No. 24-50180

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellants,

v.

XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellees.

On Appeal from the United States District Court
for the Western District of Texas

BRIEF FOR APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

A certificate of interested persons is not required, as defendants-appellees are all governmental parties. 5th Cir. R. 28.2.1.

STATEMENT REGARDING ORAL ARGUMENT

The Court has scheduled oral argument for May 1, 2024.

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INTRODUCTION

In the Inflation Reduction Act of 2022 (IRA), Congress directed the Secretary of Health and Human Services (HHS) to negotiate with drug manufacturers the prices that Medicare Parts B and D will pay for certain high-price drugs. In cases filed around the country, manufacturers of drugs selected for negotiation have challenged the constitutionality of the IRA's Negotiation Program.

In this case, the entity on which plaintiffs relied to establish venue is not a drug manufacturer (or its representative) but a trade association of certain Medicare providers—the National Infusion Center Association (NICA). Although the IRA requires participating manufacturers to make any negotiated drug prices available to providers—like NICA's members—that furnish a selected drug, NICA contends that its members will nonetheless be harmed by lower Medicare payments for these drugs.

The district court correctly held that the Medicare Act's channeling provision deprived it of subject matter jurisdiction to address NICA's claims, and that venue was thus improper. The Supreme Court, this Court, and other courts of appeals have uniformly held that judicial review of a provider's objection to the amount that Medicare will pay for items or

services is jurisdictionally barred until after the provider has presented a specific claim for payment to HHS. *See, e.g.*, *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000); *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649 (5th Cir. 2012); *Community Oncology All., Inc. v. Office of Mgmt. & Budget*, 987 F.3d 1137 (D.C. Cir. 2021). These precedents further hold that the jurisdictional bar applies even when the provider asserts constitutional claims and even if the provider objects to a Medicare payment amount for future claims. The narrow exception to the channeling requirement is plainly inapplicable here. The exception applies only in circumstances in which channeling would result in a "*complete* preclusion of judicial review." *Physician Hosps.*, 691 F.3d at 659 (quoting *Illinois Council*, 529 U.S. at 23). And NICA's members, like the Medicare providers in *Illinois Council*, can present their objections to Medicare payment amounts administratively and seek judicial review of the final agency decision.

The district court did not reach the government's alternative argument that the complaint failed to establish that any member of NICA has Article III standing. If this Court were to reach that issue, it should affirm the judgment on that basis. The complaint did not identify any member of NICA or any selected drug relevant to a member's interests.

NICA's belated efforts to cure that defect are unavailing. Although NICA's district court briefing identifies one member (BioTek) that administers a selected drug, NICA still fails to show that any of its members—BioTek included—face a concrete and imminent injury sufficient to establish Article III standing.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331 and 1346. ROA.18. On February 12, 2024, the district court entered a final judgment dismissing plaintiffs' claims for lack of subject matter jurisdiction and venue. ROA.598. On March 6, 2024, plaintiffs filed a timely notice of appeal. ROA.612. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the Medicare Act's channeling requirement deprived the district court of jurisdiction over the claims asserted by NICA, which is the only entity on which plaintiffs relied to establish venue.

2. Whether plaintiffs also failed to establish that any NICA member has Article III standing.

STATEMENT OF THE CASE

A. The Medicare Program

The Medicare program provides federally funded health coverage for individuals who are 65 or older or who have certain disabilities or medical conditions. *See* Title XVIII of the Social Security Act (Medicare Act), 42 U.S.C. § 1395 *et seq*. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program on behalf of the Secretary of HHS.

The Medicare program is divided into several Parts, which set forth the terms on which Medicare will pay providers and suppliers for items and services they furnish to Medicare beneficiaries. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). As relevant here, Medicare provides prescription drug coverage through Medicare Parts B and D. Part B pays for drugs that providers administer as part of outpatient care. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Part D subsidizes prescription drugs that beneficiaries obtain from pharmacies. *See id.* § 1395w-101 *et seq.*

B. The IRA's Reform of Medicare Payments for Prescription Drugs

1. Under various federal drug benefit programs, such as those administered by the Departments of Defense and Veterans Affairs, federal agencies have long been free to negotiate with drug manufacturers to

determine the amount that the agencies will pay for prescription drugs. *See, e.g.*, 38 U.S.C. § 8126(a)-(h). Before Congress enacted the IRA, however, CMS could not negotiate the prices that Medicare would pay for prescription drugs. As a consequence, Medicare often paid far more than other agencies pay for the same drugs. *See* Cong. Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (Feb. 2021), https://perma.cc/AZ2W-A4YY. "[I]f Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved" billions of dollars on certain high-priced prescription drugs. Staff of H. Comm. on Oversight & Reform, *Drug Pricing Investigation: AbbVie – Humira and Imbruvica* 15 (May 2021), https://perma.cc/Z2KG-ZKW3.

A "relatively small number of drugs are responsible for a disproportionately large share of Medicare costs." H.R. Rep. No. 116-324, pt. 2, at 37 (2019). In 2018, for example, "the top ten highest-cost drugs by total spending accounted for 46 percent of spending in Medicare Part B" and "18 percent of spending in . . . Part D." Office of the Assistant Sec'y for Planning & Evaluation, HHS, *Report to Congress: Prescription Drug Pricing* 7 (May 20, 2020), https://perma.cc/5GEN-LZ7F. By 2021, the top 10 drugs

by total spending accounted for 22% of spending under Part D. *See* Juliette Cubanski & Tricia Neuman, *A Small Number of Drugs Account for a Large Share of Medicare Part D Spending*, KFF (July 12, 2023), https://perma.cc/2PF2-336Z.

2. Accordingly, in the IRA, Congress directed the HHS Secretary, acting through CMS, to negotiate the prices that Medicare will pay for certain drugs. *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, tit. I, subtitle B, pt. 1, §§ 11001-11003, 136 Stat. 1818, 1833-64 (codified at 42 U.S.C. §§ 1320f-1320f-7 and 26 U.S.C. § 5000D and amending, *e.g.*, 42 U.S.C. §§ 1395w-3a, 1395w-102). Any negotiated prices for the first negotiation cycle will take effect on January 1, 2026, and at that time apply only to drugs administered as part of Medicare Part D. *See* 42 U.S.C. § 1320f(b)(1), (2); *see also* CMS, *Medicare Drug Price Negotiation Program: Revised Guidance* 167 (June 30, 2023), https://perma.cc/K6QB-C3MM (Revised Guidance) ("For initial price applicability year 2026, CMS 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 . . . eligible individuals enrolled under Part B.").

By statute, only certain drugs qualify for the Negotiation Program: those that account for the highest Medicare expenditures, that have no generic or biosimilar competitors, and that have been on the market for at least seven years. *See* 42 U.S.C. § 1320f *et seq.* From the list of qualifying drugs, the statute instructs the Secretary to select up to 10 drugs for participation in the first negotiation cycle and up to 15 drugs for participation in the second negotiation cycle. *Id.* § 1320f-1(a)-(b). Additional drugs are to be selected for future negotiation cycles. Drugs eligible for selection in one negotiation cycle may be ineligible in subsequent cycles if, for example, an approved generic competitor or licensed biosimilar to the selected drug is marketed. *Id.* § 1320f-1(e).

After selecting the negotiation-eligible drugs with the highest Medicare expenditures, the Secretary signs agreements with those manufacturers that are willing to engage in the negotiation process. 42 U.S.C. § 1320f-2. The object of the negotiations is to reach agreement on a "maximum fair price" for each selected drug. *Id.* § 1320f-3. To guide the negotiation process, Congress imposed a "[c]eiling for [the] maximum fair price," which is based on specified pricing data for each drug, *id.* § 1320f-3(c), and directed the Secretary to "aim[] to achieve the lowest maximum

fair price" that manufacturers will accept, *id.* § 1320f-3(b)(1). If negotiations are successful, a manufacturer will sign an addendum to the negotiation agreement to establish the maximum price at which the drug will be made available to Medicare beneficiaries. *Id.* § 1320f-3.

A drug manufacturer that does not wish to sign a negotiation agreement or otherwise participate in the Negotiation Program has several options. Because "[a] provider's participation in the Medicare program is completely voluntary," ROA.599, a drug manufacturer can withdraw from Medicare and Medicaid, 26 U.S.C. § 5000D(c)(1); *see also* Revised Guidance 120-21. Alternatively, the manufacturer can transfer its ownership of the selected drug to another entity and continue selling other drugs to Medicare and Medicaid. *Id.* at 131-32. If the manufacturer pursues neither option and refuses to negotiate, it can continue to provide the selected drug to Medicare beneficiaries subject to an excise tax. *See* 26 U.S.C. § 5000D(a)-(h).[1]

[1] Although not directly at issue in this appeal, plaintiffs' characterization of the excise tax (Br. 13) is mistaken in several respects. The tax would apply only to drugs administered under Medicare, and the maximum ratio of the tax to the total amount the manufacturer charges for a drug is 95%, not 1900%. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650 (Aug. 4, 2023), https://perma.cc/B9JZ-ZG7P.

C. Factual Background and District Court Proceedings

1. In August 2023, CMS published a list of the 10 drugs selected for the first round of negotiations. *See* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://perma.cc/A36P-Z88Z. The 10 drugs selected accounted for more than $50 billion of gross Medicare Part D spending between June 2022 and May 2023, and Medicare beneficiaries paid a total of $3.4 billion in out-of-pocket costs for the drugs in 2022 alone. *See Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://perma.cc/X37F-RC94.

Manufacturers of selected drugs (or their representatives) have challenged the constitutionality of the Negotiation Program in cases that are pending around the country.[2] To date, two district courts have considered such constitutional claims on the merits; both courts rejected

[2] *See Merck & Co. v. Becerra*, No. 1:23-cv-1615 (D.D.C.); *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156 (S.D. Ohio); *Bristol Myers Squibb Co. v. Becerra*, No. 3:23-cv-3335 (D.N.J.); *Janssen Pharm., Inc. v. Becerra*, No. 3:23-cv-3818 (D.N.J.); *Boehringer Ingelheim Pharm., Inc. v. HHS*, No. 3:23-cv-1103 (D. Conn.); *AstraZeneca Pharm. LP v. Becerra*, No. 1:23-cv-931 (D. Del.); *Novartis Pharm. Corp. v. Becerra*, No. 3:23-cv-14221 (D.N.J.); *Novo Nordisk Inc. v. Becerra*, No. 3:23-cv-20814 (D.N.J.).

the claims. *See AstraZeneca Pharm. LP v. Becerra*, No. 1:23-cv-931, 2024 WL 895036 (D. Del. Mar. 1, 2024) (Connolly, C.J.) (entering final judgment); *Dayton Area Chamber of Commerce v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (Newman, J.) (denying a preliminary injunction).

2. As in those cases, plaintiffs here challenge the constitutionality of the Negotiation Program. But in contrast to those cases, the only entity on which plaintiffs relied to establish venue is not a drug manufacturer (or its representative) but a trade association that represents certain Medicare providers.[3] That entity is the National Infusion Center Association—a Texas-based trade association of providers that "operate outpatient facilities to administer" infusion treatments and "receiv[e] reimbursement from Medicare for services provided to Medicare patients." ROA.18.

The complaint did not identify any NICA member at all, let alone one that administers a drug selected for the Negotiation Program. But in declarations attached to their district court brief, *see* ROA.557-58; ROA.562-

[3] The other two plaintiffs—PhRMA and the Global Colon Cancer Association—are Delaware corporations headquartered in Washington, D.C. ROA.18-20.

66, plaintiffs identified BioTek as a NICA member that is reimbursed for providing the selected drug Stelara "to patients under Part D and Part B." ROA.563. Plaintiffs' theory of injury is that if Stelara's manufacturer agrees to a negotiated price that reduces what Medicare pays for Stelara, the effect on BioTek will be to reduce the reimbursements it receives for administering the drug once the negotiated prices go into effect. The reduced reimbursements, according to plaintiffs, will in turn affect BioTek's profit margins, despite the fact that Stelara's manufacturer would be required to make the negotiated price available to BioTek if it furnishes the drug, *see* 42 U.S.C. § 1320f-2(a)(3)(B); *see also* ROA.565 (claiming that "[i]f reimbursement rates for Stelara drop, then the margins that NICA members earn with respect to Stelara will shrink in absolute terms").

3. The government moved to dismiss NICA's claims on two alternative jurisdictional grounds. First, the Medicare Act's channeling requirement deprived the district court of subject matter jurisdiction to consider NICA members' preemptive objections to the Medicare payment amounts they expect to receive. Second, the complaint failed to demonstrate that any NICA member has Article III standing.

The district court did not reach the standing argument because it held that NICA's claims are jurisdictionally barred by the Medicare Act's channeling requirement, which requires that a claim affecting Medicare payments first be presented to HHS before it can be the subject of judicial review. ROA.609. The court explained that NICA's contention that the channeling requirement does not apply to its constitutional claims is foreclosed by governing precedent. ROA.606-07 (discussing *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), and *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649 (5th Cir. 2012)). And the court determined that the lone exception to the channeling requirement was inapplicable because it applies only when "channeling a claim through the agency would result in the '*complete* preclusion of judicial review.'" ROA.607 (quoting *Family Rehab., Inc. v. Azar*, 886 F.3d 496, 504-05 (5th Cir. 2018)). Here, NICA's members can avail themselves of "established avenues for administrative review of constitutional challenges to the IRA and requests for reimbursement," so their claims "do not fall under the exception." ROA.608.

Because there was no dispute that NICA's members have not yet presented their claims to HHS, the district court dismissed NICA's claims

for lack of subject matter jurisdiction. ROA.609. In light of the dismissal of NICA's claims, the court held that venue was not proper, explaining that plaintiffs did "not offer any reasons that venue would be proper in this district if NICA is dismissed." ROA.610. No other plaintiff or defendant "resides in the district," and "nothing suggests that a substantial part of the events or omissions giving rise to the claim occurred in this district." ROA.610. Accordingly, the court dismissed the case without prejudice "in the interests of justice." ROA.610.

SUMMARY OF ARGUMENT

I. The district court correctly held that it lacked subject matter jurisdiction over the claims brought by the only entity on which plaintiffs relied to establish venue. That entity is NICA—a trade association of Medicare providers that alleged that its members will be injured if drug prices negotiated pursuant to the IRA cause their Medicare payments to be reduced. Decisions of the Supreme Court, this Court, and other circuits uniformly hold that judicial review of such claims is jurisdictionally barred until after the claims have been presented to HHS in the context of a concrete claim for Medicare payment. *See, e.g.*, *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000); *Physician Hosps. of Am. v. Sebelius*, 691

F.3d 649 (5th Cir. 2012); *Community Oncology All., Inc. v. Office of Mgmt. & Budget*, 987 F.3d 1137 (D.C. Cir. 2021).

These decisions further hold that the Medicare Act's channeling requirement applies even when the provider asserts constitutional claims, and even if the provider objects to a Medicare payment that will occur only in the future. The lone exception arises when the requirement that a claim be channeled through HHS would result in a "*complete* preclusion of judicial review." *Physician Hosps.*, 691 F.3d at 659 (quoting *Illinois Council*, 529 U.S. at 23). That exception is inapplicable here: Medicare providers such as NICA's members have a well-established administrative avenue to challenge Medicare payment amounts, and they can raise constitutional theories in that context.

II. Although the district court did not reach the issue and this Court has no occasion to do so, NICA also failed to demonstrate that any member has Article III standing to challenge the IRA. The complaint identified no specific NICA member that would suffer a concrete injury as a result of the challenged IRA provisions. Plaintiffs tried to cure that defect in their district court briefing by asserting that NICA's member BioTek will be injured by reduced Medicare payments if the manufacturer of the selected

drug Stelara negotiates a lower Medicare price. But that theory rests on an attenuated chain of speculation that falls short of establishing Article III standing. This fundamental defect also dooms plaintiffs' attempts to recast their speculative claims of future economic harm as a present procedural injury. *See Department of Educ. v. Brown*, 600 U.S. 551, 561 (2023).

STANDARD OF REVIEW

The district court's conclusion that it lacked subject matter jurisdiction is subject to de novo review in this Court, *Davila v. United States*, 713 F.3d 248, 255 (5th Cir. 2013), as is the court's determination that venue does not lie in a particular district, *see Trois v. Apple Tree Auction Ctr., Inc.*, 882 F.3d 485, 493 & n.10 (5th Cir. 2018).

ARGUMENT

I. The Medicare Act's channeling provision is a jurisdictional bar to NICA's claims.

A. Because NICA's claims arise under the Medicare Act, the channeling requirement applies.

In the Inflation Reduction Act, Congress directed the HHS Secretary to negotiate with drug manufacturers the prices that Medicare Parts B and D will pay for selected drugs. Plaintiffs' complaint alleged that the IRA's Negotiation Program is unconstitutional. The entity on which they relied

to establish venue, however, is not a drug manufacturer but an association of Medicare providers. This association, NICA, alleged that its provider members will be harmed if the Medicare payments they receive for administering selected drugs are reduced as a result of the IRA negotiations. The complaint alleged that NICA's members have a constitutionally protected interest "in being reimbursed for the treatments they provide on a non-arbitrary basis as provided by the Medicare statute," ROA.59 (Complaint ¶ 117), and that Congress should have given providers (as distinct from drug manufacturers) the "opportunity to be heard" before they "suffer significant losses from arbitrarily reduced reimbursement rates" under Medicare, ROA.53 (Complaint ¶ 106). The district court correctly held that NICA's claims are jurisdictionally barred by the Medicare Act's channeling provision, which requires that any claim arising under the Medicare Act be presented to HHS before it can be the subject of judicial review.

1. The Medicare Act divests the district courts of general federal-question jurisdiction and permits review only of a final agency decision regarding a concrete claim for Medicare reimbursement. *See American Hosp. Ass'n v. Azar*, 895 F.3d 822, 825-26 (D.C. Cir. 2018) (discussing 42

U.S.C. § 1395ii, which makes 42 U.S.C. § 405(g) and (h) applicable to Medicare). Thus, to "obtain judicial review of claims arising under the Medicare Act, a plaintiff must first present the claims to the Secretary of Health and Human Services." *Id.* at 823.

Plaintiffs' various attempts to circumvent that channeling requirement are foreclosed by the decisions of the Supreme Court and this Court. *See, e.g., Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000); *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649 (5th Cir. 2012); *see also Community Oncology All., Inc. v. Office of Mgmt. & Budget*, 987 F.3d 1137 (D.C. Cir. 2021); *Retina Grp. of New England, P.C. v. Dynasty Healthcare, LLC*, 72 F.4th 488 (2d Cir. 2023). The Supreme Court has "construed the 'claim arising under' language [in section 405(h)] quite broadly to include any claims in which 'both the standing and the substantive basis for the presentation' of the claims is the" Medicare Act, as well as any claims that are "'inextricably intertwined' with [a] claim for benefits." *Heckler v. Ringer*, 466 U.S. 602, 611, 614-15 (1984) (quoting *Weinberger v. Salfi*, 422 U.S. 749, 760-61 (1975)). This rule applies even if the claims also arise under another source of law, such as the Constitution or a separate statute. *Id.* As a result, section 405(h)'s jurisdictional bar applies to "virtually all legal

attacks" concerning Medicare reimbursements. *Illinois Council*, 529 U.S. at 13.

a. The Supreme Court has repeatedly rejected the attempts of litigants like NICA to evade the effect of section 405(h) by distinguishing their claims from the "typical" Medicare benefits case, in which "an individual seeks a monetary benefit from the agency . . . , the agency denies the benefit, and the individual challenges the lawfulness of the denial." *Illinois Council*, 529 U.S. at 10. While section 405(h) "plainly bars § 1331 review in such a case, irrespective of whether the individual challenges the agency's denial on evidentiary, rule-related, statutory, constitutional, or other legal grounds," *id.*, the reach of section 405(h) extends much further.

For instance, in *Ringer*, 466 U.S. 602, the Supreme Court held that section 405(h)'s jurisdictional bar applied to a legal challenge brought by a plaintiff who "had as yet no valid claim for reimbursement," and who sought only declaratory and injunctive relief—not an award of benefits. *Illinois Council*, 529 U.S. at 12. Because the plaintiff challenged a rule that he alleged would prevent him from receiving Medicare reimbursement for a future procedure, the Supreme Court held that his claim arose under the Medicare Act and was therefore not justiciable under section 1331. *See*

Ringer, 466 U.S. at. 620-22. The *Ringer* Court emphasized, moreover, that section 405(h)'s jurisdictional bar applies to "all aspects" of the lawsuit, both substantive and procedural, and rejected the contention that "simply because a claim somehow can be construed as 'procedural,' it is cognizable in federal district court by way of federal-question jurisdiction." *Id.* at 614.

Illinois Council reaffirmed the broad reach of section 405(h), holding that the provision applies to suits by associations of healthcare providers alleging—as NICA does—that a statute or regulation may limit their members' future Medicare reimbursements. The *Illinois Council* case was brought by an association of nursing homes that alleged that the challenged regulations "violated various statutes and the Constitution," 529 U.S. at 5, and could (among other things) reduce their members' Medicare reimbursement payments, *id.* at 6-7. The Supreme Court held that section 405(h)'s jurisdictional bar applied: If a group of providers who "*might* later seek money or some other benefit" under Medicare "challenges in advance" the lawfulness of a provision "that *might* later bar recovery of that benefit," their action is "one 'to recover on [a] claim arising under' the . . . Medicare Act." *Id.* at 10 (quoting 42 U.S.C. § 405(h)).

The *Illinois Council* Court acknowledged that the association's challenge lacked certain "features" of the typical Medicare case—including that the plaintiffs did not make claims for reimbursement and were not seeking an order requiring any such payments. 529 U.S. at 11-12. But the Supreme Court dismissed that distinction as irrelevant, rejecting the contention that the applicability of section 405(h) turns on "distinctions based upon 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 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Id.* at 13-14. The Supreme Court explained that the case arose out of the Medicare Act for the simple reason that the plaintiff sought to vindicate the nursing homes' interest in Medicare reimbursements. *See id.*

For these reasons, NICA is wrong to suggest that a claim cannot arise under the Medicare Act if it can be resolved without reference to the merits of a benefits or reimbursement decision, or without reference to provisions of the Act. Br. 35-36 (first citing *Alvarado Hosp., LLC v. Price*, 868 F.3d 983, 998 (Fed. Cir. 2017)); and then citing *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1145 (9th Cir. 2010)). *Illinois Council* makes clear that a claim can arise

under the Medicare Act even if it raises "constitutional issue[s] [that are] 'collateral' to [the] claim for benefits." 529 U.S. at 15.

b. The Supreme Court's decisions are likewise clear that section 405's channeling provision applies to claims that arise under the Constitution or another statute, as long as the action also arises under the Social Security or Medicare Acts. The Court first addressed this question in *Weinberger v. Salfi*, which involved a constitutional challenge to a statute that made the plaintiffs ineligible to receive Social Security benefits. The Court acknowledged that the plaintiffs' constitutional arguments were "critical to their complaint" and that their claims thus arose under the Constitution. *Salfi*, 422 U.S. at 760. Section 405(h) nonetheless applied because the plaintiffs' claims turned on their interest in receiving payment under the Social Security Act. *Id.* at 760-61. The Court reaffirmed this holding in *Ringer*: Although "Ringer's claim may well 'arise under' the APA in the same sense that Salfi's claim arose under the Constitution," the claim also arose under the Medicare Act—and thus section 405(h) applied. 466 U.S. at 622; *see also Illinois Council*, 529 U.S. at 5 (holding that section 405(h) applied to claims that "certain Medicare-related regulations violated various statutes and the Constitution").

The D.C. Circuit has recently applied these precedents in a case similar to this one, where an association of healthcare providers alleged that its members were injured by a different statutory program. *Community Oncology All., Inc. v. Office of Mgmt. & Budget*, 987 F.3d 1137 (D.C. Cir. 2021) (Katsas, J.). The plaintiff challenged a sequestration order—issued under the Balanced Budget Act, 2 U.S.C. § 901a—that required a 2% reduction in certain Medicare reimbursements. The plaintiff contended, as NICA does here, that its claims arose from a separate statute (in that case, the Balanced Budget Act) instead of the Medicare Act because an action required by that separate statute caused its injury. *Community Oncology All.*, 987 F.3d at 1143. The court rejected this argument. It emphasized that the providers' injury consisted of insufficient Medicare reimbursements, and so the claims were "plainly ones 'arising under' the Medicare Act." *Id.* Even accepting the plaintiff's argument that its claims arose under the Balanced Budget Act, the court made clear that "all that matters under section 405(h) is that the claims *also* arise under the Medicare Act." *Id.* at 1143 (emphasis added); *see also id.* (describing *Salfi* as controlling on this point).

2. This Court's decision in *Physician Hospitals*, 691 F.3d 649, further rebuts plaintiffs' contention that the Medicare Act's channeling provision does not bar their constitutional claims. *See* Br. 30-33. There, the plaintiffs brought a constitutional challenge to the provision of the Patient Protection and Affordable Care Act that eliminated Medicare payments for expanded physician-owned hospitals. *Physician Hosps.*, 691 F.3d at 655. In holding that the channeling requirement applied, this Court deemed it irrelevant that the claims did "not seek recovery under the Medicare Act" and "instead . . . invoke[d] the U.S. Constitution." *Id.* at 656 (quotation marks omitted). This Court explained that the Supreme Court has "explicitly rejected the argument that constitutional challenges are free from Section 405(h)'s requirements." *Id.* (citing *Salfi*, 422 U.S. at 760-61).

Physician Hospitals also shows that it is irrelevant that NICA's members cannot present concrete claims to HHS until the future. *See* Br. 38 (noting that NICA's members "currently have no claim for Medicare benefits that they can present to HHS and administratively exhaust," and that they "will not have such a claim until, at the earliest, January 2026 (when Part D price mandates take effect)"). In *Physician Hospitals*, the plaintiff objected that, to present its constitutional challenge to the

Affordable Care Act in the context of a concrete Medicare reimbursement claim, it first would have to "knock down two commercial buildings," "take two years to build a new hospital," and "treat a patient in the expansion." *Physician Hosps.*, 691 F.3d at 656. This Court held that the channeling requirement nonetheless applied. *See id.* at 655 (explaining that the Supreme Court held that the channeling requirement applied in *Illinois Council* even though the trade association argued that its members needed "advance knowledge for planning purposes" (quoting *Illinois Council*, 529 U.S. at 10)).

3. The precedents discussed above foreclose NICA's claims, which are premised on the notion that NICA's members will be injured by future reductions in their Medicare payments for selected drugs. Indeed, NICA's CEO emphasized this point in summarizing the association's interest in the lawsuit: "In short, NICA's members fear that changes to [Medicare] payment and reimbursement for certain drugs under the Drug Price Negotiation Program" will cause them financial injury. ROA.567.

Although NICA attempts to recast its claims as challenging a "separate law governing price-setting," Br. 39-41, this effort to circumvent section 405(h) fails on two fronts. To start, these IRA provisions have no

significance apart from the Medicare Act. No drug can even be selected for negotiation without reference to the Medicare Act, as only those drugs with the highest Medicare expenditures are eligible. 42 U.S.C. § 1320f-1(d)(1) (defining two categories of "negotiation-eligible drug[s]": "Part D high spend drugs" and "Part B high spend drugs"). Moreover, after a negotiated price has been reached, manufacturers are required to provide access to this price only for sales of selected drugs furnished to "maximum fair price eligible individuals"—that is, those who have qualifying coverage under the Medicare Act. 42 U.S.C. §§ 1320f(c)(2); 1320f-2(a). Thus, neither a "negotiation-eligible drug" nor a "maximum fair price eligible individual" can be identified without reference to provisions codified in Title XVIII of the Social Security Act (*i.e.*, the Medicare Act).

In addition, a provider's reimbursement for a selected drug is determined by the IRA's amendments to the Medicare Act, namely, the amendments to 42 U.S.C. §§ 1395w-3a and 1395w-102, which are codified in Title XVIII. And more fundamentally, the entire purpose of the Negotiation Program is to address drug costs within the Medicare program. That is why the challenged provisions of the IRA, the complaint, and appellants' brief are all replete with references to the Medicare Act—

because the Negotiation Program has significance only in connection with Medicare. *See* 42 U.S.C. §§ 1320f(c)(2)(A)-(B); 1320f(c)(5); 1320f-1(b)(1)(A); 1320f-1(b)(2); 1320f-1(d)(1)(A)-(B); 1320f-1(d)(2); 1320f-1(e); Complaint, ROA.18-19, 25, 27-30, 33, 37, 59, 66; Br. 6-8 (explaining how Medicare reimbursements under Parts B and D work); Br. 9-10, 12 (explaining how the Negotiation Program works by reference to Medicare Parts B and D); Br. 19 (explaining how NICA receives Medicare reimbursements and tying NICA's interest in the lawsuit to an "expected decrease in Part B and D reimbursements"); *see also* Br. 47, 53, 59-62.

Plaintiffs cannot avoid these problems by purporting to disclaim any challenge to the provisions of the Medicare Act that were amended by the IRA. Indeed, of the IRA provisions that they challenge, the ones that affect providers most directly are the amendments to sections 1395w-3a and 1395w-102, changing the Part B and Part D reimbursement formulas to account for any prices negotiated with manufacturers. Both section 1395w-3a and section 1395w-102 are codified in Title XVIII, demonstrating that plaintiffs' claims arise under the Medicare Act even under their narrow reading of the relevant precedents.

Thus, contrary to plaintiffs' suggestion, the district court did not hold that NICA's claims arose under the Medicare Act simply because NICA "challeng[ed] a separate law that might affect Medicare reimbursements," Br. 40 (alteration omitted) (quotation marks omitted). Rather, the district court concluded that NICA's claims arise under the Medicare Act because the Act provides both the standing and substantive basis for NICA's claims, and because the claims—like the Negotiation Program itself—are inextricably intertwined with the Medicare Act. ROA.623.

Plaintiffs' position is also at odds with settled precedent making clear that a claim arising under a separate statute nonetheless arises under the Medicare Act if the plaintiff is bringing the claim to vindicate or protect its interest in Medicare reimbursements. *See supra* pp. 21-23. This is so even if the law that provides the cause of action or the law that threatens the Medicare reimbursements is entirely separate from the Medicare Act. *See, e.g.*, *Ringer*, 466 U.S. 602 (APA); *Physician Hosps.*, 691 F.3d 649 (Constitution); *Community Oncology*, 987 F.3d 1137 (Constitution, Balanced Budget Act). And it is all the more true here, as the challenged provisions are replete with cross-references to the Medicare Act and would not have meaning or effect independent of that Act. Indeed, even plaintiffs accept

that a challenge to an "order . . . authorized by a provision codified outside the Medicare Act" arose under the Medicare Act when "the provision expressly cross-referenced the Medicare Act and did nothing more than reduce Medicare reimbursements," and "the plaintiff's standing and merits arguments were both directed at securing 'additional reimbursement under the Medicare Act.'" Br. 42 n.3 (discussing the D.C. Circuit's reasoning in *Community Oncology*, 987 F.3d at 1140-43). The provisions plaintiffs challenge likewise expressly cross-reference the Medicare Act, and their sole function is to affect the operation of the Medicare prescription drug programs.

NICA identifies one out-of-circuit district court case to support its contention that its claims are not barred by section 405(h), but that case is irreconcilable with the Supreme Court's decision in *Illinois Council* and this Court's decision in *Physician Hospitals* and can therefore be accorded no weight. The district court in *Association of Community Cancer Centers v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020), erred in holding that because the associations had not made "specific or individual claims for reimbursement" under Medicare, the action did not concern claims that arise under the Medicare Act. *Id*. at 491. Of course, no plaintiff in *Illinois*

Council or in *Physician Hospitals* had made specific or individual claims for reimbursement under Medicare. Moreover, the district court recognized the inconsistency between its ruling and *Salfi*'s holding that a claim can arise under the Social Security Act even though it also arises under another source of law. But the court erroneously determined that *Salfi* did not control because "plaintiffs do not seek to 'recover on any (Social Security) claim' or to challenge a rule arising under subchapter II." *Id.* at 491 n.4. Given 42 U.S.C. § 1395ii, that is a distinction without a difference.

B. The *Michigan Academy* exception does not apply because NICA's members can seek judicial review of their claims under 42 U.S.C. § 405(g).

Plaintiffs' brief attempts to resuscitate the interpretation of *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986), that the Supreme Court explicitly rejected in *Illinois Council*. Plaintiffs assert that under *Michigan Academy*, sections 405(h) and 1395ii foreclose review "only of 'amount determinations'"—not of "substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." Br. 27 (quoting *Michigan Academy*, 476 U.S. at 680). But *Illinois Council* expressly rejected that reading of the case, 529 U.S. at 15, and clarified that the *Michigan Academy* exception extends only to

circumstances in which applying the jurisdictional bar in section 405(h) "would mean no review at all," *id.* at 17; *see also Southwest Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 441 (5th Cir. 2013).

"In *Michigan Academy*, there was a legal impossibility that any claimant would obtain judicial or administrative review." *Physician Hosps.*, 691 F.3d at 659. For good reason, plaintiffs do not contend that it will be legally impossible for NICA's members to contest their Medicare payment amounts for selected drugs with negotiated prices. On the contrary, like other providers, NICA's members can challenge a Medicare payment amount through the mechanism established by section 405(g), which allows a provider to obtain judicial review of "any final decision" of the HHS Secretary on claims arising under the Medicare Act "made after a hearing to which [the plaintiff] was a party." 42 U.S.C. § 405(g).

Thus, if an infusion-center provider wants to bring claims related to its Medicare reimbursements for drugs selected for negotiation, it may present its claims to HHS, which will make a final payment determination. A dissatisfied provider may then seek judicial review of the final reimbursement decision in district court, invoking the court's jurisdiction under section 405(g), and raise its constitutional theories (and any other

theories) in that context. *See Illinois Council*, 529 U.S. at 15. "[A] court reviewing an agency determination under § 405(g)" has "authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide." *Id.* at 23. NICA's members thus remain free "to contest in court the lawfulness of any regulation or statute upon which [the reimbursement] determination depends," as NICA seeks to do in this lawsuit. *Id.*

Because the district court correctly determined that NICA has not satisfied the Medicare Act's jurisdictional prerequisites, it correctly dismissed NICA's claims for lack of subject matter jurisdiction. And as NICA is the only plaintiff residing in the chosen district, there is no dispute that venue is improper if NICA is dismissed. *See* 28 U.S.C. § 1391(e)(1); ROA.610 (observing that plaintiffs do not offer "any reasons that venue would be proper" if the court lacks jurisdiction to hear NICA's claims).

II. NICA has also failed to establish Article III standing.

Although the Court does not need to reach the issue, NICA also failed to establish Article III standing. To invoke associational standing—the sole standing theory that NICA has asserted, ROA.540-51—NICA must demonstrate (among other things) that "its members would otherwise have

[Article III] standing to sue in their own right." *Funeral Consumers All., Inc. v. Service Corp. Int'l*, 695 F.3d 330, 343 (5th Cir. 2012) (quotation marks omitted). Article III requires NICA "to make specific allegations establishing that at least one identified member ha[s] suffered or w[ill] suffer harm." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009); *see Funeral Consumers*, 695 F.3d at 344. The injury to the identified member must be "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)). "'[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).

A. NICA has not adequately alleged that its members will experience an economic injury.

Although the complaint did not identify any NICA member at all, let alone one that administers a drug selected for the Negotiation Program, plaintiffs belatedly attempted to address that deficiency in their opposition to the government's motion to dismiss. In accompanying declarations, plaintiffs identified a NICA member (BioTek) that administers an infusion

drug (Stelara) that was selected for negotiation for initial price applicability year 2026 with respect to its Part D coverage. *See generally* ROA.536, 547-48, 550. Even assuming that plaintiffs' declarations are properly considered, they do not satisfy NICA's burden to show that any of its members—BioTek included—face a concrete and imminent injury.

On the contrary, it is speculative whether Stelara's selection will affect BioTek's future Medicare payments; indeed, a negotiated price for Stelara may never take effect. That is because a selected drug is no longer subject to the Negotiation Program once CMS determines that an approved generic competitor or a licensed biosimilar to the drug is marketed, subject to a timeline specified in the statute. *See* 42 U.S.C. § 1320f-1(c). And the Food and Drug Administration has already approved two biosimilar competitors to Stelara, either of which could enter the market in the coming months. *See* ROA.588-89 (Wezlana approval); FDA, *Biosimilar Product Information*, https://www.fda.gov/drugs/biosimilars/biosimilar-product-information (last updated Apr. 16, 2024) (Selarsdi approval). Accordingly, plaintiffs' attenuated theory of economic injury—which is premised on Stelara's remaining a selected drug and affecting BioTek's reimbursement rates once any agreed-upon price goes into effect—is "too speculative to

satisfy the well-established requirement that threatened injury must be certainly impending." *Clapper*, 568 U.S. at 401 (quotation marks omitted).

Furthermore, even if Stelara remains a selected drug and a negotiated price takes effect in January 2026, plaintiffs still can only speculate as to the economic impact on BioTek. The IRA requires drug manufacturers to make the negotiated price of a selected drug available to providers that furnish the drug, such as NICA's members. *See* 42 U.S.C. § 1320f-2(a)(3)(B). Thus, providers' acquisition costs for those drugs will change along with the amount of the Medicare reimbursement. *See id.* § 1320f-2(a)(3). NICA provides no information regarding the cost at which BioTek acquires Stelara or any other drug, leaving any theory of financial harm dependent upon speculation about variables not addressed in plaintiffs' filings.

Plaintiffs' appellate brief now asserts that, "even if drug-acquisition costs fall along with reimbursement rates, the overall amount providers are paid will decrease in absolute terms." Br. 63. But they cite nothing in the complaint or subsequent declarations that supports this bare assertion or accounts for the various ways drug rebates and discounts affect the costs providers pay and the rebates they receive. *See, e.g.*, 42 U.S.C. § 1395w-3a(c)(3) (establishing that the average sales price for Part B reimbursements

is based on the net price of a drug after rebates and discounts). Indeed, elsewhere in their brief, plaintiffs speculate that the IRA "*might* affect Medicare reimbursements," and even then only "indirectly." Br. 40 (emphasis added) (alteration and quotation marks omitted).

Tacitly acknowledging that NICA's members might benefit from reduced acquisition costs, plaintiffs contend that, "[o]nce injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." Br. 63 (quoting *Texas v. United States*, 809 F.3d 134, 155-56 (5th Cir. 2015)). But as that statement reflects, plaintiffs must first demonstrate an injury. And in assessing whether they have done so, the Court must consider "offsetting benefits that are of the same type and arise from the same transaction as the costs." *Texas*, 809 F.3d at 155.

Plaintiffs alternatively seek to premise injury on the assertion that the IRA may make it more difficult for "some" of NICA's members to raise debt and equity in capital markets. Br. 62. But plaintiffs fail to identify any NICA member suffering such purported harm, much less offer any details regarding that member's efforts to obtain additional funding or the Negotiation Program's effect on those efforts. Simply gesturing to some

unspecified loss of economic prospects is not sufficient to carry NICA's burden of establishing that an identified member faces an actual or imminent injury. As the D.C. Circuit has explained, "broad-based market effects stemming from regulatory uncertainty are quintessentially conjectural, and it is difficult to imagine [an agency] action that would not confer standing under this theory." *New England Power Generators Ass'n v. FERC*, 707 F.3d 364, 369 (D.C. Cir. 2013); *AstraZeneca Pharm. LP v. Becerra*, No. 1:23-cv-931, 2024 WL 895036, at *8 (D. Del. Mar. 1, 2024) (rejecting the similar standing theory advanced by the manufacturer in that case and holding that a "loss or diminishment of an incentive to do something . . . is not a concrete injury").

Plaintiffs' reliance on *Clinton v. City of New York*, 524 U.S. 417 (1998), is wholly misplaced. Contrary to plaintiffs' assertion, the Supreme Court did not hold that Article III is satisfied by anyone asserting "probable economic injury resulting from governmental actions that alter competitive conditions." Br. 58 (quoting, without full attribution, a parenthetical statement regarding an administrative law treatise cited in *Clinton*, 524 U.S. at 433, for general support). Instead, the Supreme Court in *Clinton* undertook a close analysis of the specific injuries alleged, explaining that

the plaintiff there "was organized for the very purpose of acquiring processing facilities" and that "it had concrete plans to utilize the benefits" of the canceled tax benefit at issue in that case. *Clinton*, 524 U.S. at 432. The *Clinton* Court further noted that the plaintiff "was engaged in ongoing negotiations with the owner of a processing plant who had expressed an interest in structuring a tax-deferred sale when" the tax benefit was cancelled and was "actively searching for other processing facilities for possible future purchase if the President's cancellation [was] reversed." *Id*. It was on the basis of these specific and concrete allegations, and not some generalized sense of market changes, that the plaintiff alleged "a sufficient likelihood of economic injury to establish standing under our precedents." *Id.* NICA, by contrast, identifies no individual member that has or will suffer a specific loss as a result of the Negotiation Program, falling fall short of the detailed allegations found sufficient in *Clinton*.

Plaintiffs' discussion of *American Forest & Paper Ass'n v. EPA*, 137 F.3d 291 (5th Cir. 1998), likewise elides the details that underpin the Court's holding. Plaintiffs cite the case for the principle that a party can establish standing to challenge a provision by alleging any possible future "costs of compliance." Br. 58 (quoting *American Forest*, 137 F.3d at 296). But unlike

NICA and its members, the Association's members in that case were "an object of the action . . . at issue," *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992)—holders of discharge permits under the Clean Water Act that were required to comply with the challenged requirements or be subject to an agency veto. *American Forest*, 137 F.3d at 296. It was only because the Association's members would soon be required to apply for a new permit, thus subjecting them to the challenged requirement, that the Court held that the members had standing. *Id.* By not attending to the particulars of these cases, plaintiffs' advance a view of standing that fails to admit of any limits.

B. NICA cannot demonstrate standing by recasting its members' injuries as procedural.

NICA cannot avoid the need to demonstrate concrete injury by recharacterizing its members' injuries as procedural. "[W]hen a statute affords a litigant 'a procedural right to protect his concrete interests,' the litigant may establish Article III jurisdiction without meeting the usual 'standards for redressability and immediacy.'" *Department of Educ. v. Brown*, 600 U.S. 551, 561 (2023) (quoting *Lujan*, 504 U.S. at 572 n.7). But the plaintiff must still "demonstrat[e] that it has a 'concrete interest that is

affected by the deprivation'" of the claimed procedural right. *Id.* at 562 (quoting *Summers*, 555 U.S. at 496). The Supreme Court has repeatedly emphasized that "the 'deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.'" *Id.* (quoting *Summers*, 555 U.S. at 496).

Although plaintiffs agree in principle that NICA must show that it "has been deprived of 'a procedural right *to protect its concrete interests*,'" Br. 45 (emphasis added) (quoting *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019)), their brief does not identify any concrete interest to which the alleged procedural harms relate. Plaintiffs characterize the harm as the "'deprivation' of the full value of the products NICA's members dispense and administer . . . 'without proper process.'" Br. 47. But the "products" at issue are selected drugs and, as already discussed, NICA has failed to establish with sufficient concreteness whether or how the Negotiation Program will affect any member's profit margins on those drugs.

Plaintiffs alternatively assert that "NICA's members are *already* experiencing" a cognizable harm from the purported inability to provide "input" on the Negotiation Program's implementation. Br. 46. That

contention overlooks the extensive public feedback that CMS solicited in developing its implementation guidance, Revised Guidance 1-2, including from NICA itself, *see* CMS, *Medicare Drug Price Negotiation*, https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation (last updated Jan. 5, 2024) (collecting public comments, including ones submitted by NICA). It also underscores that the relevant harm, in plaintiffs' view, is a procedural injury *in vacuo* rather than one that relates to any deprivation of a concrete interest. If procedural claims of this type were sufficient to establish standing, any party whatsoever would have standing to bring the claims plaintiffs assert, running afoul of the settled principle that "[f]ederal courts do not exercise general legal oversight of the Legislative and Executive Branches," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423-24 (2021).

The cases plaintiffs cite are inapposite because they involve circumstances in which the litigant was an object of the challenged action and alleged that it would suffer a concrete harm because of the procedural irregularity. As this Court has emphasized, "[w]hen the suit is one challenging the legality of government action or inaction . . . [and] the plaintiff is himself an object of the action (or forgone action) at issue . . . ,

there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Texas v. United States*, 497 F.3d 491, 498 (5th Cir. 2007) (alterations in original) (quoting *Lujan*, 504 U.S. at 561-62). Thus, in *Texas*, the State had standing because it was directly regulated by the challenged procedures, which required it to participate in "mediation and secretarial approval of gaming procedures even though no court ha[d] found that Texas negotiated in bad faith," as was previously required. *Id.* at 497.

Likewise, in *Texas v. EEOC*, 933 F.3d at 447, the State had standing to challenge guidance that required it to alter its hiring laws and policies in order to avoid enforcement action. The rule thus operated directly on the State and undercut its "concrete interests" in conducting its hiring. *Id.* And in *Bertulli v. Independent Ass'n of Continental Pilots*, 242 F.3d 290, 295 (5th Cir. 2001), the plaintiff pilots had standing to challenge their loss of seniority without adequate process because they were among the class

upon which the challenged action operated, and the resulting loss of seniority was "suffered by the plaintiffs themselves." *Id.*[4]

By contrast, neither NICA nor any of its members is an object of the government action here at issue. Unlike the manufacturers of selected drugs, NICA's members are not themselves subject to the allegedly unconstitutional process or the allegedly excessive fines of which plaintiffs complain, and their theory of harm runs afoul of the rule that a plaintiff generally "must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975).

Indeed, plaintiffs make the extraordinary assertion that NICA's members would "escape" the IRA's purportedly "unconstitutional process" if "the manufacturers of the drugs they administer . . . end[] their

[4] Even further afield is *Axon Enterprise, Inc. v. FTC*, 598 U.S. 175, 192 (2023), which plaintiffs cite for the proposition that "subjection to an unconstitutionally structured decisionmaking process"—such as "an agency . . . wielding authority unconstitutionally"—is an injury "irrespective of [the] outcome." Br. 49 (alterations in original) (quotation marks omitted). NICA's members are not subject to the IRA's Negotiation Program. Moreover, *Axon* was not a case about standing, and in making the quoted statement, the Court was not addressing what it means for a procedural injury to be cognizable under Article III.

participation in Medicare and Medicaid." Br. 55. Plaintiffs' theory of standing thus turns on those third parties' future decisions, over which "[p]roviders like NICA have no say," *id.*; *see Ghedi v. Mayorkas*, 16 F.4th 456, 466 (5th Cir. 2021) (recognizing that an injury that results from "the independent action[s] of some third party" generally "cannot support traceability for standing" (alteration in original) (quoting *Lujan*, 504 U.S. at 560)). In any event, NICA's members are themselves voluntary participants in the Medicare program and likewise can choose whether to continue their participation. *See* ROA.599 ("A provider's participation in the Medicare program is completely voluntary."). The IRA establishes only a means through which the government negotiates the amount that it will pay for certain high-cost drugs—something it has long done through other programs. Market participants, including NICA's members, remain free to choose whether to do business with the government.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

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APRIL 2024

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

s/ Catherine Padhi
Catherine Padhi

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 8716 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Book Antiqua 14-point font, a proportionally spaced typeface.

s/ Catherine Padhi
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ADDENDUM

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42 U.S.C. § 405(g)-(h)

§ 405. Evidence, procedure, and certification for payments

(g) Judicial review

Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Commissioner of Social Security may allow. Such action shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia. As part of the Commissioner's answer the Commissioner of Social Security shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Commissioner of Social Security, with or without remanding the cause for a rehearing. The findings of the Commissioner of Social Security as to any fact, if supported by substantial evidence, shall be conclusive, and where a claim has been denied by the Commissioner of Social Security or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Commissioner of Social Security, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations. The court may, on motion of the Commissioner of Social Security made for good cause shown before the Commissioner files the Commissioner's answer, remand the case to the Commissioner of Social Security for further action by the Commissioner of Social Security, and it may at any time order additional evidence to be taken before the Commissioner of Social Security, but only upon a showing that there is new evidence which is material and that there is good cause for the failure to incorporate such evidence into the record in a prior proceeding; and the Commissioner of Social Security shall,

after the case is remanded, and after hearing such additional evidence if so ordered, modify or affirm the Commissioner's findings of fact or the Commissioner's decision, or both, and shall file with the court any such additional and modified findings of fact and decision, and, in any case in which the Commissioner has not made a decision fully favorable to the individual, a transcript of the additional record and testimony upon which the Commissioner's action in modifying or affirming was based. Such additional or modified findings of fact and decision shall be reviewable only to the extent provided for review of the original findings of fact and decision. The judgment of the court shall be final except that it shall be subject to review in the same manner as a judgment in other civil actions. Any action instituted in accordance with this subsection shall survive notwithstanding any change in the person occupying the office of Commissioner of Social Security or any vacancy in such office.

(h) Finality of Commissioner's decision

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, 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. § 1320f(a)-(c)

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f-1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f-2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f-3 of this title;

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1320f-4 and 1320f-5 of this title.

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

The term "initial price applicability year" means a year (beginning with 2026).

(2) Price applicability period

The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) Selected drug publication date

The term "selected drug publication date" means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

(4) Negotiation period

The term "negotiation period" means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1320f-2 of this title with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term "manufacturer" has the meaning given that term in section 1395w-3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term "maximum fair price eligible individual" means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1320f-1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term "reference product" has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term "total expenditures" includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

42 U.S.C. § 1320f-1(a)-(b), (d)(1)

§ 1320f-1. Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of subchapter XVIII" were a reference to "total expenditures for such drugs under part D of subchapter XVIII".

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such

biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) Selected drug

[omitted]

(d) Negotiation-eligible drug

(1) In general

For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) Part B high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of subchapter XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

42 U.S.C. § 1320f-2(a)

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1320f-3 of this title, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1320f-3 of this title, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any

year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1320f(c)(2) of this title, at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1320f-3(f) of this title), and for section 1320f-1(f) of this title, with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of Title 38) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1320f-1(f) of this title, including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

42 U.S.C. § 1395ii

§ 1395ii. Application of certain provisions of subchapter II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

42 U.S.C. § 1395w-3a(b)(1)

§ 1395w-3a. Use of average sales price payment methodology

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4) or in the case of such a drug or biological product that is a selected drug (as referred to in section 1320f-1(c) of this title), with respect to a price applicability period (as defined in section 1320f(b)(2) of this title), 106 percent of the maximum fair price (as defined in section 1320f(c)(3) of this title) applicable for such drug and a year during such period; or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

42 U.S.C. § 1395w-102(d)(1)

§ 1395w-102. Prescription drug benefits

(d) Access to negotiated prices

(1) Access

(A) In general

Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or, for a year preceding 2025, an initial coverage limit (described in subsection (b)(3)).

(B) Negotiated prices

For purposes of this part, negotiated prices, subject to subparagraph (D), shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) Medicaid-related provisions

The prices negotiated by a prescription drug plan, by an MA-PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1395w-132(a)(2) of this title) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396r-8(c)(1)(C) of this title.

(D) Application of maximum fair price for selected drugs

In applying this section, in the case of a covered part D drug that is a selected drug (as referred to in section 1320f-1(c) of this title), with respect to a price applicability period (as defined in section 1320f(b)(2) of this title), the negotiated prices used for payment (as

described in this subsection) shall be no greater than the maximum fair price (as defined in section 1320f(c)(3) of this title) for such drug and for each year during such period plus any dispensing fees for such drug.