2026 WL 1660347
Only the Westlaw citation is currently available.
United States District Court, W.D. Washington,
at Tacoma.

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs,

v.

Nick BROWN et al., Defendants.

CASE NO. 3:26-cv-05302-DGE

|

Signed June 09, 2026

Attorneys and Law Firms

Marlan J. Golden, Pro Hac Vice, Claire Adkins Rhodes, Pro Hac Vice, Jacob Tyler Young, Pro Hac Vice, Jessica Lynn Ellsworth, Pro Hac Vice, Susan M. Cook, Pro Hac Vice, Hogan Lovells Cadwalader US LLP, Washington, DC, Curtis C. Isacke, Gregory J. Hollon, McNaul Ebel PLLC, Seattle, WA, for Plaintiff Novartis Pharmaceuticals Corporation.

Blair A. Husted, Pro Hac Vice, Meredith M. Pohl, Pro Hac Vice, Kirkland & Ellis LLP, Washington, DC, Matthew Scott Owen, Pro Hac Vice, Gibson Dunn & Crutcher LLP, Washington, DC, Jeremy E. Roller, Arete Law Group PLLC, Seattle, WA, for Plaintiffs AbbVie Inc, Allergan Inc, Durata Therapeutics Inc, Abbvie Products LLC, Pharmacyclics LLC, and Allergan Sales LLC.

Camilo Garcia, Pro Hac Vice, Erin E. Murphy, Pro Hac Vice, Matthew Rowen, Pro Hac Vice, Philip Hammersley, Pro Hac Vice, Clement & Murphy PLLC, Alexandria, VA, Steven W. Fogg, Corr Cronin LLP, Seattle, WA, for Consol Plaintiff Pharmaceutical Research and Manufacturers of America.

Allon Kedem, Pro Hac Vice, Jeffrey Handwerker, Arnold & Porter Kaye Scholer LLP, Washington, DC, Carmela Romeo, Pro Hac Vice, Michael Mazzullo, Pro Hac Vice, Arnold & Porter Kaye Scholer LLP, New York, NY, Angelo J. Calfo, Angeli & Calfo LLC, Seattle, WA, Peter D. Hawkes, Angeli & Calfo LLC, Portland, OR, for Consol Plaintiff Astrazeneca Pharmaceuticals LP.

Aliana Claire Knoepfler, Freeman Halle, Julie Catherine Moroney, Office of the Attorney General, Seattle, WA, Kelly A. Paradis, William McGinty, Office of the Attorney General, Olympia, WA, for Defendant Nick Brown.

Aliana Claire Knoepfler, Freeman Halle, Office of the Attorney General, Seattle, WA, William McGinty, Office of the Attorney General, Olympia, WA, for Defendant Ryan Moran.

Courtney Christensen, Pro Hac Vice, Ezra B. Marcus, Pro Hac Vice, William B. Schultz, Zuckerman Spaeder LLP, Washington, DC, Jessica M. Andrade, Polsinelli PC, Seattle, WA, for Amici Curiae American Hospital Association, Washington State Hospital Association, 340B Health, and American Society of Health-System Pharmacists.

ORDER ON MOTIONS FOR PRELIMINARY INJUNCTION (DKT. NO. 14); *ABBVIE*, DKT. NO. 7; *PHRMA*, DKT. NO. 2

David G. Estudillo, United States District Judge

***1** Before the Court are motions for preliminary injunction filed by Plaintiffs AbbVie, Inc. ("AbbVie"), Novartis Pharmaceuticals Corporation ("Novartis"), and Pharmaceutical Research and Manufacturers of America ("PhRMA") (collectively, "Plaintiffs").[1] AbbVie and Novartis are pharmaceutical companies, and PhRMA is a trade organization that represents biopharmaceutical research companies. (Dkt. No. 1 at 5); *AbbVie*, Dkt. No. 1 at 8–9; *PhRMA*, Dkt. No. 1 at 6.

1 This matter involves three consolidated cases in which Plaintiffs filed motions for preliminary injunction: *AbbVie Inc. et al. v. Brown et al.*, Case No. 2:26-cv-01018-DGE ("*AbbVie*"), *Novartis Pharmaceuticals Corporation v. Brown et al.*, Case No. 3:26-cv-05302-DGE ("*Novartis*"), and *Pharmaceutical Research and Manufacturers of America v. Brown et al.*, Case No. 3:26-cv-05374-DGE ("*PhRMA*"). *AbbVie* was consolidated into the *Novartis* matter on April 6, 2026. (Dkt. No. 21.) *PhRMA* was consolidated into the *Novartis* matter on April 17, 2026. (Dkt. No. 29.) A fourth case, *AstraZeneca Pharmaceuticals LP v. Brown*, 3:26-cv-05406-DGE, was consolidated into this matter on May 22, 2026 (*see* Dkt. No. 63) but there is no motion for preliminary injunction pending.

Beginning on June 11, 2026, Plaintiffs, along with all other manufacturers selling pharmaceuticals in Washington as part of the federal 340B Program, will be prohibited, among other things, from imposing restrictions on the delivery of eligible pharmaceuticals to certain statutorily designated healthcare entities. *See* SB 5981, 69th Leg., Reg. Sess. (Wash. 2026). Plaintiffs ask the Court to enter a preliminary injunction preventing SB 5981 from going into effect. Plaintiffs argue SB 5981 violates the Supremacy Clause, is preempted by federal law, violates the dormant Commerce Clause, violates the First Amendment, and constitutes an improper Fifth Amendment taking. The Court concludes Plaintiffs are unlikely to succeed on the merits of all claims and do not otherwise meet the requirements for a preliminary injunction. Accordingly, Plaintiffs' motions for preliminary injunction ((Dkt. No. 14); *AbbVie*, Dkt. No. 7; *PhrMA*, Dkt. No. 2) are DENIED.

I FACTUAL AND PROCEDURAL BACKGROUND

A. The Federal 340B Program

The 340B Program arises out of the complex relationship between drug manufacturers, states, and the federal government and is "deeply interwoven" with other federal healthcare programs. (Dkt. No. 1 at 7.) In 1990, Congress created the Medicaid Drug Rebate Program ("MDRP"), where drug manufacturer participants were required to offer state Medicaid plans the " 'best price' " given to any other purchaser in exchange for "near-universal" Medicaid coverage of their products. (*Id.* at 6) (citation omitted). This arrangement inadvertently discouraged drug manufacturers from offering discounts for their products to charitable hospitals, leading Congress to create the 340B Program in 1992. (*Id.*) Under the 340B program, manufacturers that want their drugs covered by Medicaid and Medicare Part B must agree to offer certain drugs to certain entities at a discount. 42 U.S.C. §§ 256b(a)(1); 1396r-8(a)(1), (a)(5)(A). The providers entitled to these discounts are called "covered entities" and are defined by statute. *Id.* § 256b(a)(4). They include various government-funded hospitals and community health centers that serve low-income patients and other marginalized populations. *Id.*; *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011) (covered entities "include public hospitals and community health centers, many of them providers of safety-net services to the poor[ ]"). 340B prices are set by federal law under a statutory framework that dictates the type of drugs sold and the ceiling price for each drug. 42 U.S.C. §§ 256b(a)(1), (3). The 340B Program is "superintended" by the Health Resources and Services Administration ("HRSA"), a subunit of the U.S. Department of Health and Human Services ("HHS"). *Astra*, 563 U.S. at 113. Drug manufacturers voluntarily opt in to the program by entering into Pharmaceutical Pricing Agreements ("PPAs") with HHS to "memorialize the parties' 340B obligations[.]" 42 U.S.C. § 256b(a)(1). Plaintiffs characterize the 340B program as the " 'price of admission to participate in Medicaid and Medicare Part B.' " (Dkt. No. 1 at 8) (quoting *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1273 (W.D. Okla. 2025)).

***2** Covered entities in Washington provide a range of services to a broad spectrum of under-resourced communities and "invest 340B savings in a variety of ways based on the needs of [those] communities." (Dkt. No. 48 at 10.) These include, but are not necessarily limited to, targeted homelessness services in Seattle (Dkt. No. 42 at 4), pediatric services where 82 percent of patients are Medicaid beneficiaries (Dkt. No. 43 at 7), a low-income dental clinic that regularly accepts Medicaid or charity care patients (Dkt. No. 45 at 3–4), obstetrics services where 65 percent of births involve mothers who are tribal members (Dkt. No. 46 at 5), and a critical access hospital in a rural area with a level IV trauma designation (Dkt. No. 47 at 2). In some

communities, services provided by covered entities account for a significant amount of all medical care. For example, the Moses Lake Community Health Center ("MLCHC"), a covered entity in central Washington, provides services to more than a third of Grant County, where "95% of the patients report income below 200% of the federal poverty guidelines." (Dkt. No. 43 at 2.) In north-central Washington, Coulee Medical Center ("CMC") provides critical care to a sparsely populated area where 64 percent of the patients rely on Medicare or Medicaid.[2] (Dkt. No. 46 at 2–3.)

2 Plaintiffs assert through retained experts that a covered entity's 340B revenue has little to no impact on "charity care spending," "minimal effects on bad debt," "do not improve patient outcomes," and that a covered entity's expansion of the "use of contract pharmacies through SB 5981 is likely to be a particularly ineffective way of getting money to covered entities." *AbbVie*, Dkt. No. 12 at 8–9; *see also* Dkt. No. 11 at 7–8. Despite these expert opinions, the declarations from representatives of various covered entities in Washington identify the impact 340B revenue has on operations and the ability to provide services to economically marginalized communities.

Various Washington covered entities operate on extremely thin margins. Mike Glenn, the CEO of Jefferson Healthcare in Port Townsend, Washington, notes that Jefferson Healthcare has not had a positive operating margin since 2022, and that for fiscal year 2024, Jefferson Healthcare had an operating margin of -0.1 percent, "or slightly less than break even[.]" (Dkt. No. 45 at 3.) For 2025, Jefferson Healthcare's "current unaudited margin" is "barely positive at well under one percent." (*Id.*) Glenn cautions, "[n]o hospital can endure extended periods of negative or break-even operating margins without comprising its ability to maintain its infrastructure equipment, staffing[,] and services in the community." (*Id.*) Along the same lines, CMC operated at a margin of -2.3 percent in 2024 (Dkt. No. 46 at 4) and Summit Pacific Medical Center in Grays Harbor, Washington, operated on a tight margin of just 3.4 percent (Dkt. No. 47 at 3). The North Olympic Health Network ("NOHN") reports a loss of "at least $3,000,000" in revenue from 340B discounts since 2020, when drug manufacturers first began imposing the restrictions at issue in this lawsuit. (Dkt. No. 44 at 4.)

Covered entities are not required to pass 340B discounts directly to their individual patients (Dkt. No. 1 at 6–7), even though Congress intended the downstream effect to benefit patients. *See* H.R. Rep. No. 102-384, pt. II, at *11 (1992) (price increases of drugs to federally funded clinics and public hospitals "have in turn reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources"). Committee notes to House Report No. 102-384(II) explain that under the 340B Program, providing reduced drug prices to covered entities would enable them to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *Id.* at *12. In short, the direct beneficiaries of the 340B program are the covered entities *themselves*, rather than individual patients; Congress's intent was to assist covered entities in stretching limited federal resources so the entities could provide as much critical care as possible to under-resourced populations. *Id.* at *7 ("The purpose of H.R. 2890 is to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients.").

***3** The statute as enacted has "few" substantive requirements and restrictions. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 700 (3d Cir. 2023). Covered entities are prohibited from requesting 340B discounts for drugs that are already qualified for a Medicaid rebate (referred to as a "double discount"). 42 U.S.C. § 256b(a)(5)(A). They may not resell or otherwise transfer the discounted drugs to anyone who is not a patient of the covered entity (referred to as "diversion"), *id.* § 256b(a)(5)(B), and they must allow the Secretary of HHS and the manufacturers of a covered drug to audit, at the Secretary or the manufacturer's expense, "the records of the entity that directly pertain to the entity's compliance" with other requirements. *Id.* § 256b(a)(5)(C). If the Secretary determines a covered entity engaged in double-discounting or diversion, the entity "shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug[.]" *Id.* § 256b(a)(5)(D).

Aside from the specific requirements identified in the statute, Congress did not grant HHS broad authority to issue regulations and instead limited rulemaking authority to discrete areas, including the development of a drug-pricing system, the imposition of monetary sanctions on either the covered entities or manufacturers for violations or noncompliance, and establishment of an alternative dispute resolution ("ADR") process. *Id.* §§ 256b(d)(1)(A) ("the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section"); 256b(d)(2)(A) ("the Secretary shall provide for

improvements in compliance by covered entities with the requirements of this section to prevent diversion and violations of the duplicate discount provision"); 256b(d)(3)(A) ("the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities...and claims by manufacturers"); *see also Pharm. Rsch. & Mfrs. of Am. v. U.S. Dep't of Health & Hum. Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Congress specifically authorized rulemaking in [these] three places[.]").

HRSA and drug manufacturers are both authorized to conduct audits of covered entities to ensure compliance. 42 U.S.C. § 256b(a)(5)(C). An audit is a prerequisite for a manufacturer to initiate ADR against a covered entity. *Id.* § 256b(d)(3)(B)(iv). To conduct an audit, HRSA or the manufacturer must have "reasonable cause" that a covered entity violated the statute. Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Under HRSA guidelines, reasonable cause "means that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B)[,]" meaning that a covered entity either engaged in duplicate discounting or resold or transferred 340B drugs to someone who is not a patient of the covered entity. *Id*. In 2024, HRSA issued a final rule revising the ADR process. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28,643 (Apr. 19, 2024). It noted revisions to the 1996 manufacturer guidelines were "outside the scope of this final rule[ ]" but observed "[m]ultiple manufacturers have utilized the 1996 manufacturer audit guidelines to conduct audits of covered entities[,]" including six "[i]n the last five years[.]" *Id.* at 28,646. HRSA did not deny a requests for a manufacturer audit of a covered entity during that time, "demonstrating the guidelines are not overly burdensome or present any barriers to a manufacturer's ability to perform an audit of a covered entity." *Id.*

B. The Role of Contract Pharmacies

"During the early period of [340B] program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)[.]" Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996). In 1996, to address the lack of in-house pharmacies, HRSA issued guidance that permitted covered entities to contract with a single outside pharmacy to dispense 340B drugs. *Id.* This was "designed to facilitate [340B] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." *Id.* at 43,555. Under the arrangement, the contract pharmacy acted as an "agent" of the covered entity, meaning it would not resell the 340B drugs but would "distribute the drug on behalf of the covered entity." *Id.* at 43,550.

***4** In 2010, HRSA issued final guidelines that massively expanded the use of contract pharmacies. It permitted all covered entities, even if they had their own in-house pharmacies, to contract with an unlimited number of contract pharmacies. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA stated its guidance would "permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served." *Id.* After 2010, "the use of contract pharmacies skyrocketed." *Sanofi*, 58 F.4th at 700; (Dkt. No. 1 at 14–15) (describing the explosion of contract pharmacy arrangements). A few weeks after HRSA issued these guidelines, Congress passed the Patient Protection and Affordable Care Act, which in part expanded the definition of a covered entity within the 340B Program to include hospitals serving rural, isolated areas and added some of the enforcement provisions found in the current version of the statute. *See* Pub. L. 111–148, 124 Stat. 119, 821–822 (2010). The amended legislation said nothing about the use of contract pharmacies.

Contract pharmacies are an important part of the 340B landscape for a variety of reasons. In rural communities, a covered entity may have just one in-house pharmacy in an entire county (*see* Dkt. No. 43 at 3–4), or only one or two contract pharmacies that fall within the radius required by the drug manufacturers' policies (*see* Dkt. No. 46 at 6), meaning patients that live far away must rely on outside pharmacies to obtain their medications or travel long distances to pick up their prescriptions. Even for covered entities in urban areas, the practical reality is that covered entities must lean heavily on contract pharmacies. Sumona Das Gupta, the Pharmacy Business Officer at UW Medicine, states that more than 70% of the medications prescribed by UW Medicine are dispensed to contract pharmacies. (Dkt. No. 41 at 6.) This is not because UW Medicine prefers contract pharmacies over their

own in-house pharmacies, but because many UW Medicine patients choose not to use in-house pharmacies "due to requirements imposed by their insurers mandating the use of specific pharmacy networks or due to patients' own preferences." (*Id.* at 6–8.)

Covered entities and contract pharmacies do not physically segregate their inventory into 340B and non-340B drugs. (Dkt. No. 1 at 13); *Novartis Pharm. Corp. v. Frey*, Case Nos. 1:25-cv-00407-JCN, 1:25-cv-00416-JCN, 2025 WL 2813787, at *3 (D. Me. Sept. 23, 2025), *appeal docketed*, *AbbVie Inc., et al. v. Frey, et. al.*, Case No. 25-1914 (1st Cir.). The Parties disagree on the details and the efficacy of how 340B medications are dispensed by contract pharmacies. Plaintiffs allege contract pharmacies retroactively track and claim 340B discounts by "match[ing] pharmacy customers to the names of people who have previously visited the covered entity—even if the visit was for an unrelated condition, or occurred many years earlier, or both—so that the covered entity can try to claim the pharmacy customer is also its 'patient.' " (Dkt. No. 1 at 11–12.) The most common retroactive pricing mechanism is known as the replenishment model. Plaintiffs allege it works as follows: (1) the contract pharmacy purchases units of the drug at the commercial price and places them into its common inventory; (2) the pharmacy dispenses these units from its common inventory when customers arrive with a prescription, without regard to whether the customer is a patient of the covered entity or whether the prescription is 340B-eligible; (3) a third-party administrator later reviews claims data to analyze which transactions were for 340B drugs to a patient of a covered entity, and thus eligible for the discount; (4) once a certain number of 340B-eligible transactions occur, the covered entity or the pharmacy order "replenishment" units of the drug at the discounted 340B price; and (5) the contract pharmacy places the drugs, purchased at the 340B price, back into its common inventory, and the whole cycle starts over again. (*Id.* at 12–13); *Frey*, 2025 WL 2813787, at *3.

***5** Covered entities describe a "virtual inventory management system" for their arrangements with contract pharmacies. (Dkt. No. 43 at 5.) Under this model, "medications are dispensed from a single, commingled physical inventory, while software systems track eligibility, ownership, and compliance virtually, triggering replenishment orders only after a qualifying dispense occurs." (*Id.*) Using the virtual replenishment model eliminates the need for duplicative storage but maintains "full documentation, traceability, and audit readiness[ ]" for 340B medications. (*Id.*; *see also* Dkt. No. 44 at 4 (describing the "clean separation between retail pharmacy inventory and 340B inventory").) Das declares the virtual replenishment model has been widely adopted by covered entities and "has been subject to HRSA audits for entities utilizing contract pharmacies with no findings challenging the model itself."[3] (Dkt. No. 41 at 7.)

3 Even accepting Plaintiffs' description of the replenishment model, when asked at the hearing whether the 340B statute prohibited the use of such model to purchase and dispense 340B drugs, Plaintiffs declined to offer an opinion. Instead, Plaintiffs were willing to only offer that such model was "widely in use" and that the "federal government has not taken the position that the replenishment model cannot be used." (Dkt. No. 68 at 28–29.)

Not surprisingly, manufacturers were upset about the proliferation of contract pharmacy arrangements. They expressed concerns that the contract pharmacies—which were intended to act as intermediaries—were impermissibly profiting from 340B transactions. (*See* Dkt. No. 1 at 15) (citation omitted) (explaining the "strong incentive" to claim as many 340B-eligible transactions as possible, because the covered entity, contract pharmacy, and a third-party administrator " 'divvy up the spread between the discounted price and the higher insurance reimbursement rate[ ]' "). To illustrate, Novartis alleges a handful of massive for-profit pharmacy chains now dominate the contract pharmacy industry, "siphon[ing] about 16 percent of *all* 340B revenue." (*Id.* at 16) (citation omitted). Further, the increase in contract pharmacy arrangements "has also spawned increasing compliance failures in the 340B Program[.]" (*Id.*) AbbVie similarly raises concerns about the "windfalls" reaped by covered entities and commercial pharmacies, even though uninsured and underinsured patients do not see those benefits. *AbbVie*, Dkt. No. 1 at 22–23.

C. Manufacturers' Response to the Rise in Contract Pharmacy Arrangements and Ensuing Litigation

Starting in 2020, some manufacturers, including Novartis, began to limit both the number of contract pharmacies to which they would deliver drugs and the maximum distance between the covered entity and the pharmacy site. (*See* Dkt. No. 1 at 18.) Novartis exempted federal grantees from this policy and initially requested, but did not require, the covered entities to provide it with claims data. (*Id.* at 19.) Covered entities filed complaints with HRSA about these manufacturer-imposed conditions. (*Id.*)

In 2020, HRSA issued an advisory opinion addressing the rise of 340B manufacturer participants declining to distribute 340B-eligible drugs through contract pharmacies at the statutory ceiling price. DEP'T OF HEALTH & HUM. SERVS., *Advisory Op. 20-06 on Contract Pharmacies Under the 340B Program*, 2020 WL 11422965, at *1 (Dec. 30, 2020) (footnote omitted). HRSA stated: "[T]o 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." *Id.* HRSA also sent letters to the manufacturers in May 2021 notifying them that by placing limits on contract pharmacies and claim data, the manufactures were in violation of the 340B program. (Dkt. No. 1 at 19.)

***6** Novartis sued HRSA just weeks later in the District of Columbia. There, the district court concluded the 340B statute did not "prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." *Novartis Pharm. Corp. v. Espinosa*, Case Nos. 21-cv-1479 (DLF), 21-cv-1686 (DLF), 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021). It held the violation letters rested on an "erroneous reading of Section 340B[ ]" and vacated them. *Id.* The D.C. Circuit affirmed this ruling in 2024 and explicitly "reject[ed] HRSA's position that section 340B prohibits drug manufacturers from imposing any conditions" on the use of contract pharmacies. *Novartis Pharm. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024). It concluded Congress's silence on the issue of delivery conditions "preserves— rather than abrogates—the ability of sellers to impose at least some delivery conditions." *Id.* at 460. The Third Circuit came to a similar conclusion in 2023. *See Sanofi*, 58 F.4th at 703–704 (explaining that because HRSA had not been granted broad rulemaking authority and because the federal statute does not require manufacturers deliver drugs to an unlimited number of contract pharmacies, HRSA could not establish that the manufacturers violated 340B). The *Johnson* court noted that unreasonable restrictions imposed by the manufacturers could potentially violate the statute, but the "conditions at issue [before it did] not violate section 340B on their face."[4] 102 F.4th at 464 (declining to adjudicate HRSA's "extreme hypotheticals" and noting that courts could "sensibly adjudicate" questions about the legality of other possible conditions in the future).

4 It is notable that HRSA did "not seek to further develop the predicate facts or to further explain its position as to the specific conditions under review." *Id.* at 463. Instead, "HRSA repeatedly urged [the court] to decide the lawfulness of the disputed conditions on their face." *Id.* A more developed record that identified the impact, if any, of the disputed conditions may have led to a different result in *Johnson*.

Since these rulings, many manufacturers, including Novartis and AbbVie, have updated their policies. Novartis's current policy includes three provisions that are relevant here: First, a covered entity without an in-house pharmacy may only designate one contract pharmacy to use for 340B transactions, and a covered entity may not use a contract pharmacy if it has its own in-house pharmacy. (Dkt. No. 1 at 21; *see also* Dkt. No. 1-2.) Second, a covered entity is required to provide basic claims data to show the patient "actually was a patient of the covered entity." (Dkt. No. 1 at 21.) Third, federal grantees are still exempted from Novartis's policy. (*Id.*)

Similarly, AbbVie's policy maintains that if a covered entity has an in-house pharmacy, AbbVie will only take orders from that pharmacy. *AbbVie*, Dkt. No. 1 at 27. If a covered entity does not have an in-house pharmacy, AbbVie will take orders for one designated contract pharmacy, "provided that the one contract pharmacy is located within 40 miles of the HRSA-registered covered entity parent site, and that the covered entity submits limited claims data on 340B utilization for that pharmacy location." *Id.* AbbVie also exempts federal grantees from its policy. *Id.* PhRMA acknowledges that many of its members have also imposed conditional policies that limit covered entities to purchasing drugs through no more than one contract pharmacy and require the entities to provide claims data about the transactions for which they claim 340B pricing to enable the manufacturers to conduct an audit. *PhRMA*, Dkt. No. 1 at 14, n.1.

Policies such as those implemented by Novartis and AbbVie make it challenging for covered entities to provide their services. Prior to 2020, many covered entities operated with a "balanced budget." (*See* Dkt. No. 43 at 9.) Now, covered entities such as MLCHC are seeing a "deep decline" in the pharmacy side of their business, which creates "cascading effect[s]" for the entire organization, "culminating in a budget deficit" that has continued year to year. (*Id.*) The Washington Association for Community Health ("WACH") estimates a decrease in revenue of more than $7 million annually based on data from ten of its Federally Qualified Health Centers ("FQHCs"). (Dkt. No. 48 at 8.) The reporting requirements are also burdensome for

covered entities. For example, the NOHN, which operates in an "older, economically depressed community" in northwestern Washington, has hired two full-time employees to ensure compliance and to test samples to avoid duplicative discounts and diversions. (Dkt. No. 44 at 2, 4.) David Pearson, the CEO of WACH, states that AbbVie's current policy requires FQHCs to submit claims data to a technology platform called 340B ESP, which is used by manufacturers to monitor the 340B Program. (Dkt. No. 48 at 7.) At UW Medicine, this requires data to be pulled from "at least six different internal systems...followed by manual aggregation, validation, and submission through a third-party portal not integrated into standard workflows." (Dkt. No. 41 at 10.) Administrative burdens such as these "impact[ ] the level of services [FQHCs] can offer to their patients[ ]" and limit already lean resources. (Dkt. No. 48 at 7; *see also* Dkt. No. 43 at 6.)

D. Washington Enacts SB 5981

***7** More than 20 states have enacted laws in response to court decisions finding HRSA lacked statutory authority to prohibit the manufacturers' policies. *Frey*, 2025 WL 2813787, at *4. Washington enacted its version, SB 5981, on March 25, 2026, with an effective date of June 11, 2026. SB 5981, 69th Leg., Reg. Sess. (Wash. 2026). In enacting SB 5981, the Legislature found "that the federal 340B drug pricing program is essential for providing health care access to low-income and uninsured populations." SB 5981 § 1(1). The bill contains three provisions that are relevant here:

- "A manufacturer or a third party acting on behalf of a manufacturer may not, directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy that is under contract with a covered entity to receive and dispense a 340B drug on behalf of the covered entity, or any location authorized by a covered entity to receive such 340B drug, unless federal law prohibits receipt of the 340B drug." *Id.* § 3(1).

- "A manufacturer or a third party acting on behalf of a manufacturer may not, directly or indirectly, require a covered entity to submit any claims, utilization, purchasing, or other data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity, a pharmacy that is under contract with a covered entity to receive and dispense a 340B drug on behalf of the covered entity, or any location authorized by a covered entity to receive such 340B drug, unless federal law requires such data sharing." *Id.* § 3(2).

- Manufacturers must report certain information regarding their participation in the 340B Program before April 1 of each year, including (a) "[t]he number of units, by drug, of 340B drugs distributed to each covered entity and contract pharmacy in Washington"; (b) "[t]he aggregate discounts, by drug, provided to each covered entity and contract pharmacy on 340B drugs reported in (a) of this subsection"; and (c) "[t]he average 340B discount on each of the top 25 340B drugs dispensed in the state by each manufacturer," including the percentage of the discount imposed "due to inflationary rebate" and the discount "if it were not capped with a maximum rebate amount[.]" *Id.* § 9(7).

SB 5981 also permits a covered entity to file a civil action against a manufacturer and permits the Washington Attorney General's Office to bring an action for violations of the statute. *Id.* §§ 4(1)–(2). The terms "340B drug" and "covered entity" are defined by direct reference to the federal statutory definitions. *See id.* §§ 2(1)–(2) (citing 42 U.S.C. § 256b).

Covered entities project significant savings and other benefits for their 340B healthcare services if SB 5981 goes into effect. (*See, e.g.*, Dkt. No. 42 at 6 (projecting $85 million in 340B savings for UW Medicine); 44 at 5 (describing "hundreds of thousands of dollars" of savings for NOHN, which will allow NOHN to, among other things, "provide more affordable prescription options"); 47 at 6 (explaining that Summit Pacific's gastroenterology, cardiology, and podiatry programs are at risk due to spending cuts if SB 5981 is enjoined); 48 at 14 ("Without SB 5981, some health centers located in rural areas will be forced to consider service reductions to remain solvent.").)

E. Procedural History

On March 25, 2026, Novartis filed its lawsuit against Defendants (Dkt. No. 1) and then filed its motion for preliminary injunction on March 30 (Dkt. No. 14). AbbVie filed both its complaint and motion for preliminary injunction on March 25. *AbbVie*, Dkt. Nos. 1, 7. On April 6, 2026, this Court held a scheduling conference and consolidated *Novartis* and *AbbVie* into one matter under the Novartis caption, because the cases involved a common question of law or fact. (Dkt. No. 21) (citing Fed. R. Civ. P. 42(a)). It

then issued a briefing schedule. On April 10, 2026, PhRMA filed its complaint and motion for preliminary injunction. *PhRMA*, Dkt. Nos. 1, 2. On April 16, PhRMA filed an unopposed motion to consolidate its case into the already-consolidated *Novartis* matter. *Id.*, Dkt. No. 10. On April 17, 2026, the Court granted PhRMA's motion and consolidated PhRMA's case into the present litigation. (Dkt. No. 29.) The briefing schedule was unaltered. The Court has since granted two stipulated motions for extension of time to respond to the complaints, permitting Defendants to answer or otherwise respond to all Plaintiffs' complaints 30 days after the Court issues its order on the pending motions for preliminary injunction. (Dkt. Nos. 28, 36.) On April 27, 2026, the United States filed a statement of interest, advancing its position that SB 5981 is preempted by federal law. (Dkt. No. 37.) On May 11, 2026, a motion for leave to file an amicus curae brief in support of Defendants was filed by the American Hospital Association, the Washington State Hospital Association, 340B Health, and the American Society of Health-System Pharmacists.[5] (Dkt. No. 55.) A fourth case, *AstraZeneca Pharmaceuticals LP v. Brown*, 3:26-cv-05406-DGE, was consolidated into this matter on May 22, 2026 (Dkt. No. 63) but there is no pending motion for preliminary injunction in that case.

5 The Court hereby GRANTS the amicus parties' motion to file their amicus brief (Dkt. Nos. 55, 59) but notes that many of the arguments in the brief were substantially similar to those raised by Defendants, and accordingly, the Court did not rely on the amicus brief in resolving the issues before it.

***8** All three Plaintiffs primarily argue SB 5981 violates the Supremacy Clause, violates the intergovernmental immunity doctrine, and is preempted by federal law under the doctrines of field and obstacle preemption. (Dkt. No. 14 at 21–36); *AbbVie*, Dkt. No. 7 at 14–22; *PhRMA*, Dkt. No. 2 at 17–35. Novartis moves separately for a violation of the dormant Commerce Clause (Dkt. No. 1 at 37–38), and AbbVie separately brings claims of a violation of the Fifth Amendment Takings Clause and the First Amendment Free Speech Clause. *AbbVie*, Dkt. No. 1 at 23–27. Defendants filed their response on May 8, 2026 in support of the constitutionality of SB 5981. (Dkt. No. 40.) Plaintiffs filed replies on May 15, 2026. (Dkt. Nos. 60–62.) The Court held oral argument on May 27, 2026.

II LEGAL STANDARD

Federal Rule of Civil Procedure 65(a) governs the issuance of a preliminary injunction. To obtain a preliminary injunction, the moving party must show: (1) a likelihood of success on the merits; (2) a likelihood of irreparable harm to the moving party in the absence of preliminary relief; (3) that the balance of equities tips in favor of the moving party; and (4) that an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Generally, a preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Id.* at 22. The moving party has the burden of persuasion. *Hill v. McDonough*, 547 U.S. 573, 584 (2006). "The third and fourth factors...merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Courts consider the same factors when ruling on a motion for TRO as a motion for preliminary injunction. *See Stuhlbarg Int'l Sales Co. Inc. v. John D. Brush and Co., Inc.*, 240 F.3d 832, 839 n.7 (9th Cir. 2001) (the analysis for a TRO and a preliminary injunction are "substantially identical").

The Ninth Circuit has also articulated an alternative "sliding scale" approach pursuant to which the first and third *Winter* factors are analyzed on a continuum; under such standard, a weaker showing on the merits, combined with a stronger demonstration on the balancing test, might warrant preliminary injunctive relief, assuming the second and fourth Winter elements are met. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131–1135 (9th Cir. 2011). Under this "sliding scale" method, the movant need only raise "serious questions going to the merits," but the balance of hardships must tip "sharply" in the movant's favor. *Id.* at 1131–1132; *see also Farris v. Seabrook*, 677 F.3d 858, 864 (9th Cir. 2012).

III DISCUSSION

A. Likelihood of Success on the Merits

The Ninth Circuit considers the likelihood of success on the merits as " 'the most important' *Winter* factor; if a movant fails to meet this 'threshold inquiry,' the court need not consider the other factors[.]" *Disney Enters., Inc. v. VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (citation omitted). Even if a likelihood of success is not established, a preliminary injunction may be

appropriate "if a movant raises 'serious questions going to the merits' and the 'balance of hardships...tips sharply towards' it, as long as the second and third *Winter* factors are satisfied." *Id.* (quoting *Cottrell*, 632 F.3d at 1134–1135).

1. The Supremacy Clause and the presumption against preemption

Under the Supremacy Clause, "the Laws of the United States which shall be made in Pursuance" of the Constitution are "the supreme Law of the Land[,]...any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. Through this mandate, Congress possesses the power to preempt state law, either implicitly or through express language in a statute. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376–377 (2015).

***9** "Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Courts should presume that the " 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.' " *Arizona v. United States*, 567 U.S. 387, 400 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). If the federal statute has more than one plausible reading, "courts ordinarily 'accept the reading that disfavors pre-emption.' " *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (citation omitted); *see also AbbVie, Inc. v. Fitch*, 152 F.4th 635, 645 (5th Cir. 2025) (citation omitted) ("when there is doubt about preemption, the 'tie goes to the state[ ]' ").

At the hearing, Plaintiffs argued there are three scenarios in which the presumption against preemption is "inverted" and does not apply. (Dkt. No. 68 at 8.) Plaintiffs argue all three scenarios are present in this case and suggest the doctrines are not "hermetically sealed" from one another (*id.* at 25); they urge the Court to adopt an expansive view of the Supremacy Clause that pulls from all three doctrines. The Court declines the invitation to do so. *See United States v. California*, 921 F.3d 865, 880, 884 n.9 (9th Cir. 2019) (explaining the doctrines are related but "distinct" and cautioning against the failure to "accurately distinguish between the doctrines of intergovernmental immunity and obstacle preemption"); *see also Geo Grp., Inc. v. Newsom*, 50 F.4th 745, 758 (9th Cir. 2022) (en banc) ("Modern Supremacy Clause cases discuss two separate doctrines: intergovernmental immunity and preemption."). With this in mind, the Court turns to determining whether the presumption against preemption applies.

a. Intergovernmental immunity doctrine

Plaintiffs first argue the presumption against preemption does not apply when a state statute violates the intergovernmental immunity doctrine by singling out the federal government or those with whom it deals. (Dkt. No. 14 at 35–36); *AbbVie*, Dkt. No. 7 at 15–18; *PhRMA*, Dkt. No. 2 at 18–21. First identified in *McCulloch v. Maryland*, 17 U.S. 316 (1819) and evolving since then, the intergovernmental immunity doctrine is now understood as "prohibiting state laws that *either* 'regulat[e] the United States directly *or* discriminat[e] against the Federal Government or those with whom it deals' (*e.g.*, contractors)." *United States v. Washington*, 596 U.S. 832, 838 (2022) (quoting *North Dakota v. United States*, 495 U.S. 423, 435 (1990) (plurality opinion) (emphasis added in *Washington*)). A state law discriminates against the federal government or its contractors if it singles them out for less favorable treatment. *Washington v. United States*, 460 U.S. 536, 546 (1983).

Plaintiffs argue they should be treated as federal contractors, because they have entered contracts with the federal government by opting into the 340B Program. But the PPAs between HHS and the manufacturers are not "transactional, bargained-for contracts[ ]"; rather, "[t]hey are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra*, 563 U.S. at 113. Put another way, the PPAs "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them....as the means by which drug manufacturers opt into the statutory scheme." *Id.* at 118. Though Plaintiffs argue otherwise, this arrangement is distinct from that in *Washington*, where the state enacted a workers compensation law that applied only to federal contract workers " 'engaged in the performance of work, either directly or indirectly, for the United States.' " 596 U.S. at 838 (citation omitted). The statute at issue in *Washington* made it easier for contract workers at the Hanford nuclear site to establish entitlement to workers' compensation, which in turn increased the cost to the federal government, because the federal government pays workers' compensation claims for federal

contractors at Hanford. *Id.* Here, Plaintiffs do not cite, and the Court is not aware of, any evidence or legal authority supporting the proposition that the manufacturers' participation in a voluntary regulatory program somehow confers federal contractor status. As the Court understands it, Plaintiffs are not "employees, contract workers, suppliers, or instrumentalities[ ]" of the federal government and therefore do not fall within a category of entity with whom the government "deals." *Pharm. Rsch. & Mfrs. of Am. v. Frey*, Case No. 1:25-cv-00469-JCN, 2026 WL 184504, at *5–7 (D. Me. Jan. 23, 2026), *appeal docketed*, *AbbVie Inc., et al. v. Frey, et. al.*, Case No. 26-1099 (1st Cir.).

***10** Further, as the Court will explain later, it cannot conclude that SB 5981 discriminates against 340B manufacturers, because the state law does not treat non-340B manufacturers better than 340B manufacturers. *See* Section III(A)(2) *infra*. Therefore, Plaintiffs have not shown a likelihood of success on the merits of a violation of the intergovernmental immunity doctrine. Other courts considering similar claims are in agreement. *See Frey*, 2025 WL 184504, at *5–7 (discussing intergovernmental immunity doctrine and concluding the plaintiff did not have a likelihood of success on either basis); *AstraZeneca Pharms. LP v. Lopez*, Case No. 25-00369 MWJS-WRP, 2026 WL 497141, at *15–16 (D. Haw. Feb. 23, 2026), *appeal docketed*, Case No. 26-1172 (9th Cir.) (same); *AbbVie, Inc. v. Weiser*, 811 F. Supp. 3d 1264, 1275–1276 (D. Colo. 2025), *appeal docketed*, Case No. 25-1439 (10th Cir.) (distinguishing case from *McCulloch v. Maryland*, where the "the direct subject of state regulation was itself a federal instrumentality").

b. State interference in an inherently federal relationship

Second, Plaintiffs argue the presumption against preemption does not apply where the state attempts to regulate a relationship between a private party and the federal government that is governed exclusively by federal law. Leaning on *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) and *Geo Grp.*, 50 F.4th 745, Plaintiffs argue SB 5981 impermissibly attempts to get in the middle of a purely federal relationship.

The Court finds both *Buckman* and *Geo Group* to be distinguishable here. In *Buckman*, the plaintiffs' attempts to recover damages based on state tort claims were deemed an attempt to regulate the "relationship between a federal agency and the entity it regulates" by authorizing private parties to sue medical device manufacturers for making fraudulent representations to the Food and Drug Administration ("FDA"). 531 U.S. at 343, 347. The state tort claims "inevitably conflict[ed]" with the FDA's responsibility to address fraud consistently with its statutory and regulatory objectives. *Id.* at 349–351. The Supreme Court held that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied[ ]' " and therefore declined to apply a presumption against preemption. *Id.* at 347 (citation omitted). Plaintiffs argue SB 5981 is similar because it too attempts to intermeddle in a purely federal relationship. But the Court sees a distinction between a state tort claim such as the one in *Buckman*, which permitted private fraud claims based on subject matter within the FDA's regulatory framework, and SB 5981, which regulates the delivery and distribution of 340B drugs within a gap in the 340B statutory scheme.

Geo Group is likewise inapplicable. There, the Ninth Circuit held that the presumption "does not apply when a state law would interfere with inherently federal relationships." *Id.* at 761. The state law at issue in *Geo Group* prohibited local governments in California from expanding or entering into new agreements with private detention facilities that contract with Immigration and Customs Enforcement ("ICE"). *Id.* at 752. The court observed that the law "[gave] California a 'virtual power of review' over ICE's contracting decisions" and "effectively 'place[d] a prohibition on the Federal Government' from operating with its desired personnel[.]" *Id.* at 761 (citations omitted). It would "override the federal government's decision, pursuant to discretion conferred by Congress, to use private contractors to run its immigration detention facilities." *Id.* at 750–751. Put simply, the California law was a "regulation of federal contractors" within an area of "significant federal presence," i.e., immigration. *Id.* at 761–762 (citation and quotation marks omitted). Accordingly, the court declined to apply the presumption against preemption. *Id.* at 761. By contrast, SB 5981 does not attempt to regulate the relationship between the federal government and federal contractors, because as discussed above, drug manufacturers are not "employees, contract workers, suppliers, or instrumentalities[ ]" of the federal government. *Frey*, 2026 WL 184504, at *6. Because drug manufacturers are not contractors, SB 5981 does not override a congressional mandate requiring the use of contractors to carry out federal objectives. Nor does SB 5981 regulate within an area of "significant federal presence" such as immigration. *Geo Grp.*, 50 F.4th at 761 (citation and quotation marks omitted).

***11** Put more simply, Plaintiffs ask the Court to essentially conclude that if a private entity enters a contractual relationship with the federal government pursuant to the Spending Clause, states are automatically precluded from regulating the private entity in any way—even in the absence of a clear mandate from Congress to that effect. The Court is not inclined to agree with that position, as it would collapse the guardrails of federalism in the Spending Clause context by automatically prohibiting states from regulating in areas traditionally left to them. *See Arizona*, 567 U.S. at 400 (citation omitted). At least two other district courts have expressed similar concerns. *See St. Luke's Health Sys., Ltd. v. Labrador*, 782 F. Supp. 3d 953, 978–979 (D. Idaho 2025) ("This interpretation further reflects the Supreme Court's long-held understanding that ordinary preemption principles apply to Spending Clause legislation—even if private parties happen to be the recipients of the federal funds."); *Citizens for Honesty and Integrity in Reg'l Plan. v. Cnty. of San Diego*, 258 F. Supp. 2d 1132, 1137 (S.D. Cal. 2003) ("[I]f a private citizen could bind unconsenting States to the terms of legislation enacted under the Spending Clause, then the concept of federalism would be a dead letter."), *vacated for lack of jurisdiction*, 399 F.3d 1067, 1068 (9th Cir. 2005). Though not binding, these cases underscore the principle that just because the Spending Clause is invoked when private parties become the recipients of federal funds does not mean states are automatically prohibited from regulating in those areas.

Moreover, SB 5981 does not seek to regulate the relationship between manufacturers and HRSA. That relationship is governed by § 340B itself and the PPA executed between them. The only relationship affected is the delivery relationship between a covered entity and a manufacturer—a relationship § 340B is silent about.

In short, the Court concludes that SB 5981 does not attempt to regulate or intervene in a relationship that "originates from, is governed by, and terminates according to federal law[,]" *Buckman*, 531 U.S. at 347, such that the presumption against preemption should not apply.

c. Field preemption

Plaintiffs' third basis for arguing the presumption against preemption does not apply is when the state passes a law within an area that is historically regulated by the federal government exclusively. This argument will be addressed below in the discussion on field preemption. *See* Section III(A)(3) *infra*.

d. The presumption against preemption applies in this case.

Defendants argue the presumption against preemption applies in areas of law traditionally reserved for the states, including public health, and accordingly, that the presumption applies in this case. (Dkt. No. 40 at 27–28.) The Court concurs.

The Supreme Court has held, "[t]he presumption against federal pre-emption of a state statute designed to foster public health...has special force when it appears, and the Secretary has not decided to the contrary, that the two governments are pursuing 'common purposes[.]' " *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (citing *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 421 (1973)). In *Dublino*, the Supreme Court rejected a preemption challenge to a state statute that "went beyond the federal requirements[,]" holding, "[t]he mere fact that the New York program imposed a nonfederal obstacle to continued eligibility for benefits did not provide a sufficient basis for pre-emption[.]" *Id.* at 666–667 (citing favorably to *Dublino*). In *Walsh*, the Court noted that the "mere fact" the state law "impose[d] a modest impediment to access to prescription drugs provided at government expense does not provide a sufficient basis for pre-emption[.]" *Id.* at 667.

As in *Walsh*, it appears here that the federal and state governments are pursuing "common purposes." 538 U.S. at 666 (citation and quotation marks omitted). The goal of § 340B is "simple: stretch scarce healthcare dollars and expand access to essential medications for vulnerable communities." *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 534 (5th Cir. 2026); *see also* H.R. Rep. No. 102-384, pt. II, at *12 (providing reduced drug prices to covered entities would enable them to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services[ ]"). Similarly, SB 5981's stated goal is to "provid[e] health care access to low-income and uninsured populations[ ]," and that "prohibiting drug manufacturers from imposing restrictions on 340B covered entities is necessary to ensure the integrity of the 340B program and protect Washington's vulnerable patients, their access to medications, and safety net providers' ability to serve their patients." SB

5981 §§ 1(1), (8). As explained by various Washington healthcare professionals, covered entities are already operating on thin margins. (Dkt. Nos. 45 at 3; 46 at 4; 47 at 3.) Using contract pharmacies allows covered entities to better capture the discounts afforded to them by the 340B Program. (*E.g.*, Dkt. No. 41 at 6 (contract pharmacies are "essential" to UW Medicine participation in the 340B Program because more than 70 percent of prescriptions were dispensed at community pharmacies as of 2025).) Manufacturer policies such as those enacted by AbbVie and Novartis stymie these discounts by limiting contract pharmacy arrangements and imposing burdensome costs on covered entities to comply with their policies. (*E.g.*, Dkt. No. 45 at 5 (Jefferson Healthcare is experiencing an estimated $524,000 in lost revenue from the 340B Program because of drug manufacturers' restrictions on the use of contract pharmacies).) SB 5981 eliminates these barriers, which allows greater discounts to flow to covered entities so they can continue to provide healthcare services to marginalized communities, as identified in the statute. *See* SB 5981 § 1(4) ("The 340B drug pricing program and contract pharmacies are crucial to Washington's safety net providers by ensuring patients can access their prescribed medications, while providing additional resources to 340B covered entities to serve vulnerable and underserved populations."). This outcome is aligned with the goals of the 340B Program. As a result, the Court finds the presumption against preemption applies in this case, because Washington is regulating in its lane to foster public health and is pursuing a common purpose alongside the 340B Program. *Walsh*, 538 U.S. at 666.

2. The Court declines to adopt the Fourth Circuit's framework in *McCuskey*.

***12** Plaintiffs implore the Court to adopt the Fourth Circuit's analysis striking down a similar state law as laid out in *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, 171 F.4th 675 (4th Cir. 2026).[6] Though considerable time was spent during oral argument discussing what standard, exactly, the Fourth Circuit is applying in *McCuskey*, the Court remains uncertain whether *McCuskey*'s outcome is premised on the intergovernmental immunity doctrine, a traditional preemption analysis, or something in between. Notwithstanding, the Court concludes *McCuskey*'s heightened preemption standard based on Congress's Spending Clause power is not persuasive and declines to follow.

6 On June 2, 2026, the Fourth Circuit granted a petition for rehearing en banc. *See* --- F.4th ----, 2026 WL 1493394 (Mem).

It appears that *McCuskey* borrows the antidiscrimination rule from the intergovernmental immunity context and applies it to cases in which the Spending Clause is invoked. *McCuskey*, 171 F.4th at 688 (stating, without citation, that "[t]wo principles guide our assessment here. First, the type of interference matters. Second, in the spending-power context, the type of bargain struck by Congress matters."). Curiously, the Fourth Circuit underscored that the "intergovernmental immunity doctrine does not control here[,]" yet concluded that the same concerns "animating" that doctrine, i.e., a " 'contract-law analogy[,]' " applied to its analysis of legislation enacted pursuant to Congress's spending powers.[7] *Id.* at 689. The reasoning in *McCuskey* goes: because the challenged state statute "injects the State" into the contractual relationship between the federal government and the manufacturers and imposes obligations on manufacturers based on their participation in the 340B Program, it "alters the 340B program's fundamental bargain." *Id.* at 689, 691–692. It does so by allegedly changing the terms of drug manufacturers' federally created relationships with covered entities by requiring them to deliver drugs to an unlimited number of contract pharmacies. *Id.* at 692. In other words, the state law "singles out 340B manufacturers and explicitly adds requirements to compel the very result HHS could not mandate." *Id.* The conclusion that the state law was preempted, then, is premised on the court's determination (without citation) that "spending-power legislation can oust the state even without laying comprehensive terms, when the state *directly* regulates on the basis of voluntary participation in the federal program." *Id.* at 695 n.12.

7 The dissent in *McCuskey* criticizes the majority's novel theory and points out that in all the briefing submitted by the parties, "not one word was devoted to Congress' spending power or why it should change our preemption analysis." 171 F.4th at 697 (Benjamin, J., dissenting).

As the Court sees it, *McCuskey* seems to stand for the principle that drug manufacturers bargained with HHS for the 340B Program *as is*, and that any attempt by the state of Washington to legislate in the delivery gap infringes into federal territory because of the unique spending power legislation at issue here. *E.g.*, *PhRMA*, Dkt. No. 2 at 28; *McCuskey*, 171 F.4th at 692. This position is unpersuasive for several reasons. First, as already discussed, the PPAs are not arms-length contract arrangements, and drug manufacturers are not agreeing to perform functions of the federal government directly or indirectly, nor are they providing

goods or services to the federal government. *See* Section III(A)(1)(a) *supra*. They are merely opting into a program that grants them access to Medicaid and Medicare coverage of their products by agreeing to sell certain drugs to certain other entities at a discount. *See Frey*, 2025 WL 2813787, at *1 ("All drug manufacturers who want their drugs to be covered under Medicaid and Medicare Part B must enter into an agreement with the Secretary of [HHS] to comply with 340B program requirements, including that drug manufacturers must sell covered outpatient drugs to covered entities at or below a ceiling price."). The terms and conditions of that agreement are pre-set and nonnegotiable. *McCuskey* notes, "[c]ourts have already made clear that Congress *did not* require manufacturers to distribute drugs to an unlimited number of contract pharmacies as part of the 340B program." 171 F.4th at 692 (citing *Sanofi*, 58 F.4th at 703–704). Though this statement is true in isolation, the holding in *Sanofi* was limited to the question of whether HHS could *mandate* that manufacturers deliver to unlimited contract pharmacies; it did not touch the question of whether a state, in its independent authority, could. *Sanofi*, 58 F.4th at 704–705. *Sanofi*, therefore, does not provide support for the theory that there is some "careful bargain" struck by Congress and the manufacturers that is undermined by state laws such as SB 5981.[8] *McCuskey*, 171 F.4th at 692.

8 In support of this argument, Plaintiffs cite to *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981) for the principle that "legislation enacted pursuant to the spending power is much in the nature of a contract[,]" and therefore, the conditions of the contract must be clearly stated at the outset. *PhRMA*, Dkt. No. 2 at 28 (quoting *Pennhurst*, 451 U.S. at 17). But *Pennhurst* dealt with the question of whether the federal government, in enacting a "mere federal-state funding statute," intended to impose conditions on the grant of federal money to states. 451 U.S. at 18. The Supreme Court cautioned that if Congress is attaching strings to the receipt of federal grants, "it must do so unambiguously." *Id.* at 17. By contrast here, the manufacturers are not recipients of federal grant money; rather, they are voluntary participants in a federal program that requires them to opt in to a set of obligations memorialized in a PPA. *Pennhurst*'s " 'contract law analogy' " proffered by Plaintiffs and *McCuskey*, *see* 171 F.4th at 689 (citations omitted), is inapposite.

***13** This leads into the second reason the Court declines to follow *McCuskey*. Even accepting Plaintiffs' assertions as true that there is some bargain between manufacturers and the federal government inherent in the 340B Program, the program has long permitted the use of contract pharmacies. In the early days of the 340B Program, HRSA was aware that only a small percentage of covered entities at that time used in-house pharmacies and was concerned that the purposes of the 340B Program would be defeated if covered entities could not use outside pharmacy services. *See* 61 Fed. Reg. at 43,549–43,550. The first contract pharmacy arrangements went into effect in 1996. *See id.* at 43,550 (HRSA permitting a covered entity to arrange with one contract pharmacy to act as an "agent," where it would "not resell a prescription drug but rather distribute the drug on behalf of the covered entity[ ]"). HRSA's guidelines that permitted unlimited contract pharmacy arrangements were issued in 2010—more than 15 years ago. 75 Fed. Reg. at 10,273. Shortly after, Congress passed legislation that *expanded* the definition of a covered entity within the 340B Program, further underscoring that Congress chose not to limit the use of contract pharmacies even in light of HRSA's published guidance. *See* Pub. L. 111–148, 124 Stat. 119, 821–822 (2010). Because contract pharmacies have long been a part of the 340B Program in practice, there is no real argument to be made that when drug manufacturers are "bargaining for" contracts with HHS, they did not expect that contract pharmacies would be used. In other words, the "fundamental bargain" between manufacturers and Congress, even as framed in *McCuskey*, included the use of contract pharmacies in carrying out the goals of the 340B Program to some degree.

Finally, *McCuskey* appears to adopt the antidiscrimination rule from the intergovernmental immunity doctrine analysis, despite concluding that doctrine "does not control here." 171 F.4th at 689. Under the current understanding of the doctrine, "a state law is [ ] no longer unconstitutional just because it indirectly increases costs for the Federal Government, so long as the law imposes those costs in a neutral, nondiscriminatory way." *Washington*, 596 U.S. at 839. The Supreme Court explained in *North Dakota*, "the question [of] whether a state regulation discriminates against the Federal Government cannot be viewed in isolation. Rather, the entire regulatory system should be analyzed to determine whether it is discriminatory 'with regard to the economic burdens [of] that result.' " 495 U.S. at 435 (citation omitted). Put differently, "[t]he State does not discriminate against the Federal Government and those with whom it deals unless it treats someone else better than it treats them." *Washington*, 460 U.S. at 544–545 (footnote omitted).

In *McCuskey*, the Fourth Circuit concluded that the challenged state law "targets *only* manufacturers that participate in the 340B program[ ]" and "imposes restrictions *only* on drug manufacturers when they *comply* with their end of the 340B bargain." 171

F.4th at 691. By "singl[ing] out" manufacturers that participate in the 340B Program and subjecting them to the state law, the state "targets [them]...for unfavorable treatment." *Id.* at 692. This conclusion, in part, formed the basis for the court's preemption finding.

Here, Plaintiffs have not proposed a relevant set of comparators, nor have they identified how someone else is being treated better than them. Under SB 5981, non-340B participants are not required to sell discounted drugs to "covered entities" as defined by § 256b(a)(1), so naturally they are not subject to SB 5981's delivery requirements or the prohibition on requesting claims data. *See* SB 5981 §§ 3(1)–(2). Indeed, there would be no reason for non-340B manufacturers to impose delivery conditions on contract pharmacies (and therefore no reason for the state law to target them) because non-340B manufacturers sell all their drugs at the commercial price, and presumably would be uninterested in self-imposed limits on sales. *Accord. California*, 921 F.3d at 881 (the antidiscrimination rule does not attach where the state "merely references or even singles out federal activities in an otherwise innocuous enactment[ ]"; rather, it applies only "where a state's discrimination negatively affect[s] federal activities in some way[ ]"). On the most granular level, then, SB 5981 imposes some level of discrimination between 340B and non-340B participants because the former are subjected to the state law and the latter are not. However, within the "entire regulatory system" of the 340B Program, *North Dakota*, 495 U.S. at 435, it is unclear how the state law is discriminatory, because there are no other pharmaceutical companies that are similarly situated to the 340B participants in this context. Plaintiffs do not argue that there are non-340B participants doing business in Washington, nor that the burdens imposed by SB 5981 show that Washington impermissibly favors non-340B manufacturers over participating manufacturers.

***14** To conclude, the Fourth Circuit's creation of a heightened preemption standard for statutes enacted pursuant to Congress's Spending Clause power is not convincing. The Court therefore declines Plaintiffs' request to adopt the reasoning in *McCuskey*.

3. Field Preemption

With this understanding, the Court turns to Plaintiffs' preemption arguments. Field preemption "fundamentally is a question of congressional intent[.]" *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990). In cases such as this one, where a statute does not expressly preempt state law, preemption " 'can be inferred from a framework of regulation so pervasive that Congress left no room for the States to supplement it or 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.' " *Frey*, 2025 WL 2813787, at *7 (quoting *Arizona*, 567 U.S. at 399 (internal quotation marks and modifications omitted)). However, field preemption should not be inferred lightly; "[j]ust because 'federal provisions [a]re sufficiently comprehensive to meet the need identified by Congress d[oes] not mean that States and localities [a]re barred from identifying additional needs or imposing further requirements in the field.' " *Fitch*, 152 F.4th at 645–646 (quoting *Hillsborough Cnty. v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 717 (1985)).

To assess field preemption, courts must first "delineate the pertinent regulatory field[.]" *Nat'l Fed'n of the Blind v. United Airlines, Inc.*, 813 F.3d 718, 734 (9th Cir. 2016). The second step is to "survey the scope of the federal regulation within that field." *Id.* The field must be defined with specificity. *Id.* Other courts considering this issue have examined fields including the " 'practice of pharmacy,' " *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (citation omitted), the "distribution of drugs to patients and the role of pharmacies in this distribution," *Murrill*, 166 F.4th at 539, or the provision of "discounted drugs for needy patients," *Fitch*, 152 F.4th at 646. Defendants here request the Court broadly define the field as "distribution of drugs by pharmacies[.]" (Dkt. No. 40 at 28.) At the hearing, the Court expressed skepticism that SB 5981 is regulating drugs in a traditional sense, because it instead appears aimed at generating revenue to financially prop up covered entities. (*See* Dkt. No. 68 at 51.) Though SB 5981 technically falls within the expansive field definition suggested by Defendants, "there can be no inference of preemptive intent because there is no dominant federal interest" in fields such as drug distribution. *Frey*, 2025 WL 2813787, at *7. Zooming in on narrower definitions, other courts have proposed fields such as "340B pricing or entity eligibility to access manufacturers' drugs at 340B discounted prices[,]" *AbbVie Inc. v. Skrmetti*, Case No. 3:25-cv-00519, 2025 WL 1805271, at *12 (M.D. Tenn. June 30, 2025) (describing the manufacturers' proffered field definition), or "the 340B program requirements[,]" *McCuskey*, 171 F.4th at 691. Plaintiffs here request the Court apply a more specific definition and define the relevant field as "manufacturers' obligations under the federal 340B Program[.]" (Dkt. No. 14 at 22–23); *see also*

AbbVie, Dkt. No. 7 at 22 (describing field as "the price of entry for Medicaid and Medicare Part B"); *PhRMA*, Dkt. No. 2 at 23 (describing field as manufacturers' obligations under the 340B program).

***15** The Court concludes that even if it applied Plaintiffs' more specific definition of the field, "the language of 340B is insufficient to imply a congressional intent to preclude all state regulation in the field." *Frey*, 2025 WL 2813787, at *8. This is because § 340B is silent as to many of the details regarding manufacturers' obligations to offer and provide 340B-eligible drugs. *E.g.*, *Sanofi*, 58 F.4th at 704 (explaining that the "purchased by" provision of § 340B imposes a price term for drug sales to covered entities but "leav[es] all other terms blank[ ]"); *Fitch*, 152 F.4th at 646 (acknowledging silence in § 340B regarding drug distribution and delivery). Further, the practice of pharmacy and drug regulation falls under the umbrella of public health, which is traditionally left to state regulation. *Walsh*, 538 U.S. at 654, 666; *Wyeth v. Levine*, 555 U.S. 555, 567, 578–579; *see also Fusion IV Pharms., Inc. v. Herold*, Case No. CV 19-1127 PA (FFMx), 2019 WL 12375427, at *3 (C.D. Cal. June 21, 2019) (citing various journal articles stating same).

SB 5981 addresses manufacturers' restrictions and/or conditions on the distribution and delivery of 340B drugs to covered entities. SB 5981 § 3(1). This is a subject that does not fall within a specific field Congress manifested an intent to occupy exclusively. *Fitch*, 152 F.4th at 646 ("Congress chose not to regulate distribution to patients, indicating that it did not intend to occupy the entire field in this area."); *McClain*, 95 F.4th at 1143 (Congress's decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field."). While the silence in § 340B has been interpreted by at least two circuits as permitting drug manufacturers to impose some delivery conditions, *see Sanofi*, 58 F.4th at 704; *Johnson*, 102 F.4th at 460, that silence can equally be viewed as permitting state involvement. Other courts are in accord. *E.g.*, *Murrill*, 166 F.4th at 540; *Fitch*, 152 F.4th at 646; *McClain*, 95 F.4th at 1144; *Frey*, 2025 WL 2813787, at *8; *Skrmetti*, 2025 WL 1805271, at *12–13.

Therefore, given § 340B's silence on the "acts and transactions required to accomplish the objectives of the 340B program[,]" *Frey*, 2025 2813787, at *8, the Court concludes Plaintiffs are unlikely to succeed on the merits of their field preemption claims. At this stage, it requires too much of a stretch in assuming Congress's intent in leaving the matter of 340B drug delivery unaddressed. *See McClain*, 95 F.4th at 1144 ("[W]e must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted.").

4. Conflict Preemption

Next, Plaintiffs argue SB 5981 is unconstitutional because of obstacle preemption. Obstacle preemption occurs when, relevant here, "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress[.]' " *Hillsborough Cnty.*, 471 U.S. at 713 (citations omitted). To determine if obstacle preemption exists, "the Supreme Court has instructed that [courts] employ [their] 'judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects.' " *California*, 921 F.3d at 879 (citation omitted). However, " '[t]he mere fact that there is tension between federal and state law is not enough to establish conflict preemption.' " *CDK Glob. LLC v. Brnovich*, 16 F.4th 1266, 1274 (9th Cir. 2021) (citation omitted). " 'In the absence of irreconcilability' between state and federal law, 'there is no conflict preemption.' " *Id.* (quoting *California*, 921 F.3d at 882).

At oral argument, Plaintiffs acknowledged that providing discounted drugs to covered entities was one potential objective of the statute, but that the statute contains three implicit objectives aimed at balancing the competing needs of manufacturers and covered entities in the 340B Program. The first was to provide a limited subsidy, not an open-ended subsidy, to covered entities to do with the money what they wish. (Dkt. No. 68 at 30–31.) The second, related objective was to ensure the subsidy was not so large that it disincentivized manufacturers from participating in Medicaid and Medicare Part B. (*Id.* at 32.) The third was a goal of national uniformity in implementing the 340B Program. (*Id.* at 40.) Plaintiffs cite to *Astra* to argue the subsidy provided to covered entities was not intended to be unlimited, because Congress had to balance various tradeoffs and considerations in implementing the 340B Program and further, that Congress intended for HHS to be the sole enforcer of the program. *Astra* is distinguishable because there, the Supreme Court held there is no private right of action within the 340B statutory scheme that would permit covered entities to advance claims that manufacturers were overcharging 340B healthcare facilities in violation

of their PPAs. 563 U.S. at 116–118. The Court observed that overcharge claims by private parties would undermine HHS's "efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 120. The difference, however, is that HHS has explicit statutory authority to prevent "prevent overcharges and other violations of the discounted pricing requirements" specified in the statute. 42 U.S.C. § 256b(d)(1)(A). The statute says no such thing about a manufacturer's authority to limit the number of 340B subsidies a covered entity may claim. And the Court is unaware of any language in the 340B statute preventing covered entities from using a replenishment model to purchase 340B drugs. While the Court does not disagree that Congress intended to "strike a balance among a variety of interests" in enacting the 340B Program generally, *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011) (plurality op.), the same could be said for all legislation Congress enacts. But as discussed, Congress did not undertake regulation of the delivery of 340B drugs in its legislative process, nor has it since involved itself in defining the role of contract pharmacies in the program. That leaves such matters to the states, absent some future congressional mandate.

***16** Plaintiffs also lean on the Eighth Circuit's decision in *Forest Park II v. Hadley* in support of their argument that SB 5981 obstructs the objectives of Congress by directly interfering with Congress's statutory intent by "plac[ing] additional requirements on federal program participants[.]" 336 F.3d 724, 734 (8th Cir. 2003). *Forest Park II* dealt with an operator of a building financed through a federal subsidized housing program which sought to prepay its mortgage and withdraw from the program under the program terms. *Id.* at 727. Although the operator satisfied the federal withdrawal requirements, a Minnesota state law imposed additional conditions and a different schedule for participants to withdraw. *Id.* at 730. In that way, the effect of the state law "force[d] the federal government to continue to provide financial assistance to the participant when both the federal government and the participant have chosen to end their relationship." *Id.* at 732. No such direct conflict is present in this case, because SB 5981 is not altering the relationship between the manufacturers and HRSA; rather, it is placing a restriction on manufacturers from imposing their own delivery conditions on covered entities, which merely regulates the relationship between private parties.

In the Court's view, the core congressional objective underlying the 340B Program is to provide drug discounts to covered entities so they may generate revenue to provide healthcare services to low-income communities. *See also Murrill*, 166 F.4th at 534 (the goal in enacting § 340B was to "stretch scarce healthcare dollars and expand access to essential medications for vulnerable communities[ ]"); *McClain*, 95 F.4th at 1139 (§ 340B incentivizes manufacturers to provide covered entities with "pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty levels[ ]"); *Espinosa*, 2021 WL 5161783, at *7 (the 340B Program "provides discounts on drugs to certain kinds of healthcare facilities[ ]"). Indeed,

> [i]t would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. *Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law*.

61 Fed. Reg. at 43,550 (emphasis added). The goals of SB 5981, such as preventing manufacturers from imposing limits on drug distribution to covered entities and promoting the financial savings of covered entities under the 340B Program so they may "reinvest in their operations, expand services, and support underserved communities[,]" SB §§ 1(7)–(8), appear to be in harmony with the federal goals of providing discounted drugs to covered entities so they may "stretch scarce healthcare dollars and expand access to essential medications for vulnerable communities." *Murrill*, 166 F.4th at 534. Nevertheless, Plaintiffs argue SB 5981 interferes with execution of the 340B Program in several ways. The Court takes each in turn.

a. SB 5981 may regulate conduct on which federal law is silent.

Plaintiffs argue that because federal law has given manufacturers "discretion to set reasonable limits on the use of contract pharmacies to claim 340B pricing," Washington's attempts to restrict that discretion creates an obstacle to the execution of the

340B Program. (Dkt. No. 14 at 27–29.) Plaintiffs raise many of the same arguments in favor of obstacle preemption as they do for conflict preemption. (*Id.* at 28 (arguing that the silence in § 340B gives manufacturers discretion to impose delivery conditions)); *PhRMA*, Dkt. No. 2 at 27 (same). In response, Defendants assert that Plaintiffs' briefing misunderstands the effect of statutory silence in the contract pharmacy context. (Dkt. No. 40 at 36.) They point out that Congress has been aware of the role of contract pharmacies for decades and has chosen not to regulate them, nor has it enacted new legislation even in the face of more than 20 state laws like SB 5981, which Defendants argue shows Congress has decided to " 'tolerate whatever tension there [is] between' " federal and state law. (*Id.*) (quoting *Wyeth*, 555 U.S. at 575 (internal citation omitted)).

***17** The Parties' shared understanding that the 340B Program is silent regarding delivery terms leads the Court to approach this claim like Plaintiffs' field preemption claims. Though Plaintiffs contend " 'that this silence *preserves*—rather than abrogates—the ability of sellers to impose at least some delivery conditions[,]' " (Dkt. No. 14 at 28 (quoting *Johnson*, 102 F.4th at 460) (emphasis added by Novartis)), it is difficult to conclude that such silence should be understood as Congress permitting drug manufacturers to impose delivery conditions as they please but restricting states' ability to do the same. Plaintiffs are not helped by *McDaniel v. Wells Fargo Invs., LLC*, 717 F.3d 668 (9th Cir. 2013), which they assert supports their argument that SB 5981 targets the delivery policies authorized in *Johnson* and *Sanofi*. (Dkt. No. 14 at 29.) In other words, the state "abridge[s] implicit rights created when federal law intentionally authorizes conduct." (*Id.*) But in *McDaniel*, the Ninth Circuit explained that California Labor Code § 450(a), which prohibits coerced patronization by employers, conflicted with federal law that directed securities firms to implement policies designed to prevent employees from misusing material, non-public information. 717 F.3d at 671, 675–676. The federal law imposed "affirmative, supervisory duties" on securities firms to prevent insider trading and vested them with discretion to decide for themselves how best to monitor their employees' trading. *Id.* at 673. The California state law was therefore in direct conflict with federal law, because "federal law grants an actor 'a choice,' and state law 'would restrict that choice,' " especially in a situation where the choice was a " 'significant [federal] regulatory objective.' " *Id.* at 675 (quoting *Williamson v. Mazda Motor of Am.*, 562 U.S. 323, 332 (2011)). But here, the manufacturers' policies are not a response to some *affirmative duty* imposed by federal law. Rather, *Johnson* and *Sanofi* recognized the statute's silence on the topic of delivery conditions and held that the silence "implies that manufacturers *may* impose distribution conditions by contract[.]" *Johnson*, 102 F.4th at 460. Just because manufacturers chose to do so does not turn that choice into a congressional mandate.

As far as the Court can tell, § 340B does not include a ceiling on the number of discounted drugs covered entities may obtain through the program, and as already mentioned, nothing in the statute prohibits use of the replenishment model to obtain 340B drugs. *See generally* 42 U.S.C. § 256b. Though Plaintiffs implore the Court to read an upper limit on 340B transactions into the legislation, the Court cannot discern that in the federal statute's silence, Congress intended to give drug manufacturers discretion to impose delivery conditions but simultaneously intended to prohibit states from doing the same. At any rate, "[t]he bottom line is that 'congressional and regulatory silence usually defeats a claim of preemption, not the other way around.' " *Lopez*, 2026 WL 497141, at *13 (quoting *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 985 (7th Cir. 2012)). For the same reasons as with Plaintiffs' field preemption claims, the Court finds Plaintiffs have not shown a likelihood of success on their conflict preemption claims premised on the silence embedded in § 340B.

b. SB 5981 does not increase the burden on manufacturers or impose additional obligations.

Plaintiffs next argue that SB 5981 "expands the universe of transactions for which manufacturers must provide 340B discounts." (Dkt. No. 14 at 29.) They argue SB 5981 "ratchets up" the price of admission for manufacturers to access Medicaid and Medicare Part B by widely permitting use of the replenishment model. (*Id.* at 30.) At the hearing, Plaintiffs conceded that the federal government has not taken the position that the replenishment model cannot be used but argued the replenishment model was nevertheless not within the spirit of § 340B. (Dkt. No. 68 at 28–29.) In its statement of interest, the United States adds that state laws like SB 5981 will disincentivize manufacturers to participate in Medicaid and Medicare Part B because the "costs of participating in these programs [might] outstrip the benefits[.]" (Dkt. No. 37 at 16–17.) Defendants argue any concerns about a decrease in manufacturer participation are speculative and better addressed through lobbying Congress or the Washington legislature. (Dkt. No. 40 at 38.)

Plaintiffs argue that the state's attempt to fill the gap left open by Congress imposes additional obligations on them that they did not bargain for in voluntarily contracting with HHS. (Dkt. No. 14 at 30–31); *PhRMA*, Dkt. No. 2 at 26–29. But this argument rests on the implicit assumption that when manufacturers deliver 340B drugs to contract pharmacies, the contract pharmacies are not acting as agents of a covered entity and instead are purchasing and disbursing the 340B drugs to consumers without regard to whether the consumers are patients of the covered entities. From Plaintiffs' perspective, it is improper to use the replenishment model to deliver 340B drugs to contract pharmacies on behalf of a covered entity because the contract pharmacies impermissibly profit from these transactions. This assumption matters, because if taken as true, SB 5981 compels manufacturers to make 340B sales they would not be obligated to make under federal law, which of course would "alter[ ] the 340B program's fundamental bargain." *McCuskey*, 171 F.4th at 692. In support of this argument, Plaintiffs point to the Western District of Oklahoma's decision in *Drummond*, which found an analogous state law was preempted. 808 F. Supp. 3d at 1276–1277. But importantly, the court in *Drummond* "[a]ccept[ed] that Oklahoma's delivery regulation in the context of the replenishment model operate[d] as a price regulation[.]" *Id.* at 1277. In other words, the *Drummond* court took the manufacturer at its word in concluding the replenishment model "muddies the waters as to who is the actual purchaser of the 340B drugs[.]" *Id.* at 1276.

***18** The Court concludes, along with several other district and circuit courts, that SB 5981 purports to regulate drug delivery, rather than price. *Murrill*, 166 F.4th at 540 (explaining that § 340B does not regulate the distribution of drugs nor the roles of pharmacies in distribution, which are the "precise subjects addressed" by the challenged state law); *Fitch*, 152 F.4th at 646 (same); *Skrmetti*, 2025 WL 1805271, at *12 (the challenged state law does not "say[ ] anything about the *pricing* of 340B drugs; [it] entirely concern[s] the *delivery* of 340B drugs"); *Frey*, 2025 WL 2813787, at *8 (citing favorably to *Skrmetti* and finding the same); *Lopez*, 2026 WL 497141, at *6–7 (explaining that the challenged state law regulates "delivery and availability" of 340B drugs, "not the amount charged for those drugs[ ]"); *Weiser*, 811 F. Supp. 3d at 1279 (dismissing manufacturer's argument that reference to the 340B program in the state statute means that the statute regulates price). Looking at the program through this lens, SB 5981 does not actually impose additional obligations on the manufacturers; it mandates that manufacturers must *deliver* those drugs to a "pharmacy under contract with a covered entity to receive and dispense a 340B drug[,]" rather than directly to the covered entity, SB 5981 § 3(1), but it does not affirmatively impose a change in the number of 340B transactions that are occurring with each covered entity or for each 340B drug, nor does it alter the price of those transactions. Similarly, even if the state law promotes more 340B sales, it cannot compel the manufacturers to sell 340B drugs they otherwise would not have sold, because as all Parties acknowledge, there is nothing explicit in the text of § 340B that places an upper limit on the number of 340B sales that may be conducted. Put another way, the manufacturers' performance obligations are exactly the same under both federal and state law.

Plaintiffs argued at the hearing that SB 5981 goes further than the comparative state laws from Louisiana and Arkansas because it regulates the "acquisition" of drugs too, which can only be understood to regulate drug transactions themselves, rather than after-the-fact delivery. (Dkt. No. 68 at 16–17.) But as Defendants pointed out, the state laws at issue in other cases included remarkably similar language prohibiting the acquisition and/or delivery of 340B drugs, which are tied up together in the replenishment model. (*Id.* at 46–47); *Murrill*, 166 F.4th at 536–537 (Louisiana law states that "[a] manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity[.]"); *Fitch*, 152 F.4th at 641 (Mississippi law states that drug manufacturers "shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity[.]"); *Skrmetti*, 2025 WL 1805271, at *4 (Tennessee state law prohibits drug manufacturers from "deny[ing], impos[ing] any restrictions or prohibitions on, discriminat[ing] against, or otherwise limit[ing] the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity[.]"). SB 5981 uses the same language nearly verbatim: "A manufacturer or a third party acting on behalf of a manufacturer may not, directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity[.]" SB 5981 § 3(1). The Court therefore sees no reason to treat "acquisition" separately from "delivery" in this context.

As to the United States's argument that manufacturers will withdraw from Medicaid and Medicare Part B if SB 5981 goes into effect, such an argument is speculative at this time. The United States points to one manufacturer, Bausch Health, that withdrew

from the Medicaid and 340B programs in late 2025 because of " 'legislative changes.' "[9] (Dkt. No. 37 at 16) (citation omitted). The United States hypothesizes that other manufacturers may follow suit and asserts Congress has sole discretion to determine what conditions to impose on 340B participation, "regardless of whether Washington's regulations are significant enough to alter any manufacturer's cost-benefit analysis." (*Id.* at 16–17.) This statement alone reveals the speculative nature of the United States's concerns as they relate to SB 5981.

9 The Court questions whether these "legislative changes" are in fact a reference to state laws such as SB 5981. The statement is located on a section of Bausch Health's Form 10-Q from October 2025 titled "Health Care Reform," the bulk of which focuses on the impact of the 2022 Inflation Reduction Act ("IRA"). Bausch Health Cos. Inc., Quarterly Report (Form 10-Q), at 53 (Oct. 30, 2025); *see also AbbVie*, Dkt. No. 10 at 1555. The report explains that one of Bausch Health's drugs was selected as part of an IRA price negotiation program and also identifies "IRA-like price controls on manufacturers[ ]" and "legislation intending to impact pricing" imposed by states. Bausch Health Cos. Inc. at 53. Taken in context, the statement that "numerous legislative changes have caused the Company and other pharmaceutical manufacturers to reevaluate participation in optional Federal programs[ ]" is not clearly tied to the 340B Program or laws similar to SB 5981. *Id.*

***19** On the present record, the Court concludes that Plaintiffs have not met their burden to show a likelihood of success on their claim that SB 5981 imposes additional obligations to manufacturers that participate in the federal 340B Program.[10]

c. SB 5981 does not invite conflicting adjudications or impose novel penalties for the same conduct.

10 Plaintiffs also express frustration that contract pharmacies and third-party intermediaries are apparently profiting off the replenishment model. (*E.g.*, Dkt. No. 1 at 15–16) (describing the dominance of for-profit pharmacy chains and pharmacy benefit managers that "dominate the contract pharmacy industry[ ]" and "siphon" huge chunks of 340B revenue). Even taking these assertions as true, they are better understood as policy concerns, because § 340B and its accompanying regulations permit (and more recently, have expanded access to) contract pharmacy arrangements. *See* 75 Fed. Reg. at 10,273. Plaintiffs' policy arguments "must be directed to Congress, not to [the courts]." *Harris v. Mangum*, 863 F.3d 1133, 1140 (9th Cir. 2017).

Plaintiffs also argue that SB 5981 "further frustrates Congress's objectives[ ]" by creating a duplicative enforcement scheme, where the same conduct could be adjudicated via the federal ADR process or through a lawsuit brought by the Washington Attorney General or covered entity. (Dkt. No. 14 at 31–33.) Plaintiffs argue federal law is "riddled with nuanced eligibility issues implicating HRSA's unique expertise[,]" rendering it impossible for two separate adjudicators to apply the 340B standards consistently and uniformly. (*Id.* at 33–34.) Defendants contend SB 5981's enforcement scheme is directed at conduct not implicated in the federal statute, meaning the state law obligations operate alongside, and consistent with, federal law. (Dkt. No. 40 at 39–40.) They argue the state law is not preempted merely because SB 5981 incorporates definitions from federal law. (*Id.* at 41.)

Courts have found that state efforts to impose additional remedies for the same violations under federal law are more likely to be preempted. *E.g.*, *Idaho Bldg. & Constr. Trades Council, CFL-CIO v. Inland Pac. Chapter of Associated Builders & Contractors, Inc.*, 801 F.3d 950, 961 (9th Cir. 2015) (citing *Arizona*, 567 U.S. at 400) (finding a state law preempted when it " 'add[ed] a state-law penalty for conduct proscribed by federal law[ ]' "). Such a conflict is not present here, because SB 5981 and the 340B ADR process address different violations. To illustrate: the ADR process under federal law is available to a covered entity that claims "it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price[.]" 42 C.F.R. § 10.21(a)(1). ADR is also available to manufacturers that claim a covered entity has engaged in duplicate discounting or diversion. *Id.* § 10.21(a)(2). By contrast, SB 5981 permits a covered entity or the Attorney General to bring a civil action against a manufacturer or third party acting on behalf of a manufacturer for a violation of the state statute, *see* SB 5981 §§ 4(1)–(2), which the Court has already concluded regulates delivery conditions. As summed up by the Fifth Circuit in *Murrill*,

***20** [I]f a manufacturer believes a covered entity has engaged in duplicate discounting, "only the 340B statute provides recourse...and [the state statute] has nothing to say about it." Conversely, if a manufacturer refuses to deliver discounted

> drugs to a contract pharmacy acting on behalf of a covered entity, "only [the state statute] provides recourse" because § 340B is silent on delivery logistics.

166 F.4th at 541 (quoting *Fitch*, 152 F.4th at 647). Similarly here, SB 5981's "penalties are aimed at activity that falls outside the purview of 340B[.]" *McClain*, 95 F.4th at 1145.

Plaintiffs point to the fact that SB 5981 defines its terms by incorporating federal law terms, arguing that for the state to establish a violation of state law, it necessarily must prove that every 340B condition was satisfied. (Dkt. No. 14 at 32) (citing SB 5981 §§ 2(1), (2)). According to Plaintiffs, this makes enforcement under SB 5981 a question of price, because establishing a violation includes demonstrating " 'the covered entity or contract pharmacy in question was [not] delivered drugs at the discounted rate.' " *Id.* at 32–33 (quoting *Drummond*, 808 F. Supp. 3d at 1279). But this argument is just a recast version of Plaintiffs' earlier claim that SB 5981 regulates price rather than conduct, which the Court has already dismissed. *See* Sections III(A)(3); (4)(a)–(b) *supra*; *accord. Sanofi*, 58 F.4th at 704 (the "purchased by" provision of § 340B "imposes only a price term for drug sales to covered entities, leaving all other terms blank[ ]"). The Court concludes there is no conflict between SB 5981 and the 340B Program premised on competing adjudications or enforcement.

d. SB 5981 does not obstruct 340B audits.

Finally, Plaintiffs allege SB 5981's provision that prevents claims data would interfere with their ability to conduct audits of covered entities as they are entitled to do under the 340B framework. (Dkt. No. 14 at 28–29); *AbbVie*, Dkt. No. 7 at 20–21; *PhRMA*, Dkt. No. 2 at 30–32. Defendants contend that SB 5981 cannot pose an obstacle to the 340B Program because the state law claims data provision only applies " 'unless federal law requires such data sharing.' " (Dkt. No. 40 at 42) (quoting SB 5981 § 3(2)). Defendants point to HRSA guidance from 2024 to assert the reasonable cause standard is not " 'overly burdensome' and does not 'present any barriers to a manufacturer's ability to perform an audit of a covered entity.' " (*Id.* at 42) (quoting 89 Fed. Reg. at 28,646). They submit the preliminary expert report of Dr. Madeline Carpinelli Wallack, the co-founder and CEO of Rx|X Advisory Services, a "compliance and consulting firm that works with covered entities" on 340B compliance. (Dkt. No. 50-1 at 2.) Dr. Wollack states in her "years of experience" conducting 340B audits, "HRSA does not have stringent criteria for approving manufacturer audits." (*Id.* at 21.)

Plaintiffs' concerns regarding their ability to access evidence of possible violations are reasonable. They rely on the Fourth Circuit's decision in *McCuskey*, where the court found that "[i]n practice, for manufacturers to get [ ] documentation or reasonable cause, they likely need to 'require' submission of claims or utilization data as a condition of delivery to contract pharmacies." 171 F.4th at 694. The court then confirmed that the challenged state law "prevents exactly that"—in effect, finding that the state law was not just in tension with federal law, but "frustrate[d] the operation of the audit mechanism and thus the enforcement of § 340B." *Id.* In *Drummond*, the court relied on "compelling testimony" in an evidentiary hearing to find that claims data was necessary for establishing reasonable cause to instigate an audit. 808 F. Supp. 3d at 1278.

***21** This Court sees a distinction between *requiring* covered entities to provide claims data to manufacturers—which federal law does not do—and *preventing* manufacturers from conditioning drug delivery on the provision of claims data. Even without an explicit requirement to provide claims data, the ADR process has been functioning adequately since its inception. And nothing in SB 5981 "prevents manufacturers from *asking* for needed information about disputed drug reimbursement claims[.]" *Skrmetti*, 2025 WL 1805271, at *15. HRSA guidance notes in the five years prior to its issuance in April 2024, "HRSA has not denied a request for a manufacturer audit of a covered entity," 89 Fed. Reg. at 28,646, which further underscores that manufacturers can initiate audits (and have) without the information they now argue is a necessity. Plaintiffs have not provided record evidence to show that the provision of claims data alone is necessary to satisfy the reasonable cause standard. Neither do they present evidence that they have ever been denied the ability to conduct an audit upon request, nor that they have been required by HRSA to submit this type of claims data to bolster a request for an audit. As observed by the Middle District of Tennessee, "if a manufacturer has an articulable basis for suspecting that a covered entity is engaging in prohibited conduct, it likely will have reasonable cause to request an audit." *Skrmetti*, 2025 WL 1805271, at *16. Any allegations by Plaintiffs that SB 5981's prohibition on *requiring* claims data somehow obstructs the federal ADR process is speculative at this time. There

is insufficient evidence at this point to show that the audit process would be substantially frustrated by SB 5981, and therefore, Plaintiffs have not shown a likelihood of success on the merits that SB 5981 is preempted because it interferes with 340B audits.

In conclusion, the Court finds Plaintiffs have not established a likelihood of success on the merits of their various Supremacy Clause claims.

5. Dormant Commerce Clause Claim

Novartis separately contends that SB 5981 impermissibly regulates out-of-state commerce in violation of the dormant Commerce Clause. (Dkt. No. 14 at 37–38.) "Although the Commerce Clause is by its text an affirmative grant of power to Congress to regulate interstate and foreign commerce, the Clause has long been recognized as a self-executing limitation on the power of the States to enact laws imposing substantial burdens on such commerce." *South–Central Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87 (1984). "This limitation on state power has come to be known as the dormant Commerce Clause." *Nat'l Ass'n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1147 (9th Cir. 2012). The goal of modern dormant Commerce Clause jurisprudence is aimed at prohibiting state laws that are "designed to benefit in-state economic interests by burdening out-of-state competitors." *Id.* at 1148 (citations omitted). "A critical requirement for proving a violation of the dormant Commerce Clause is that there must be a *substantial burden* on *interstate commerce*." *Id.*; *see also Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 376 (2023) (rejecting an " 'almost *per se*' rule" that any question about the ability of a state to "project its power extraterritorially" violates the dormant Commerce Clause).

Novartis argues SB 5981 violates the dormant Commerce Clause because it targets the sale of drugs from manufacturers to wholesalers and therefore regulates "wholly out-of-state conduct." (Dkt. No. 14 at 37.) It does so via the replenishment model, as described by the manufacturers. To illustrate, manufacturers sell their drugs to wholesale distributors at the commercial price, and the wholesalers then sell those drugs to pharmacies at the commercial price. (Dkt. No. 1 at 43.) The pharmacies place the drugs into a common inventory and dispense them to its patients with no eye to whether any of the drugs are eligible for 340B pricing. (*Id.* at 43–44.) Then, when a covered entity claims that a previously dispensed drug was 340B eligible, the wholesaler ships the pharmacy a new, discounted "replenishment" drug, and then finally, requests a refund for the difference between the 340B drug and its commercial price from the manufacturer. (*Id.* at 44.) Through these exchanges, Novartis alleges SB 5981 "seeks to 'directly control[ ] commerce occurring wholly outside the boundaries of [the] State." (Dkt. No. 14 at 37–38) (citation omitted).

Novartis's argument fails for two related reasons. First, as Defendants note, the conduct SB 5981 regulates (the delivery and distribution of 340B drugs) is intrastate in nature and falls within the scope of Washington's police powers. (*See* Dkt. No. 40 at 50.) Second, Novartis's dormant Commerce Clause claim is dependent on the Court taking at face value Novartis's suggestion that under the replenishment model, contract pharmacies *purchase* 340B drugs and then sell those drugs to consumers untethered to a covered entity, rather than merely *taking custody* of the drugs on behalf of the covered entity. Under Novartis's theory, SB 5981 could pose a burden to interstate commerce, because it would dictate the terms of the replenishment model transactions between manufacturers and wholesalers, which apparently occur out-of-state. (*See* Dkt. No. 1 at 44.) But if the contract pharmacies are merely agents of the covered entities, Novartis's theory falls apart. As discussed in the preemption context, *see* Section III(A)(4)(b) *supra*, Novartis's obligations under the state statute appear no different than under federal law; SB 5981 merely prevents Novartis from imposing its own restrictions on the number of transactions it will fulfill with a covered entity via a contract pharmacy. Put another way, if there was no SB 5981, Novartis would still be selling its drugs to wholesalers, and wholesalers would still be requesting 340B reimbursements after contract pharmacies dispensed 340B drugs and then "replenished" their stock. The only difference is one of degree, i.e., how many of those transactions are taking place.

***22** Novartis's claim separately fails because the "dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach, absent protectionist intent or effect[,]" and Novartis does not argue SB 5981 has either. *See Skrmetti*, 2025 WL 1805271, at *23 (citing favorably to *Nat'l Pork Producers* and rejecting a similar dormant Commerce Clause claim). Though it does not say so explicitly, Novartis appears to request the Court apply a per se rule that invalidates SB 5981 merely because it has "extraterritorial effects[,]" *Nat'l Pork Producers*, 598 U.S. at 373 (citation and quotation marks omitted), which the Supreme

Court has held is insufficient to prohibit a state law under the dormant Commerce Clause. Thus, the Court finds Novartis has not met its burden to show it is likely to succeed, or even a serious question, on the merits of its dormant Commerce Clause claim.

6. Takings Clause Claim

The Fifth Amendment prohibits "private property" from being "taken for public use, without just compensation." U.S. CONST. amend. V; *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 160 (1980) (the Fifth Amendment applies to the federal government but the same prohibition "applies against the states through the Fourteenth Amendment[ ]"). Under the Fifth Amendment framework, "[w]hen the government physically takes possession of an interest in property for some public purpose, it has a categorical duty to compensate the former owner...regardless of whether the interest that is taken constitutes an entire parcel or merely a part thereof." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002) (citation omitted). These takings come in the form of a physical taking or a regulatory taking, both of which entitle the property owner to just compensation.[11] *See Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–148 (2021) (describing physical versus regulatory takings). If a physical taking occurs, courts assess them "using a simple, *per se* rule: The government must pay for what it takes." *Id.* at 148.

11 AbbVie moved for preliminary injunction based only on its physical takings claim. *See generally AbbVie*, Dkt. No. 7 at 23–25. Defendants assert AbbVie has waived a regulatory taking argument because it did not challenge SB 5981 as an unconstitutional regulatory taking in its motion for preliminary injunction. (Dkt. No. 40 at 56.) In its reply, AbbVie notes that it did not move for a preliminary injunction on the basis of a regulatory takings claim but raised it "[i]n the alternative" in its complaint. (Dkt. No. 61 at 17 n.2); *AbbVie*, Dkt. No. 1 at 52. The Court only addresses the issue of physical takings in this order but agrees that AbbVie has not waived its regulatory takings claim outside the preliminary injunction context.

AbbVie argues SB 5981 effects a per se taking of AbbVie's property because it "compels discounted sales under terms AbbVie would never otherwise accept—and that the 340B Program does not require—so that other private parties can then sell the drugs at market price and retain the profits." *AbbVie*, Dkt. No. 7 at 23. AbbVie argues the state of Washington is forcing discounted sales of its drugs that would not otherwise occur, because without the state law, AbbVie would deny covered entities unlimited access to contract pharmacy arrangements, meaning that fewer 340B sales would occur. *Id.*

AbbVie cannot show a likelihood of success on the merits of its Takings Clause claim. First, SB 5981 does not require AbbVie to sell its drugs in Washington at all. But AbbVie, through choosing to participate in Medicare and Medicaid Part B, has by extension chosen to participate in the 340B Program, meaning that if it sells drugs in Washington, it must do so according to the terms of the 340B Program. Its voluntary participation in the program, on its own, means there is no physical taking. *See AstraZeneca Pharms. LP v. Bailey*, Case No. 2:24-cv-04143-MDH, 2025 WL 644285, at *4 (W.D. Mo. Feb. 27, 2025) (citations omitted) ("When an entity voluntarily participates in a federal program, it forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation."). In reply, AbbVie argues the voluntariness of the 340B Program does not impact the takings analysis, because AbbVie never voluntarily accepted a benefit from Washington, nor did it undertake any 340B obligations outside those outlined in its PPA. (Dkt. No. 61 at 16.) AbbVie cites to case law generally finding that a voluntary exchange for a benefit does not exist if the benefit is illusory. (*Id.* at 15–16) (citing *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023) and *Horne v. Dep't of Agric.*, 576 U.S. 350 (2015)). But aside from these cases, AbbVie does not provide legal authority to explain *why* new regulatory conditions (imposed by parties not bound by the original agreement) "must be accompanied by a separate benefit to maintain the voluntary nature of the program for purposes of a takings claim." *Frey*, 2025 WL 2813787, at *14.

***23** Second, AbbVie argues SB 5981 is compelling sales that would not otherwise occur, because under SB 5981, AbbVie cannot refuse to sell drugs to covered entities that do not comply with its contract pharmacy arrangement policy. (*See* Dkt. No. 61 at 15.) This argument is merely a different shade of Plaintiffs' earlier argument that SB 5981 imposes additional and somehow impermissible obligations on drug manufacturers. As the Court noted there, § 340B places no limits on the number of contract pharmacy transactions that may occur, *see* 75 Fed. Reg. at 10,273, nor does the statute prohibit use of the replenishment model to deliver and disburse 340B drugs. Accordingly, AbbVie's argument that SB 5981 is compelling sales that would not

have occurred save for the enactment of SB 5981—and therefore is effectuating takings—does not hold water, because SB 5981 has not pushed AbbVie's required 340B sales above some defined threshold set by the statute. The only 340B sales limits AbbVie alleges it must now exceed are the ones AbbVie has *itself* imposed. This does not amount to an unconstitutional taking.

The Court is persuaded by the Fifth Circuit and several district courts that have recently rejected nearly identical takings challenges, concluding that state laws that prohibit manufacturers from limiting the number of contract pharmacies to which they will deliver 340B drugs purchased by covered entities do not constitute a per se taking. *See Fitch*, 152 F.4th at 643 (observing that the challenged state law did not "impose on drug manufacturers a positive obligation to directly transfer or sell their drugs to anyone[,]" nor did it require manufacturers to sell larger quantities of their drugs at discounted prices than is mandated under federal law); *Murrill*, 166 F.4th at 543 (noting that the challenged state law does not deprive manufacturers of anything they are entitled to under § 340B, nor does it compel manufacturers to complete more sales); *Skrmetti*, 2025 WL 1805271, at *19 (observing that manufacturers do not like state laws similar to SB 5981 because they believe the laws increase the volume of drug sales at the 340B price). Because AbbVie has not shown a likelihood of success on the merits that SB 5981 is an unconstitutional physical taking, the Court declines to find in AbbVie's favor on this claim as well.

7. First Amendment Compelled Speech Claim

"Laws that require disclosures of information, including both government reporting requirements and direct disclosure requirements, are subject to First Amendment scrutiny." *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 153 F.4th 795, 810 (9th Cir. 2025), *petition for cert. docketed*, *Pharm. Rsch. & Mfrs. of Am. v. O'Day*, Case No. 25-1018 (2026). However, such laws may be subject to different levels of scrutiny depending on what they mandate. *Id.* AbbVie argues SB 5981 compels manufacturers to engage in compelled speech by sharing "sensitive information about their business strategies with the Washington State Health Care Authority," *AbbVie*, Dkt. No. 7 at 25 (citing SB 5981 § 9(7)), which AbbVie argues cannot meet the strict scrutiny standard required for compelled speech claims. Specifically, AbbVie argues SB 5981 qualifies as a content-based restriction on speech because it "force[s] a manufacturer to speak only when the 340B Program is the subject, and explain in detail what manufacturers must say, meaning they constitute content-based regulations of speech." *Id.* Defendants argue strict scrutiny does not apply, because government reporting requirements are not content-based compelled speech. (Dkt. No. 40 at 58–60.)

Stolfi guides the Court's analysis. There, the Ninth Circuit considered an Oregon law that required pharmaceutical manufacturers to disclose "information related to the costs, revenues and prices of certain prescription drugs[ ]" to a state agency. 153 F.4th at 805. The plaintiff brought a First Amendment claim, arguing much like AbbVie here that the reporting requirements constituted compelled speech. The court specifically distinguished the two cases AbbVie relies on in this case, noting that in *NetChoice, LLC v. Bonta*, 113 F.4th 1101 (9th Cir. 2024), the court did not consider whether "governmental reporting requirements are categorically compelled speech requirements presumptively subject to strict scrutiny[ ]"; in *X Corp. v Bonta*, it applied strict scrutiny, because the challenged state law "required companies 'to recast [their] content-moderation practices into language prescribed by the State, implicitly opining on whether and how certain controversial categories of content should be moderated.' " *Stolfi*, 153 F.3d at 817–818 (quoting 116 F.4th 888, 901 (9th Cir. 2024)). The court ultimately concluded government reporting requirements that "mandate the 'report' of political or ideological statements [ ] are subject to strict scrutiny[,]" and then declined to apply that standard to the Oregon reporting requirement law because it "[did] not compel the covered entities to make subjective political or ideological statements." *Id.* at 818–819. The *Stolfi* court went on to apply an intermediate scrutiny analysis for commercial speech to the challenged law. *See id.* at 821– 825.

***24** Here, under SB 5981, drug manufacturers like AbbVie are required to report certain information regarding their participation in the 340B Program before April 1 of each year. The information includes: (a) "[t]he number of units, by drug, of 340B drugs distributed to each covered entity and contract pharmacy in Washington"; (b) "[t]he aggregate discounts, by drug, provided to each covered entity and contract pharmacy on 340B drugs reported in (a) of this subsection"; and (c) "[t]he average 340B discount on each of the top 25 340B drugs dispensed in the state by each manufacturer," including the percentage of the discount imposed "due to inflationary rebate" and the discount "if it were not capped with a maximum rebate amount[.]" SB 5981 § 9(7).

Though AbbVie argues this information is "sensitive, proprietary business information," *AbbVie*, Dkt. No. 7 at 26, the Court concludes the SB 5981 reporting requirements are comparable to those in *Stolfi*, which were not subject to strict scrutiny. Much like the law at issue in *Stolfi*, SB 5981 does not compel drug manufacturers to make "subjective political or ideological statements." 153 F.4th at 819. Instead, it "communicate[s] the terms of...commercial transactions" by requiring manufacturers to report information such as the number of units of drugs, the aggregate discounts by drug, and the average discount of the top 25 340B drugs dispensed in Washington that year. *Id.* at 821; SB 5981 § 9(7). Further, SB 5981's reporting requirements "improve[ ] the 'free flow of commercial information[,]' " *Stolfi*, 153 F.4th at 822 (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976)), which is tied to SB 5981's stated purpose of "providing transparency across the spectrum of 340B program participants to ensure the program is operating within the original intent set forth by [C]ongress." SB 5981 § 1(9). AbbVie argues in reply that SB 5981 "forces manufacturers to speak only about the increasingly contentious 340B Program" within the context of the "hotly contested political and legal battle between states and manufacturers over state regulation of the 340B Program" (Dkt. No. 61 at 17–18), which lifts SB 5981 into political speech territory. The Court disagrees. "[A]lthough drug pricing decisions may implicate controversial public policy issues, this fact is insufficient to transform the required reports into noncommercial speech." *Stolfi*, 153 F.4th at 824. At their core, SB 5981's reporting requirements appear to be economic in nature and "tethered to commercial transactions[,]" *Stolfi*, 153 F.4th at 821, and therefore, the Court finds there is not a serious question on the merits that strict scrutiny should apply.

AbbVie argues in the alternative that even if the Court applies the less stringent standard for commercial speech, SB 5981 violates the Free Speech Clause. *AbbVie*, Dkt. No. 7 at 26 n.3; (Dkt. No. 61 at 18). Defendants respond that SB 5981 "easily" withstands the intermediate level of scrutiny applicable to commercial speech. (Dkt. No. 40 at 61.)

To meet the intermediate scrutiny standard, SB 5981's reporting requirements must "directly advance a substantial governmental interest, and the means chosen must not be more extensive than necessary."[12] *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1275 (9th Cir. 2023) (citation and quotation marks omitted). AbbVie argues Defendants cannot satisfy intermediate scrutiny because SB 5981 lacks a legitimate purpose and does not further an interest in transparency. (Dkt. No. 61 at 18.) The Court concludes that at this stage, AbbVie has not established a serious question on the merits that the intermediate scrutiny standard is not met.

12 Courts also apply a "lower standard" to commercial compelled speech in certain contexts, which "requires the compelled speech be 'reasonably related' to a substantial government interest and not be 'unjustified or unduly burdensome.' " *Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1275 (citing *Zauderer v. Off. of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 651 (1985)). To qualify for *Zauderer*'s lower standard, the compelled commercial speech must disclose "purely factual and uncontroversial information[.]" *Zauderer*, 471 U.S. at 651. Defendants note that for purposes of Plaintiffs' motion they assume intermediate scrutiny applies, but invoke *Zauderer* to argue SB 5981's reporting requirements "arguably only implicate a form of rational basis review[.]" (Dkt. No. 40 at 61 n.12.) Because AbbVie did not address this theory in its reply (*see generally* Dkt. No. 61), the Court believes it unnecessary to conduct a separate analysis for commercial speech under the *Zauderer* standard.

***25** First, the Court concludes Washington's interests in the reporting requirements of SB 5981 are substantial. In the text of the statute, the legislature found that prohibiting manufacturers' drug policies is "necessary to ensure the integrity of the 340B program and protect Washington's vulnerable patients, their access to medications, and safety net providers' ability to serve their patients[,]" and further, "that there is a vested state and public interest in providing transparency across the spectrum of 340B program participants to ensure the program is operating within the original intent set forth by [C]ongress." SB 5981 §§ 1(8)–(9). Though AbbVie argues curiosity alone does not meet the standard for a substantial government interest (Dkt. No. 61 at 18) (citing *Int'l Dairy Food Ass'n v. Amestoy*, 92 F.3d 67, 74 (1996)), it does not meaningfully challenge Defendants' contention that the reporting requirements will give the state "insights into the revenue generated by hospitals, community health centers, and their contracted pharmacies...that is not discernable from existing sources[ ]"; provide it data to "assess safety net provide revenue and unmet need when engaging in policymaking" and "decid[e] how to allocate state resources"; and inform the state's healthcare purchasing. (Dkt. No. 49 at 3.) This Court agrees with the *Stolfi* court that Washington "has a substantial interest in reducing [the pharmaceutical industry's informational] asymmetries, facilitating informed commercial transactions, and improving the efficiency of the pharmaceutical market." 153 F.4th at 826.

Next, AbbVie argues that because Washington is seeking to compel additional 340B discounts from AbbVie, the reporting requirements "more closely resemble[ ] a competition-driven fishing expedition than an effort in transparency." (Dkt. No. 61 at 18.) But the Court is persuaded that "collecting and publishing information about drug pricing, costs, and pharmaceutical market conditions 'directly advances' " Defendants' stated interests in "provid[ing] crucial insight into the opaque 340B program" for more informed policymaking. *Stolfi*, 153 F.4th at 827; (Dkt. No. 40 at 61–62).

As a final matter, the reporting requirements appear no more extensive than necessary to further the state's interests. *Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1275. The required disclosures are limited specifically to objective data about drug pricing within the 340B Program. The information reported under the statute is not subject to public disclosure and the annual health authority report compiling this data (and others) "must be aggregated and must not reveal information specific to individual...manufacturers, or discount amounts paid in connection with individual prescription drugs." SB 5981 §§ 9(8); 11(a)(2). Further, "courts have repeatedly characterized the mechanism of disclosure here—wherein the State rather than a regulated entity makes disclosed information available to the public—as narrowly tailored." *Stolfi*, 153 F.4th at 828 (collecting cases).

In conclusion, AbbVie has not shown a likelihood of success on the merits that SB 5981's reporting requirements do not pass intermediate scrutiny.

B. Irreparable Harm

Though the first *Winter* factor is dispositive, the Court briefly addresses whether Plaintiffs have established a likelihood of irreparable harm. For purposes of injunctive relief, irreparable harm constitutes "harm for which there is no adequate legal remedy, such as an award of damages." *Ariz. Dream Act Coal. v. Brewer*, 757 F.3d 1053, 1068 (9th Cir. 2014). "It is well established that the deprivation of constitutional rights 'unquestionably constitutes irreparable injury.' " *Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). "Where the constitutional claim is tenuous, however, irreparable harm will not be found likely to occur." *Cal. Pawnbrokers Ass'n, Inc. v. Carter*, Case No. 2:16-cv-02141-JAM-KJN, 2016 WL 6599819, at *11 (E.D. Cal. Nov. 8, 2016) (citing *Goldies Bookstore, Inc. v. Superior Ct. of State of Cal.*, 739 F.2d 466, 472 (9th Cir. 1984)). "Purely economic harms are generally not irreparable, as money lost may be recovered later, in the ordinary course of litigation." *Idaho v. Coeur d'Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015). Finally, "[s]peculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction." *Caribbean Marine Servs. Co., Inc. v. Baldrige*, 844 F.2d 668, 674 (9th Cir. 1988).

***26** As a threshold matter, because the Court concludes Plaintiffs' constitutional claims are unlikely to succeed on the merits, their likelihood of irreparable harm is similarly "tenuous." *See Cal. Pawnbrokers*, 2016 WL 6599819, at *11. Plaintiffs next argue SB 5981 puts them in a "lose-lose situation[,]" where they must decide whether to expend "significant resources" to comply with the law's requirements, or risk "significant" monetary penalties if they choose not to comply. (Dkt. No. 14 at 38.) Additionally, Plaintiffs assert the financial losses associated with compliance are unrecoverable, and therefore appropriate for prospective relief, because "there is no way for a covered entity or contract pharmacy to automatically refund [Plaintiffs] for unlawfully received discounts[.]" *AbbVie*, Dkt. No. 9 at 15; *see also id.*, Dkt. No. 7 at 27; *PhRMA*, Dkt. Nos. 3 at 7; 4 at 6. Plaintiffs do not provide evidence that explains why any financial losses would be unrecoverable (absent a reference to the state's sovereign immunity) so this argument is speculative at this time. (*E.g.*, Dkt. No. 60 at 17.) Likewise, Plaintiffs' argument that SB 5981 will require it to "divert substantial resources from research and development of new drug therapies[ ]" (Dkt. No. 14 at 39) is merely a repackaged version of the economic injury argument, and further, is speculative. At bottom, many of Plaintiffs' claims of irreparable injury boil down to the argument that SB 5981 requires Plaintiffs to make 340B drug sales they do not want to make, and that they will lose profits complying with the law. Such an argument invokes only economic injury, which "does not support a finding of irreparable harm[.]" *Rent-A-Center, Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir. 1991).

Plaintiffs' arguments that they will suffer irreparable harm in "less-quantifiable" ways are also deficient. (Dkt. No. 14 at 39.) Though stigma and reputational harm are appropriate for injunctive relief, *Rent-A-Center*, 944 F.2d at 603, Plaintiffs have not

established that such harms are likely, rather than merely possible. *See Cottrell*, 632 F.3d at 1131 ("Under *Winter*, plaintiffs must establish that irreparable harm is *likely*, not just possible, in order to obtain a preliminary injunction."); *Winter*, 555 U.S. at 22 ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.").

C. Public Interest and Balance of the Equities

The final two *Winter* factors require the Court to " 'balance the competing claims of injury and [ ] consider the effect on each party of the granting or withholding of the requested relief.' " 555 U.S. at 24 (citation omitted). These factors "merge when the Government is the opposing party." *Nken*, 556 U.S. at 435. "Generally, public interest concerns are implicated when a constitutional right has been violated, because all citizens have a stake in upholding the Constitution." *Preminger v. Principi*, 422 F.3d 815, 826 (9th Cir. 2005).

Plaintiffs argue SB 5981 would not benefit the public because it would not increase patient access to 340B drugs, nor would it change the prices customers pay for those drugs; instead, the increased volume of 340B discounts would "cause[ ] a cascade of downstream harms." (Dkt. No. 14 at 40.) They further argue Defendants have no interest in enforcing an unconstitutional law or circumventing the "public interest...embodied in Congress's effort to preserve the integrity and financial viability of the nation's federal healthcare programs[.]" *AbbVie*, Dkt. No. 7 at 27–28. Defendants argue SB 5981 addresses the "untenable" financial losses to covered entities and their patients caused by manufacturer policies that restrict access to contract pharmacies and "helps ensure covered entities' financial viability and the provision of essential health services[.]" (Dkt. No. 40 at 68, 70.)

The Court acknowledges that both parties have legitimate interests at stake here, but because Plaintiffs have not shown a likelihood of success on the merits of their various constitutional claims, and because Defendants have a substantial interest in promoting 340B sales to covered entities in Washington so they can use those discounts to "sustain critical [healthcare] programs[ ]" (*id.* at 69), these final *Winter* factors are not dispositive.

IV CONCLUSION

Having considered Plaintiffs' motions for preliminary injunction ((Dkt. No. 14); *AbbVie*, Dkt. No. 7; *PhRMA*, Dkt. No. 2), the United States's statement of interest (Dkt. No. 37); Defendants' response (Dkt. No. 40), Plaintiffs' replies (Dkt. Nos. 60–62), and the remainder of the record, Plaintiffs' motions are DENIED.

All Citations

Slip Copy, 2026 WL 1660347

End of Document