

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

THE CAMPS INITIATIVE,

Plaintiff,

v.

**UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, et
al.,**

Defendants.

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Civil Action No. 4:26-cv-00099-O

ORDER

Before the Court are Plaintiff’s Motion for Injunction, Brief, and Appendix in Support, ECF Nos. 9-11; Plaintiff’s Motion to Expedite Briefing, ECF No. 12; Defendant’s Motion for Leave to File Brief Exceeding Page Limitation, ECF No. 28; Defendant’s Response, ECF No. 29; Plaintiff’s Motion for Leave to File Brief Exceeding Page Limitation, ECF No. 30; Plaintiff’s Motion for Leave to File an Exhibit Under Seal, ECF No. 34; Plaintiff’s Reply, ECF No. 24; Defendant’s Motion to Dismiss, ECF No. 26; Plaintiff’s Response, ECF No. 35; Defendant’s Reply, ECF No. 38; Defendant’s Motion to Strike, ECF No. 40; Brief of Accountable for Health and Additional Amici Curiae in Support of Defendants’ Motion to Dismiss, ECF No. 42; and Plaintiff’s Request for Hearing and Oral Argument, ECF No. 43. Having reviewed the briefing and applicable law, the Court **DENIES as moot** Plaintiff’s order to expedite briefing, ECF No. 12, Defendant’s Motion to Strike,¹ and Plaintiff’s Motion for a Hearing, ECF No. 43; **GRANTS**

¹ The Motion to Strike concerns the second declaration of Del Piano and references to it contained in Plaintiff’s reply brief for the Motion for a Preliminary Injunction and opposition to the Defendant’s Motion to Dismiss. ECF No. 40. Because this opinion does not rely on this evidence, the Court **DENIES** the Motion to Strike as moot.

Defendant’s and Plaintiff’s Motion for Leave to File Brief Exceeding Page Limitation, ECF Nos. 28 and 30 respectively; **GRANTS** Plaintiff’s Motion to File Exhibit Under Seal, ECF No. 34; **DENIES** Plaintiff’s Motion for a Preliminary Injunction, ECF No. 9; and **GRANTS** Defendant’s Motion to Dismiss, ECF No. 26.

I. BACKGROUND²

This case involves a challenge to a Department of Health and Human Services (“the Government”) Rule that reclassifies skin substitutes as incidental-to supplies for Medicare reimbursement purposes. Medicare is a federally funded health insurance program. *See* 42 U.S.C. § 1395. Relevant to this dispute, Medicare Part B is a voluntary supplementary medical insurance program covering physician’s services, outpatient hospital care, and certain other services. 42 U.S.C. § 1395j. Medicare pays for covered services based on a fee schedule established each year by the Secretary of the Department of Health and Human Services. 42 U.S.C. § 1395w-4. Under the payment system, participating providers agree to accept the amount determined under the fee schedule.

Skin substitutes are “a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers.” *Final Rule: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies*, 90 Fed. Reg. 49266, 49486 (Nov. 5, 2025) (internal quotation marks omitted). Previously, Medicare paid for skin substitutes related to services under the Physician Fee Schedule based on the statutorily defined Average Sales Price of

² Unless otherwise cited, the Court’s recitation of the facts is taken from Plaintiff’s Complaint. *See* Pl.’s Compl., ECF No. 1. At this stage, these facts are taken as true and viewed in the light most favorable to Plaintiff. *See Sonnier v. State Farm Mut. Auto Ins.*, 509 F.3d 673, 675 (5th Cir. 2007).

the product at a 106% rate in physician’s offices and at a lesser rate for skin substitutes furnished in outpatient settings. 90 Fed. Reg. at 49487; *see also* 42 U.S.C. § 1395w-3a (describing Average Sales Price); 42 U.S.C. §§ 1395j, 1395k, 1395l (Medicare Part B generally). In response to “several novel industry practices . . . causing a significant increase in spending under Medicare Part B for skin substitute products in the non-facility setting,” the Government proposed and, following a notice-and-comment period, finalized a rule modifying the payment policy under the Physician Fee Schedule applicable to skin substitutes. 90 Fed. Reg. at 49486. The new policy reclassifies skin substitutes as “an incident-to supply for payment purposes under the [Physician Fee Schedule] unless a skin substitute is approved as a drug or biological under Section 351 of the [Public Health Services] Act.” 90 Fed. Reg. at 49493. This Rule results in a “90% decrease in reimbursement for skin substitutes”³ under the Physician Fee Schedule. The new policy went into effect on January 1, 2026.

Plaintiff The CAMPs Initiative (“Plaintiff”) is a Fort Worth-based nonprofit corporation composed of skin substitute manufacturers and distributors. Plaintiff’s mission is to “raise public awareness about the importance of skin substitutes, educate policymakers on their role in wound care, advocate for fair and transparent national policies, and support and participate in litigation to defend the interests of innovative skin-substitute manufacturers.”⁴ None of Plaintiff’s members are Medicare beneficiaries or enrollees. Plaintiff initiated this action on January 29, 2026, requesting a preliminary injunction asking the “Court stay the Rule under Section 705 of the Administrative Procedure Act on a nationwide basis pending a ruling on the merits, or in the

³ Pl.’s Resp. 1, ECF No. 35.

⁴ Compl. ¶ 9, ECF No. 1.

alternative, preliminarily enjoin the Rule’s enforcement on a nationwide basis.”⁵ Defendants opposed and filed a Motion to Dismiss. Both are ripe for the Court’s review.

II. LEGAL STANDARD

A. Preliminary Injunction

A preliminary injunction is an “extraordinary remedy” and will be granted only if the movant clearly carries its burden on all four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). Issuing a preliminary injunction should be “the exception rather than the rule,” *Miss. Power & Light Co.*, 760 F.2d 618, 621 (5th Cir. 1985), and the Court will not issue a preliminary injunction unless the movant establishes: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm; (3) the balance of hardships weighs in the movant’s favor; and (4) the issuance of the preliminary injunction will not disserve the public interest. *Daniels Health Sci., LLC v. Vascular Health Scis., LLC*, 710 F.3d 579, 582 (5th Cir. 2013); *accord Janvey v. Alguire*, 647 F.3d 585, 595 (5th Cir. 2011). Of these factors, likelihood of success on the merits is the most important. *Tesfamichael v. Gonzales*, 411 F.3d 169, 176 (5th Cir. 2005).

B. Motion to Dismiss

Federal courts are courts of limited jurisdiction and must have “statutory or constitutional power to adjudicate the case.” *Home Builders Ass’n of Miss. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). Federal law gives the federal district courts original jurisdiction over “all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. A party seeking relief in a federal district court bears the burden of establishing

⁵ Mot. Prelim. Inj. 3, ECF No. 9.

the subject matter jurisdiction of that court. *United States v. Hays*, 515 U.S. 737, 743 (1995). Rule 12(b)(1) of the Federal Rules of Civil Procedure authorizes the dismissal of a case for lack of jurisdiction over the subject matter. *See* FED. R. CIV. P. 12(b)(1). A motion to dismiss pursuant to Rule 12(b)(1) for lack of subject matter jurisdiction must be considered by the court before any other challenge because “the court must find jurisdiction before determining the validity of a claim.” *Moran v. Kingdom of Saudi Arabia*, 27 F.3d 169, 172 (5th Cir. 1994) (internal citation omitted); *see also Ruhrgas AG v. Marathon Oil Company*, 526 U.S. 574, 577 (1999) (“The requirement that jurisdiction be established as a threshold matter . . . is inflexible and without exception[.]”) (citation and internal quotation marks omitted). In ruling on a 12(b)(1) motion to dismiss, the court may rely on: “1) the complaint alone; 2) the complaint supplemented by undisputed facts; or 3) the complaint supplemented by undisputed facts and the court's resolution of disputed facts.” *MCG, Inc. v. Great Western Energy Corporation*, 896 F.2d 170, 176 (5th Cir. 1990) (citing *Williamson v. Tucker*, 645 F.2d 404, 413(5th Cir. 1981)).

III. DISCUSSION

A. Subject Matter Jurisdiction

The Court does not have subject matter jurisdiction over this case because Plaintiff has failed to demonstrate that its challenge falls within the narrow *Illinois Council* exception to the channeling requirement. “The Medicare Act limits the jurisdiction of federal courts to review claims brought under the Act by requiring that ‘virtually all legal attacks’ be brought through the agency.” *Nat’l Athletic Trainers’ Ass’n, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 455 F.3d 500, 503 (5th Cir. 2006) (hereafter “*NATA*”) (citing *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (hereafter “*Ill. Council*”). 42 U.S.C. § 405(h), incorporated into the Medicare Act by 42 U.S.C. § 1395ii, requires a plaintiff to exhaust administrative remedies before

filing a claim in federal court. This is known as the “channeling requirement.” *Sw. Pharmacy Sols., Inc. v. Centers for Medicare & Medicaid Servs.*, 718 F.3d 436, 440 (5th Cir. 2013). The channeling requirement has an exception “where application of § 405(h) would not simply channel review through the agency[] but would mean no review at all.” *Ill. Council*, 529 U.S. at 19. A plaintiff must demonstrate “either a legal impossibility that *any* claimant would obtain judicial or administrative review, or hardship from administrative channeling that was sufficiently widespread to threaten the loss of any judicial review” to meet this exception. *Sw. Pharmacy Sols., Inc.*, 718 F.3d at 441 (internal quotation omitted) (emphasis added). Here, Plaintiffs have not and cannot fulfill the channeling requirement because they are neither beneficiaries nor providers. *See NATA*, 455 F.3d at 504; *see also Sw. Pharmacy Sols.*, 718 F.3d at 440.

Plaintiff first argues that the channeling exception applies only for “entities that can administratively exhaust,”⁶ and since it cannot use the Medicare appeals process, it is excused from the channeling exception. Plaintiff is incorrect: the channeling exception applies “only when there is no third party with an interest and a right to seek administrative review. If third parties have an incentive, and are properly aligned to bring an administrative challenge, the plaintiff’s inability or difficulty would not trigger the *Illinois Council* exception.” *Sw. Pharmacy Sols., Inc.*, 718 F.3d at 441 (cleaned up); *see also Physician Hosps. of Am.*, 691 F.3d at 659 (alleging that one plaintiff cannot channel its claim is “insufficient to constitute a complete preclusion of judicial review”) (cleaned up). Thus, Plaintiff cannot argue that the exemption applies simply because it is unable to bring an administrative challenge to the Rule. *See e.g., NATA*, 455 F.3d at 504 (finding

⁶ Pl.’s Resp. 20, ECF No. 35.

the channeling exception divested athletic trainers who could not bring an administrative claim of jurisdiction when physicians using their services could bring an administrative claim).

A plaintiff may still invoke the *Illinois Council* channeling exception if it can show there is not “an adequate proxy in the administrative review process.” 42 U.S.C. § 504(h). The burden is on the plaintiff to make this demonstration, and it must “go beyond showing its own hardship and indicate that the difficulty it encounters is sufficiently widespread as to threaten the loss of any judicial review.” *Sw. Pharmacy Sols., Inc.*, 718 F.3d at 441 (quoting *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 657 (5th Cir. 2012)) (emphasis added).

Plaintiff asserts it does not have an adequate proxy because it has “unique interests” and “no other entity is directly attacked in the same way.”⁷ But the Fifth Circuit does not require an exact alignment between the interests of the party and the interests of the entity capable of bringing the suit: as long as there are “parties with an interest and a right to seek administrative review,” the *Illinois Council* exception does not apply. *Physician Hosps. of Am.*, 691 F.3d at 657; *see also NATA*, 455 F.3d at 504. Furthermore, the Fifth Circuit has specifically found if “physicians have administrative remedies available to them that have yet to be exhausted and sufficient incentive to challenge the rule . . . the *Illinois Council* exception does not apply.” *NATA*, 455 F.3d at 507. When physicians use a Plaintiff’s product, they have “sufficient incentive” if challenging the Rule would help them “reduce their costs.” *See, e.g., id.* (reasoning that physicians had sufficient incentive to challenge a rule because they “can reduce their costs by employing athletic trainers”). Other courts have reached the same conclusion. *See, e.g., StimLabs, LLC v. Becerra*, 636 F. Supp. 3d 165, 173 (D.D.C. 2022) (finding “[p]roviders of [medical manufacturer’s] products . . . [h]ave

⁷ Pl.’s Resp. 24, ECF No. 35.

an obvious incentive to present claims and exhaust administrative remedies: if they do not challenge the denial of coverage and overpayment notices, they will be required to repay large sums to CMS and will not be reimbursed for future use of the products”).

The Court agrees with the Government that physicians have an incentive to challenge the Rule. Under the prior policy, physicians who were reimbursed based on the Average Sales Price of skin substitutes—but who acquired them at a discount—were able to retain the difference when treating Medicare patients.⁸ Thus, physicians have incentive to challenge the reimbursement rates under the Rule’s reclassification of skin substitutes because they will make less money as a result of the new policy. Plaintiff even admits that the Rule requires “cuts that will impact physicians”⁹ and that “a Medicare provider or supplier . . . could submit a claim for payment to Medicare for a skin substitute product, obtain an initial determination, [and] pursue an administrative appeal.”¹⁰ Thus, the Court finds that the physicians have adequate incentive and ability to bring a claim, meaning they are an adequate proxy and the channeling requirement bars jurisdiction.

Plaintiff’s attempt to distinguish this case from Fifth Circuit precedent misses the mark. It principally argues that the plaintiffs’ direct relationship with entities capable of bringing Medicare administrative challenges in *NATA* and *Southwest Pharmacy Solutions* allowed those entities to serve as adequate proxies but that no comparable relationship exists here.¹¹ *NATA*, 455 F.3d at 507; *Sw. Pharmacy Sols.*, 718 F.3d at 444. But the Fifth Circuit has said that the mere “the absence

⁸ See *Medicare Bleeds Billions on Pricy Bandages, and Doctors Get a Cut*, N.Y. TIMES, Apr. 14, 2025, available at <https://www.nytimes.com/2025/04/10/health/skin-substitutesmedicare-costs.html>.

⁹ Compl. ¶ 50, ECF No. 1.

¹⁰ *Id.* at ¶76.

¹¹ Pl.’s Resp. 23, ECF No. 35 (In *NATA*, “[t]he athletic trainers, therefore, were employees of the physicians, so those physicians served as adequate proxies, standing in the place of their employees in their practice to advocate for the practice’s reimbursement.”); *id.* at 24 (In *Southwest Pharmacy Solutions*, the pharmacies “sold prescriptions directly to beneficiaries so they could obtain authorization to channel a beneficiary’s claim[.]”)

of any relationship between [Plaintiff] and the [beneficiaries or providers]” is not enough to “prevent an alignment of interests such that the practical effect of § 405(h) would be a complete preclusion of judicial review.” *Sw. Pharmacy Sols., Inc.*, 718 F.3d at 445 (internal quotations omitted). As explained above, there are financial interests providing physicians with incentive to challenge the Rule. *See also Farmville Drug Discount, Inc. v. Sebelius*, No. 4:12-cv-109-D, 2013 WL 1246815, at *9 (E.D.N.C. Mar. 27, 2013) (finding sufficient alignment between non-preferred pharmacies without administrative remedies and Medicare enrollees because “[a]n enrollee patronizing a non-preferred pharmacy naturally would be interested in paying the lower preferred pharmacy co-payment for a medication and therefore would be inclined to bring a challenge”). Nor does Plaintiff’s reliance on the outlier case *Akebia Therapeutics v. Becerra* move the needle. 548 F. Supp. 3d. 274 (D. Mass. 2021). The Court does not find it persuasive, in part because it inconsistent with binding Fifth Circuit precedent *NATA*.

Finally, Plaintiff’s argument that “Plaintiff and its members must sit on the sidelines while the government targets them and destroys their businesses, on mere speculation that an unrelated and unknown third party might bring suit”¹² cannot possibly be the law is unavailing. “A party may not circumvent the channeling requirement by showing merely that ‘postponement of judicial review would mean added inconvenience or cost in an isolated, particular case.’” *Physician Hosps. of Am.*, 691 F.3d at 657, 679 (explaining that the Supreme Court contemplated that the narrowness of the channeling exception “comes with a price” and some “plaintiffs will suffer a delay-related hardship” under the doctrine).

¹² *Id.* at 1.

Plaintiff does not “provide another basis on which we could conclude that the challenges in this case present a ‘*complete* preclusion of judicial review.’” *Physician Hosps. of Am.*, 691 F.3d at 659 (quoting *Ill. Council*, 529 U.S. at 22–23) (emphasis in original). Thus, Plaintiff has “not met [its] burden of alleging more than that” the physicians might not channel its claim. *Id.*

Because physicians using the products manufactured and distributed by Plaintiff could challenge this Rule, the channeling requirement applies, and the Court does not have jurisdiction. Plaintiff does not challenge the Government’s assertion that the APA and Declaratory Judgment Act do not provide independent basis for jurisdiction. *Black v. N. Panola Sch. Dist.*, 461 F.3d 584, 588 n.1 (5th Cir. 2006) (“A party's failure to respond to arguments raised in a motion to dismiss constitutes waiver or abandonment of those issues at the district court level.”); *see also Humana Inc. v. U.S. Dep’t Health & Hum. Servs.*, No. 4:24-cv-1004-O, ECF No. 56, at *4 (N.D. Tex. July 18, 2025) (O’Connor, J.) (concluding that the plaintiffs are “mistaken” in asserting that the case arises out of the APA rather than the Medicare statute).

B. Leave to Amend

Plaintiff has not explained the facts that they could provide showing liability. As such, leave to amend is **DENIED**. *See Joseph v. Bach & Wasserman, L.L.C.*, 487 F. App’x 173, 178 (5th Cir. 2012); *see also Pierce v. Hearne Indep. Sch. Dist.*, No. 14–50788, 2015 WL 81995, at *5 (5th Cir. Jan. 7, 2015) (“[t]he court may deny leave to amend, however, if the defects are incurable or the plaintiffs have already alleged their best case”).

IV. CONCLUSION

The channeling requirement of 42 U.S.C. § 405(h) applies because there is an entity with ability and incentive to bring a claim via the agency’s administrative process. *NATA*, 455 F.3d at 504; *Sw. Pharmacy Sols.*, 718 3.d at 444. This requirement has not been satisfied. Thus, the

Court does not have subject matter jurisdiction over Plaintiff's claims. The Court **GRANTS** the Motion to Dismiss **without prejudice** (ECF No. 26) and **DENIES** the Motion for a Preliminary Injunction (ECF No. 9).

SO ORDERED on this **12th day of March, 2026**.


Reed O'Connor
CHIEF UNITED STATES DISTRICT JUDGE