IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMGEN INC.,
One Amgen Center Drive
Thousand Oaks, CA 91320

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201;

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201;

HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857;

CAROLE JOHNSON, in her official capacity as Administrator of the Health Resources and Services Administration,
5600 Fishers Lane
Rockville, MD 20857;

KRISTA M. PEDLEY, in her official capacity as Director of the Office of Special Health Initiatives,
5600 Fishers Lane
Rockville, MD 20857; *and*

EMEKA EGWIM, in his official capacity as Director of the Office of Pharmacy Affairs,
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

Civil Action No. 22-3763

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Amgen Inc. ("Amgen") brings this action against Defendants the U.S. Department of Health and Human Services ("HHS"); Xavier Becerra, in his official capacity as Secretary of HHS; the Health Resources and Services Administration ("HRSA"); Carole Johnson, in her official capacity as Administrator of HRSA; Krista M. Pedley, in her official capacity as Director of HRSA's Office of Special Health Initiatives; and Emeka Egwim, in his official capacity as the Director of HRSA's Office of Pharmacy Affairs (collectively, "Defendants"), and alleges as follows:

INTRODUCTION

1. Defendant HRSA—together with a national network of for-profit pharmacy chains—has worked to dramatically expand a federal program designed to assist safety-net healthcare providers. In doing so, HRSA has disregarded the text of the governing statute and flouted the rulings of federal courts, including this Court. Plaintiff Amgen, one of HRSA's latest targets, brings this lawsuit to seek relief under the Administrative Procedure Act ("APA").

2. The 340B Drug Pricing Program, 42 U.S.C. § 256b ("Section 340B") was created in 1992 in order to allow certain healthcare providers ("covered entities") to purchase drugs from manufacturers at reduced prices. *See* 42 U.S.C. § 256b. The program was designed to reduce costs for these covered entities, many of which provide safety-net services to low-income populations. But the statute also imposes hard limits. For example, covered entities may not receive "duplicate discounts" on drugs purchased at 340B prices, nor may they "resell or otherwise transfer the drug to a person who is not a patient of the entity," § 256b(a)(5)(A), (B).

3. The 340B statute defines covered entities—i.e., the designated beneficiaries of the 340B program—with a high level of specificity. The current version of the statute lists 15

categories of covered entities. *See* 42 U.S.C. § 256b(a)(4). Completely absent from that list—and completely absent from the statute—is any discussion of third-party "contract pharmacies," like Walgreens or CVS. *See Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479 (DLF), 2021 WL 5161783, at *6 (D.D.C. Nov. 5, 2021) (340B statute is "silent as to what distribution requests manufacturers must accept" from covered entities).

4. HRSA first attempted to change that in 1996, four years after the 340B Program's enactment. In guidance, HRSA recognized that the statute was "silent as to permissible drug distribution systems." 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996). But because some covered entities lacked an in-house pharmacy, HRSA allowed each covered entity to select a *single* outside "contract pharmacy" to dispense 340B-priced drugs. *Id.* To guard against fraud and abuse, HRSA also required contract pharmacies to "establish and maintain a tracking system suitable to prevent diversion," and the agency advised that contract pharmacies should dispense 340B-priced drugs "only" (1) "[u]pon presentation of a prescription bearing the covered entity's" identifying information or (2) based on "a prescription ordered by telephone" by a covered entity affiliate who "states that the prescription is for an eligible patient." *Id.* at 43,553.

5. In 2010—nearly two decades after the 340B statute's enactment—HRSA took a different tack. The agency altered its 1996 guidance and purported to allow covered entities to enter into 340B arrangements with an *unlimited* number of contract pharmacies. *See* 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010). The impact of that change reflected in the 2010 guidance has been dramatic. Between April 2010 and April 2020, the number of contract pharmacy arrangements increased by more than 4,000%, from 2,321 to 100,451—with each covered entity contracting with an average of 22 contract pharmacies (rather than the 1 envisioned under the 1996 guidance). Aaron Vandervelde et al., BRG, *For-Profit Pharmacy Participation in the 340B Program* at 4

(Oct. 2020).[1] And profits on 340B-priced drugs—originally designed to benefit covered entities—are now spread "across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." *Id.* at 7. More than half of all contract pharmacy profits go to just four large, for-profit pharmacy chains. *Id.*

6. This explosive growth has been accompanied by sophisticated business arrangements aimed at maximizing contract pharmacy profits rather than ensuring program integrity. Under the "replenishment model," pharmacies no longer dispense 340B-priced drugs only to 340B patients bearing a 340B prescription, as HRSA had previously provided. Instead, contract pharmacies dispense 340B-priced drugs to *any* customer with a prescription from *any* prescriber—and then run a black-box algorithm *after* the drug has been dispensed in a purported effort to evaluate, *ex post facto*, whether the dispensed drug indeed went to a patient of a covered entity eligible to obtain 340B drugs. If the algorithm answers "yes," then the contract pharmacy authorizes its covered entity partner to "replenish" the pharmacy's general inventory with a new 340B-discounted order. Making matters worse, contract pharmacies are often compensated by the covered entity in part based on the number of 340B-priced prescriptions they fill—so there is an obvious incentive for the contract pharmacy to weight its algorithms to unearth "340B-eligible" transactions with the most tenuous of links to any covered entity. In short, the replenishment model that contract pharmacies have created is a recipe for duplicate discounting and unlawful transfers of medications purchased at the 340B price, leading to increased violations of the 340B statute.

[1] *Available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

7. In the face of these developments—which HRSA itself has actively facilitated through its 2010 guidance allowing an unlimited number of contract pharmacies—the agency took no meaningful action. So in 2020, in order to curb the above excesses, some manufacturers announced new policies addressing the extent to which they would provide 340B-priced drugs to contract pharmacies.

8. HRSA took the position, in the summer of 2020, that the agency lacked the authority to enforce its 2010 guidance against manufacturers.[2] But in a December 2020 Advisory Opinion, HRSA declared for the first time that "drug manufacturers are required by statute to provide 340B drugs to multiple contract pharmacies." *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 56 (D. Del. 2021) ("*AstraZeneca I*"). That Advisory Opinion was challenged—and struck down—in federal court. Judge Stark ruled that the Advisory Opinion was "legally flawed" because it "wrongly determine[d]" that the 340B statute "mandates . . . an unlimited number of contract pharmacies." *Id.* at 58–59.

9. HRSA was undeterred. The agency continued to defend a series of six violation letters that HRSA had issued to manufacturers in May 2021. Those letters were substantively identical—effectively form letters—and they were based on the same flawed reasoning set out in the December 2020 Advisory Opinion. For example, the letters all claimed that the relevant manufacturers were in "direct violation of the 340B statute" based on purported "statutory obligations" to provide 340B-priced drugs to an unlimited number of contract pharmacies.

[2] *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *13 (S.D. Ind. Oct. 29, 2021) (citing Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (attached as Exhibit C)).

10. In separate lawsuits before four different federal district courts, *all six violation letters were vacated* in whole or in part. Two district courts, including this Court, invalidated three of the letters because (like the Advisory Opinion) they were based on the incorrect understanding that the 340B statute somehow unambiguously *requires* manufacturers to provide 340B-priced drugs to multiple contract pharmacies. *See Novartis*, 2021 WL 5161783; *AstraZeneca Pharms. LP v. Becerra*, No. 21-27-LPS, 2022 WL 484587 (D. Del. Feb. 16, 2022) ("*AstraZeneca II*"). A third district court vacated a fourth letter in light of HRSA's inconsistent positions regarding its enforcement authority. *See Eli Lilly & Co. v. U.S. Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, at *22 (S.D. Ind. Oct. 29, 2021) ("*Eli Lilly*"). And a fourth district court partially vacated the remaining letters and remanded to HRSA to assess "the number of permissible contract pharmacy arrangements" that manufacturers could be required to supply under the 340B statute. *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, No. CV 21-00634 (FLW), 2021 WL 5150464, at *53 (D.N.J. Nov. 5, 2021).[3]

11. On December 1, 2021, Amgen announced that effective January 3, 2022, it would modify the extent to which it provided certain drug products at the 340B discounted price to contract pharmacies. As detailed further below, Amgen would continue to provide 340B-priced drugs to contract pharmacies where (1) a single contract pharmacy is designated by a covered entity that does not have an in-house pharmacy; (2) a contract pharmacy is wholly owned by or under common ownership with a covered entity; (3) a covered entity is a federal grantee; ***or*** (4) a

[3] While this litigation was underway, HRSA issued a violation letter to a seventh manufacturer, who challenged the letter in this Court. *See Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 1:21-cv-02826-DLF (D.D.C. filed Oct. 25, 2021). That case is currently stayed pending the outcome of the *Novartis* appeal.

covered entity submits de-identified claims data through a designated platform, for the purpose of demonstrating that the 340B-priced drugs are being dispensed to patients of the covered entity.

12. Despite several court losses, HRSA pressed forward without any visible adjustments to its enforcement approach or legal theories. In May and June of this year—months after federal courts had issued the above opinions—HRSA sent additional violation letters to two more companies that were virtual carbon copies of the May 2021 letters that had been vacated.

13. On October 17, 2022, HRSA sent a substantively identical letter to Plaintiff Amgen (hereinafter, the "Violation Letter") (attached as Exhibit A). Like the letters that multiple courts—including this Court—have rejected as legally flawed, the letter claimed that Amgen is in "direct violation of the 340B statute" because its policy does not provide discounted drugs to an unlimited number of contract pharmacies. Violation Letter at 1. As in the previous letters, HRSA reiterated its position—based on a misunderstanding of the statute—that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* And as in the previous letters, HRSA demanded that Amgen "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2.

14. In short, HRSA issued the same form letter to Amgen that federal courts had consistently invalidated on various grounds. The agency did not offer a revised statutory interpretation—even though the statutory interpretation in its letter had been rejected on multiple occasions. *See, e.g.*, *Novartis*, 2021 WL 5161783, at *9; *AstraZeneca II*, 2022 WL 484587, at *6. Nor did HRSA explain its shifting views on the agency's enforcement authority, or provide more specificity on the particular number of contract pharmacy arrangements required under its reading

of the statute—even though the agency's previous letters had been invalidated for those very reasons. *See Eli Lilly*, 2021 WL 5039566, at *22; *Sanofi-Aventis*, 2021 WL 5150464, at *53.

15. Over the past year-and-a-half, HRSA has issued ten form violation letters to manufacturers, yet not a single one has survived the scrutiny of a federal court. HRSA's recent letter to Amgen—just like all the other letters—is arbitrary, capricious, and contrary to law. The Court should declare it invalid and set it aside.

JURISDICTION AND VENUE

16. This Court has jurisdiction pursuant to 28 U.S.C. § 1331. This action arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706.

17. This Court has authority to grant declaratory and injunctive relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, the APA, 5 U.S.C. § 702, and the Court's inherent equitable powers.

18. HRSA's Violation Letter, which "determined" that Amgen's policy has resulted in overcharges and violates Section 340B, and which threatened civil monetary penalties against Amgen, is a final agency action, as discussed further below. The Letter is therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities, some of whom reside in this District, and a substantial part of the events or omissions giving rise to the claim also occurred in this District.

PARTIES

20. Plaintiff Amgen is a corporation organized under the laws of the State of Delaware and headquartered in Thousand Oaks, California. Amgen is one of the world's leading

biotechnology companies, and works to transform new ideas and discoveries into medicines for patients with serious illnesses. Amgen participates in the 340B program.

21. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C., and is responsible for HRSA and the 340B program.

22. Defendant Xavier Becerra is the Secretary of HHS. His official address is in Washington, D.C. He has ultimate responsibility for oversight of the activities of HRSA, including the administration of the 340B program and the actions complained of herein. He is sued in his official capacity.

23. Defendant HRSA is an administrative agency within HHS headquartered in Rockville, Maryland, and is responsible for administering the 340B program.

24. Defendant Carole Johnson is the Administrator of HRSA. Her official address is in Rockville, Maryland. Administrator Johnson is directly responsible for the administration of the 340B program and the actions complained of herein. Administrator Johnson, among her other duties, has ultimate responsibility for the Office of Pharmacy Affairs, which is headed by Director Emeka Egwim and, as a constituent part of HRSA, is involved directly in the administration of the 340B program. Administrator Johnson issued the Violation Letter, which is a final agency action that is the subject of this complaint. Administrator Johnson is sued in her official capacity.

25. Rear Admiral Krista M. Pedley is the Director of the Office of Special Health Initiatives, the parent office of the Office of Pharmacy Affairs. Her official address is in Rockville, Maryland. Director Pedley is sued in her official capacity.

26. Defendant Emeka Egwim is the Director of the Office of Pharmacy Affairs. His official address is in Rockville, Maryland. The Office of Pharmacy Affairs is a constituent part of

HRSA and is involved directly in the administration of the 340B program. Director Egwim is sued in his official capacity.

FACTUAL BACKGROUND

A. The 340B Program

27. The 340B Drug Pricing Program was established by Congress through statute in 1992. Congress designed it to assist statutorily-defined "covered entities," which are hospitals and other providers that offer "clinical care to large numbers of uninsured" patients. H.R. Rep. No. 102-384, pt. 2, at 12 (1992), 1992 WL 239341.

28. The 340B program sought to address an inadvertent consequence of the Medicaid Drug Rebate Program ("MDRP"). Before the MDRP was enacted in 1990, manufacturers voluntarily "offered discounts" on drugs that they sold to "hospitals and other safety-net providers." Nicholas C. Fisher, *The 340B Program: A Federal Program in Desperate Need of Revision*, 22 J. Health Care L. & Pol'y 25, 29 (2019). The MDRP provided that Medicaid drug rebates would be based on the manufacturers' "Best Price," but the value of that "Best Price" was driven lower by discounts that manufacturers provided in other circumstances. That made it too costly for manufacturers to continue to provide voluntary discounts to safety-net providers. *See id.* at 29–30. As a result of this disincentive, manufacturers largely stopped offering voluntary discounts to safety-net providers. *Id.* The 340B statute addressed that problem by restoring the discounts to safety-net providers, *i.e.* "covered entities," and by amending the MDRP so that the 340B discounts would not factor into the "Best Price" calculation. *See* 106 Stat. at 4962 (codified at 42 U.S.C. § 1396r-8(c)(1)(C)).

29. Under the 340B program, covered entities "save[] billions of dollars per year by obtaining . . . drugs at [a] discount." *Cares Cmty. Health v. HHS*, 944 F.3d 950, 955 (D.C. Cir.

2019). In theory, those discounts—and the above-cost reimbursements that covered entities often receive when drugs are dispensed to insured patients—"help safety-net providers fund the uncompensated care they supply and expand the services they offer." *Id.* There is growing evidence, however, that covered entity hospitals frequently pocket the profits derived from 340B discounts rather than reinvesting those resources to serve vulnerable patient populations. *See, e.g.*, Alliance for Integrity & Reform of 340B, *Left Behind: An Analysis of Charity Care Provided by Hospitals Enrolled in the 340B Discount Program* at 9–10 (Feb. 2022) (concluding that "65 percent of 340B hospitals provide less charity care than the national average for all short-term acute care hospitals, including for-profit hospitals").[4] For instance, a recent piece of investigative journalism in the *New York Times* illustrated how hospital chains "nakedly capitaliz[e]" on the 340B program by acquiring community hospitals in order to access lucrative 340B discounts—only to "slash[] services" in poorer communities and expand into affluent suburbs where insured patients can pay full freight for brand-name drugs. *See* Katie Thomas & Jessica Silver-Greenberg, *Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, N.Y. Times (Sept. 27, 2022) (attached as Exhibit B).[5] That approach turned one community hospital into a "hollowed-out" shell of its former self, even as it generated north of $100 million in profits for a major hospital chain. *Id.*

30. Section 340B instructs that HHS enter into "agreement[s]" with pharmaceutical manufacturers providing that the price that the manufacturers offer to certain statutorily defined "covered entit[ies]" can be no more than a certain ceiling price for the manufacturer's covered

[4] *Available at* https://340breform.org/wp-content/uploads/2022/02/AIR340B_LeftBehind_2022.pdf.

[5] *Available at* https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html?smid=tw-share.

outpatient drugs. 42 U.S.C. § 256b(a)(1). That ceiling price is determined by calculating the difference between the manufacturer's Average Manufacturer Price and the Medicaid unit rebate amount for the covered outpatient drug, as determined under the Medicaid drug rebate statute. *Id.* § 256b(a)(1)-(2), (b). Section 340B requires manufacturers to offer this discounted price to covered entities, but it does not create any obligation for manufacturers to offer that price or provide 340B discounted drugs to any other parties, such as contract pharmacies, or require that manufacturers otherwise engage with contract pharmacies. To the contrary, the statute specifies that covered entities may not "resell or otherwise transfer the drug to a person who is not a patient of the entity," § 256b(a)(5)(A), (B).

31. Section 340B lists specific categories of covered entities that must be offered drugs at the discounted price under the 340B program. 42 U.S.C. § 256b(a)(4). In 2010, Congress amended the 340B statute to add new categories of covered entities, bringing the total of "covered entity" types to 15. *See* Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) (codified at 42 U.S.C. § 256b(a)(4)). These entities are defined with a high level of specificity, and include:

a. "A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)," 42 U.S.C. § 256b(a)(4)(A);

b. "An entity receiving a grant under section 256a of this title," 42 U.S.C. § 256b(a)(4)(B);

c. "A family planning project receiving a grant or contract under section 300 of this title," 42 U.S.C. § 256b(a)(4)(C);

d. "An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease)," 42 U.S.C. § 256b(a)(4)(D);

e. "A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV," 42 U.S.C. § 256b(a)(4)(E);

f. "A black lung clinic receiving funds under section 937(a) of title 30," 42 U.S.C. § 256b(a)(4)(F);

g. "A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act," 42 U.S.C. § 256b(a)(4)(G);

h. "A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988," 42 U.S.C. § 256b(a)(4)(H);

i. "An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act," 42 U.S.C. § 256b(a)(4)(I);

j. "Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to [42 U.S.C. § 256b(a)(7)]," 42 U.S.C. § 256b(a)(4)(J);

k. "An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to [42 U.S.C. § 256b(a)(7)]," 42 U.S.C. § 256b(a)(4)(K);

l. "A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that" meets various requirements as set forth in the statute, 42 U.S.C. § 256b(a)(4)(L);

m. "A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act," that would meet certain additional requirements, 42 U.S.C. § 256b(a)(4)(M);

n. "An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets" certain additional requirements, 42 U.S.C. § 256b(a)(4)(N);

o. "An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act," and that meets certain additional requirements, 42 U.S.C. § 256b(a)(4)(O).

32. This list of covered entity types does not include "contract" or other third-party pharmacies. *See AstraZeneca I,* 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

33. The agreement that HHS enters into with pharmaceutical manufacturers under the statute is known as the Pharmaceutical Pricing Agreement and Addendum ("PPA"). The terms of the PPA are not negotiable. *See Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 118 (2011). Indeed, "[t]he statutory and contractual obligations, in short, are one and the same." *Id.* Nothing in the PPA requires manufacturers to sell to, distribute to, or otherwise deal with contract pharmacies, third-party administrators, or any party other than covered entities. The PPA defines

"covered entity" specifically to refer to healthcare entities described in Section 340B(a). *See* Sample PPA.[6]

34. Congress gave HHS tools to enforce its PPAs with pharmaceutical manufacturers, including the authority to impose substantial "civil monetary penalties" on a manufacturer who "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds" the statutory ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi), (d)(1)(B)(vi)(III).

35. Although it is nominally optional for pharmaceutical manufacturers to participate in the 340B program, *see Astra*, 563 U.S. at 117–18, manufacturers have no choice as a practical matter. If a manufacturer does not participate in the 340B program for any of its covered drug products, all of the manufacturer's prescription drug products are ineligible for coverage under the Medicaid and Medicare programs. 42 U.S.C. § 1396r-8(a)(1), (5).

36. Congress prohibited covered entities from taking certain actions that would be inconsistent with the 340B program. For example, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] [a 340B discounted] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

37. Similarly, a covered entity cannot cause "duplicate discounts or rebates," which occur when a covered entity purchases from the manufacturer a unit of covered outpatient drug at the discounted 340B price and then also seeks a Medicaid rebate on that same unit to be invoiced to the manufacturer. The covered entity cannot dispense discounted 340B drugs to Medicaid beneficiaries (which thereby triggers a manufacturer rebate obligation to Medicaid) without taking certain steps to prevent a duplicate discount. *Id.* § 256b(a)(5)(A).

[6] *Available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

38. Congress instructed HHS to implement improvements in covered entity compliance with the statutory bars on duplicate discounts, reselling, and transfers. 42 U.S.C. § 256b(d)(2)(B). Among other things, HHS must have a process for imposing sanctions on covered entities that violate these statutory prohibitions. *Id.* § 256b(d)(2)(B)(v).

39. Congress also required covered entities to permit both HHS and the 340B drug manufacturers to audit "the records of the entity that directly pertain to the entity's compliance with" the bars on duplicate discounts, reselling, and transfers. *Id.* § 256b(a)(5)(C). However, HRSA has imposed a number of significant restrictions that undermine the practical benefit of the audit process. *See AstraZeneca I*, 543 F. Supp. 3d at 57 n.12 (noting "serious concerns about [manufacturers'] inability to conduct effective audits of covered entities"). For example, manufacturers must hire outside auditing firms; must submit audit work plans for HRSA approval; and may audit only one covered entity at a time. *See* 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996).

40. Under the statute, where an audit finds a violation, the manufacturer may initiate an alternative dispute resolution ("ADR") proceeding. 42 U.S.C. § 256b(d)(3)(A). But no valid regulations governing ADR proceedings exist. HRSA attempted to issue a rule establishing ADR procedures in December 2020, but a court issued a preliminary injunction after finding that those rules were promulgated without going through a proper notice and comment process. *See Eli Lilly & Co. v. Cochran*, 2021 WL 981350, at *11 (S.D. Ind. Mar. 16, 2021). As a result, no valid ADR process is currently available to address 340B program abuse.[7]

[7] HRSA has proposed a new ADR rule, but it has not yet taken effect. *See 340B Drug Pricing Program; Administrative Dispute Resolution*, 87 Fed. Reg. 73,516 (Nov. 30, 2022). The last time HRSA proposed an ADR rule for the 340B program, the agency waited four years to adopt it. *See* 85 Fed. Reg. 80,632 (Dec. 14, 2020) (finalizing ADR rule following Notice of Proposed Rulemaking in 2016).

41. HRSA's authority to promulgate regulations governing the ADR process and to impose monetary sanctions was established through statutory provisions enacted in 2010. *See* Pub. L. No. 111-148, Title II, § 2501(f)(1), Title VII, §§ 7101(a)–(d), 7102, 124 Stat. 309, 821, 823. No 340B provisions—including the provisions added in 2010—confer any authority to regulate contract pharmacies.

B. HRSA Guidance on Contract Pharmacies

42. The term "contract pharmacy" is not a statutory term, and the contract pharmacy arrangements with covered entities were nowhere authorized by Congress. The term has come to be understood in this context to refer to a for-profit pharmacy that, as HRSA has acknowledged, does not qualify as a "covered entity" under Section 340B but has entered into an arrangement with one or more covered entities. *See* Email from Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, HRSA to Lilly USA, LLC (June 11, 2020).[8]

43. From 1992—when the 340B program was established—until 1996, there was no HRSA guidance purporting to authorize contract pharmacies, and instead the only activity contemplated was that covered entities would purchase and dispense 340B discount drugs exclusively through their in-house pharmacies to their eligible patients who were treated at that location.

1. 1996 Guidance

44. In 1996, HRSA issued guidance that led to contract pharmacies participating in the 340B program in a narrow way and in limited numbers. *See Notice Regarding Section 602 of the*

[8] Second Am. Compl., Ex. C, *Eli Lilly v. Beccera*, ECF No. 103-4.

Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996).

45. The 1996 guidance explained that covered entities could contract with a single pharmacy location for the purpose of "facilitat[ing] program participation for those eligible covered entities that do not have access to appropriate 'in-house' pharmacy services." 61 Fed. Reg. at 43,551; *see also Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 72 Fed. Reg. 1540 (Jan. 12, 2007) (confirming that the 1996 guidance provided that a "covered entity could contract with *only one* pharmacy to provide all pharmacy services for any particular site of the covered entity" (emphasis added)). The 1996 guidance did not obligate manufacturers to sell or provide prescription drugs to contract pharmacies at the 340B price; instead, it put forth HRSA's non-binding interpretation of how covered entities may choose to do business. *See* 61 Fed. Reg. 43,550 ("We believe that these guidelines create no new law and create no new rights or duties."); *see also* Michelle M. Stein, *HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies* at 1, Inside Health Policy (Aug. 20, 2020).[9]

46. HRSA's guidance did not identify any statutory support for its conclusion that use of a contract pharmacy is permissible. Instead, HRSA acknowledged that "[t]he statute is silent as to permissible drug distribution systems" but asserted that it does not contain "a requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." 61 Fed. Reg. at 43,549. HRSA asserted that its 1996 guidance was lawful because, in its view, it was "clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* But HRSA recognized

[9] *Available at* https://insidehealthpolicy.com/daily-news/hrsa-urges-pharma-continue-340b-discounts-contract-pharmacies.

that, even under its reading of the statute, any obligation to deal with a contract pharmacy must be predicated on the existence of an agency relationship between the covered entity and the contract pharmacy. *See* 61 Fed. Reg. at 43,550.

47. The 1996 guidance included multiple important limits on the ability of contract pharmacies to dispense 340B discounted drugs. Indeed, HRSA specified the means for determining in advance of dispensing whether the customer receiving the 340B-purchased medication was in fact an eligible patient of a covered entity eligible to benefit from the discount (a discount the covered entity is not obliged to pass on to the patient). The 1996 HRSA guidance stated that a contract pharmacy should dispense a 340B discounted drug to a customer only after an explicit, individualized, advance determination that the prescription-holding patient is an eligible patient receiving relevant treatment from a covered entity. HRSA specified that determination should be based on confirmable information at the time of the dispensing: either (a) "presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." *Id.* at 43,556. HRSA explained that "[t]he contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program." *Id.* at 43,553.

48. The 1996 guidance helped to deter 340B program abuse, particularly because the single contract pharmacy that a covered entity used would typically maintain a separate inventory of 340B drugs that it would dispense only to the covered entity's patients. The guidance

emphasized that "[t]his situation is akin to a covered entity having its own pharmacy." 61 Fed. Reg. at 43,550. This regulatory structure was in place for well over a decade.

2. 2010 Guidance

49. In 2010, HRSA changed its longstanding position and issued guidance that covered entities could enter into an *unlimited* number of contract pharmacy arrangements that would enable the contract pharmacies to obtain 340B discount drugs. HRSA, *Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010). *Id.* at 10,273. HRSA did not identify a statutory basis for its interpretation, but claimed it "impose[d] [no] additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." *Id.*

50. The 2010 guidance stated that covered entities were required to include certain "essential elements" in their contract pharmacy arrangements, including that "[t]he covered entity . . . purchase the drug, maintain title to the drug and assume responsibility for establishing its price." *Id.* at 10,277. The guidance also provided that "[t]he contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity." *Id.* at 10,278. HRSA took no action, however, to ensure such elements were actually incorporated into contract pharmacy arrangements entered into by covered entities.

51. In particular, HRSA did not alter its broad 2010 guidance or take enforcement action even after it learned that contract pharmacies often operate on a model that has been referred to as the "replenishment" model. The "replenishment" model does not follow HRSA's 1996 guidance that a contract pharmacy dispense a 340B drug only based on (a) "presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the

patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity" or (b) "receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient." 61 Fed. Reg. at 43,556.

52. Rather, under the replenishment model, drugs purchased at the 340B discount price are placed in the contract pharmacy's general inventory and the contract pharmacy dispenses the 340B discounted drugs to customers without any determination as to whether that customer is a 340B eligible patient of a covered entity. Later, at periodic intervals, the contract pharmacies' employee data analysts make after-the-fact assessments regarding which sales they deem to be prescriptions that should be covered by the 340B Program. *See* OIG, *Contract Pharmacy Arrangements in the 340B Program* at 14 (Feb. 4, 2014) ("2014 OIG Report") (noting that many "covered entities use administrators that determine 340B eligibility *after* drugs [are] *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible" (emphasis altered)).[10] The third-party administrator typically uses a black-box algorithm to determine whether it can somehow link each customer to a covered entity. *See* Vandervelde et al., *supra*, at 4.

53. HRSA later acknowledged in 2020 that its 2010 policy is not binding, stating that it "strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements," but that "[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy to ensure clarity in program requirements across all the

[10] *Available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

interdependent aspects of the 340B Program." Michelle M. Stein, *HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies*, Inside Health Policy (Aug. 20, 2020).[11]

54. HRSA admitted that its policy was not binding against the backdrop of a court ruling that HRSA lacked general rulemaking authority under the 340B statute. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 41–45 (D.D.C. 2014). The district court in that case had explained that Section 340B authorized HRSA to conduct only three specific types of rulemaking: (1) to establish an administrative dispute resolution ("ADR") process; (2) to issue standards of methodology for calculating ceiling prices; and (3) to impose monetary sanctions. *Id.* at 41.

C. Increased Use and Abuse of Contract Pharmacy Arrangements

55. In 2018, the GAO found that, since HRSA issued its 2010 guidance, use of contract pharmacies had "increased more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off. ("GAO"), *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* at 10 (June 2018) ("2018 GAO Report").[12] Moreover, the number of claims for manufacturers to provide 340B discounts tripled between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020).[13] A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in the 340B program as contract pharmacies. Vandervelde et al., *supra*, at 4; *see also* Adam Fein, *Exclusive: 340B Continues Its Unbridled*

[11] *Available at* https://insidehealthpolicy.com/daily-news/hrsa-urges-pharma-continue-340b-discounts-contract-pharmacies.

[12] *Available at* https://www.gao.gov/assets/gao-18-480.pdf.

[13] *Available at* https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html.

Takeover of Pharmacies and PBMs, Drug Channels (June 15, 2021) (estimating more than 140,000 contract-pharmacy arrangements as of June 2021).[14] By 2020, a covered entity was contracting with an average of 22 contract pharmacies—far from the *single* contract pharmacy permitted prior to 2010—and the average distance between a covered entity and its contract pharmacies was 334 miles, compared to 34 miles in 2010. Vandervelde et al., *supra*, at 4.

56. This vast expansion in the number of contract pharmacies has coincided with a sharp divergence from the contract pharmacy model provided for in HRSA's 1996 guidance, where a single contract pharmacy was "akin to a covered entity having its own pharmacy." 61 Fed. Reg. at 43,551. That guidance required covered entities to purchase drugs at the 340B discount price and directed that those drugs be shipped to a specific contract pharmacy for dispensing from a particular inventory of 340B drugs *only* to customers with prescriptions identifying them as patients of the relevant covered entity. *Id.* at 43,552. Contract pharmacy arrangements now, by contrast, operate under a "replenishment model."

57. As explained above, *see supra* ¶ 6, the replenishment model means that the contract pharmacy does not determine at the time of dispensing whether a customer receiving 340B purchased drugs is an eligible 340B patient of a covered entity. Further, when the pharmacy receives 340B discounted drugs, it places them in its single, undifferentiated inventory from which it dispenses prescription drugs to all of its customers. *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions*, 115th Cong. 11 (May 15, 2018) (testimony of Ann Maxwell, HHS Assistant Inspector Gen. for Evaluation and Inspections, Off. of Inspector Gen. ("OIG")) ("OIG Testimony") (testifying that "many contract pharmacies dispense drugs to all of their customers—340B-eligible

[14] *Available at* https://perma.cc/X3UM-ZH8C.

or otherwise—from their regular inventory" and that "OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements").

58. HRSA does not regulate or prescribe the process for identifying the prescriptions that are claimed to be eligible to be filled with 340B discounted drugs. Nor have covered entities, contract pharmacies, or third-party administrators made their algorithms public, precluding HRSA and drug manufacturers from understanding the algorithms and assessing their accuracy.

59. Contract pharmacies profit significantly through arrangements with covered entities in multiple ways. Typically, the contract pharmacy will charge its customers and their insurers the full retail price, and will not pass on any of the savings from the discounted price paid to the manufacturer. *See* GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements* at 4 (Dec. 2019) (explaining that under the 340B program, drugs can be purchased "at the 340B price for all eligible patients regardless of the patients' income or insurance status" and purchasers "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"). The difference between the full retail price that contract pharmacies receive from their customers and their insurers and the heavily discounted 340B price that the contract pharmacy pays for new drugs to "replenish" its general inventory generates substantial revenue, a significant portion of which is pocketed by the contract pharmacy (and thus not provided to the covered entity contrary to the reason for creation of the 340B Program). For the time period "[b]etween 2013 and 2018, the [National Community Pharmacists Association] reported that the average gross margin on all prescription medicines ranged between 22% and 23%." Vandervelde et al., *supra*, at 4. For drugs purchased at the 340B price, in contrast, industry experts have estimated the average gross margin

to be 72%. *Id.* According to one estimate, "340B covered entities and their contract pharmacies generated over $13 billion in profits from 340B[-]purchased medicines in 2018." *Id.* at 7.

60. Many contract pharmacy arrangements are based on percentage-based profit sharing, where the contract pharmacy is paid a fee by the covered entity that it calculates as "a percentage of revenue generated for each 340B prescription." 2018 GAO Report at 25. In 2018, the GAO found that the fees that covered entities paid to contract pharmacies based on a percentage of revenue "ranged from 12 to 20 percent of the revenue generated." *Id.* at 27. Alternatively, or sometimes in addition to the percentage-based fee, the contract pharmacy may require the covered entity to pay a flat fee for each prescription that the contract pharmacy dispensed that it later relied on to secure a 340B discount. *Id.* at 26. Some flat fees are as high as $1,750 for certain brand drug prescriptions. *Id.*

61. Third-party administrators take another portion of the 340B revenue generated for each prescription. The third-party administrators do so by charging the covered entities an additional fee, often for each prescription identified as eligible. 2018 GAO Report at 28–30. Notably, in many instances, the third-party administrator is paid only for prescriptions that the administrator determines to be eligible to be filled with a 340B discounted drug. In addition, the fees that covered entities are charged by third-party administrators are sometimes based on a percentage of the 340B discount. *Id.* These fee structures create an obvious incentive for administrators' algorithms to identify (and misidentify) as many "340B-eligible" prescriptions as possible in order to justify claiming a 340B discount on subsequent "replenishment" orders.

62. The massive profits generated by contract pharmacy arrangements are frequently not shared with safety-net *patients*. The GAO found that only 54% of covered entities who responded to its request for data reported offering some discount on 340B drugs to low-income,

uninsured patients in their contract pharmacy arrangements. 2018 GAO Report at 30. A survey of covered entities by the HHS Office of Inspector General also found that many of them "do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements." HHS-OIG, Stuart Wright, HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program* at 14 (Feb. 4, 2014).[15]

63. Although Congress established the 340B program to benefit covered entities named by the statute, the "profits on 340B purchased medicines are now distributed across a vertically integrated supply chain that includes . . . pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups." Vandervelde et al., *supra*, at 4. Of the approximately 27,000 contract pharmacies participating in the 340B program, more than half of all profits realized by contract pharmacies are made by just four large, for-profit pharmacy chains: Walgreens, CVS, Walmart, and Cigna's Accredo specialty pharmacy. *Id*. at 7; *see also* 2018 GAO Report at 20 (stating the majority (75%) of 340B contract pharmacies are chain pharmacies). The five largest pharmacy chains "represented a combined 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide." 2018 GAO Report at 21. National pharmacy chains have disclosed that 340B profits are so significant as to be material to their business operations. *See* Walgreens Boots Alliance, Inc., Form 10-K, at 22 (Oct. 14, 2021) ("Changes in pharmaceutical manufacturers' pricing or distribution policies and practices as well as applicable government regulations, including, for example, in connection with the federal 340B drug pricing program, could also significantly reduce our profitability.");[16] CVS Health Corp., Form 10-K, at 22–23 (Feb. 9, 2022) ("A reduction in Covered Entities' participation in contract pharmacy

[15] *Available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[16] *Available at* https://sec.report/Document/0001618921-21-000085/wba-20210831.htm.

arrangements, as a result of the pending enforcement actions or otherwise, a reduction in the use of the Company's administrative services by Covered Entities, or a reduction in drug manufacturers' participation in the program could materially and adversely affect the Company.").[17]

64. The exponential increase in use of contract pharmacies also creates serious concerns about the integrity of the 340B program, including by multiplying the chances of unlawful transfers of 340-priced drugs to non-340B patients, in direct violation of the statute.

65. The potential for diversion has been exacerbated by HRSA's failure to clearly define 340B-eligible "patients." HRSA has attempted to provide guidance, but the GAO has observed: "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly. Stakeholders we interviewed, including those representing covered entities and drug manufacturers, raised concerns that the guidance will be interpreted too broadly leading to cases of unintended diversion—that is, using 340B drugs for individuals who HRSA did not intend as eligible patients, but who may not be clearly prohibited in the guidance. . . . The agency itself has recognized the need to further specify the definition of a 340B patient to ensure that it is interpreted correctly." GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* at 22 (Sept. 2011) ("2011 GAO Report").[18]

66. Publicly-available evidence confirms that this system with its perverse incentives has led to widespread abuses of the 340B program. As detailed in a GAO report, HRSA has

[17] *Available at* https://sec.report/Document/0000064803-22-000008/cvs-20211231.htm.

[18] *Available at* https://www.gao.gov/assets/gao-11-836.pdf.

identified hundreds of instances of diversion. 2018 GAO Report at 37; *see also* 2011 GAO Report at 28 ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for diversion that HRSA uncovered through audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44; *see also id.* ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices.").

67. HRSA is aware that contract pharmacy participation in the 340B program generates a large revenue stream for national for-profit chain pharmacies that the 340B statute was not enacted to provide. For example, in 2017, the Director of HRSA's Office of Pharmacy Affairs testified that contract pharmacy profiteering from their arrangements with covered entities was "a business matter between the parties and their contract." *Examining HRSA's Oversight of the 340B Drug Pricing Program; Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 115 Cong. 79 (July 18, 2017) (testimony of Capt. Krista M. Pedley, Director, Off. of Pharmacy Affairs, HRSA). She noted that HRSA does not prohibit covered entities from sharing with contract pharmacies the revenue that results from the financial spread between the heavily discounted 340B prices that covered entities pay to the manufacturer and the full, undiscounted reimbursements that the covered entities receive from insurance companies. *Id.* In other words, that revenue now supports contract pharmacies and third-party administrators rather than covered entity services benefitting safety-net patients. *Id.*

68. HRSA also knows that contract pharmacy arrangements create a substantial risk of (1) statutorily-prohibited transfers of 340B-priced drugs to non-340B patients and (2) duplicate discounts in which manufacturers are unlawfully forced into paying twice the discount that is set

by statute. *See* 75 Fed. Reg. at 10,274 (commenter noting that the 2010 guidance "d[id] not adequately describe safeguards that will combat drug diversion and duplicate discounts"). For example, HRSA previously advised covered entities to implement multiple audit and other programs to police their contract pharmacy arrangements and halt diversion and other abuses, but as HHS's Inspector General reported in 2014, "most covered entities [it studied] do not conduct all the oversight activities" HRSA recommends. *See* 2014 OIG Report at 2. The upshot is that, as the GAO concluded, HRSA "does not know the scope of the assessments [conducted by covered entities] and whether they are effective at identifying the full extent of non-compliance." 2018 GAO Report at GAO Highlights. "Given these weaknesses," the GAO concluded, "HRSA does not have a reasonable assurance that covered entities adequately identified and addressed non-compliance with 340B Program requirements." *Id.*

69. Moreover, although covered entities and contract pharmacies are supposed to implement plans to ensure 340B compliance, HRSA reviews these plans only if it conducts an audit, and HRSA typically audits only around 1.5% of covered entities. *Opportunities to Improve the 340B Pricing Program: Hearing Before the H. Subcomm. on Health of the Comm. on Energy and Commerce*, 115th Cong. 31–32 ("July 11, 2018 H. Subcomm. Hearing") (testimony of Debra Draper, Director, Health Care Team, GAO). As a GAO witness summarized, HRSA has left the "method of ensuring compliance . . . up to the covered entities." *Id.* at 43.

70. HRSA has disclaimed legal authority to regulate arrangements between contract pharmacies and covered entities—while simultaneously asserting that manufacturers somehow are obligated by statute to provide discounted 340B covered outpatient drugs to contract pharmacies. *Id.* at 40 ("The other issue is that HRSA doesn't have legal authority over these arrangements.

They discuss it as a private business matter between the covered entity and contract pharmacies and third-party administrators.").

71. In responding to GAO concerns about 340B program abuses relating to contract pharmacies, HRSA asserted that "[w]hile HHS appreciates the recommendations to issue guidance, we would face challenges with issuing guidance on 340B policy matters in cases where our enforcement authority is quite limited. HHS notes that HRSA currently lacks explicit general regulatory authority in the 340B statute to issue regulations on most aspects of the 340B Program." 2018 GAO Report at 69; *see also Novartis*, 2021 WL 5161783, at *8 ("HRSA lacks the authority to issue a legislative rule.").

72. Likewise, in the audits conducted by HRSA in fiscal year 2019, HRSA officials reported to GAO that there were instances where HRSA "did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use." GAO, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 15-16 (Dec. 2020) ("Drug Pricing Program").[19]

73. Similarly, in July 2020, HRSA took the position that "its enforcement powers were limited and that it lacked authority to 'compel[ ]' manufacturers 'to provide 340B discounts on drugs dispensed by contract pharmacies.'" *Eli Lilly*, 2021 WL 5039566, at *13 (quoting Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020) (attached as Exhibit C)). In an email to covered entities on July 8, 2020, HRSA Communications Director Martin Kramer stated that although the agency "strongly

[19] *Available at* https://www.gao.gov/assets/gao-21-107.pdf.

encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements," "HRSA's current authority to enforce certain 340B policies . . . is limited" because the agency lacked "comprehensive regulatory authority" "to develop enforceable policy that ensures clarity in program requirements." *Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806-YGR, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email).

74. HRSA has not "issued guidance on how covered entities should prevent duplicate discounts in Medicaid managed care," and the agency "has indicated that it is not pursuing new guidance." GAO, *340B Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 at 30 (Jan. 2020).[20] Because there is no guidance in place, HRSA effectively does not require covered entities to address identified instances of duplicate discounts, which the GAO considered "contrary to federal law." *See id.* at 26.

75. HRSA's lack of oversight of contract pharmacy arrangements is important for multiple reasons. *First*, it underscores the flaws in HRSA's attempt to read the statute to require manufacturers to provide discount drugs to contract pharmacies. There is no plausible basis to interpret the statute to mandate that manufacturers provide 340B discounted drugs to contract pharmacies, yet simultaneously infer that there is no authority for HRSA to engage in meaningful oversight of those pharmacies. Indeed, as just discussed, HRSA expressly declined to "issue eligibility findings" based on "a failure to oversee 340B Program compliance at contract pharmacies" on the grounds that "the 340B statute does not address contract pharmacy use." GAO, *Drug Pricing Program*, *supra*, at 15–16. If the statute does not *permit* HRSA to oversee contract

[20] *Available at* https://www.gao.gov/assets/gao-20-212.pdf

pharmacies' participation in the 340B program, then clearly it does not *require* manufacturers to provide 340B-priced drugs to contract pharmacies.

76. *Second*, the fact that HRSA does not police the detailed contractual relationships between covered entities, third-party administrators, and contract pharmacies confirms that the agency is not aware of whether those arrangements even constitute the type of principal-agent fiduciary agreements that the agency's Chief Legal Officer opined is required to trigger a manufacturer obligation to provide 340B discounted drugs to contract pharmacies. *See* Advisory Opinion 20-06 On Contract Pharmacies Under the 340B Program at 1 (Dec. 30, 2020) ("Advisory Opinion") ("[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 drugs to those covered pharmacies . . . ." (emphasis added)).

77. Even where HRSA audits covered entities and discovers violations, HRSA does "not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing an audit." July 11, 2018 H. Subcomm. Hearing at 54 (statement of Rep. H. Morgan Griffith). In the limited cases where HRSA conducted re-audits of covered entities that had compliance issues, HRSA found repeated instances of noncompliance. *Id.* at 55 (GAO witness testifying that HRSA should require "more rigorous information . . . from the covered entities as to what they've done"). To Amgen's knowledge, HRSA has never directly audited any third-party administrator or contract pharmacy to address compliance concerns under HRSA's contract pharmacy policies. *See* 42 U.S.C. § 256b(a)(5)(C).

D. HRSA's 2020 Advisory Opinion

78. On December 30, 2020, HHS's General Counsel issued an Advisory Opinion stating for the first time that drug manufacturers are "*obligated*" to provide 340B discounted drugs

to an *unlimited* number of contract pharmacies, if the contract pharmacies are "acting as agents of a covered entity." Advisory Opinion at 1; *AstraZeneca I*, 543 F. Supp. 3d at 55–56 ("The [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies."). The Advisory Opinion did not point to any evidentiary basis for concluding that any contract pharmacy acts as an agent of a covered entity, much less that all 27,000 contract pharmacies currently receiving 340B discounts do so. To Amgen's knowledge, HRSA has never attempted to make such findings, nor has the agency provided any mechanism for drug manufacturers to evaluate in advance whether any contract pharmacy is in fact the agent of a covered entity.

79. Despite HRSA's prior statements that Section 340B was silent on the question of contract pharmacies, the Advisory Opinion asserted that the statute unambiguously requires manufacturers to accede to contract pharmacy arrangements because the statute requires manufacturers to "offer" covered 340B drugs at or below the ceiling price for "purchase by" covered entities. Advisory Opinion at 2; *see also AstraZeneca II*, 2022 WL 484587 at *7 (D. Del. Feb. 16, 2022) ("[HRSA's] position has not been consistent over the past 25 years."). The Advisory Opinion claimed that a covered entity purchases and holds title to the 340B drugs even when they are delivered to a different party, such as a contract pharmacy, for inclusion in an undifferentiated inventory of products that is dispensed to customers without regard to whether they are patients of the covered entity. *See id.* at 3. According to the Advisory Opinion, covered entities take title regardless of whether the delivery location is "the lunar surface, low-earth orbit, or a neighborhood pharmacy." *Id.*

80. Among other flaws, the Advisory Opinion relied upon two erroneous assumptions: (1) contract pharmacies or other third parties are in fact agents of covered entities and (2) covered

entities retain title at all times to drugs purchased at the 340B price. Even as it expressly endorsed the replenishment model that is widely used by contract pharmacies, *id.* at 6 n.6, the Advisory Opinion failed to explain how contract pharmacies could retain title to drugs purchased at the 340B price when such drugs are not segregated from the general inventory.

81. The Advisory Opinion's position that the statute precludes manufacturers from attaching any conditions to their offers of 340B-priced drugs was also inconsistent with HRSA's historic acknowledgment that manufacturers may include reasonable terms in connection with such offers. Guidance HRSA issued in 1994, for example, made clear that in contracts with covered entities, manufacturers could include "provisions that address customary business practice, request standard information, or include other appropriate contract provisions." *Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines*, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994). HRSA has also endorsed manufacturers' ability to use alternate allocation procedures that involve "restricted distribution" when there is a limited supply of the drug. *See 340B Drug Pricing Program Notice: Clarification of Non-Discrimination Policy*, at 1 (May 23, 2012).[21] Indeed, HRSA itself publishes these restricted distribution plans on its website. *See id.* at 2.

E. HRSA's Violation Letters to Manufacturers

82. On May 17, 2021, HRSA issued substantively identical violation letters to United Therapeutics, Sanofi, Novo Nordisk, Novartis, Eli Lilly, and AstraZeneca. A few months later, on October 4, 2021, the agency issued another substantively identical violation letter to Boehringer Ingelheim. Each letter claimed that the relevant manufacturer was in "direct violation of the 340B

[21] *Available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/non-discrimination-05-23-2012.pdf.

statute" because its policy did not provide discounted drugs to an unlimited number of contract pharmacies. In each letter, HRSA took the position that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." And HRSA demanded that the relevant manufacturer "must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." HRSA further demanded that manufacturers withdraw their policies and reimburse covered entities for alleged overcharges, or otherwise face civil monetary penalties.

83. The violation letters sent by HRSA to pharmaceutical manufacturers all adopted the same legally flawed interpretation of the 340B statute that was advanced by the 2020 Advisory Opinion. *See AstraZeneca II*, 2022 WL 484587 at *4 (D. Del. Feb. 16, 2022) ("The Court agrees . . . that the Violation Letter is based on the same legally flawed reading of the 340B statute that plagued the Opinion.") (internal quotation marks omitted).

F. Litigation Challenging the Advisory Opinion and Violation Letters

84. Various suits were brought by pharmaceutical manufacturers against HRSA and HHS, challenging their interpretation of the 340B statute and response to manufacturer policies, including the violation letters. *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. filed Jan. 12, 2021); *AstraZeneca Pharms. v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. filed Jan. 12, 2021); *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-00634-FLW-LHG (D.N.J. filed Jan. 12, 2021); *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-00806-FLW-LHG (D.N.J. filed Jan. 15, 2021); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479-DLF (D.D.C. filed May 31, 2021); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686-DLF (D.D.C. filed June 23, 2021);

Boehringer Ingelheim Pharms., Inc. v. Becerra, No. 1:21-cv-2826-DLF (D.D.C. filed Oct. 25, 2021).

85. On June 16, 2021, the first federal district court to substantively address claims regarding the Advisory Opinion found that the Advisory Opinion was "legally flawed" because it wrongly concluded that the contract pharmacy framework was mandated by the statute. *AstraZeneca I*, 543 F. Supp. 3d at 59.

86. Two days later, on June 18, 2021, HHS withdrew the Advisory Opinion, purportedly "in the interest of avoiding confusion and unnecessary litigation." *See* Notice of Withdrawal from Daniel J. Barry, Acting Gen. Counsel, HHS at 2 (June 18, 2021) ("Advisory Opinion Withdrawal"). [22]

87. Despite withdrawing the Advisory Opinion, HRSA persisted in its interpretation of the statute. For example, HRSA continued to issue violation letters to manufacturers, *see supra* ¶¶ 82–83, and continued to defend the validity of those letters in court—even though they rested on the same flawed legal reasoning that grounded the Advisory Opinion.

88. Between October 2021 and February 2022, four federal district courts issued opinions addressing claims related to the violation letters. All four district courts vacated the challenged letters and remanded to HRSA for further proceedings.

89. Two district courts vacated the challenged violation letters because they were based on an incorrect reading of the 340B statute. *See Novartis*, 2021 WL 5161783; *AstraZeneca II*, 2022 WL 484587. Both district courts held that the 340B statute is silent regarding any manufacturer obligation to contract pharmacies under the 340B program, and that the statute does

[22] Notice, Ex. 1, at 2, *Eli Lilly v. Beccera*, ECF No. 119-1.

not expressly require manufacturers to provide drugs at the 340B price to contract pharmacies. *See Novartis*, 2021 WL 5161783, at *9; *AstraZeneca II*, 2022 WL 484587, at *6.

90. A third district court vacated the challenged violation letter in light of HRSA's inconsistent positions regarding its authority to enforce the 340B statute. *See Eli Lilly*, 2021 WL 5039566, at *22. The district court recognized that the 340B statute was "silen[t] both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers," but nevertheless determined that HRSA could require manufacturers to provide 340B-priced drugs to contract pharmacies. *Id.* at *14–20.

91. A fourth district court partially vacated the challenged violation letters for HRSA to assess "the number of permissible contract pharmacy arrangements" that manufacturers could be required to provide with 340B-discounted drugs. *Sanofi-Aventis*, 2021 WL 5150464, at *53. The district court concluded that HRSA could require manufacturers to provide 340B discounted drugs to at least one contract pharmacy per covered entity, but did not determine whether the statute required manufacturers to provide them to more than one contract pharmacy. *See id.* at *43–45, *48.

G. Amgen's Policy

92. On December 1, 2021—after multiple district courts had ruled that HRSA's interpretations of the 340B statute were flawed and inconsistent, and that the 340B statute was silent as to any manufacturer obligation to provide 340B-priced drugs to contract pharmacies—Amgen announced that, beginning January 3, 2022, it would implement a new policy with regard to contract pharmacies. *See* Exhibit D.

93. Amgen explained that it would provide certain self-administered, pharmacy benefit Amgen products purchased at the 340B price—specifically Repatha®, Enbrel®, Otezla®, and

Aimovig®—only to locations registered as 340B covered entities or child sites. Amgen continues, however, as a matter of policy, to offer drugs at the 340B discounted price in certain circumstances. Amgen does so based on the company's commitment to the healthcare safety net and the mission of the 340B program.

94. First, any 340B covered entity that does not have an in-house pharmacy is allowed to designate a single contact pharmacy location to receive products purchased at the 340B price.

95. Second, covered entities who are federal grantees—i.e., those covered entities that are specifically identified in the 340B statute at 42 U.S.C. § 256b(a)(4)(A)–(K)—remain eligible to place orders of 340B-priced drugs to be dispensed through contract pharmacies.

96. Third, contract pharmacies that are wholly owned by or under common ownership with a covered entity remain eligible to receive orders of 340B-priced drugs purchased by the affiliated covered entity.

97. Fourth, covered entities that submit claims data for their contract pharmacies through the 340B ESP™ platform remain eligible to place orders of 340B-priced drugs to be dispensed through contract pharmacies. *See also* 42 U.S.C. § 256b(a)(5)(C) (requiring covered entities to permit manufacturers to audit "the records of the entity that directly pertain to the

entity's compliance with" the statutory prohibitions on duplicate discounts, reselling, and transfers).

98. Amgen's policy is more generous than the 340B statute requires, and more permissive of contract pharmacy arrangements than HRSA's own pre-2010 guidance. *See supra* ¶¶ 42–48. Amgen implemented its policy on January 3, 2022.

H. HRSA's February 2022 Letter and Amgen's Response

99. HRSA sent a letter to Amgen on February 23, 2022, regarding Amgen's policy. *See* Exhibit E.

100. Despite HRSA's withdrawal of the Advisory Opinion and two federal court rulings declaring HRSA's interpretation of the 340B statute invalid, HRSA asserted in the letter that "[t]he 340B statute requires manufacturers to honor purchases by covered entities regardless of the dispensing mechanism." *Id.* at 1.

101. HRSA explained in the letter that it had "reviewed the information submitted in [Amgen's] November 30, 2021, correspondence," and "request[ed] responses" to a series of ten questions about Amgen's 340B policy. *Id.*

102. HRSA noted that it would "continue[] to review Amgen's policy, including the responses to the questions" listed in the letter. *Id.* at 2.

103. HRSA requested a response to the letter by March 9, 2022.

104. Amgen responded to HRSA's letter on March 9, 2022. *See* Exhibit F.

105. Amgen observed that the company was in compliance with its obligations under the 340B statute. In support, Amgen pointed to multiple federal court rulings and the text of the 340B statute. *See id.* at 1.

106. Amgen's letter included responses to HRSA's questions regarding Amgen's policy.

107. Amgen explained that it "remain[ed] committed to the 340B program" and that its policy would "work to ensure the benefits of the 340B program." *Id.* at 6. Amgen further noted that it would "work with the administration, policymakers, and the biopharmaceutical industry to ensure the program is executed in a way that benefits covered entities and the safety net they provide." *Id.*

I. Further Correspondence

108. On May 31, 2022, HRSA sent an additional letter to Amgen requesting that Amgen "provide a description of Amgen's currently implemented or proposed policy," including "any time limitations on submissions of claims, along with any additional restrictions or changes made to Amgen's contract pharmacy policy since Amgen's initial notification to HRSA on November 30, 2021, and when these changes were or will be implemented." *See* Exhibit G at 1.

109. On June 14, 2022, Amgen responded with a letter to HRSA. *See* Exhibit H. Amgen explained that it had "not changed the terms of its policy since it was initially announced and implemented," and that "[i]n the course of implementing its policy, Amgen ha[d] addressed questions and offered clarifications by updating its Frequently Asked Questions ("FAQs") document, which is publicly available." *Id.* at 1–2.

J. Additional Violation Letters Issued to Other Manufacturers

110. On May 6, 2022, HRSA issued a violation letter to Merck that was substantively identical to the violation letters the agency had previously issued to other manufacturers, and which have been consistently set aside by federal courts.

111. On July 8, 2022, Merck filed a lawsuit against HRSA in this Court, challenging the May 6 letter and its erroneous interpretation of the 340B statute. *See Merck Sharp & Dohme v.*

Dep't Health & Human Servs., No. 1:22-cv-01986-DLF (D.D.C. filed July 8, 2022). That case is currently stayed pending the outcome of the *Novartis* appeal.

112. On June 27, 2022, HRSA issued a violation letter to UCB that was also substantively identical to the violation letters the agency had previously issued to other manufacturers, and which have been consistently set aside by federal courts.

113. On September 23, 2022, UCB filed a lawsuit against HRSA in this Court, challenging the June 27 letter and its erroneous interpretation of the 340B statute. *See UCB v. Becerra*, No. 1:22-cv-02893-DLF (D.D.C. filed Sept. 23, 2022). That case is currently stayed pending the outcome of the *Novartis* appeal.

114. By June 2022, HRSA had thus issued substantively identical violation letters to the following nine manufacturers: AstraZeneca, Eli Lilly, Novartis, Novo Nordisk, Sanofi-Aventis, United Therapeutics, Boehringer Ingelheim, Merck, and UCB.

K. The Violation Letter Issued to Amgen

115. On October 17, 2022, HRSA issued a Violation Letter to Amgen that was also substantively identical to the violation letters the agency had previously issued to other manufacturers, and which have been consistently set aside by federal courts.

116. Specifically, the Violation Letter claims that Amgen is in "direct violation of the 340B statute" because its policy does not provide discounted drugs to an unlimited number of contract pharmacies. Exhibit A at 1. In the letter, HRSA takes the position that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.* And HRSA demands that Amgen "must immediately begin offering its covered outpatient drugs

at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy." *Id.* at 2.

117. The Violation Letter thus rests on the same flawed analysis that this Court and other federal courts have rejected. *See, e.g.*, *Novartis*, 2021 WL 5161783; *AstraZeneca II*, 2022 WL 484587. The Violation Letter does not even attempt to address those federal court decisions, even though Amgen specifically brought that legal authority to HRSA's attention. *See* Exhibit F at 1 (Mar. 9, 2022 Letter from Amgen to HRSA) (citing decisions and emphasizing that "various federal courts" had "recently ruled[] that [the 340B] statute does not expressly require manufacturers to provide discounts to contract pharmacies").

118. Further, although the Violation Letter purports to address Amgen's policy, it does not acknowledge any of the specific features of that policy, let alone explain why Amgen's policy in particular does not comply with the 340B statute. For example, the Violation Letter does not mention that Amgen's policy includes a claims data option, which allows a covered entity to obtain 340B pricing through an unlimited number of contract pharmacy arrangements as long as the covered entity submits underlying claims data. The Violation Letter's one-size-fits-all approach is especially incongruous because—in correspondence with HRSA and at HRSA's request—Amgen provided detailed and timely information about the specific features of its policy. In other words, in the process of issuing yet another form letter, HRSA appears to have ignored information at its disposal regarding the specific aspects of Amgen's policy.

119. On November 17, 2022, Amgen responded to HRSA's Violation Letter. *See* Exhibit I. Amgen pointed out that HRSA's Violation Letter "rests on a fundamentally flawed interpretation of the 340B statute." *Id.* at 1. The Violation Letter was "substantively identical to letters HRSA ha[d] sent to other pharmaceutical companies," and those letters had been

"consistently invalidated by federal courts." *Id.* at 1. Amgen also explained that "as currently structured by HRSA, the audit and ADR process is inadequate for addressing the abuses of contract pharmacies." *Id.* at 4. Amgen emphasized that HRSA has no lawful basis to impose civil monetary penalties, which can be issued only for "knowing[] and intentional[]" overcharges. *Id.* at 5. Amgen's policy had not resulted in any overcharges, let alone "knowing[] and intentional[]" ones. *Id.* HRSA did not reply to Amgen's letter.

HRSA'S LETTER CONSTITUTES FINAL AGENCY ACTION

120. The Violation Letter constitutes final agency action reviewable under the APA. *See, e.g.*, *Eli Lilly*, 2021 WL 5039566, at *15; *Sanofi-Aventis*, 2021 WL 5150464 at *33.

121. *First*, the Violation Letter is not "of a merely tentative or interlocutory nature," but rather "mark[s] the consummation of the agency's decisionmaking process." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 597 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 117 (1997)). HRSA's first letter to Amgen—sent in February 2022—communicated that HRSA was "continu[ing] to review Amgen's policy." Exhibit E at 2. By contrast, the Violation Letter states that HRSA "has completed its review" of Amgen's policy. Violation Letter at 1. HRSA explains that it has reached its conclusions "[a]fter review of this policy and an analysis of the complaints HRSA has received from covered entities." *Id.* Nothing in the Violation Letter suggests that HRSA's determination is preliminary, tentative, or subject to further review.

122. *Second*, the Violation Letter is final agency action because it "determine[s]" Amgen's "obligations" under the 340B statute, and that determination carries "legal consequences." *Hawkes*, 578 U.S. at 597 (quoting *Bennett*, 520 U.S. at 117). HRSA asserts that it has conclusively "determined that Amgen's actions have resulted in overcharges and are in direct violation of the 340B statute." Violation Letter at 1. The agency has thus taken the final position

that the statute requires 340B discounted drugs be provided to an unlimited number of contract pharmacies.

123. *Third*, the Violation Letter claims that Amgen's "[c]ontinued failure to provide the 340B price to covered entities using contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in [civil monetary penalties]." Violation Letter at 2. The Violation Letter thus creates an "increased risk of prosecution and penalties," further confirmation that the Letter constitutes final agency action. *Ipsen Biopharms. v. Azar*, 943 F.3d 953, 957 (D.C. Cir. 2019).

124. *Fourth*, HRSA has conceded that other, substantively identical violation letters are reviewable as final agency action under the APA. *See, e.g.*, Gov't Mem. Supporting Summ. J. Mot. at 25–26, 50, *Novartis*, ECF No. 13-1 (repeatedly characterizing challenged violation letter as "final agency action"). Because the APA's final agency action requirement is not jurisdictional, *see, e.g.*, *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 184 (D.C. Cir. 2006), HRSA has "thus waived any argument that the [Violation Letter] was not a final agency action." Suppl. Brief for the Fed. Defs. at 17–18, *Eli Lilly & Co. v. Becerra* (7th Cir. Nos. 21-3128, 21-3405), ECF No. 76,.

125. *Finally*, Amgen does not have an adequate alternative for seeking review of HRSA's interpretation of the statute, as set forth in the Violation Letter. The 340B statute does not contain a provision for review of a letter of this type, nor does the Violation Letter itself indicate that it may be appealed or otherwise formally contested administratively. In the absence of review by this court, Amgen will be forced to either (1) run the risk of civil monetary penalties by continuing to implement its policy, or (2) halt implementation of its policy, which would require it to provide 340B discounted drugs to an unlimited number of contract pharmacies in conflict with the requirements of the statute.

CLAIMS FOR RELIEF

COUNT I: Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C)
(Agency Action Taken In Excess of Statutory Jurisdiction or Authority)

126. Plaintiff incorporates by reference paragraphs 1–125 as if fully set forth herein.

127. The APA provides that the Court "shall . . . hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," 5 U.S.C. § 706(2)(C).

128. HHS and HRSA are "agencies" under the APA, 5 U.S.C. § 551(1), and the Violation Letter is a final, reviewable "agency action for which there is no other adequate remedy in a court," 5 U.S.C. §§ 551(13), 704.

129. The 340B statute does not require manufacturers to provide drugs at the 340B price to an unlimited number of contract pharmacies. Instead, the statute requires manufacturers to offer drugs at discounted 340B prices only to "each covered entity." 42 U.S.C. § 256b(a)(1). The statute further specifies that drugs must be "purchased by a covered entity" to be eligible for a 340B discount, *id.*, and it expressly prohibits covered entities from transferring drugs purchased at the 340B discount to any person—including for-profit commercial entities—that is not a patient of a covered entity, *id.* § 256b(a)(5)(B).

130. Congress defined "covered entities" to consist of 15 types of entities that are specifically identified in the statute. Contract pharmacies are not within this statutory definition of "covered entities." *See AstraZeneca I*, 543 F. Supp. 3d at 60 ("It is hard to believe that Congress enumerated 15 types of covered entities with a high degree of precision and intended to include contract pharmacies as a 16th option by implication.").

131. Congress knew how to include entities with a contractual relationship with a covered entity within the scheme of the statute if it so desired. In earlier versions of the 340B bill, Congress would have covered drugs "purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with" a covered entity. H.R. 5193 (as amended by the Senate, Oct. 1, 1992). Congress did not enact that provision.

132. Moreover, other parts of the 340B statute refer to different types of representatives of covered entities, and another part of the law that originally established the 340B program expressly referenced "a commercial entity operating under contract." 38 U.S.C. § 8126(h)(3). Thus, "[i]f Congress intended to include agents or contract arrangements within the definition of 'covered entity,' it evidently knew how to do so," but the statute as enacted does not. *AstraZeneca I*, 543 F. Supp. 3d at 60.

133. As this Court has held, "[t]he plain language, purpose, and structure of the [340B] statute do not prohibit the manufacturers from imposing *any* conditions on their offers of 340B-priced drugs to covered entities." *Novartis*, 2021 WL 5161783, at *9. Rather, the 340B statute "is silent as to permissible drug distribution systems . . . . [and] also silent as to what distribution requests *manufacturers* must accept." *Id.* at *6 (internal quotation marks omitted); *see also AstraZeneca I*, 543 F. Supp. 3d at 59 ("The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs.").

134. Yet HRSA has concluded that Amgen's policy constitutes a "direct violation of the 340B statute" because the policy places reasonable limits on the extent to which Amgen provides 340-priced drugs to contract pharmacies. Violation Letter at 1. That interpretation plainly contradicts the statute, which is silent on the contract pharmacy question. *Cf. Novartis*, 2021 WL

5161783, at *9 (nothing in statute prevents manufacturers from establishing "*any* conditions on their [340B] offers").

135. The Violation Letter is thus contrary to the 340B statute because it is based on the erroneous conclusion that the statute prohibits a manufacturer such as Amgen from placing any reasonable limits on its provision of 340B-priced drugs to contract pharmacies.

136. Nor may HRSA seek to impose a requirement that is absent in the statute itself. As this Court has held, HRSA has no "gap filling" authority to impose requirements beyond those outlined in the 340B statute. *See Novartis*, 2021 WL 5161783, at *8 ("[T]he agency's shifting guidance illustrates that it is attempting to fill a gap in the statute, and this the agency cannot do."). Indeed, Congress has expressly declined to provide HRSA with broad rulemaking authority in the 340B context, instead cabining HRSA's rulemaking powers to specific substantive areas—none of which is relevant here. *See PhRMA*, 43 F. Supp. 3d at 41. And HRSA itself has recognized that the agency has no authority to enforce guidance absent a clear violation of the 340B statute. *See Eli Lilly*, 2021 WL 5039566, at *13.

137. For these reasons, the Violation Letter is "in excess of statutory jurisdiction, authority, or limitations" and must be held unlawful and set aside. 5 U.S.C. § 706(2)(C).

COUNT II: Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)
(Arbitrary and Capricious Agency Action)

138. Plaintiff incorporates by reference paragraphs 1–137 as if fully set forth herein.

139. The APA provides that a court "shall . . . 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).

140. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection

between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

141. HRSA's Violation Letter is arbitrary and capricious for multiple reasons, including the following.

142. *First*, the Letter "is based on the 'unjustified assumption' that Congress imposed [HRSA's] interpretation as a statutory requirement" and is therefore "legally flawed." *AstraZeneca I*, 543 F. Supp. 3d at 59–62 (quoting *Am. Lung Ass*'n *v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)); *see also AstraZeneca II*, 2022 WL 484587, at *6 (violation letter was invalid because it rested on a "flawed statutory interpretation"); *Novartis*, 2021 WL 5161783, at *9 (violation letter's "legal reasoning . . . rests upon an erroneous reading of Section 340B"). The Violation Letter concludes that "Amgen's actions . . . are in *direct violation* of the 340B statute," purportedly because the statute "*requires* that manufacturers" provide 340B drugs without restriction and because manufacturers have signed PPAs obligating their compliance "with these [statutory] *requirements*." Violation Letter at 1. The Letter further contends that HRSA "has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute *requires* manufacturers to honor such purchases regardless of the dispensing mechanism." *Id.* Because it is apparent that HRSA "wrongly believes that [its] interpretation is compelled by Congress," the Letter must be vacated. *See AstraZeneca I*, 543 F. Supp. 3d at 61–62 (quoting

Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin., 471 F.3d 1350, 1354 (D.C. Cir. 2006)); *see also AstraZeneca II*, 2022 WL 484587, at *6; *Novartis*, 2021 WL 5161783, at *9.

143. *Second*, HRSA has repeatedly shifted course in its guidance regarding contract pharmacies, but none of HRSA's letters to Amgen even acknowledge those past changes. HRSA's 1996 guidance interpreted the statute as authorizing only a *single* contract pharmacy per covered entity. HRSA's 2010 guidance concluded that the statute requires manufacturers to provide 340B discounted drugs to multiple contract pharmacies, but was directed to covered entities. *AstraZeneca I*, 543 F. Supp. 3d at 55. The December 2020 Advisory Opinion was "the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies." *AstraZeneca I*, 543 F. Supp. 3d at 55–56. Further, whereas the Advisory Opinion claimed that contract pharmacies are entitled to 340B discounted drugs insofar as they act as agents for covered entities, *see* Advisory Opinion at 1, that justification is nowhere present in the Violation Letter to Amgen (or any of the other form violation letters) and was seemingly abandoned without explanation or comment. Moreover, HRSA *withdrew* the December 2020 Advisory Opinion on June 18, 2021, purportedly "in the interest of avoiding confusion and unnecessary litigation," yet continued to threaten enforcement actions based substantially on the same contentions expressed in that Advisory Opinion. *See also Novartis.*, 2021 WL 5161783, at *8 (discussing HRSA's "shifting guidance" on contract pharmacies).

144. The Violation Letter fails even to mention this history of HRSA's shifting positions. By definition, that deficiency renders the Violation Letter arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (agency must "at least 'display awareness

that it is changing position' and 'show that there are good reasons for the new policy'" (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

145. *Third*, the Violation Letter does not explain why HRSA's interpretation is permissible under the statute. HRSA's unclear reference to prior HRSA statements is wholly inadequate, given the multitude of conflicting past positions HRSA has taken on this issue. Furthermore, the Violation Letter contains a conclusory analysis of the statute that does not address the contrary arguments based on the statute's text and structure and the background against which the statute was enacted. Because HRSA's Letter lacks adequate explanation, it is arbitrary and capricious. *See CSI Aviation Servs. v. DOT*, 637 F.3d 408, 414–416 (D.C. Cir. 2011) (agency violation letter, including its interpretation of the statute, must be adequately explained, such that a court can "evaluate the agency's rationale at the time of decision" (citation omitted)).

146. *Fourth*, HRSA has not provided any evidentiary support for its factual assertions. The Violation Letter is nothing more than a form letter: it repeats exactly the same words that HRSA has used in prior violation letters sent to other manufacturers—letters that have been uniformly vacated by federal courts. The Violation Letter purports to "determin[e]" that that Amgen's "actions have resulted in overcharges," but identifies no factual basis for that conclusion. Further, because the Violation Letter is a form letter, it does not address any specific aspect of Amgen's policy—such as the fact that any covered entity may obtain 340B pricing through an unlimited number of contract pharmacies as long as the covered entity provides claims data. HRSA's one-size-fits-all approach—and its willful blindness to the relevant legal and factual circumstances—render the Violation Letter arbitrary and capricious.

147. *Fifth*, HRSA has failed to account for multiple important aspects of the 340B contract pharmacy problem, including the substantial growth of contract pharmacies in recent

years; the evidence that such contract pharmacies are facilitating unlawful transfers to non-340B patients and not providing benefits to underserved patients but rather are reaping windfall financial profits through the 340B program; the serious flaws in the audit and ADR processes that render them insufficient to address such issues; and various rulings from federal courts holding that HRSA's legal theories are invalid and its actions impermissible.

COUNT III: Violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(D)
(Agency Action Taken Without Observance of Procedure Required by Law)

148. Plaintiff incorporates by reference paragraphs 1–147 as if fully set forth herein.

149. The APA provides that the Court "shall . . . hold unlawful and set aside agency action" taken "without observance of procedure required by law," 5 U.S.C. § 706(2)(D), or that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C).

150. HHS and HRSA are "agencies" under the APA, 5 U.S.C. § 551(1), and the Letters constitute final, reviewable "agency action for which there is no other adequate remedy in a court," 5 U.S.C. §§ 551(13), 704.

151. HRSA has adopted a new interpretation of the statute that requires manufacturers to provide 340B discounted drugs to an unlimited number of contract pharmacies.

152. HRSA is treating that interpretation as binding on manufacturers, and has threatened manufacturers that do not abide by HRSA's interpretation with civil monetary penalties.

153. HRSA's new interpretation thus amounts to a legislative rule under the APA: it is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," 5 U.S.C. § 551(4), and the purportedly binding nature of that interpretation renders the rule legislative, not interpretive, in nature. *See, e.g.*, *Nat'l Council for*

Adoption v. Blinken, 4 F.4th 106, 114 (D.C. Cir. 2021) (agency guidance was legislative rule where it created new legal obligations and "expose[d] [parties] to enforcement actions").

154. HRSA did not provide for notice and comment prior to announcing its new interpretation, and thus violated the APA's notice-and-comment requirement. 5 U.S.C. § 553.

155. HRSA also lacks statutory authority to impose a legislative rule of this type. *See PhRMA*, 43 F. Supp. 3d at 41.

COUNT IV: Unconstitutional and Unauthorized Taking of Private Property Without Just Compensation

156. Plaintiff incorporates by reference paragraphs 1–155 as if fully set forth herein.

157. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, . . . found to be . . . contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

158. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

159. The Takings Clause applies to personal property. *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015).

160. HRSA's actions amount to a confiscatory taking: it forces Amgen to transfer its property—the drugs it manufactures—to contract pharmacies, at significantly under-market prices, without just compensation.

161. That is not only a taking, but a taking that is unauthorized both by the U.S. Constitution and by statute.

162. As a constitutional matter, "it has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). Therefore,

the Constitution prohibits the government from taking Amgen's personal property for the sole purpose of transferring it to other private parties, even if just compensation is paid.

163. As a statutory matter, HRSA has no authority to effect a taking of this nature. No statute gives HRSA authority to require Amgen to transfer its personal property to other private parties.

164. Moreover, HRSA's actions cannot be justified by virtue of Amgen's "voluntary" participation in the 340B program. As noted above, Amgen's participation is hardly voluntary in light of the reality that manufacturers must agree to participate in the 340B program regarding *all* of their drugs in order for *any of* their drugs to be eligible under Medicare and Medicaid. Moreover, the unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to participate in a government program. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013)

165. HRSA's actions amount to an unconstitutional and coercive condition, by forcing Amgen to either provide its property to contract pharmacies at a significantly below-market price, or alternatively be precluded from participating in Medicare and Medicaid, which represents a massive market for Amgen's products.

166. At a minimum, the serious constitutional concerns raised by HRSA's actions require a narrow construction of the statute, and thus weigh heavily against HRSA's latest interpretation that requires Amgen to provide certain products to contract pharmacies at the 340B discount price.

COUNT V: Violation of U.S. Constitution, Art. I, § 1
(Unconstitutional Delegation of Legislative Power; Major Questions Doctrine)

167. Plaintiff incorporates by reference paragraphs 1–166 as if fully set forth herein.

168. Under Article I, § 1 of the U.S. Constitution, "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." Under Article I, § 1, only Congress may engage in lawmaking.

169. "Congress is not permitted to abdicate or to transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529–30 (1935).

170. The nondelegation doctrine is grounded in the principle of preserving the separation of powers. It prohibits Congress from assigning its legislative power to another branch of government.

171. While Congress may delegate power to executive agencies, the statutory delegation must include an "intelligible principle" to guide the exercise of the relevant agency's delegated authority. *See, e.g., Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)).

172. Congress expressly declined to provide HRSA with broad rulemaking authority with regard to the 340B program, and confined agency rulemaking powers to specific aspects of the statute, none of which authorizes expansion of the statutorily identified covered entities. *See PhRMA*, 43 F. Supp. 3d at 41. The 340B statute does not authorize HRSA to alter the statute's text through enforcement action or sub-regulatory guidance, nor has Congress delegated "gap-filling" authority to HRSA. *See generally Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995).

173. If HRSA were understood to have such authority, that interpretation would violate the nondelegation doctrine because the 340B statute lacks any "intelligible principles" that would guide the agency's policymaking decisions with respect to contract pharmacies.

174. Relatedly, because HRSA can point to no "clear congressional authorization" for the authority it seeks to exercise, its approach runs afoul of the major questions doctrine. *See West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022); *see also Nat'l Fed'n of Indep. Bus. v. Dep't of Labor*, 142 S. Ct. 661, 668–69 (2022) (Gorsuch, J., concurring) (noting that nondelegation and major questions doctrines are "closely related" in that "[b]oth are designed to protect the separation of powers and ensure that any new laws governing the lives of Americans are subject to the robust democratic processes the Constitution demands").

175. HRSA asserted in 2020 a previously "unheralded" authority purportedly now found in a 1992 statute to force manufacturers into an unlimited number of arrangements with contract pharmacies, which are mentioned nowhere in the statute. *See West Virginia*, 142 S. Ct. at 2610 (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). The newly discovered statutory reading has resulted in significant economic consequences, including an explosion in the size and scope of the 340B program. *See id.* at 2608 (doctrine applies in matters of "economic . . . significance" (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000))). The 340B statute does not confer the enforcement authority that HRSA "claim[s] to be lurking there" based on the agency's flawed interpretation of the statute. *Id.* at 2609.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

A. Declare that the Violation Letter is in excess of statutory authority, without observance of procedure required by law, is arbitrary, capricious, and is contrary to law on the grounds recited above;

B. Vacate the Violation Letter on the grounds recited above;

C. Declare that Amgen is not required to provide 340B discounted drugs to anyone other than a covered entity, and specifically not to contract pharmacies;

D. Declare that Amgen's policy, as set forth in its December 1, 2021 Letter, complies with Section 340B;

E. Issue permanent injunctive relief preventing Defendants from implementing or enforcing the Letter, through ADR proceedings or otherwise;

F. Issue permanent injunctive relief preventing Defendants from imposing civil monetary penalties against Amgen based on the Violation Letter or its rationale;

G. Award Plaintiff reasonable attorneys' fees and costs, plus interest accruing thereon, to the extent available under the law; and

H. Award such other relief as the Court may deem just and proper.

Dated: December 19, 2022

/s/ Beth S. Brinkmann

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