IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, ***Plaintiff,*** **v.** **JONATHAN SKRMETTI, in his official capacity as Attorney General of Tennessee,** ***Defendant.***	**No. _____** **Judge: _____**

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMES NOW THE PLAINTIFF, by and through counsel, and for its complaint in this cause of action would state as follows:

1. Recently enacted Tennessee Senate Bill 1414 ("S.B. 1414") violates the United States Constitution's Supremacy Clause, dormant Commerce Clause, and Due Process Clause. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brings this Complaint and states as follows:

PRELIMINARY STATEMENT

2. S.B. 1414 is Tennessee's attempt to rewrite the terms of a federal program. As the bill's own author aptly introduced it: "Senate Bill 1414 is the 340B bill." Tenn. S. Com. & Lab. Comm. Hr'g Mar. 25, 2025 at 10:30 ("Mar. 25 Comm. Hr'g").[1] The substance and subject of the state law is unabashedly a federal drug pricing program reflecting a delicate, carefully calibrated balance struck by the United States Congress. State laws that attempt to rework that federal program are preempted. *Pharm. Rsch. & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439, 453-60 (S.D. W. Va. 2024) (concluding that state 340B statute was preempted because it conflicted with exclusive federal enforcement authority and limited access to the federal remedial regime); *cf. Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011) (holding common law remedy displaced because Congress trusted federal agency alone with administration of the program).

3. The 340B Drug Pricing Program, 42 U.S.C. § 256b ("340B"), a federal program enacted in 1992, is a unique form of privately funded federal subsidy. It requires that drug manufacturers make an "offer" to sell certain of their drugs to 15 statutorily enumerated types of healthcare providers ("covered entities") at "strikingly generous" prices—often "penn[ies] per unit." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024); 42 U.S.C. § 256b(a)(1), (4). Covered entities, in turn, are limited in what they can do with 340B-priced

[1] https://tnga.granicus.com/player/clip/31757?view_id=793&redirect=true.

drugs: By statute, they are barred from selling *or* transferring 340B-priced drugs to anyone other than their patients, which is known as "diversion." 42 U.S.C. § 256b(a)(5)(B).

4. Congress could not outright mandate these penny-price sales by manufacturers—doing so would invite constitutional challenge. Instead, Congress struck a specific bargain with drug manufacturers reflecting a careful balance of interests: If drug manufacturers agree to make a bona fide *offer* to sell certain drugs at 340B prices to covered entities, those drugs would also be eligible for reimbursement under Medicare Part B and the federal share of Medicaid. Otherwise, they would not. As two federal Courts of Appeals have made clear, Congress's chosen framework permits drug manufacturers to impose reasonable conditions on the offers they are required to make to covered entities. *See Novartis*, 102 F.4th at 460-61; *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 703-06 (3d Cir. 2023). Under fundamental principles of contract law, if covered entities accede to those conditions, they accept the terms of the offer and may purchase 340B-priced drugs. *See infra* ¶¶ 10-12, 45, 49-50, 96-102, 132; Williston on Contracts § 6:11 (4th ed.) ("Thus, if an act is requested [as part of an offer], that very act and no other must be performed."). If covered entities reject the conditions, the offer is rejected and no purchase of the 340B-priced drugs occurs. *Id.* ("[B]ecause the offeror is entitled to receive what it is it has bargained for, if any provision is added to which the offeror did not assent, the consequence is . . . that the offer is rejected, and that the offeree's power of acceptance thereafter is terminated.").

5. To incentivize continued participation and maintain uniformity, Congress authorized the U.S. Secretary of Health and Human Services ("HHS"), superintended by federal courts, to administer and enforce 340B through a range of carefully balanced and exclusive federal mechanisms. 42 U.S.C. § 256b(d). Those mechanisms include a unique administrative dispute

resolution ("ADR") scheme run by the U.S. Health Resources and Services Administration ("HRSA"), a subcomponent of HHS. *Id.* Congress intended HHS to "hold the control rein" to ensure that 340B would be administered "harmoniously on a uniform, national basis." *Astra USA, Inc.*, 563 U.S. at 120.

6. At the heart of this litigation is an effort to protect the integrity and viability of 340B by honoring the bounds Congress set on the program. Congress created 340B to help underserved patient populations of covered entities. But in recent years, 340B has become a lucrative moneymaker for national pharmacy chains, who are not supposed to profit from the program, and others who seek to enrich themselves at the expense of these underserved patients.

7. Over the past decade, concerns about diversion and illegal "duplicate discounts" in the 340B program have skyrocketed as covered entities have teamed up with so-called "contract pharmacies"—mostly for-profit pharmacies—nationwide to find ways to maximize the volume of 340B drug price reductions. Under the now prevailing product "replenishment model," contract pharmacies first order drugs at market prices, and then, following sale of those drugs, seek to replenish their inventories with 340B-priced drugs by retroactively identifying, via black-box algorithms, drugs that are purportedly eligible for 340B pricing.

8. As a result, the volume of drugs purchased at reduced 340B pricing has exploded. *See infra* ¶¶ 43-44. In 2023, discounted 340B purchases reached a record *$66.3 billion*, a $12.6 billion increase from 2022 and a $61 billion increase from 2010.[2] Those 2023 purchases reflect manufacturer-provided discounts of *$57.8 billion* from market rates. *Id.* And because the contract

[2] Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html; Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S. Cal. (Oct. 14, 2021), https://bit.ly/3FFSemV.

pharmacies claim the 340B pricing retroactively, almost no 340B price reductions are passed on to patients.[3]

9. The United States Government Accountability Office ("GAO") and the HHS Office of the Inspector General have warned about the risks of abuse created by the use of contract pharmacies and the product replenishment model. *See infra* ¶¶ 68-69. Manufacturers, including many PhRMA members, have identified specific concerns and independently adopted policies to address them. *See infra* ¶ 90. Although the exact contours of the policies differ, they are all intended to curb abuse, and generally (1) provide a limit on the number of outside pharmacies with which a covered entity may contract to receive 340B-priced drugs, such as so-called "one contract pharmacy policies," and (2) require the contract pharmacy to submit data supporting their claims for the 340B-priced drugs, referred to as "claims data policies," as a condition precedent to receiving 340B-priced drugs.

10. Both the D.C. and Third Circuits have held that, under federal law, these types of policies are reasonable and permissible conditions drug manufacturers may impose on the 340B offers they make to covered entities. *Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-06. Specifically, to help prevent 340B drugs from being diverted, manufacturers can include a condition that they will deliver 340B-priced drugs to the covered entity itself or, if the covered entity lacks an in-house pharmacy, one designated "contract pharmacy." *Novartis*, 102 F.4th at 460-64; *id.* at 456-58 (explaining how covered entities' use of an "unlimited" number of contract pharmacies materially changed the nature of the program and substantially inflated the volume of 340B-priced drugs); *Sanofi*, 58 F.4th at 704 ("Congress's use of the singular 'covered entity' in

[3] IQVIA. *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf.

the 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies.").

11. Similarly, under federal law, those same two federal appellate courts have held that manufacturers can lawfully include conditions requiring covered entities to provide certain details regarding the prescriptions on which they sought 340B pricing, known as claims data. *Novartis*, 102 F.4th at 463; *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *4 (D.D.C. Nov. 5, 2021), *aff'd*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi*, 58 F.4th at 701. This information is critical to determining whether a 340B prescription qualifies for the 340B pricing and, if not, to access the federal enforcement regime for redress. *See infra* ¶¶ 57, 94-102, 137.

12. If a covered entity, or a contract pharmacy purporting to act on its behalf, does not accept an offer with those conditions, there is no qualifying 340B "purchase" under 42 U.S.C. § 256b(a)(1), and therefore no obligation on manufacturers to provide 340B pricing.

13. In response to adverse federal court decisions interpreting the federal 340B statute, covered entities' representatives have turned to the states, including Tennessee, arguing that states can bar the very same conditions that federal law expressly permits these manufacturers to impose.

14. Numerous lawmakers, including one of S.B. 1414's own authors, recognized that Tennessee would be entering a domain already under federal control. Mar. 25, 2025 Comm. Hr'g at 15:10-15 (S.B. 1414 author Senator Richard Briggs: "[340B] is a complicated program, particularly with the relationship with the federal government."); Tenn. House Ins. Comm. Hr'g Mar. 5, 2025 at 46:30-37 (Tennessee Representative recognizing that federal government is evaluating 340B issues that S.B. 1414 seeks to govern);[4] *id*. at 47:45-48:00 (Tennessee

[4] https://tnga.granicus.com/player/clip/31486?view_id=824&redirect=true.

Representative asks: "This is so convoluted. Why is it so convoluted?" The Committee Chair responds: "There is something called the federal government involved.").

15. This type of meddling in a purely federal program is preempted. As one court has already held, laws that wrest enforcement control over the federal program from the federal government by imposing a state enforcement regime and that preclude collection of claims data violate the Supremacy Clause. *Morrisey*, 760 F. Supp. 3d at 453-60 (holding that the Supreme Court in *Astra* "has already found that such attempts to enforce 340B are contrary to law").

16. Those conclusions equally apply to S.B. 1414. In multiple ways, it purports to change the requirements of the federal 340B program and the conditions under which manufacturers are forced to provide their drugs at reduced prices. That violates the Supremacy Clause.

17. The law explicitly prohibits manufacturers from undertaking several actions that are fully permissible under federal law and that can be imposed as conditions as part of the manufacturers' offer of 340B-priced drugs. TN Code § 47-18-136(a). **First**, it breaks the federal remedial regime by essentially hiding from manufacturers details on 340B-priced drugs that are dispensed and by explicitly limiting manufacturers' federal audit rights. *Id.* § 47-18-136(a)(1) (barring collection of information, including "health information, claims or utilization data, purchasing data, payment data, or other data"), (4) (prohibiting manufacturers from "impos[ing] any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"). Under the federal regime, manufacturers must first audit a covered entity before initiating ADR and must also show good cause to the federal agency in order to initiate that first-step audit. *See infra* ¶ 135. S.B. 1414 directly interferes with both steps of that process, hiding from manufacturers the very information needed to initiate

audits and then *also* prohibiting their ability to exercise federal audit rights even where they have evidence of abuses.

18. **Second**, it prohibits manufacturers from adopting alternative pricing mechanisms, such as a "cash replenishment model," "cash-rebate model," or "credit model," that will provide greater transparency, are already in use for certain types of covered entities with the federal government's blessing and ensure manufacturers can comply with overlapping statutory commands. *Id.* § 47-18-136(a)(3).[5] It also specifies that manufacturers cannot reverse, resubmit, or ***even clarify*** if a 340B claim is compliant with federal law. *Id.* § 47-18-136(a)(2).

19. **Third**, it broadly prohibits manufacturers from imposing conditions such as credentialing or "any requirement determined by the attorney general . . . to interfere with the ability of a 340B entity to access discounts provided under the 340B program." *Id.* § 47-18-136(a)(5)-(6).

20. **Finally**, S.B. 1414 conflicts with the federal regime by forcing drug manufacturers to provide 340B-priced drugs to an *unlimited* number of contract pharmacies and locations, unless the manufacturer had preexisting limits or requirements in place before June 1, 2025 and does not change them. *Id.* § 47-18-136(c). Among other things, this state law requirement purports to outlaw drug manufacturers' ability to impose a one contract pharmacy condition on their offers—a condition that federal law allows.

[5] A cash replenishment, cash-rebate, or credit model may vary by manufacturer, but generally work as follows: Entities first buy manufacturer medicines at commercial prices, as they do under the current product replenishment model. *See infra* ¶ 107. After identifying a prescription as 340B-eligible, a covered entity submits a rebate claim to the manufacturer electronically. The manufacturer then issues a rebate representing the difference between the commercial price and the 340B price. That method is faster, simpler, and more transparent, and it gives a manufacturer the information needed to restore the 340B statute's guardrails.

21. In addition to those sharp conflicts, S.B. 1414 also impermissibly intrudes on the exclusive federal enforcement regime that Congress established, setting up a separate adjudicator and imposing draconian penalties. Because S.B. 1414 is tied to 340B, a Tennessee decisionmaker will need to decide multiple questions of federal law before imposing liability. 42 U.S.C. § 256b(a)(4)-(5). If Tennessee and other states are permitted to render decisions on these core federal issues, the uniform federal program will cease to be federal or uniform, directly contradicting the Supreme Court's reasoning in *Astra*.

22. S.B. 1414's penalties also conflict with the carefully balanced provisions in the federal statute. S.B. 1414 imposes a draconian $50,000 per violation penalty, with "[e]ach package of 340B drugs" constituting a "separate violation," as well as potential criminal penalties, and authorizes private rights of action by deeming a violation to be an "unfair or deceptive act or practice." TN Code § 47-18-136(d). The threat of harsh penalties imposed by states, including Tennessee, will transform 340B into something Congress never intended. Drug manufacturers may decide to opt out of key federal programs as a result, defeating the carefully balanced purposes of 340B entirely. *See Astra*, 563 U.S. at 120; *see also Novartis*, 102 F.4th at 462 (noting federal government's argument that 340B's "enforcement scheme is carefully calibrated, which tends to suggest that it is exclusive").

23. Although S.B. 1414's grandfather-like provision states that "subsection (c) does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025," TN Code § 47-18-136(c), many of S.B. 1414's substantive prohibitions are contained in subsection (a). The statute does not make clear how subsections (a) and (c) interact, and the Attorney General has provided no guidance on that issue. The statute also does not explain how revisions to manufacturer policies may implicate the grandfather-like provisions in subsection (c),

and the Attorney General has also provided no guidance on that issue either. That is important because, in light of new federal law developments and changes in the way that 340B functions, manufacturers routinely update their policies. Moreover, the provision expressly does not shield manufacturers' imposition of future conditions—conditions which would fully comply with federal law. For those reasons, the provision does not exempt S.B. 1414 from preemption.

24. Meanwhile, this expansion of 340B beyond federal bounds will further line the pockets of for-profit pharmacies and administrators, which were never intended to profit from 340B. *See* Fiscal Rev. Comm., Tenn. Gen. Assembly, Fiscal Mem. on S.B. 1414 as Amended at 2 (Mar. 31, 2025) (noting that "third-party administrators[] and contract pharmacies will experience an increase in business revenue as a result of the removal of restrictions and limitations on the 340B program"). As reflected in a recent report from the Minnesota Department of Health, approximately $1 out of $6 dollars of gross revenue by covered entities nationwide went to contract pharmacies and third-party administrators, who run the black-box algorithms to find allegedly 340B-eligible patients. Minn. Dep't of Health, 340B Covered Entity Report at 9 (Nov. 25, 2024).[6] Both CVS and Walgreens, for example, have publicly disclosed that 340B profits are material to their finances and that a reduction in contract pharmacy arrangements "could materially and adversely affect" their finances. CVS, SEC Form 10-K at 23 (2024);[7] Walgreens, SEC Form 10-K at 30 (2024).[8]

[6] https://www.health.state.mn.us/data/340b/docs/2024report.pdf.

[7] https://d18rn0p25nwr6d.cloudfront.net/CIK-0000064803/69ae70d3-3fe0-44a0-b601-f21026f8a49a.pdf.

[8] https://investor.walgreensbootsalliance.com/static-files/503eb8a7-cc54-446f-ba70-3460819aad71.

25. S.B. 1414 attempts to regulate in an exclusively federal field and, worse, directly conflicts with the federal statute. It is both field and conflict preempted under the Supremacy Clause.

26. S.B. 1414 also violates the Constitution's dormant Commerce and Due Process Clauses. S.B. 1414 is a textbook dormant Commerce Clause violation. No members of PhRMA are headquartered in Tennessee. And PhRMA's members primarily sell their drugs through wholesalers and distributors, who are also primarily located outside of Tennessee. Because S.B. 1414 applies to transactions between manufacturers and wholesalers/distributors, S.B. 1414 thus directly regulates wholly out-of-state transactions. Even worse, it does so with discriminatory intent and effect to privilege in-state 340B Program participants—pharmacies and covered entities—over out-of-state Program participants: manufacturers. Finally, S.B. 1414's broad prohibitions on "interference" provides no discernible standard by which manufacturers could conform their conduct or that would constrain enforcement, violating basic principles of due process. *See infra* ¶¶ 157-65.

27. PhRMA brings this action to declare unlawful this improper state intrusion into the federal 340B scheme and to enjoin preliminarily and permanently Defendant from enforcing S.B. 1414 against PhRMA's members and as to the sale of their drugs.

PARTIES

28. PhRMA, a trade association representing the nation's leading innovative biopharmaceutical research companies, advocates for policies that encourage the discovery and development of important new pharmaceutical products.

29. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to supply their drugs at a steeply reduced price under S.B. 1414 or otherwise face significant monetary and criminal penalties. On

its face, S.B. 1414 appears to prohibit all "requirements, prohibitions, limitations or restrictions" not "in place on or before June 1, 2025." TN Code § 47-18-136(c). PhRMA has members that have claims data policies and one contract pharmacy policies that existed before June 1, 2025. Those PhRMA members now risk violating S.B. 1414 if they modify their policies. Moreover, PhRMA members, with and without pre-existing policies, are foreclosed from imposing additional, new limitations.

30. Neither the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

31. Defendant Jonathan Skrmetti is the Attorney General of the State of Tennessee and is sued in his official capacity. The Attorney General has general enforcement authority over the Tennessee Consumer Protection Act, and is authorized to bring an appropriate action or proceeding in any court of competent jurisdiction. TN Code § 47-18-114. The Attorney General has his principal office in this district at 500 Dr. Martin Luther King Blvd., Nashville, Tennessee 37202.

JURISDICTION AND VENUE

32. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

33. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

34. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

35. Venue is proper in this district because this action challenges a Tennessee law applicable to the sale of PhRMA's members' drugs in this district, and thus S.B. 1414 purports to

directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within this district. 28 U.S.C. § 1391(b)(2).

36. Substantial amounts of PhRMA's members' drugs are sold under the 340B program to covered entities in this district. For example, HHS's website reflects that there are numerous covered entity sites in the Middle District of Tennessee. *See* HRSA, Covered Entity Search Criteria, https://340bopais.hrsa.gov/coveredentitysearch. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, S.B. 1414 is likely to be enforced against PhRMA members in this district.

37. Venue is also proper in this district because Defendant maintains his principal office in Nashville, in this district. 28 U.S.C. § 1391(b)(1).

BACKGROUND

A. The History of 340B

38. Congress established 340B in 1992 to restore drug discounts that had been provided voluntarily by manufacturers to a select group of safety-net providers before Congress passed the Medicaid Drug Rebate Program ("MDRP") in 1990. Indeed, Congress carefully restricted the list of eligible 340B covered entities to certain enumerated types of entities that "provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992) ("House Report").

39. Prior to the enactment of 340B, drug manufacturers had offered discounts on certain outpatient drugs on a voluntary basis to direct healthcare providers like covered entities, but not to pharmacies. *See* Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision After Two-And-A-Half Decades of Uncertainty*, 22 J. Health Care L. & Pol'y 25, 29-30 (2019) ("Prior to the MDRP, drug manufacturers regularly offered discounts to . . . hospitals

and other safety net providers"). When Congress passed the MDRP in 1990, that law took the manufacturers' previous *voluntary* "large discounts" to safety net providers like covered entities and factored it into the calculation of *required* "best price" for purposes of determining Medicaid rebates. *Id.* at 29-30. The "unintended consequence" of this pricing "snafu" was that drug manufacturers were "disincentivized" from continuing to provide the voluntary discounts they had provided to safety net providers prior to the MDRP's passage. *See id.*; *see also* H.R. Rep. No. 102-384, pt. 2, at 9-10 (1992).

40. Congress created 340B to address the limited problem created by the MDRP's enactment, specifically to restore the discounts that were previously offered voluntarily by manufacturers. *See* Pub. L. No. 102-585, 106 Stat. 4943, 4962; *see also* House Report at 12. When Congress passed 340B, the legislative history indicates that it intended to restore "discounts to these clinics, programs, and hospitals," i.e., "direct clinical care" entities, which had previously received voluntary discounts. House Report at 12.

41. When it passed the 340B law in 1992, Congress estimated that the Program would only include approximately 90 hospitals, 85 family-planning clinics, 120 AIDS-intervention sites, 54 AIDS drug purchasing assistance programs, a network of hemophilia treatment centers with 150 facilities, and 2,225 health centers that qualified to participate. *Id.* at 13.

B. The Operation and Growth of 340B

42. 340B has grown dramatically in the intervening years.

43. In 2023, 340B purchases reached a record *$66.3 billion*, a $12.6 billion increase from 2022 and a $61 billion increase from 2010.[9] There has been no similar increase in the relevant underserved patient populations that could explain this explosive growth.

44. With the list price value (*i.e.*, based on wholesale acquisition cost) of 340B purchases rising to $124.1 billion in 2023 alone, *id.*, 340B has become the second largest government pharmaceutical program, exceeded only by Medicare Part D.[10]

45. 340B is supposed to be governed by a federal statutory framework. Under 340B, participating manufacturers "*shall offer*" to each "covered entity" (as delineated by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute), *if* such drugs are offered to any other purchasers, meaning manufacturers must make a genuine offer to covered entities for purchase of 340B-priced drugs. 42 U.S.C. § 256b(a)(1). That requirement does not involve an obligation to provide 340B-priced drugs to an unlimited number of contract pharmacies. *See infra* ¶¶ 49-50, 96-102, 132.

46. Federal law defines "covered entity" for purposes of 340B to mean an entity that "is one of" 15 types of specifically enumerated categories of healthcare providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-priced drugs and does not seek or cause a duplicate Medicaid discount (*see infra* ¶ 51). 42 U.S.C. § 256b(a)(5).

---

[9] Adam J. Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html; Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S. Cal. (Oct. 14, 2021), https://bit.ly/3FFSemV.

[10] Adam J. Fein, *The 340B Program Reached $54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023), https://www.drugchannels.net/2023/09/exclusive-340b-program-reached-54.html.

47. Federally Qualified Health Centers, children's hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as "covered entities" eligible to enroll and participate in 340B. 42 U.S.C. § 256b(a)(4); *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Retail pharmacies are not among the listed covered entities.

48. Federal law defines the "ceiling price" for purposes of 340B to mean "the maximum price that covered entities may permissibly be required to pay for the drug." 42 U.S.C. § 256b(a)(1). That ceiling price is deeply reduced compared to the drug's market price.

49. Manufacturers must "offer" their covered outpatient drugs at or below the applicable "ceiling price" to "covered entities," and only "covered entities" may receive this pricing under the express terms of federal law. *See id.*

50. Identifying the specific obligations imposed by 340B's "shall offer" provision on drug manufacturers requires the interpretation of 42 U.S.C. § 256b(a)(1). According to courts that have reviewed this question to date, a drug manufacturer must provide some meaningful path for covered entities to obtain these medications at the 340B price. *See* 42 U.S.C. § 256b(a)(1); *Novartis*, 102 F.4th at 462-64; *Sanofi*, 58 F.4th at 703. But the statute does not mandate a commitment to provide 340B-priced drugs to an unlimited number of contract pharmacies of a covered entity's choosing. *Novartis*, 102 F.4th at 461 ("The requirement to 'offer' drugs at a certain 'price' does not prohibit distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree."); *see also Sanofi*, 58 F.4th at 703.

51. The 340B statute, in turn, forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), demonstrating that 340B is intended to be a closed system.

52. Manufacturers "opt into" 340B by signing a form federal contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That form contract is known as the PPA. *Id.* at 117. PPAs do not vary between manufacturers, but "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118.

53. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from the 340B program. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). The manufacturer, in turn, may be forced to withdraw from participating in Medicaid, and their drugs will no longer be eligible to receive reimbursements under Medicaid and Medicare Part B, which would have a profound impact on many vulnerable patient populations and our healthcare system. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

54. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B's oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation of the 340B program. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120.

55. Congress carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audits, ADR, and an enforcement scheme directed by HHS. For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

56. The imposition of penalties for violating 340B is directly committed to HHS: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties of up to $5,000 on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. 42 U.S.C. § 256b(d)(1)(B)(vi) (adjusted for inflation, $7,000). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price."

57. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of HHS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR).

58. These regulations must "designate or establish a decision-making official or decision-making body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and claims by manufacturers that violations of [statutory prohibitions on unlawful transfers of 340B drugs and duplicate discounts] have occurred." *Id.* (codified at 42

U.S.C. § 256b(d)(3)(B)(i)); *see* 42 C.F.R. § 10.20 (setting out requirements for ADR review panels).

59. HRSA regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii).

60. To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

61. Federal regulations issued in 2024 make clear HRSA's view that it has federal statutory authority to address issues regarding manufacturer contract pharmacy policies, including through ADR. *See* 89 Fed. Reg. 28,643, 28,649 (Apr. 19, 2024) (defining overcharge to encompass "a claim that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price or the manufacturer does not offer the 340B ceiling price"). In other words, the federal government believes it has authority to address the same precise subject matter S.B. 1414 purports to regulate. *Id.*; 42 U.S.C. § 256b(d)(1) (covering "overcharges and other violations of the discounted pricing requirements").

62. Covered entities must also comply with requirements under 340B. As explained above, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B) (prohibiting unlawful transfers). Covered entities are also prohibited from seeking or causing unlawful "duplicate discounts or rebates" from manufacturers. *Id.* § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the

same drug. A covered entity that engages in unlawful transfers or duplicate discounting, which would violate § 256b(a)(5), no longer qualifies as a covered entity under the federal statute. *Id.* § 256b(a)(4) (specifying that to qualify as a covered entity, the entity must "meet[] the requirements described in paragraph (5)"). Whether a healthcare entity qualifies as a "covered entity" is a decision entrusted to the federal government.

C. Contract Pharmacy Abuses

63. As noted above, 340B requires that a manufacturer offer 340B pricing only to a "covered entity." 42 U.S.C. § 256b(a)(1).

64. Retail pharmacies are not "covered entit[ies]," so they are ineligible to receive 340B pricing.

65. But certain private, for-profit entities—including the largest national chain pharmacies—have, in increasing numbers, sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is typically accomplished through complicated contractual arrangements between a covered entity, a pharmacy, and other entities like a third-party administrator.

66. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-priced drugs are legally permitted to be dispensed only to patients of 340B covered entities. Inevitably, and at great financial benefit to themselves, contract pharmacies sell drugs purchased at 340B prices to patients who are ineligible to receive such 340B-priced drugs. *See infra* ¶¶ 79-81. Contract pharmacies also reap financial benefit when they dispense to 340B-eligible patients: by extracting dispensing fees and a portion of the 340B "spread" (the difference between the 340B

price and what payers reimburse them for the drug), for-profit pharmacies divert value Congress intended to go to covered entities and their patients.

67. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 10 (2018) ("2018 GAO Report"), https://www.gao.gov/assets/gao-18-480.pdf. A more recent study put the increase between 2010 and 2020 at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4, Berkeley Rsch. Grp. (Oct. 2020), https://tinyurl.com/3rk5v8nu. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), https://tinyurl.com/5n7bmw5m.

68. Several federal watchdogs, including the GAO and HHS's own Office of the Inspector General ("OIG"), have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful claims for 340B drugs. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts."); HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy

Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.

69. Here is how the system has evolved over recent years: Under the product "replenishment model" now in widespread use by contract pharmacies,[11] the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients)—at prices significantly above the 340B price. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ. Labor, & Pensions*, 115th Cong. 11 (2018) (statement of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) ("Maxwell Testimony"), https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-115shrg30195.pdf ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)).

70. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify individuals with some relationship to a covered entity—purported covered entity "patients" who were not previously identified as covered entity "patients" at the time the drug was dispensed. *Novartis*, 102 F.4th at 457 (noting that the third-party administrators who run these algorithms "often receive a larger fee for every prescription deemed eligible for the discount").[12] These black-box algorithms likely result in contract pharmacies claiming prescriptions as 340B-eligible where the individual who was dispensed the

[11] A recent U.S. Senate report confirmed: "With the rise of contract pharmacy use in the 340B Program, most covered entities now use the virtual inventory/product replenishment model to dispense 340B drugs." U.S. Sen. Comm. On Health, Educ., Lab. & Pensions, 119th Cong., *Congress Must Act To Bring Needed Reforms To The 340B Drug Pricing Program* 31 (Apr. 2025).

[12] *See, e.g.*, 2018 GAO Report at 2; Maxwell Test. at 11.

drug is not a covered entity "patient." *See* HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), https://bit.ly/3eWKmBQ.[13] This process operates in an "after-the-fact" manner inconsistent with the specific program guidance published by HRSA. Although that guidance provides that each prescription be verified as 340B eligible at the time of drug dispensing, no prescriptions are verified in this manner under the replenishment model. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996); *see Novartis*, 102 F.4th at 457 ("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.").[14]

71. The pharmacies then purchase additional drugs at the 340B price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported covered entity patients. Again, this is done after the fact, without the benefit of data verifying that these retroactively deduced prescriptions were actually 340B eligible.

72. Once those replenishment drugs are received, the cycle starts anew: the 340B-priced drugs are again commingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M.

[13] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* Maxwell Test. at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B price because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), *see* Maxwell Test. at 11. This demonstrates how contract pharmacies can expand the definition of an eligible "patient" to cover additional, non-340B prescriptions. *See also Novartis*, 102 F.4th at 458 (remarking on this very issue).

[14] This is one reason why purchases of 340B-priced drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, at 5, PIONEER HEALTH (Mar. 2022), https://bit.ly/3MShVog.

Pedley ¶ 11, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-00634-PGS-JBD (D.N.J. June 24, 2021), ECF No. 93-2 (HRSA Director of Office of Pharmacy Affairs stating that under the product replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

73. On information and belief, supported by publicly available information, covered entities *do not* retain title to the drugs throughout the process, and contract pharmacies *do not* act as agents of covered entities and instead serve as independent contractors at most. *See, e.g.*, Walgreens Contract §§ 3.3.5, 8.10, *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-1603 (D.D.C. Nov. 29, 2024), ECF No. 24-2 (showing contract pharmacies take title to the 340B drugs and do not operate as agents of covered entities); Dallas County, 340B Contract Pharmacy Services Agreement – ReCept Pharmacy at 5 (Comm'rs Ct.) ("County shall purchase 340B Drugs through a written contract with the Supplier and shall hold title to such drugs from the time the Supplier fills the order from ReCept [(the contract pharmacy)] made on behalf of the County until the time that ReCept takes delivery of the drugs."), https://dallascounty.civicweb.net/document/22291/340B%20Contract%20Pharmacy%20Services%20Agreement%20-%20ReC.pdf; *see also* Pharmacy Services Agreement Between the County of Monterey and CVS Pharmacy, Inc. at 9, https://monterey.legistar.com/View.ashx?M=F&ID=7977212&GUID=F2A35B03-7A27-42B4-B968-A2C23EBFB315.

74. Indeed, on information and belief, covered entities do not even know beforehand that a contract pharmacy or a third-party administrator is submitting an order for 340B-priced drugs nominally in its name.

75. As is evident, the product replenishment model seeks to lower the price of drugs for commercial pharmacies and covered entities, not patients—by seeking to replenish contract

pharmacy inventories with 340B-priced drugs. There is no dispute that the pharmacies could replenish their inventories by ordering the drugs at market prices, but they instead attempt to do so at 340B prices.

76. On information and belief, the majority of Tennessee contract pharmacies operate using the product replenishment model. Indeed, S.B. 1414 attempts to give free reign to covered entities and contract pharmacies to use the product replenishment model and any other alternative models by barring manufacturers from "impos[ing] any requirements relating to inventory management systems of 340B drugs." TN Code § 47-18-136(a)(3).

77. This product "replenishment" practice can provide a windfall for covered entities and pharmacies. *See* U.S. Gov't Accountability Off., GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* 5 (2019), https://www.gao.gov/assets/gao-20-108.pdf (explaining that covered entities "purchase [340B-priced] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). As the D.C. Circuit noted, "[t]he covered entity, the pharmacy, and the third-party administrator [who runs the algorithms referenced above] often divvy up the spread between the discounted price and the higher reimbursement rate." *Novartis*, 102 F.4th at 457. Accordingly, "[e]ach of these actors . . . has a financial incentive to catalog as many prescriptions as possible as eligible for the discount." *Id.* at 457-58.

78. Both CVS and Walgreens, two of the largest for-profit pharmacy retailers, have publicly disclosed that 340B profits are material to their finances. *See supra* ¶ 24.

79. By contrast, patients routinely do not receive the benefit of the discount in the form of lower prescription costs. *See* Summ. J. Hr'g Tr. at 60:2-7, *PhRMA v. Murrill*, No. 6:23-cv-00997, ECF No. 78 (June 7, 2024) (Counsel for covered entity Intervenors: "Under replenishment, . . . the pharmacy is not going to know that that's a 340B eligible patient. That's not in the record the pharmacy has available."); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, at 3, 12, IQVIA (2022), https://tinyurl.com/mvuy8276 (concluding that "most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts" and that stakeholders in the 340B program, such as contract pharmacies, are "profit[ing] from 340B revenue"); Rory Martin & Harish Karne, *The 340B Drug Discount Program Grew to $124B in 2023*, at 6, IQVIA (2024), https://tinyurl.com/y9aeb727 ("If a substantial number of states pass [policies prohibiting the use of contract pharmacy restrictions], it could further accelerate 340B growth in the coming years" and "reignite the problem of duplicate discounts, since it is difficult to determine the 340B status of prescriptions that are filled at contract pharmacies.").

80. Recent evidence continues to reinforce these conclusions. For example, media reporting has revealed how in many cases 340B price reductions are not passed on to vulnerable populations in the form of lower prices. *See* Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL ST. J. (Dec. 20, 2022), https://tinyurl.com/bdhhzdhr (explaining that many hospitals do not pass on 340B discounts to their patients and that 340B appears to bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods); Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. TIMES (Sept. 24, 2022), https://tinyurl.com/28ubr4hd (explaining how one hospital "nakedly capitaliz[ed] on" 340B to turn

a profit); Joseph Walker, *Employers Get Big Drug Discounts Through Program for Hospitals That Serve Poor Patients,* WALL ST. J. (Mar. 15, 2025), https://tinyurl.com/y34ctaf5 (explaining how sophisticated middlemen help employers tap 340B to save money on prescription drug programs, a far cry from the program's original focus on aiding low-income patients).

81. Similarly, a recent GAO report surveying hospitals found that, of the 30 hospitals surveyed that reported use of contract pharmacies, almost half (14) indicated that they do not provide *any* discounts at contract pharmacies, 10 reported they provide discounts at some contract pharmacies, and only six provided discounts at all contract pharmacies. U.S. Gov't Accountability Off., GAO-23-106095, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* at 16 (2019), https://www.gao.gov/assets/gao-23-106095.pdf. Even among those that do provide discounts, most (10) reported that it varied by pharmacy or patient circumstances, three reported using the patient's co-pay as the "discount," two reported that they charged more than the 340B price the hospital paid, and only one reported charging less than the 340B price. *Id.* at 17.

82. In Tennessee, many contract pharmacies are not even located in low-income districts. A 2024 report from the Pioneer Institute found 46% of 340B pharmacies in the state, supposedly serving the poor, are located in affluent neighborhoods. Pioneer Inst., *340B in Tennessee* (2024).[15]

83. Other state level reports similarly demonstrate that covered entities and their contract pharmacies provide little financial benefit to vulnerable populations. A 2024 report from North Carolina's treasurer focusing on North Carolina's State Health Plan and purchased oncology drugs found that 340B hospitals applied an average markup of 5.4 times their discounted

[15] https://pioneerinstitute.org/wp-content/uploads/Tennessee-2024.pdf.

acquisition costs compared to the 2.9 times markup applied by non-340B hospitals. N.C. Treasurer, *Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program* at 14-15 (2024).[16] And while North Carolina's 340B hospitals reported an average 15.5% net profit margin compared to the 9.4% profit margin for non-340B hospitals, some of the hospitals reporting the lowest levels of charity care were 340B hospitals and 15.6% of 340B hospitals spent less than 1% on charity care. *Id.* at 19-20.

84. This unlawful and unauthorized expansion of the federal 340B subsidy has other repercussions as well. Expanding the subsidy has led to increased consolidation in the healthcare system, with large hospital beneficiaries snapping up smaller physician providers with "no evidence of hospitals using the surplus . . . to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality." Sunita Desai, Ph.D. & J. Michael McWilliams, M.D., Ph.D., *Consequences of the 340B Drug Pricing Program*, 378 NEW ENG. J. MED., 539, 546 (2018).[17]

85. Besides taking 340B price reductions intended for vulnerable populations, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); 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 (2011), https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared

[16] https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment.

[17] https://www.nejm.org/doi/pdf/10.1056/NEJMsa1706475.

to in-house pharmacies."). Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

86. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A). Unlawful duplicate discounting forces the manufacturer to provide a discount on its drug twice-over—once under 340B to the covered entity, and again in the form of a rebate to the state Medicaid agency.

87. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (2020), https://www.gao.gov/assets/gao-20-212.pdf. As the GAO explains, this is because of the difficulty of auditing and obtaining reliable data for covered entities with "complex" networks of contract pharmacies. 2018 GAO Report at 45.

D. Covered Entities' Repeated Efforts To Expand 340B

88. Covered entities have repeatedly attempted to circumvent federal authority over 340B to impose their own preferred obligations on 340B manufacturers.

89. In 2006, covered entities filed suit against several pharmaceutical manufacturers, claiming that they had been overcharged for 340B-priced drugs in violation of the PPAs between manufacturers and the federal government. *Astra*, 563 U.S. at 116-17. In 2009, on review, the Supreme Court unanimously rejected such private actions as an alternative 340B enforcement mechanism, emphasizing the need for 340B to be uniformly administered with an eye toward implications for other federal healthcare programs. *Id.* at 120. As the Supreme Court held, "Congress vested authority to oversee compliance with the 340B Program in HHS and assigned

no auxiliary enforcement role to covered entities." *Id.* at 117. Rather than allowing "340B entities to launch lawsuits in district courts across the country," with the attendant "risk of conflicting adjudications," "Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers." *Id.* at 120-21. "Congress thus opted to strengthen and formalize HRSA's enforcement authority, to make the new adjudicative framework *the proper remedy*[.]" *Id.* at 121-22 (emphasis added).

90. Approximately ten years later, with the continued explosion in contract pharmacy arrangements, the increased use of the product replenishment model and documented problems with program integrity, certain PhRMA members independently adopted new and different policies to address the 340B abuses reported by federal watchdogs. *See, e.g.*, First Am. Compl. ¶¶ 48-52; *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027 (D. Del. Feb. 12, 2021), ECF No. 13.

91. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS, Off. of the Sec'y, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020) ("Advisory Opinion"), https://tinyurl.com/2s4f924r (emphasis added); *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 55-56 (D. Del. 2021). Although the Advisory Opinion was subsequently vacated on other grounds, it demonstrated HHS's understanding that, at a minimum, an agency relationship is required between a covered entity and its contract pharmacy, echoing prior HRSA

guidance. 61 Fed. Reg. at 43,550, 43,555 (HRSA 1996 guidance stating that a covered entity without an in-house pharmacy could contract with *one* contract pharmacy to serve as its "agent").

92. In May 2021, HRSA issued letter decisions to the manufacturers that were implementing policies to address 340B abuses, including PhRMA members.[18] Litigation ensued.

93. In the context of those suits, courts have repeatedly concluded that the scope of manufacturers' obligations does not encompass offering or providing 340B-priced drugs to an unlimited number of contract pharmacies—one of the requirements Tennessee seeks to impose here.

94. The D.C. Circuit in *Novartis* and the Third Circuit in *Sanofi*, considering two of these lawsuits, began their recent analyses by explaining how the federal statute works and how contract pharmacy and claims data policies interact with it.[19]

95. In *Novartis*, one manufacturer was "willing to work with at least one contract pharmacy designated or previously used by the [covered] entity," so long as the "contract pharmacies provide claims data for contract-pharmacy orders." 102 F.4th at 463. The other manufacturer "intend[ed] to deliver section 340B drugs to a covered entity's in-house pharmacy

[18] *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are in Violation of the 340B Statute*, Health Res. & Servs. Admin., HRSA Letter to AstraZeneca Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2nybf4z2 (last visited May 2024); HRSA Letter to Lilly USA, LLC Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/5xkem3y7 (last visited May 2024); HRSA Letter to Novartis Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/jytw6xd6 (last visited May 2024); HRSA Letter to Novo Nordisk Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/ycxwceaz (last visited May 2024); HRSA Letter to Sanofi Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2veh5838 (last visited May 2024); HRSA Letter to United Therapeutics Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, https://tinyurl.com/2p85wz8d (last visited May 2024).

[19] One appeal remains pending. *See Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

or to a single contract pharmacy designated by the covered entity." *Id.* at 463-64. In *Sanofi*, two manufacturers permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy." 58 F.4th at 701. A third manufacturer similarly permitted the use of "one contract pharmacy" if the covered entity "d[id] not have an in-house pharmacy," but also permitted the use of "an unlimited number of contract pharmacies" if the covered entity "agree[d] to provide claims data." *Id.*

96. 340B requires that manufacturers "offer each covered entity covered outpatient drugs for purchase' at or below a specified ceiling 'price." *Novartis*, 102 F.4th at 460 (quoting 42 U.S.C. § 256b(a)(1)). The covered entity who receives such an "offer" can then accept the terms of the offer and "purchase" the covered outpatient drugs, or they can decide to not "assent to the same terms" and thus reject the 340B offer. *Id.* (quoting 1 *Corbin on Contracts* § 1.11 (2023)); *see also Sanofi*, 58 F.4th at 703 (holding that manufacturers are required to only "present the drugs [with conditions permitted] for covered entities' acceptance"). Indeed, that Congressional mandate does not "require the offeror to accede to any distribution terms demanded by the offeree." *Novartis*, 102 F.4th at 461; *Sanofi*, 58 F.4th at 703 (holding that the word "offer" does not "imply that the offeror must deliver good wherever and to whomever the buyer demands"). Where a covered entity rejects the offer, the manufacturer has fulfilled its 340B duty and there is no 340B purchase to which the 340B ceiling price applies. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703-04.

97. The D.C. Circuit rejected the assertion that 340B requires manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *Novartis*, 102 F.4th at 460. As the D.C. Circuit concluded, Congress chose to impose only certain restrictions on 340B-participating manufacturers—most notably that they make a "bona fide" offer, *i.e.*, that they

"propose to sell covered drugs to covered entities at or below a specified monetary amount." *Id.* Congress's judgment means that manufacturers remain free to impose "conditions on the distribution of covered drugs to covered entities." *Id.* at 459-60.

98. And the D.C. Circuit similarly rejected the notion that purported silence allowed for imposition of an unlimited contract pharmacy requirement. As that court noted, purported "silen[ce] about delivery conditions . . . preserves—rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Id.* at 460-61. The court also noted that this silence did not mean that manufacturers have carte blanche as to conditions. *Id.* at 462-63. Instead, Congress carefully circumscribed the obligations it placed on manufacturers, only permitting conditions that would not move offers out of the realm of "bona fide" offers. *Id.* The court expressly left to the federal government adjudication of "more onerous conditions" on offers than the ones before it, reviewed by federal courts. *Id.* at 464.

99. The Third Circuit's decision in *Sanofi* likewise rejected one of the very same obligations Tennessee seeks to impose here. 58 F.4th at 703-04. The Third Circuit noted that "Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* at 704 (340B does not "require[] delivery to an unlimited number of contract pharmacies"). The Third Circuit also expressly enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government "from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies"); *id.* at 704 (noting that "'Congress knew how to' grant covered entities permission to contract with third parties for

distribution . . . but did not" (quoting *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 36, 39 (2016))).

100. In doing so, the Third Circuit concluded that, despite the statute's "silence" as to the number of permitted contract pharmacies, such an unlimited contract pharmacy requirement "overstepped the statute's bounds," as reflected in 340B's structure and other considerations. *Sanofi*, 58 F.4th at 707. The Third Circuit left open the possibility, however, that the federal obligation may require that manufacturers offer to deliver 340B-priced drugs to some pharmacies in certain circumstances (for example, a single contract pharmacy where a covered entity lacks its own in-house pharmacy). 42 U.S.C. § 256b(a)(1); *Sanofi*, 58 F.4th at 703-04. Thus, *Sanofi* ultimately recognizes there is no gap in 340B into which states can step—instead the question requires interpretation of federal law. *Id.* at 705.

101. Two other courts are in accord. The U.S. District Court for the District of Columbia, likewise found in *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), and the court of appeals affirmed, *Novartis*, 102 F.4th at 455, that the 340B statute permits drug manufacturers to impose reasonable conditions regarding contract pharmacies as part of the manufacturers' participation in 340B, including a reasonable limitation on where manufacturers will send 340B-priced drugs. *Novartis*, 2021 WL 5161783, at *7. In a similar vein, the U.S. District Court for the District of Delaware found in *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021) that Congress chose not to require manufacturers to provide 340B-priced drugs to an unlimited number of contract pharmacies. *AstraZeneca*, 543 F. Supp. 3d at 58-59.

102. The same is true of manufacturers' conditions on their offers of 340B-priced drugs that require covered entities and contract pharmacies to provide certain claims data related to the

prescriptions that were purportedly dispensed as 340B drugs. Courts have concluded that manufacturers may impose such conditions (including to help fulfill statutory audit protections), and that those conditions on a 340B offer satisfy the federal obligation. *See Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* ("For its part, [plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463 (affirming holding). That leaves covered entities free to accept such offers, along with their terms, or reject them.

103. For their part, covered entities have sought to use the federal ADR mechanism, which is overseen by a panel within HHS, to enforce this purported obligation to provide 340B-priced drugs to any and all contract pharmacies identified by a covered entity. In those proceedings, a group of covered entities alleged that a drug manufacturer "ha[d] violated the 340B statute and regulations by failing to offer covered outpatient drugs at the 340B ceiling price through Petitioner's contract pharmacy arrangements." Those entities asked the panel "to order [the manufacturer] to resume offering covered outpatient drugs at the 340B ceiling price to Petitioner through its contract pharmacies; and to order [the manufacturer] to pay Petitioner an amount equal to the 340B discounts that [the manufacturer] has failed to provide." Petition for Damages and Equitable Relief ¶ 1, *Open Door Cmty. Health Ctrs. v. AstraZeneca Pharms., LP*, ADR ID: 210112-1 (HHS ADR Bd. Jan. 13, 2021), https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2021/01/open-door-adr-petition.pdf?rev=99130335a69d448fafa0110cab3230f6&hash=676DEFD45F067461E1FB3E72CD3CA492; *see also* Petition for Monetary Damages and Equitable Relief ¶¶ 35-37, *Univ. of Wash. Med. Ctr. v. AstraZeneca Pharms. LP*

(HHS Bd. Sept. 29, 2023) (Petition by a different group of covered entities asserting panel has jurisdiction over contract pharmacy disputes).

104. Dissatisfied with the federal outcomes to date, covered entities turned their sights to lobbying states. They seek to change the federal program by imposing on manufacturers, including by mandating that manufacturers take actions that even the federal agency tasked with 340B's administration and enforcement cannot require.

105. The repercussions of those efforts, if allowed to stand, will be intensified by the recently enacted Inflation Reduction Act ("IRA").[20] The IRA establishes the Medicare Drug Price Negotiation Program, under which HHS is to "negotiate" with manufacturers "maximum fair prices" for certain drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide drugs under these so-called maximum fair prices, except that they need not provide access to the maximum fair prices when drugs are 340B eligible and the 340B price is lower than the maximum fair price. *Id.* § 1320f-2(d). That is, manufacturers need not provide duplicate 340B and "maximum fair price" discounts. *Id.* To avoid duplicate discounting, this scheme necessarily requires identifying when a drug subject to the maximum fair price is dispensed as a 340B drug—further demonstrating the "interdependent nature" of Medicare and the 340B program. *Astra*, 563 U.S. at 120.

106. The Centers for Medicare and Medicaid Services ("CMS") has issued final IRA guidance for avoiding duplicate discounting under the Medicare Drug Price Negotiation Program. Under that guidance, a manufacturer bears the burden of determining and verifying whether a "claim for a selected drug is a 340B-eligible claim." CMS, Medicare Drug Pricing Negotiation

[20] Several of PhRMA's members have drugs that are subject to the IRA's Medicare Drug Price Negotiation Program, including Boehringer Ingelheim Pharmaceuticals, Bristol Myers Squibb Company, Astellas, Novo Nordisk, and Merck.

Final Guidance ("Final Guidance") at 60;[21] *see also* CMS, Medicare Drug Price Negotiation Program Draft Guidance ("Draft Guidance"), at 48 (A manufacturer must "indicate[] that the claim for [a] selected drug is a 340B-eligible claim and the 340B ceiling price is lower than the [maximum fair price] for the selected drug.").[22] To facilitate the identification of 340B drugs, dispensing entities are encouraged to use claims codes indicating which drugs are dispensed under the 340B program, and to provide prescriber identification information to help manufacturers identify "whether a prescription was written by a prescriber with a high percentage of claims originating from a 340B covered entity." Draft Guidance at 41; Final Guidance at 45, 57. Commenters noted "that, under the nonduplication approach described by CMS in the draft guidance, [IRA] Manufacturers would likely mandate 340B claims data submission from covered entities." Final Guidance at 57. "Many commenters strongly opposed CMS allowing for such mandates and stated that, at minimum, CMS should evaluate and regulate the data requirements imposed by [IRA] Manufacturers on covered entities." *Id.* In response to such comments, CMS stated it "will not prescribe a specific nonduplication approach that [IRA] Manufacturers must follow or impose parameters" on it, and noted in its justification that manufacturers bear the burden for ensuring nonduplication. *Id.* at 57-58.

107. In recent months, some manufacturers, including PhRMA members, have sought to adopt models known as "cash replenishment," "cash-rebate," and "credit models". Although the exact specifics may vary, the models generally work as follows. As with the product replenishment model, entities first buy manufacturer medicines at commercial prices, as they do

[21] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

[22] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

under the current product replenishment model. After identifying a prescription as 340B-eligible, a covered entity submits a rebate claim to the manufacturer electronically. The manufacturer then issues a rebate representing the difference between the commercial price and the 340B price. These methods are faster, simpler, and more transparent, and give a manufacturer the information needed to restore the 340B statute's guardrails.

108. Considering that context, a federal court recently held that the federal 340B statute "explicitly contemplates a rebate mechanism," and that the information gathered through use of these models was necessary to determine if impermissible duplication has occurred. *See Eli Lilly v. Kennedy*, No. 1:25-cv-00117, slip op. at 19 n.11, 27-28 (D.D.C. May 15, 2025).

E. Tennessee Enacts S.B. 1414 To Impose State-Law Conditions On 340B

1. S.B. 1414's Passage And Requirements

109. On May 5, 2025, Tennessee enacted S.B. 1414.

110. S.B. 1414 has the purpose and effect of regulating a federal program. Indeed, S.B. 1414 is clear that its regulatory object is the federal 340B program and without that federal program, S.B. 1414 would have no independent effect. *See* TN Code § 47-18-136(g)(1) ("340B drug" means a "drug that is a covered outpatient drug within the meaning of 42 U.S.C. § 256b(a)(1); and is purchased by a 340B entity or would have been purchased by a 340B entity but for a restriction or limitation described in § 56-7-3119(b)").

111. S.B. 1414 includes several prohibitions that apply explicitly to manufacturers. It instructs that "a drug manufacturer or their agent or affiliate, shall not, either directly or indirectly" (1) "Impose additional requirements or limitations on a 340B entity, including requiring the submission of any health information, claims or utilization data, purchasing data, payment data, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless such data submission is explicitly required by the United States department

of health and human services or applicable state law"; (2) "Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of business and not related to the 340B program"; (3) "Impose any requirements relating to inventory management systems of 340B drugs, unless such requirement is required by the United States department of health and human services or applicable state law; (4) "Impose any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"; (5) "Impose requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities; or (6) "Impose any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program." TN Code § 47-18-136(a).

112. S.B. 1414 also provides that "[a] drug manufacturer, or its agent or affiliate, shall not, either directly or indirectly, deny, impose any restrictions, prohibitions, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity unless such receipt is prohibited by the United States department of health and human services or applicable state law." *Id.* § 47-18-136(c).

2. Enforcement

113. S.B. 1414 does not acknowledge the limitations on enforcement power Congress deemed necessary to maintain the 340B program's delicate balance.

114. Instead, S.B. 1414 makes a violation of its provisions a violation of the Tennessee Consumer Protection Act. *Id.* §§ 47-18-136(d); S.B. 1414 § 2. The Tennessee Consumer Protection Act gives enforcement authority to the Tennessee Attorney General over violations of that section.

115. The civil remedies and penalties provided for include compliance with requests for information, restraining orders and other injunctive relief, reimbursement for costs and expenses of investigation and prosecution, and a civil penalty of $50,000 per violation where "[e]ach package of 340B drugs applicable to a violation of [S.B. 1414] subsection (a) or (c) constitutes a separate violation." *Id.* §§ 47-18-106, 108, 136(d)(2).

116. S.B. 1414 also subjects violators to criminal penalties. S.B. 1414 § 2. Violations of its provisions are declared to be an unfair or deceptive act in violation of the Tennessee Consumer Protection Act. As a result, a violation of S.B. 1414 is a Class B misdemeanor. TN Code § 47-18-104(a).

117. By defining a violation of its provisions as an unfair or deceptive act under the Tennessee Consumer Protection Act, S.B. 1414 effectively creates a private right of action. *See* S.B. 1414 § 2; TN Code § 47-18-109(a)(1) ("Any person who suffers an ascertainable loss of money or property … as a result of the use or employment by another person of an unfair or deceptive act or practice described in § 47-18-104(b) and declared to be unlawful by this part, may bring an action individually to recover actual damages."). Put differently, S.B. 1414 appears to empower private entities in Tennessee to circumvent the ADR system established by Congress as 340B's sole enforcement mechanism.[23]

118. These procedures and remedies differ dramatically from, and extend far beyond, the procedures and remedies that the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d). This includes Tennessee's provision of criminal penalties.

[23] *See Astra*, 563 U.S. at 118 ("The absence of a private right to enforce the statutory ceiling price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing.").

119. S.B. 1414 expressly predicates its purported addition of a state law obligation on the existence of an underlying federal obligation. TN Code § 47-18-104(a), (c).

120. As a result, in any state enforcement proceeding, a state adjudicator will be required to answer multiple questions of federal law to determine if a manufacturer violated S.B. 1414. These include, among other things, whether under *federal* law (1) a particular covered entity has permissibly contracted with a contract pharmacy under federal law and has the necessary "principal-agent" relationship required to even arguably comply with federal law, 42 U.S.C. § 256b(a)(5)(A)-(B); (2) the covered entity continues to "hold title" to the 340B-priced drugs throughout all relevant transactions (which does not occur under the prevailing product "replenishment model"); (3) all of the individuals receiving 340B-priced drugs meet the federal definition of a 340B patient; (4) the particular prescriptions at issue qualify for 340B prices; and (5) the 340B price reductions are duplicative of Medicaid rebates applicable to the same prescriptions, *id.*§ 256b(a)(5)(A). A state adjudicator will also be required to determine if a covered entity continues to qualify for participation in the federal program. For example, a covered entity that sells or transfers 340B-priced drugs to anyone other than its patients is no longer eligible to receive 340B-priced drugs. *Id.* § 256b(a)(5). Similarly, covered entities violating prohibitions on duplicate discounts are ineligible to receive any 340B-priced drugs. *Id.* § 256b(a)(4)-(5). Under S.B. 1414, a Tennessee state adjudicator court will be required to make these determinations to adjudicate any purported violation of S.B. 1414.

121. S.B. 1414's provisions are set to take effect on July 1, 2025.

CLAIMS FOR RELIEF

CLAIM I
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and the Federal 340B Statute)

122. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

123. Federal law is "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.

124. S.B. 1414 is preempted under the Supremacy Clause because it intrudes upon the exclusive field created by 340B and, worse, does so in a way that directly conflicts with the federal statute's terms and in a manner that is likely to generate conflict between state and federal regulators.

125. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1325 (10th Cir. 2010).

126. Field preemption is especially likely where a state law "'diminish[es] the [Federal Government]'s control over enforcement' and 'detract[s] from the integrated scheme of regulation' created by Congress." *Arizona*, 567 U.S. at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

127. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 120 (noting the "interdependent" nature

of 340B with other federal programs). No room exists for state supplantation in this field. Congress created the exclusively federal field here through enactment of 340B. *See supra* ¶¶ 38-62, 103. Unlike some other federal healthcare programs, where Congress has assigned the states significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); *id.* § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

128. The system crafted by Congress did not impose open-ended obligations on manufacturers. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed and limited system. Congress carefully defined those eligible to receive 340B drugs (enumerated covered entities), set the nature of the benefit (obligation to offer drugs), and imposed limitations on that benefit (to whom covered entities may furnish 340B-priced drugs). Congress spoke in exacting detail because maintaining a delicate balance in the 340B program, given its interconnection with other federal programs, is essential to ensure that the program achieves its purpose without becoming too onerous for manufacturers. Finally, Congress set out an exclusive federal enforcement scheme to maintain the federal programs as a harmonious whole. Each of these features reinforces that the 340B program is an area of dominant federal concern.

129. S.B. 1414 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding and materially altering the scope of manufacturers' obligations and rights, and by implementing a competing enforcement regime. That is far more than 340B requires, permits, or contemplates. *Sanofi*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating part of what Tennessee is now attempting to do).

130. That intrusion into the field of the operation of 340B is made clear by S.B. 1414's scope. Tennessee pharmacies can freely order any drug legally available to them at market pricing. S.B. 1414 does not seek to expand access to drugs generally—it merely seeks to compel 340B pricing for drug orders. In doing so, Tennessee attempts to forcibly insert itself into an arena occupied exclusively by the federal government (i.e., 340B's reticulated scheme setting forth who can receive 340B-priced drugs). But the federal 340B scheme leaves no room for state supplementation. S.B. 1414's imposition of additional obligations and a separate enforcement scheme is accordingly preempted as an impermissible intrusion into a federally dominated field.

131. S.B. 1414 is also conflict preempted. Conflict preemption arises when "[state] law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), or "interferes with the methods by which the federal statute was designed to" achieve those purposes and objectives, *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) (state law preempted because it would "upset[] the balance of public and private interests so carefully addressed by the [federal statute]"). A conflict exists between the 340B statute and federal PPAs, on the one hand, and S.B. 1414, on the other, for several reasons.

132. S.B. 1414 disregards and conflicts with careful limitations in the federal regime, designed to maintain the delicate balance struck by Congress. As to covered entities, Congress sharply limited what they could do with 340B-priced drugs, prohibiting covered entities from reselling or transferring them to anyone other to their own patients. 42 U.S.C. § 256b(a)(5)(B). As to manufacturers, 340B requires only that manufacturers "offer" 340B-priced drugs to covered entities (*i.e.*, that they provide some meaningful path for covered entities to access these medications). *See id.* § 256b(a)(1); *Novartis*, 102 F.4th 460-64; *Sanofi*, 58 F.4th at 703. The offers

can include reasonable conditions, including both one contract pharmacy restrictions and a requirement that claims data be provided. *Novartis*, 2021 WL 5161783, at *8 (holding that, under federal law, manufacturers are permitted to require certain types of data as a precondition of their "offer" of 340B-priced drugs); *id.* ("For its part, [the plaintiff manufacturer] convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B."); *Novartis*, 102 F.4th at 463-64 (affirming holding); *Sanofi*, 58 F.4th at 704. As those decisions make clear, other types of conditions would also be permissible so long as they do not render an offer non-bona fide. Finally, Congress provided for an exclusive enforcement regime, which includes (among other things), the right of manufacturers to audit a covered entity. 42 U.S.C. § 256b(a)(5)(C).

133. S.B. 1414's rewriting of the program's terms conflicts with the 340B statute in multiple ways and so is preempted. To name just a few, non-exhaustive examples:

134. *First*, S.B. 1414's prohibitions on manufacturers gathering information and explicit limitations on the "frequency, duration, or scope of audits" are preempted. TN Code § 47-18-136(a)(1), (4). If those limits stand, they will essentially break the federal remedial regime. *See Morrisey*, 2024 WL 5147643, at *7-8 (holding similar state law that barred collection of claims data was preempted because it conflicted with manufacturers' 340B audit rights); *Eli Lilly v. Kennedy*, No. 1:25-cv-00117, slip op. at 28, 30 (D.D.C. May 15, 2025) (affirming manufacturers' right to "impose data-reporting conditions on covered entities," explaining why claims data is important to maintaining program integrity, and requiring federal agency to take it into account when considering how manufacturers can structure their program participation).

135. Under the federal regime, manufacturers must first audit a covered entity before initiating ADR. *See* 42 U.S.C. § 256b(a)(5)(C), (d)(3)(B)(iv). However, manufacturers are only permitted to conduct an audit where they "ha[ve] documentation which indicates there is reasonable cause." 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). "Reasonable cause" is defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibition on transfer or sale, or the prohibition on duplicate discounting. *Id.* Accordingly, to even access the audit process to engage in an ADR proceeding, manufacturers must be able to access information that will allow them to determine if reasonable cause exists to suspect a covered entity is violating 340B's provisions. But Tennessee's comprehensive bar on requesting any such data hides from manufacturers evidence of federal violations and handicaps manufacturers from being able to meaningfully utilize the federal resolution process that Congress provided. *See* TN Code § 47-18-136(a)(1) (referring to "health information, claims or utilization data, purchasing data, payment data, or other data").

136. Not only does S.B. 1414 restrict access to the federal enforcement regime by curtailing manufacturers' ability to collect information, with the limited exception provided by the grandfather-like provision, it also appears to *explicitly* restrict manufacturers' ability to audit full stop. S.B. 1414 specifies that manufacturers may not "[i]mpose any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities." TN Code § 47-18-136(a)(4). But audits for 340B compliance are a creature of federal 340B law and are meant as a tool to ensure covered entity compliance with 340B rules. 42 U.S.C. § 256(a)(C) (providing that manufacturers can audit covered entities with regard to "the entity's compliance [with the bars on duplicate discounting and diversion] with respect to drugs of the manufacturer"). And it is the federal government that is explicitly given control over the

"number, duration, and scope of audits." *Id.* (specifying that the Secretary establishes procedures governing those aspects of audits). Yet, S.B. 1414 now seeks to impose its own limitations on manufacturers' audit rights.[24] The Supremacy Clause prohibits this type of conditioning of the exercise of federal rights.

137. *Second*, S.B. 1414's bar on "impos[ing] any requirements relating to inventory management systems of 340B drugs" or "requir[ing] a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless the actions are in the normal course of business and not related to the 340B program" directly interferes with the ability of manufacturers to structure their 340B program transactions in ways fully compliant with federal law and that are intended to increase transparency. TN Code § 47-18-136(a)(2), (3). These provisions appear to be aimed at preventing the use of cash replenishment, cash-rebate, or credit models, by individual manufacturers. Under those models generally, though specific terms may differ, manufacturers will provide cash rebates when covered entities submit a 340B-rebate claim to the manufacturer, rather than sell the 340B-priced drugs at an upfront reduced price.[25] S.B. 1414 attempts to prevent their use despite the federal statute providing for use of rebates and the fact that the federal government has already explicitly blessed use of rebate models for certain covered entities, known

[24] The State may contend that it is only limiting manufacturers' ability to require audits beyond those required of general commercial pharmacies and providers. But that is not true. As relevant here, this statutory audit mechanism is a unique feature of federal law to ensure compliance with the provisions of federal law and is a unique process established by Congress.

[25] Tenn. House Fin., Ways & Means Comm. Hr'g Apr. 14, 2025 at 7:28-7:35 (S.B. 1414 author stating: "[S.B. 1414] keeps the front-end discount instead of the back-end rebate.") (https://tnga.granicus.com/player/clip/31937?view_id=804&redirect=true); Tenn. House Floor Session Apr. 16, 2025 at 5:00:36-5:00:44 (S.B. 1414 author stating: "Manufacturers would be precluded from trying to shift the program from an upfront discount to a post-sale rebate model." (https://tnga.granicus.com/player/clip/31956?view_id=776&redirect=true); Mar. 25 Comm. Hr'g at 17:00-17:08 (same).

as AIDS Drug Assistance Programs. *See* 42 U.S.C. § 256b(a)(1) ("taking into account any *rebate* or discount" (emphasis added); *see also* 63 Fed. Reg. 35,239, 35,240 (June 29, 1998) (recognizing that use of a rebate option is "consistent with the section 340B rebate program").

138. Moreover, in the recent *Lilly* decision, the United States District Court for the District of Columbia held that these alternative models are allowed by the federal statute. *See Eli Lilly v. Kennedy*, No. 1:25-cv-00117, slip op. at 19 n.11, 22 (D.D.C. May 15, 2025). Yet, Tennessee now seeks to explicitly prevent their use.

139. *Third*, the bar on manufacturers imposing conditions such as credentialing or "any requirement determined by the attorney general . . . to interfere with the ability of a 340B entity to access discounts providing under the 340B program" turns the Attorney General, instead of Congress, into the arbiter of the scope of an acceptable federal offer and attached conditions. TN Code § 47-18-136(a)(5)-(6). As just one example, the statute's broad bar on credentialing and certification requirements conflicts with the federal statute's certification requirements. *See* 42 U.S.C. § 256b(a)(7).

140. *Fourth*, S.B. 1414 reworks manufacturers' obligations under the federal program. Indeed, Tennessee is now seeking to impose as a matter of state law a bar on restrictions on contract pharmacy use and claims data collection, requirements even the federal government has been enjoined from levying. *Sanofi*, 58 F.4th at 706; *see also Novartis*, 102 F.4th at 463-64 (explaining these reasonable conditions can be included as part of a manufacturer's 340B offer). By rewriting the terms of the required federal offer and barring manufacturers from including these conditions, S.B. 1414 dramatically expands manufacturers' obligations under a federal program. As courts have recognized, this expansion of obligations under a federal incentive program is preempted. *Forest Park II v. Hadley*, 336 F.3d 724, 732-33 (8th Cir. 2003) (holding states may not impose

additional obligations on participants in incentive-based, federal programs, even where the federal statute does not explicitly bar such additional obligations). Tennessee's efforts both conflict with the plain text of 340B's requirements and stand as an obstacle to the carefully circumscribed and federally managed closed system Congress created.

141. S.B. 1414 cannot be saved by its grandfather-like provision. Although S.B. 1414's grandfather-like provision states that "subsection (c) does not apply to any requirements, prohibitions, limitations, or restrictions in place on or before June 1, 2025," TN Code § 47-18-136(c), many of S.B. 1414's substantive prohibitions are contained in subsection (a). The statute does not make clear how subsections (a) and (c) interact, and the Attorney General has provided no guidance on that issue. That is important because, in light of new federal law developments and changes in the way that 340B functions, manufacturers routinely update their policies. Moreover, the provision expressly does not shield manufacturers' imposition of future conditions—conditions which fully comply with federal law. For those reasons, the provision does not exempt S.B. 1414 from preemption.

142. Nor can S.B. 1414 be saved by recasting it as a distribution requirement. Tennessee is attempting to regulate who can receive 340B-priced drugs, not drugs in general. No one suggests that manufacturers will not provide market-priced drugs to pharmacies. The aim instead is to force manufacturers to provide those same drugs to those same pharmacies at a lower price. *Morrisey*, 760 F. Supp. 3d at 455-56 (recognizing that similar state statute was actually about forcing manufacturers to provide 340B pricing, not about delivery). Indeed, absent the pricing requirement, Tennessee's law would be meaningless. *See* TN Code § 47-18-136(g)(1) ("340B drug" means a drug that "is eligible for any offer for reduced prices by a manufacturer under 42. U.S.C. § 256b(a)(1)"); *id.* § 47-18-136(g)(2) ("340B entity" means "a covered entity participating

in the federal 340B drug discount program, as defined in section 340B of the Public Health Service Act, 42 U.S.C. § 256b, including the entity's pharmacy or pharmacies.").

143. *Fifth*, S.B. 1414's state-law enforcement provisions both conflict with the carefully calibrated system created by Congress to ensure 340B compliance and raise the specter of inconsistent adjudications. *See Morrisey*, 760 F. Supp. 3d at 453-60 (holding similar state law was preempted because it conflicted with 340B's enforcement regime). Among other reasons, S.B. 1414 conflicts because it skews the carefully balanced enforcement scheme enacted by Congress. Congress specified certain limited civil penalties that could be levied in limited circumstances. 42 U.S.C. § 256b(d)(1)(B)(vi)(II) (setting a maximum of $5,000 per violation). Yet, S.B. 1414 imposes a draconian penalty of $50,000 per violation, with every package of drugs constituting a separate violation. TN Code § 47-18-136(d). S.B. 1414 also imposes *criminal* liability, when Congress chose not to do so. *See supra* ¶ 116.

144. Congress also intentionally chose not to authorize a private right of action for covered entities under 340B. *See Astra*, 563 U.S. at 117-22. S.B. 1414 destroys that calibrated system by appearing to introduce a private right of action, in direct contravention of the Supreme Court's determination in *Astra*. *See supra* ¶ 117. The layering on of additional penalties and adjudicators wildly unbalances Congress's system, and threatens the same inconsistent adjudications identified in *Astra* because Tennessee cannot enforce S.B. 1414 without adjudicating multiple questions of federal law.

145. *Finally*, S.B. 1414 frustrates the "accomplishment and execution of the full purposes and objectives of Congress," *Hines*, 312 U.S. at 67, in various ways in addition to those described above. For example, by purporting to impose additional, onerous terms on 340B (including terms the Third Circuit has held not even the federal government can impose),

S.B. 1414 increases the cost of manufacturer participation in the federal Medicare Part B and Medicaid programs. As another example, S.B. 1414's mandates will contribute to duplicate discounts and diversion of 340B drugs to ineligible recipients, both of which the federal scheme forbids. In addition, S.B. 1414 conflicts with the federal Medicare Drug Price Negotiation Program by frustrating the disclosure of claims data that is necessary to prevent duplicate discounting with the "maximum fair prices" established under the Inflation Reduction Act. *See* 42 U.S.C. § 1396r-8(a)(5)(C).

146. For all of these reasons and more, S.B. 1414 is preempted, and its enforcement should be enjoined.

CLAIM II
(Declaratory/Injunctive Relief—Commerce Clause)

147. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

148. Under our constitutional framework, states may not directly regulate conduct that takes place wholly in another state. "[A]ll States enjoy equal sovereignty." *Shelby Cnty. v. Holder*, 570 U.S. 529, 535 (2013). "A basic principle of federalism is that each State may make its own reasoned judgment about what conduct is permitted or proscribed within its borders, and each State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003) (citation omitted).

149. While the Supreme Court recently clarified that state laws regulating conduct within the state's borders in a way that might have an "extraterritorial effect" in other states are not categorically barred, it also made clear that it was not addressing a state law that "directly regulated out-of-state transactions." *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 374,

376 n.1 (2023). The understanding that states may not impose on other states' regulatory powers follows from several Constitutional provisions. States are denied certain powers that a sovereign might ordinarily impose, U.S. Const. art. I, § 10; and required to honor certain rights of other states, U.S. Const. art. IV, §§ 1, 2, 3. Similarly, the Due Process Clause limits a state's ability to regulate conduct occurring wholly outside its borders. *See Watson v. Emps. Liab. Assurance Corp.*, 348 U.S. 66, 70 (1954) (recognizing "the due process principle that a state is without power to exercise 'extra territorial jurisdiction,' that is, to regulate and control activities wholly beyond its boundaries"); *Home Ins. Co. v. Dick*, 281 U.S. 397, 407-08 (1930) (similar).

150. Most notably, the Commerce Clause provides that "[t]he Congress shall have Power … To regulate Commerce … among the several States." U.S. Const. art. I, § 8, cl. 3. Under that clause, states are prohibited from directly "control[ling] commerce occurring wholly outside [its] boundaries." *Healy v. Beer Inst.*, 491 U.S. 324, 335-36 (1989); *see also, e.g.*, *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality op.). While the Court recently considered the reach of the dormant Commerce Clause, it did not disturb its prior precedent establishing that state laws are unconstitutional where they "directly regulate[] out-of-state transactions by those with no connection to the State." *Pork Producers*, 598 U.S. at 374, 376 n.1.

151. S.B. 1414 is unconstitutional under these principles. S.B. 1414 bans all pharmaceutical manufacturers, many of whom have no physical presence in Tennessee, from "directly or indirectly" (1) imposing "additional requirements or limitations on a 340B entity"; (2) requiring "a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of business and not related to the 340B program"; (3) imposing "any requirements relating to inventory management systems of 340B drugs, unless

such requirement is required by the United States department of health and human services or applicable state law"; (4) imposing "any requirement relating to the frequency, duration, or scope of audits that are not imposed on pharmacies or providers that are not 340B entities"; (5) imposing "requirements relating to accreditation, recertification, credentialing, or recredentialing that are not imposed on pharmacies or providers that are not 340B entities"; or (6) imposing "any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program." TN Code § 47-18-136(a); *id.* § 47-18-136(c) (barring manufacturers from directly or directly denying or imposing "any restrictions or prohibitions on, discriminate against, or otherwise limit the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity or other location that is under contract with, or otherwise authorized by, a 340B entity to receive 340B drugs on behalf of the 340B entity unless such receipt is prohibited by the United States department of health and human services or applicable state law."). The Tennessee Code does not impose a geographic limitation on its definition of "340B entity" or "location." *Id.*; *id*. § 63-10-204(36).

152. Moreover, manufacturers who are mostly located outside of Tennessee predominantly sell and deliver their drugs through distributors and wholesalers who are also located outside of Tennessee.

153. As a result, S.B. 1414 regulates conduct occurring wholly beyond the borders of Tennessee. S.B. 1414 will apply to out-of-state transactions between out-of-state manufacturers and out-of-state distributors and set the price as to those transactions. Not only will it require manufacturers to provide the 340B price on transactions, it will also, given the offer-and-acceptance regime, force manufacturers to enter into many 340B transactions that they otherwise would not.

154. S.B. 1414 is also discriminatory. It privileges in-state participants in the 340B program by providing them monetary benefits not contemplated by Congress, while imposing a significant burden on out-of-state manufacturer participants in the 340B program. *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 364 (2022) ("[U]nder this Court's dormant Commerce Clause decisions, no State may use its laws to discriminate purposefully against out-of-state economic interests.").

155. Finally, the extraterritorial reach of S.B. 1414 is further heightened by the remedies available for violations of S.B. 1414. S.B. 1414 authorizes restraining orders and injunctive relief, among other things. TN Code § 47-18-108. Of course, given that much of the conduct regulated will occur out of state, S.B. 1414 gives Tennessee state decisionmakers authority to regulate conduct far outside of Tennessee's borders—conduct that is likely entirely lawful in the state in which it actually occurs.

156. By directly regulating commerce that occurs entirely outside of its borders, S.B. 1414 violates the Constitution's bar on extraterritorial state regulation. *See Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666-71 (4th Cir. 2018) (striking down a Maryland drug-pricing law that "directly regulates the price of transactions that occur outside Maryland[,]" where the law allowed "Maryland to enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland"); *see also Ass'n for Accessible Meds. v. Ellison*, 704 F. Supp. 3d 947, 951 (D. Minn. 2023) (concluding that Minnesota statute that barred manufacturers from "impos[ing], or caus[ing] to be imposed, an excessive price increase, whether directly or through a wholesale distributor, pharmacy, or similar intermediary, on the sale of any generic or off-patent drug sold, dispensed, or delivered to any consumer in the state" violated the dormant Commerce Clause (citation omitted)).

CLAIM III
(Declaratory/Injunctive Relief—Due Process Clause)

157. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

158. The Fourteenth Amendment's Due Process Clause provides that no state may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1.

159. Under the Due Process Clause, a statute is unconstitutionally vague if it "fail[s] to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or if it "authorize[s] or even encourage[s] arbitrary and discriminatory enforcement." *Tenn. Educ. Ass'n v. Reynolds*, 732 F. Supp. 3d 783, 806 (M.D. Tenn. 2024) (citing *Platt v. Bd. of Commr's on Grievances & Discipline*, 894 F.3d 253, 246 (6th Cir. 2018)).

160. Where, as here, a statute imposes criminal in addition to civil penalties, concerns about vagueness are at their zenith. As the Supreme Court has instructed: "The degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment." *Vill. Of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *see also Winters v. New York*, 333 U.S. 507, 515 (1948). Laws imposing criminal penalties are subject to a more exacting standard because the "consequences of imprecision" are particularly "severe" when a law imposes criminal penalties. *Sessions v. Dimaya*, 584 U.S. 148, 156 (2018); *see also Hoffman Estates*, 455 U.S. at 499.

161. This is also true where, as here, First Amendment interests are implicated. These First Amendment interests include the right to publicize information about unlawful activity, conduct audits, file public complaints, and seek information. Indeed, "[w]hen a statute is capable

of reaching First Amendment freedoms, the doctrine demands a greater degree of specificity than in other contexts." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253-54 (2012) (stricter application of vagueness doctrine is appropriate where statute involves speech in order "to ensure that ambiguity does not chill protected speech"); *Smith v. Goguen*, 415 U.S. 566, 572-73 (1974) (considering First Amendment implications in applying due process vagueness analysis); *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972) ("[W]here a vague statute abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of those freedoms." (internal quotations and citations omitted)).

162. In the Sixth Circuit, "[a] vague ordinance violates the Constitution in two significant respects: such an ordinance fails, (1) to define the offense with sufficient definiteness that ordinary people can understand prohibited conduct, and (2) to establish standards to permit police to enforce the law in a non-arbitrary, nondiscriminatory manner." *Belle Maer Harbor v. Charter Twp. of Harrison*, 170 F.3d 553, 556 (6th Cir. 1999). "The second prong—providing minimal guidelines to govern the conduct of law enforcement—constitutes the more important aspect of the vagueness doctrine." *Id*. at 556-57. This is so because undefined prosecutorial discretion furnishes officers with "a convenient tool for harsh and discriminatory enforcement against particular groups deemed to merit their displeasure." *Id*. at 559 (quoting *Papachristou v. City of Jacksonville*, 405 U.S. 156, 170 (1972)) (internal quotation marks omitted). S.B. 1414 is insufficiently definite, and hands the Tennessee Attorney General virtually unlimited enforcement discretion against manufacturers.

163. In its "catch-all" provision, S.B. 1414 broadly states that a manufacturer may not "[i]mpose any requirement determined by the attorney general and reporter to interfere with the ability of a 340B entity to access discounts provided under the 340B program." TN Code § 47-

18-136(a)(6). S.B. 1414 does not define the term "interfere." *Cf. Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (affirming district court grant of summary judgment to plaintiffs where law prohibited "interfer[ing] with or disturb[ing] in any way or in any place the students or teachers of any school or college in this State" and noting that "[i]t is hard to know where to begin with the vagueness problems with th[e] statute"); *United States v. Elliot*, No. 2:17-cr-33, 2018 WL 11478272, at *1, *3 (N.D. Ga. Aug. 8, 2018) (concluding regulation that prohibited "[a]ny act or conduct by any person which interferes with, impedes or disrupts the use of the project" was unconstitutionally vague as applied); *Corp. of Haverford Coll. v. Reeher*, 329 F. Supp. 1196, 1208-09 (E.D. Pa. 1971) *supplemented*, 333 F. Supp. 450 (E.D. Pa. 1971) (collecting cases where prohibitions on interference were deemed unconstitutionally vague).

164. Manufacturers, including PhRMA's members, are entitled to publicize information about unlawful transfers or duplicate discounting occurring at particular contract pharmacies or covered entities, to audit covered entities and their records relating to contract pharmacies, to file complaints in the context of the federal system that Congress created, and to seek information regarding, and clarify claims from, covered entities and contract pharmacies. But S.B. 1414's plain language prohibits them from doing so. Uncertainty as to the scope of prohibited conduct and speech—which S.B. 1414 presents—is the precise problem with vague laws.

165. S.B. 1414's broad and undefined prohibition against "interfer[ing]" with a 340B entity's access to discounts also fails to provide minimal enforcement guidelines to Tennessee's Attorney General. The lack of clear definition requires the Attorney General to interpret and enforce the statute based on subjective criteria, which will lead to inconsistent and discriminatory enforcement against manufacturers, undermining the principles of fair notice and legal restraint essential to due process. *Belle Maer Harbor*, 170 F.3d at 559 ("Due process requires at least

sufficient exactness to prevent arbitrary enforcement and give notice of what an individual must to do comply with the enactment.").

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that S.B. 1414 is unconstitutional and violates federal law;

b. issue an order and judgment declaring that S.B. 1414's provisions are unlawful as to PhRMA's members covered outpatient drugs sold through the 340B Drug Pricing program;

c. enjoin, preliminarily and permanently, the implementation and enforcement of S.B. 1414 against PhRMA's members and members' affiliates, officers, agents, representatives or contractors;

d. enjoin, preliminarily and permanently, the implementation and enforcement of S.B. 1414 as to the sale of PhRMA's members' drugs under 340B;

e. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

f. grant any other relief the Court finds just and appropriate.

Dated: May 22, 2025

Respectfully submitted,

LEWIS THOMASON, P.C.

/s/ Charles W. Cagle

Charles W. Cagle (B.P.R. No.: 013738)
Katherine R. Kimmel (B.P.R. No.: 038320)
424 Church Street, Suite 2500
Nashville, TN 37219
(615) 259-1366
ccagle@lewisthomason.com
kkimmel@lewisthomason.com

Attorney for Plaintiff