IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* **KWAME RAOUL, in his official capacity as ATTORNEY GENERAL of the STATE OF ILLINOIS,** *Defendant.*	**No.** _____ **Judge:** _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to "offer" their products at steeply discounted rates to an enumerated and clearly defined list of "covered entities." Such price controls can disincentivize innovation and destabilize markets, and Congress carefully crafted Section 340B and limited participation in the program to fifteen—and only fifteen—types of covered entities. Off-site, for-profit pharmacy chains that contract with covered entities to dispense 340B drugs were *not* included on the list of covered entities. Yet a number of States, including Illinois, have recently passed laws purporting to require manufacturers to offer 340B-discounted pricing for sales at an unlimited number of these so-called "contract pharmacies." These provisions impose immense costs on manufacturers—and generate big profits for pharmacies—yet produce little benefit for patients.

2. Courts have rebuffed federal efforts to force manufacturers like Plaintiff AstraZeneca Pharmaceuticals LP to offer 340B-discounted drugs for sales occurring through

contract pharmacies. The U.S. Court of Appeals for the Third Circuit held that AstraZeneca's decision to restrict its offer of 340B-discounted drugs for contract pharmacy sales "do[es] not violate Section 340B," and the Court "enjoin[ed] [federal officials] from enforcing against" AstraZeneca any "reading of Section 340B" that would require AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir. 2023). The Third Circuit's decision was then incorporated into a permanent injunction, issued by the federal district court in Delaware, protecting AstraZeneca's right to proceed with its contract pharmacy policy.

3. The D.C. Circuit similarly "reject[ed] [the] position that section 340B prohibits drug manufacturers from imposing any conditions on" the offer of "discounted drugs to covered entities" who use contract pharmacies. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024). And the D.C. Circuit specifically upheld manufacturer policies requiring covered entities to provide claims data associated with 340B contract pharmacy orders, which allows manufacturers to prevent the improper diversion of their 340B-discounted medicines while imposing only "minimal" burdens on covered entities. *Id.* at 463-64.

4. Dissatisfied with the scope of federal law, on August 7, 2026, Illinois enacted a statute seeking to achieve under state law precisely the same result that federal courts have resoundingly rejected. Known as H.B. 2371, the Illinois statute requires pharmaceutical manufacturers that participate in the federal 340B program—and *only* those manufacturers—to offer 340B-discounted pricing for sales at an unlimited number of contract pharmacies.

5. H.B. 2371 directly and exclusively targets participants in the federal 340B program. It prohibits such manufacturers from "deny[ing], restrict[ing], prohibit[ing], condition[ing], or otherwise interfer[ing] with, either directly or indirectly, the acquisition of a 340B drug by, or

delivery of a 340B drug to, a 340B covered entity or a 340B contract pharmacy authorized to receive 340B drugs on behalf of the 340B covered entity." H.B. 2371, 104th Gen. Assemb. § 15(a) (2026). The law defines "340B drug" to mean a drug that "has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B covered entity." *Id.* § 10. For 340B program participants, therefore, H.B. 2371 extends Section 340B's price caps beyond the scope of the federal program to reach unlimited contract pharmacy sales—in effect, vastly expanding discounts under the federal program to an entirely new category of transactions.

6. Illinois's attempt to impose discriminatory burdens on federal-program participants violates the doctrine of intergovernmental immunity under the Supremacy Clause, which forbids "discriminat[ing] against the Federal Government *or those with whom it deals* (*e.g.*, contractors)." *United States v. Washington*, 596 U.S. 832, 838 (2022) (emphasis added). It also directly conflicts with federal law and "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *McHenry Cnty. v. Kwame Raoul*, 44 F.4th 581, 591 (7th Cir. 2022) (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)). And it impermissibly seeks to add burdensome new conditions to a federal spending-power bargain created by Congress, even though the federal government has not invited the States to do so.

7. AstraZeneca brings this action to enjoin enforcement of H.B. 2371. AstraZeneca argues that H.B. 2371 cannot validly be enforced against AstraZeneca for five separate and independent reasons.

8. ***First***, H.B. 2371 violates the Supremacy Clause of the U.S. Constitution. *See* U.S. Const. art. VI, cl. 2. Under principles dating back to *McCulloch v. Maryland*, 17 U.S. 316 (1819), the Supremacy Clause prohibits States from adopting laws that "*either* 'regulat[e] the United States directly *or* discriminat[e] against the Federal Government or those with whom it deals' (*e.g.*,

contractors).'" *Washington*, 596 U.S. at 838. Yet that is precisely what Illinois's law does: It discriminates against drug manufacturers who elect to deal with the federal government. On its face, H.B. 2371 applies *only* to manufacturers who have contracted with the federal government to participate in the 340B program, imposing costly obligations *only* on them. As a result, the State's law discourages manufacturers from voluntarily entering into such agreements to participate in the 340B program, as well as the other federal programs (Medicare Part B and Medicaid) with which it is intertwined.

9. ***Second***, H.B. 2371 violates the Supremacy Clause by directly interfering with federal interests under Section 340B itself. Rulings of the Third and D.C. Circuits make clear that the federal 340B statute does *not* obligate manufacturers to deliver discounted drugs to unlimited contract pharmacies. State officials may not impose this obligation on AstraZeneca either. Nor may any State engraft new, costly obligations under state law onto an existing federal benefits program—especially one, like the 340B program, that involves nationally uniform standards and exclusive enforcement by federal agencies. And Illinois also may not preclude manufacturers from conditioning their sales-offer under the federal program on the submission of claims data, which is necessary for manufacturers to meaningfully access the 340B program's audit and administrative dispute resolution procedures.

10. ***Third***, H.B. 2371 also creates a conflict with—and thus is preempted by—federal patent law. In *Biotechnology Industry Organization* (*BIO*) *v. District of Columbia*, the Federal Circuit squarely held that federal patent law "prohibits states from regulating the price of patented goods." 496 F.3d 1362, 1372 (Fed. Cir. 2007). Yet H.B. 2371 does precisely that. It requires manufacturers like AstraZeneca to offer steeply discounted prices for the sale of their patented

drugs, thereby extending federal price caps to an additional category of patented drug sales (contract pharmacy sales) that federal courts have held are *not* required under the 340B program.

11. ***Fourth***, H.B. 2371 violates the Contracts Clause of the U.S. Constitution. *See* U.S. Const. art. I, § 10, cl. 1. The 340B program is enforced through agreements between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services (HHS). 42 U.S.C. § 256b(a)(1). H.B. 2371 substantially interferes with the operation of those agreements, and with manufacturers' rights and obligations thereunder, by imposing costly new obligations only on manufacturers who sign such agreements.

12. ***Fifth***, H.B. 2371 violates the U.S. Constitution's Takings Clause. *See* U.S. Const. amend. V. Under the Takings Clause, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). But H.B. 2371 requires manufacturers like AstraZeneca to transfer their property (prescription drugs) to other private parties (covered entities and the pharmacies with which they contract). This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. But in fact they are not: Manufacturers are compensated at steeply discounted prices, well below fair market value.

13. AstraZeneca therefore seeks an order: (1) declaring that H.B. 2371 violates the Supremacy Clause and is preempted by Section 340B; (2) declaring that H.B. 2371 is preempted by federal patent law as applied to AstraZeneca's patented products; (3) declaring that H.B. 2371 is unconstitutional as applied to AstraZeneca under the federal Contracts Clause; (4) declaring that H.B. 2371 is unconstitutional as applied to AstraZeneca under the federal Takings Clause; and (5) enjoining Attorney General Kwame Raoul and any other Illinois officials from enforcing

H.B. 2371 against AstraZeneca through investigative demands, administrative proceedings, lawsuits seeking civil penalties or other relief, or in any other manner.

JURISDICTION AND VENUE

14. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the Constitution of the United States) and 28 U.S.C. § 1338(a) (civil action arising under any Act of Congress relating to patents). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02.

15. This Court also has inherent equitable powers to enjoin actions of state officials that contradict the federal Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 690-91 (1949).

16. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because this action challenges an Illinois law that applies to and purports to regulate the sale of AstraZeneca's products in this District. AstraZeneca makes its drugs available and offers its products to multiple 340B-covered entities within this District, and these entities maintain multiple contract pharmacy arrangements. The challenged law (if not invalidated) would apply to conduct and property in this District, including AstraZeneca's, and is highly likely to be enforced in this District.

17. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(1) because Defendant maintains offices in this District, through which Defendant would enforce the law challenged in this action.

PARTIES TO THE ACTION

18. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development,

manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

19. Defendant Kwame Raoul is the Illinois Attorney General. In that role, he enforces the challenged legislation. This suit is brought against him in his official capacity only. The Attorney General maintains an office in Chicago, Illinois.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

20. Section 340B of the Public Health Service Act established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

21. As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III). The 340B statute also regulates covered entities, which may not obtain 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"), nor resell or otherwise transfer such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(A), (B).

22. Congress enacted Section 340B to give covered entities access to prescription drugs at below-market prices, thereby helping them serve their uninsured and indigent patients. *See* H.R. Rep. No. 102-384, pt. 2, at 7-12 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

23. Congress has added to the list of 340B-covered entities over time, and today there are fifteen delineated categories of covered entities. 42 U.S.C. § 256b(a)(4)(A)-(O).

24. Notably, Congress has *never* included pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259, at 1-2 (1992) (requiring manufacturers to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

25. The 340B program has its own federal enforcement provisions and administrative dispute-resolution process. Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under this section [340B], and claims by manufacturers . . . of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). Under that statutory mandate, the Health Resources and Services Administration (HRSA), the subagency of HHS that oversees the 340B program, has established "requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. 80,632 (Dec. 14, 2020). The ADR Rule authorizes panels of federal officers to resolve claims for monetary damages, as

well as other unspecified equitable relief sought by claimants. 42 C.F.R. § 10.21(a). And it empowers ADR panels to address a range of factual and legal disputes, including "those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales." 85 Fed. Reg. at 80,636.

26. Importantly, before a manufacturer may access the ADR process, HRSA requires the manufacturer to first audit a covered entity. *See* 42 U.S.C. § 256b(d)(3)(B)(iv); 89 Fed. Reg. 28,643, 28,644 (Apr. 19, 2024) ("[M]anufacturers are required to audit a covered entity prior to filing an ADR claim"). And under HRSA regulations, a manufacturer may only initiate an audit when it can point to "documentation which indicates that there is reasonable cause," with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Thus, absent such "documentation," the ADR process is unavailable to a manufacturer.

27. HRSA revised the ADR Rule in 2024. *See* 89 Fed. Reg. at 28,643. Among other things, the revised rule gives "340B ADR Panel[s]" responsibility to resolve disputes related to "overcharge[s]," which include claims that a manufacturer has "limited [a] covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. §§ 10.3, 10.21.

Contract Pharmacy Use Leads to Abuse and Profiteering

28. At the time of Section 340B's enactment, manufacturers provided discounted drugs directly to covered entities, who in turn provided them to their patients for free or at cost.

29. Section 340B does not require manufacturers to make 340B-discounted drugs available for sales at or through contract pharmacies—or indeed, for sales at *any* entity not specifically enumerated in the statute. In the decades since the enactment of the program, however, HRSA has issued two non-binding "guidance" documents purporting to authorize covered entities

to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B.

30. In 1996, HRSA issued guidance providing that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now access 340B discounts for sales at a *single* outside pharmacy of their choice. 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996) (1996 Guidance).

31. At that time, most contract pharmacies maintained a separate physical inventory of 340B-purchased drugs, and they dispensed drugs from that separate inventory when presented with a prescription designated as 340B-eligible. Maintaining a separate inventory was a simple and effective way to ensure compliance with the 340B statute's prohibitions against diversion and duplicate discounts. It was also rare for covered entities to use a contract pharmacy: By 2000, only 47 covered entities (out of more than 11,500) had registered contract pharmacies with HRSA.

32. Then, in 2010, HRSA released new guidance stating that covered entities could now access discounts for sales at "multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (2010 Guidance). The 2010 Guidance thus purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States, and purported to require manufacturers to offer 340B discounts for unlimited sales at such contract pharmacies.

33. The 2010 Guidance triggered a massive surge in the number of contract pharmacy arrangements through which covered entities receive 340B discounts. *See Novartis Pharms.*, 102 F.4th at 457 (noting a "significant expansion"). In 2018, the Government Accountability Office

reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 in 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Report), http://bit.ly/4ncwsh0. These numbers have continued to grow. Today, more than 33,000 different pharmacies participate in the 340B program, with more than 194,000 individual contracts. Adam J. Fein, *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market*, Drug Channels Inst. (Jul. 11, 2023), http://bit.ly/3Kj5aXR. The vast majority of these contract pharmacies (75% as of 2018) are for-profit retail chain pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

34. Make no mistake, the boom in contract pharmacy sales has been fueled by the prospect of outsized profit margins on 340B-discounted drugs. As the D.C. Circuit explained:

> While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis Pharms., 102 F.4th at 457-58; *see also* Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (describing mechanics of contract pharmacy replenishment model). Since a 340B discount is applied for the contract

pharmacy sale—even though the sale has *also* benefitted from the full insurance reimbursement—this dynamic results in substantial arbitrage revenues. *See Sanofi*, 58 F.4th at 699 ("[T]hey turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount.").

35. This approach to distributing 340B-priced drugs is commonly known as the "replenishment" model, and it is now the dominant model used by covered entities. Under the replenishment model, the experience of an insured patient purchasing medicine from a contract pharmacy is identical regardless of whether the patient is dispensed a drug purchased at the 340B price or a drug purchased at the commercial price. When an insured patient purchases medications at a contract pharmacy, the patient generally pays the copay set by the patient's insurer, and the insurer pays the rest of the commercial price—even if the dispensed drug had been acquired by the pharmacy at the 340B price, or will subsequently be reclassified as a 340B-priced sale through a replenishment model.

36. When an insured patient fills a prescription, and the patient and his or her insurer together pay the pharmacy the commercial price, the difference between the commercial price paid for the medication and the 340B price it was purchased at generates revenue. Covered entities employing the replenishment model often use the terms "340B savings" or "340B revenue" to refer to the revenue generated when insured patients are dispensed drugs purchased at the 340B price and the pharmacy receives payment from the insurer and the patient at the commercial price.

37. Typically, covered entities' agreements with their contract pharmacies provide that the covered entity will pay the pharmacy a dispensing fee for each drug sale the pharmacy makes under their contract pharmacy arrangement. Although their arrangements with covered entities

vary, contract pharmacies generally charge a "dispensing" fee of approximately 20% of the gross sales price for their role in 340B sales.

38. In addition to replenishing 340B sales as described above, a growing number of contract pharmacies—including large, for-profit pharmacies like Walgreens, CVS, and Kroger—are now employing an approach that is even more brazen about using the 340B program to generate arbitrage revenue: so-called "credit replenishment." Under this approach, the contract pharmacy's inventory is "virtually replenished" through a paper fiction—namely, by recharacterizing the prior transaction to make it appear as if the previously dispensed unit had been bought at the 340B price originally. To do so, the wholesaler simply credits the contract pharmacy for the commercial price; charges the 340B price to the covered entity; and then requests a refund from the manufacturer for the difference between the wholesale and 340B prices. This is a purely financial maneuver: No new product is purchased, nor is any product distributed as a result. Contract pharmacies have contractual agreements with covered entities explicitly designed to implement credit replenishment, and contract pharmacies solicit covered entities' consent to enter those agreements.

39. Under the replenishment model, as Senator Chuck Grassley put it in a letter to HRSA, hospitals and the for-profit pharmacies with whom they contract "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), http://bit.ly/3Kj55Dx. Contract pharmacies routinely siphon off 20-30% of this "spread," leading them to retain up to $5 billion in annual profits from 340B sales. *See* Neal Masia, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019* 2, Alliance for Integrity & Reform (May 2021), http://bit.ly/4bM7sHE; Laura Joszt, *340B, Biosimilars, and*

More in the Future of Specialty Pharmacy, Am. J. of Managed Care (May 4, 2022), https://bit.ly/4c61Do6 (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"); Walgreens Boots Alliance, Inc., Form 10-K at 23 (Oct. 15, 2020), https://bit.ly/3KveDrI (noting that "[c]hanges in pharmaceutical manufacturers' . . . distribution policies . . . in connection with the federal 340B drug pricing program[] could . . . significantly reduce [Walgreens's] profitability"); Rebecca Pifer Parduhn, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2020), https://bit.ly/3P9xmdF (reporting that CVS Health "said its 340B product lines were stagnant" after contract-pharmacy restrictions were imposed).

40. Although some of the money generated through contract pharmacy sales is passed on to covered entities, most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs). Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa.

41. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. Likewise, the HHS Office of Inspector General found in 2014 that some contract pharmacies do not offer 340B-discounted prices to uninsured patients at all. HHS-OIG,

Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), http://bit.ly/3W6GSmm. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.* By contrast, the GAO noted that 17 of the 23 surveyed covered entities that had *in-house* pharmacies reported offering discounts at those pharmacies. 2018 GAO Report at 30 n.46. Most recently, a report by the Senate Committee on Health, Education, Labor & Pensions found that major covered entities do not directly pass on 340B discounts to patients, with one entity stating to the Committee that "reducing patients' drug expenses is not the purpose of the 340B Program." S. Comm. on Health, Educ., Labor & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 9 (Apr. 2025), http://bit.ly/3IDTE8P.

42. In fact, some contract pharmacy service agreements authorize contract pharmacies to *deny* services to uninsured patients.

43. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme.

44. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts. *See Novartis Pharms.*, 102 F.4th at 458. HRSA's 1996 guidance sought to limit abuse of the program by adopting safeguards for contract pharmacy use, instructing that a covered entity "should establish [a] prior authorization protocol, assuring that the individual's status as a patient of the entity is confirmed by the entity in advance of [receiving] product." 61 Fed. Reg. at 43,553. And the 2010 guidance, in authorizing use of multiple contract pharmacies, identified several further safeguards as "essential elements to

address in contract pharmacy arrangements," including that covered entities must "maintain title to the drug." 75 Fed. Reg. at 10,277.

45. Yet covered entities and their contract pharmacies now routinely violate those safeguards. They rarely use "prior authorization protocol[s]" to determine patient eligibility "in advance of" receiving 340B drugs. 61 Fed. Reg. at 43,553. Instead, under the replenishment model used by most covered entities, 340B eligibility is determined only *after* the patient has left the pharmacy—days, weeks, or sometimes even months later—when a third-party entity (often referred to as a "third-party administrator" or "TPA") combs through the pharmacy's prior sales data for 340B-eligible sales. Once the TPA has identified enough 340B-eligible sales to notionally deplete a contract pharmacy's virtual inventory, it places an order on behalf of the covered entity, thereby supposedly "replenishing" the drug that has already been dispensed with another 340B-priced drug. That replenishment order is then shipped directly to the contract pharmacy, which takes title to the drug and puts it in the pharmacy's general inventory, where it can be distributed to *any* pharmacy customer—whether 340B eligible or not.

46. Thus, under the replenishment model, covered entities rarely, if ever, "maintain title to the drug" through dispensing. 75 Fed. Reg. at 10,277. Instead, replenishment drugs are almost always delivered directly to the contract pharmacy, without a covered entity ever taking physical possession of the product, and title is almost always transferred to the contract pharmacy upon receipt. Moreover, contract pharmacies rarely act as agents of the covered entity; instead, contract pharmacies are typically independent contractors with respect to the acquisition and sale of 340B drugs, as stated in their agreements with covered entities. Indeed, replenishment sales are often placed on behalf of a covered entity without the covered entity's review or prior approval—or even without the covered entity's awareness.

47. The prevalence of the replenishment model for contract pharmacy sales has also led to significant abuse. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28 (Sept. 23, 2011), http://bit.ly/4nQl5LK. The report further found that "HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

48. These structural problems have only intensified over time, as the use of the replenishment model and multiple contract pharmacies has become rampant. The 2014 OIG report determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." 2014 OIG Report at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45.

49. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. *See* HRSA, *Program Integrity: FY19 Audit Results*, http://bit.ly/4nj5ft0. Indeed, out of 200 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *Id.*

50. Covered entities in Illinois, like other covered entities around the country, have steadily increased the number of their contract pharmacy relationships over the last decade. Illinois covered entities now often have dozens of relationships with contract pharmacies, many of which are located outside the State. These include agreements with large corporations like Walmart, Walgreens, CVS, and Optum. For instance, one Illinois covered entity, The University of Chicago Medical Center, has 287 contract pharmacy relationships that span 20 different States. *See* HRSA, Office of Pharmacy Affairs 340B OPAIS, *The University of Chicago Medical Center*, Contract Pharmacies, https://340bopais.hrsa.gov/CeDetails/17429.

51. Illinois covered entities generate millions of dollars in annual revenue from reselling 340B-discounted drugs at commercial prices to fully insured patients. Contract pharmacies that contract with Illinois covered entities generate hundreds of millions, if not billions, of dollars from dispensing 340B-discounted drugs at commercial prices to fully insured patients.

AstraZeneca's Participation in the 340B Program

52. AstraZeneca is a global, science-led, patient-focused pharmaceutical company dedicated to transforming the future of healthcare by unlocking the power of what science can do for people, society, and the planet. AstraZeneca is committed to ensuring its life-changing and life-saving products and treatments are available to as many people as possible. AstraZeneca manufactures several products on which it holds patents, which are subject to protections set out in the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) and other federal patent laws.

53. AstraZeneca has participated in the 340B program since 1993, when it signed its pharmaceutical pricing agreement (PPA) to enter the program.

54. To comply with its obligations under the PPA and the 340B program, AstraZeneca offers its patented products at steep discounts to 340B-eligible covered entities. For example, a

prescription for 90 tablets of AstraZeneca's patented product Farxiga retails for hundreds of dollars commercially, but can be purchased for less than a dollar with a 340B discount. Similarly, a prescription for 60 tablets of AstraZeneca's patented product Xigduo retails for hundreds of dollars commercially, but can be purchased for less than a dollar with a 340B discount.

55. AstraZeneca offers its products to 340B covered entities through wholesalers, just as it offers its products to other purchasers. Covered entities acquire AstraZeneca's 340B-discounted drugs by accepting AstraZeneca's offer—that is, by asking a wholesaler to purchase the AstraZeneca product at the 340B price.

56. There is no difference between AstraZeneca products that are offered under the 340B program and AstraZeneca products *not* offered under the 340B program, other than the price at which they are offered.

57. AstraZeneca products sold through the 340B program are identical to the same AstraZeneca products sold at commercial price in terms of the physical content of the products, their packaging, labeling, and National Drug Code.

58. In August 2020, in light of the surge in covered entities accessing 340B-pricing through contract pharmacies—and a sharp increase in accompanying abuse of the program—AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance.

59. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not maintain their own on-site dispensing pharmacy, AstraZeneca offers discounted drugs for sales at a single contract pharmacy site for each covered entity. But AstraZeneca no longer offers 340B discounts for drugs sold at an unlimited number of contract pharmacies.

60. AstraZeneca's policy is consistent with the letter and intent of the 340B program—limiting the potential for abuse, while still enabling all covered entities and their patients to continue to access AstraZeneca's medicines at 340B prices. Under AstraZeneca's policy, over 13,000 covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to make 340B discounts available, including numerous covered entities in Illinois. AstraZeneca is committed to working with all covered entities to ensure that every patient can obtain needed medicines at prices they can afford.

61. Under AstraZeneca's contract pharmacy policy, AstraZeneca has ceased offering 340B discounts for drugs sold at an unlimited number of contract pharmacies. Covered entities remain able to obtain 340B pricing for AstraZeneca products in unlimited quantities, either through their in-house pharmacy or their designated contract pharmacy. Contract pharmacies also remain able to obtain unlimited quantities of AstraZeneca products at rates negotiated outside the 340B program. Patients of covered entities are similarly able to obtain unlimited amounts of AstraZeneca products through covered entities and contract pharmacies.

62. AstraZeneca's policy does not prevent any pharmacy from receiving deliveries of, or otherwise acquiring, products manufactured by AstraZeneca. Nor does AstraZeneca's policy prevent any covered entity from receiving or acquiring products manufactured by AstraZeneca.

63. AstraZeneca's policy is not a *delivery* restriction. It does not affect the delivery of AstraZeneca products that have actually been purchased. Indeed, no covered entity has *ever* purchased an AstraZeneca drug at a 340B price for sales at a non-designated contract pharmacy but had AstraZeneca (or a wholesaler) refuse delivery of that drug.

64. Instead, AstraZeneca's policy is a restriction on the circumstances under which it *offers* its products at 340B-discounted prices. Under the policy, covered entities are not offered—

and are thus unable to purchase—AstraZeneca's drugs at 340B prices for sales at non-designated contract pharmacies. In practice, this means wholesalers are not able to collect 340B prices on AstraZeneca products for sales at non-designated contract pharmacies. But the policy does not prevent covered entities from purchasing the same AstraZeneca products at *commercial* prices, including for sales at a non-designated contract pharmacy.

65. In response to AstraZeneca's new contract pharmacy policy and other manufacturers' adoption of similar policies, HHS and HRSA issued an Advisory Opinion on December 30, 2020, asserting that the 340B statute requires manufacturers to offer 340B-discounted drugs for sales at unlimited contract pharmacies.

66. In early 2021, AstraZeneca filed suit in the U.S. District Court for the District of Delaware against HHS and HRSA, challenging the Advisory Opinion. On June 16, 2021, the court issued a detailed opinion finding the Advisory Opinion unlawful. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). The court concluded that Section 340B "says nothing about the permissible role (if any) of contract pharmacies," and that, in light of this "total omission," the Advisory Opinion's attempt to impose an obligation on AstraZeneca to make discounted drugs available for sales at unlimited contract pharmacies was "legally flawed." *Id.* at 59. The agency withdrew the Advisory Opinion following the court's ruling.

67. In a second ruling, the court addressed AstraZeneca's challenge to a "violation letter" issued by HRSA, which adopted the same position as the Advisory Opinion. The court again rejected the agency's view that Section 340B obligates drug manufacturers to make 340B-discounted drugs available for unlimited contract pharmacy sales. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022). The court reiterated "key points" from its prior opinion, including that Congress "did not clearly intend for drug manufacturers to

be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *Id.* at *5-*6.

68. On January 30, 2023, the U.S. Court of Appeals for the Third Circuit affirmed. In a consolidated opinion addressing AstraZeneca's case and appeals in parallel actions by other manufacturers, the Third Circuit held that the Advisory Opinion and violation letter were "unlawful," and it "enjoin[ed] HHS from enforcing [them] against" AstraZeneca. *Sanofi*, 58 F.4th at 706. The court of appeals also held that AstraZeneca's policy of not offering discounts for sales at unlimited "contract pharmacies do[es] not violate Section 340B." *Id.*

69. The government neither sought en banc review of the Third Circuit's decision nor filed a petition for certiorari in the U.S. Supreme Court.

70. On May 5, 2023, the Delaware court issued a final judgment in AstraZeneca's case, to which the government stipulated. The court's order provides that it is:

a. "DECLARED that Advisory Opinion 20-06 and the Violation Letter from the Health Resources and Services Administration to Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca), dated May 17, 2021 (Violation Letter), are unlawful;

b. DECLARED that AstraZeneca's policy limiting the use of contract pharmacies under Section 340B of the Public Health Service Act (Section 340B), 42 U.S.C. § 256b—namely, that covered entities may use an in-house pharmacy and, if they do not have an in-house pharmacy, they may use one contract pharmacy—does not violate Section 340B;

c. ORDERED that the Violation Letter is VACATED as contrary to law pursuant to 5 U.S.C. § 706;

d. ORDERED that Defendants, including their officers, agents, and employees, are ENJOINED from enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."

Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123.

71. As a result of the Third Circuit's ruling and the Delaware court's injunction, AstraZeneca is entitled to proceed with its lawful contract pharmacy policy.

72. More recently, AstraZeneca has further modified its contract pharmacy policy to promote program integrity. On October 1, 2024, AstraZeneca updated its contract pharmacy policy to require covered entities to report a limited set of claims data for contract pharmacy dispenses that were replenished using 340B-priced drugs. On May 1, 2026, AstraZeneca further updated its policy, imposing a universal claim data requirement, mandating that all covered entities submit 340B claims data, including for in-house pharmacy dispenses.

73. AstraZeneca's collection of 340B claims data enables AstraZeneca to detect and prevent violations of the 340B statute's program integrity provisions, including its prohibition on duplicate discounts. A duplicate discount occurs when a manufacturer pays a separate rebate to a payer for a drug that was purchased, credited, or replenished at the 340B price. The 340B statute expressly prohibits duplicate discounts under Medicaid. 42 U.S.C. § 256b(a)(5)(A).

74. Other types of duplicate discounts are prohibited under payer-manufacturer contracts or other federal laws. For instance, the Inflation Reduction Act (IRA) requires HHS to "negotiate" with manufacturers for a "maximum fair price" that Medicare will pay for certain drugs, which must include a discount of at least 20%. 42 U.S.C. § 1320f-3(a). Under the IRA, each manufacturer must make its drug available at the "maximum fair price"—but *not* if the drug is

available at a lower 340B price. *Id.* § 1320f-2(d). To ensure compliance with the IRA and prevent duplicative price reductions under Section 340B and the IRA, the Centers for Medicare and Medicaid Services (CMS) has charged manufacturers with identifying instances where a drug has been dispensed as a 340B drug. *See* CMS, Medicare Drug Pricing Negotiation Final Guidance 58-60 (Oct. 2, 2024), https://bit.ly/4zdb0im.

75. Without access to claims data, however, AstraZeneca lacks sufficient information to adequately identify and prevent these and other duplicate discounts. That is because the information AstraZeneca needs to directly connect payer rebates to 340B dispenses is *not* otherwise available to AstraZeneca as part of the 340B purchasing process. And requests by manufacturers for participants in the system (including covered entities and contract pharmacies) to provide the necessary information on a voluntary basis have been consistently spurned. AstraZeneca's policies mandating the provision of claims data were implemented to solve this information asymmetry, providing AstraZeneca with the information it needs to ensure 340B program integrity.

76. Manufacturers like AstraZeneca do have a statutory right to conduct audits of covered entities regarding compliance with Section 340B's anti-duplication requirement, and they may compel the reporting of some data in connection with those audits. 42 U.S.C. § 256b(a)(5)(C); *see Novartis Pharms.*, 102 F.4th at 463. But HRSA regulations provide that a manufacturer may only initiate an audit when it can furnish "documentation which indicates that there is reasonable cause" for such an audit, with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. at 65,409. As a result, a manufacturer must already have

"documentation" showing that a covered entity has engaged in duplicate discounting before it may obtain permission to audit that entity.

77. Covered entities generally do not voluntarily provide manufacturers with the information or data required to establish "reasonable cause." And without the ability to establish reasonable cause, AstraZeneca is effectively unable to access its audit rights.

78. Given these challenges, AstraZeneca's contract pharmacy policy as of May 1, 2026, requires covered entities to submit claims data for 340B purchases and dispenses at all contract pharmacies. The data that AstraZeneca requires covered entities to submit was already required of pharmacies when they submit claims to payers; and HRSA requires covered entities to maintain the same data in the regular course of business, with one minor exception for the unique identification number of the covered entity.

79. In *Novartis Pharmaceuticals*, the D.C. Circuit upheld a manufacturer claims data policy that was materially identical to AstraZeneca's current policy. 102 F.4th at 464. Among other things, the court explained that the request for information was consistent with HRSA guidance, under which "drug manufacturers may require [such] 'standard information' from covered entities." *Id.* at 463 (quoting 59 Fed. Reg. 25,114). The court also emphasized that "record evidence" showed "the burden of providing the claims data is 'minimal.'" *Id.*

Illinois Enacts Legislation Requiring Manufacturers to Make 340B-Discounted Drugs Available for Unlimited Contract Pharmacy Sales

80. On June 1, 2026, the Illinois Legislature passed H.B. 2371, which Governor JB Pritzker signed into law on August 7, 2026.

81. The law took effect immediately. *See* H.B. 2371 § 99.

82. H.B. 2371 imposes three discrete prohibitions.

83. *First,* no drug manufacturer "may deny, restrict, prohibit, condition, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity or a 340B contract pharmacy authorized to receive 340B drugs on behalf of the 340B covered entity unless the receipt is prohibited by federal law." *Id.* § 15(a).

84. *Second*, no drug manufacturer "may impose any restriction on the ability of a 340B covered entity to contract with or designate a 340B contract pharmacy, including restrictions relating to the number, location, ownership, or type of 340B contract pharmacy." *Id.* § 15(b).

85. *Third*, no drug manufacturer "may require or compel a 340B covered entity or 340B contract pharmacy to: (1) submit or otherwise provide ingredient cost or pricing data pertinent to 340B drugs unless required by State or federal law; (2) institute requirements in any way relating to how a 340B covered entity manages its inventory of 340B drugs that are not required by a State or federal agency, including requirements relating to the frequency or scope of audits of inventory management systems of a 340B covered entity or 340B contract pharmacy; or (3) submit data or information that is not required by a State or federal law as a condition for a 340B covered entity, its 340B contract pharmacy, or a location otherwise authorized by a 340B covered entity to receive 340B drugs." *Id.* § 15(c).

86. H.B. 2371 defines its basic terms by reference to federal law. It defines "340B drug" to mean "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a 340B covered entity." *Id.* § 10. It defines "340B covered entity" to mean "an entity in Illinois that qualifies as a covered entity under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b(a)(4)." *Id.* And it names and defines various other critical terms by reference to the 340B program. *See, e.g.*, *id.* (naming and defining "340B

contract pharmacy," "340B drug discount program," and "340B grantee"). The statute's definitions thus make clear that the federal 340B program is its regulatory object.

87. H.B. 2371 also seeks to control which individuals may access drugs that have been purchased by a covered entity through the 340B program. Federal law provides that covered entities "shall not resell or otherwise transfer" such drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). HRSA has issued non-binding guidance interpreting the statutory term "patient." 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996). H.B. 2371 effectively crafts its *own* state-law definition of that federal term, providing that "[e]ach 340B covered entity shall dispense or administer 340B drugs *only when in connection with an outpatient health care service received by the patient within the last 18 months*." H.B. 2371 § 30 (emphasis added).

88. H.B. 2371 further requires that each "340B covered entity . . . develop and maintain a policy that ensures it is not placing an order for a 340B drug to replenish a prior pharmacy dispense if any other 340B covered entity will place an order for a 340B drug to replenish the same prior pharmacy dispense." *Id.* § 35. That policy must "also include a process to reimburse a manufacturer for any duplicate 340B discount the covered entity receives." *Id.*

89. H.B. 2371 also includes legislative "findings" that further confirm that the law seeks to regulate Section 340B program participation. First, the Legislature found that "[t]he federal 340B statute is silent on distribution of 340B-acquired drugs to 340B covered entities and their contract pharmacy partners." *Id.* § 5(2). Second, the Legislature found that it must "ensure that 340B covered entities continue to be allowed to contract with pharmacies to receive 340B drugs and dispense them to the patients of 340B covered entities in accordance with federal law." *Id.* § 5(3). These findings confirm that H.B. 2371's sole focus is ensuring that the 340B program operates in the manner that the State's Legislature prefers.

90. Indeed, H.B. 2371 effectively adds contract pharmacies to the list of covered entities that Congress created. While it does not expressly include contract pharmacies in its definition of "340B covered entities," it treats them identically to covered entities under the law, including by requiring manufacturers to allow *both* "340B covered entities" *and* "340B contract pharmacies" to "acqui[re]" drugs at federally mandated 340B prices. *Id.* § 15(a). As the federal court in Delaware noted, "[i]t is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication." *AstraZeneca*, 543 F. Supp. 3d at 60. Yet Illinois law now expressly treats contract pharmacies the same as "340B covered entities."

91. H.B. 2371 does not account for HRSA's enforcement authority or for the congressionally mandated procedures for administrative dispute resolution. *See* 42 U.S.C. § 256b(d)(3).

92. The Illinois Attorney General is authorized to enforce the provisions of H.B. 2371 under his "general authority under the Attorney General Act." H.B. 2371 § 40(a).

93. A violation of H.B. 2371 is punishable by "injunctive relief," "money damages," a "civil penalty of up to $1,000 for each violation," or "any other relief" that a court orders. *Id.* § 40(b). "Each individual transaction . . . of 340B drugs that is subject to a prohibited act . . . shall constitute a separate violation." *Id.* § 15(d).

94. Compliance with H.B. 2371 would cost AstraZeneca approximately $2.5 million per month, as a result of being forced by the law to provide access to 340B discounts for unlimited contract pharmacy sales.

LEGAL ALLEGATIONS

H.B. 2371 Violates the Supremacy Clause

95. The Supremacy Clause of the U.S. Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. The doctrine of federal preemption that arises out of the Supremacy Clause requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder v. Casey*, 487 U.S. 131, 138 (1988) (quoting *Free v. Bland,* 369 U.S. 663, 666 (1962)).

96. Under principles dating back to *McCulloch v. Maryland*, 17 U.S. 316 (1819), States may not adopt laws that "*either* 'regulat[e] the United States directly *or* discriminat[e] against the Federal Government *or those with whom it deals*' (*e.g.*, contractors)." *Washington*, 596 U.S. at 838 (quoting *North Dakota v. United States*, 495 U.S. 423, 435 (1990)) (final emphasis added); *see, e.g.*, *McHenry Cnty.*, 44 F.4th at 593 n.6 ("[D]iscriminatory regulation aimed at federal contractors . . . would be invalid under the intergovernmental immunity doctrine."); *CoreCivic, Inc. v. Governor of N.J.*, 145 F.4th 315, 321 (3d Cir. 2025) (Bibas, J.) (discussing the Supremacy Clause's nondiscrimination requirement). That is because the Supremacy Clause, under principles sometimes referred to as intergovernmental immunity, "prohibit[s] States from interfering with or controlling the operations of the Federal Government." *Washington*, 596 U.S. at 838.

97. States thus may not "single . . . out 'for less favorable treatment'" those that deal with the federal government, "or regulate them 'unfavorably on some basis related to their governmental status.'" *McHenry Cnty.*, 44 F.4th at 593 (quoting *Washington*, 596 U.S. at 839) (cleaned up). "Th[is] nondiscrimination rule finds its reason in the principle that the States may

not directly obstruct the activities of the Federal Government." *North Dakota*, 495 U.S. at 437-38 (citing *McCulloch*, 17 U.S. at 425-37). And "a regulation imposed on one who deals with the Government has as much potential to obstruct governmental functions as a regulation imposed on the Government itself." *Id.* at 438.

98. To comply with the Supremacy Clause, therefore, a state law that affects federal contractors must be *generally applicable*: It must "be one that is imposed on some basis unrelated to the object's status as a Government contractor or supplier, that is, that it be imposed equally on other similarly situated constituents of the State." *Id.* at 437-38; *accord McHenry Cnty.*, 44 F.4th at 593 (state laws do not unconstitutionally discriminate "so long as the[y] impose[] . . . costs in a neutral, nondiscriminatory way") (citation omitted).

99. H.B. 2371 directly violates these principles. On its face, the Act applies *only* to federal contractors—namely, drug manufacturers who sign PPAs with the HHS Secretary to participate in the 340B program. And it singles out those manufacturers for special (unfavorable) treatment: Only a PPA signatory must offer its products at sharply reduced prices for unlimited contract pharmacy sales; and only a PPA signatory is subject to the law's further restrictions on its inventory-management and audit practices. The Act imposes no such requirements on manufacturers who *do not* sign PPAs.

100. Indeed, far from being generally applicable, every relevant provision of the Act depends on 340B status: The Act applies only to drugs "that ha[ve] been subject to any offer for reduced prices by a manufacturer" under the 340B program, and only to transactions involving a "covered entity" that "qualifies" as such "under Section 340B." H.B. 2371 §§ 10; 15. The law accordingly discriminates "[o]n its face." *Washington*, 596 U.S. at 839. More than that, H.B. 2371 is entirely parasitic on Section 340B; if the federal law were repealed, the Act would have no

effect. It applies only to manufacturers who participate in the 340B program (not all manufacturers), requiring them to provide discounts to 340B covered entities (not all hospitals) for unlimited sales to pharmacies that contract with covered entities (not all pharmacies).

101. H.B. 2371 thus violates the Supremacy Clause because it "singl[es] out the Federal Government for unfavorable treatment" by imposing "costs" on manufacturers who have signed PPAs, even though manufacturers without such contracts with the federal government "do not bear" the same costs; and it also regulates those manufacturers "on [the] basis [of] their governmental 'status.'" *Id.* (quoting *North Dakota*, 495 U.S. at 438).

102. H.B. 2371 also violates the Supremacy Clause because it means that a manufacturer cannot participate in the federal 340B program unless the manufacturer *also* meets the *additional* obligations imposed by Illinois's law. But a state may not "require[] qualifications" for those doing government work "in addition to those that the Government has pronounced sufficient." *Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187, 190 (1956) (quoting *Johnson v. Maryland*, 254 U.S. 51, 57 (1920)); *see City of Country Club Hills v. U.S. Dep't of Hous. & Urb. Dev.*, 2001 WL 1117276, at *6-7 (N.D. Ill. Sept. 17, 2001) (Supremacy Clause barred city from requiring HUD or its contractors to make additional repairs not required by HUD regulation). Nor may a State "deny to those failing to meet its own qualifications the right to perform the functions within the scope of the federal authority." *Sperry v. Florida ex rel. Fla. Bar*, 373 U.S. 379, 385 (1963); *see, e.g.*, *Leslie Miller*, 352 U.S. at 189-90 (invalidating state law that imposed extra licensing requirements on federal defense contractor).

103. Here, H.B. 2371 conditions a manufacturer's ability to participate in the 340B program in Illinois on its satisfaction of *additional* legal requirements imposed by the State. In effect, Illinois has raised the cost of participation in the federal program—not as an incidental

effect of a generally applicable state law, but as a direct and intended consequence of Illinois's decision to *target* the federal program. Doing so interferes with important federal interests. Indeed, the United States has explained that its "interest in determining" the price of admission to the 340B program "could hardly be stronger." Br. for the United States as Amicus Curiae (U.S. Br.) 22, *AstraZeneca Pharms., LP v. Lopez*, No. 26-1172 (9th Cir. Apr. 3, 2026), Doc. 15.1. To allow States to alter the terms of participation in federal programs—and to punish the participants in those programs—in such a manner is antithetical to the fundamental principle that "the Laws of the United States … shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2.

H.B. 2371 Is Preempted by Section 340B

104. H.B. 2371 also violates the Supremacy Clause because it upsets the careful bargain that Congress created under Section 340B as an exercise of its spending power. As the federal government itself has explained, laws like H.B. 2371 directly modify "the costliness of Medicare and Medicaid participation," U.S. Br. 22, with the result that they "risk disincentivizing" participation in those programs and threaten to make "millions of patients" worse off, U.S. Br. 17-18.

105. The mandates that H.B. 2371 imposes on drug manufacturers, and its associated enforcement mechanisms, conflict with the 340B statute and impermissibly interfere with important federal policies and objectives.

106. ***First***, by requiring drug manufacturers to offer 340B pricing for unlimited contract pharmacy sales—thereby drastically increasing their costs of participating in the 340B program—H.B. 2371 impermissibly "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *McHenry Cnty.*, 44 F.4th at 591 (quoting *Arizona v. United States*, 567 U.S. 387, 399 (2012)).

107. Covered entities, and their contract pharmacy partners, use 340B discounts to "turn a profit," by reselling discounted drugs at full price to insured patients. *Sanofi*, 58 F.4th at 699.

But such discounts impose corresponding costs on drug manufacturers. Prior to H.B. 2371's enactment, manufacturers were obligated to offer such discounts only for sales directly to covered entities themselves: Federal courts determined that Section 340B does *not* obligate manufacturers to "help [covered entities] maximize their 340B profits" by offering discounts for contract pharmacy sales. *Id.* at 704; *accord Novartis*, 102 F.4th at 459.

108. H.B. 2371 is designed to counteract those rulings, by requiring manufacturers who participate in the 340B program to offer those very discounts under state law. Under the law, a manufacturer must offer 340B discounts for unlimited contract pharmacy sales—despite the Third and D.C. Circuits' holdings that federal law imposes no such requirement. Imposing such a requirement will enable covered entities and their associated contract pharmacies to "squeeze [more] revenue out of" the federal program. *Sanofi*, 58 F.4th at 704. But in so doing, the law imposes a corresponding cost on manufacturers—from whom the additional revenue is "squeeze[d]"—significantly increasing the burdens of participating in a federal program beyond those that Congress intended when it crafted the program.

109. In effect, Illinois has used manufacturers' participation in the federal 340B program as leverage to extract additional money from them under state law. The result is to "exert an extraneous pull on the scheme established by Congress," thus "skew[ing]" the "delicate balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 353 (2001); *City of Country Club Hills*, 2001 WL 1117276, at *6 (city building enforcement against HUD and its agent preempted because "increased costs" were an obstacle to executing HUD's policies).

110. The magnitude of this additional burden is significant. As noted, compliance with H.B. 2371 would cost AstraZeneca approximately $2.5 million per month, as a result of being forced by the law to provide access to 340B discounts for unlimited contract pharmacy sales.

111. Other States have defended similar contract pharmacy laws by claiming that they regulate only drug distribution, which the 340B statute does not address. Illinois's Legislature claims to have taken the same tack, purporting to make "findings" that "[t]he federal 340B statute is silent on distribution of 340B-acquired drugs to 340B covered entities and their contract

pharmacy partners," and that "[i]t is within the traditional authority of the State to regulate the acquisition and delivery of drugs to pharmacies and providers." H.B. 2371 § 5(1), (2).

112. Even if that were true—even if H.B. 2371 regulated delivery rather than pricing—that would not save the law from preemption. Imposing a costly new delivery obligation on transactions under a federal program just as readily "discourage[s]" participation in the program and impermissibly disrupts the careful Spending Clause bargain that Congress created. *Buckman*, 531 U.S. at 350.

113. But in fact it is *not* true: Although it refers to the "acquisition" and "delivery" of 340B drugs, H.B. 2371 regulates drug *pricing*. The law dramatically expands the range of transactions in which manufacturers must provide access to their products at prices that have been reduced under the formula prescribed by Section 340B.

114. By prohibiting manufacturers from restricting their offer of 340B-priced sales to contract pharmacies, H.B. 2371 on its face regulates pricing—and insofar as manufacturers are affected, *only* regulates pricing. The statute does not affect any aspect of drug acquisition or delivery, such as packaging requirements, shipping conditions, shipping costs, or other logistics and specifications. To the contrary, whether a contract pharmacy pays a commercial price or the 340B price is the *only* thing that distinguishes a sale that complies with H.B. 2371 from a sale that violates the law. It thus forces manufacturers to offer 340B-discounted prices for unlimited contract pharmacy sales, even though manufacturers like AstraZeneca would otherwise refuse to offer such pricing under their contract pharmacy policies.

115. Further, by prohibiting AstraZeneca from conditioning its offer of 340B prices on the provision of claims data, H.B. 2371 further undermines the bargain Congress created. As the D.C. Circuit held, the federal 340B statute allows manufacturers to impose "conditions" on the offer of 340B-priced drugs, especially when—as with claims data—the burden is "minimal." *Novartis*, 102 F.4th at 463. Illinois's law takes away that right, thereby increasing the obligations and burdens of 340B participation. But "[t]he determination of what conditions to impose on 340B-participating manufacturers rests with Congress, not the States." U.S. Br. 18.

116. The Supremacy Clause prohibits States from engrafting new, costly state law obligations like H.B. 2371 onto an existing federal program and overturning the careful balance of benefits and burdens that Congress established.

117. H.B. 2371 will cause substantial economic harm to AstraZeneca, which would lose approximately $2.5 million per month as a result of being forced by the law to provide access to 340B discounts for unlimited contract pharmacy sales.

118. The burden imposed by H.B. 2371 on AstraZeneca's participation in the 340B program is compounded by the laws of several other states, which have recently adopted comparable statutes. Arkansas, Colorado, Hawaii, Kansas, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Nebraska, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, and West Virginia have all passed similar—but somewhat different—laws requiring manufacturers to make 340B discounts available for contract pharmacy sales. AstraZeneca now must navigate complying with all these laws and their slight variations, while still balancing its 340B participation and the federal requirements.

119. ***Second***, in addition to preventing States from burdening participation in federal programs, the Supremacy Clause prohibits States from establishing parallel regimes that encroach on the federal government's authority to set and define federal enforcement priorities. *See Buckman*, 531 U.S. at 349-51.

120. When it created the 340B program, Congress centralized enforcement of the program in HHS. Indeed, Section 340B does not invite States to play any role in enforcement of the program or its requirements, nor does it invite States to regulate any aspect of sales under the program.

121. H.B. 2371 directly interferes with the robust federal enforcement regime that Congress has enacted for the 340B program, which includes the ADR process, required auditing provisions for manufacturers and covered entities, and the possibility of civil monetary penalties in the event of a manufacturer overcharge or diversion by a covered entity.

122. Indeed, H.B. 2371 expressly *prevents* manufacturers from using the federal enforcement regime. "[M]anufacturers are required to audit a covered entity prior to filing an ADR claim," 89 Fed. Reg. at 28,644; *see* 42 U.S.C. § 256b(d)(3)(B)(iv), but a manufacturer must have "documentation" indicating diversion or duplicate discounts before it may initiate such an audit, 61 Fed. Reg. at 65,409. Yet H.B. 2371 restricts manufacturers' ability to collect necessary claims data regarding the purchase and dispensing of 340B drugs by covered entities and contract pharmacies, because it forbids them from requiring the submission of such data from covered entities and their contract pharmacies. H.B. 2371 § 15(c)(1), (3).

123. Without this claims data, manufacturers are unable to adequately identify duplicate discounts or diversion. They are likewise significantly hampered in establishing the "reasonable cause" required to conduct audits of covered entities, as is their statutory right. *See* ¶¶ 26, 76-77, *supra*.

124. "By restricting the very method by which data collection is made," H.B. 2371 "frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit required to access the alternative dispute resolution system." *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 453 (S.D. W. Va. 2024).

125. The data-collection restriction conflicts with federal law in other ways, too. Under the Inflation Reduction Act, Congress has instructed HHS to "negotiate" with manufacturers regarding the "maximum fair price" that Medicare will pay for certain drugs. 42 U.S.C. § 1320f-3(a). A manufacturer whose drug is selected for "negotiation" must make the drug available at the "maximum fair price" unless it is available at a lower 340B price. *Id.* § 1320f-2(d). To ensure compliance with the IRA and to prevent duplicative price reductions under Section 340B and the IRA, the Centers for Medicare and Medicaid Services (CMS) has charged manufacturers with identifying instances where a drug has been dispensed as a 340B drug. *See* CMS, Medicare Drug Pricing Negotiation Final Guidance 58-60 (Oct. 2, 2024), https://bit.ly/4zdb0im. But H.B. 2371 restricts manufacturers' ability to obtain the data that manufacturers need to make those identifications. It therefore inhibits manufacturers' ability to avoid such unlawful duplicate price

reductions under Section 340B and the IRA, conflicting with federal law. *See* 42 U.S.C. § 1320f-2(d) (providing that manufacturers "shall not be required" to provide duplicate discounts).

126. Recognizing that manufacturers who lack claims data run a significant risk of paying duplicate discounts, moreover, HRSA recently approved a pilot program under which manufacturers may first receive claims data from covered entities before paying 340B rebates. *See* 91 Fed. Reg. 48,883 (Aug. 3, 2026). As HRSA explained, obtaining such data "will enable manufacturers to better identify 340B transactions both for purposes of their nonduplication efforts in MDPNP [*i.e.*, the Inflation Reduction Act's Medicare Drug Price Negotiation Program] and deduplication in Medicaid Managed Care," as well as supporting "program integrity measures and overall transparency." *Id.* at 48,890. AstraZeneca is eligible to participate in the pilot program, under which eligibility is limited to "selected drugs for [the MDPNP's] initial price applicability year 2026 and 2027." *Id.* at 48,884. AstraZeneca has two drugs selected for those years: Farxiga has been selected for 2026; Calquence has been selected for 2027. *See* CMS, *Selected Drugs and Negotiated Prices* (May 22, 2026), https://tinyurl.com/3yzzfx39. AstraZeneca intends to participate in the pilot program with respect to both drugs.

127. The data identified as appropriate for a manufacturer to receive under the pilot program is precisely the same data that H.B. 2371's data-collection restriction forbids them to request. *See* 91 Fed. Reg. at 48,903; H.B. 2371 § 15(c). H.B. 2371 thus precludes manufacturers like AstraZeneca from participating in the pilot program, because it forbids them from collecting the data that the pilot program contemplates.

128. Indeed, H.B. 2371's interference with a manufacturer's ability to audit covered entities is *express*: The law directly restricts their ability to "institute requirements in any way relating to . . . the frequency or scope of audits of inventory management systems." H.B. 2371 § 15(c)(2).

129. H.B. 2371 interferes with enforcement of the 340B program in yet another respect too: It requires state officials to adjudicate disputes about the meaning and application of federal terms and provisions.

130. H.B. 2371 enables the Attorney General to initiate an enforcement proceeding. *See* H.B. 2371 § 40.

131. In any state enforcement proceeding, a state adjudicator would be required to consider and resolve questions of federal law in order to determine whether a manufacturer has violated H.B. 2371. Among other things, the adjudicator would need to decide whether the 340B drugs to which the manufacturer allegedly denied or restricted access were intended for "a patient of the entity," as required for eligibility under the 340B program. 42 U.S.C. § 256b(a)(5)(B). That question turns on the definition of "patient of the entity" under federal law. The adjudicator would also be required to determine whether a particular covered entity continues to qualify for participation in the 340B program, which depends on whether the entity sells or transfers 340B-drugs to anyone other than its patients or seeks duplicate discounts. *See id.* § 256b(a)(4) (defining "'covered entity'" to "mean[] an entity that meets the requirements described in paragraph (5)," which includes the prohibitions on diversion and duplicate discounts). These issues are often disputed and have been the subject of federal litigation. *See, e.g.*, *Amgen Inc. v. Becerra*, No. 1:24-cv-3571 (D.D.C. filed Dec. 20, 2024); *Albany Med Health Sys. v. HRSA*, No. 1:23-cv-3252 (D.D.C. filed Oct. 31, 2023).

132. In *Astra USA, Inc. v. Santa Clara County*, the Supreme Court held that private entities may not bring actions under state contract law to enforce the provisions of manufacturers' 340B pharmaceutical pricing agreements. 563 U.S. at 113-14. "Congress made HHS administrator of … the 340B Program." *Id.* at 120. Suits by private entities, the Court explained, "would undermine the agency's efforts" to administer the program "harmoniously and on a uniform, nationwide basis." *Id.* "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*

133. H.B. 2371 makes that risk unavoidable. The federal administrative process assigns responsibility to HRSA to resolve disputes related to "overcharge[s]," which include claims that a manufacturer has "limited [a] covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." 42 C.F.R. §§ 10.3, 10.21. Answering these questions is central to

HHS's enforcement of the program on a uniform, national basis. Allowing States to provide their own—potentially conflicting—answers will interfere with that uniform system of enforcement. H.B. 2371 requires state officials to do precisely that.

134. By inserting Illinois and its officials into the program that Congress adopted, the law frustrates the accomplishment of Congress's objectives and interferes with Congress's chosen method of oversight.

135. ***Third***, H.B. 2371 "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *McHenry Cnty.*, 44 F.4th at 591 (quoting *Arizona*, 567 U.S. at 399), because it attempts to redefine the class of individuals eligible to receive drugs purchased through the 340B program. *See* H.B. 2371 § 30. But Congress alone may determine which individuals are eligible to receive 340B drugs, which depends on the meaning of the federal term "patient of the entity" under Section 340B. 42 U.S.C. § 256b(a)(5)(B).

H.B. 2371 Is Preempted by Federal Patent Law as Applied to AstraZeneca's Patented Products

136. As applied to AstraZeneca's patented products, H.B. 2371 is also preempted by the federal patent laws because it regulates the prices at which patented drugs may be sold.

137. The Constitution gives Congress exclusive authority to establish a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. Under the federal patent law, inventors are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *BIO*, 496 F.3d at 1372. The public can benefit from immediate access to new inventions during the exclusivity period; and after the period expires, the public gets "lower price[s] through unfettered competition." *Id.* at 1373. The States are not free to upset that finely calibrated system: "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a

judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989).

138. State laws that cap or fix the prices at which patented drugs may be sold are accordingly preempted by federal patent law, as the Federal Circuit has explained, because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia law that prohibited patented drugs from "being sold in the District for an excessive price." *Id.* at 1365. The court explained that, notwithstanding "the District's judgment" that drug manufacturers were charging "excessive prices" that "threaten[ed] the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need," the law was "contrary to the goals established by Congress in the patent laws." *Id.* at 1365, 1374 (quoting D.C. Code § 28-4551). The District's law was therefore preempted because "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Id.* at 1374.

139. A district court in Colorado recently reached the same conclusion. There, Colorado had empowered a state board "to control the price of certain drugs for Colorado consumers." *Amgen Inc.*, *et al. v. Mizner*, No. 1:25-cv-03452, 2026 WL 1943512, at *1 (D. Colo. July 1, 2026). A manufacturer challenged the board's decision to cap the price of one of the manufacturer's patented drugs to approximately 70% of its wholesale price. *Id.* Applying the Federal Circuit's reasoning from *BIO*, the district court preliminarily enjoined Colorado's "upper payment limit" for the drug. *Id.* at *4. The court rejected an argument that the manufacturer would not "actually be harmed by the price cap given the convoluted way" that the drugs are "paid for at various levels

of the supply chain." *Id.* at *2. Semantics aside, what mattered for preemption purposes was the fact that, "as a result" of the board's action, the manufacturer would "receive less money from its wholesalers" for its patented drug sales and would "fare more poorly in negotiations with other purchasers." *Id.* These financial effects "change[d] the bargain struck by Congress" through the federal patent laws. *Id.* at *3. The court thus held that Colorado's "attempt to rebalance Congress's patent system" was "preempted by federal law." *Id.* at *6.

140. The same analysis applies to H.B. 2371. Like the Colorado law invalidated in the *Amgen* case and the District of Columbia law invalidated in *BIO*, H.B. 2371 restricts the prices at which manufacturers must offer their patented drugs by requiring them to make 340B discounts available for unlimited contract pharmacy sales. Whereas Section 340B caps drug prices with respect to a manufacturer's offer to sell its drugs to a limited set of specifically enumerated covered entities, H.B. 2371 purports to extend those price caps to a category of sales—unlimited contract pharmacy sales—where federal courts have held that manufacturers are *not* required to offer them under the federal program. Accordingly, H.B. 2371 functions as a price cap for unlimited contract pharmacy sales, impermissibly constraining manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *BIO*, 496 F.3d at 1372.

141. But even if H.B. 2371 could somehow be construed as a regulation of delivery, rather than a regulation of pricing, it would *still* be preempted, because the costly new obligations it imposes—however they are described—indisputably "result" in manufacturers "receiv[ing] less money" for sales of their patented drugs, *Amgen*, 2026 WL 1943512, at *2, and thus constrain manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *BIO*, 496 F.3d at 1372.

142. H.B. 2371 is thus preempted by federal patent law as applied to AstraZeneca's patented products. States are not permitted to set the prices of patented drugs or to "re-balance" the "rewards and incentives" embodied in the federal patent laws, as Illinois has done here. *Id.* at 1374.

H.B. 2371 Violates the Contracts Clause

143. H.B. 2371 also violates the Contracts Clause of the U.S. Constitution. Article I, section 10, clause 1 of the Constitution provides that "No State shall . . . pass any . . . Law impairing the Obligation of Contracts." The Supreme Court "has outlined a three-step inquiry to determine whether or not a law violates the contract clause." *Chicago Bd. of Realtors, Inc. v. City of Chicago*, 819 F.2d 732, 736 (7th Cir. 1987) (citing *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 411-12 (1983)). First, the courts ask whether the state law "in fact operates as a substantial impairment of existing contractual relationships." *Id.* Second, if the court finds substantial impairment, it "must inquire whether the city has a significant and legitimate public purpose justifying" the state law. *Id. Third*, if the State presents a legitimate justification for the impairment, the court must determine "whether the effect of the [law] on contracts is reasonable and appropriate given the public purpose behind" the state law. *Id.*; *accord Alarm Detection Sys., Inc. v. Vill. of Schaumburg*, 930 F.3d 812, 822 (7th Cir. 2019) (collapsing these same questions into a two-part framework).

144. H.B. 2371 fails at every stage of this test. H.B. 2371 substantially impairs a contractual relationship. As explained above, the 340B program operates through contracts, which are called pharmaceutical pricing agreements (or "PPAs"). PPAs are "uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. While PPAs are not "transactional, bargained-for contracts," *id.*, they

nonetheless announce the parties' rights and obligations like any other contract, and manufacturers like AstraZeneca are entitled to rely on the PPA's terms when developing their business.

145. Among those terms is the requirement that manufacturers offer discounted drugs only for sales to a specifically delineated set of "covered entities." As the Third Circuit held, and the D.C. Circuit later underscored, neither the 340B statute nor the PPA requires AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Novartis Pharms.*, 102 F.4th at 461 (quoting *Sanofi*, 58 F.4th at 703).

146. H.B. 2371 operates as a substantial impairment of AstraZeneca's PPA with the HHS Secretary. AstraZeneca joined the 340B program with the expectation and understanding that it would be required to offer discounts only for a limited category of sales, and it accepted that obligation. The Act seeks to unilaterally expand AstraZeneca's obligations under that contract—without AstraZeneca's consent—by requiring AstraZeneca to offer discounts for an entirely new category of sales: contract pharmacy sales.

147. The U.S. Supreme Court has held that similar expansions of beneficiaries to a contract constitute substantial impairment under the Contracts Clause. *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245-46 (1978) (Contracts Clause prohibited State from requiring company to provide additional pension benefits after it had agreed to provide pension benefits under specific contractual conditions); *see also United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 630 (5th Cir. 2010) (Contracts Clause prohibited state from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions).

148. Any justification Illinois might offer for H.B. 2371 would be insufficient under the Contracts Clause. Illinois cannot claim that its law is necessary to "ensure that 340B covered entities continue to be allowed to contract with pharmacies to receive 340B drugs and dispense

them to the patients of 340B covered entities in accordance with federal law," in order to "preserv[e] and improv[e] access to health care services." H.B. 2371 § 5(3). Nor can it plausibly assert that H.B. 2371 is required to "[a]ddress[] accessibility" of AstraZeneca's medications. *Id.* § 5(4). AstraZeneca's policy *already* ensures that every covered entity is offered those drugs at a discounted price. Indeed, AstraZeneca's policy goes further, allowing covered entities to designate a single contract pharmacy if they do not have an on-site pharmacy. And H.B. 2371 is not "in accordance with federal law"; it surpasses and conflicts with it.

149. Illinois has no legitimate justification for requiring discounts for unlimited contract pharmacy sales, which will advance the economic interests of for-profit entities at the expense of companies like AstraZeneca, particularly where Congress itself has not required them.

150. Nor can Illinois justify H.B. 2371 as a cost-reduction mechanism for patients. Nothing in the Act requires that discounts must be passed on to patients, and in fact studies show that most 340B discounts for contract pharmacy sales *are not* passed on to patients, who must pay full price for their drugs. *See* ¶ 41, *supra*.

151. Finally, even if Illinois could articulate a legitimate justification for H.B. 2371's impairment of AstraZeneca's PPA, that justification would not be reasonable and necessary to achieve the State's goals.

H.B. 2371 Violates the Takings Clause

152. The Takings Clause of the U.S. Constitution provides that "private property" may not "be taken for public use, without just compensation." U.S. Const. amend. V.

153. Under the Takings Clause, although the government may take private property "for public use" so long as it pays "just compensation," the government may never take private property for *private* use, regardless of the amount of compensation paid. As the U.S. Supreme Court has explained, "the sovereign may not take the property of *A* for the sole purpose of transferring it to

another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo*, 545 U.S. at 477. Such takings for private use are always unlawful, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

154. H.B. 2371 takes the private property of manufacturers like AstraZeneca for private, not public, use. The law forces manufacturers to offer their prescription drugs to other private (non-governmental) entities—namely, to covered entities and the pharmacies with which they contract—at prices that AstraZeneca would not otherwise offer (and is not required to offer under federal law). Once the 340B-priced offer compelled by H.B. 2371 has been accepted by a covered entity, AstraZeneca has no choice under the law but to relinquish custody, title, and control of its product.

155. This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. *See id.* But manufacturers are *not* justly compensated for the forced transfers covered by the law: The law requires manufacturers to make these transfers at steeply discounted prices, well below fair market value.

156. This forced transfer results in the "physical appropriation" of manufacturers' prescription drugs by contract pharmacies and covered entities, and it therefore constitutes "a *per se* taking." *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 149 (2021).

157. H.B. 2371 accordingly violates the Takings Clause of the U.S. Constitution.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – H.B. 2371 Violates the Supremacy Clause, U.S. Const. art. VI, cl. 2)

158. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

159. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law that discriminates against the federal government or those with whom it does business. *Washington*, 596 U.S. at 838.

160. H.B. 2371 unconstitutionally interferes with the operations of the federal government and discriminates against government contractors. *See Washington*, 596 U.S. at 838. The law imposes additional burdens and regulations on drug manufacturers *only if* those manufacturers choose to contract with the federal government. Because H.B. 2371 applies *only* to federal contractors—namely, drug manufacturers who sign PPAs with the HHS Secretary to participate in the 340B program—and singles out those manufacturers for unfavorable treatment, the law violates the Supremacy Clause.

161. For these reasons, H.B. 2371's provisions requiring manufacturers to offer 340B discounts for unlimited contract pharmacy sales and imposing other restrictions on manufacturers' rights to freely contract with covered entities and pharmacies are preempted by federal law under the Supremacy Clause.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – H.B. 2371 Violates the Supremacy Clause, U.S. Const. art. VI, cl. 2)

162. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

163. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *McHenry Cnty.*, 44 F.4th at 591 (citation omitted).

164. H.B. 2371 creates such an obstacle to the accomplishment and execution of Congress's objectives for the 340B statute. It imposes significant new costs for participating in a federal benefits program, changing the careful bargain Congress created as an exercise of its spending power and thereby "exert[ing] an extraneous pull on the scheme established by Congress" and "skew[ing]" the "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348, 353. In addition, Section 340B includes a comprehensive regime for enforcement and management of the program, which includes the ADR process, audits, and civil monetary penalties. H.B. 2371's attempt to insert into Congress's program a layer of enforcement by state officials under Illinois law frustrates Congress's purposes and interferes with the carefully specified federal regime it created.

165. H.B. 2371 further "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *McHenry Cnty.*, 44 F.4th at 591 (citation omitted), because it purports to redefine the term "patient," which is a federal statutory term that must be applied uniformly across the 340B program. Yet Illinois's law, by providing its *own* definition of "patient," seeks to control even which individuals may access drugs purchased by a covered entity through the 340B program. *Federal law* already makes these decisions, and requires that related disputes be handled under federal law. Illinois's attempts to supplant the federal definition of a federal term with a state-specific definition are preempted.

166. H.B. 2371's restriction on manufacturers' ability to collect claims data also "frustrates drug manufacturers' ability to take the initial steps necessary to start the very audit required to access" Section 340B's alternative dispute resolution system. *Morrisey*, 760 F. Supp. 3d at 453. It likewise conflicts with other federal laws and regulations, including by interfering with a manufacturer's ability to meet its obligations under the Inflation Reduction Act and by

preventing manufacturers, including AstraZeneca, from participating in HRSA's rebate pilot program.

167. For these reasons, H.B. 2371's provisions requiring manufacturers to offer 340B discounts for unlimited contract pharmacy sales, imposing restrictions on manufacturers' rights to freely contract with covered entities and pharmacies, barring manufacturers from obtaining claims data from covered entities and pharmacies, and empowering Defendant to pursue purported violations of the statute, are preempted by federal law under the Supremacy Clause.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – H.B. 2371 is Preempted by Federal Patent Law and the Supremacy Clause, U.S. Const. art. VI, cl. 2)

168. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

169. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law." *Felder*, 487 U.S. at 138 (quoting Free, 369 U.S. at 666). Moreover, the Constitution assigns exclusive authority to regulate patents to the U.S. Congress. With respect to pharmaceuticals, Congress has enacted comprehensive legislation establishing the scope of patent rights under federal law. Thus, state laws that cap or fix drug prices are preempted by federal patent law because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374.

170. H.B. 2371 requires manufacturers to make 340B discounts available for unlimited contract pharmacy sales, and it empowers Defendant to pursue purported violations of the statute. As applied to AstraZeneca's patented products, those provisions are preempted by federal patent law under the Supremacy Clause.

171. The obligation imposed by H.B. 2371 on manufacturers—to offer 340B discounts for unlimited contract pharmacy sales—caps the prices at which manufacturers can sell their patented drugs and constrains manufacturers' "opportunity" to take advantage of the benefits of exclusivity "during the patent's term." *Id.* at 1372. The Act therefore impermissibly seeks to "re-balance" the "rewards and incentives" embodied in the federal patent laws in a manner that is beyond a state's powers. *Id.* at 1374. H.B. 2371 is therefore preempted by federal patent law under the Supremacy Clause as applied to AstraZeneca's patented products.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – H.B. 2371 Violates the Contracts Clause, U.S. Const. art. I, § 10, cl. 1)

172. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

173. Under the Contracts Clause, U.S. Const. art. I, § 10, cl. 1, "[n]o State shall . . . pass any . . . Law impairing the Obligation of Contracts." The Contracts Clause thus prohibits States from enacting legislation that "operate[s] as a substantial impairment of a contractual relationship." *Alarm Detection Sys., Inc. v. Vill. of Schaumburg*, 145 F.4th 675, 679 (7th Cir. 2025) (quoting *Sveen v. Melin*, 584 U.S. 811, 819 (2018)).

174. H.B. 2371 violates the Contracts Clause. It substantially impairs AstraZeneca's PPA with the HHS Secretary by requiring AstraZeneca to offer 340B discounts for unlimited contract pharmacy sales, thus purporting to substantially expand AstraZeneca's obligations under the agreement beyond what the agreement itself provides.

175. Illinois has no valid justification for impairing AstraZeneca's PPA. AstraZeneca's policy ensures that every covered entity is offered 340B drugs at statutorily required prices. The policy also allows covered entities without an on-site pharmacy to utilize a single contract

pharmacy, which is more than the statute requires. Compelling AstraZeneca to provide 340B-discounted drugs for unlimited contract pharmacy sales advances the economic interests of private entities at AstraZeneca's expense, with little to no benefit to 340B patients.

176. Even if Illinois could identify a legitimate justification for impairing AstraZeneca's PPA, it would not be reasonable and necessary to achieve the State's goals.

177. H.B. 2371 is also unconstitutional under the Contracts Clause to the extent it requires AstraZeneca to offer 340B discounts for sales at contract pharmacies that do not qualify as covered entities, and which therefore are not included within the anticipated or actual scope of the PPA that AstraZeneca signed with the HHS Secretary.

FIFTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – H.B. 2371 Violates the Takings Clause, U.S. Const., amend. V)

178. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

179. Under the Takings Clause of the Fifth Amendment of the U.S. Constitution, the government may not take "private property" for private use—such as requiring the transfer of ownership from one private party to another—even if just compensation is paid. *See Kelo*, 545 U.S. at 477.

180. H.B. 2371 takes private property for private use by forcing manufacturers to transfer 340B-discounted drugs—including relinquishing title and control of the drugs—to private, non-governmental entities (covered entities and their contract pharmacies) at non-commercial prices that AstraZeneca would not otherwise offer.

181. H.B. 2371 also denies manufacturers just compensation because it requires that their drugs be transferred to these private entities at below-market prices.

182. The forced transfer of drugs under H.B. 2371 constitutes a *per se* taking.

183. H.B. 2371 is therefore unconstitutional under the Takings Clause.

PRAYER FOR RELIEF

NOW, THEREFORE, AstraZeneca requests a judgment in its favor against the Illinois Attorney General as follows:

A. Declare that H.B. 2371 violates the Supremacy Clause and is preempted by Section 340B and is therefore null, void, and unenforceable;

B. Declare that H.B. 2371 is preempted by federal patent law, and therefore null, void, and unenforceable, as applied to AstraZeneca's patented products;

C. Declare that H.B. 2371 is unconstitutional as applied to AstraZeneca under the Contracts Clause of the U.S. Constitution;

D. Declare that H.B. 2371 is unconstitutional as applied to AstraZeneca under the Takings Clause of the U.S. Constitution;

E. Declare that AstraZeneca is not required to offer 340B discounts for unlimited contract pharmacy sales under Illinois law;

F. Issue preliminary and permanent injunctive relief preventing Defendant from implementing or enforcing H.B. 2371 against AstraZeneca or any of its affiliates, officers, agents, or contractors;

G. Issue preliminary and permanent injunctive relief preventing Defendant from seeking civil penalties, equitable relief, or any other remedy based on any alleged violation of H.B. 2371 by AstraZeneca or any of its affiliates, officers, agents, or contractors;

H. Award AstraZeneca reasonable attorneys' fees and costs, as appropriate; and

I. Grant such other and further relief as the Court may deem appropriate.

Dated: August 14, 2026

Respectfully submitted,

/s/ Daniel E. Raymond

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* *Applications to be admitted pro hac vice forthcoming*