UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, *Plaintiff,* v. DIANA ESPINOSA, Acting Administrator, Health Resources and Services Administration, *et al.*, *Defendants.*	No. 21-cv-1479 (DLF)
UNITED THERAPEUTICS CORPORATION, *Plaintiff,* v. DIANA ESPINOSA, Acting Administrator, Health Resources and Services Administration, *et al.*, *Defendants.*	No. 21-cv-1686 (DLF)

MEMORANDUM OPINION

This case concerns conditions that plaintiffs Novartis Pharmaceuticals Corporation and United Therapeutics Corporation have imposed on discounted drug purchases by certain safety-net health care providers. The plaintiffs brought this suit to prevent threatened enforcement actions by the Health Resources and Services Administration (HRSA). Before the Court are the plaintiffs' Motions for Summary Judgment, Dkt. 19 (*Novartis*); Dkt. 14 (*United Therapeutics*), and the defendants' Motions for Summary Judgment, Dkt. 13 (*Novartis*), Dkt. 16 (*United*

Therapeutics).[1] For the reasons that follow, the Court will grant in part and deny in part the plaintiffs' motions for summary judgment and deny the defendants' motions.

I. BACKGROUND

A. Statutory and Regulatory Framework

In 1992, Congress enacted the Veterans Health Care Act (VHCA), Pub. L. No. 102-585, 106 Stat. 4943. Relevant here, the VHCA added Section 340B to the Public Health Service Act (PHSA), Pub. L. No. 78-410, 58 Stat. 682 (1944), which created a program (the "340B Program") for certain healthcare providers ("covered entities") to purchase certain drugs from drug manufacturers at reduced prices. *See* § 602, 106 Stat. at 4967–71 (codified at 42 U.S.C. § 256b). Drug manufacturers can participate in the 340B Program by entering into voluntary agreements with the Secretary of Health and Human Services "under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price . . . reduced by the [statutory] rebate percentage." 42 U.S.C. § 256b(a)(1); *see also Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011) ("Section 340B . . . imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." (internal citations omitted)). The statutory scheme starts with a carrot. The 340B Program allows the drugs of participating manufacturers to be eligible for reimbursement under Medicaid and Medicare Part B. *See* 42 U.S.C. § 1396r–8(a). Because covered entities are mostly "providers of safety-net services to the poor," *Astra*, 563 U.S. at 113, this price cap helps contain costs for low-

[1] The Court held a joint motions hearing in these related cases after the parties in *Novartis* agreed to consolidate a hearing on Novartis's motion for a preliminary injunction with a hearing on the merits in both cases. *See* Minute Order of July 15, 2021. For clarity, the Court will note the accompanying case name in a parenthetical following the citation of each docket entry.

income providers, *see AstraZeneca Pharmaceuticals LP v. Becerra*, No. 21-cv-27-LPS, 2021 WL 2458063, at *1 (D. Del. June 16, 2021); *see also* 42 U.S.C. § 256b(a)(4) (listing fifteen classes of covered entities).

The benefits of the 340B Program do not come without strings attached. Covered entities cannot receive "duplicate discounts" on drugs purchased at 340B prices. 42 U.S.C. § 256b(a)(5)(A). They also "shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). To police compliance, manufacturers and the Secretary are permitted "to audit at the Secretary's or the manufacturer's expense the records of the [covered] entit[ies]." *Id.* § 256b(a)(5)(C). Failure to comply with these requirements can lead to sanctions for covered entities. *See id.* § 256b(a)(5)(D).

Since 1994, when the 340B program was created, HRSA has issued several nonbinding interpretive guidance documents that set forth the parameters of the program. In 1994, HRSA explained that covered entities could "use a purchasing agent without forfeiting its right to section 340B drug discounts," regardless of whether the agent only "negotiates the drug purchasing contracts . . . or actually receives drug shipments for distribution" without falling afoul of the drug diversion prohibition. Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (1994). HRSA also took positions on what manufacturers could not do. They could "not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" or "place limitations on the transactions . . . which would have the effect of discouraging entities from participating in the discount program." *Id.* And manufacturers could "not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions." *Id.*

In 1996, HRSA considered the question of how covered entities could distribute discounted drugs to their patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (1996). HRSA recognized that Section 340B "[wa]s silent as to permissible drug distribution systems." *Id.* at 43,549. It took the position that covered entities could contract with outside pharmacies to (1) receive shipment of the discounted drugs from the manufacturer, (2) distribute those drugs to the covered entities' patients, and (3) place 340B-priced orders to refill their inventories. *See id.* at 43,549–50, 43,552. The reason for this practice, HRSA explained, was that only approximately four percent of covered entities had in-house pharmacies. *See id.* at 43,550. HRSA stated that "[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." *Id.* "Otherwise, [the covered entities] 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." *Id.* HRSA considered contract pharmacies in this arrangement to be "act[ing] as . . . agent[s] of the covered entit[ies]." *Id.*

HRSA's interpretation of Section 340B also included obligations. Manufacturers were obligated "to sell the drug at the discounted price" to covered entities that purchase drugs in this fashion. *Id.* at 43,549; *see also id.* at 43,555 ("Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price."). Covered entities also remained under "the statutory prohibition on drug diversion" when employing contract pharmacies. *Id.* at 43,550. To that end, contract pharmacies were required to "provide the covered entity with reports" and "establish and maintain a tracking system suitable

to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity." *Id.* at 43,555. HRSA also stated that Section 340B contained a "limitation of one pharmacy contractor per entity." *Id.*

In 2007, HRSA provided notice that it was considering changes to the general operation of the 340B Program. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1540 (2007). After seeing success in an early-2000s pilot program that allowed "[t]he use of multiple contract pharmacy service sites" and "the utilization of a contract pharmacy to supplement in-house pharmacy services," the agency "propose[d] new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites" and allow covered entities with in-house pharmacies to utilize contract pharmacies as well. *Id.* at 1540.

HRSA finalized these changes in 2010. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (2010). The 2010 guidelines maintained the above parameters but also shifted from allowing "a single point for pharmacy services, either an in-house pharmacy or an individual contract pharmacy" to permit covered entities "to use multiple pharmacy arrangements as long as they comply with guidelines developed to help ensure against diversion and duplicate discounts." *Id.* at 10,272–73. HRSA explained that this change would help "covered entities . . . 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.* at 10,273. This comment responded to concerns that covered entities had expressed about "patients [who] . . . face[d] transportation barriers or other obstacles that limit[ed] their ability to fill their prescriptions." *Id.*

Although the agency did not proceed through notice-and-comment rulemaking, it nonetheless responded to comments on this proposal. First, HRSA stated that its "guidance neither impose[d] additional burdens upon manufacturers, nor" did it "create[] any new rights for covered entities under the law." *Id.* It agreed that "independent audits can play an important role in ensuring program integrity," and it revised the guidelines "to state that the covered entit[ies] must have sufficient information to meet [their] obligation[s] of ensuring ongoing compliance" with the 340B Program. *Id.* at 10,274. Nonetheless, the agency "d[id] not agree that utilization of more than one contract pharmacy create[d] an automatic cause to suspect diversion." *Id.* Nor did it impose any new inventory or record control mechanisms. *See id.* at 10,275.

But the agency did establish some additional parameters. HRSA required covered entities to "have a written contract in place between itself and a specified pharmacy." *Id.* at 10,277. And it made covered entities responsible for "purchas[ing] the drug, maintain[ing] title to the drug and assum[ing] responsibility for establishing its price." *Id.* For distribution purposes, covered entities could purchase and pay for the drug, but the agency required the manufacturer to "ship[] the drug directly to the contract pharmacy." *Id.*

Around the same time in 2010, Congress added a stick to the 340B program by giving the Secretary the authority to seek civil monetary penalties from manufacturers "that knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the maximum applicable [discounted] price." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 825 (2010) (codified at 42 U.S.C. § 256b(d)(1)(vi)). Congress also amended Section 340B(a)(1) to require manufacturers to "offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any

other purchaser at any price." *Id.* § 7102(b)(1), 124 Stat. at 827 (also known as the "Shall Offer" provision).

B. Procedural History

Concerned about the potential for increased fraud, duplicate discounts, and drug diversion, Novartis and United Therapeutics notified HRSA of their intention to change their 340B drug policies as a result of HRSA's 2010 guidelines. *See* Verified Compl. ¶¶ 32–39, 49, Dkt. 1 (*Novartis*); Compl. ¶¶ 53–72, 74, Dkt. 1 (*United Therapeutics*). Novartis's new policy honors (1) all covered pharmacy arrangements in which "the contract pharmacy is located within a 40-mile radius of the covered entity" and (2) all contract pharmacies of "[f]ederal grantee covered entities." *Novartis* Compl. ¶¶ 42–43. The company also offers exemptions "if a hospital covered entity brings a special circumstance to Novartis's attention." *Id.* ¶ 44. If Novartis receives an order from a covered entity ineligible under these policies, it does not convert the order to a full-price order but rather declines to fill the order. *Id.* ¶ 48.

United Therapeutics takes a slightly different approach. It honors only purchases directed to those contract pharmacies that were "used by the related covered entity to make a valid 340B purchase of [its] drug[s] during the first three quarters of the 2020 calendar year." *United Therapeutics* Compl. ¶ 75. And covered entities that have had neither a contract pharmacy during that period nor an in-house pharmacy are permitted to designate a single contract pharmacy. *Id.* ¶ 76. United Therapeutics also requires all covered entities using contract pharmacies "to regularly provide claims data to [United Therapeutics] via a third-party platform, among other things, allowing [the manufacturer] to confirm that contract pharmacies are genuinely acting on behalf of a covered entity." *Id.* ¶ 77.

In response to these policy changes by drug manufacturers, the General Counsel of HHS issued an Advisory Opinion in December 2020. *See* A.R. 6832–36, Dkt. 25 (*Novartis*). The Department "conclude[d] that to the extent contract pharmacies [we]re acting as agents of a covered entity, a drug manufacturer in the 340B Program [wa]s 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.* at 6832. The agency found that Section 340B's "purchased by" language was abundantly clear. *Id.* at 6833. This language provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . *purchased by a covered entity* . . . does not exceed [the ceiling price]." *Id.* In the Department's view, "[i]t is difficult to envision a less ambiguous phrase." *Id.*; *see id.* at 6834 (stating that "the situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant"). The Advisory Opinion further stated that the agency's view was also supported by the purpose and history of the program and the Department's longstanding interpretation of the statute. *See id.* at 6834–36. Finally, the Department rejected the drug manufacturers' arguments that their actions were necessary to prevent duplicate discounting and drug diversion on the grounds that the statute provided only two mechanisms for dispute resolution, neither of which permitted manufacturers to impose the restrictions on 340B purchasers. *See id.* at 6836–38.

This opinion was quickly challenged, and it did not withstand judicial scrutiny. In June 2021, the U.S. District Court for the District of Delaware held that "the Opinion [wa]s legally flawed" because it "wrongly determine[d] that purportedly unambiguous statutory language mandate[d] its conclusion regarding covered entities' permissible use of an unlimited number of

contract pharmacies." *AstraZeneca*, 2021 WL 2458063, at *8. Judge Stark first explained "that the government's position on drug manufacturers' obligations with respect to participation in the 340B Program ha[d] *not* remained constant but ha[d], instead, materially shifted." *Id.* at *6 (emphasis in original). Over twenty-five years, "the government ha[d] dramatically expanded how covered entities may purchase 340B drugs," and this expansion of covered entities' rights had in turn expanded manufacturers' duties. *Id.* at *7.

On the merits, Judge Stark found that "[t]he statute [wa]s silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs" and that this was "a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.* at *9. He explained that the "purchased by" language of Section 340B(a)(1) directly imposed an obligation only on the Secretary "and only indirectly impose[d] obligations on manufacturers" without speaking "to the amount of . . . drugs purchased or the model by which the drugs are distributed." *Id.* The government's position had effectively added a requirement to the 340B statute—*i.e.*, "pharmaceutical manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies"—that is not contained in the statute and therefore not compelled by it. *Id.* at *10. And because the Department "wrongly believe[d] that [its] interpretation [wa]s compelled by Congress," *id.* at *11 (quoting *Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006)), the Opinion was unlawful, *id.* at *8. The Department responded by withdrawing the Opinion. *See* Notice of Withdrawal (June 18, 2021), *available at* https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf (last visited Nov. 5, 2021).

In the meantime, the agency had begun an investigation of Novartis's and United Therapeutics's 340B practices. On May 17, 2021, HRSA sent letters to the companies concluding that their "actions have resulted in overcharges and are in direct violation of the 340B statute." *Novartis* Compl. Ex. 2, at 1, Dkt. 1-2 (Violation Letter); *United Therapeutics* Compl. Ex. 2, at 1, Dkt. 1-2 (Violation Letter). HRSA explained that the "Shall Offer" language of Section 340B(a)(1) imposed a "requirement" that was "not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1. According to HRSA, the statute did not "grant[] manufacturer[s] the right to place conditions on [their] fulfillment of [their] statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1. And manufacturers were "expected to provide the same opportunity for 340B covered entities and non-340B [drug] purchasers to purchase covered outpatient drugs." *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1. The agency argued that it had made this requirement "plain, consistently since the" 1996 guidelines, "that the 340B statute require[d] manufacturers to honor such purchases regardless of the dispensing mechanism." *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1. Rejecting the companies' anti-fraud arguments, HRSA noted that the statute provides mechanisms for addressing drug manufacturers' concerns about the potential for fraud, diversion, and duplicate discounting, namely an audit of covered entities and an administrative dispute resolution process. *Novartis* Violation Letter at 2; *United Therapeutics* Violation Letter at 2. It did not, however, "permit a manufacturer to impose industry-wide, universal restrictions." *Id.* The letters closed by threatening enforcement action if the companies did not comply. *Id.*

Both companies responded by filing these suits under the Administrative Procedure Act (APA) seeking, among other things, declaratory relief that the agency's position is unlawful, vacatur of the Violation Letters, and injunctive relief barring enforcement actions. *See Novartis* Compl. 25; *United Therapeutics* Compl. 51. On July 15, 2021, with the consent of the parties, the Court consolidated resolution of Novartis's preliminary injunction motion with the cross-motions for summary judgment filed by the parties in both cases. *See* Minute Order of July 15, 2021. These motions are now ripe for decision.

II. LEGAL STANDARDS

A court grants summary judgment if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A "material" fact is one with potential to change the substantive outcome of the litigation. *See id.* at 248; *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006). A dispute is "genuine" if a reasonable jury could determine that the evidence warrants a verdict for the nonmoving party. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb*, 433 F.3d at 895.

In an Administrative Procedure Act case, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). The Court will "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or "unsupported by substantial evidence," *id.* § 706(2)(E).

III. ANALYSIS

The question properly before the Court is whether the Violation Letters—which conclude that the manufacturers' conditions "are in direct violation of the 340B statute," *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1—are unlawful.

In assessing this question, the Violation Letters are not entitled to *Chevron* deference. That degree of deference is appropriate only when an agency employs "'delegated legislative power' from Congress," *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 17–18 (D.C. Cir. 2019) (quoting *Am. Mining Cong. v. Mine Safety & Health Admin*, 995 F.2d 1106, 1109 (D.C. Cir. 1993)), and intends to act with "the 'force and effect of law,'" *id.* at 18 (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2122 (2016)). Although Congress granted HRSA the power to bring enforcement actions, *see* 42 U.S.C. § 256b(d)(1)(B), the Violation Letters at issue here do not have the force of law. These enforcement notices also do not have general applicability but instead target Novartis and United Technologies because of their particular 340B drug policies. *See Kaufman v. Nielsen*, 896 F.3d 475, 484–85 (D.C. Cir. 2018). Finally, HRSA has waived *Chevron* deference by expressly claiming *Skidmore* deference instead. *See* Defs.' Mem. of P. & A. in Opp'n to Pl.'s Mot. for Prelim. Inj. at 39, Dkt. 13-1; *see also HollyFrontier Cheyenne Refining, LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2180 (2021) (declining to address *Chevron* when the government has not invoked it). Accordingly, the Court will "accept the agency's interpretation" of Section 340B set forth in the Violation Letters "only if it is the best reading of the statute," *Guedes*, 920 F.3d at 17, and it will give the agency's interpretation deference only proportionate to its "power to persuade," *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

A. The Statute's Text

With that framework in mind, this Court starts, as always, with the text. *Ross v. Blake*, 578 U.S. 632, 638 (2016). The relevant text from Section 340B is as follows:

> The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug . . . in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

42 U.S.C. § 256(a)(1). As HRSA has long recognized, "[t]he statute is silent as to permissible drug distribution systems." 61 Fed. Reg. at 43,549. It is also silent as to what distribution requests *manufacturers* must accept. *See AstraZeneca Pharms.*, 2021 WL 2458063, at *9. The statute's silence on these questions suggests "that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies." *Id.*

HRSA resists this reading of the statute, finding a clear statutory directive in Section 340B's "Shall Offer" provision which requires manufacturers to offer their drugs to covered entities at the discounted price if they offer them to other purchasers. *See* Defs.' *Novartis* Mem. at 23; Defs.' *United Therapeutics* Mem. at 18–20 (citing 42 U.S.C. § 256b(a)(1)). HRSA's interpretation, however, stretches the "Shall Offer" provision beyond its plain meaning. An "offer" is defined as "[t]he act or instance of presenting something for acceptance." *Offer* (def. 1), Black's Law Dictionary (11th ed. 2019). Here, even with the added conditions imposed by the drug manufacturers' new policies, both manufacturers continue to present their drugs to

covered entities, as the "Shall Offer" provision requires.[2] Novartis's policy offers discounted drugs to covered entities that provide drugs through in-house pharmacies, through any contract pharmacy within a forty-mile radius of the covered entity, through any contract pharmacy of a federal grantee, and through any contract pharmacy specially exempted from this policy. *See Novartis* Compl. ¶¶ 42–44. United Therapeutics offers discounted drugs to covered entities through all contract pharmacies used in the first three quarters of 2020 and through a single contract pharmacy for covered entities that did not have a contract pharmacy in that time, so long as they provide claims data to the company. *See United Therapeutics* Compl. ¶¶ 75–77. Although the manufacturers' offers are subject to more conditions than they previously were, they are still meaningful, *bona fide* offers, notwithstanding HRSA's argument to the contrary, *see* Defs.' Mem. of P. & A. in Opp'n to Pl.'s Mot. for Summ. J. at 26, Dkt. 16-1 (*United Therapeutics*). A cursory review of the plaintiffs' new conditions shows that covered entities now have far more opportunities to purchase drugs at 340B prices than they did when HRSA limited covered entities to one contract pharmacy.

To be sure, Section 340B does not expressly grant manufacturers the authority "to place conditions on [their] fulfillment of [their] statutory obligations." *Novartis* Violation Letter at 1; *United Therapeutics* Violation Letter at 1. But neither does the "Shall Offer" provision nor any other language in Section 340B *prohibit* manufacturers from placing *any* conditions on covered

[2] The government is incorrect that the record contains evidence of 340B violations. Although the record contains evidence that some covered entities were refused 340B pricing, *see, e.g.*, *Novartis* A.R. 1468, 1474, 2592; A.R. 5766, 5769, Dkt. 23 (*United Therapeutics*), it does not show that any of those entities were not offered 340B pricing upon compliance with the manufacturers' policies. That is what HRSA would need to show for the record to establish a 340B violation. The Court will not consider the government's recently filed Notice of Filing Corrected Document from the Administrative Record, Dkt. 26 (*United Therapeutics*), because it is untimely. *See* Pl.'s Response, Dkt. 28 (*United Therapeutics*).

entities. Indeed, HRSA itself has long recognized that manufacturers are allowed to "include provisions" in their contracts with covered entities "that address customary business practice, request standard information, or include other appropriate contract provisions." 59 Fed. Reg. at 25,114. The additional conditions added to the manufacturers' new policies certainly extend beyond those that the manufacturers previously imposed. But HRSA does not adequately explain why the plain language of the statute allows manufacturers to impose only the conditions they previously imposed.

As additional justification for its position, HRSA contends that the "Shall Offer" provision in Section 340B is an anti-discrimination provision that forbids manufacturers from offering drugs to covered entities on different terms or with different requirements than they offer to commercial entities. *See* Defs.' *Novartis* Mem. at 22–24; Defs.' *United Therapeutics* Mem. at 19–21. It is true that HRSA's guidance documents have long taken the position that Section 340B prohibits discrimination. *See, e.g.*, 59 Fed. Reg. at 25,113 (forbidding manufacturers from "singl[ing] out covered entities from their other customers for restrictive conditions" and from requiring covered entities' "assurance[s] of compliance with section 340B provisions"). But on its face, the "Shall Offer" provision—which requires only that manufacturers "shall . . . offer each covered entity covered drugs" at a discounted rate "if such drug is made available to any other purchaser at any price," 42 U.S.C. § 256b(a)(1)—provides no statutory hook for HRSA's guidance. And it would be strange to treat Section 340B's "Shall Offer" language as incorporating a broad anti-discrimination rule when Congress knows full well how to forbid discrimination. In another healthcare provision, for example, Congress used the word "discriminate" to ban discrimination. *See* 42 U.S.C. § 300gg-5(a) ("A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not

discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law."). Congress also has used similarly clear language in other contexts to prohibit various types of discrimination. *See, e.g.*, *id.* § 2000e-2(a) (prohibiting employment actions on the basis of race, color, religion, sex, or national origin). Neither the "Shall Offer" provision nor any other in Section 304B contains such clear language that forbids drug manufactures from imposing *any* additional conditions—no matter how minor—on covered entities that purchase drugs at 340B discount prices.

Lacking a clear textual hook for its interpretation of Section 340B, HRSA invokes the statute's purpose to defend its Violation Letters. *See, e.g.*, Defs.' *United Therapeutics* Mem. at 25–27. The purpose of Section 340B is clear—it provides discounts on drugs to certain kinds of healthcare facilities. To that end, the more opportunities that covered entities have to purchase discounted drugs, the more money they can save. But "no legislation pursues its purposes at all costs." *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987) (per curiam)). And Section 340B is no exception. The statute clearly prohibits covered entities from receiving duplicate discounts on drugs, and it directs the Secretary to determine an enforcement mechanism. 42 U.S.C. § 256b(a)(5)(A). It also prohibits covered entities from reselling or transferring discounted drugs to anyone who is not a patient of the covered entity.[3] *Id.* § 256b(a)(5)(B). To effectuate these anti-fraud provisions, the statute

[3] United Therapeutics' argument that deliveries to covered pharmacies are a transfer in violation of this provision, *see* Mem. in Supp. of Pl.'s Mot. for Summ. J. at 28–31, Dkt. 14-1 (*United Therapeutics*), is unpersuasive. First, the reference to "patients" in the statutes suggests that the concern is transfers to end users of the drugs, not possible intermediaries. Second, this position would suggest that the use of any courier, including the U.S. Postal Service, UPS, or FedEx, for drug distribution would be impermissible. Finally, under this reading, the plaintiffs' current policies would be problematic because they allow some contract pharmacy use.

requires covered entities to allow audits by either the Secretary or the manufacturer, and it subjects covered entities to sanctions for noncompliance. *Id.* § 256b(a)(5)(C)–(D). This structure suggests that Congress did not intend Section 340B's purpose to be pursued at all costs.[4]

Even so, HRSA's Violation Letters gesture toward this statutory structure as further justification for its interpretation of Section 340B. *See Novartis* Violation Letter at 2; *United Therapeutics* Violation Letter at 2 (explaining that, because the 340B statute has mechanism to address fraud, it "does not permit a manufacturer to impose industry-wide, universal restrictions"). And certainly where, as here, the statutory text is silent on an issue of statutory interpretation, structure and purpose inform the meaning of a statute. *See Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 332 (D.C. Cir. 2020). Although HRSA's Violation Letters mention 340B's statutory structure, the agency invokes this justification only in response to the manufacturers' anti-fraud rationales, and it does not develop the structural argument in its briefs as a basis for its interpretation of Section 340B.[5] *See Novartis* Violation Letter at 2; *United Therapeutics* Violation Letter at 2. It instead asserts, without any analysis, that the built-in audit and ADR

[4] The Court does not find the reasoning of *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-81, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), persuasive. That court interpreted Section 340B's "Shall Offer" language in light of the statute's purpose and concluded that it precludes manufacturers from conditioning their offers. *See id.* at *18–19. For the reasons stated in this opinion, *see infra* 16–18, this Court rejects HRSA's interpretation that Section 340B's plain language, purpose, and structure preclude the manufacturers from imposing *any* new conditions, *see* Defs.' *United Therapeutics* Mem. at 41–42; Defs.' *Novartis* Reply at 14–15.

[5] In its briefs, HRSA raised the structure point to explain why its actions were not arbitrary and capricious. *See* Defs.' *United Therapeutics* Mem. at 41–42; Defs.' *Novartis* Reply at 14–15. But it did not argue that the structure shows that the agency's position is in accordance with the statute. And in *Novartis*, HRSA raised the argument only in its reply brief. *See Baloch v. Norton*, 517 F. Supp. 2d 345, 348 n.2 (D.D.C. 2007) (courts are not required to consider new arguments in a reply).

mechanisms preclude drug manufacturers from imposing *any* additional conditions to police fraud in connection with 340B purchases. *See* Defs.' Reply at 14–15, Dkt. 23 (*Novartis*); Defs.' *United Therapeutics* Mem. at 41–42; Defs.' Reply at 18, Dkt. 22 (*United Therapeutics*). HRSA makes no attempt to explain why Section 340B's structure prohibits *any* additional conditions, no matter how minor, and for the reasons stated above, it cannot. HRSA also does not explain why Section 340B's structure prohibits the *specific* conditions that Novartis and United Therapeutics have imposed under their new 340B policies. For its part, United Therapeutics convincingly argues that the claims data conditions that it has added to its new 340B policy will enable it to better utilize the anti-fraud audit and ADR procedures that Congress established for manufacturers in Section 340B. *See United Therapeutics* Mem. at 37–39. Because the parties have not adequately argued their respective positions on Section 340B's structure, the Court declines to decide whether Section 340B permits or prohibits any of the specific conditions at issue here.[6]

Finally, HRSA's guidance documents do not provide further support for the agency's interpretation of Section 340B. First, even though the agency asserts that its guidance documents reflect the agency's "longstanding interpretation of the statute," Defs.' *Novartis* Mem. at 2, 9, 22–25; Defs.' *United Therapeutics* Mem. at 2, 7, 28–29, its position has in fact shifted over time. In 1996, when the government first established guidance for covered entities' use of contract pharmacy services, HRSA set a "limitation of one pharmacy contractor per entity." 61 Fed. Reg. at 43,555. In 2010, however, the agency changed its position by permitting covered entities "to use multiple pharmacy arrangements." 75 Fed. Reg. at 10,273. HRSA recognized then that it

[6] The Court cannot decide those questions without appropriate briefing because they likely turn, for example, on the mechanics of how audits work and the degree to which the manufacturer conditions at issue here undermine the operation of the 340B program.

was changing its position from its 1996 guidelines, *see id.* at 10,272–73, but it paradoxically stated that its new "guidance neither impose[d] additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law," *id.* at 10,273. This is incorrect. By changing its position on "what covered entities *may* do," the agency necessarily changed its position on "what drug manufacturers *must* do." *AstraZeneca*, 2021 WL 2458063, at *7. Second, the agency's shifting guidance illustrates that is it attempting to fill a gap in this statute, and this the agency cannot do. Any such gap-filling must be accomplished by a legislative rather than an interpretive rule. *See Nat'l Mining Ass'n v. Kempthorne*, 512 F.3d 702, 709 (D.C. Cir. 2008); *see also Am. Mining Cong.*, 995 F.2d at 1109–12 (explaining the distinction between legislative rules and interpretive rules). But HRSA lacks the authority to issue a legislative rule. *See* Defs.' Notice of Suppl. Authority at 3 n.1, Dkt. 29 (*Novartis*) ("HRSA [has] acknowledged that it lacks an explicit grant of comprehensive rulemaking authority."); *see also Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 46 (D.D.C. 2014) (finding the same for an Orphan Drug Rule in the context of the 340B Program). As such, HRSA cannot circumvent this requirement by calling its gap-filling "interpretive guidance."[7]

[7] The agency also leans on legislative history to support its interpretation. *See* Defs.' *Novartis* Mem. at 25–26; Defs.' *United Therapeutics* Mem. at 27–28. In general, citation to legislative history is problematic. *See generally* Antonin Scalia, A Matter of Interpretation 36 (1997) (describing the use of legislative history to be like picking out one's friends at a party). And in any event, there is insufficient evidence to support HRSA's argument, *see* Defs.' *Novartis* Mem. at 25 (discussing S. Rep. No. 102-259, at 1–2 (1992)), that the Senate's removal of a provision in Section 340B that would have required covered entities to use in-house pharmacies shows that the statute requires manufacturers to accept all outside pharmacy arrangements, *cf. Bridgestone/Firestone, Inc. v. Pension Benefit Guar. Corp.*, 892 F.2d 105, 110 (D.C. Cir. 1989) (finding that the absence of specific language that Congress considered in the final statute did not speak to whether Congress rejected that scheme).

B. Remedy

Pursuant to 28 U.S.C. § 2201, the Court will declare that the plaintiffs' policies do not violate Section 340B under the positions advanced in the Violation Letters and developed in this litigation. The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities. Therefore, the Court will set aside those letters. *See* 5 U.S.C. § 706(2). Based on the current record, however, the Court will not go as far as the plaintiffs have requested and declare that their policies are permissible under Section 340B. Nor will the Court issue any injunctive relief at this time. In granting this narrow relief, the Court expresses no view as to whether any other legal theory—such as one based on the structure of Section 340B—rules out the plaintiffs' *specific* conditions.

* * *

The parties in these related cases have raised legitimate concerns about the operation of the 340B program. The drug manufacturers have highlighted credible evidence that HRSA's recent guidelines permitting covered entities to use multiple pharmacies to distribute discounted drugs to patients have increased the potential for fraud in the 340B program. *See Novartis* Compl. ¶¶ 38, 72; *United Therapeutics* Compl. ¶¶ 5, 8, 53, 58, 60, 63, 65–66. At the same time, HRSA has expressed legitimate concerns about the degree to which the manufacturers' new conditions have made it difficult for covered entities to obtain certain drugs at discounted prices. *See, e.g.*, *Novartis* A.R. 1468, 1474, 2592, 3136, 5256, 5744, 5748; *United Therapeutics* A.R. 5766, 5769.

But Section 340B does not say as much as any of the parties in these two cases argue. The Violation Letters contain legal reasoning that rests upon an erroneous reading of Section 340B. The statute's plain language, purpose, and structure do not *prohibit* drug manufacturers

from attaching any conditions to the sales of covered drugs through contract pharmacies. Nor do they *permit* all conditions. Accordingly, any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here.

CONCLUSION

For the above stated reasons, the plaintiffs' Motions for Summary Judgment are granted in part and denied in part, and the defendants' Motion for Summary Judgment is denied. An order consistent with this decision accompanies this memorandum opinion.

Dabney L. Friedrich

DABNEY L. FRIEDRICH
United States District Judge

November 5, 2021