

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

NATIONAL INFUSION CENTER
ASSOCIATION, on behalf of itself and its
members; GLOBAL COLON CANCER
ASSOCIATION, on behalf of itself and its
members; and PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA, on
behalf of itself and its members,

Plaintiffs,

vs.

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

Defendants.

Civil Action No. 1:23-cv-00707-DAE

NOTICE OF APPEAL

Notice is hereby given that Plaintiffs, the National Infusion Center Association, the Global Colon Cancer Association, and the Pharmaceutical Research and Manufacturers of America, appeal to the United States Court of Appeals for the Fifth Circuit regarding this Court's Order dated February 12, 2024 (a copy of which is attached hereto), dismissing Plaintiff the National Infusion Center Association for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1) and dismissing the case as to all parties for lack of venue under Federal Rule of Civil Procedure 12(b)(3).

Dated: March 6, 2024

Respectfully submitted,

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER	§	No. 1:23-CV-707
ASSOCIATION et al.,	§	
<i>Plaintiffs,</i>	§	
	§	
vs.	§	
	§	
XAVIER BECERRA, in his official	§	
capacity as Secretary of the	§	
Department of Health and	§	
Human Services, et al.,	§	
<i>Defendants.</i>	§	

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services, the U.S. Department of Health and Human Services, Chiquita Brooks-Lasure, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services, and the Centers for Medicare and Medicaid Services' (collectively, "Defendants") Motion to Dismiss (Dkt. # 39).

The Court finds this matter suitable for disposition without a hearing. After careful consideration of the memoranda filed in support of and against the motions, the Court **GRANTS** Defendants' Motion to Dismiss (Dkt. # 39).

BACKGROUND

Medicare is the federal medical insurance program for the aged and disabled. 42 U.S.C. § 1395. A provider’s participation in the Medicare program is completely voluntary. See 42 C.F.R. § 489.10. The Secretary (“Secretary”) for the Department of Health and Human Services (“HHS”) operates Medicare through the Centers for Medicare and Medicaid Services (“CMS”), which in turn hires contractors to perform administrative functions on CMS’s behalf. 42 U.S.C. § 1395u.

Medicare offers two prescription drug programs – Medicare Part B and Part D. Medicare Part B covers medically necessary and preventative healthcare services, including prescription drugs. 42 U.S.C.

§§ 1395k(a)(1), 1395x(s)(2)(A). Under Part B, CMS will reimburse prescription drug providers, based on the “average sales price” of the drug. See 42 U.S.C. § 1395w-3a. Medicare Part D is a voluntary outpatient drug benefit, provided by privately-operated plans. 42 U.S.C. § 1395w-102.

As part of the Inflation Reduction Act of 2022 (“IRA” or “the Act”), Congress directed HHS to establish a “Drug Price Negotiation Program.” 42 U.S.C. § 1320f(a). Through this program, the HHS ranks and selects “negotiation-eligible drugs” and then negotiates with the manufacturers to determine a “maximum fair price.” 42 U.S.C. § 1320f–2(a)(1); 1320f–1(b)(1)(A). Once a

maximum fair price is set, manufacturers must provide the drugs at that price to individuals, pharmacies, providers, and other entities participating in Medicare. 42 U.S.C. § 1320f–2(a)(1). Manufacturers that fail to do so may pay a per-unit penalty of ten times the difference between the price charged and the maximum fair price, transfer its interest in the drug to another entity, or withdraw from Medicare and Medicaid Programs. 42 U.S.C. § 1320f–6(b); CMS, Medicare Drug Price Negotiation Program: Revised Guidance 129–131 (June 30, 2023), <https://perma.cc/K6QB-C3MM> (“Revised Guidance”); 26 U.S.C. § 5000D(c)(1).

HHS will begin implementing the program in 2026. U.S.C. § 1320f. The IRA does not allow for administrative or judicial review of “selection of drugs,” “determination of negotiation-eligible drugs,” “determination of qualifying single source drugs,” and “determination of a maximum fair price.” *Id.* § 1320f–7.

There are three plaintiffs: PhRMA, Global Colon Cancer Association (“GCCA”), and National Infusion Center Association (“NICA”). PhRMA is a non-profit corporation that serves as the “pharmaceutical industry’s principal policy advocate.” (Dkt. # 1 at 10.) PhRMA’s members include pharmaceutical and biotechnology companies. (*Id.*) GCCA is a non-profit corporation that represents “millions of colon cancer patients worldwide[.]” (Dkt. # 1 at 9.) NICA is a non-profit corporation that represents non-hospital, community-based infusion providers. (Dkt. # 1 at 8.) NICA is the only plaintiff that resides in this district.

(Id. at 8–10.) The remaining Plaintiffs, PhRMA and GGCCA, reside outside the state of Texas.

Plaintiffs assert that the IRA Drug Pricing Program is unconstitutional because it (1) violates the nondelegation doctrine (2) the Excessive Fines Clause of the Eighth Amendment and (3) the Due Process Clause of the Fifth Amendment.

(Dkt. # 1.) Plaintiffs named four defendants: 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).

(Dkt. # 1.) Plaintiffs ask this court for declare the IRA Drug Pricing Program and excise tax is unconstitutional, enjoin HHS from implementing the IRA Drug Pricing Program, and award Plaintiffs with reasonable attorney’s fees and costs under 28 U.S.C. § 2412. (Dkt. # 1 at 57.)

Plaintiffs filed a Motion for Summary Judgment on August 10, 2023. (Dkt. # 35.) The Defendants filed a Motion to Dismiss on August 28, 2023. (Dkt. # 39.) The case was reassigned to the undersigned on September 21, 2023. (Dkt. # 46.) The Plaintiffs filed a Response to the Motion to Dismiss on September 25, 2023. (Dkt. # 47.) The Defendants filed a Reply on October 13, 2023. (Dkt. # 49.) On November 2, 2023, Defendants filed a Notice of Supplemental Authority.

(Dkt. # 50.) On November 7, 2023, Plaintiffs filed a Response to the Notice of Supplemental Authority. (Dkt. # 52.)

LEGAL STANDARD

A. Motion to Dismiss under 12(b)(1)

A motion to dismiss under Rule 12(b)(1) of the Federal Rules of Civil Procedure challenges a federal court’s subject matter jurisdiction. See Fed. R. Civ. P. 12(b)(1). Under Rule 12(b)(1), a claim is properly dismissed for lack of subject matter jurisdiction when a court lacks statutory or constitutional authority to adjudicate the claim. Home Builders Assoc. of Mississippi, Inc. v. City of Madison, 143 F.3d 1006, 1010 (5th Cir. 1998).

In considering a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction, “a court may evaluate (1) the complaint alone, (2) the complaint supplemented by undisputed facts evidenced in the record, or (3) the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.” Den Norske Stats Oljeselskap As v. HeereMac Vof, 241 F.3d 420, 424 (5th Cir. 2001) (citation omitted).

B. Motion to Dismiss for Improper Venue

Federal Rule of Civil Procedure 12(b)(3) allows a party to move to dismiss an action for “improper venue.” Fed. R. Civ. P. 12(b)(3). Once a defendant raises improper venue by motion, “the burden of sustaining venue will be on [the]

Plaintiff.” Cincinnati Ins. Co. v. RBP Chem. Tech., Inc., No. 1:07-CV-699, 2008 WL 686156, at *5 (E.D. Tex. 2008). “Plaintiff may carry this burden by establishing facts that, if taken to be true, establish proper venue.” *Id.* (citations omitted).

If venue is improper, the Court must 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); Fed. R. Civ. P. 12(b)(3).

DISCUSSION

Defendants argue that this Court lacks jurisdiction over Plaintiff NICA for two reasons. (Dkt. # 39 at 1.) First, Defendants argue that NICA has not satisfied the jurisdictional prerequisites of the Medicare Act. (*Id.* at 2.) Second, Defendants contend that NICA has not identified a member with Article III standing. (*Id.* at 1.) For these reasons, Defendants contend that NICA is not a proper plaintiff. If the Court agrees and dismisses NICA, Defendants ask the Court to find that venue is improper.

I. NICA Has Not Satisfied the Jurisdictional Prerequisites under the Medicare Act

Congress has divested the courts of federal question jurisdiction over “any claim arising under” the Medicare Act, unless the claim has been (1)

presented to the agency and (2) administrative remedies have been exhausted.¹ 42 U.S.C. § 405(g) and (h). Section 1395ii incorporates 405(g) and (h) into the Medicare Act (or subchapter XVIII, Ch. 7, Title 42). 42 U.S.C. § 1395ff(b)(1)(A). That said, the Supreme Court has recognized an exception to this jurisdictional bar when requiring “channeling a claim through the agency would result in the ‘*complete* preclusion of judicial review.’” Fam. Rehabilitation, Inc. v. Azar, 886 F.3d 496, 504–505 (5th Cir. 2018) (quoting Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 23 (2000)). Therefore, this Court must first analyze whether NICA’s claim “arises under” the Medicare Act. If it does, the Court must then decide whether the exception applies here.

A. NICA’s claim “arises under” the Medicare Act

Section 405(h) bars federal-question jurisdiction for claims that “arise under” the Medicare Act. 42 U.S.C. § 405(g) and (h); 42 U.S.C. § 1395ii. Ill. Council, 529 U.S. at 13. “[V]irtually all legal attacks under the Act [must] be brought through the agency.” Physician Hosps. of Am. v. Sebelius, 691 F.3d 649, 653 (5th Cir. 2012) (quoting Ill. Council, 529 U.S. at 13.) A claim arises under the Medicare Act when “both the standing and the substantive basis for the

¹The exhaustion requirement is waivable, but the requirement that a claim be presented to the Agency is not waivable. See Smith v. Berryhill, 139 S.Ct. 1765, 1773–74 (2019).

presentation of the claims” is the Medicare Act. Heckler v. Ringer, 466 U.S. 602, 615 (1984) (quoting Weinberger v. Salfi, 422 U.S. 749, 760–61 (1975)).

Plaintiffs contend that the channeling provision in 405(h) does not apply to their claim because the claims are not an “initial determination[s] of benefits” but instead “constitutional challenges” to the IRA. (Dkt. # 47 at 17.)

The Supreme Court and the Fifth Circuit have held that federal question jurisdiction bars claims that “arise under” the Medicare Act, even when the claim is for reimbursement or is a constitutional challenge. Ill. Council, 529 U.S. at 13, Physician Hosps., 691 F.3d at 659. In Ill. Council, the Supreme Court determined that a constitutional challenge to Medicare regulations that affected future reimbursement still “arises under” the Medicare Act. 529 U.S. at 10–13 (finding that the jurisdictional bar applied when plaintiffs “needing advance knowledge for planning purposes, together bring a § 1331 action challenging such a rule or regulation on general legal grounds). Similarly, in Physician Hosps., a trade group and a hospital sought declaratory and injunctive relief on the basis that a provision of the Patient Protection and Affordable Care Act that limited Medicare reimbursements was unconstitutional. 691 F.3d at 659. There, the Fifth Circuit also found that the claims arose under the Medicare Act, even though the challenges were constitutional, because the Act still provided “both the standing and substantive basis for the presentation of the constitutional contentions.” Id. at

659. Both Ill. Council and Physician Hosps. teach that even a constitutional challenge to a statute may “arise under” the Medicare Act.

For these reasons, Plaintiffs’ claims arise under the Medicare Act, even though the challenges are constitutional and the requested relief is injunctive. Physician Hosps., 691 F.3d at 656 (“The Supreme Court has also explicitly rejected the argument that constitutional challenges are free from Section 405(h)’s requirements[.]”); True Health Diagnostics, LLC v. Azar, 392 F. Supp. 3d 656, 662 (E.D. Tex. 2019) (“The term ‘arising under’ is broadly construed to encompass all claims for relief, regardless of whether the claimant seeks benefits, or declaratory or injunctive relief.”). Ultimately, a claim arises under the Medicare Act if the Act provides the “standing and substantive basis for the presentation of the constitutional contentions.” Physician Hosps., 691 F.3d at 656 (quoting Salfi, 422 U.S. at 760–61). Here, just like the plaintiffs in Ill. Council and Physician Hosps., Plaintiffs ask the Court to hold that a law affecting future reimbursements is unconstitutional. These claims arise under the Medicare Act.

Plaintiffs argue that §1395ii does not incorporate Section 405(h) channeling to the claims here because §1395ii incorporates Section 405(h) only to the Medicare Act (or subchapter XVIII) and portions of the Drug Pricing Program were established in subchapter XI. However, Plaintiffs do in fact challenge portions of subchapter XVIII, where portions of the Drug Pricing Program were

enacted, like Section 1395w-3a. (See Dkt # 1, at ¶ 21). Even so, a claim “arises under” the Medicare Act (or subchapter XVIII) when the claim is “inextricably intertwined” with a claim for Medicare payments, providing the standing and substantive basis for the claim. Am. Med. Hospice Care, LLC v. Azar, 2020 WL9814144, 5:20-cv-757, at *4 (W.D. Tex. Dec. 9, 2020) (citing Weinberger v. Salfi, 422 U.S. 749, 760–61 (1975), Heckler v. Ringer, 466 U.S. 602, 614–15 (1984)). Plaintiffs would not have standing or a substantive basis for a claim for reimbursement without the Medicare Act. Therefore, these claims arise under the Medicare Act and Section 405(h) channeling applies.

B. “Complete Preclusion to Judicial Review” Exception

The Supreme Court has recognized an exception to the channeling doctrine, even when a claim arises under the Medicare Act, when “channeling a claim through the agency would result in the ‘*complete* preclusion of judicial review.’” Azar, 886 F.3d 496, 504–05 (5th Cir. 2018) (quoting Shalala, 529 U.S. 23 (2000)). “This exception is narrow...” Id. Therefore, Plaintiffs “must show either that bringing its claim administratively is a ‘legal impossibility,’ or that it faces a ‘serious practical roadblock to having [its] claims reviewed in any capacity, administratively or judicially.’” Id. (quoting Physician Hosps., 691 F.3d at 505.)

Plaintiffs have not shown that there is “no way of having their claims reviewed[,]” either legally or practically. Physician Hosps., 691 F.3d at 659. There

are established avenues for administrative review of constitutional challenges to the IRA and requests for reimbursement. See, e.g., 42 U.S.C. § 1395ff(b)(1), 1395ff(b)(2)(A). Both the Medicare Act and CMS regulations offer expedited review of constitutional claims that Plaintiffs could use. See 42 U.S.C. § 1395ff(b)(1)(F)(2); 42 C.F.R. § 405.990(c)(2). Plaintiffs may bring a civil action only after the agency “determines that that are no material issues of fact in dispute and that the only issues to be adjudicate are ones of law or regulation that the Department of Appeals Board does not have authority to decide[.]” 42 U.S.C. § 1395ff(b)(2)(C). While channeling may cause a time delay, delay-related hardships do not justify an exception. Physician Hosps., 691 F.3d at 659.

Plaintiffs point to the bar of administrative review in 42 U.S.C. § 1320f-7(2)–(3). (Dkt. # 47 at 19.) Section 1320f-7 only bars administrative or judicial review of the certain aspects of the Drug Pricing Program, like the “determination of maximum fair price” or “the selection of drugs.” 42 U.S.C. § 1320f-7(2)-(3). It does not preclude administrative review for a constitutional challenge or a claim for reimbursement. See 42 U.S.C. § 1320f-7(2)–(3); 42 U.S.C. § 1395ff(b)(1)(F)(2); 42 C.F.R. § 405.990(c)(2). Plaintiffs are therefore not precluded from presenting their constitutional challenge to the Secretary, and the claims do not fall under the exception.

The Court lacks jurisdiction over NICA's claims because the claims here "arise under" the Medicare Act and the claims do not fall under the exception carved out for when claims may completely avoid judicial or administrative review. Therefore, NICA's claims are dismissed without prejudice.

II. With NICA dismissed, Venue is No Longer Proper in this District.

Rather than asking the Court to dismiss PhRMA and GCCA's claims for lack of jurisdiction, Defendants ask the Court to instead dismiss the case for improper venue.

"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).

Venue is proper in (1) judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located, (2) a judicial district in which 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 (3) if there is no district in which an action may otherwise be brought as provided in this section, any judicial district in which any defendant is subject to the court's personal jurisdiction over such action. 28 U.S.C. § 1391(b)

Venue is only proper in the Western District of Texas because NICA resides here. (Dkt. # 1 at 8.) With NICA dismissed, no defendant would reside in

this district, no plaintiff resides in this district, and nothing suggests that a substantial part of the events or omissions giving rise to the claim occurred in this district. See 28 U.S.C. § 1391(e)(1). Plaintiffs do not offer any reasons that venue would be proper in this district if NICA is dismissed. (See Dkt. # 47 at 20.)

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).

Neither party offered a transferee venue. More importantly, the same federal jurisdictional defect likely exists for PhRMA and GCCA, as nothing suggests that either party has presented its claims to the Secretary. Therefore, in the interests of justice, the Court will dismiss the case without prejudice.

CONCLUSION

For the reasons stated in this Order, the Court dismisses Plaintiff NICA for lack of subject matter jurisdiction under Fed. Rule of Civ. P. 12(b)(1) and dismisses the case for lack of venue under Fed. Rule of Civ. P. 12(b)(3). Defendants’ Motion to Dismiss (Dkt. # 39) is therefore **GRANTED**, and Plaintiffs’ Motion for Summary Judgment (Dkt. # 35) is **MOOTED**. This dismissal is **WITHOUT PREJUDICE**. The case shall be **CLOSED**.

IT IS SO ORDERED.

DATED: Austin, Texas, February 12, 2024.



Hon. David Alan Ezra
Senior U.S. District Judge