrain Cancer Center ("PCC")—which employs only one physician across two clinics in poor, rural parts of Louisiana—forecasts $200,000 in losses, "an unsustainable" amount for such a small practice. *See* Declaration of Kathy W. Oubre, M.S. ("Oubre Declaration"), attached hereto as **Exhibit 7**, ¶¶ 2–3. In Texas, The Center for Cancer and Blood Disorders ("CCDB"), which runs eight clinics and treats 6,000 new patients per year, projects a "conservative[]" loss of $2.2 million in 2021, which, like other community oncology practices, will increase significantly each year. Declaration of Barry Russo ("Russo Declaration"), attached hereto as **Exhibit 8**, ¶ 3. And the Virginia Cancer Institute ("VCI") anticipates losses so significant that it will be "forced to eliminate many nursing and support positions" and will no longer be able to provide cancer treatment to Medicare patients at its eight clinics. Declaration of Thomas Gallo ("Gallo Declaration"), attached hereto as **Exhibit 9**, ¶ 6.

At a macro level, the U.S. Oncology Network ("USON"), which provides oncology practice management solutions to the largest nationwide network of community oncologists in the United States, estimates a *$300 million* loss in 2021 across its 480 oncology practices due to

implementation of the MFN Interim Final Rule. *See* Seiden Decl., Ex. 1, ¶ 18. According to USON, most oncology clinics in the U.S. "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." *Id*. ¶ 12. "Hence, the price of drugs that [USON] practices will administer under the MFN Rule in January 2021 will be set by pre-existing contracts. It would be extremely difficult, if not impossible, to renegotiate these contracts before the MFN Rule begins to reduce reimbursement rates beginning on January 1." *Id*. ¶ 13. In short, if the MFN Interim Final Rule is not enjoined, USON's 480 clinics "will incur staggering losses within days after the Rule's January 1, 2021 effective date." *Id*. ¶ 19. Such losses will only fuel the trends of the last 12 years, which saw 1,748 community oncology clinics and/or practices across the country close, be acquired by hospitals, undergo corporate mergers, or report that they were struggling financially. *See* Okon Decl., Ex. 2, ¶ 8. All told, "[t]he Rule will have a deeply destructive effect on community-based oncology practices." *Id*. ¶ 9.

Such pervasive, immediate, and drastic economic consequences readily meet the definition of irreparable harm for purposes of obtaining injunctive relief—especially where the harm compromises, reduces, or eliminates healthcare services. *See, e.g., Risteen v. Youth For Understanding, Inc*., 245 F. Supp. 2d 1, 16 & n.4 (D.D.C. 2002) ("The loss of health insurance benefits—particularly for those who are unemployed—constitutes irreparable harm for purposes of a preliminary injunction.") (collecting cases).

The facts in *Texas Children's Hosp.* closely parallel those presented here. There, two hospitals sought injunctive relief on the ground that they stood to lose millions of dollars in revenue due to changes made by CMS to its calculation of hospital-specific Medicaid payments. *Texas Children's Hosp.*, 76 F. Supp. 3d at 229. In determining whether the plaintiffs would suffer

irreparable harm absent an injunction, this Court focused on whether the alleged injuries were "certain, imminent, and unrecoverable." *Id*. at 242 (quoting *Nat'l Wildlife Fed. v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002)). First, the Court explained that the harms were "certain" because the new rule was already in effect; it was not a hypothetical question whether the government would ultimately recoup funds from the plaintiffs. *Id*. at 243. Second, the Court found that the alleged harm was "imminent" because although the government had not yet sought to recoup the funds at issue, it "could move to" do so starting January 1, 2015—three days after the court issued its opinion. *Id*. Those funds, in turn, were "unrecoverable" because once recoupment occurred, there was no way for the hospitals to get the monies back. *Id*. The Court noted that the plaintiffs' harm would be compounded because they would be forced "to reallocate resources" away from "other important services and programs . . . to cover even more of the costs of treating Medicaid patients." *Id*. at 243–44. All told, the Court concluded that "the harm the plaintiffs face[d] [was] irreparable." *Id*. at 245.

This Court's analysis in *Texas Children's Hospital* leads to the same conclusion here. The harm to COA's members is "certain" because the MFN Interim Final Rule, like the Medicaid rule in *Texas Children's Hospital* has already been promulgated. As in *Texas Children's Hospital,* the harms here are "imminent" because the reimbursement changes under the MFN Interim Final Rule will begin on January 1, 2021. The injuries are "unrecoverable" as well, as COA's members have no way to recoup their losses once the MFN Interim Final Rule goes into effect. Like the plaintiffs in *Texas Children's Hospital*, COA's members will be forced to "reallocate resources to cover even more of the costs of treating [Medicare] patients," thus "compound[ing]" the harm. *Id*. at 243-44. The harm to COA's members is, therefore, certain, imminent, and unrecoverable.

CMS's own analysis supports this conclusion. The Agency projects that in 2021 alone, the MFN Interim Final Rule will reduce Medicare Part B drug expenditures—and thus revenues for providers—by almost *$5 billion*. *See* 85 Fed. Reg. at 76,238. Describing the very circumstances faced by COA's members, CMS acknowledges that, starting January 1, 2021, 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." *Id*. at 76,236. For COA's members, the answer to that question is "no." As such, the Court should find that COA's members will suffer irreparable harm if injunctive relief is not granted. *See, e.g., D.C.*, 444 F. Supp. 3d at 33 (issuing preliminary injunction where plaintiffs alleged "anticipated injuries" totaling hundreds of thousands of dollars "in the form of significant administrative burdens and costs, including staffing and training costs, notification costs, and costs from expanding employment and training programs"); *Alcresta Therapeutics, Inc. v. Azar*, 755 F. App'x 1, 5 (D.C. Cir. 2018) (affirming lower court's finding of irreparable harm where plaintiff estimated $15.3 million in lost sales due to change in Medicare billing codes, which would "likely . . . force[] [the company] to cease operations" within two years unless relief was granted); *Int'l Long Term Care, Inc. v. Shalala*, 947 F. Supp. 15, 18 (D.D.C. 1996) (finding irreparable harm where nursing home "might well be forced to close its doors" if its participation in Medicare was terminated); *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs*., No. CV 20-1630 (JEB), 2020 WL 5232076, at *38 (D.D.C. Sept. 2, 2020), *appeal docketed Whitman- Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 220-5331 (D.C. Cir. Nov. 9, 2020) (finding irreparable harm where hospitals demonstrated that repeal of rule prohibiting discrimination on the basis of gender identity "will lead to a significant increase in demand for their health-care services from LGBTQ patients who fear discrimination at the hands of external providers").

B. The Cancer Patients Treated by COA's Members Will Suffer Irreparable Harm by Loss of Access to Care.

The MFN Interim Final Rule will also inflict irreparable, and, in some cases, deadly, harm on the cancer patients COA's members serve. This is not conjecture. As noted above, *see supra* Background § II(V), CMS itself has expressly acknowledged the grave harm that Medicare patients may suffer if the MFN Interim Final Rule goes into effect.

The data from oncology clinics across the county corroborate CMS's findings. USON notes that of the 38 oncology drugs subject to the MFN Interim Final Rule, 22 of them are used to treat advanced cancers, each with the goal of extending patient lives. Seiden Decl., Ex.1, ¶ 22. For example, one of those drugs, pembrolizumab (for which there is no generic or biosimilar alternative), has doubled median survival for patients with lung cancer. *Id*. According to USON, administering a drug like pembrolizumab typically costs between $10,000 to $15,000 *per administration*. *Id*. ¶ 16. In 2019, pembrolizumab was administered to Medicare patients in USON's network more than 20,000 times. *Id*. Under the MFN Interim Final Rule, oncology practices will receive nearly $2,000 less in Medicare reimbursement for pembrolizumab *per administration*. *Id*. Assuming demand for the drug remains the same, USON's clinics will lose a staggering $41 million in revenue over the course of five years under the MFN Interim Final Rule. *Id*. If USON's clinics close or otherwise decide to stop administering pembrolizumab—which is extremely likely—some 20,000 lung cancer patients will be left without alternative treatment. And that is just for *one drug*.

In New Mexico, patients at the Gallup Cancer Center will be forced to travel 140 miles *each way* for cancer treatment if it is forced to close. McAneny Decl., Ex. 3, ¶ 3. The Albuquerque Cancer Center will be forced right away to stop seeing Medicare patients when the MFN Interim Final Rule goes into effect, or face having to close its doors entirely. *Id*. ¶ 8. The local hospitals,

meanwhile, are not only at full capacity, they have *shut down* outpatient services due to the COVID-19 pandemic. *Id.* ¶ 9. Medicare patients, as a result, will have nowhere to turn.

The same is true in New York, where "all 10,064 [NYCBS] patients" treated with a drug subject to the MFN Interim Final Rule will be adversely affected. Vacirca Decl., Ex. 4, ¶ 6. NWOH similarly forecasts all five of its clinics will go out of business, leaving its patients—half of whom are Medicare patients—no choice but to receive treatment at a 340B hospital, which is not an option due to the COVID-19 PHE. Kay Decl., Ex. 6, ¶ 4. In North Texas, CCBD's patients will be left to travel "anywhere from 50 to 90 miles" to receive cancer treatment if the MFN Interim Final Rule goes into effect. Russo Decl., Ex.8, ¶ 4. The burden of seeking alternative care is even worse for PCC's Louisiana patients, who will have to travel more than 300 miles to receive cancer treatment if, as PPC projects, its clinics cannot provide treatment. Oubre Decl., Ex. 7, ¶ 5.

Surely, "HHS [cannot] dispute that lack of coverage for a medically necessary item constitutes irreparable harm." *Alcresta Therapeutics,* 755 F. App'x at 5. If the MFN Interim Final Rule is not enjoined, the cancer patients served by COA's members will not be able to obtain medically necessary treatment. Such a harrowing prospect certainly meets the definition of irreparable harm. *See, e.g.*, *Texas Children's Hosp.*, 76 F. Supp. 3d at 243 ("reducing hospital services to children" who receive treatment through Medicaid constitutes irreparable harm); *Alcresta Therapeutics*, 755 F. App'x at 5 (preventing cystic fibrosis patient from obtaining necessary medical device constitutes irreparable harm).

C. COA and its Members Will Suffer Irreparable Harm to their Notice and Comment Rights under the APA.

It is well-established that "[a] party experiences actionable harm when [it has been] 'deprived of a procedural protection to which [it] is entitled' under the APA. *N. Mariana Islands*, 686 F. Supp. 2d at 17 (quoting *Sugar Cane Growers Cooperative of Florida v. Veneman*, 289 F.3d

89, 94–95 (D.C. Cir. 2002)) (alterations omitted). This is because the APA—and particularly the notice-and-comment provisions under the APA—"are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). Violating this "elementary principle," therefore, is permissible "only when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *Capital Area Immigrants' Rights Coal. v. Trump* ("CAIR"), 471 F. Supp. 3d 25, 2020 WL 3542481, at *12 (D.D.C. 2020) (quoting *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012)); *Petry v. Block*, 737 F.2d 1193, 1200 (D.C. Cir. 1984).

CMS plainly did not have "good cause" to bypass the notice-and-comment requirements under the APA. *See supra* Argument § I(A). Injunctive relief, therefore, should be granted, as CMS's decision to flout the APA will cause immense and irreparable harm to COA and its members.

To justify the issuance of a preliminary injunction for a procedural violation, the movant must demonstrate that "the ability to comment" on the challenged rule is "linked to [a] concrete interest. . . ." *CAIR*, 2020 WL 3542481, at *10. As this Court recently explained, an organization challenging a procedural violation "faces irreparable harm where (1) the actions taken by the defendant have perceptibly impaired the organization's programs and (2) the defendant's actions directly conflict with the organization's mission." *NAACP*, 2020 WL 5995032, at *5 (quoting *League of Women Voters v. Newby*, 838 F.3d 1, 8 (D.C. Cir. 2016)) (cleaned up). Under the APA,

relief is "especially warranted" if the rule "will have significant effects" on a "complex and far-reaching regulatory scheme." *N. Mariana Islands*, 686 F. Supp. 2d at 17–18 (citation omitted).

Here, the MFN Interim Final Rule will "perceptibly impair[]" COA and its members' programs; indeed, with hundreds of millions of dollars in losses at stake, *see* Seiden Decl., Ex. 1, ¶ 18, numerous oncology clinics across the country will be forced to close their doors (or, at the very least, stop providing treatment to Medicare patients) if relief is not granted. This outcome "directly conflicts" with COA's mission of ensuring that cancer patients receive quality, affordable, and accessible cancer care in their own communities. *See* Compl. ¶ 21. Such circumstances undoubtedly meet the definition of irreparable harm. *See, e.g.*, *Open Communities All. v. Carson*, 286 F. Supp. 3d 148, 178 (D.D.C. 2017) (changes in calculations to HUD's voucher program would cause irreparable harm to plaintiff-organization dedicated to assisting voucher holders gain access to better housing); *NAACP*, 2020 WL 5995032, at *5 (changes to Postal Service's procedures caused irreparable harm to the NAACP by "frustrating its mission" to eliminate discrimination and requiring diversion of its resources); *CAIR*, 2020 WL 3542481, at *10 (holding that plaintiff would suffer irreparable harm if not permitted to comment on an immigration law).

The scale of the Medicare program and the extent to which it will be affected by the MFN Interim Final Rule supports this conclusion. As this Court has explained, "the more expansive the regulatory reach of [the] agency's rule[], the greater the necessity for public comment." *N. Mariana Islands*, 686 F. Supp. 2d at 17 (quoting *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981)) (cleaned up). The government's own statements make clear that the MFN Interim Final Rule "will dramatically alter" healthcare in the United States. *Id*. *See, e.g.*, Compl. ¶ 29 (quoting President Trump's promise that the MFN Interim Final rule will

"completely restructure the prescription drug market, in terms of pricing and everything else"). Absent an injunction, this compete restructuring of the prescription drug market will occur despite the fact that "it has not been tested via exposure to diverse public comment." *N. Mariana Islands*, 686 F. Supp. 2d. at 18 (citation omitted). The stakes could not be higher. To deprive COA of the ability to comment on a rule that will affect the financial livelihood of its members and the lives of the patients they serve would undoubtably cause irreparable harm. *See Texas Children's Hosp.*, 76 F. Supp. 3d at 247 (finding irreparable harm where plaintiff-hospitals were not given opportunity to comment on change to Medicaid calculation methodology); *D.C.*, 444 F. Supp. 3d at 6 (granting nationwide injunction due to USDA's failure to comply with APA prior to passing dramatic changes to SNAP program).

That CMS has allowed comments to be submitted *after* the MFN Interim Final Rule goes into effect does not change this conclusion. The harms will begin January 1, 2021—before the comment deadline on January 26, and long before CMS could meaningfully consider them. "[P]ermitting the submission of views after the effective date (of a regulation) is no substitute for the right of interested persons to make their views known to the agency in time to influence the rule making process in a meaningful way." *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1158 (D.C. Cir. 1981) (citation omitted); *N. Mariana Islands*, 686 F. Supp. 2d at 18 (an agency is "far less likely to be receptive to comments" submitted after the rule has gone into effect). The very point of Section 553 is "to ensure affected parties have a chance to participate in/influence agency decisionmaking at an early stage, when it is more likely to give real consideration to alternative ideas." *Id*. (quoting *New Jersey*, 626 F.2d at 1049). Thus, COA's harm cannot be rectified by CMS's perfunctory, post-implementation comment period. *D.C.*, 444 F. Supp. 3d at 32 ("Nodding to concerns raised by commenters only to dismiss them in a

conclusory manner is not a hallmark of reasoned decisionmaking.") (citation omitted).

D. COA and its Members Will Suffer Irreparable Harm to their Constitutional Rights.

Finally, COA and its members will suffer irreparable harm based solely on the fact that their constitutional rights have been invaded by CMS. Importantly, "suits for declaratory and injunctive relief against the threatened invasion of a constitutional right do not ordinarily require proof of any injury other than the threatened constitutional deprivation itself." *See Davis v. District of Columbia*, 158 F.3d 1342, 1346 (D.C. Cir. 1998). In fact, "there is a '*presumed* availability of federal equitable relief against threatened invasions of constitutional interests.'" *Id.* (citing *Hubbard v. EPA*, 809 F.2d 1, 11 (D.C. Cir. 1986) (quoting *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388, 404 (1971) (Harlan, J., concurring)) (emphasis added). For this reason, the D.C. Circuit has repeatedly held even a "prospective violation of a constitutional right" sufficiently constitutes "irreparable injury." *See, e.g., Karem v. Trump*, 960 F.3d 656, 667 (D.C. Cir. 2020) (internal quotations omitted) (citing *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013); *Doe v. Trump*, 275 F. Supp. 3d 167, 216 (D.D.C. 2017) *Mills v. District of Columbia*, 571 F.3d 1304, 1312 (D.C. Cir. 2009) ("It has long been established that the loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'"); *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Other Circuits are in accord. *See Ross v. Meese*, 818 F.2d 1132, 1135 (4th Cir. 1987) ("denial of a constitutional right . . . constitutes irreparable harm for purposes of equitable jurisdiction."); IIA WRIGHT & MILLER, FEDERAL PRACTICE & PROCEDURE §

2948.1 (2005) ("[w]hen an alleged deprivation of a constitutional right is involved, most courts hold that no further showing of irreparable injury is necessary.").

As discussed above, the MFN Interim Rule runs afoul of the Constitution in several ways. *See* Argument § C. For this reason alone, COA and its members have established irreparable harm.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR COA.

COA must show the balance of equities and public interest weigh in favor of preliminary relief. *NAACP*, 2020 WL 5995032, at *3 ("Where the federal government is the opposing party, the balance of equities and public interest factors merge."). Here, that burden is decisively met.

The balance-of-equities factor requires the Court to assess the "competing claims of injury and consider the effect on each party of the granting or withholding of the requested relief." *Texas Children's Hosp.*, 76 F. Supp. 3d at 245 (citations and alterations omitted). Here, the balance-of-equities analysis is simple: (1) preserve the status quo pending ultimate resolution of the case at no prejudice to the government; or (2) upend the Medicare Part B drug reimbursement program by allowing an executive order signed in violation of the APA and COA's constitutional rights—on the eve of the presidential election—to go into effect. The implications of choosing the latter course are profound. To borrow from this Court's opinion in *D.C.*, "[o]nce that egg has been scrambled, restoring the status quo ante will be considerably more disruptive." 444 F. Supp. 3d at 49 (citation and alterations omitted).

The harm that would be imposed on COA and its members would be far greater than any harm that would be imposed on the government if injunctive relief is issued. As of this filing—less than two weeks before the MFN Interim Final Rule goes into effect—"it is not known how oncology practices are to properly bill the Medicare fee-for-service program for MFN Drugs; how Medicare contractors will adjudicate and process claims for reimbursement for MFN Drugs to

assure the timely flow of payment; or how practices are to account for inventory purchased before and after the effective date of the MFN Interim Final Rule." Okon Decl., Ex. 2, ¶ 17. Suspending the implementation of the MFN Interim Rule for a relatively brief period to allow the Court to consider the legality of this "historic" and "transformative" seven-year plan, *see* Compl. ¶ 29, would cause no harm to the government and prevent destructive consequences to cancer care providers and their patients. *See 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) (noting if defendants prevailed, a TRO and preliminary injunction "will have merely delayed their preferred regulatory outcome").

Moreover, Defendants have not established that the MFN Interim Final Rule is necessary to lower the cost of drugs during the COVID-19 pandemic—or, for that matter, at any other time. According to a recent analysis from Avalere Health, one of the country's leading healthcare consulting firms, less than 1% of Medicare beneficiaries will experience reduced out-of-pocket costs for the 50 drugs subject to the MFN Interim Final Rule. *See* Compl. ¶ 41. In other words, 99% of the Rule's intended beneficiaries will not benefit at all from its implementation. The balance of equities, therefore, clearly weighs in COA's favor. *See, e.g.*, *Texas Children's Hosp.*, 76 F. Supp. 3d at 246 (plaintiffs-hospitals' request "to preserve the status quo" favored an injunction); *NAACP*, 2020 WL 599032, at *13 (the balance of equities favored an injunction because "[d]efendants identif[ied] no harms to themselves whereas Plaintiff has demonstrated serious, immediate, and recurring harms to its members and to itself as an organization").

Finally, the public interest weights in favor of an injunction. Indeed, "as courts have held in the context of Medicare-reimbursement cases, 'the Secretary's compliance with applicable law constitutes a separate, compelling public interest[,]'" as there is "a robust public interest in safeguarding access to healthcare." *Texas Children's Hosp.*, 76 F. Supp. 3d at 246 (quoting *In re*

Medicare Reimbursement Litig., 309 F.Supp.2d 89, 99 (D.D.C. 2004)); *N. Mariana Islands*, 686 F. Supp. 2d at 21 ("The public interest is served when administrative agencies comply with their obligations under the APA."); *Cent. United Life, Inc. v. Burwell*, 128 F. Supp. 3d 321, 330 (D.D.C. 2015), a*ff'd sub nom. Cent. United Life Ins. Co. v. Burwell*, 827 F.3d 70 (D.C. Cir. 2016) ("Forcing federal agencies to comply with the law is undoubtedly in the public interest. . . ."). Here, the public has an immense interest in seeing that drastic changes to the Medicare Part B drug reimbursement system are made fairly and legally.

CONCLUSION

COA respectfully requests a TRO and preliminary injunction barring Defendants from continuing to implement the MFN Final Rule and preventing the proposed adjustments to the Medicare reimbursement scheme from becoming operative. If the Court is not inclined to rule on the papers, COA respectfully requests a hearing on this Motion before January 1, 2021.

Respectfully submitted,

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Dated: December 18, 2020

Attorneys for Plaintiff Community Oncology Alliance, Inc.

CERTIFICATE OF SERVICE

I, Kierstan L. Carlson, hereby certify that, on this 18th day of December 2020, a true and correct copy of the foregoing Motion for a Temporary Restraining Order and Preliminary Injunction, and the Memorandum of Points and Authorities in Support Thereof were served upon Defendants via first-class mail at the following addresses:

U.S. Department of Health and Human Services
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The Hon. Alex M. Azar II
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I further certify that a copy of the Motion and Memorandum of Points and Authorities were served upon Rachel Westmoreland, Trial Attorney for the U.S. Department of Justice, by email to rachael.westmoreland@usdoj.gov.

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