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

COMPLAINT

Plaintiff Community Oncology Alliance, Inc. ("COA") hereby files this Complaint against Defendants 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") (HHS, Secretary Azar, CMS, and Administrator Verma are collectively referred to herein as

"Defendants"), seeking declaratory and injunctive relief for statutory and constitutional violations, and alleges as follows.

PRELIMINARY STATEMENT

1. This Complaint seeks a declaratory judgment and injunctive relief to prevent Defendants' efforts to implement an "Interim Final Rule" that will transform—in a manner that exposes the health and safety of cancer patients and other patients with potentially life-threatening diseases to real danger—the method by which healthcare providers are reimbursed for their use of Medicare Part B drugs in saving seniors' lives. Among these providers are the members of Plaintiff COA—the country's only nonprofit organization dedicated solely to representing, supporting, and recognizing independent community oncology practices—comprised of individuals from multiple levels of the cancer care delivery system, including oncologists, hematologists, pharmacists, mid-level providers, and oncology nurses. COA's purpose for commencing this action is urgent: Not only does this Interim Final Rule violate both statutory and constitutional law, it creates and imposes a radical new reimbursement regime in the middle of the COVID-19 pandemic and resulting public health emergency (referred to herein as the "COVID-19 PHE").[1] If not enjoined, the MFN Interim Final Rule will force oncologists practicing in community oncology clinics to administer therapies that will be reimbursed at a rate that is significantly less than the cost of those therapies, resulting in dire consequences to COA's members and the seniors they serve. As a result, oncologists will be left with the untenable choice of suffering business-threatening losses by accepting below-cost reimbursement or by having to

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

transition the care of seniors who comprise a significant volume of their existing practices to other providers (such as 340B hospitals). Either way, the harm will be irreparable.

2. After several years of unsuccessfully attempting to change drug prices through legislative or administrative 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. By this Executive Order, President Trump 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.

3. In November 2020, approximately two weeks after the presidential election, CMS issued what it titled the "Most Favored Nation (MFN) Model" Interim Final Rule (hereafter the "MFN Interim Final Rule"). Purportedly issued pursuant to Section 1115A of the Social Security Act, 42 U.S.C. § 1315a, the MFN Interim Final Rule claims 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* Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, (Nov. 27, 2020).

4. With certain limited exceptions and exclusions not relevant here, the MFN Interim Final Rule requires CMS to reduce the pertinent Medicare Part B drug statutory reimbursement

formula—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.

5. Despite promulgating the MFN Interim Final Rule pursuant to Section 1115A, the Rule is neither a "model" nor a "test" as permitted by Section 1115A; instead, the MFN Interim Final Rule implements a *mandatory*, seven-year *nationwide* program whereby healthcare providers will be reimbursed initially for 50 specifically designated drugs in accordance with an entirely new international pricing scheme. These 50 drugs account for nearly 80% of the Part B drug spending. Notably, 38 of these drugs are used by oncologists/hematologists to treat cancer and blood disorders, including the latest cutting-edge immunotherapies that have had dramatic results in improving cancer survival for Americans. If not enjoined, the MFN Interim Final Rule will force oncologists practicing in community oncology clinics to administer therapies that will be reimbursed at a rate that is significantly less than their cost, resulting in dire consequences to COA's members and the seniors they serve. Moreover, CMS has advised that it intends to add new drugs each year that will be subject to the same novel and untenable pricing scheme.

6. Apart from the numerous legal defects that attend to the MFN Interim Final Rule, the Rule will not address deficits in care or, with regard to drug prices, accomplish its professed goal of causing manufacturers to lower the price of these 50 Part B drugs. Indeed, CMS's own actuaries have acknowledged that their "assumptions reflect that some manufacturers will adhere to their current pricing instead of lowering sales prices in response to" the MFN Interim Final Rule. *Id*. at 76,237. Worse still, CMS actuaries have admitted that when reimbursement for the 50 drugs is artificially cut on January 1, 2021, physicians "will need to decide if the difference

between the amount that Medicare will pay and the price they must pay to purchase the drugs would allow them to continue offering the drugs." *Id.* at 76,236.

7. CMS acknowledges that, as a result of the MFN Interim Final Rule, some 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 drugs covered by the MFN Interim Final Rule, *id.* at 76,237–38, and that in year 2023, nearly one in five Medicare Part B seniors will forgo such treatment due to the MFN Interim Final Rule. As a result, CMS forecasts that half of the projected savings to Medicare "would be due to lost utilization" of these drugs. *Id.* at 76,239.

8. While CMS acknowledges the extreme financial hardship and negative effect on patient care that the MFN Interim Final Rule is expected to have under the Medicare fee-for-service program, it ignores two major factors:

a. First, CMS ignores the potential compounding effect of this change in reducing payment amounts under (i) commercial payor contracts and (ii) Medicare Advantage Organization ("MAO") contracts,[2] as certain payors may base their respective payment rates to providers on the new Medicare pricing methodology of the MFN Interim Final Rule. While the MFN Interim Final Rule is intended to apply to Medicare fee-for-service payments, MAO plans negotiate rates under provider contracts with providers. Importantly, CMS has taken the position that the non-interference provisions of "Section 1854(a)(6)(B)(iii) of the Social Security Act

[2] A "Medicare Advantage Organization" is a type of health insurance plan in the United States that provides Medicare benefits through a private-sector health insurer.

prohibit[] CMS from interfering in the payment arrangements between MAOs and contract providers."[3]

b. Second, the MFN Interim Final Rule ignores the increased administrative burdens placed on providers—especially during the COVID-19 PHE, when resources to provide care to the most vulnerable of seniors are already considerably strained—by potentially forcing providers to separately account for or inventory Medicare Part B drug products that are 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 of 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.

9. As explained herein, the MFN Interim Final Rule is unlawful in three broad respects:

a. 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, and for this reason alone should be struck down.

b. Second, the MFN Interim Final Rule fails to meet the requirements of Section 1115A in several critical ways, including: (a) by 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) by selecting a "model" in the absence

[3] *See* Letter dated May 1, 2013 from Cheri Rice, Director, Medicare Plan Payment Group, to Medicare Advantage Organizations and other organizations. *See* https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/PaymentReduct ions.pdf.

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) by 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 and other seniors. *Id.* § 1315a(c). Moreover, CMS's waiver of certain statutory provisions under Section 1115A contravenes the provision that such waiver is permitted "solely for purposes of" testing the model during the first phase. *Id.* § 1315a(d)(1). As the MFN Interim Final Rule is neither a test nor a model in accordance with Section 1115A, CMS has no authority to waive any of the Medicare or other cited provisions, including the Part B drug payment provisions.

c. Third, in bypassing Congress altogether in rewriting the Medicare Modernization Act of 2003 ("MMA"), Defendants violated, and are continuing to violate, the separation-of-powers doctrine essential to our government's constitutional structure. The MMA, enacted by Congress, provides an express statutory formula by which Medicare Part B outpatient providers or suppliers (not including hospitals) are to be 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 legislative authority. Doing so amounts to a violation of the Presentment Clause, the separation of powers, and the Non-Delegation Doctrine.

10. 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 cancer care for seniors who will not be able to be treated by their oncologists, with a significant number of seniors having to forgo treatment altogether, or being unable to find or afford

treatment when their local community oncology practice is forced to absorb losses causing the practice to shut down or join a more expensive hospital. Unless this unconstitutional program is stopped, community and rural oncology practices will close and cancer patients will suffer and, in some cases, die.

THE PARTIES

11. COA is a non-profit corporation incorporated under the laws of Tennessee and has a principal place of business located at 1225 New York Avenue, NW, Suite 600, Washington, DC.

12. HHS is an Executive Branch agency that oversees federal programs affecting essential health and human services and has a principal place of business located at 200 Independence Avenue, SW, Washington, DC.

13. Secretary Azar is the current Secretary of HHS and has a principal place of business located at 200 Independence Avenue, SW, Washington, DC.

14. CMS is an administrative agency within HHS that administers the Medicare program and has a principal place of business located at Woodlawn, Baltimore County, Maryland.

15. Administrator Verma is the current Administrator of CMS and has a principal place of business located at 200 Independence Avenue, SW, Washington, DC.

JURISDICTION, VENUE, AND STANDING

16. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331, because the suit arises under both the Constitution and the laws of the United States.

17. Venue is proper in the United States District Court for the District of Columbia pursuant to 28 U.S.C. § 1391, because this is the judicial district in which Defendants reside and/or the judicial district in which a substantial part of the events giving rise to the claims occurred. Venue is also proper under 2 U.S.C. § 922(a)(2), because this is a constitutional challenge.

18. The MFN Interim Final Rule is an interim final rule, which constitutes final agency action, and is therefore reviewable under APA, 5 U.S.C. §§ 701–06.

19. Although certain actions by CMS through CMMI are barred from judicial review under 42 U.S.C. § 1315a(d)(2), the claims asserted in this Complaint are not barred. 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); *see also Am. Hosp. Assoc. v. Azar*, 967 F.3d 818, 823-24 (D.C. Cir. 2020); *Am. Hosp. Assoc. v. Azar*, 964 F.3d 1230, 1238-39 (D.C. Cir. 2020). None of COA's claims falls within the limited categories enumerated in § 1315a(d)(2) as exempt from judicial review. Instead, COA alleges that the MFN Interim Final Rule is invalid because: (1) it was promulgated without required notice and comment procedures; (2) CMS exceeded its authority to issue and implement the MFN Interim Final Rule; and (3) the MFN Interim Final Rule is unconstitutional. Thus, this Court has jurisdiction to review COA's claims.

20. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201, and this Court has the authority to grant declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202.

21. COA has standing to bring this suit through the doctrine of associational standing because its members are "person[s] adversely affected or aggrieved" by Defendants' actions and COA seeks declaratory and injunctive relief concerning the legality of those actions. *See* 5 U.S.C. § 702.

a. First, COA's members would otherwise have standing to sue in their own right. COA represents more than 5,000 healthcare providers comprised of individuals from multiple levels of the cancer care delivery system including community oncology centers.[4]

b. Second, COA seeks to protect interests that are germane to COA's purpose, which is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities. COA brings this action to stop the impermissible implementation of the MFN Interim Final Rule, which threatens cancer patients' ability to obtain affordable cancer care in their own communities, and the ongoing viability of independent, non-hospital affiliated community oncology practices that treat a substantial number of the nation's cancer patients.

c. Third, this action seeks declaratory and injunctive relief only, which the U.S. Court of Appeals for the District of Columbia Circuit recognizes is the type of relief that does not require the participation of individual members in the lawsuit.

FACTUAL BACKGROUND

A. *The Longstanding Medicare Part B Drug Reimbursement Formula*

22. Medicare Part B governs reimbursement or payment for certain physician services, drugs, and supplies considered medically necessary to treat a disease or condition.

23. Professional medical services rendered by physicians participating in Medicare are reimbursed at the lesser of either: (a) the actual service charge; or (b) the fee schedule established by CMS under the authority provided in 42 U.S.C. § 1395W-4 (subject to exceptions).

24. In addition, 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

[4] COMMUNITY ONCOLOGY ALLIANCE, https://www.communityoncology.org/home/coa-membership/membership-information (last visited December 11, 2020).

providers are entitled to bill for these drugs pursuant to 42 U.S.C. § 1395u(o)(1). In the community-based oncology setting, they are typically infusible treatment drugs, such as chemotherapy and immunotherapies, and other drugs administered in a physician-office setting to treat cancer patients.

25. Medicare Part B drugs are reimbursed through a different method than professional medical services. The reimbursement method for Medicare Part B drugs is currently fixed by an express formula. Specifically, under 42 U.S.C. § 1395u(o)(1), the amount payable for such drugs furnished on or after January 1, 2005, is determined pursuant to a statutory formula whereby payment for Medicare Part B drugs, such as oncological drugs, equals the ASP for the drugs plus 6% (excluding the effects of sequestration discussed below). *See* 42 U.S.C. § 1395w-3a(b).

26. As a result of subsequent sequestration cuts resulting from Congress's inability to reach a budget agreement regarding certain economic thresholds established by the Balanced Budget Act, as amended by the Budget Control Act, the Office of Management and Budget—through HHS and CMS—reduced the pertinent Part B drug statutory reimbursement formula from ASP plus 6% to ASP plus 4.3%. If CMS is permitted to implement the MFN Interim Final Rule, Part B drug reimbursement will be further reduced to payment based on international pricing, which is defined as a:

> [P]rice that reflects the lowest per capita Gross Domestic Product adjusted (GDP-adjusted) price of any non-U.S. member country of the Organization for Economic Co-operation and Development (OECD) with a GDP per capita that is at least sixty percent of the U.S. GDP per capita, plus an alternative add on amount based upon a formula that will result in a flat add on amount, rather than a percentage.

See 85 Fed. Reg. 76,181.

B. Background of Pricing Concerns Preceding the MFN Interim Final Rule

27. 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 under the MFN Interim Final Rule. *See* 83 Fed. Reg. 54,546 (Oct. 30, 2018) ("ANPRM"). CMS, however, did not move forward with this proposed rulemaking.

28. In the meantime, in his State of the Union Address in February 2019, President Trump "ask[ed] the Congress to pass legislation that finally takes on the problem of global freeloading."[5] A bill was never passed into law. Later, on July 24, 2020, President Trump signed four executive orders with the stated intention of "massively lower[ing] prescription drug costs and increas[ing] Americans' access to life-saving medications."[6] President Trump stated that these executive orders reflected the "most far-reaching prescription drug reforms ever issued

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

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

by a President. Nothing even close."[7] The press release announcing the four executive orders was titled, "Congress Didn't Act on Prescription Drug Prices. So President Trump Did."[8]

29. One of the four executive orders was titled "Lowering Drug Prices by Putting America First," which was withheld by President Trump pending his proposed discussions with the pharmaceutical industry. On its website, the White House claimed that this order would institute a new and even more radical version than that set forth 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."[9] Even though President Trump described all four of the August 2020 orders that he signed as "sweeping," he singled out this most-favored-nation order as "transformative," "very dramatic," "historic," and "the most far-reaching prescription drug reforms ever issued." *Id.* He further promised that, along with the other three executive orders, the most-favored-nation order would "completely restructure the prescription drug market, in terms of pricing and everything else." *Id.*

30. On September 13, 2020, President Trump released the fourth executive order. In it, he announced that "[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. Based on that policy to lower costs—and without

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[7] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White House (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices/.

[8] *See Congress Didn't Act on Prescription Drug Prices. So President Trump Did.* (July 27, 2020), *available at* https://www.whitehouse.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did (hereinafter "July 2020 Press Release").

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

considering the effects on patient care—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 clear focus of the Administration's policy was to reduce drug costs, not to address "deficits in care" as required by Section 1115A.

C. The Interim Final Rule is Issued Without a Formal Notice-and-Comment Process

31. On November 27, 2020, Defendants issued the MFN Interim Final Rule. Earlier that same day, President Trump held a press conference to announce the "groundbreaking" rule instigated by the fourth executive order, describing it as "probably the biggest story that we've ever had relative to drug prices. There's never been anything like this."[10] Secretary Azar agreed, declaring in a contemporaneous press release that the new program "will be the most significant single action any administration has ever taken to lower American drug costs."[11]

32. Rather than proceeding through publication as a notice of proposed rulemaking for public comment, the MFN Final Interim Rule became *effective immediately* upon publication in the Federal Register. *See* 85 Fed. Reg. 76,180. Although the MFN Interim Final Rule allowed the public to submit comments for consideration during the ensuing 60 days (which COA did, by preliminary comment), this comment period ends well after the Rule's provisions commence and

[10] *Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans* (Nov. 20, 2020), *available at* https://www.whitehouse.gov/briefings-statements/remarks-president-trumpdelivering-lower-prescription-drug-prices-americans (hereinafter "Nov. 2020 White House Remarks").

[11] Press Release, Ctrs. for Medicare & Medicaid Servs., *Trump Administration Announces Prescription Drug Payment Model to Put American Patients First* (Nov. 20, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-announces-prescription-drug-payment-model-put-american-patients-first (hereinafter "2020 CMS Press Release").

provides no meaningful ability on the part of stakeholders to participate in a true notice-and-comment process.

33. The justification offered by HHS for giving the MFN Final Interim Rule immediate effect was high drug prices including the economic disruption caused by the COVID-19 PHE that supposedly required HHS to reduce drug prices and provide "immediate relief to Medicare beneficiaries." *Id.* at 76,249. Not only is this purported justification inconsistent with the notion of "testing" a "model" under Section 1115A, its premise is the opposite of reality: The COVID-19 PHE has placed unprecedented pressure on community oncology practices, particularly as hospitals are stretched to the breaking point treating COVID-19 patients. Burdening these practices with reimbursement cuts at this time is both counterproductive and unconscionable.

D. The Sweeping Scope of the MFN Interim Final Rule

34. Unless enjoined, the MFN Interim Final Rule will remain in place for an initial period of seven years ending December 31, 2027, *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") every quarter 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 that is at least 60% of the United States. 85 Fed. Reg. at 76,196. Currently, that encompasses nearly two dozen countries, including those with government-run, single-payer healthcare systems such as Canada and Sweden. *Id.* at 76,200.

35. The MFN Interim Final Rule operates by reducing the rate of reimbursement for drugs administered by Medicare providers in the outpatient setting, with certain exceptions. Providers such as COA's members typically purchase and store on site the drugs they administer

to seniors before receiving reimbursement, which creates significant financial risks even without the dramatic cuts that the MFN Interim Final Rule will impose.

36. 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, tbl. 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.*

37. 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. *See id.* at 76,254. That means that reimbursement could decline even more precipitously than the stated MFN Interim Final Rule percentage for any given year. It also means that the MFN Interim Final Rule effectively regulates the prices of drugs reimbursed *outside* of Medicare Part B, as certain commercial plans and MAOs base their reimbursement specifically on Medicare reimbursement rates.

38. The MFN Interim Final Rule will initially apply to 50 single-source drugs and biologicals with the highest Part B spending, subject to certain narrow exclusions. *See id.* at 76,181. CMS estimates that in the first year, those 50 drugs will account for nearly 80% of the Part B drug spending.[12] CMS plans to extend the Rule every year to cover new drugs that rise to be among the top 50 drugs based on updated annual Medicare Part B spending. *Id.* at 76,192.

[12] *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.

Subject to narrow exceptions, drugs already covered by the Rule will remain covered, so the scope of drugs covered by the MFN Interim Final Rule will only increase beyond 50 drugs over time. *Id.*

39. Of the 50 drugs identified in the MFN Interim Final Rule, 38 are used by oncologists/hematologists to treat cancer and blood disorders, including the latest cutting-edge immunotherapies that have had dramatic results in improving cancer survival for Americans. If upheld, the MFN Interim Final Rule will force oncologists in community oncology 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 with crippling losses, and a significant number of seniors will be forced to forgo treatment altogether, or not be able to find or afford treatment, when the local community oncology practice's losses cause the practice to shut down or join with a more expensive hospital.

40. 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 in the MFN Interim Final Rule that it did not believe the 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.

41. The effect of the MFN Interim Final Rule on the oncology practices of COA's members is dramatic and life threatening. It will increase—not reduce—the costs of cancer care

for Medicare and seniors. Indeed, in a just-released analysis, Avalere Health—a leading consulting firm specializing in policy and data analysis in the healthcare arena—concluded that less than 1% of Medicare beneficiaries will experience reduced out-of-pocket costs if the 50 drugs designated by the MFN Interim Final Rule are subject to the mandatory rate adjustments.[13]

42. As CMS itself acknowledges in the MFN Interim Final Rule, based on the analysis from its own actuaries, when reimbursement for the 50 covered drugs is cut on January 1, 2021, physicians "*will need to decide if the difference between the amount that Medicare will pay and the price they must pay to purchase the drugs would allow them to continue offering the drugs.*" 85 Fed. Reg. 76,236 (emphasis added). According to the CMS actuaries, when physicians are unable to provide drugs due to this arrangement, seniors are left with the distressing "*options*" of: (a) traveling to one of the few facilities excluded from the experiment; (b) finding a hospital with 340B Drug Pricing Program discounts; or (c) having to "*forgo access*" altogether. *Id*. at 76,237 (emphasis added).

43. Even with the first two options, seniors with cancer would have to sever ties with their existing oncologists and find new oncologists in the middle of their treatment. With the third option, *there is simply no treatment*. The CMS actuaries estimate that in the first year of the program (2021) a striking 9% of seniors will *"forgo access"* to treatment, while 11% will find treatment elsewhere. *Id*. at 76,237, tbl. 11 (emphasis added). The CMS actuaries further estimate that after two years, nearly one third of Medicare seniors will be displaced, *with nearly one in five seniors not getting treated for cancer and other serious diseases*. *Id.* Simply put, *by CMS's own*

[13] *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").

analysis, the MFN Interim Final Rule presents a morbidity and mortality risk in the lives of seniors with cancer and other serious diseases. In other words, the CMS actuaries openly acknowledge that the MFN Interim Final Rule will reduce access to care; such outcomes are anathema to a civilized healthcare system.

E. CMS's Issuance of the MFN Interim Final Rule Violated the APA Because CMS Lacked "Good Cause" to Dispense with Notice-and-Comment Requirements and Make the MFN Interim Final Rule Immediately Effective.

44. With limited exception, 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 rulemakings. 5 U.S.C. § 553(b)–(c). *See also* 42 U.S.C. § 1395hh(a)(3), (b). The purpose of notice-and-comment rulemaking is to give "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *UPMC Mercy v. Sebelius*, 793 F. Supp. 2d 62, 69 (D.D.C. 2011); *see also Chamber of Com. v. U.S. Dep't of Health & Hum. Servs*., No. 20-CV-07331, 2020 WL 7043877, at *6 (N.D. Cal. Dec. 1, 2020) (explaining that the purpose of the notice-and-comment rulemaking is to give "interested parties a meaningful opportunity to participate in the rulemaking process and assure that the agency's decisions will be informed and responsive") (citation and internal quotation marks omitted).

45. Adherence to notice-and-comment rulemaking procedures is critical with respect to changes to Medicare. "As Medicare has grown, so has Congress's interest in ensuring that the public has a chance to be heard before changes are made to its administration." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808–09 (2019) ("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."). Indeed, Congress heightened the notice-and-comment requirements for regulations issued under Medicare. *See generally* 42 U.S.C. § 1395hh(a)(3), (b).

46. An agency may bypass notice-and-comment rulemaking requirements 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). This Circuit has long held that the good cause exception to the APA's notice-and-comment requirement is to be "narrowly construed and only reluctantly countenanced." *See New Jersey v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980) (collecting cases).

47. The APA further demands that federal agencies provide a minimum amount of notice before making any substantive rule effective. It specifically provides that a substantive rule must be published "not less than 30 days before its effective date" unless "otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. § 553(d)(3); *see also* 42 U.S.C. § 1395hh(e)(1)(B).

48. The "good cause" exception "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.*, No. 20-CV-07331, 2020 WL 7043877, at *7 (citation omitted).

49. CMS issued the MFN Interim Final Rule on November 27, 2020, more than two months after the President issued Executive Order 13948. The Rule was not promulgated through a notice-and-comment rulemaking process; instead, it was published in the Federal Register as an *immediately effective* Interim Final Rule with Comment. 85 Fed. Reg. 76,180 *et seq.*

50. CMS attempts to justify its promulgating the Rule as an interim final rule rather than through the notice-and-comment procedures required under the APA, 5 U.S.C. § 553(b), by contending that it had "good cause" because the COVID-19 PHE "exacerbated" the "serious economic and health consequences" caused by "high drug prices." *See* 85 Fed. Reg. 76,248–50. To that end, the MFN Interim Final Rule claims 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 that 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 asserts that the "general financial instability" of Medicare beneficiaries has been worsened by the COVID-19 PHE, particularly "in communities of color. . . ." *Id.*

51. The MFN Interim Final Rule 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.*

52. In fact, CMS's reliance on the "good cause" exception is mere pretext. The MFN Interim Final Rule is not a response to a newly-developed emergency situation. To the contrary, Congress has recognized the need to address Medicare Part B reimbursements for years, *see supra* ¶ 28, and CMS has been evaluating its reimbursement methods since at least two years before the COVID-19 PHE even arose, *see supra* ¶¶ 27, 29.

53. Further highlighting the pretextual nature of CMS's "good cause" rationale is the fact that there is no mention of COVID-19 anywhere in Executive Order 13948 or in statements made by the President or Secretary Azar regarding the shift to a most-favored-nation approach.

And, the MFN Interim Final Rule was not promulgated until November 2020, more than eight months after COVID-19 spread to the United States. *See supra* ¶ 31.

54. The MFN Interim Final Rule is internally contradictory with respect to its ability to address the economic impacts of the COVID-19 PHE. More importantly, it ignores other deleterious effects that the Rule will have on beneficiaries and providers alike.[14]

55. 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.[15] However, CMS elsewhere admits that the MFN Interim Final Rule will reduce beneficiaries' access to drugs and may cause them to pay more. *See* 85 Fed. Reg. 76237, 76247. Specifically, the MFN Interim Final Rule states that (a) the Rule itself may cause *nearly 10%* of Medicare beneficiaries to have "no access" to their Medicare 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*"

[14] Further exposing CMS's flawed logic, the MFN Interim Final Rule expressly *excludes* all drugs authorized "to treat patients with suspected or confirmed COVID-19," purportedly because applying the "MFN Model" would impair the "rapid, widespread availability of such drugs in the U.S." 85 Fed. Reg. 76,191. Thus, CMS clearly understands that the MFN Interim Final Rule may cause a scarcity of covered Part B drugs and took steps to protect drugs needed to treat COVID-19 patients while simultaneously relying on the COVID-19 PHE as the purported "good cause."

[15] 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 if the 50 drugs designated by the MFN Interim Final Rule are subject to the mandatory rate adjustments. *See* Avalere Study, *supra* note 13. Thus, industry experts are already discovering additional flaws in CMS's logic, evidencing the necessity of a full notice-and-comment period.

may cause seniors to incur "*additional medical expenses.*" 85 Fed. Reg. 76,237 (including Table 11), 76,247 (emphasis added).

56. CMS further admits that the MFN Interim Final Rule may cause providers to suffer financial hardships through reduced reimbursement for drugs purchased to care for seniors. *See generally* 85 Fed. Reg. 76,222; *see also id.* at 76,247 (recognizing the "unusually high degree of uncertainty" about the potential effects of the MFN Interim Final Rule). And the MFN Interim Final Rule simultaneously fails to account for the business disruptions likely to result from the Rule's implementations. *See supra* ¶¶ 1, 10.

57. None of the facts cited by CMS as "good cause" justifies circumventing the procedural protections provided by the APA's rulemaking requirements. This is particularly so when viewed alongside (a) the substantial harm the MFN Interim Final Rule threatens to cause to interested parties and (b) the fact that, because there is only a *post-promulgation* comment period, Medicare Part B reimbursement rates will be affected before CMS has even considered critical input from interested parties.[16]

58. While it 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).

[16] 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.

59. 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's procedural protections. In *Chamber of Commerce*, the U.S. District Court for the Northern District of California invalidated a DHS 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.*, No. 20-cv-07331, 2020 WL 7043877, at *6 (citing 85 Fed. Reg. 63,901 & 63,908). The same is true here.

60. 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.

61. Thus, CMS did not have "good cause" to issue the MFN Interim Final Rule without notice-and-comment or to make it immediately effective, and the Rule is invalid.

F. The MFN Interim Final Rule Fails to Meet the Requirements of Section 1115A of the Social Security Act

62. Through the MFN Interim Final Rule, the Center for Medicare and Medicaid Innovation ("CMMI") is purporting to exercise its authority under Section 1115A to "test" a "model" nationwide with respect to the top 50 physician-administered Medicare Part B drugs. It further relies on Section 1115A to waive certain statutory requirements of Medicare and certain other provisions to carry out such "test" of a "model."

63. Section MFN Interim Final Rule, however, does not constitute a "test" of a "model" as permitted under Section 1115A(b). Instead, the MFN Interim Final Rule completely 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 then the testing "expan[sion]" under Section 1115A(c) (*i.e.*, Phase II).

64. The MFN Interim Final Rule was adopted pursuant to the Patient Protection and Affordable Care Act ("ACA"). The ACA, in turn, created CMMI as a department within CMS. *See* Pub. L. No. 1148, § 3021, 124 Stat. 119, 389 (2010) (codified at 42 U.S.C. § 1315a).

65. Section 1115A clarifies that the purpose of CMMI is to perform a "test" of certain "innovative payment and service delivery models" that are selected "in accordance with selection criteria under paragraph (2)" 42 U.S.C. § 1315a(a)(1), (b)(1)(2). The selection criteria under paragraph (2) corresponds to Phase I of the process.

66. 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." 42 U.S.C. § 1315a(b)(2)(A) (the "Selection Criteria"). During Phase I, CMS is 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).

67. CMS may only move to Phase II of the process if certain conditions are met. The first condition is that CMS must take into account "the evaluation under subsection (b)(4)" of Phase I. The second condition is that rulemaking must be conducted to permit CMS 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*. § 1315a(c) (emphasis added). This provision makes clear that it is only in Phase II that testing be done on a nationwide basis, and that Phase II testing cannot be done unless Phase I has been properly completed.

68. While the terms "test" and "model" are not specifically defined in Section 1115A, when considering the provisions of Section 1115A as a whole, it is 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.

69. Thus, CMS's non-compliance with Section 1115A is *ultra vires*.

a. First, with regard to the Selection Criteria of Phase I, CMS has not provided "evidence that the model addresses either: (i) a defined population; or (ii) deficits in care leading to poor clinical outcomes or potentially avoidable expenditure." Nor could it. First, the Interim Final Rule applies nationwide, not to any specific or defined population. It includes no sample group against which to measure sample results and is mandatory for all providers who bill Medicare for separately payable Part B medicines (with limited exceptions) and applies 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 expenditure. Rather, the MNF Interim Final Rule emphasizes that its intent is to ensure a *continuation* of access to care, not to describe or address *deficits* in such access: "As such, an important aspect of testing models is that beneficiaries *must continue* to have access to and receive needed care." *See* 85 Fed. Reg. 76,224

(emphasis added).[17] Without any evidence to support the Selection Criteria, the MFN Interim Final Rule fails to comply with Section 1115A.

b. Second, under Phase I, CMS did not have 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).

c. Third, as the MFN Interim Final Rule is not a test in accordance with the requirements of Phase I, CMS did not have the authority under Section 1115A to waive or amend Medicare provisions or other statutory provisions. Section 1115A is clear that CMS's waiver authority is limited "solely for purposes of carrying out this section with respect to testing models described in subsection (b)" (*i.e.*, Phase I). 42 U.S.C. § 1315a(d)(1).

70. Rather than confining itself to the tailored requirements of Section 1115A, the MFN Interim Final Rule lunges to the outcome it seeks, but cannot justify—*i.e.*, a seven-year, mandatory, nationwide reimbursement regime based on no sample testing. The purpose of the MFN Interim Final Rule is not to address deficits of care but solely to implement a sweeping scheme designed solely (and ineffectively) to cause drug companies to lower their prices. This contravenes the letter and spirit of Section 1115A.

G. The MFN Interim Final Rule Violates the Presentment Clause

71. The Presentment Clause requires "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it become[s] a Law, be presented to the President

[17] Indeed, as described in paragraph 6, *supra*, CMS acknowledges that the MNF Interim Final Rule will create—rather than address—shortages or deficits in care.

of the United States; If he approve[s] he shall sign it, but if not he shall return it." U.S. CONST. art. I, § 7, cl. 2.

72. 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). 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.

73. 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.

74. Section 1115A permits the Secretary to waive any provision of the Medicare statute—as well as other important provisions of the Social Security Act—solely for the purpose of testing under Phase I. *See* 42 U.S.C. § 1315a(d)(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 and the issuance of the MFN Interim Final Rule violates the Presentment Clause as interpreted by the Supreme Court.

75. 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. Under the MFN Interim Final Rule's mandate, those provisions are deprived of any "legal force or effect" for covered providers.

76. 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.

77. 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 ("Medicare pays substantially more" than other countries do "because [of] . . . the methodology in section 1847A of the Act.").

78. 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.[18]

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

79. Article I of the U.S. Constitution vests "[a]ll legislative Powers" in Congress. U.S. CONST. Art. I.

80. 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. INS v. Chadha*, 462 U.S. 919, 951 (1983) ("The Constitution sought to divide the delegated powers of the new federal government into three defined categories, legislative, executive and judicial, to assure, as nearly as possible, that each Branch of government would confine itself to its assigned responsibility.").

81. Congress violates this prohibition 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.

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

82. Courts have historically looked for "an intelligible principle" to guide the agency's exercise of authority. *Gundy v. United States*, 139 S. Ct. 2116, 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).

83. If authorized by Section 1115A (which it is not), the MFN Interim Final Rule embodies an unconstitutional delegation of legislative power to the Executive Branch. There was no congressionally enacted "intelligible principle" to which Secretary Azar was "directed to conform." *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).

84. 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."[19] By allowing the Administration to adopt and implement the MFN Interim Final Rule, Section 1115A provides no intelligible principle to guide CMS's decision-making process.

85. 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:

[19] *See* Executive Order 13948, *supra* ¶ 2.

"[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*."[20] 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."[21]

86. That such a "historic," "transformative," and "revolutionary" effort to "completely restructure the prescription drug market, in terms of pricing and everything else,"[22] is being planned, modified, and enacted within the administrative offices of the Executive Branch—as opposed to Congress—is both telling and constitutionally incurable.

I. Implementation of the MFN Interim Final Rule Will Cause Irreparable Harm

87. If the MFN Interim Final Rule goes into effect, it will irreparably harm seniors—particularly the nation's most vulnerable cancer seniors—as well as community oncology clinics and other providers across the country that provide essential treatment of cancer and other serious, life-threatening diseases to America's seniors.

88. First, the MFN Interim Final Rule's imposition of lower reimbursement costs for cancer drugs will intensify the shift currently playing out in oncology, where enormous financial incentives have pushed primary treatment of cancer away from local, independent community

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[20] *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").

[21] 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.").

[22] *See* July 2020 White House Remarks, *supra*; *see also 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").

practices to more expensive institutional and hospital settings. The MFN Interim Final Rule will augment this trend considerably, thereby causing substantial and irreparable economic hardship on community cancer practices.[23] Indeed, CMS's cuts to Part B drug reimbursement in 2005 and 2012 resulted in a combined 30% decrease in the percentage of chemotherapy delivered in independent community cancer clinics—dropping from 84% in 2004 to 54% in 2014, with the remainder delivered in the more expensive hospital outpatient setting.[24] By taking direct aim at the profitability of oncology clinics, the MFN Interim Final Rule will only serve to fuel the trends of the last 12 years, which saw 1,748 community oncology clinics and/or practices close, be acquired by hospitals, undergo corporate mergers, or report that they were struggling financially.[25] Such a course will cause permanent and irreparable harm to oncology clinics nationwide.

89. "Although as a 'general rule, economic harm does not constitute irreparable injury,' economic loss caused by federal agency action is an exception: typical economic harm is not irreparable because it is generally recoverable as monetary damages." *District of Columbia*

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[23] *See* COA, 2016 Community Oncology Practice Impact Report: Tracking the Changing Landscape of Cancer Care (2016), https://communityoncology.org/wp-content/uploads/2016/09/PracticeImpactReport-2016-Report.pdf (hereinafter "COA 2016 Impact Report"); COA, 2018 Community Oncology Alliance Practice Impact Report (2018), https://communityoncology.org/wp-content/uploads/2018/06/COA-Practice-Impact-Report-2018-FINAL.pdf (hereinafter "COA 2018 Impact Report")

[24] *See* Kathryn V. Fitch et al., *Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014* (April 2016), Milliman, https://www.milliman.com/-/media/milliman/importedfiles/uploadedfiles/insight/2016/trends-in-cancer-care.ashx.

[25] *See* COA 2020 Community Oncology Alliance Practice Impact Report, https://communityoncology.org/wp-content/uploads/2020/04/COA_PracticeImpactReport2020_FINAL.pdf (hereinafter "COA 2020 Impact Report").

v. U.S. Dep't of Agric., 444 F. Supp. 3d 1, 34 (D.D.C. 2020) (quoting *Davis v. Pension Benefit Guar. Corp*., 571 F.3d 1288, 1295 (D.C. Cir. 2009)) (alterations omitted). This exception is especially true here, as "the APA's waiver of sovereign immunity does not extend to damages claims." *Id*. (citing, *inter alia*, 5 U.S.C. § 702). As a result, Plaintiffs will be unable to recover any economic losses caused by the MFN Interim Final Rule's revisions to Congress's reimbursement scheme. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-1630, 2020 WL 5232076, at *40 (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). For this reason, the "[i]mposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury." *D.C.*, 444 F. Supp. 3d at 34 (quoting *Chamber of Commerce v. Edmondson*, 594 F.3d 742, 770-71 (10th Cir. 2010)).

90. Second, the MFN Interim Final Rule will cause a shift in care treatments. CMS itself has expressly conceded that some Medicare patients may receive inferior therapies with "lower efficacy or greater risks" and may end up "postponing or forgoing treatment" altogether. 85 Fed. Reg. at 76,244. Indeed, CMS's own estimates show that, within three years, nearly one in five Medicare Part B seniors may forgo access to drugs covered by the MFN Interim Final Rule, *id.* at 76,237–38, and that half of the projected savings to Medicare "would be due to the lost utilization" of these drugs, *id*. at 76,239. Similarly, CMS admitted that the MFN Interim Final Rule will cause shortages of drugs and delays in access—foreseeing that seniors will "experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." *Id*. at 76,244. These threats 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 reduce the chance for survival.

91. Third, the MFN Interim Final Rule will irreparably harm seniors and oncology clinics by depriving them of their procedural rights to notice-and-comment under the APA. Stripping interested parties of the chance to offer comments under the APA constitutes irreparable harm so long as "the ability to comment" on the particular rule is "linked to [a] concrete interest. . . ." *Capital Area Immigrants' Rights Coal. v. Trump*, No. CV 19-2117 (TJK), 2020 WL 3542481, at *10 (D.D.C. June 30, 2020) (quoting *Iyengar v. Barnhart*, 233 F. Supp. 2d 5, 12–13 (D.D.C. 2002)). As this Court has explained, irreparable harm exists if the APA violation will lead to a "substantial loss in funding," *D.C. v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 42 (D.D.C. 2020) (collecting cases), or if the APA violation "will 'perceptibly impair' [an organization's] programs and 'directly conflict with the organization's mission," *Open Communities All. v. Carson*, 286 F. Supp. 3d 148, 178 (D.D.C. 2017) (cleaned up). Irreparable harm similarly exists where the APA violation "will have significant effects" on a "complex and far-reaching regulatory regime" and the affected party has articulated "meaningful concerns about the Rule." *N. Mariana Islands v. United States,* 686 F. Supp. 2d 7, 17–18 (D.D.C. 2009).

92. Here, it is without question that the MFN Interim Final Rule will cause COA's members to suffer "a substantial loss in funding," *see supra* ¶ 39, which in turn will "perceptibly impair" COA's mission of ensuring that cancer patients receive quality, affordable, and accessible cancer care in their own communities, see *supra* ¶ 21. By the same token, the MFN Interim Final Rule "will have significant effects" on a "complex and far-reaching regulatory regime," as the Rule represents a profound shift in the entire Medicare Part B reimbursement system. Indeed, according to Secretary Azar, the MFN Interim Final Rule "will be the most significant single

action any administration has ever taken to lower American drug costs."[26] President Trump agreed, declaring on Twitter: "YOU KNOW THAT DRUG PRICES ARE COMING DOWN, BIG. Favored Nations Clause means USA will pay the lowest price of any nation in the World. Never done before. Watch!!!"[27] COA and its members, in turn, have meaningful and urgent concerns about the dangerous and adverse effects the MFN Interim Final Rule will have on the manner in which oncology clinics provide care to the nation's most vulnerable cancer patients.

93. Fourth, the MFN Interim Final Rule will irreparably harm seniors and oncology clinics by depriving them of their constitutional rights. "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." *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013) (citation and quotation marks omitted). *See also Karem v. Trump*, 960 F.3d 656, 667 (D.C. Cir. 2020). Indeed, "[w]hen an alleged deprivation of a constitutional right is involved, . . . most courts hold that no further showing of irreparable injury is necessary." *Advance Am. v. FDIC*, No. CV 14-953 (GK), 2017 WL 2672741, at *10 (D.D.C. Feb. 23, 2017) (quoting 11A Charles Alan Wright et al., *Federal Practice & Procedure* § 2948.1 (3d ed. 2005)). Here, the MFN Interim Final Rule is unconstitutional on multiple levels, violating the Presentment Clause, the Non-Delegation Clause, and the Separation of Powers Doctrine.

[26] 2020 CMS Press Release, *supra* note 11.

[27] President Donald J. Trump (@realDonaldTrump), TWITTER (Aug. 2, 2020, at 8:01 AM), https://twitter.com/realDonaldTrump/status/1289894127778377728.

CLAIMS FOR RELIEF

COUNT I

The MFN Interim Final Rule Violated the APA by Failing to Comply with the Procedures Required under 5 U.S.C. § 553 (Declaratory and Injunctive Relief – 5 U.S.C. § 706(2)(D))

94. COA incorporates its allegations in Paragraphs 1–93 as if set forth at length herein.

95. The APA requires courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

96. Under the APA, a federal agency must publish notice of proposed rulemakings in the Federal Register and provide the public with an opportunity to comment on such proposed rulemakings unless 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).

97. The APA further demands that federal agencies publish a substantive rule "not less than 30 days before the notice before its effective date" unless "otherwise provided by the agency for good cause found and published with the rule." 5 U.S.C. § 553(d)(3); *see also* 42 U.S.C. § 1395hh(e)(1)(B)(ii).

98. The MFN Interim Final Rule violated the APA because it was issued without the required notice-and-comment rulemaking procedures, and without the statutorily required "good cause" to dispense with such procedures.

99. The MFN Interim Final Rule also ran afoul of APA requirements because it became effective immediately upon publication without the 30-day delay required under § 553(d)(3) and without the "good cause" required to abandon the statute's notice requirement.

100. The MFN Interim Final Rule was issued on November 27, 2020, as an interim final rule with immediate effect. The MFN Interim Final Rule explicitly admits that CMS dispensed with "normal rulemaking requirements" and waived the delay in effective date, but contends that CMS has "good cause" for doing so because the COVID-19 PHE "exacerbated" the "serious economic and health consequences" cause by "high drug prices." 85 Fed. Reg. 76248-76250 (same factual basis for both "good cause" exceptions).

101. CMS's attempted articulation of "good cause" fails on all accounts. *See supra* ¶¶ 44–61. Indeed, the MFN Interim Final Rule states that the COVID-19 PHE requires extraordinary and emergency adjustments to Medicare Part B reimbursement formulas and that the MFN Interim Final Rule will provide relief to Medicare beneficiaries; however, the Rule was not promulgated in response to COVID-19, and, in actuality, it will cause harm to interested parties.

102. WHEREFORE, COA respectfully requests the Court to enter a declaratory judgment finding that the MFN Interim Final Rule violates the APA because it was promulgated "without observance of procedure required by law." COA further requests that the Court vacate and set aside the MFN Interim Final Rule pursuant to 5 U.S.C. § 706(2)(D) and enter a permanent injunction ordering Defendants to immediately cease implementation and/or enforcement of the MFN Interim Final Rule.

COUNT II

The MFN Interim Final Rule Exceeds CMS's Statutory Authority Under 42 U.S.C. § 1315a and Constitutes an *Ultra Vires* Agency Action (Declaratory and Injunctive Relief – 5 U.S.C. § 706(2)(C))

103. COA incorporates its allegations in Paragraphs 1–102 as if set forth at length herein.

104. "'[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) (citing *Arlington v. FCC*, 569 U.S. 290, 317 (2013) (Roberts, C.J., dissenting)).

105. The APA requires courts to "hold unlawful 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).

106. Separate and apart from the APA, this Court has an independent duty to set aside agency action that is *ultra vires*, even if such action was otherwise not subject to judicial review. *See Azar*, 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).

107. CMS was not authorized to issue the MFN Interim Final Rule under the provision in 42 U.S.C. § 1315a(a)(1) permitting the HHS Secretary to "to test innovative payment and service delivery models to reduce program expenditures" selected in accordance with Phase I while "preserving or enhancing the quality of care furnished to individuals."

108. The MFN Interim Final Rule is *ultra vires* and violates the limitations on CMS's authority to "test payment and service delivery models in accordance with selection criteria." 42 U.S.C. § 1315a(b)(1). As described above, *supra* ¶¶ 62–70, the MFN Interim Final Rule is not a "test" of a "model" under the statute. Instead, it represents a fundamental and extensive replacement of the Medicare Part B drug pricing and reimbursement scheme. The MFN Interim Final Rule also specifically contradicts Congress' intent to have a two-phased approach to testing of pricing models, jumping straight to implementation on a nationwide basis.

109. The MFN Interim Final Rule is not "in accordance with selection criteria" as required by 42 U.S.C. § 1315a(b)(1) because there has been no determination (nor is there evidence) "that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures," as required under § 1315a(b)(2)(A). Instead, the MFN Interim Final Rule identifies *all* seniors who will receive a covered drug. 85 Fed. Reg. 76183.

110. The MFN Interim Final Rule similarly fails to identify—but instead creates—"deficits in care" leading to either "poor clinical outcomes or potentially avoidable expenditures" for that broad population, as required by the statute. And, as written, it will not "preserv[e] or enhanc[e] the quality of care" enjoyed by Medicare beneficiaries. 42 U.S.C. § 1315a(b)(2)(A).

111. WHEREFORE COA respectfully requests a declaratory judgment be entered declaring the MFN Interim Final Rule "not in accordance with law" because it was promulgated "in excess of statutory jurisdiction, authority, or limitations," and/or *ultra vires.* COA further requests that the Court vacate and set aside the MFN Interim Final Rule pursuant to 5 U.S.C. § 706(2)(C) and enter a permanent injunction ordering Defendants to immediately cease implementation and/or enforcement of the MFN Interim Final Rule.

COUNT III

The MFN Interim Final Rule is Unconstitutional – Presentment Clause, Non-Delegation Doctrine, and Separation of Powers
(Declaratory and Injunctive Relief – Administrative Procedure Act, 5 U.S.C. § 706(2)(B))

112. COA incorporates its allegations in Paragraphs 1–111 as if set forth at length herein.

113. 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).

114. Even apart from the APA, courts must set aside agency action that violates the Constitution. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 n.2 (2010).

115. In implementing the MFN Interim Final Rule, Defendants violated, and are continuing to violate, the Presentment Clause, the Non-Delegation Doctrine, and the separation of powers essential to our government's constitutional structure.

116. 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. The Presentment Clause bars "unilateral [Executive] action that either repeals or amends parts of duly enacted statutes." *Clinton*, 524 U.S. at 439.

117. This presentment requirement was considered so important to the Founders that they took effort to prevent its circumvention. As a result, the President is entrusted with only the limited authority in the lawmaking process to nullify *proposed* legislation. Under the Presentment Clause's mandate, the President (or other parts of the Executive Branch) has no authority to nullify, alter, or amend existing legislation.

118. 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.

119. If CMS's interpretation is correct (which it is not), then the MFN Interim Final Rule violates the Presentment Clause because CMS's waivers in the MFN Interim Final Rule have the "legal . . . effect" of making numerous provisions in the Medicare statutes "entirely inoperative" and without "legal force." *Id.* at 438, 441.

120. In so doing, the waivers also have the "practical effect" of "rejecting the policy judgment made by Congress." *Id.* at 444. Indeed, CMS has not only suspended enforcement of certain provisions, it replaced these superseded statutory provisions with entirely new requirements reflecting its "own policy judgment." *Id*. at 438, 444.

121. By creating a new Medicare drug pricing system with new obligations, CMS is impermissibly usurping the lawmaking process to itself.

122. Therefore, if the MFN Interim Final Rule is authorized by statute, then the MFN Interim Final Rule violates the Presentment Clause at Article I, Section 7, of the U.S. Constitution.

123. Moreover, 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.

124. The Supreme Court has interpreted this language to bar delegation of "the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935).

125. The Supreme Court has also used this language to "derive[] the non-delegation doctrine: that Congress may not constitutionally delegate its legislative power to another branch of Government." *Touby v. United States*, 500 U.S. 160, 164-65 (1991). In exercising its legislative power, Congress may leave a certain amount of discretion to executive agencies and officials but must guide the exercise of that discretion with an "intelligible principle." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019).

126. The MFN Interim Final Rule conflicts with the Article I, Section 1, of the U.S. Constitution in violation of APA, 5 U.S.C. § 706(2)(B), for the following reasons.

127. Although cloaked as a "test," the MFN Interim Final Rule purports to discard Medicare's statutory pricing nationwide and adopt a drastically different pricing system for nearly the entirety of Medicare Part B's drug expenditures for the better part of a decade. *See supra* ¶ 36.

128. 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 interpreted by CMS in promulgating the MFN Interim Final Rule, none of the limitations of the statute constrain the Agency's discretion and there is no "intelligible principle" to which the Agency is directed to conform.

129. Therefore, if the MFN Interim Final Rule is authorized by statute, then Section 1315a(d) violates Article I, Section 1 of the U.S. Constitution and the Non-delegation Doctrine.

WHEREFORE, COA respectfully requests a declaratory judgment be entered declaring Defendants' conduct to be unconstitutional and declaring that the MFN Interim Final Rule violates the Presentment Clause at Article I, Section 7, of the U.S. Constitution, the Non-delegation Doctrine at Article I, Section 1 of the U.S. Constitution and/or the separation of powers. COA further respectfully requests a permanent injunction ordering Defendants to immediately cease implementation and/or enforcement of the MFN Interim Final Rule.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter Judgment in its favor and grant the relief sought herein as follows:

1. A declaration that the MFN Interim Final Rule is invalid because it failed to comply with the APA's procedural requirements, exceeded the agency's statutory authority, is

ultra vires, and/or violated the non-delegation doctrine, the Presentment Clause, and the separation of power.

2. Entry of a preliminary and permanent injunction barring defendants from further implementing or enforcing the MFN Interim Final Rule in any way whatsoever, and vacating the MFN Interim Final Rule.

3. An Order awarding Plaintiff's attorney's fees and costs; and

4. Such other and further relief as this Court deems just and proper.

Respectfully submitted,

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