IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, *et al.*	*	
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	*	Civil Action No. CCB-20-3531
v.	*	
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ALEX M. AZAR II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services, et al.*	*	
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MEMORANDUM

On November 27, 2020, the United States Department of Health and Human Services ("HHS") promulgated an interim final rule to require reimbursements made for certain drugs covered by Medicare Part B to be based on the lowest price in a group of "most favored nations" rather than the average U.S. sales price. The new reimbursement scheme commences on January 1, 2021, leaving providers little over a month to prepare for a new pricing model, attempt to renegotiate contracts, and work with patients to transition them to alternative therapies—if any exist—to manage their long-term care and avoid potentially catastrophic consequences to their health. This rule was promulgated without the usual notice and comment procedures, which the government argues was for good cause. In this action, the plaintiffs seek a temporary restraining order and preliminary injunction to bar implementation of the rule. The matter has, for the purpose of a temporary restraining order, been fully briefed, and oral argument was heard on December 18, 2020. For the reasons stated herein, the motion for a temporary restraining order will be granted.

BACKGROUND

Since at least 2018, President Donald Trump has sought by various means to lower drug prices. *See* 85 Fed. Reg. 76181 (Nov. 27, 2020). To achieve that goal, the Centers for Medicare

and Medicaid Services ("CMS"), a division of HHS, published in October of 2018 an advance notice of proposed rulemaking, which it later abandoned as the President sought to address the problem of high drug prices through legislation. (*See* ECF 24-1, Pl.'s Br., at 16). After that effort ultimately failed, on July 24, 2020, President Trump signed a series of "transformative" executive orders designed to "massively lower" the cost of prescription drugs. (*See id*. at 16–17).[1] Pursuant to those executive orders, on November 27, 2020, CMS published in the Federal Register its Most Favored Nation Rule—the subject of this litigation—to implement "a new Medicare payment model" which would "test whether more closely aligning payment for Medicare Part B drugs and biologicals . . . 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." 85 Fed. Reg. 76180. This new reimbursement model was promulgated pursuant to 42 U.S.C. § 1315a, which allows the agency to test payment and service delivery "models" to reduce program expenditures while at the same time "preserving or enhancing the quality of care[.]" 42 U.S.C. § 1315a(a)(1). If a model is successful, the agency may follow statutorily prescribed procedures to expand the scope of the model for testing on a larger, possibly even nationwide, basis. *See id*. § 1315a(c). The "model" proposed by CMS in this case features immediate "mandatory, nationwide participation," 85 Fed. Reg. 76188, and covers the fifty drugs and biologicals that account for the highest Medicare Part B reimbursement spending, *id*. at 76189, with additional drugs to be phased in over the model's seven-year duration, *id*. at 76192. CMS projects this model will impact nearly $5 billion

[1] The transcript of the President's remarks upon signing the executive orders is available at http://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices (last visited Dec. 18, 2020).

in Medicare Part B spending in its first year alone—and nearly $70 billion over the model's duration. *See id*. at 76238.

The rule took effect upon publication and, although CMS will accept comments for sixty days, until January 26, 2021, 85 Fed. Reg. 76180, the new model, which is expected to reduce Medicare Part B expenditures significantly, is slated to begin on January 1, 2021. *Id*. at 76181. CMS did not provide the usual notice and comment period prior to promulgation of the rule. Instead, it found there was good cause to waive both the notice and comment period and the delay in effective date required under the Administrative Procedure Act (the "APA") and the Social Security Act because "delaying implementation of this [rule] is contrary to the public interest[.]" *Id*. at 76250. CMS relies on the rising cost of drug prices and the economic consequences of the COVID-19 pandemic to justify dispensing with the required procedures. In its finding of good cause, CMS stated that "[h]igh drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment" insofar as "[i]ncreasing premiums, out-of-pocket costs . . . and increases in drug prices" have caused Part B beneficiaries to "divert scarce resources to pharmaceutical treatments and away from other needs[.]" *Id*. at 76249. "The COVID-19 pandemic," CMS asserts, "has rapidly exacerbated these problems." *Id*. Even before COVID-19 struck, the cost of Part B drugs increased by over nine percent between 2009 and 2017. *Id*. But since the pandemic struck, the United States has seen "historic levels of unemployment" that have "strain[ed] budgets[.]" *Id*. CMS notes that we have seen some "positive economic and employment trends since the initial peak in April," but states that a surge "may lead to additional hardship and requires immediate action." *Id*. Thus, "because of the particularly acute need for affordable Medicare Part B drugs now, in the midst of the COVID-19 pandemic[,]" CMS found there was good cause to forgo notice and comment. *Id*.

The plaintiffs[2] in this action are organizations which represent members including—among other constituencies—provider groups, doctors, patients, and pharmaceutical companies. (ECF 1, Compl. ¶¶ 15–18). The National Infusion Center Association ("NICA"), for example, represents community-based infusion providers which provide important healthcare services. NICA fears the rule at issue in this litigation will, because of the small margins on which many of its community-based centers operate, "immediately imperil" their ability "to care for patients" as the rule may force them to "shutter their doors entirely." (*Id.* ¶¶ 17, 73). This entails great risks for patients who rely on drugs covered under Medicare Part B to treat, for example, multiple sclerosis and cancer. (*Id.* ¶ 73; *see also* ECF 24-17, Ex. N, Decl. of Dr. Joshua David Katz; ECF 24-16, Ex. M, Decl. of Michael Seldin). CMS acknowledges that its rule could disrupt care, potentially forcing beneficiaries "to travel to seek care from an excluded provider" or perhaps even "postpon[e] or forgo treatment" altogether. 85 Fed. Reg. 76244. Within the first year of the test, CMS projects a nine percent increase in the rate at which patients at non-safety-net providers may have no access to covered medications. *Id.* at 76237.

The plaintiffs filed a complaint initiating this action on December 4, 2020, just a week after the rule took effect and just two weeks after it was announced. (ECF 1). On December 10, 2020, they moved for a temporary restraining order and preliminary injunction pending resolution on the merits. (ECF 24). The new reimbursement scheme at the heart of the challenged rule is scheduled to take effect on January 1, 2021, only twenty-two days after the request for injunctive relief was filed. Accordingly, the court issued an accelerated briefing schedule. (ECF 31). The matter is now fully briefed, the court has accepted an amicus brief

[2] The plaintiffs include the Association of Community Cancer Centers, the Global Colon Cancer Association, the National Infusion Center Association, and the Pharmaceutical Research and Manufacturers of America. (ECF 1, Compl. ¶¶ 15–18).

filed by the American Society of Clinical Oncology (ECF 39), and oral argument was heard on December 18, 2020 (ECF 40).

DISCUSSION

In this case, the plaintiffs seek to enjoin enforcement of CMS's Most Favored Nation Rule on the grounds that it (1) violates the APA for failure to provide a notice and comment period; (2) exceeds the authority provided to CMS by the Social Security Act; and (3) violates the Constitution's bicameralism and presentment and separation of powers requirements. In response, CMS raises a jurisdictional challenge as well as a challenge to the merits of each alleged violation. The court will first address the issue of jurisdiction and then turn to the merits.

I. Jurisdiction

Courts have an "independent obligation to determine whether subject matter jurisdiction exists," *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006), and if at any time the court determines that it lacks subject matter jurisdiction, the court must dismiss the action, Fed. R. Civ. P. 12(h)(3). To invoke federal subject matter jurisdiction under 28 U.S.C. § 1331, a plaintiff need only plead a colorable claim arising under the Constitution or laws of the United States. *Holloway v. Pagan River Dockside Seafood, Inc.*, 669 F.3d 448, 453 (4th Cir. 2012). The plaintiffs claim this court has jurisdiction under 28 U.S.C. § 1331 (federal question), as well as under 28 U.S.C. § 1346 (United States as defendant) and 5 U.S.C. §§ 701–06 (the Administrative Procedure Act).[3] (ECF 1, Compl. ¶ 11). And they have pled a colorable claim that, at a minimum, the promulgation of the Most Favored Nation rule without notice and comment procedures was a violation of the APA.

[3] The APA does not provide an independent basis for subject matter jurisdiction. *See Sigmon Coal Co., Inc. v. Apfel*, 226 F.3d 291, 301 (4th Cir. 2000).

Still, the government asserts that section 405(g) of the Social Security Act, which is incorporated into the Medicare statute, bars judicial review of claims arising under the Social Security Act (and the Medicare statute) unless a claimant first has obtained a final decision from the Secretary. (*See* ECF 33, Def.'s Br., at 17). Because the plaintiffs did not first present a claim to the agency and exhaust their administrative remedies, the government argues, they may not raise their challenge in this court.

"We begin, as always, with the text of the statute." *Permanent Mission of India to the United Nations v. City of New York*, 551 U.S. 193, 197 (2007). The Social Security Act, in a section titled "Evidence, procedure, and certification for payments," provides in relevant part:

> The findings and decisions of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). Thus, any claim "arising under this subchapter"—that is, brought under subchapter II ("Federal Old-Age, Survivors, and Disability Insurance Benefits")—is barred unless a claimant first raises the claim with the Secretary pursuant to section 405(g).

Section 1395ii of the Medicare Act makes section 405(h) applicable to the Medicare Act to the same extent as it applies to the Social Security Act. 42 U.S.C. § 1395ii. Specifically, it provides that certain subsections of "section 405 of this title[] shall also apply *with respect to this subchapter* to the same extent as [it is] applicable with respect to subchapter II . . . ." 42 U.S.C. § 1395ii (emphasis added). Thus, in most cases, a claim that is not first channeled through the agency may not be reviewed by a district court. Significantly, though, section 1395ii—like section 405(h)—only bars actions arising under the subchapter in which it appears.

As the government admits, the plaintiffs' claims arise under 42 U.S.C. § 1315a, which is in subchapter XI ("General Provisions, Peer Review, and Administrative Simplification"), whereas section 1395ii is in subchapter XVIII ("Health Insurance for Aged and Disabled"). (*See* ECF 33 at 16, 18). The plaintiffs do not make any specific or individual claims for reimbursement under subchapter XVIII. Accordingly, the plain text of the relevant statutes demonstrates that the plaintiffs are not subject to the jurisdictional bar in section 405(h). Having pled a colorable claim raising a federal question based on the APA and its application to a separate subchapter of title 42, the plaintiffs properly have invoked this court's subject matter jurisdiction.[4]

II. Standing

Courts likewise have an "independent obligation to assure that standing exists[.]" *See Summers v. Earth Island Inst.*, 555 U.S. 488, 499 (2009). An irreducible constitutional minimum, standing requires that plaintiffs have suffered (1) an injury in fact, (2) caused by the defendant, and (3) which likely could be redressed by a favorable decision of the court. *Id.* at 493; *see also Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). "When standing is challenged on the pleadings, we accept as true all material allegations of the complaint and

[4] The government asserts three other arguments regarding a jurisdictional bar, all of which are unavailing. The first is that 42 U.S.C. § 1395ff(b) bars the court's jurisdiction over this action, but that provision applies to appeals of initial determinations of benefits under part A and part B of subchapter XVIII, which are not at issue in this matter. (*See* ECF 33 at 18). The second is based loosely on the command of *Weinberger v. Salfi*, 422 U.S. 749, 761–62 (1975), that a claim arises under an act when the act provides both "the standing and the substantive basis for the present contentions." *Salfi* considered a constitutional challenge to a denial of individual benefits under subchapter II and noted that even though appellees raised constitutional claims, the substance of those claims was based in the Social Security Act. *Id.* "To contend that such an action does not arise under the Act whose benefits is sought is to ignore both the language and the substance of the complaint and judgment." *Id.* The court therefore held that section 405(h) barred federal question jurisdiction. In this case, though, plaintiffs do not seek to "recover on any (Social Security) claim" or to challenge a rule arising under subchapter II. *Id.* at 762. And finally, the third is that 42 U.S.C. § 1315a, the statute under which this rule was promulgated, prohibits judicial review of challenges to the selection, elements, parameter, scope, and duration of a model. 42 U.S.C. § 1315a(d)(2). Because the court does not reach the plaintiffs' statutory challenge to the model, the court need not reach this argument at this stage of the proceedings.

construe the complaint in favor of the complaining party." *S. Walk at Broadlands Homeowner's Ass'n v. Open Band at Broadlands, LLC*, 713 F.3d 175, 181–82 (4th Cir. 2013) (internal quotation marks and citation omitted).

Because the plaintiffs in this action are organizations and because their pleadings indicate they intend to rely, at least in part, on injuries to their members rather than to themselves, the court looks not just to the injuries alleged to the organization but also to injuries to its members who could have brought suit in their own right. *See Summers*, 555 U.S. at 494; *see also Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 (1976). For an organization to have representational standing, a court must be satisfied that (1) the organization's members would have standing to sue in their own right; (2) the interests the organization seeks to protect are germane to the organization's purpose; and (3) neither the claim nor the relief sought requires the participation of individual members in the lawsuit. *S. Walk*, 713 F.3d at 184; *see also Casa de Maryland, Inc. v. Wolf*, No. 8:20-cv-02118-PX, --- F. Supp. 3d. ----, 2020 WL 5500165, at *11 (D. Md. Sept. 11, 2020) (appeal filed). While violation of a procedural right "*in vacuo*" is insufficient by itself to confer Article III standing, a procedural injury that is tethered to some "concrete interest" adversely affected by the procedural deprivation is sufficient. *See Summers*, 555 U.S. at 496.

The court is satisfied that NICA has representational standing.[5] The rule at issue in this litigation, by reducing reimbursements for Medicare Part B drugs and upending the status quo in the industry, will "immediately imperil" the ability of NICA's community-based infusion providers "to care for patients, risking both disease flares that often become medical emergencies with lifelong repercussion and exponentially higher medical costs caused by disease

[5] Due to the compressed schedule in which the court must rule on this motion, it is unable to evaluate whether each plaintiff and its constitutent members have standing. But so long as one plaintiff has standing, the court may reach the merits.

undermanagement." (ECF 1, Compl. ¶¶ 17, 73). In the Declaration of Dr. Joshua David Katz, the plaintiffs document a striking example of the rule's likely harms to NICA members—at least one infusion treatment covered by the MFN rule, Ocrevus, is "the only FDA approved therapy" for primary progressive multiple sclerosis. "By rendering it economically impossible to continue infusing Ocrevus," Dr. Katz warns, "the MFN Rule forces providers to cease treating these patients without the ability to provide any other options." (ECF 24-17, Ex. N, Decl. of Dr. Joshua David Katz, ¶ 10). An infusion center that must discontinue care for economic reasons is essentially forced into malpractice, as a disruption in treatment for multiple sclerosis "can cause immediate rebound disease activity" and "even more intense symptoms than those previously experienced." (*Id.* ¶¶ 6, 11). The plaintiffs' complaint further alleges that community-based infusion centers are so reliant on drug reimbursements to break even that the rule likely "will force community-based infusion providers to shutter their doors entirely." (ECF 1 ¶ .). Construing the facts most favorably to the plaintiffs, this concrete injury, traceable to the rule at issue and caused by CMS, may be remedied by an injunction. *See Lujan*, 504 U.S. at 560–61. Additionally, CMS's decision to forgo notice and comment rulemaking implicates these severe economic impacts. As counsel indicated at oral argument, the plaintiffs would have used a notice and comment period to protect their economic interests by, at the very least, advocating for a delay in implementation of the model to provide them with time to renegotiate contracts and to transition patients to alternative therapies. (*See* ECF 40 at 20). Thus, even were NICA's only injury procedural, the deprivation of notice and comment in this case is not a deprivation "*in vacuo*" but rather is one that affects "a concrete interest" sufficient to confer Article III standing. *Summers*, 555 U.S. at 496.

The second and third requirements for representational standing are also met in this case. The interests which NICA seeks to protect in this action are certainly germane to its purpose, as NICA "devote[s] significant time and resources to representing" providers of Medicare Part B drugs and their patients. *Casa de Maryland*, 2020 WL 5500165, at *12. Nor do the plaintiffs' legal challenges require participation of individual members in the lawsuit, as the "ultimate remedy" sought is "setting aside the rule[], not money damages" that would require individual members to join the litigation as parties. *Id.*[6] Accordingly, on the basis of its procedural injury as well as the severe economic harm which imminently threatens its members, NICA has standing to pursue, at a minimum, its claim under the APA.[7]

III. Temporary Restraining Order

A party seeking a temporary restraining order or a preliminary injunction must show that: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm absent relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *See Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 20 (2008); *Roe v. Dep't of Def.*, 947 F.3d 207, 219 (4th Cir. 2020); *see also Maages Auditorium v. Prince George's Cty., Md.*, 4 F. Supp. 3d 752, 760 n.1

[6] For the purposes of this motion, the court is only evaluating NICA's standing, but it appears likely that this analysis applies to other plaintiffs as well

[7] CMS's arguments that third-party standing is "generally forbidden" and that the court may not consider harms to NICA's constitutent members misses the point. (ECF 33 at 36–37). The plaintiffs here do not seek to assert claims on behalf of unconnected third parties, but rather seek to assert claims as to which their members have a significant interest. The cases cited by the government deal only with the general presumption against third party standing and not with the more nuanced questions of organizational and representational standing which are applicable to this action. *Compare Bailey v. Atl. Auto. Grp.*, 992 F. Supp. 2d 560, 566 (D. Md. 2014) (concerning plaintiffs' standing to raise claims of third parties against defendants with whom they had no dealings in the context of a putative class action) *with Casa de Maryland*, --- F. Supp. 3d. ----, No. 8:20-cv-02118-PX, 2020 WL 5500165, at *17 (D. Md. Sept. 11, 2020) (appeal filed) (concerning an organizational plaintiff's ability to demonstrate irreparable harm by way of its individual members where the organizational plaintiff had representational standing).

(D. Md. 2014) (standard for TRO is the same as for a preliminary injunction), *aff'd*, 681 Fed. App'x 256 (4th Cir. 2017).[8]

A. Likelihood of Success on the Merits

The court concludes that the plaintiffs have demonstrated a likelihood of success on the merits of their claim under the APA.[9] The APA provides that, prior to promulgation of a final rule, an agency must publish a general notice of proposed rulemaking in the Federal Register and must allow "interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b), (c). This notice-and-comment process includes three steps. First, the agency "issues a general notice of proposed rulemaking, ordinarily by publication in the Federal Register." *Casa de Maryland*, 2020 WL 5500165, at * 23 (quoting *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015)) (internal quotation marks and alterations omitted). Second, the agency allows for a comment period wherein interested persons make the submissions described in section 553(c). *See id.* Third, "to afford the public meaningful participation, the agency must consider and respond to significant comments received during the period for public comment." *Id.* This three-step process is designed to allow for robust participation and influence by the public *prior* to the promulgation of the rule, "when the agency is more likely to give real consideration to alternative ideas." *United States v. Dean*, 604 F.3d 1275, 1280–81 (11th Cir. 2010). The importance of these notice and comment procedures "cannot be overstated" as agencies "benefit[] from the experience and input of comments by the public," which ensure informed decisionmaking. *N.C. Growers'*

[8] Though the standard for evaluating a temporary restraining order is the same as for a preliminary injunction, the accelerated briefing schedule and time constraints of a motion for temporary restraining order dictate that the court's analysis cannot be as thorough as it would be when evaluating a motion for preliminary injunction.

[9] The court does not today reach the plaintiffs' arguments concerning the statutory authority of CMS or the constitutionality of the rule.

Ass'n, Inc. v. United Farm Workers, 702 F.3d 755, 763 (4th Cir. 2012); *see also Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). Accordingly, the APA authorizes courts to set aside agency actions that are "without observance of procedure required by law." 5 U.S.C. § 706(2); *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) (courts reviewing agency action must ensure agencies comply with procedural requirements of the APA). While review of an agency's final decision may be narrow, "we must be strict in reviewing an agency's compliance with procedural rules." *N.C. Growers' Ass'n*, 702 F.3d at 764 (quoting *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985)).

Despite the importance of notice and comment procedures, the APA includes a narrow exception that allows agencies to dispense with such procedures for good cause.[10] The exception applies only "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B). The requirement that the agency explain its basis for bypassing the typical notice and comment process "is not a procedural formality but serves the crucial purpose of ensuring that the exceptions do not 'swallow the rule.'" *N.C. Growers' Ass'n*, 702 F.3d at 766. Still, the good cause exception exists as "an important safety valve" to be employed "where delay would do real harm." *Dean*, 604 F.3d at 1279.

To invoke the good cause exception, the burden is on the agency to establish that notice and comment may be dispensed with. *Nat. Res. Def. Council*, 894 F.3d at 113–14. This

[10] An agency is also required to publish a substantive rule at least thirty days before its effective date, unless it finds good cause to do otherwise and explains that rationale in the rule. 5 U.S.C. § 553(d)(3). Though CMS's rule was not published thirty days in advance of its effective date, it adopts the same reasoning explaining why good cause existed to forgo that requirement. 85 Fed. Reg. 76250. The plaintiffs here seem to primarily take issue with the lack of notice and comment, and the court will likewise focus its attention on that issue.

exception is to be narrowly construed and "only reluctantly countenanced." *Id.* (internal quotation marks and citation omitted); *see also Mack Trucks Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012). The good cause inquiry is "meticulous and demanding[,]" *Sorenson Commc'ns, Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (quoting *N.J. Dep't of Envt'l Protection v. EPA*, 626 F.2d 1038, 1046 (D.C. Cir. 1980)), and the exception is generally limited to "emergency situations" or to situations "where delay could result in serious harm[,]" *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (internal citation omitted). Courts review an agency's finding of good cause de novo. *See Sorenson Commc'ns*, 755 F.3d at 706 & n.3 (concluding that review of an agency's legal conclusions concerning good cause is de novo because agencies have "no interpretive authority over the APA" but noting that the courts defer to an agency's factual findings and expert judgments therefrom unless arbitrary and capricious). Courts consider an explanation for good cause that the agency has "advanced at the time of the rule making" and post-hoc explanations are viewed with "skepticism." *N.C. Growers' Ass'n*, 702 F.3d at 767. Nor may a court "supply a reasoned basis" for agency action "that the agency itself has not given." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

In this case, the plaintiffs attack CMS's invocation of good cause on two grounds. First, they argue that CMS has forfeited its ability to claim good cause due to its own delay in promulgating a rule it first contemplated many months if not years ago. (*See* ECF 24-1 at 22). And second, they argue that CMS has failed to adequately justify its invocation of the good cause exception. (*See id.* at 23–25). Because CMS has expressly invoked only the public interest prong of the good cause exception, the court will proceed to analyze CMS's rationale

under that provision.[11] *See* 85 Fed. Reg. 76250 (noting that delaying implementation of the rule would be contrary to the public interest).

The public interest prong may be invoked where notice and comment are "contrary to the public interest," which requires finding that "the interest of the public would be defeated by any requirement of advance notice." *N.C. Growers' Ass'n,* 702 F.3d at 767 (quoting *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001)); *see also Mack Trucks*, 682 F.3d at 94–95. When an agency argues that its action is in the public interest, courts will only agree "in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *Mack Trucks*, 682 F.3d. at 95. That is, "[t]he question is not whether *dispensing* with notice and comment would be contrary to the public interest, but whether *providing* notice and comment would be contrary to the public interest." *Id.* This exception is "appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal," which may occur where the announcement of a proposed rule would precipitate activity by affected parties that would harm the public welfare. *Id.* For example, if "announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent[]" then notice and comment could be dispensed with to prevent a rule from being evaded. *Id.* (internal quotation marks omitted).

A review of the caselaw reveals that courts have indeed been reluctant to uphold invocation of the good cause exception, doing so primarily in circumstances where it was

[11] Though there is no "rigid requirement that an agency must explicitly invoke the good cause exception, the contemporaneous record must manifest plainly the agency's reliance on the exception in its decision to depart from the required notice and comment procedures." *N.C. Growers' Ass'n*, 702 F.3d at 768. The contemporaneous record here contains neither an explicit nor an implicit reference to the "impracticability" prong, which requires showing that "the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." *Id.* at 766 (quoting *Nat'l Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 384–85 (2d Cir. 1978)). Nor does the record make reference to the "unnecessary" prong, which applies when a rule is "a routine determination, insignificant in nature and impact, and inconsequential to the public." *Id.* (quoting *Mack Trucks*, 682 F.3d at 94).

necessary to issue rules of life-saving importance immediately, or where delaying implementation of a rule would jeopardize the very reason for implementing the rule in the first place. *See Jifry v. FAA*, 370 F.3d 1174, 1179–81 (D.C. Cir. 2004) (good cause where September 11 terrorist attacks and national security concerns prompted the FAA to revoke the certificates of certain FAA airmen); *Hawaii Helicopter Operators Ass'n v. FAA*, 51 F.3d 212, 214–15 (9th Cir. 1995) (good cause where recent increase in fatal helicopter crashes prompted the FAA to enact regulations requiring flight patterns at a higher altitude over Hawaii's complex terrain); *Mobil Oil Corp. v. Dep't of Energy*, 728 F.2d 1477, 1492–93 (Temp. Em. Ct. App. 1983) (good cause where drastic economic harms of price discrimination and market dislocation which price control rule sought to prevent was likely to result if price controls were announced in advance)*; cf. United States v. Gould*, 568 F.3d 459, 470 (4th Cir. 2009) (good cause to bypass notice and comment for a rule making SORNA retroactive because there was a need for legal certainty and because there was a concern for public safety in getting sex offenders registered quickly).

More often, agencies struggle to legitimately show, as the standard requires, that providing notice and comment would harm the public interest. *See Sorenson Commc'ns*, 755 F.3d at 706–07 (agency speculation that funding shortfall would result absent immediate promulgation of rule without notice and comment was insufficient to establish good cause where the record was "simply too scant to establish" a fiscal emergency); *Tennessee Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1145 (D.C. Cir. 1992) (agency relied on mere speculation that notice of a regulation affecting construction of pipeline infrastructure would spur a rush to construct more pipelines); *Capital Area Immigrants' Rights Coalition v. Trump*, --- F. Supp. 3d ----, No. 19-2117 (JKT), 2020 WL 3542481, at *13 (D.D.C. June 30, 2020) (record insufficient to justify invocation of good cause where defendants relied on a single newspaper article to demonstrate

that an influx of asylum seekers would result if notice and comment preceded an immigration rule change); *Dialysis Patient Citizens v. Burwell*, No. 4:17-CV-16, 2017 WL 365271, at *4 (E.D. Tex. Jan. 25, 2017) (agency failed to demonstrate a crisis sufficient to invoke good cause because, among other reasons, they could not produce a single example of the harm the rule sought to prevent).

The purported justification for invoking the good cause exception in this case falls flat. First, like the factually deficient justifications cited in *Tennessee Gas Pipeline* and *Sorenson Communications*, CMS here relies more on speculation than on evidence to establish that the COVID-19 pandemic has created an emergency in Medicare Part B drug pricing sufficient to justify dispensing with valuable notice and comment procedures. In its rationale, CMS cites fifteen distinct sources in support of its various assertions, but most of those sources link to studies relating to drug pricing and health indicators from well before the pandemic existed, and none specifically address the cost of the particular drugs covered by the rule. *See* 85 Fed. Reg. 76249. And for the proposition, central to CMS's justification for dispensing with notice and comment, that "the COVID-19 pandemic has rapidly exacerbated" the problem of high drug prices, CMS does not cite to any source at all. *See id*. CMS asserts that the six million "fee-for-service beneficiaries without supplemental coverage" and the twelve million beneficiaries dually eligible for Medicare and Medicaid are particularly resource-strained at this time. *See id*. Yet the agency does not indicate in its rationale the extent to which these beneficiaries will experience immediate economic relief as a result of reduced copays under the MFN rule, and concedes elsewhere that the number of Medicare beneficiaries with supplemental coverage vastly outnumbers those without such supplemental coverage. *See id*. at 76183 n.22; (*see also* ECF 24-15, Ex. L, Decl. of Andrew Spiegel, ¶¶ 24–25 (noting that "more than 94 percent of fee-

for service Medicare patients using MFN drugs have supplemental coverage" and that such coverage means those patients will not see reduced out of pocket costs as a result of the rule)). It is also far from clear whether the agency has made any attempt to balance the potential economic benefits to some beneficiaries against the loss in access to medication that the plaintiffs assert will befall all beneficiaries if the pricing model goes into effect on January 1, 2021. While it may be that the anticipated benefits of the rule eventually would be borne out by empirical study, CMS's conclusory and speculative assertions do not provide, particularly in the short term, a reasoned basis sufficient to justify denying to the public the beneficial requirements of the sixty-day notice and comment period. An agency may not rely solely on its own expertise to establish good cause; findings of fact are required. *See Sorenson Comm'ns*, 755 F.3d at 706–07; *Tennessee Gas Pipeline*, 969 F.2d at 1145–46. Here, those findings are "simply too scant to establish" that the COVID-19 pandemic's recent surge is increasing the financial burden on beneficiaries due to increased costs associated with the drugs covered by the MFN rule or that the rule will immediately decrease drug costs for those individuals. *Sorenson Commc'ns*, 755 F.3d at 707.

And even assuming that the agency's justification had adequate support in the administrative record, this case—which concerns a rule aiming to "alleviate general financial instability" by reducing the cost of Medicare Part B drugs—is readily distinguishable from the national security cases, *see Jifry*, 370 F.3d 1174, and the life-threatening safety cases, *see Hawaii Helicopter Operators Ass'n*, 51 F.3d 212, that often justify waiver of notice and comment procedures. While this case does involve the use of price controls, as in *Mobil Oil*, 728 F.2d 1477, that case dealt with *changes* to statutorily imposed price controls, whereas this case deals with a regulation that would for the first time *implement* the use of a price control mechanism not

provided for by Congress. Nor does CMS claim that providing notice and comment would have precipitated activity by affected parties that would harm the public welfare; there is, for example, no articulated fear that pharmaceutical companies or providers might connive to raise prices to boost profits in advance of implementation of the rule. *See Mack Trucks*, 682 F.3d at 95.

Most importantly, though, CMS's invocation of good cause, which attempts to tie increased drug prices and financial insecurity to the urgent need for relief during the pandemic, turns on its head the relevant legal test this court must apply to determine whether good cause exists. It was CMS's burden, in issuing its findings of good cause, to demonstrate why notice and comment would be *detrimental* to the public interest. *See N.C. Growers' Ass'n*, 702 F.3d at 767 (noting that good cause requires showing that "the interest of the public would be defeated by any requirement of advance notice"). Even giving due deference to CMS's findings of fact, nothing in CMS's rationale explains why "the usual procedures" of notice and comment "would defeat the purpose of the proposal[.]" *Mack Trucks*, 682 F.3d at 95. Where, as here, the purpose of the rule is to test, over a period of seven years, a transformative new model of drug reimbursements that may affect untold numbers of beneficiaries and billions of dollars in spending on pharmaceuticals, there is a significant benefit in providing advance notice and comment procedures, and nothing in the agency's rationale explains why the relatively brief delay that would result from a notice and comment period would obstruct the purpose of testing such a long-term model.[12]

[12] It is important to distinguish between this rule's purpose and its justification for dispensing with required procedures. Though the bulk of this memorandum concerns the alleged good cause justification, the purpose of the proposal, by its own terms, is not to provide relief during the pandemic, but rather to test a new payment system for Medicare Part B drug reimbursement. *See* 85 Fed. Reg. 76180 (the rule is designed to "test whether more closely aligning payment for Medicare Part B drugs and biologicals . . . with international prices . . . can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care[.]"). Only one sentence in the "Purpose" section of the rule's Executive Summary even refers to the pandemic, with the rest of the four paragraphs in that section leaving little doubt that the rule was animated by a desire to achieve pricing parity with comparator countries. *See, e.g.*, *id*. at 76180, 76181 ("Medicare pays substantially more than other countries

The court is not unsympathetic to CMS's desire to test a new model to rein in Medicare Part B drug costs. But an agency may not dispense with notice and comment procedures merely because it wishes to implement what it sees as a beneficial regulation immediately. Agencies presumably always believe their regulations will benefit the public. If an urgent desire to promulgate beneficial regulations could always satisfy the requirements of the good cause exception, the exception would swallow the rule and render notice and comment a dead letter. *See N.C. Growers' Ass'n*, 702 F.3d at 766. In sum, then, the court cannot conclude that providing notice and comment would be contrary to the public interest—indeed, notice and comment may have served exactly its intended and beneficial purpose here. The allegations in the plaintiffs' complaint and the information in their declarations exemplify why courts have "only reluctantly countenanced," *Nat. Res. Def. Council*, 894 F.3d at 113–14, the good cause exception. It is possible, for example, that even if the MFN rule proves to be a valid model, public comment might have persuaded the agency to delay or alter the implementation of the rule in order to account for the difficulty of transitioning patients to alternative drugs or therapies and the economic effects likely to be felt by providers. For these reasons, the court finds that the plaintiffs have demonstrated they are likely to prevail on the merits with respect to their procedural challenge under the APA.[13]

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for many of the highest-cost Medicare Part B drugs" and "[t]he MFN Model aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that takes into account the discounts that other countries enjoy"). Further, CMS notes explicitly that it "is taking action on President Trump's goal to lower drug costs and seeking to realign financial incentives by implementing the Most Favored Nation (MFN) Model" for a seven-year test. *See id.* at 76180. CMS's claims about the urgency presented by the pandemic appear almost exclusively in its rationale for dispensing with notice and comment and constitute a justification rather than a purpose.

[13] Additionally, the fact that this regulation has been on CMS's regulatory agenda for months, if not years, is a factor which supports the court's findings. *See Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018) ("Good cause cannot arise as a result of an agency's own delay"); *see also National Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 16 (D.D.C. 2017) (collecting cases illustrating that the D.C. Circuit has repeatedly rejected good cause when an agency delays implementing its decisions); *Chamber of Commerce v. Dep't of Homeland Security*, No. 20-cv-07331-JSW, 2020 WL 7043877, at *8 (N.D. Cal. Dec. 1, 2020) (noting that the pandemic is an event beyond the agency's control, but it was within the agency's control to take action earlier than it

B. Irreparable Harm

The court concludes that the plaintiffs have demonstrated they are likely to suffer irreparable harm absent injunctive relief. A party seeking a TRO must demonstrate irreparable harm that "cannot be fully rectified by the final judgment after trial." *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 216 (4th Cir. 2019) (internal quotation marks omitted). The Supreme Court has clarified that plaintiffs must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 22 (2008); *see also Roe*, 947 F.3d at 229. The harm to be suffered must not be remote or speculative, but actual and imminent. *Mountain Valley Pipeline*, 915 F.3d at 216. If a movant has an adequate remedy in damages, a preliminary injunction will usually be denied, though economic loss may constitute irreparable harm where no remedy is available at the conclusion of the litigation, *see id.*, or in the event monetary losses are so severe as to threaten insolvency, *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994).

The plaintiffs have shown an abundance of irreparable harm that is likely to occur absent an injunction. The MFN rule in its first year would reduce Medicare drug expenditures by nearly $5 billion, and accordingly would drastically reduce revenues for providers, many of whom already operate on thin profit margins. (ECF 24-1 at 36). Because the government is protected by sovereign immunity and no monetary damages are available, these severe economic losses

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did, where the agency had some semblance of the rule at issue on its regulatory agenda since 2017). In this case, CMS announced a favored nations drug-pricing scheme in 2018, the Trump Administration issued an executive order requiring the Secretary of HHS to implement a favored nations scheme in July 2020, and CMS issued the rule in November 2020. (ECF 24-1 at 22–23). These delays suggest that, to some extent at least, CMS is "decrying an emergency of its own creation[.]" *Nat'l Venture Capital Ass'n*, 291 F. Supp. 3d at 17. Given the administration's previous unsuccessful attempts to implement the regulation or to persuade Congress to address the issue through legislation, its last minute, end-of-the-term invocation of the recent surge in COVID-19 cases as a justification for immediate action is cause for skepticism and undermines the agency's asserted rationale.

can qualify as irreparable harm. *See* 5 U.S.C. § 702 (waiving sovereign immunity only for actions "seeking relief other than monetary damages"); *Dep't of the Army v. Blue Fox, Inc.*, 525 U.S. 255, 263 (1999) (claim for money damages falls outside section 702's waiver of sovereign immunity); *see also E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1280 (9th Cir. 2020); *N.C. Growers' Ass'n, Inc. v. Solis*, 644 F. Supp. 2d 664, 670 (M.D.N.C. 2009) ("Plaintiffs' economic losses are unrecoverable in that suits for economic damages against the federal government and federal agencies are barred by the sovereign immunity doctrine."). Nor are these vast economic losses merely irretrievable—they also threaten "the very existence," *Otsuka Pharm. Co., Ltd. v. Burwell*, No. GJH-15-852, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015), of at least some of the organizational plaintiffs' members' businesses, (*see* ECF 24-13, Ex. J, Decl. of Amitabh Chandra ¶¶ 60–62; ECF 24-19, Ex. P, Decl. of Brian Nyquist ¶ 14; ECF 24-20, Ex. Q, Decl. of Edwin Charles Schadewald III, ¶¶ 9–11). Further, the court notes, but does not presently rely on, the irreparable harms that are likely to befall the patients who rely on NICA providers for Medicare Part B drugs subject to this rule. Providers of oncological care, for example, may be "unable to keep their doors open, particularly in rural and underserved areas, reducing the availability of critical treatments" for cancer patients. (ECF 24-1 at 35; *see also* ECF 24-11, ECF 25-8, Ex. H, Decl. of Britton L. Pim ¶¶ 15–24; ECF 24-13, Ex. J, Decl. of Amitabh Chandra ¶ 62).[14]

The plaintiffs also allege significant procedural injuries related to these impending economic harms. As the Supreme Court has stated, a procedural injury standing alone is

[14] The MFN rule does contain a hardship provision, but that provision is "limited to cases where the MFN participant experiences a financial loss," and requires providers to submit requests within sixty days "following the end of the performance year" for which the provider seeks an exemption. 85 Fed. Reg. 76222–74. And as the plaintiffs argue, the hardship provision thresholds are unlikely to rescue many providers with slim profit margins. (*See* ECF 24-1 at 38).

insufficient to support a finding of irreparable harm, but it may be sufficient if it also detrimentally affects some other concrete interest of the plaintiffs. *See Summers*, 555 U.S. at 496; *see also Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009); *Manzanita Band of Kumeyaay Nation v. Wolf*, --- F. Supp. 3d ----, No. 20-cv-02712 (TNM), 2020 WL 6118182, at *8 (D.D.C. Oct. 16, 2020) (appeal filed); *cf. Invenergy Renewables LLC v. United States*, 422 F. Supp. 3d 1255, 1290 (Ct. Int'l Trade 2019) ("A procedural violation can give rise to irreparable harm justifying injunctive relief because lack of process cannot be remedied with monetary damages or post-hoc relief by the court."); *Los Padres Forestwatch v. U.S. Forest Serv.*, 776 F. Supp. 2d 1042, 1051–52 (N.D. Cal. 2011) (finding sufficient harm to support preliminary injunction based on procedural injury resulting from deprivation of opportunity to participate in administrative process under NEPA in addition to threatened environmental harm).

Consider *Northern Mariana Islands v. United States*, a case in which DHS promulgated an interim rule, without notice and comment, that would "dramatically alter" the regulation of foreign guestworkers in the Commonwealth of the Northern Mariana Islands. 686 F. Supp. 2d at 14, 17. In that case, the Commonwealth showed irreparable harm because, even if the court were ultimately to decide the merits of the APA claim in the Commonwealth's favor, the "damage done by DHS's violation of the APA cannot be fully cured by later remedial action" because DHS would be "far less likely to be receptive to comments" once the program structured by the rule "has begun operation[.]" *Id.* at 18. Without an injunction, the Commonwealth would "never have an equivalent opportunity to influence the Rule's contents." *Id.* at 18–19.

Like the Commonwealth in *Northern Mariana Islands*, the plaintiffs here have suffered and will continue to suffer irreparable harm due to their inability to participate in notice and

comment procedures. In this case, CMS has promulgated a rule that in less than two weeks will "dramatically alter" the pharmaceutical market and Medicare Part B itself; CMS concedes that the rule is likely to affect nearly $5 billion in Medicare Part B reimbursements in its first year alone. 85 Fed. Reg. 76238. The plaintiffs have articulated meaningful concerns that were likely within their rights to air, which the agency was required by the APA to give "consideration," 5 U.S.C. 553(c), and which now the agency will be far less receptive to hearing. Once the new pricing scheme goes into effect on January 1, 2021, the plaintiffs will likely never have "an equivalent opportunity to influence the Rule's contents." *Northern Mariana Islands*, 686 F. Supp. 2d at 18–19; *cf. Nat'l Fed'n of the Blind v. U.S. Dep't of Educ.*, 407 F. Supp. 3d 524, 533 (D. Md. 2019) (deprivation of right to participate in notice and comment prior to a regulation's adoption can constitute injury to confer standing). This procedural violation, affecting concrete interests, is a significant injury in its own right.

In sum, the plaintiffs have carried their burden by showing that being deprived of the ability to have their comments considered prior to promulgation of a rule which threatens—starting on January 1—to cause severe economic losses and to shutter operations that provide critical medical care to recipients of Medicare Part B drugs constitutes irreparable harm sufficient to warrant a temporary restraining order.

C. Balance of Equities and Public Interest

The court concludes that the balance of the equities and the public interest weighs strongly in favor of issuing a TRO.[15] The third and fourth elements necessary for a temporary restraining order are whether the balance of equities and the public interest favor an injunction. *See Winter*, 555 U.S. at 20. When a temporary restraining order is sought against the

[15] The interests of affected patients, even if not cognizable as a harm to the named plaintiffs, certainly may be considered in weighing the balance of equities and the public interest.

government, and "the government's interest *is* the public interest," these last two factors merge. *Pursuing Am. Greatness v. Fed. Elec. Comm'n*, 831 F.3d 500, 511 (D.C. Cir. 2016); *see also Nken v. Holder*, 556 U.S. 418, 435 (2009) (assessing harm to the opposing party and weighing the public interest merge when the government is the party opposing a stay). The court must balance the significant irreparable harms identified above against the harms that CMS asserts will arise from temporarily enjoining enforcement of the challenged rule.

As noted extensively throughout this memorandum, the MFN rule was promulgated without adequate procedure, depriving the plaintiffs of an opportunity to comment on a potentially drastic revision to an important regulatory system with far-reaching consequences. The rule at issue threatens not just to harm the livelihoods of healthcare providers, but also to shutter community-based healthcare facilities, without which many patients may have to travel long distances to obtain medical care. (*See* ECF 24-13, Ex. J, Decl. of Amitabh Chandra ¶¶ 60–62; ECF 24-19, Ex. P, Decl. of Brian Nyquist ¶ 14). Worse yet, this may, as one provider network points out, cause some patients to confront "an impossible choice among untenable options: (1) accept alternative, inferior treatment, (2) go elsewhere for treatment, or (3) forgo treatment altogether." (ECF 24-16, Letter from Network Oncology, at 13). One drug covered by the Most Favored Nation rule is Ocrevus, which is the only therapy the FDA has approved to treat primary progressive multiple sclerosis. As Dr. Joshua David Katz's affidavit states, the rule will render it "economically impossible" to continue infusing Ocrevus, leaving providers with no alternative treatment and causing the thousands of multiple sclerosis patients "who are presently able to live a normal, fulfilling, and productive life" to "face relentlessly progressive symptoms that may result in blindness, the inability to walk, imbalance, falls, and a shortened life expectancy." (ECF 24-17, Ex. N, Decl. of Dr. Joshua David Katz, ¶¶ 6, 10). Thus, even if

facilities do not close entirely, the rule threatens to severely disrupt the treatment of patients, including those with multiple sclerosis, for whom regular treatment is critical to disease management. Furthermore, because the new reimbursement scheme commences on January 1, 2021, providers were given scarcely a month to grasp the impact this complicated rule would have to their healthcare practices; attempt to renegotiate contracts, which in some instances were negotiated up to a year in advance; and work with patients to determine whether and how they may be transferred to alternative therapies to manage their long-term care and avoid potentially catastrophic consequences to their health. Notice and comment procedures, aside from giving providers and patients more time to adjust to such important changes, also would allow the very concerns raised by the plaintiffs in their motion for a temporary restraining order to be heard and considered by the agency prior to promulgation.

On the other hand, CMS argues that there is "inherent harm" in preventing an agency "from enforcing regulations that Congress found to be in the public interest" and that the public would benefit from reducing drug prices in the midst of the COVID-19 pandemic. (ECF 33 at 44). Of course, Congress has also determined, in passing the APA, that it is in the public interest to allow the public to comment on proposed regulations prior to their promulgation. *See Mack Trucks*, 682 F.3d. at 95. And given the limited duration of a temporary restraining order, it would be more accurate to say—at least at this stage of the proceedings—that the court would be *delaying* the implementation of the rule rather than *preventing* it. The court acknowledges and gives weight to CMS's desire to lower drug prices to benefit seniors, but CMS has adduced no evidence that any harm will result if its seven-year test does not commence on January 1. Nor is any burden likely to befall CMS itself as a result of an injunction, as it already has a longstanding reimbursement scheme in place, and it is already committed to accepting comments

through much of January. Should CMS ultimately prevail in this litigation, it will suffer only a delay in implementation of the rule. In sum, the balance of equities and the public interest favor an injunction.

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For the reasons described herein, the plaintiffs have shown that they are likely to succeed on the merits, that they would suffer irreparable harms absent an injunction, and that the balance of equities and the public interest tips in their favor. The court will therefore grant a temporary restraining order.

IV. Scope of Injunction

Having determined that the plaintiffs are entitled to a temporary restraining order, the court must determine its proper scope. The Constitution vests the district courts with "the judicial Power of the United States." U.S. Const. art III, § 1; *see also Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015). That power "is not limited to the district wherein the court sits but extends across the country." *Id.* Accordingly, it is "not beyond the power of a court" to issue a nationwide injunction "in appropriate circumstances[.]" *Id.* At bottom, "[c]rafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance and legal issues it presents." *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2088 (2017) (per curiam) (denying in part a request to stay a nationwide injunction in a challenge to an executive order suspending entry of foreign nationals from seven countries).

Two recent decisions in the United States Courts of Appeals demonstrate that nationwide injunctions are appropriate under certain circumstances. For example, in *Texas v. United States*, the Fifth Circuit Court of Appeals considered the government's argument that an injunction

barring implementation of the Obama Administration's Deferred Action for Parents of Americans and Lawful Permanent Residents program should be limited to Texas or the other plaintiff states. 809 F.3d at 188. Noting that the Constitution, the immigration laws, and the Supreme Court all suggested immigration policy required a uniform approach, the court upheld a nationwide injunction. *Id.*; *see also Int'l Refugee Assistance Project,* 137 S. Ct. at 2088 (noting a nationwide injunction enjoining enforcement of an immigration ban was appropriate with respect to parties similarly situated to named plaintiffs). Likewise, the Ninth Circuit Court of Appeals upheld a nationwide injunction barring enforcement of Forest Service regulations promulgated without notice and comment procedure, citing the command of section 706 of the APA that a reviewing court shall "hold unlawful and set aside" agency action found to be "not in accordance with law." *Earth Island Inst. v. Ruthenbeck,* 490 F.3d 687, 699 (9th Cir. 2007) (quoting 5 U.S.C. § 706), *aff'd in part and rev'd in part on other grounds by Summers v. Earth Island Inst.,* 555 U.S. 488 (2009).

Additionally, federal courts over the years have issued "hundreds" of nationwide injunctions "reaching beyond the parties in the lawsuit[,]" especially when such a scope is considered "necessary to afford complete relief." *District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 46 (D.D.C. 2020). When a plaintiff prevails on a challenge under the APA to a rule of broad applicability, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. *Lujan v. Nat'l Wildlife Fed'n,* 497 U.S. 871, 890 n.2; *see also District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d at 47–48 (collecting cases).[16]

[16] The Fourth Circuit Court of Appeals, in an August 5, 2020, panel decision, invalidated a nationwide injunction restraining the government from enforcing an immigration rule which the district court found was promulgated in violation of the APA. *Casa de Maryland, Inc. v. Trump,* 971 F.3d 220 (4th Cir. 2020). On December 3, 2020, the Fourth Circuit Court of Appeals granted a rehearing en banc. *See Casa de Maryland, Inc. v. Trump,* 981 F.3d 311

This case lies at the intersection of *Texas v. United States* and *Earth Island Institute v. Ruthenbeck*. Here, as in *Earth Island Institute*, the defendants are charged with procedural violations implicating the APA's command to set aside agency action not in accordance with required procedure. And, like the regulatory and statutory framework at issue in *Texas v. United States*, the MFN rule by its own terms "necessitates" a "nationwide scope." 85 Fed. Reg. 76246. When the government was asked at oral argument how it might implement the new model without the uniformity which the model purports to require, the government had no concrete suggestions. But even if CMS were willing to shoulder the complex and daunting burden of administering its rule in compliance with a limited order, any such order would undermine the comprehensive nationwide test the rule purports to undertake.

Instead, it is appropriate here to enter a temporary restraining order that, while nationwide in scope, is also limited in that it simply preserves the status quo without requiring the agency to take any affirmative action. The government offers no persuasive rationale for such an order to be administered on anything less than a nationwide basis. The plaintiffs in this action represent numerous medical providers and pharmaceutical companies, and collectively they are likely to constitute a significant portion of all parties who might be subject to the rule. A piecemeal approach is not appropriate in this case, even if it may be in others. *See Carmen's Corner Store v. U.S. Small Bus. Admin.*, 469 F. Supp. 3d 459, 480–81 (D. Md. 2020) (granting injunctive relief only to named plaintiffs where circumstances demonstrated that to do otherwise would result in overbroad and insufficiently tailored relief). And a court order should not cause confusion about which companies or providers are subject to a rule and which are not; instead, a court order must be clear and definite. Accordingly, the "equities of the case" call for, and the

(4th Cir. 2020). Accordingly, the panel decision is not controlling. *See* United States Court of Appeals for the Fourth Circuit Local Rule 35(c) (Dec. 9, 2019).

court will issue, an order temporarily restraining the government from enforcing the contested rule. *See Int'l Refugee Assistance Project*, 137 S. Ct. at 2088.

CONCLUSION

Agencies have broad discretion, within the confines of the statutory authority delegated to them by Congress, to sift competing policy proposals and promulgate regulations. And CMS's concerns about the cost of Medicare Part B drugs may eventually justify adopting a most favored nation rule to test an alternative pricing scheme.[17] But the "good cause" rationale advanced by CMS is insufficient to dispense with the notice and comment procedures which are required under the Administrative Procedures Act and which are essential to ensuring civic participation in the rulemaking process as well as informed agency decisionmaking. Accordingly, the court will grant the plaintiffs' motion for a temporary restraining order. A separate order follows.

12/23/2020
Date

/s/
Catherine C. Blake
United States District Judge

[17] The court reiterates that it is expressing no opinion on the merits of the plaintiffs' statutory or constitutional challenges to this rule.