UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER ASSOCIATION *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Defendants.

Case No. 1:23-cv-00707

DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This lawsuit is the continuation of a long-running, as-yet-unsuccessful lobbying effort by the primary trade association for pharmaceutical manufacturers, the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA—an advocacy organization that has no apparent connection to the Western District of Texas—filed this lawsuit, along with two other membership associations, to achieve through the courts what it has already tried and failed to achieve through the legislative process. Plaintiffs seek a court order that would nullify key provisions of the Inflation Reduction Act (IRA), in which Congress authorized the Secretary of Health and Human Services to try and negotiate a better deal for Medicare beneficiaries and the American taxpayer on some of the pharmaceutical industry's most lucrative drugs. Underscoring the degree to which this suit is driven by policy objections rather than any concrete injury, Plaintiffs seek that relief before any drugs are selected for the program (later this week), before any prices are agreed upon (by August 2024), and before any new prices take effect (in 2026).

So what connects this case to the Western District of Texas? Even on Plaintiffs' telling, but the thinnest of reeds: of the three Plaintiff associations, one of them—the National Infusion Center Association (NICA), which does not even represent members who manufacture or sell prescription drugs—"resides" in this district, 28 U.S.C. § 1391(e)(1)(C). On that basis alone, Plaintiffs claim that venue here is appropriate. *See* Compl. ¶ 19, ECF No. 1. And that might have been right, except for one foundational oversight: this Court lacks subject-matter jurisdiction over NICA's claims, so NICA does not belong in this case at all. For that reason, venue is improper in this district.

First, NICA lacks Article III standing. NICA alleges that it represents outpatient facilities that, among other services, administer infusion drugs covered under Medicare Part B. As a membership association, NICA can carry its burden to show standing only if (among other things) it identifies at least one member that would otherwise have standing on its own. NICA has not identified a single member. Even if it had, Plaintiffs' allegations of harm to NICA's members fall far short of showing that any particular member would itself have Article III standing. They have not identified any particular drug (much less one administered by a particular NICA member) that is certain (or even

likely) to be selected for negotiation. And Medicare expenditures on infusion drugs under Medicare Part B will not even be *considered* as part of the drug-selection criteria during the first two years of the IRA's Drug Price Negotiation Program—meaning that there is no basis for theorizing that the price Medicare pays under Part B for any drug administered by NICA members will be affected until at least 2028, more than four years from now. At this early stage, it is entirely speculative whether and which drugs covered under Part B may be selected for price applicability year 2028, or any following year.

Nevertheless, Plaintiffs hypothesize that, in 2028 or later, unidentified NICA members will see diminished revenue because they will receive lower reimbursements from Medicare for the (currently hypothetical) selected infusion drugs that they administer to Medicare patients. But Plaintiffs do not explain how those reimbursements are determined or (more importantly) how that determination interacts with the prices that individual providers currently pay for particular drugs—much less why any particular NICA member who administered a hypothetically selected drug will make less profit from administration of that drug to Medicare patients as a result of the Negotiation Program. Plaintiffs' vague and speculative allegations do not represent the sort of concrete, particularized, and actual or imminent injury that Article III requires.

Second, even if NICA had carried its burden to show Article III standing, it faces another, independent jurisdictional problem: Congress has long required that healthcare providers dissatisfied with their Medicare reimbursements first present and exhaust those claims through an administrative process before suing in federal court. As the Supreme Court and the Fifth Circuit have repeatedly emphasized, "virtually all legal attacks" relating to Medicare reimbursements—including constitutional claims like those alleged here—must "be brought through the agency" first. *Nat'l Athletic Trainers' Ass'n, Inc. v. HHS*, 455 F.3d 500, 503–04 (5th Cir. 2006) (quoting *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000)). Plaintiff NICA has not complied with these requirements.

Because the Court lacks subject-matter jurisdiction over NICA, it must be dismissed under Federal Rule of Civil Procedure 12(b)(1). The same is likely true for the other two Plaintiffs, for reasons that overlap in part with the reasons that NICA lacks standing—but the Court need not decide

those issues, because without NICA, there is no basis for venue here. Accordingly, the entire case should be dismissed for lack of venue under Federal Rule of Civil Procedure 12(b)(3).[1]

BACKGROUND

I. Statutory Background

A. Medicare is a federal program that pays for covered healthcare services provided to program beneficiaries as well as for prescription drugs. *See generally* 42 U.S.C. §§ 1395 *et seq.* The Medicare statute is divided into five "Parts," which set forth the terms by which Medicare will pay for benefits. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). "Traditional Medicare comprises Part A, which covers medical services furnished by hospitals and other institutional care providers, and Part B, which covers outpatient care like physician and laboratory services," as well as drugs administered (commonly in providers' offices) as part of that care. *Cares Cmty. Health v. HHS*, 944 F.3d 950, 953 (D.C. Cir. 2019) (internal quotation marks omitted); *see* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). In 2003, Congress added Medicare Part D, which provides "a voluntary prescription drug benefit program that subsidizes the cost of prescription drugs and prescription drug insurance premiums for Medicare enrollees." *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 749 (3d Cir. 2017); *see* 42 U.S.C. §§ 1395w-101 *et seq.*

Prior to the IRA, Congress barred the Secretary from negotiating with drug manufacturers for the costs of covered medications under Part D. *See* 42 U.S.C. § 1395w-111(i). This model contributed to rapidly rising costs to Medicare in recent years. Medicare Part D spending has doubled over the last decade, and it "is projected to increase faster than any other category of health spending." S. Rep. No. 116-120, at 4 (2019); *see also* Cong. Budget Office (CBO), *Prescription Drugs: Spending, Use, and Prices* 16 (2022), https://perma.cc/9WPC-VLFC. Much of that increase is attributable to a "relatively small number of drugs [that] are responsible for a disproportionately large share of Medicare costs." H.R.

[1] Although (at the parties' joint request) the Court has already issued a scheduling order for briefing cross-motions for summary judgment, Order, ECF No. 34, in the interests of efficiency and judicial economy, Defendants respectfully request that the Court first consider the threshold issues of jurisdiction and venue raised in this motion. Because granting this dispositive motion would obviate the need to consider summary judgment at all, Defendants will shortly file a separate motion seeking a modification to the briefing schedule.

Rep. No. 116-324, pt. II, at 37 (2019). Congressional reports have found that generic competitors face many legal and practical obstacles to market entry, sometimes leaving only a single manufacturer of a particular drug on the market for extended periods of time. *See* Staff of H. Comm on Oversight and Reform, 117th Cong., *Drug Pricing Investigation: AbbVie—Humira and Imbruvica* 36 (2021). And the payment formula for drugs covered under Part B permits a manufacturer of a drug without generic competition to "effectively set[] its own Medicare payment rate." Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 84 (2022), https://perma.cc/5X4R-KCHC. The result has been a shift of financial burden to the Medicare program, which undermines the program's premise of leveraging market competition to reduce prices for beneficiaries and taxpayers. *Id.* at 120.

B. This status quo is unsustainable; the IRA seeks to correct course. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001–11003 (codifying 42 U.S.C. §§ 1320f–1320f-7 and 26 U.S.C. § 5000D). As relevant here, the IRA requires the Secretary, acting through the Centers for Medicare & Medicaid Services (CMS), to establish the Drug Price Negotiation Program, through which he will negotiate the prices Medicare pays for certain covered drugs: those that have the highest Medicare expenditures and have long enjoyed little market competition. *See* 42 U.S.C. §§ 1320f *et. seq.* The Negotiation Program applies only to the prices that Medicare pays for drugs that the Program covers. *See, e.g.*, *id.* § 1320f-1(b), (d).

To carry out the Negotiation Program, the statute requires CMS to first identify a set of negotiation-eligible drugs and then to select up to 10 such drugs for negotiation for initial price applicability year 2026, up to 15 drugs each for price applicability years 2027 and 2028, and up to 20 for price applicability year 2029 and subsequent years. *Id.* § 1320f-1(a)–(b). In the first two years—that is, for the up to 25 drugs selected for price applicability years 2026 and 2027—CMS will identify negotiation-eligible drugs from among those with the highest total expenditures under Part D alone. *Id.* § 1320f-1(a), (d)(1). Only later—for initial price applicability year 2028 and beyond—will CMS take expenditures under Part B into account. *Id.* Accordingly, CMS has confirmed, in its guidance for the first price applicability year of the Program, that it "does not expect manufacturers to provide access

to the [negotiated price] of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to [negotiated-price] eligible individuals enrolled under Part B." CMS, Medicare Drug Price Negotiation Program: Revised Guidance 167 (June 30, 2023), https://perma.cc/K6QB-C3MM ("Revised Guidance") (providing Program guidance for initial price applicability year 2026, pursuant to Congress's directive, *see* Pub. L. No. 117-169, § 11001(c)). And (absent a change in policy) the same will be true the following year, consistent with the same statutory terms. *See* 42 U.S.C. § 1320f-1(d)(1).

After selecting the drugs, CMS is directed to negotiate with the manufacturer of each selected drug, in an effort to reach agreement on a "maximum fair price" for that drug, taking into account statutorily prescribed categories of information. 42 U.S.C. § 1320f-3(e). Congress both imposed a "ceiling for [the] maximum fair price," based on pricing data for the subject drugs, *id.* § 1320f-3(c), and directed CMS to "aim[] to achieve the lowest maximum fair price" that manufacturers will accept, *id.* § 1320f-3(b)(1). CMS will sign agreements with willing manufacturers to negotiate prices for selected drugs and then to provide Medicare beneficiaries access to the drugs at those prices. *Id.* § 1320f-2. A manufacturer that does not wish to sign such an agreement—or to otherwise participate in the Negotiation Program—has several options. It can continue selling its drugs to Medicare beneficiaries at non-negotiated prices and pay an excise tax (which is calculated as a percentage of the sales of designated drugs dispensed, furnished, or administered to individuals under the terms of Medicare). 26 U.S.C. § 5000D(a)–(d); IRS Notice No. 2023-52 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P. It can continue selling its other drugs to Medicare but transfer its interest in the selected drug to another entity, which can then make its own choices about negotiations. *See* Revised Guidance at 131–32. Or it can withdraw from the Medicare and Medicaid programs—in which case it will incur no excise tax and no other liability. *See id.* at 33–34, 120–21, 129–31; 26 U.S.C. § 5000D(c)(1).

II. Litigation Background

Plaintiffs bring a facial constitutional challenge to the portions of the IRA that create the Negotiation Program, asserting that these provisions violate (1) the nondelegation doctrine, Compl. ¶¶ 130–34; (2) the Excessive Fines Clause of the Eighth Amendment, *id.* ¶¶ 136–41; and (3) the Due Process Clause of the Fifth Amendment, *id.* ¶¶ 143–48. The complaint names four Defendants, none of which resides in Texas: the United States Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), Xavier Becerra (in his official capacity as Secretary of HHS), and Chiquita Brooks-LaSure (in her official capacity as Administrator of CMS).

There are three Plaintiffs. The first is PhRMA, which describes itself as the "pharmaceutical industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts." *Id.* ¶ 23. PhRMA is a "corporation organized and existing under the laws of the State of Delaware, with offices located in Washington, D.C." *Id.* PhRMA does not appear to have, nor does it allege, any relevant connection to the Western District of Texas.

The second Plaintiff is the Global Colon Cancer Association (GCCA), which alleges that it advocates "for the millions of colon cancer patients worldwide by promoting access to quality medical treatments, advocating for patient-centered policy to ensure increased awareness and screening, and helping its member organizations collaborate and innovate." *Id.* ¶ 22. GCCA, like PhRMA, is a "corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Washington, DC." *Id.* Like PhRMA, GCCA does not allege, and does not appear to have, any relevant connection to the Western District of Texas.

The third Plaintiff—the most important one for purposes of this motion—is NICA, a Texas corporation that, unlike PhRMA and GCCA, "resides in this district." *Id.* ¶¶ 19–20. NICA characterizes itself as an advocacy organization that "represents non-hospital, community-based infusion providers that allow patients to receive care safely and efficiently in high-quality, lower-cost settings." *Id.* ¶ 20. According to Plaintiffs, "'[i]nfusion' or 'infusion therapy' refers to the delivery of medications directly into the veins of a patient." Decl. of Brian J. Nyquist ("Nyquist Decl.") ¶ 3, ECF

No. 35-3. NICA itself does not actually provide infusion care to any patients, but its members do—according to the complaint, "NICA's members operate outpatient facilities to administer [infusion] treatments, receiving reimbursement from Medicare for services provided to Medicare patients." Compl. ¶ 21; *see also* Nyquist Decl. ¶¶ 9–10. Plaintiffs do not allege that NICA or any of its members manufacture or sell prescription drugs. None of NICA's members are identified in the complaint (or in any of Plaintiffs' other filings).

ARGUMENT

This case should be dismissed for lack of venue because the Court does not have subject-matter jurisdiction over Plaintiff NICA—the only party with any relevant connection to this District.

I. Plaintiff NICA should be dismissed for lack of subject-matter jurisdiction.

Standing is "an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To show Article III standing, a plaintiff "bears the burden of establishing" that it has "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). These elements "are not mere pleading requirements but rather an indispensable part of the plaintiff's case." *Lujan*, 504 U.S. at 561. The standing inquiry is "especially rigorous when reaching the merits" would require a court to decide the constitutionality of an act of Congress. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 408 (2013) (internal quotation marks omitted). As always, "the party asserting jurisdiction bears the burden of proof." *Martin v. PepsiAmericas, Inc.*, 628 F.3d 738, 740 (5th Cir. 2010). NICA has not come close.

Even if Plaintiff NICA could show standing, "virtually all legal attacks" relating to Medicare reimbursements must "be brought through the agency" first. *Nat'l Athletic Trainers' Ass'n*, 455 F.3d at 503–04 (quoting *Illinois Council*, 529 U.S. at 13). NICA has not complied with this requirement.

For either or both of these reasons, Plaintiff NICA should be dismissed for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).

A. NICA has not identified any member with Article III standing.

To establish associational standing, a membership organization must demonstrate that "(a) its members would otherwise have [Article III] standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Funeral Consumers All., Inc. v. Serv. Corp. Int'l*, 695 F.3d 330, 343 (5th Cir. 2012) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). At the first step, each plaintiff "organization must show an individual [member] who has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged official conduct, and the injury or threat of injury must be both real and immediate, not conjectural or hypothetical." *Id.* at 344 (internal quotation marks and brackets omitted). NICA has not satisfied these requirements here.

To start, Plaintiffs' complaint does not identify a single member of NICA (nor does Plaintiffs' summary-judgment motion). Instead, the complaint merely states generally that NICA "represents non-hospital, community-based infusion providers" that "administer [infusion] treatments" and "receiv[e] reimbursement from Medicare for services provided to Medicare patients." Compl. ¶¶ 20–21. Plaintiffs' failure to take even this first step toward meeting their burden to plead Article III standing—identifying a member—alone requires NICA's dismissal. *See, e.g.*, *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (requiring, among other things, "at least one *identified* member" (emphasis added)).

Even if they had identified a member, Plaintiffs' allegations would still be insufficient. That is because, to show associational standing, it is not enough to identify *any* member; NICA instead must identify a member that would otherwise have Article III standing on its own—*i.e.*, one that "has sustained or is immediately in danger of sustaining some direct injury as the result of the challenged" statutory provisions. *Funeral Consumers*, 695 F.3d at 344 (quoting *Nat'l Treasury Emps. Union v. U.S. Dep't of Treasury*, 25 F.3d 237, 242 (5th Cir. 1994)). Plaintiffs' complaint falls far short of that burden.

The Supreme Court and the Fifth Circuit "have repeatedly reiterated that," to support Article III standing, a "'threatened injury must be certainly impending to constitute injury in fact,' and that

'[a]llegations of *possible* future injury are not sufficient.'" *Crane v. Johnson*, 783 F.3d 244, 251 (5th Cir. 2015) (quoting *Clapper*, 568 U.S. at 409); *see also Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 537 (5th Cir. 2019) ("By ensuring a future injury is not 'too speculative,' the imminence requirement 'reduce[s] the possibility of deciding a case in which no injury would have occurred at all.'" (quoting *Lujan*, 504 U.S. at 564 n.2)). This threshold requirement is no less stringent when an association seeks to sue on behalf of its members. *See, e.g.*, *Summers*, 555 U.S. at 497 (rejecting contention that standing can be established by "accepting the organization's self-description of the activities of its members" and determining that "there is a statistical probability that some of those members are threatened with concrete injury").

Here, Plaintiffs make a single conclusory allegation theorizing future injury to unidentified NICA members: that "once the Program begins applying to provider-administered drugs under Medicare Part B and Part D," NICA "expects" that the reimbursements that its members receive for selected drugs under Part B will "be based on the IRA's 'maximum fair price'"—supposedly leading its members' "revenues [to] fall precipitously." Compl. ¶ 21. But several factual allegations are missing from the complaint that would be necessary to bring this hypothesized possibility of injury anywhere close to a concrete, particularized, and actual or imminent injury to one of NICA's members.

As an initial matter, to meet their Article III burden for this theorized injury, Plaintiffs would need to allege that an identified member administers a particular drug under Part B that is actually going to be selected for negotiation. *See generally Crane*, 783 F.3d at 251. No such allegation appears in the complaint—and for good reason. An allegation of that sort would necessarily rest on impermissible speculation about uncertain future events—because, in at least the first two negotiation cycles of the Negotiation Program, *none* of the drugs selected for negotiation and provided at the negotiated price will be infusion drugs under Part B that providers (such as NICA's unidentified members) administer. *See* 42 U.S.C. § 1320f-1(a), (d)(1) (providing that the Program generally begins to take Part B drug expenditures into account for price applicability year 2028). This means that the *prices* of infusion drugs administered under Part B by NICA members—on which Plaintiffs' alleged

theory of lower "reimbursement," Compl. ¶ 21, entirely depends—will not be affected until 2028 at the earliest (and it may be later than that).[2]

In the intervening years, numerous factors could change current predictions about which drugs may be selected in any given negotiation year (even setting aside the fact that Plaintiffs have not actually made predictions about *any* particular drugs). For example, a generic or biosimilar competitor could enter the market, removing a lucrative drug from the list of those eligible for negotiation under mandatory statutory criteria, *see* 42 U.S.C. § 1320f-1(e), or other market forces could lead Medicare expenditures to decrease with respect to a particular infusion drug, causing it to be pushed far down the list of drugs eligible for selection, *see id.* § 1320f-1(a), (d)(1). Of course, it is certainly *possible* that an infusion drug covered under Part B and administered by an as-yet unidentified NICA member will eventually be selected and provided at a negotiated price. After all, such drugs will eventually be *eligible* for selection for purposes of coverage under Part B. But hypothesizing about these possible future events at this early stage in the Program's implementation would be "too speculative to satisfy the well-established requirement that threatened injury must be certainly impending." *Clapper*, 568 U.S. at 401 (internal quotation marks omitted); *see also Lujan*, 504 U.S. at 564 n.2 (the concept of "imminence" "has been stretched beyond the breaking point when . . . plaintiff alleges only an injury at some indefinite future time"); *Attala Cnty., Miss. Branch of NAACP v. Evans*, 37 F.4th 1038, 1043 (5th Cir. 2022) (a plaintiff must show a "real and immediate threat," and "immediacy does imply a short timeframe"). Presumably, that is why Plaintiffs have not even tried to offer any such predictions.

Moreover, even overlooking those pleading deficiencies, the actual mechanism of the asserted injury to NICA's unidentified members—*i.e.*, feared lower "reimbursements," Compl. ¶ 21, for administering drugs under Part B subject to a negotiated price several years from now—is largely unexplained in Plaintiffs' filings. The complaint asserts that NICA's member "providers generally are

[2] As explained, *see supra* at 4–5, CMS has thus far only published guidance for initial price applicability year 2026, but (absent a change in policy) no drug covered under Part B will be selected for price applicability year 2027 either, consistent with the same statutory provisions. *See* 42 U.S.C. § 1320f-1(a), (d)(1); Revised Guidance at 167.

reimbursed by Medicare based on the average sales price of the drug and for some related costs." *Id.* But Plaintiffs do not allege any details regarding how that reimbursement will be determined—either "generally," *id.*, or with respect to particular members administering particular drugs. Nor do Plaintiffs acknowledge that, if their prediction is correct that the prices of drugs selected for negotiation will decrease, *see, e.g.*, Pls.' Mot. for Summ. J. at 9, ECF No. 35, then many providers will be *saving* money on their drug-acquisition costs for any selected drugs under Medicare Part B. *See* 42 U.S.C. § 1320f-2(a)(3) (requiring that participating manufacturers sell selected drugs provided to Medicare beneficiaries at no more than the negotiated price, including to providers). Plaintiffs' vague and incomplete narrative is thus insufficient for the Court to assess whether the possible future selection of a particular drug under Part B would actually affect any particular NICA member's profits—even if Plaintiffs had plausibly alleged that a particular drug administered by a particular member was going to be selected for negotiation in the future.

As an example of the sort of uncertainties that are unaccounted for in the complaint, consider an infusion provider that currently acquires drugs at above-average prices—and, presumably, roughly half of them do. Even if that provider administers a drug under Part B that is (eventually) selected, and even assuming that the price of that drug falls as a result of the negotiation process, it is possible that this hypothetical provider's *savings* on drug-acquisition costs, 42 U.S.C. § 1320f-2(a)(3), would outweigh any losses caused by future changes to Medicare reimbursements for those drugs, *see id.* § 1395w-3a(b)(1). Hypotheticals like this one reveal the problem with assessing standing based on vague speculation—rather than based on concrete allegations about an actual identified NICA member-provider that currently profits from administering an actual drug under Medicare Part B that is going to be selected, and which can actually explain how the challenged statute threatens some "certainly impending" financial injury. *Clapper*, 568 U.S. at 409 (internal quotation marks omitted).

In sum, to show that their feared "revenue decreases," Compl. ¶ 21, are "real and immediate," *Funeral Consumers*, 695 F.3d at 344, Plaintiffs would have to show that an identified NICA member will actually see reduced profits from administering a particular selected drug after the negotiated price

goes into effect in 2028 or later. They have not met this burden. Accordingly, NICA should be dismissed for lack of Article III standing.

B. NICA has not satisfied the jurisdictional prerequisites of the Medicare Act.

Separate from NICA's failure to establish the necessary elements of Article III standing, it also fails to satisfy another jurisdictional hurdle: the channeling requirements of the Medicare Act.

1. Congress has broadly divested courts of subject-matter jurisdiction (including under the general federal-question jurisdiction statute) "on any claim arising under" the Medicare Act, except as provided in 42 U.S.C. § 405(g). *Id.* § 405(h); *see id.* §§ 1395ff(b)(1)(A), 1395ii (incorporating § 405(h) into the Medicare Act); *Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984) (noting that section 405(g) is the "sole avenue for judicial review for all 'claim[s] arising under' the Medicare Act"). The authorization of judicial review under 42 U.S.C. § 405(g) "contains two separate elements: first, a 'jurisdictional' requirement that claims be presented to the agency, and second, a 'waivable . . . requirement that the administrative remedies prescribed by the Secretary be exhausted.'" *Smith v. Berryhill*, 139 S. Ct. 1765, 1773–74 (2019) (quoting *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976)). A plaintiff does not satisfy the jurisdictional prerequisite of "presenting" a claim within the meaning of section 405(g) unless the plaintiff lodges the claim with the agency through one of the established avenues for administrative review—such as by raising the challenge in the administrative process that applies to requests for Medicare reimbursement. *See, e.g.*, 42 U.S.C. § 1395ff(b)(1).

So, for example, in *Shalala v. Illinois Council on Long Term Care, Inc.*, an association of nursing homes sought to challenge Medicare regulations that governed the sanctions imposed upon nursing homes that provide care to Medicare beneficiaries and who do not comply with Medicare's numerous statutory and regulatory requirements. 529 U.S. at 4–6. The Supreme Court explained that 42 U.S.C. § 405(g) and (h) channel "most, if not all, Medicare claims through this special review system," including "virtually all legal attacks" on Medicare-related regulatory obligations. *Id.* at 8, 13. The Court thus held that these provisions require channeling regardless of the "'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus the 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature

of the relief sought," as well as "a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Id.* at 13–14.

Under these precedents, a claim thus arises under the Medicare laws for channeling purposes when the Medicare Act "provides both the standing and the substantive basis for" the claim—regardless of whether the claim can be characterized as *also* arising under other statutes or constitutional guarantees. *Id.* at 11. In other words, even if NICA's "claims could be described as arising under the Constitution or [another statute], all that matters under section 405(h) is that the claims also arise under the Medicare Act." *Cmty. Oncology All., Inc. v. OMB*, 987 F.3d 1137, 1143 (D.C. Cir. 2021) (no jurisdiction over challenge to sequestration orders required by the Balanced Budget Act that affected future Medicare Part B reimbursements) (citing *Illinois Council*, 529 U.S. at 5; *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975)).

2. Here, channeling is required, because Plaintiff NICA's claims arise under the Medicare Act at least in part—indeed, their participation in this lawsuit rests entirely on the theory that they will (eventually) receive unlawfully low Medicare Part B reimbursements because of a future shift in reimbursement methodology under a provision of the Inflation Reduction Act that amends the Medicare Act. *See* 42 U.S.C. § 1395w-3a(b)(1)(B). But although it was Plaintiffs' burden to establish subject-matter jurisdiction, *see TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021), none of these channeling principles are addressed in the complaint (or in Plaintiffs' summary-judgment motion). And Plaintiff NICA does not allege that any of its members has ever presented a claim for reimbursement to the agency raising the issues alleged in the complaint, nor that it has exhausted administrative remedies, nor that any exception to either of those obligations could possibly apply here. That is reason enough to dismiss NICA for lack of jurisdiction.

These channeling requirements are equally applicable where, as here, Plaintiffs allege that their claims arise under the Constitution, rather than solely or directly under the Medicare Act. "[V]irtually all legal attacks," including constitutional claims, must be "brought through the agency," when those legal attacks seek increased Medicare reimbursement or social-security benefits. *Nat'l Athletic Trainers' Ass'n*, 455 F.3d at 503 (quoting *Illinois Council*, 529 U.S. at 13). And "[t]he fact that the agency might

not provide a hearing for that *particular contention*, or may lack the power to provide one, . . . is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Illinois Council*, 529 U.S. at 23 (citations omitted). In other words, it is enough that, after the fact, "a court reviewing an agency determination under § 405(g) has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide." *Id.* at 23; *see also Ringer*, 466 U.S. at 615 ("[W]e held that a constitutional challenge to the duration-of-relationship eligibility statute pursuant to which the claimant had been denied benefits, was a 'claim arising under' Title II of the Social Security Act within the meaning of 42 U.S.C. § 405(h), even though we recognized that it was in one sense also a claim arising under the Constitution." (citing *Salfi*, 422 U.S. at 760–61)).

Likewise irrelevant is the fact that the relief Plaintiffs are requesting in *this* lawsuit is not the payment of any specific reimbursement claim. That distinction is again foreclosed by precedent: that NICA or its members "do[] not *directly* seek Medicare benefits does not bar application of § 405." *Johnson v. HHS*, 142 F. App'x 803, 804 (5th Cir. 2005) (emphasis added) (citing *Illinois Council*, 529 U.S. at 15); *see also Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 656 (5th Cir. 2012) ("The plaintiffs seek to distinguish *Salfi* as a case about the recovery of Social Security benefits, while their case pertains to declaratory and injunctive relief. Again, the Court has rejected this argument." (citing *Ringer*, 466 U.S. at 615–16)). And there can be little doubt that NICA's claims (as well as its theory of standing) ultimately depend entirely on its desire for greater reimbursements under the Medicare Act. *See, e.g.*, Compl. ¶¶ 4, 15, 20–21, 39, 66, 68, 106, 117, 144 (making dozens of references to Medicare reimbursement for providers); *see also Illinois Council*, 529 U.S. at 11; 42 U.S.C. § 1395w-3a(b)(1)(B) (provision of the Medicare Act relating to the future reimbursement payments that Plaintiff NICA claims will eventually harm its members). This result should come as no surprise: especially when it comes to health care providers dissatisfied with their Medicare reimbursement amounts, "the presentment requirement generally prevents anticipatory legal challenges to Medicare rules and regulations." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 826 (D.C. Cir. 2018).

3. To be sure, "[i]n *Illinois Council*, the Supreme Court created a very narrow exception to the channeling requirement 'where application of § 405(h) would not simply channel review through the

agency, but would mean no review at all.'" *Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 440 (5th Cir. 2013) (quoting *Illinois Council*, 529 U.S. at 19). But as the Fifth Circuit has often explained, that "very narrow exception" applies only "if further postponement of judicial review would have the effect of foreclosing judicial review entirely." *Id.* "Section 405(h) requires that short of a *complete* preclusion of judicial review, a party must channel his or her claims to the Secretary prior to litigating in federal court." *Physician Hosps.*, 691 F.3d at 653 (internal quotation marks omitted). Indeed, in the Fifth Circuit, even "[t]he fact that a plaintiff would suffer great hardship if forced to proceed through administrative channels before obtaining judicial review is insufficient to warrant application of the *Illinois Council* exception." *Sw. Pharmacy*, 718 F.3d at 441.

That exception thus does not apply here. If NICA's speculation turns out to be correct and its members face lower reimbursement payments from Medicare at some point in 2028 or later, and if NICA believes that those lower reimbursement payments are attributable to provisions of the Negotiation Program that they believe to be unlawful, *then* its members can present that argument to the agency in the context of a specific claim for increased Medicare reimbursement. *See* 42 U.S.C. § 1395ff(a), (b). And if that claim is rejected during the administrative process, the provider could *then* sue in federal court, where its constitutional arguments for greater reimbursement would be adjudicated. There is thus no "complete preclusion of judicial review" here, *Physician Hosps.*, 691 F.3d at 653—only channeling into the administrative forum that Congress created, followed by federal-court review (if necessary) of the agency's determination.

Of course, as the Supreme Court and the Fifth Circuit have each recognized, at least in some cases, requiring plaintiffs to "bring[] claims administratively" first "comes 'at a price, namely, occasional individual, delay-related hardship.'" *Physician Hosps.*, 691 F.3d at 653 (quoting *Illinois Council*, 529 U.S. at 13). But that potential for "hardship" is "one that Congress was aware it was imposing on health-care providers" like NICA's members. *Id.* "'If the balance is to be struck anew, the decision must come from Congress' and not from the courts." *Id.* (quoting *Ringer*, 466 U.S. at 627).

Finally, Plaintiff NICA might "argue[] that, because it is an association, not an individual, it cannot take advantage of the special review channel" created for health care providers. *Illinois Council*,

529 U.S. at 24. Yet again, the Supreme Court has rejected this argument: an association like NICA "speaks only on behalf of its member institutions, and thus has standing only because of the injury those members allegedly suffer." *Id.* "It is essentially" NICA's provider-members whose "rights to review . . . are at stake. And the statutes that create the special review channel adequately protect those rights." *Id.* The Fifth Circuit reiterated this principle just last year. *See La. Indep. Pharmacies Ass'n v. Express Scripts, Inc.*, 41 F.4th 473, 481 n.4 (5th Cir. 2022) (citing *Illinois Council*, 529 U.S. at 25).

The result is that, with respect to Plaintiff NICA, "[t]he association or its members must proceed instead through the special review channel that the Medicare statutes create." *Illinois Council*, 529 U.S. at 5. Unless and until that happens, this Court lacks jurisdiction over NICA's claims.

* * *

For these reasons, the Court lacks subject-matter jurisdiction over any of NICA's claims—both as a matter of Article III standing and channeling under the Medicare Act. NICA must therefore be dismissed from the litigation. *See* Fed. R. Civ. P. 12(b)(1), (h)(3); *see also Duarte ex rel. Duarte v. City of Lewisville*, 759 F.3d 514, 520 n.3 (5th Cir. 2014) ("[S]tanding 'is to be assessed under the facts existing when the complaint is filed.'" (quoting *Lujan*, 504 U.S. at 569 n. 4)).

II. Upon NICA's dismissal, this case should be dismissed for lack of venue.

Once NICA is dismissed from this action, the rest follows as a matter of course. Rule 12(b)(3) authorizes a district court to "dismiss an action where venue in that court is improper." *Blacklands R.R. v. Ne. Tex. Rural Rail Transp. Dist.*, No. 1:19-cv-250, 2019 WL 3613071, at *2 (E.D. Tex. Aug. 5, 2019) (internal quotation marks omitted). And where, as here, the case is brought against "an agency of the United States," venue is proper only in a "judicial district in which (A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (C) the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). "Once defendants raise the issue of improper venue, the plaintiffs have the burden to prove that the chosen venue is proper." *EnviroGLAS Prods., Inc. v. EnviroGLAS Prods., LLC*, 705 F. Supp. 2d 560, 567 (N.D. Tex. 2010).

Plaintiffs' only theory of venue depends entirely on NICA's residence. *See* Compl. ¶ 19 ("Venue is proper in this district because this action seeks relief against federal agencies and officials acting in their official capacities, and Plaintiff NICA resides in this district. *See* 28 U.S.C. § 1391(e)(1)."). Accordingly, because the Court lacks subject-matter jurisdiction over NICA, there is no basis for venue in this district: no defendant resides here, *see* 28 U.S.C. § 1391(e)(1)(A), none of the "events or omissions giving rise to the claim occurred" here, *see id.* § 1391(e)(1)(B), and no (proper) plaintiff resides here, *see id.* § 1391(e)(1)(C).

Of course, a plaintiff who lacks standing (or is otherwise beyond the subject-matter jurisdiction of the court) cannot create venue where it would not otherwise exist. *See Miller v. Albright*, 523 U.S. 420, 426–27 (1998) ("[T]he District Court concluded that Mr. Miller did not have standing and dismissed him as a party. Because venue in Texas was therefore improper, *see* 28 U.S.C. § 1391(e), the court transferred the case to the District Court for the District of Columbia, the site of the Secretary's residence.") (op. of Stevens, J.); *Inst. of Certified Pracs., Inc. v. Bentsen*, 874 F. Supp. 1370, 1372 (N.D. Ga. 1994) ("Having found that the Institute lacks standing to bring this action and has failed to state a claim upon which relief can be granted, plaintiff cannot manufacture venue by adding the Institute as a party."); *A.J. Taft Coal Co. v. Barnhart*, 291 F. Supp. 2d 1290, 1304 (N.D. Ala. 2003) ("Venue is proper in this court because at least one Alabama plaintiff had standing."); *see also* 14D Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3815 (4th ed.) ("[V]enue cannot be based on the joinder of a plaintiff" that has been added "for the purpose of creating venue in the district."). If that were *not* the rule, then PhRMA could have enlisted *anyone* with policy objections to the IRA to serve as a nominal plaintiff, solely to create venue in this District (or in any other district of its choosing)—a result that would encourage forum shopping and undermine both the federal venue statute and Article III of the Constitution. Accordingly, the entire case should be dismissed for lack of venue.

One additional point warrants mention. Separate from Rule 12(b)(3), 28 U.S.C. § 1406 provides that, in the case of improper venue, the district court "shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." 28 U.S.C.

§ 1406(a). As between those options, the district court generally has "broad discretion." *McCormick v. Payne*, No. 3:15-cv-2729-M, 2015 WL 7424772, at *3 (N.D. Tex. Nov. 23, 2015). But here, "the interest[s] of justice" favor dismissal, rather than transfer—even assuming that there is some other district in which this suit "could have been brought." 28 U.S.C. § 1406(a).[3]

Plaintiffs are a group of uncommonly sophisticated and well-represented litigants, who presumably selected this venue intentionally, with awareness of the downside risk: that their only claim to venue would turn on whether NICA was an appropriate plaintiff. *See* Compl. ¶ 19. And Plaintiffs had ample opportunity to prepare detailed factual allegations on this subject, as the IRA was enacted over a year ago. There is no reason for this Court to rescue these Plaintiffs from the consequences of their own strategic litigation choices. *See* 14D Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3827 (4th ed.) ("[D]istrict courts often dismiss rather than transfer under Section 1406(a) if the plaintiff's attorney reasonably could have foreseen that the forum in which the suit was filed was improper and that similar conduct should be discouraged."). In addition, dismissal will cause minimal (if any) prejudice: if they can overcome their jurisdictional problems, Plaintiffs (or some subset of Plaintiffs) can refile in another district where there is no venue problem. *See* Compl. ¶¶ 22–23; Fed. R. Civ. P. 41(b) (providing that dismissal for improper venue is not "an adjudication on the merits" and thus would not have any preclusive effect).

CONCLUSION

For these reasons, the Court should dismiss Plaintiff NICA for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and then dismiss this case for lack of venue under Federal Rule of Civil Procedure 12(b)(3).

[3] Plaintiffs PhRMA and GCCA likely also lack standing, but the Court need not decide those issues now, given the straightforward and insurmountable venue defect that is immediately revealed by NICA's dismissal. As to PhRMA and GCCA, the Court can decide venue before standing. *See Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007) ("[A] federal court has leeway to choose among threshold grounds for denying audience to a case on the merits." (internal quotation marks omitted)).

Date: August 28, 2023

Respectfully submitted,

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