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

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

Plaintiffs,

vs.

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

Defendants.

Civil Action No. 1:23-cv-00707

PLAINTIFFS' OPPOSITION TO THE GOVERNMENT'S MOTION TO DISMISS

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INTRODUCTION

The Government asserts that Plaintiffs allege only "hypothetical" future injuries to NICA members. MTD2. But that completely disregards the allegations actually set forth in the Complaint. The Government ignores forms of injury that NICA's members are suffering *now*—"constitutionally [de]ficient procedures," including deprivation of "any opportunity to weigh in on key determinations," elevating "[t]he risk of erroneous deprivation" of property interests, Compl. ¶¶ 144, 146-47; being subject to unconstitutionally structured decision-making, *id.* ¶¶ 71-92; and the use of constitutionally excessive fines to enforce the unlawful process, *id.* ¶¶ 57, 61. Those are "here-and-now injur[ies]." *Axon Enter. v. FTC*, 598 U.S. 175, 192 (2023).

The Government asserts that NICA will be harmed, if at all, only by Part B reimbursements that will not be subject to controlled pricing until 2028, which the Government says is too far in the future. But that ignores that NICA is asserting *procedure*-based harms, which a plaintiff may assert "without meeting all the normal standards for redressability and immediacy." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992). Such constitutional harms, standing alone, confer standing on NICA.

Furthermore, NICA separately asserts economic harms that *also* would be sufficient standing alone to establish standing. The Government's focus on Part B ignores the Complaint, which alleges that the IRA will harm NICA's members through not only *Part B* price caps, but also *Part D* caps: NICA's members receive reimbursements for "operating *outpatient* facilities for administering biological treatments" covered "under Medicare Part B *and Part D*." Compl. ¶¶ 4, 21 (emphasis added). That is why NICA alleges that the IRA will harm its members and "Medicare Part B *and Part D* beneficiaries." *Id.* ¶ 21 (emphasis added). And as noted in the attached declarations, one of the ten drugs HHS just selected for the first year of controlled pricing is sold by NICA members through their pharmacies, and NICA members will suffer economic harm from reduced Part D

reimbursements. In any event, the Part B harms on which the Government focuses are sufficiently *certain* for standing purposes, even if a couple years off; the Fifth Circuit has upheld standing for still more remote injuries. *E.g.*, *Am. Forest & Paper Ass'n v. EPA*, 137 F.3d 291, 296 (1998).

The Government's motion should be denied.

BACKGROUND

A. NICA and Its Members

NICA is a non-profit Texas corporation headquartered in Austin, Texas. Compl. ¶ 20. NICA is an association of non-hospital, community-based infusion providers that provide care to patients safely and efficiently in high-quality, lower-cost settings. *Id.* NICA's members include BioTek reMEDys. Ex. A, Decl. of Brian Zweben ¶¶ 2-3 (Zweben Decl.). A full list of NICA's members is available at NICA's website. *See Provider Members*, NICA, https://bit.ly/3EsPN95.

"Infusion" or "infusion therapy" refers to the delivery of medications directly into a patient's veins. Decl. of Brian Nyquist ¶ 3, ECF No. 35-3 (Nyquist Decl.). Millions of patients rely on infusion to treat a host of complex conditions, including Crohn's disease, rheumatoid arthritis, and multiple sclerosis. *Id.* ¶ 6; Compl. ¶ 21. Infusion centers typically provide infusion services more economically and conveniently than hospitals. Nyquist Decl. ¶ 5. Many infusion centers also operate in-house pharmacies that bill Part D plans and dispense medications to patients to self-administer or to be administered by the infusion center. Ex. B, Supp. Decl. of Brian Nyquist (Supp. Nyquist Decl.) ¶¶ 10-11.

B. Medicare's Traditional Market-Based Reimbursement Scheme

A high proportion of NICA members' patients are covered by Medicare. Compl. ¶ 8. For such patients, providers obtain reimbursement from Medicare for drugs that are infused or dispensed. As relevant here, Medicare includes two major prescription drug programs.

First, Medicare Part B covers medically reasonable and necessary medicines that are

furnished incident to a physician's service. *See* 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Medicare Part B has, with certain exceptions, long reimbursed providers based on market prices. Part B reimbursement rates generally are based on the drug's "average sales price"—incorporating a weighted average of manufacturer sales prices to U.S. purchasers—plus a specified percentage (generally 6%). *See* 42 U.S.C. § 1395w-3a. Infusion providers generally obtain reimbursement under Part B for the medicines they furnish. Supp. Nyquist Decl. ¶¶ 11-12; Zweben Decl. ¶ 5.

Second, Medicare Part D allows beneficiaries to enroll in privately operated plans covering outpatient drugs not covered by Part B. *See* 42 U.S.C. § 1395w-102. Part D drug prices also are market-based; Part D plans are administered by private plan sponsors, which negotiate prices with manufacturers. Supp. Nyquist Decl. ¶¶ 15-20. Infusion providers obtain Part D reimbursements for the drugs they dispense through their in-house pharmacies. *Id.* ¶ 12; Zweben Decl. ¶ 5.

C. The IRA's Drug Pricing Program

The IRA upends Medicare's traditional market-based reimbursement system. Although the statute directs HHS to establish a "Drug Price *Negotiation* Program," 42 U.S.C. § 1320f(a) (emphasis added), the Program in fact empowers HHS to set drug prices by administrative *fiat*.

HHS Ranks and Selects "Negotiation-Eligible Drugs"

The IRA directs HHS to rank "negotiation-eligible drugs" based on Medicare's total annual expenditures. *Id.* § 1320f–1(b)(1)(A). Drugs with the highest total expenditures are ranked highest. *Id*. The IRA directs HHS to select ten Part D drugs in 2023, with "maximum fair prices" (MFP) taking effect in 2026; then an increasing number of the highest-ranked drugs will be selected annually. *Id.* § 1320f–1(a)(1)-(4). Part B drugs will be added beginning in 2026, with maximum prices taking effect in 2028. *Id.* § 1320f–1(a)(1), (3). The first ten drugs were selected last month.

HHS Sets "Maximum Fair Prices" Through Sham "Negotiations"

Once drugs are selected, the IRA directs HHS to "enter into agreements with manufactur-

ers" whereby the parties "negotiate to determine (and … agree to) a maximum fair price." *Id.* § 1320f–2(a)(1). Manufacturers of drugs on the first list of selected drugs must enter into these "agreements" by October 1, 2023. *Id.* §§ 1320f(d)(2)(A), 1320f–2(a). The ensuing "negotiations" then must conclude by August 1, 2024. *Id.* §§ 1320f(d)(5), 1320f–3(b)(2)(E).

The IRA's "negotiation" process includes a sham offer/counteroffer framework, *id.* § 1320f–3(b)(2)(C)-(D), but that is where any resemblance to ordinary commercial negotiations ends. The IRA places a "ceiling" on how *high* a price HHS can offer. *Id.* § 1320f–3(c). But with one minor exception, the statute does not limit how *low* a price HHS can demand, *id.* § 1320f–3(b)(2)(F), and it commands HHS to "aim[] to achieve the lowest maximum fair price." *Id.* § 1320f–3(b)(1). While HHS must "consider" specified "factors," the IRA sets no criteria for how HHS must weigh them. *Id.* § 1320f–3(e).

Once HHS has imposed an MFP, the manufacturer must provide "access to such price to" a wide array of individuals, pharmacies, providers, and other entities participating in Medicare. *Id.* § 1320f–2(a)(1). Manufacturers that fail to do so must pay a per-unit penalty of *ten times* the difference between the price charged and the HHS-imposed price. *Id.* § 1320f–6(b).

Noncompliant Manufacturers Must Pay a Crippling "Excise Tax"

The linchpin of the IRA's forced-negotiation scheme is a so-called "excise tax"—a steep, escalating penalty for every day the manufacturer has not, by the deadline, (1) entered into an "agreement" to "negotiate" an MFP, or (2) "agreed" to the MFP that HHS imposes. 26 U.S.C. § 5000D(b). While labeled an "excise tax," it is intended to coerce rather than to raise revenue.

The size of this "tax" is staggering. It applies to *all* U.S. sales of the drug, not just Medicare sales. *See id*. The tax is calculated using a formula based on a high "applicable percentage" of the drug's total cost (price plus tax) that increases for each quarter of noncompliance. *Id.* § 5000D(d). Per the Congressional Research Service, "[t]he excise tax rate" thus "range[s] from 185.71% to

1,900% of the selected drug's price depending on the duration of noncompliance." CRS, *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* 4 (Aug. 10, 2022).

The excise-tax penalty may be "[s]uspen[ded]," 26 U.S.C. § 5000D(c), but only if the manufacturer terminates agreements that eliminate coverage under Medicare Part D, Medicare Part B, *and* Medicaid—not just for drugs subject to the IRA's Drug Pricing Program, but for *all* of the manufacturer's drugs. *See id.*; 42 U.S.C. § 1396r-8(a)(1). That would leave Medicare and Medicaid participants without access to badly needed medications. Compl. ¶¶ 118, 126.

The IRA Limits Notice-and-Comment Rulemaking and Judicial Review

Providers have no say in how HHS implements key parts of the Program. Before implementation decisions are made, there is no right to participate: HHS "shall implement [the Program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f. And the IRA purports to insulate key decisions from scrutiny: "There shall be no administrative or judicial review" of key HHS determinations, including "selection of drugs," "determination of negotiation-eligible drugs," "determination of qualifying single source drugs," and "determination of a maximum fair price." *Id.* § 1320f–7(2)-(3).

D. CMS Guidance and the Initial List of Selected Drugs

In March 2023, CMS issued Initial Guidance on the Drug Pricing Program for 2026. *See* CMS, *Medicare Drug Price Negotiation Program* (Mar. 15, 2023). While CMS "voluntarily" solicited comments on some aspects of the Initial Guidance, it adopted others as final. Those encompass some of the Program's most critical elements, including "the requirements governing the identification of qualifying single source drugs, the identification of negotiation-eligible drugs, the ranking of negotiation-eligible drugs and identification of selected drugs, and the publication of the list of selected drugs." *Id.* at 4. CMS also claimed the unconditional right to "make changes to any policies, including policies on which CMS has not expressly solicited comment." *Id.* at 2.

In June 2023, CMS issued Revised Guidance for 2026. *See* CMS, *Medicare Drug Price Negotiation Program* (June 30, 2023). In August, CMS announced the first ten "qualifying single source drugs" selected for "negotiation." CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (August 2023), https://bit.ly/3Ewqkvg.

ARGUMENT

I. THIS COURT HAS JURISDICTION OVER NICA'S CLAIMS

A. NICA Has Standing

"A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *Babbitt v. United Farm Workers Nat. Union*, 442 U.S. 289, 298 (1979). "But one does not have to await the consummation of threatened injury to obtain preventive relief." *Id.* (cleaned up). The plaintiff need only show that "the threatened injury is certainly impending, or there is a substantial risk that the harm will occur," *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565 (2019) (citation omitted); it is enough that the injury is "fairly likely," *Crawford v. Hinds Cnty. Bd. of Supervisors*, 1 F.4th 371, 376 (5th Cir. 2021). Here, the Complaint alleges two independent forms of injury sufficient for Article III: constitutional and economic. And Plaintiffs have identified a named NICA member suffering both forms of injury.

1. NICA Alleges Constitutional Injuries

The Government's motion rests entirely on a mischaracterization of NICA's injuries. Attempting to portray NICA's claims as limited to reductions in far-off reimbursements, the Government ignores harms the IRA inflicts *now* by depriving NICA's members of constitutionally required due process, impermissibly delegating legislative power to the agency, and coercing compliance via excessive fines. These are quintessential procedural injuries: an unconstitutional decision-making scheme.

"A plaintiff can show a cognizable injury if it has been deprived of 'a procedural right to

protect its concrete interests.'" *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (cleaned up); *accord Lujan*, 504 U.S. at 573 n.8. "[A] party is 'interested' in any agency proceeding when that proceeding has the potential to deprive it of some material benefit." *Kinetica Partners, LLC v. Dep't of Interior*, 505 F. Supp. 3d 653, 672-73 (S.D. Tex. 2020). "The loss is not merely the subsequent deprivation, but the right not to suffer a deprivation without proper process." *Bertulli v. Indep. Ass'n of Cont'l Pilots*, 242 F.3d 290, 295 (5th Cir. 2001). Because "'procedural rights' are special," a "person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy." *Lujan*, 504 U.S. at 572 n.7. A "[p]laintiff can establish injury-in-fact by showing that it was deprived of a procedure designed to protect it from the *risk* of real harm." *Kinetica Partners*, 505 F. Supp. 3d at 672 (emphasis added). A "litigant has standing if there is *some possibility*" enforcing the procedural right "will prompt the [defendant] to reconsider the decision." *Mass. v. EPA*, 549 U.S. 497, 518 (2007) (emphasis added). The Government's motion never engages with the "special" nature of procedural injuries: A litigant asserting a procedural injury need not "establish with any certainty" that the procedural error "will cause" harm and may challenge a process although its outcome "will not be completed for many years." *Lujan*, 504 U.S. at 572 n.7.

The Government ignores NICA's *immediate* procedural injury to focus on the *downstream* property interests (reimbursement) that the IRA threatens. Straining to reframe NICA's injuries as purely monetary harms, the Government asserts (MTD11-12) that NICA must show that its members "will actually see reduced profits from administering a particular selected drug after the negotiated price goes into effect." But that is not the standard. Although a plaintiff asserting a "deprivation of a procedural right" must identify "some concrete interest that is affected by the deprivation," *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009), a "*risk* of real harm" in the future is enough, *Kinetica*

Partners, 505 F. Supp. 3d at 672 (emphasis added). Indeed, "[i]f a plaintiff also had to prove a free-standing substantive injury, there would be no reason to allow procedural-injury standing." *Id*.

In *LifeNet, Inc. v. HHS*, 617 F. Supp. 3d 547, 559 (E.D. Tex. 2022), for example, an air-ambulance service (LifeNet) had standing to challenge a rule establishing an arbitration process for out-of-network reimbursement. The Government argued that LifeNet lacked standing because it was merely a "nonparticipating provider" that was paid a "fixed amount" under contract with a *separate* provider, and only the separate provider (not LifeNet) was able to use the arbitration process. *Id.* at 558-59. But LifeNet had standing because the arbitration rule "strip[ped] away" procedural protections for its interests—creating a "significant risk" that, as a result of receiving lower reimbursements, the separate provider would terminate its agreement with LifeNet. *Id.* at 559. The court rejected the Government's argument that this injury was too "speculative." *Id.* at 560.

In *Beeman v. TDI Managed Care Servs.*, 449 F.3d 1035, 1039-40 (2006), the Ninth Circuit applied this standard to reject essentially the argument the Government makes here. The court upheld pharmacies' standing to assert procedural injuries based on the "possibility" that allegedly deficient processes would compromise their eventual reimbursement rates. The statute there required pharmaceutical benefit managers (PBMs) to disclose studies on drug pricing. Although PBMs would be able to "unilaterally set" reimbursements later, the pharmacy plaintiffs successfully argued that they had a *procedural* right to the studies because "recipients of the studies could use th[e] information to evaluate what should be actual market prices, negotiate fairer reimbursement rates, lobby for legislative intervention should that be necessary, and ascertain payments made to PBMs." *Id.* The Ninth Circuit agreed that the procedural injury was "a lack of information, the denial of which then adversely affect[ed] *the possibility* such information [would] improve reimbursement rates *at some point in the future*." *Id.* at 1040 (emphasis added). The court rejected the PBMs' argument that "the

use of the information in this manner" was "too remote to create standing." *Id.* at 1039.

Here, "[t]he loss" alleged "is not merely the subsequent deprivation" of property—as the Government contends—"but the right not to suffer a deprivation without proper process." *Bertulli*, 242 F.3d at 295. NICA's members are *already* experiencing that harm. They are not mere busybodies, but participants in the Medicare program whose businesses the IRA will upend. The threat to their concrete interests—fair and lawful reimbursements—is at least as concrete as the possible future contractual harm in *LifeNet* or the threat to eventual pharmacy payments in *Beeman*.

Due Process. The IRA deprives NICA's members of "any opportunity to weigh in on key determinations," and these "constitutionally [de]ficient procedures" multiply "[t]he risk of erroneous deprivation" of property interests "in adequate reimbursement," the "ability to continue serving Medicare patients," and even the ability "to stay in business." Compl. ¶¶ 144, 146-47. NICA's members have a concrete "interest in receiving the reimbursements to which they are statutorily entitled, as well as to continue operating their businesses and providing treatment to patients," Compl. ¶ 15. The constitutional harm "is not merely the subsequent deprivation, but the right not to suffer a deprivation without proper process." *Bertulli*, 242 F.3d at 295.

The Complaint identifies ways in which IRA's constitutionally inadequate procedures are currently harming Plaintiffs, including NICA's members. The IRA requires HHS to implement the program for 2026-2028 by "program guidance," rather than notice-and-comment rulemaking that would permit public input. IRA §§ 11001(c), 11002(c). The IRA compounds this barrier by providing "no administrative or judicial review" of key determinations, including "[t]he selection of drugs," "the determination of negotiation-eligible drugs," "the determination of qualifying single source drugs," and "[t]he determination of a maximum fair price." 42 U.S.C. § 1320f–7(2)-(3); *see* Compl. ¶ 69. That is a clear "deprivation of a procedural right." *EEOC*, 933 F.3d at 447.

To have standing, NICA need not show that inadequate procedures *will* lead to particular outcomes, or *when* they will do so, only "some possibility" that adequate procedures would protect its interests. *EPA*, 549 U.S. at 518. That "possibility" is plain here. For example, "CMS adopted its interpretation of 'qualifying single source drug' and 'marketing' as final …, without notice or any opportunity for manufacturers, providers, patients, or the public to comment." Compl. ¶ 91 (cleaned up). The agency misinterpreted "qualifying single source drug" to include "distinct drugs that treat two different diseases but share the same active moiety." *Id.* ¶ 83. This definition "harms" NICA's members by covering "a broader swath of the treatments providers administer," so providers "have their reimbursement rates slashed" for a broader swath of drugs. *Id.* ¶ 88. Given the chance, NICA would have opposed that "broad interpretation," which "strays far from the statutory text." *Id.* ¶ 84.

Improper Delegation. The IRA also harms NICA through an unconstitutional delegation of legislative power to HHS. The Constitution's "separation of governmental powers" is "essential to the preservation of liberty." *Mistretta v. US*, 488 U.S. 361, 380 (1989). For that reason, "subjection to an unconstitutionally structured decisionmaking process"—such as "an agency … wielding authority unconstitutionally"—is an injury "irrespective of [the] outcome." *Axon Enter.*, 598 U.S. at 189, 192. Rights to a "[]constitutionally structured decisionmaking process … are 'effectively lost' if review is deferred"; being subject to improper decision-making is itself a "here-and-now injury," regardless of whether it has yet produced financial harm. *Id.*

In *Texas v. United States*, 497 F.3d 491, 495 (5th Cir. 2007), for example, Texas had standing to challenge a regulation requiring it to negotiate with Indian tribes regarding governance of gambling activities. The Fifth Circuit "agree[d]" with Texas that "standing exist[ed]" because the regulation "violate[d] the … nondelegation doctrine[]" and inflicted "the injury of being compelled to participate in an invalid administrative process." *Id.* at 499, 496-97. "Texas's only alternative to

participating in this allegedly invalid process [was] to forfeit its sole opportunity to comment upon [tribal] gaming regulations, a forced choice that [was] itself sufficient to support standing." *Id.* at 497 (citation omitted).

The IRA's improper delegation of legislative power inflicts a similar injury. "[T]he IRA's novel structure concentrates substantial power over a significant part of the economy in an administrative agency with no checks to ensure public accountability." Compl. ¶ 81. Congress unconstitutionally "delegated unfettered discretion to HHS to set prices"—including by redefining key statutory terms—which is "a wholly legislative function." *Id.* ¶¶ 75, 79. The delegation is an obvious effort to escape accountability: If Congress had adopted price controls transparently, it would have faced "significant public criticism." *Id.* ¶ 5. The IRA inflicts a separation-of-powers injury by imposing on NICA members legislative decisions rendered by an unaccountable agency. *See Axon Enter.*, 598 U.S. at 192. That injury, which has *already* been inflicted by HHS's improper rulemaking and which a ruling in NICA's favor would remedy, independently supports standing.

Excessive Fines. For similar reasons, the IRA harms NICA by imposing MFPs via a "negotiation" process that depends on the threat of unconstitutionally excessive fines. The massive, escalating "excise tax" is the "hammer through which the Drug Pricing Program is enforced." Compl. ¶ 57. Without it, manufacturers could decline unfairly low prices; the excise tax prevents manufacturers from "walk[ing] away" from sham negotiations and "doing anything but acquiescing to whatever price HHS demands." *Id.* ¶¶ 57, 61. The excise tax thus is the linchpin of the IRA's price-setting scheme: It undermines manufacturers' ability "to hold the line against [agency] overreaching." *Ass'n of Am. R.R.s v. DOT*, 896 F.3d 539, 543 (D.C. Cir. 2018) (cleaned up).[1]

[1] Although the IRA's compliance mechanism works by exerting influence on manufacturers, a litigant has standing when complained-of harm results from "the predictable effect of Government action on the decisions of third parties." *Dep't of Com.*, 139 S. Ct. at 2566 (citation omitted). A plaintiff can rely on governmental action aimed at third parties if those "third parties … react in

2. NICA Alleges an Economic Injury

Although NICA's constitutional harms suffice, the Government also underplays the economic harms the IRA will imminently inflict on NICA's members, wrongly asserting they will suffer no injury until at least 2028, after Part B infusion drugs have effective MFPs. To adequately plead economic injury, a plaintiff must allege "that it will *likely* suffer financial harm." *LifeNet*, 617 F. Supp. 3d at 559 (emphasis added); *see Bryant v. Yellen*, 447 U.S. 352, 368 (1980) (economic injury sufficiently certain where challenged statute was "likely" to affect whether property would be sold at below-market prices). NICA's members *will* suffer economic harm as a result of the MFP on Part D and Part B drugs—indeed, a Part D drug dispensed by NICA members has *already* been selected.

The Government's premise (MTD9-10) is that "infusion drugs administered under Part B by NICA members … will not be affected until 2028," so far in the future that injuries are "too speculative." But as Plaintiffs have alleged and declared, Compl. ¶¶ 21, 49; Supp. Nyquist Decl. ¶ 19, NICA's members administer Part B drugs that *will* become eligible for MFPs; the Government merely argues (MTD10) that Part B drugs are not subject to the MFP *quite yet*. Financial harm that "*will*" occur confers associational standing even when the harm will manifest in future years. *See Am. Forest & Paper Ass'n*, 137 F.3d at 296. In *American Forest*, for example, EPA required Louisiana to obtain its approval before granting discharge permits. *Id.* at 294. A trade association challenged the rule even though it "ha[d] not alleged that any of its members ha[d] applied for a new permit or sought to modify an existing one." *Id.* EPA responded as the Government does here: the claimed injury was "linked by a series of dubious assumptions about the circumstances under which EPA might" deny a permit. *Id.* at 296. But the Court "d[id] not find the permit holders' injuries speculative," since permits "must be renewed every five years," and "[m]odifications to

predictable ways." *Id.* Plaintiffs have alleged that manufacturers have "no choice" but to submit in view of the exorbitant excise tax. Compl. ¶¶ 21, 55, 61, 64.

existing permits must also be cleared with [the agencies]." *Id.* Permit holders' "need to comply, coupled with EPA's frank announcement of its intentions, belie[d] the agency's claim that any injury [was] speculative." *Id.*

Here, the financial injury to NICA's members from lost Part B revenue for drugs subject to MFPs is just as "imminent" and non-"speculative." *Id.* "[W]ithin ten years, *half* of all Medicare drug spending will be for drugs whose price is set under th[e] program." Compl. ¶ 49. Because NICA members' businesses depend on dispensing and administering high-expenditure Part B drugs, there is no question that "a significant and growing number of" Part B drugs NICA members dispense *will be* subject to MFPs. *Id.* ¶ 21. This will occur no later than 2028, which is comparable to the "five year[]" period at issue in *American Forest*. 137 F.3d at 296.

In any event, the Government's sole focus on Part B drugs ignores key allegations in the Complaint—and, for that matter, reality. "NICA members that provide infusion services and pharmaceuticals to Medicare patients are reimbursed through both Part B and Part D." Supp. Nyquist Decl. ¶ 10. The Complaint thus alleges that the IRA will harm NICA's members not only through *Part B* price caps, but also through *Part D* price caps: "members of NICA" receive reimbursements for "operating *outpatient* facilities for administering biological treatments," Compl. ¶ 4 (emphasis added), and these treatments are covered "under Medicare Part B *and Part D*," *id.* ¶ 21 (emphasis added). That is why NICA alleges that IRA pricing provisions will harm both its members and "Medicare Part B *and Part D* beneficiaries." *Id.* (emphasis added). "[C]onstru[ing] the complaint in favor of [Plaintiffs]" means "accept[ing] as true" the allegations that NICA's members will suffer injury from Part D price caps. *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

Indeed, this has already occurred precisely as alleged. The first list of drugs selected for negotiation includes Stelara®, which several NICA members—including BioTek—administer, and

for which they are reimbursed "under both Part B and Part D." Supp. Nyquist Decl. ¶ 16; *see id.* ¶ 12; Zweben Decl. ¶ 5; *see also* HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023), https://bit.ly/460imGp. Stelara® will be subject to the MFP in 2026. When that occurs, "the margins that NICA members earn on those drugs will decrease, causing them to incur losses on services to Medicare patients." Compl. ¶ 66. Details of that process are set forth below.[2]

For Part D drugs, "the negotiated prices used for payment … shall be no greater than the maximum fair price … for such drug and for each year during such period plus any dispensing fees for such drug." 42 U.S.C. § 1395w-102(d)(1)(D). Under Part B, "the amount of payment" to providers will be "106 percent of the maximum fair price." *Id.* § 1395w-3a(b)(1)(B). Once a drug has been selected, therefore, "reimbursement rates … will be based on the IRA's 'maximum fair price,' and revenues will fall precipitously." Compl. ¶ 21. Plaintiffs allege that "these reimbursement changes will cause major revenue decreases for many of NICA's members and that, as a result, a substantial number of NICA's members will have no choice but to scale back operations, to reduce or eliminate the services they provide to Medicare patients, or even to go out of business." *Id.*

Further, although the 2026 MFP applies only to Part D drugs, it will also lower providers' *Part B* reimbursements for selected drugs (including Stelara®) that are administered under both Parts.

[2] The Government argues (MTD11) that "Plaintiffs do not allege any details regarding how [NICA's members'] reimbursement[s] will be determined." As the following paragraphs show, Plaintiffs *do* allege such details (now supplemented by declarations). And in any event, "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan*, 504 U.S. at 561. In *Bennett v. Spear*, for example, plaintiffs had standing to challenge "restrictions on lake levels" because they "alleg[ed] that the amount of available water [would] be reduced and that they [would] be adversely affected thereby." 520 U.S. 154, 167-68 (1997). The Court explained that, from this "general factual allegation[]," "it [was] easy to presume specific facts under which [the] petitioners [would] be injured—for example, the Bureau [of Reclamation's] distribution of the reduction pro rata among its customers." *Id.* at 168. It is just as "easy to presume specific facts under which" NICA's members will suffer economic injury as a result of the IRA.

See Supp. Nyquist Decl. ¶¶ 13-16. Part B "providers generally are reimbursed by Medicare based on the average sales price of the drug." Compl. ¶ 21; Supp. Nyquist Decl. ¶ 8. Currently, the typical Part B reimbursement is "106 percent" of the drug's "average sales price." 42 U.S.C. § 1395w–3a(b)(1)(B); *see also* Supp. Nyquist Decl. ¶ 8. For selected drugs that are reimbursed under both Part D and Part B, the 2026 MFP will lower the "average sales price," because it is calculated using sales *under both Parts*. *See generally* 42 U.S.C. § 1395w–3a; 86 Fed. Reg. 64996, 65220 (Nov. 19, 2021). When the MFP takes effect, therefore, "the six percent margin paid to the provider [will] decrease[] in absolute terms, and the provider [will be] financially harmed as a result." Supp. Nyquist Decl. ¶ 15. Thus, because "NICA's members provide and are reimbursed for Stelara® under both Part B and Part D," its average sales price will drop when the MFP takes effect in 2026, and "the margins that NICA members earn with respect to Stelara® will shrink in absolute terms." *Id.* ¶ 16. "The upshot is that NICA's members will be affected by impending price negotiation with respect to Stelara® regardless of whether they are reimbursed for Stelara® under Part D or Part B." *Id.* ¶ 13.

Finally, because the IRA impairs NICA members' reimbursements, it "is *already* impacting the ability of NICA's members," some of whom "are currently courting private equity investments," "to raise debt and equity funding." Supp. Nyquist Decl. ¶ 20 (emphasis added). This loss of business opportunity is yet another concrete harm. *See, e.g.*, *El Paso Cnty. v. Trump*, 408 F. Supp. 3d 840, 851 (W.D. Tex. 2019) (injury-in-fact exists "where the economic injury stems from the 'loss of a non-illusory opportunity' to obtain 'a benefit'" (citation omitted)).

Waving away all of these harms—and presuming that NICA does not know its own members' interests—the Government contends (MTD11) that Plaintiffs cannot demonstrate economic harm to NICA's members because "it is possible that [a] provider's *savings* on drug-acquisition costs" under 42 U.S.C. § 1320f-2(a)(3) "would outweigh any losses caused by" the

IRA. The Government's speculation that reducing drug prices and reimbursements would somehow benefit NICA (*see* MTD11) contradicts the Complaint's detailed pleadings, Compl. ¶¶ 21, 39, 66. And the Government provides no reason that the purported "savings," which it admits are "hypothetical," actually "would outweigh any losses." MTD11. It merely suggests (MTD11) the outcome "is possible," ignoring that the Court "must construe the complaint in favor of the complaining party." *Warth*, 422 U.S. at 501. Even if the Government might later introduce evidence to support this "possib[ility]," "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan*, 504 U.S. at 561 (cleaned up).

In any event, "standing analysis is not an accounting exercise." *Texas v. United States*, 809 F.3d 134, 156 (5th Cir. 2015) (citation omitted). "Once 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." *Id.* at 155-56 (quoting 13A Charles A. Wright et al., Fed. Prac. & Proc. § 3531.4, at 147 (3d ed. 2015)). In stock-manipulation cases, for example, investors have standing without having to demonstrate that they did not benefit from the defendant's price manipulation, because "the mere fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing." *In re Barclays Liquidity Cross & High Frequency Trading Litig.*, 390 F. Supp. 3d 432, 444 (S.D.N.Y. 2019); *accord Alaska Elec. Pension Fund v. Bank of Am. Corp.*, 175 F. Supp. 3d 44, 53 (S.D.N.Y. 2016).

3. NICA Has Identified Specific Members Harmed by the IRA

The Government argues (MTD8) that dismissal is warranted because the Complaint does not specify injuries to named NICA members. This argument is moot, since Plaintiffs' declarations specify harm to BioTek, a NICA member. "[I]t is within the trial court's power to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff's standing." *Warth*, 422 U.S. at 501; *see Ambraco, Inc. v.*

Bossclip B.V., 570 F.3d 233, 238 (5th Cir. 2009). And in any event, there is "no precedent holding that an association must set forth the name of a particular member in its complaint in order to survive a Rule 12(b)(1) motion to dismiss based on a lack of associational standing." *Hancock Cnty. Bd. of Sup'rs v. Ruhr*, 487 F. App'x 189, 198 (5th Cir. 2012). *Summers* (cited at MTD8-9) involved the validity of a nationwide injunction based on record evidence, not a motion to dismiss, and courts have rejected the Government's reading of *Summers* time and again. *See, e.g.*, *Am. C.R. Union v. Martinez-Rivera*, 166 F. Supp. 3d 779, 804 (W.D. Tex. 2015) ("A plaintiff is not required to name names in a complaint in order to properly allege injury in fact to its members." (citing *Summers*)).

B. No Jurisdictional Prerequisites Bar NICA's Claims

The Government also contends that the complaint should be dismissed for "fail[ure] to satisfy … the channeling requirements of the Medicare Act." MTD12. In the Government's view, Plaintiffs were required under 42 U.S.C. § 405 to present their facial constitutional claims against the IRA in administrative proceedings before bringing suit, and Plaintiffs' failure to affirmatively plead presentment and exhaustion in the complaint is an independent basis for dismissal.

On the face of the statute, however, the Medicare Act's channeling provisions do not apply. Section 405(g) authorizes judicial review of "any final decision of the Commissioner of Social Security made after a hearing to which he was a party." Section 405(h) then provides that "[n]o … decision of the Commissioner of Social Security shall be reviewed by any person … except as herein provided"—*i.e.*, as provided in Section 405(g). The government says that Section 405 applies to reimbursement decisions under Medicare via Sections 1395ff and 1395ii of Title 42. By its plain terms, Section 1395ff provides for "judicial review … as is provided in section 405(g)," but *only* with respect to appeals from an "initial determination [of benefits] under subsection (a)(1)." 42 U.S.C. § 1395ff(b)(1). The constitutional challenges to the IRA at issue plainly are not challenges to "initial determination[s] of benefits." "Agency actions that are not

'initial determinations' are therefore not eligible for §405(g) judicial review under §1395ff(b)(1)(A)." *D&G Holdings, LLC v. Becerra*, 22 F.4th 470, 474 n.4 (5th Cir. 2022).

Nor does Section 1395ii apply. It provides that the Section 405(h) review scheme "shall … apply *with respect to this subchapter*," 42 U.S.C. § 1395ii (emphasis added)—that is, with respect to subchapter XVIII of the Social Security Act, known as the Medicare Act, which is codified at 42 U.S.C. §§ 1395-1395lll. But the Drug Pricing Program that Plaintiffs challenge *was not established* under subchapter XVIII, but rather in subchapter XI:

> PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e–3) the following new part:

IRA § 11001(a), 136 Stat. 1833.

Since Plaintiffs challenge a program in subchapter XI, "the plain text of the relevant statutes demonstrates that the plaintiffs are not subject to the jurisdictional bar in section 405(h)." *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 509 F.Supp.3d 482, 491 (D. Md. 2020) (*ACCC*). In *ACCC*, the plaintiffs challenged the legality of an administrative rule, "promulgated pursuant to 42 U.S.C. § 1315a, which allows the agency to test payment and service delivery 'models.'" *Id.* at 488. Since the challenged rule was promulgated under § 1315a, the court explained, "the plaintiffs' claims ar[o]se under 42 U.S.C. § 1315a, which is in subchapter XI …, whereas section 1395ii is in subchapter XVIII." *Id.* at 491. And the plaintiffs did "not make any specific or individual claims for reimbursement under subchapter XVIII." *Id.* The same analysis applies here: Plaintiffs have not submitted reimbursement claims under subchapter XVIII, and their facial constitutional challenges arise under the IRA's Drug Pricing Program in subchapter XI.

The Government tries to avoid this obvious conclusion by arguing (MTD14) that NICA's claims ultimately depend "on its desire for greater reimbursements under the Medicare Act." That is incorrect: NICA's *claims* are constitutional challenges under the separation of powers, Excessive

Fines Clause, and Due Process Clause, *see* Compl. at 53-57 (Claims for Relief); NICA's *standing* is grounded in constitutional harm from the operation of the IRA, *see supra* Section I.A.1; and NICA's *requested relief* is invalidation of the Drug Pricing Program, *see* Compl. at 57. The Government's cases are not to the contrary. Indeed, in *every case* cited by the Government, the challenge was to or arose under a provision of subchapter XVIII. *See, e.g.*, *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 7 (2000) (plaintiff challenged regulations under 42 U.S.C. § 1395i-3, which is in subchapter XVIII).[3] The Government cites no case like this one—a facial constitutional challenge to a statute in a *different* subchapter—where Section 405 channeling was found to apply.

Other IRA provisions confirm that Section 405 channeling does not apply. Rather than channeling IRA decisions *through* the agency, Congress expressly exempted them from *any* administrative review. If there can be "no administrative … review" *at all* for such determinations, 42 U.S.C. § 1320f-7(2)-(3), then obviously there can be no channeling of challenges involving such determinations. Thus, far from trying to channel legal challenges to the IRA's price-setting scheme through the agency via Section 405, Congress was focused on *precluding* administrative review of the IRA's price-setting scheme.

II. VENUE IS PROPER IN THIS DISTRICT FOR ALL OF PLAINTIFFS' CLAIMS

"[V]enue is proper as to all plaintiffs if suit is brought in a district where any one or more of the plaintiffs resides." *Crane v. Napolitano*, 920 F. Supp. 2d 724, 746 (N.D. Tex. 2013), *aff'd*,

[3] *See, e.g.*, *Heckler v. Ringer*, 466 U.S. 602, 610 & n.7 (1984) (plaintiffs alleged Medicare payment rules were inconsistent with 42 U.S.C. § 1395y); *Cmty. Oncology All. v. OMB*, 987 F.3d 1137, 1143 (D.C. Cir. 2021) (plaintiffs alleged "members have not received the full reimbursement allegedly owed to them under 42 U.S.C. § 1395w-3a"); *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 652, 656 (5th Cir. 2012) (plaintiffs challenged lack of reimbursement under 42 U.S.C. §1395nn); *Johnson v. HHS*, 142 F. App'x 803, 804 (5th Cir. 2005) (plaintiff challenged agency's right to settlement proceeds under Medicare Secondary Payer statute, 42 U.S.C. § 1395y).

783 F.3d 244 (5th Cir. 2015). A court "must accept as true all allegations in the complaint and resolve all conflicts in favor of the plaintiff." *Texas v. HHS.*, --- F. Supp. 3d ---- 2023 WL 4629168, at *3 (W.D. Tex. July 12, 2023). "[T]he court is permitted to look at evidence beyond simply those facts alleged in the complaint and its proper attachments." *Id.* (citation omitted). Here, NICA is a resident of Austin, Texas. And because Plaintiffs have presented "sufficient facts to support [NICA]'s standing to assert [its] claims," NICA "was not improperly or collusively joined." *Crane*, 910 F. Supp. 2d at 747. Accordingly, "venue is proper in this district as to all plaintiffs." *Id.*

Even if this Court concludes that NICA has standing to assert only some of its claims, venue still would still be proper as to all claims under the pendent venue doctrine. "Under this doctrine, venue exists where claims arise out of the same operative facts even if venue over the pendent claim would not otherwise be proper." *Droplets, Inc. v. Adobe Sys., Inc.*, 2008 WL 11446843, at *4 (E.D. Tex. Aug. 29, 2008); *see Merchs. Fast Motors Lines, Inc. v. ICC*, 5 F.3d 911, 921 (5th Cir. 1993) (recognizing doctrine). Courts determining pendent venue consider whether "judicial economy is best served by adjudicating th[e] claims in a single forum." *Shippitsa Ltd. v. Slack*, 2019 WL 3304890, at *7 (N.D. Tex. July 23, 2019) (citation omitted).

Here, all claims asserted by all Plaintiffs arise out of the same nucleus of operative facts: a Drug Pricing Program that authorizes HHS to impose unfair prices without external input or accountability. In this facial constitutional challenge, all facts relevant to the claims concern the IRA itself and the relevant constitutional provisions. Adjudicating these claims together will "further[] the goals of judicial economy, convenience, and fairness to the litigants." *Seamon v. Upham*, 563 F. Supp. 396, 399 (E.D. Tex. 1983). Splitting the claims into multiple lawsuits in multiple districts, by contrast, would create needless delay and complication for the parties and the judicial system.

CONCLUSION

This Court should deny the Government's Motion to Dismiss.

Dated: September 25, 2023

Respectfully submitted,

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Counsel for Plaintiff Pharmaceutical Research and Manufacturers of America

Exhibit A

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

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

Plaintiffs,

v.

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

Defendants.

Civil Action No. 1:23-cv-00707

DECLARATION OF BRIAN ZWEBEN

I, Brian Zweben, declare and state as follows:

1. I am over eighteen (18) years of age, am of sound mind, and have never been convicted of a felony. I am fully capable and competent to testify to and have personal knowledge of the matters stated in this declaration. Every statement of fact contained herein is true and correct to the best of my knowledge.

2. I am the President of BioTek reMEDys ("BioTek"). BioTek is an integrated infusion therapy provider and specialty pharmacy that supplies therapies, biologics, and pharmaceuticals to patients suffering from chronic conditions and rare diseases.

3. BioTek consists of three entities, which are individually and collectively members of the National Infusion Center Association ("NICA"). Valustar, LLC ("BioTek South") is a Delaware limited liability company doing business in Texas. AZBDBR, LLC ("BioTek West") is a Delaware limited liability company doing business in Arizona. BioTek reMEDys, Inc. ("BioTek Parent") is a Delaware corporation doing business in Delaware and owns 100% of BioTek South and BioTek West. The three BioTek entities are referred to collectively herein as "BioTek." BioTek has been a member of NICA since at least 2020.

4. BioTek West, BioTek South, and BioTek Parent dispense pharmaceuticals through their specialty pharmacies and are frequently reimbursed for those pharmaceuticals under Medicare Part D. BioTek also administers pharmaceuticals directly through infusion therapy and is frequently reimbursed for those pharmaceuticals under Medicare Part B. Medicare patients make up a large proportion of the patients to whom BioTek provides pharmaceuticals and infusion therapy.

5. One of the drugs administered and dispensed by BioTek South, BioTek West, and BioTek Parent is Stelara (ustekinumab). The first dose of Stelara is generally administered intravenously, while subsequent doses are self-administered via injection. When BioTek administers Stelara to a patient intravenously at one of its infusion centers, BioTek is reimbursed under Part B. When BioTek dispenses Stelara to a patient through one of its pharmacies for self-administered injections by the patients, BioTek is reimbursed under Part D.

6. Pursuant to 28 U.S.C. § 1746 and other appliable law, I declare under penalty of perjury that the foregoing is true and correct, and within my personal knowledge.

Executed this 19 day of September, 2023.

Brian Zweben Digitally signed by Brian Zweben Date: 2023.09.19 16:27:09 -04'00'

Brian Zweben

Exhibit B

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

NATIONAL INFUSION CENTER ASSOCATION, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	Civil Action No. 1:23-cv-00707

SUPPLEMENTAL DECLARATION OF BRIAN NYQUIST

I, Brian James Nyquist, declare and state as follows:

1. I am over eighteen (18) years of age, am of sound mind, and have never been convicted of a felony. I am fully capable and competent to testify to and have personal knowledge of the matters stated in this declaration. Every statement of fact contained herein is true and correct to the best of my knowledge.

2. I am the chief executive officer of the National Infusion Center Association ("NICA"), a nonprofit trade association. NICA is the nation's voice for non-hospital, community-based infusion providers.

3. "Infusion" or "infusion therapy" refers to the delivery of medications directly into the veins of a patient. Infusion therapies typically are used when oral medications are insufficient, inappropriate, or unavailable. Many of the newest and most effective treatments are therapeutic biological products (or "biologics") derived from living cells. Biologics cannot be taken orally in pill form, as they will not remain molecularly stable and effective after exposure to the digestive system. Thus, they must be administered directly into the blood stream intravenously via infusion therapy or indirectly via injection therapy.

4. Biologics are critical treatments for many chronic diseases. They reduce healthcare consumption by decreasing the use of opioid-based pain medications, optimizing health outcomes, and maximizing quality of life. Most importantly, biologics minimize the physical, emotional, and economic burdens of disease. Innovative drugs and biologics save patients' lives.

5. Certain biologics therapies must be administered and supervised by a medical provider, and patients needing those treatments traditionally have two options for receiving them: infusion centers or hospitals. Infusion centers are non-hospital locations, such as specialist physicians' offices or freestanding ambulatory centers, where drug treatments can be administered by an appropriate provider. Hospitals also offer these therapies, but hospital administration is typically more expensive and takes longer than administration at an infusion center.

6. Millions of patients rely on biologics to treat a variety of complex, chronic conditions. Many of the newest infusible medications are used to treat autoimmune conditions, which are diseases in which the body's immune system turns on itself, attacking healthy cells mistaking them as foreign cells. Examples of autoimmune disorders include inflammatory bowel diseases, including Crohn's disease and ulcerative colitis; rheumatoid arthritis; multiple sclerosis; psoriasis;

psoriatic arthritis; and lupus. Infusion therapy is also used to treat other conditions, such as resistant infections, many types of cancer, migraines, osteoporosis, osteoarthritis, and hemophilia.

7. In general, patients receiving infusion therapies require such treatment because (1) their condition is unresponsive to, or difficult to treat with, conventional treatment modalities; (2) the patient has exhausted conventional treatment options; or (3) the patient's condition is so aggressive and severe that, in their physician's medical opinion, a therapeutic biologic is necessary.

8. NICA's members are in the business of extending and improving patients' lives by providing them with new and innovative drugs and biologics. To continue serving patients, NICA members must earn a margin on the infusion services and pharmaceuticals they provide. That margin consists of the difference between (a) the cost incurred to acquire and provide pharmaceuticals and infusion treatments to the patient; and (b) the revenue generated by providing the infusion service and/or pharmaceuticals, which historically is based on the average sales price (ASP) of the pharmaceutical plus 6%, plus a reimbursement amount for the administration services. The margin earned by NICA members on infusion services and pharmaceuticals allows NICA members to cover operating costs, maintain fiscal solvency, and continue serving patients. Most of NICA's members are small businesses that are already struggling to subsist on narrow margins. If those margins are compressed, NICA members will suffer financial harm, and some may go out of business.

9. Medicare beneficiaries constitute a high proportion of patients in the majority of infusion centers—including NICA's members. For some infusion centers, Medicare patients are the vast majority of the patients that provider serves.

10. NICA members that provide infusion services and pharmaceuticals to Medicare patients are reimbursed through both Part B and Part D.

11. For example, BioTek reMEDys ("BioTek") is an integrated infusion therapy provider and specialty pharmacy that supplies therapies, biologics, and pharmaceuticals to patients suffering from chronic conditions and rare diseases. BioTek dispenses pharmaceuticals through their specialty pharmacies and is frequently reimbursed for those pharmaceuticals under Medicare Part D. BioTek also administers pharmaceuticals directly through infusion therapy and is frequently reimbursed for those pharmaceuticals under Medicare Part B. BioTek has been a member of NICA since at least 2020.

12. One of the drugs administered and dispensed by BioTek is Stelara® (ustekinumab). The first dose of Stelara® is generally administered intravenously, while subsequent doses are self-administered via injection. When BioTek administers Stelara® to a patient intravenously at one of its infusion centers, BioTek is reimbursed under Part B. When BioTek dispenses Stelara® to a patient for self-administered injections, BioTek is reimbursed under Part D. Other NICA members are also reimbursed for Stelara® provided to patients under Part D and Part B.

13. Further, price negotiations with respect to Stelara® reimbursements under Part D will affect reimbursement rates for NICA members who are reimbursed for providing Stelara® under Part B. For example, a 130 mg vial of Stelara® (National Drug Code No. 57894-0054-27) is most commonly administered by providers and billed under Part B—but in some instances, it may be billed under Part D when acquired through a specialty pharmacy. The government's calculation of total gross expenditures for Stelara® under Part D for Initial Price Applicability Year (IPAY) 2026 includes this National Drug Code ("NDC"), and NICA expects that the Maximum Fair Price ("MFP") for Stelara® will likewise include and apply to this NDC. Since this NDC is also used to

calculate the ASP for Stelara® dosages administered under Part B, the ASP for Stelara® under Part B will be impacted by price negotiations with respect to reimbursements for Stelara® under Part D. In short, a decrease in reimbursements rates for Stelara® under Part D will cause a decrease in reimbursement rates for Stelara® under Part B. The upshot is that NICA's members will be affected by impending price negotiations with respect to Stelara® regardless of whether they are reimbursed for Stelara® under Part D or Part B.

14. NICA's members will suffer financial injury if drugs that they receive reimbursements for under Part B and Part D are subject to "negotiation" under the Drug Price Negotiation Program implemented by the Inflation Reduction Act.

15. The Drug Price Negotiation Program was enacted to impose downward pressure on the price of certain drugs by subjecting them to "negotiation" and imposing a "Maximum Fair Price" for drugs selected for price negotiation. NICA members frequently provide pharmaceuticals and infusion services to patients covered by Medicare and receive reimbursements for those pharmaceuticals and services under Part D and Part B. NICA members will suffer financial injury if those reimbursements decrease because such decreases will affect the margins that NICA's members earn on those pharmaceuticals. For example, when NICA members provide drugs and biologics to Medicare patients under Part B, Medicare calculates the reimbursement paid to the provider as the ASP of the drug plus six percent. When HHS imposes a "Maximum Fair Price" for a drug that is lower than the ASP, the six percent margin paid to the provider decreases in absolute terms, and the provider is financially harmed as a result. Decreased reimbursement rates will also affect the market price that NICA's members are able to charge private payors for those same pharmaceuticals.

16. To take one example, one of the initial drugs designated for "negotiation" is Stelara. As noted, NICA's members provide and are reimbursed for Stelara® under both Part B and Part D. If reimbursement rates for Stelara® drop, then the margins that NICA members earn with respect to Stelara® will shrink in absolute terms, even if NICA members maintain the same margin percentage. If margins drop significantly, the NICA members may ultimately be forced to make formulary decisions regarding whether they will continue offering the drug to patients at all. The ultimate effect would be to decrease patient access to Stelara®.

17. If Stelara® and other drugs provided by NICA and its members are subjected to "negotiation" under the scheme established by the Inflation Reduction Act, the consequences for NICA and its members will be significant. As noted above, Medicare beneficiaries make up a substantial proportion of the patients served by NICA's members, and under the existing drug price regime, NICA members generally break even or earn narrow margins when providing pharmaceuticals and services to Medicare patients. If reimbursement rates drop for pharmaceuticals provided to those patients under Part D or Part B, NICA members may be forced to stop seeing Medicare patients entirely. And if decreased reimbursement rates result in downward pressure on market prices for drugs selected for "negotiation," many NICA members will be in financial peril and may shut down entirely. The unintended consequence would be an exodus of Medicare and commercial-payor patients from infusion centers to hospitals—which provide infusion services and pharmaceuticals to patients at a significantly *higher* cost than infusion centers.

18. NICA would also suffer injury if a manufacturer chooses to withdraw from Medicare or Medicaid rather than negotiate or agree to a "Maximum Fair Price," because in that circumstance, NICA would no longer be able to receive reimbursements for providing that

manufacturer's drugs to Medicare patients. NICA's members would then suffer financial injury in the form of lost reimbursement revenues, while the patients served by NICA's members would lose access to those medications.

19. It is a virtual certainty that HHS will continue to designate drugs for "negotiation" that are provided by NICA's members to Medicare patients and for which NICA receives reimbursements under Part B and Part D.

20. The drug price "negotiation" scheme implemented by the Inflation Reduction Act is already impacting the ability of NICA's members to raise debt and equity funding for their operations. Because NICA's members subsist on narrow margins with substantial costs, the ability of NICA's members to raise capital on favorable terms is critically important to their financial solvency. But the terms on which NICA's members can raise debt and equity capital are directly impacted by their current economic prospects and projected margins, and the Drug Price Negotiation Program is already affecting (and will continue to affect) the economic prospects and cost margins of NICA's members. For example, some of NICA's members are currently courting private equity investments as a means of obtaining additional funding for their infusion centers and in-house pharmacies and are already being impacted by the Drug Price Negotiation Program because they are rely on reimbursements for Stelara® (and other drugs) under both Part D and Part B. As HHS continues to designate more and more drugs dispensed by NICA's members, these negative effects on NICA's members ability to raise debt and equity financing on favorable terms will continue to cause financial injury to NICA's members.

21. NICA's members are in the business of extending and improving patients' lives by providing them with new and innovative drugs and biologics. However, providers administering these innovative treatments are only able to continue operating because they have built business

operations around obtaining reimbursement for those treatments at market prices. Market-based reimbursement is the foundation of how providers serve the needs of their patients and keep their doors open. The "negotiation" scheme implemented by the Inflation Reduction Act threatens to upend this ecosystem by giving HHS unilateral authority to set drug prices while insulating those decisions from administrative and judicial review.

22. In short, NICA's members fear that changes to payment and reimbursement for certain drugs under the Drug Price Negotiation Program will throw their financial stability into peril. And if NICA members stop providing drug and biologic therapies, patients nationwide will suffer from their inability to quickly, easily, and/or cheaply get the medications on which they rely to live their lives.

23. I declare under penalty of perjury that the foregoing is true and correct.

Executed this 25th day of September, 2023.

DocuSigned by:
Brian Nyquist
0B99D3761108488...

Brian J. Nyquist