IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS U.S. LLC,
55 Corporate Drive
Bridgewater, NJ 08807

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services,
Office of the Secretary
200 Independence Avenue, SW
Washington, DC 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,
Office of the Administrator
5600 Fishers Lane
Rockville, MD 20857

Defendants.

Civil Action No. 24-3496

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi"), by and through its undersigned attorneys, alleges as follows:

INTRODUCTION

1. In *Novartis Pharmaceuticals Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024), the D.C. Circuit held that pharmaceutical manufacturers may impose conditions on their offers of discounted drugs to eligible healthcare providers (known as "covered entities") participating in the 340B Drug Pricing Program, which was established under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.

2. The D.C. Circuit's decision followed an earlier decision by the Third Circuit that rejected the government's enforcement threats against manufacturers, including Sanofi, for adopting policies to address waste and abuse in the 340B Program. The Third Circuit held that manufacturers did not need to deliver discounted drugs wherever and whenever requested by covered entities. *See Sanofi Aventis U.S. LLC v. Dep't of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023).

3. In both cases, the courts of appeals enforced a fundamental principle of administrative law: Where a statute is silent, private parties have freedom to act, and the government lacks authority to impose legal obligations—or to make enforcement threats—that go beyond the statute. This bedrock principle applies with full force to the 340B Program and limits the government's ability to take enforcement action against participating manufacturers.

4. In the wake of these decisions, Sanofi, a leading global pharmaceutical manufacturer, decided to implement a new initiative (the "Credit Model") to further address waste and abuse in the 340B Program.

5. Under the Credit Model, Sanofi will continue to offer pharmaceutical drugs to covered entities at discounted prices, as Section 340B requires. Sanofi will simply effectuate that discount in a new way for certain covered entities. Instead of reducing the upfront price of its drugs for these covered entities, Sanofi will now give those entities a direct cash credit to implement the statutory discount.

6. In addition, for certain covered entities, Sanofi will adopt a patient eligibility condition to ensure that the covered entities receive the statutory discount when they dispense 340B-priced drugs to their patients, as Section 340B permits, but not when they dispense those drugs to others—an unlawful practice known as diversion. *See* 42 U.S.C. § 256b(a)(5)(B).

7. On November 1, 2024, Sanofi informed the government agency that administers the 340B Program—the Health Resources and Services Administration ("HRSA"), which is part of the Department of Health and Human Services ("HHS")—of these planned changes in the company's business operations.

8. On December 13, 2024, after several exchanges with Sanofi, HRSA declared in a letter (the "Violation Letter") that these changes violate Section 340B for two reasons—first, because Sanofi failed to obtain the agency's prior approval; and second, because both components of the Credit Model purportedly violate Sanofi's obligations under Section 340B.

9. In addition to declaring the Credit Model illegal, HRSA threatened to expel Sanofi from federal prescription drug programs (including Medicare Part B and Medicaid)—an enormous blow for any pharmaceutical manufacturer—and to pursue draconian civil monetary penalties if Sanofi were to implement the Credit Model over the agency's objections.

10. HRSA's ban on Sanofi's Credit Model is just the latest example of the agency's ongoing refusal to enforce the 340B statute's prohibition on diverting 340B-priced drugs to persons who are not patients of the covered entity. As Sanofi alleges in a pending, related case against HHS and HRSA, HRSA has been withholding evidence of its refusal to enforce the statute. *See* Compl. ¶ 1, No. 1:24-cv-01603-DLF (D.D.C.). Had HRSA vigilantly enforced Section 340B's prohibition on diversion—instead of turning a blind eye to systemic violations that have caused the 340B Program to spiral out of control—Sanofi may not have needed to adopt its own measures to reduce the incidence of statutory violations.

11. Sanofi's planned Credit Model is fully consistent with Section 340B, and HRSA's contrary position is unlawful. Nothing in Section 340B prohibits Sanofi from implementing its Credit Model. The statute expressly contemplates that manufacturers may effectuate the discounted price through a post-purchase credit. And the statute does not prohibit manufacturers from attempting to prevent unlawful diversion. Nor does Section 340B require Sanofi to obtain the government's prior approval before implementing its business plans. But in light of the government's enforcement threats, Sanofi brings this suit to confirm its freedom to proceed.

12. This Court should vacate HRSA's determination that Sanofi's Credit Model violates Section 340B, declare that the Credit Model complies with the statute, and enjoin HRSA from taking enforcement action against Sanofi for implementing the Credit Model.

JURISDICTION AND VENUE

13. This Court has jurisdiction under 28 U.S.C. § 1331 because Sanofi's claims arise under the Administrative Procedure Act ("APA"). *See* 5 U.S.C. §§ 702, 704, 706.

14. This Court has the authority to grant declaratory relief and to vacate HRSA's Violation Letter under the Declaratory Judgment Act, the APA, and this Court's inherent equitable powers. *See* 28 U.S.C. §§ 2201, 2202; 5 U.S.C. §§ 702, 706.

15. Venue is proper in this district under 28 U.S.C. § 1391(e) and 5 U.S.C. § 703.

PARTIES

16. Plaintiff Sanofi is a global healthcare leader that produces and sells prescription medicines and other consumer health products. Sanofi participates in the 340B Program.

17. Defendant HHS is an agency of the United States government.

18. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity.

19. Defendant HRSA is an HHS agency.

20. Defendant Carole Johnson is the Administrator of HRSA and is sued in her official capacity.

STATEMENT OF FACTS

I. The 340B Program

21. Section 340B "requires drug manufacturers to sell certain drugs to covered entities at bargain prices." *Novartis*, 102 F.4th at 455. The "covered entities" eligible for discounts benefit from 340B Program participation "through insurance reimbursements that exceed the marked-down cost of the drugs." *Id.*; *see* 42 U.S.C. § 256b(a)(4).

22. Section 340B requires the Secretary of Health and Human Services to sign an agreement with manufacturers known as a Pharmaceutical Pricing Agreement. Under the Pharmaceutical Pricing Agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price," and "the amount required to be paid (*taking into account any rebate or discount,* as provided by the Secretary) to the manufacturer for covered outpatient drugs" cannot exceed the "ceiling price." 42 U.S.C. § 256b(a)(1) (emphasis added).

23. The price discounts for covered entities under Section 340B are steep. "In some instances," manufacturers must offer drugs to covered entities at a price "as low as a penny per unit." *Novartis*, 102 F.4th at 456.

24. A manufacturer that fails to comply with Section 340B can face termination of its Pharmaceutical Pricing Agreement—and with that, exclusion from

Medicare Part B and Medicaid, which together constitute "almost half the annual nationwide spending on prescription drugs." *Sanofi*, 58 F.4th at 699. Section 340B also authorizes agency enforcement actions and civil monetary penalties for manufacturers' violations. 42 U.S.C. § 256b(d)(1)(B)(vi); *see Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 117–20 (2011).

25. In order to prevent waste and abuse in the program, Section 340B prohibits "duplicate discounts or rebates," which occur when the same prescription receives both a 340B discount and a Medicaid rebate. 42 U.S.C. § 256b(a)(5)(A).

26. Section 340B also prohibits "diversion," which occurs when a covered entity transfers discounted drugs to persons who are not its "patient[s]." *Id.* § 256b(a)(5)(B). A covered entity engaged in diversion not only is liable to the manufacturer for the entire value of the discount (which the covered entity must repay), *see id.* § 256b(a)(5)(D), but also is ineligible to obtain 340B pricing. *Id.* § 256b(a)(4) (a "'covered entity'" means "an entity that meets the requirements described in paragraph (5)," among others).

27. Although Section 340B does not define the statutory term "patient," HRSA has interpreted the term in guidance documents. For example, in 1996 guidance, HRSA explained that an individual is a "patient" of a covered entity if: (1) the covered entity maintains records of the individual's health care; (2) the individual receives health care services from a professional employed by the covered entity (or otherwise affiliated such that responsibility for the care remains with the covered entity); and (3) the care the individual receives from the covered entity is consistent

with the range of services for which the covered entity receives funding. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157–58 (Oct. 24, 1996). HRSA explained that an individual is not a "patient" of a covered entity if, by contrast, "the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *Id.* at 55,158.

28. Section 340B is agnostic with respect to whether the ceiling price is effectuated through a upfront discount or a subsequent credit or rebate. Indeed, HRSA has conceded that "Section 340B has no explicit language as to whether the required reduction in price should be obtained by an initial reduction in the purchase price (i.e., a discount mechanism) or received as a required reduction in cost rebated after purchase, dispensing, and payment are completed (i.e., a rebate option)." Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Rebate Option, 62 Fed. Reg. 45,823, 45,824 (Aug. 29, 1997). To that end, in the past, HRSA has approved of manufacturers effectuating 340B pricing through rebates, rather than up-front discounts. For example, in 1994 guidance, HRSA addressed the topic of retroactive discounts for the period when manufacturers were first implementing the 340B program, and stated that covered entities "may request *retroactive discounts (discounts, rebates, or account credit)* for covered outpatient drugs purchased retroactive to December 1, 1992." Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,112 (emphasis

added). In other words, manufacturers that had charged covered entities the higher commercial price could comply with Section 340B by paying retroactive "discounts, rebates, or account credit" to effectuate the 340B price. *Id.*

29. HRSA has also stated that credits are appropriate in connection with newly launched drugs. For such drugs, the agency has directed manufacturers to estimate the ceiling price while waiting for the ceiling price to be calculated, "which should occur no later than the 4th quarter that the drug is available for sale," and to then "offer to *refund or credit* the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred." 42 C.F.R. § 10.10(c) (2019) (emphasis added).

30. Similarly, HRSA has issued guidance regarding "a rebate option for State AIDS Drug Assistance Programs (ADAPs) receiving funds under Title XXVI of the PHS Act as an optional alternate means of accessing section 340B discount pricing." Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35,239, 35,239 (June 29, 1998). This guidance recognized that rebates might be permissible in other contexts, too. *See id.* at 35,241 (stating that the agency "*[a]t this time*" was not "propos[ing] a rebate program for all covered entities" (emphasis added)).

31. Another regulation permits looking beyond the initial order price in assessing compliance with Section 340B. Under Section 10.11(b)(4), "[a]n instance of overcharging may occur at the time of initial purchase *or* when subsequent ceiling

price recalculations due to pricing data submitted to CMS or new drug price estimations as defined in § 10.10(c) result in a covered entity paying more than the ceiling price due to failure or refusal to *refund or credit* a covered entity." 42 C.F.R. § 10.11(b)(4) (emphasis added).

32. In short, HRSA's practices confirm what is evident from the statutory text itself: Section 340B does not require that manufacturers effectuate the ceiling price through an upfront discount and does not prohibit manufacturers from effectuating the ceiling price through a post-purchase credit.

II. 340B Program Waste and Abuse and the Contract Pharmacy Cases

33. The 340B Program has increased dramatically in size and scope since its inception in 1992. In 2023 alone, drug sales as part of the 340B Program topped $66 billion, a 23% increase over the previous year. *Compare* HRSA, 2023 340B Covered Entity Purchases (Oct. 2024), https://perma.cc/4UKS-YZAD, *with* HRSA, 2022 340B Covered Entity Purchases (Sept. 2023), https://perma.cc/G8QW-46HU. And as the Government Accountability Office ("GAO") reported, hospital participation in the 340B Program has more than tripled since 2009. *See* GAO, *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, at 6, GAO-20-108 (Dec. 2019), https://perma.cc/DS2V-YL8Y.

34. With the Program's growth has come an increase in waste and abuse. HRSA has recognized this itself through its own audits of covered entities. *See, e.g.*, HRSA, Program Integrity: FY19 Audit Results (Aug. 2024), https://perma.cc/48S9-

TGJQ (reporting widespread duplicate discounting in violation of the statutory prohibition).

35. The use of so-called "contract pharmacies"—for-profit, commercial pharmacies that enter into agreements with covered entities—to distribute 340B drugs has been a leading driver of this growth in waste and abuse.

36. In 1996, four years after the 340B Program was created, HRSA issued guidance purporting to allow contract pharmacies to dispense 340B-priced drugs by signing agreements with covered entities. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996). That guidance provided that a covered entity could enter into such an arrangement with a maximum of one contract pharmacy. *Id.* at 43,555. In 2010, however, HRSA issued new guidance that purported to authorize a massive expansion of contract-pharmacy participation in the 340B Program, by stating that a covered entity could contract with an *unlimited* number of contract pharmacies, without even as much as a geographical restriction. *See* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

37. The government recognized that this model exposed the 340B Program to more waste and abuse resulting from both duplicate discounts and diversion. For example, HHS found that "contract pharmacy arrangements create complications in preventing duplicate discounts." HHS Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431, at 2 (Feb. 2014), https://perma.cc/HQY9-DFKU. And the GAO warned that

"[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836, at 28 (Sept. 2011), https://perma.cc/N5AY-ZZ45.

38. Those increased risks of duplicate discounting and diversion were realized. By the end of 2020, HRSA had issued more than 1,500 findings of covered-entity noncompliance among the limited number of audits it conducted between 2012 and 2019. *See* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO-21-107, at 13 (Dec. 2020), https://perma.cc/EBS2-MFNB. Those findings included more than 500 instances of diversion and nearly 500 instances of duplicate discounting. *See id.*

39. Waste and abuse have skyrocketed in the 340B Program in large part because of what has become the prevailing method for dispensing 340B drugs. Under this method, known as the "replenishment model," most pharmacies do not keep separate inventories of 340B drugs. Instead, pharmacies "fill prescriptions from inventories that intermingle discounted and non-discounted drugs." *Novartis*, 102 F.4th at 457. Importantly, "[o]nly after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount." *Id.* After concluding that drugs were dispensed to patients of a covered entity, the pharmacies then "replenish [those drugs] with 340B drugs [at 340B prices]." HRSA,

340B Drug Pricing Program Notice, Release No. 2013-1, at 2–3 (Feb. 7, 2013), https://perma.cc/3EPG-4CEK.

40. In 2020, several manufacturers, including Sanofi, responded to this explosive growth in waste and abuse with a variety of initiatives designed to improve integrity in the 340B Program by placing conditions or limits on the use of contract pharmacies. For example, Sanofi announced that it would continue to deliver discounted drugs to an unlimited number of contract pharmacies, but would begin to require covered entities to submit claims data that could help Sanofi identify unlawful duplicate discounts. Other manufacturers announced different policies, including policies that allowed discounted drugs to be delivered only to a single contract pharmacy.

41. The government took swift enforcement action in response. HHS and HRSA took the "position that section 340B prohibits drug manufacturers from imposing any conditions on the distribution of discounted drugs to covered entities." *Novartis*, 102 F.4th at 459. The agencies declared that "Section 340B unambiguously requires drug makers to deliver 340B drugs to an unlimited number of contract pharmacies." *Sanofi*, 58 F.4th at 701. And HRSA sent manufacturers, including Sanofi, enforcement letters "order[ing] them to rescind" their contract-pharmacy policies and to "reimburse covered entities for any overcharges" or face civil monetary penalties. *Id.*

42. Several manufacturers, including Sanofi, filed lawsuits challenging these administrative actions. To date, two federal courts of appeals have rejected the

federal government's position and held that Section 340B permits manufacturers' contract-pharmacy policies, including Sanofi's. *Novartis*, 102 F.4th at 452; *Sanofi*, 58 F.4th 696. No federal court of appeals has held otherwise.

43. The Third Circuit held that Sanofi's integrity initiative and other manufacturers' similar "restrictions on delivery to contract pharmacies do not violate Section 340B." *Sanofi*, 58 F.4th at 706. That is because Section 340B requires merely that manufacturers "offer" drugs to covered entity at a discounted price. *Id.* at 703. As a result, the statute does not require "delivery to an unlimited number of contract pharmacies." *Id.* at 704. The Third Circuit also rejected the government's argument that "drug makers may not tack on measures of their own"—like Sanofi's data-submission requirement—to existing statutory compliance measures in an attempt to prevent statutory violations. *Id.* at 705.

44. The D.C. Circuit similarly held that Section 340B "does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities." *Novartis*, 102 F.4th at 464. That court explained that manufacturers may impose conditions on drug distribution unless the conditions are "onerous enough" that they "effectively increase the contract 'price.'" *Id.* at 462. The conditions in that case—which also included the collection of claims data—"neither preclude[d] [manufacturers] from making a bona fide 'offer'" to provide discounted drugs to covered entities "nor increase[d] its contract 'price.'" *Id.* at 464. The conditions thus did "not violate Section 340B on their face." *Id.*

III. Sanofi's Credit Model

45. Although the courts of appeals confirmed manufacturers' freedom to set the terms on which they would "offer" drugs to covered entities at the statutory discount, waste and abuse in the 340B Program have unfortunately persisted.

46. The results of HRSA's own limited efforts to audit covered entities tell the story. In 2021, for example, HRSA audited 200 covered entities to review their compliance with the requirements of Section 340B. *See* HRSA, Program Integrity: FY21 Audit Results (Oct. 2024), https://perma.cc/CNK7-459G. Those audits revealed widespread failure to comply with the statutory prohibitions on duplicate discounting and diversion. *See id.*

47. Sanofi's experience confirms HRSA's observations. Sanofi regularly receives invoices from state Medicaid programs for rebates on 340B drugs. When paid, those rebates result in statutorily prohibited duplicate discounts. Opacity in the 340B Program makes it difficult—at times, impossible—for Sanofi to avoid those duplicate discounts. Sanofi has also identified instances of diversion. For example, one covered entity disclosed to Sanofi that it continuously diverted drugs to ineligible individuals from 2015 through August 2023, without HRSA detecting the diversion.

48. These continued problems appear to stem from several causes, all related to the replenishment model's disconnect between when a drug is dispensed and when the drug is deemed eligible for the 340B discount. Covered entities' third-party administrators ("TPAs") typically determine whether a drug was dispensed to a covered entity's patient—and thus subject to the 340B discount—only after the drug

is dispensed. This delay makes it harder to prevent duplicate discounts because a prescription's eligibility for the 340B discount or a Medicaid rebate is determined by different parties at different times and in different transactions. Covered entities' and their TPAs' overbroad interpretations of the statutory term "patient" also result in retroactive application of the 340B discount to ineligible prescriptions—that is, diversion.

49. In light of these persistent problems, Sanofi now plans to change the mechanism through which it sells drugs to certain covered entities at the 340B price in order to further address waste and abuse in the 340B Program. Under the Credit Model, Sanofi will implement two changes designed to ensure that Sanofi charges the 340B price for prescriptions that are eligible for the discount, but not for those that are ineligible, while also protecting against parties other than covered entities seeking duplicate discounts on the same 340B-priced drugs (in connection with Medicaid or otherwise).

50. ***First***, for hospital covered entities[1] and consolidated health center covered entities, Sanofi will sell drugs at the 340B price by directly crediting those entities the difference between the drug's 340B price and the wholesale acquisition cost (the "WAC" price), which is the price manufacturers charge wholesalers prior to

[1] Hospital covered entities include critical access hospitals, disproportionate share hospitals, rural referral centers, and sole community hospitals.

any discounts or rebates.[2] Sanofi will thus continue to offer its drugs to these covered entities at the 340B price but will simply effectuate that price differently.

51. More specifically, under Sanofi's Credit Model, hospital covered entities and consolidated health center covered entities will place an order with a wholesaler for Sanofi's drugs at the WAC price; the drugs will be dispensed to a 340B patient; the covered entity or its TPA will submit claims data for the prescriptions; and the covered entity will realize the 340B discount through Sanofi's payment of a standalone credit, thereby ensuring the covered entity does not pay the higher price.

52. Sanofi will offer covered entities the ability to secure the 340B credit within 30 days of an order—and thus before the wholesaler's bill becomes due under commercially prevalent terms—so long as the covered entity submits claims data within 22 days of the order. Covered entities thus will always be offered—and should always pay—the 340B price, not the WAC price, for Sanofi's drugs. Sanofi will of course continue to work with covered entities in good faith, as it has always done, in the event a covered entity notifies the company that it cannot access drugs at the 340B price.

53. Implementing the 340B price in this way will allow Sanofi to protect against illegal duplicate discounts by ensuring that a 340B-priced prescription is not later subject to another applicable discount. In such instances, Sanofi will continue to pay the credit to the covered entity to effectuate the 340B price, but will use the

[2] All other covered entities—i.e., all covered entities that are not hospital or consolidated health centers—are excluded from this initiative.

data to reject or recover duplicate discounts paid to state Medicaid agencies or other third parties.

54. ***Second***, for hospital covered entities only, Sanofi will issue a 340B credit only for prescriptions that are dispensed to a covered entity's "patient" as defined by HRSA's 1996 guidance—not for those dispensed to any other individuals. Sanofi will use purchase and claims data submitted by covered entities to apply HRSA's patient definition.

55. Specifically, Sanofi will provide the 340B credit when the individual receiving a prescription (1) is currently receiving medical care from the covered entity, and (2) receives health care services from a health care professional who is employed by or similarly affiliated with the covered entity. For prescriptions that arise from a referral following a patient encounter at the covered entity (i.e., where the health care services are provided by someone unaffiliated with the covered entity), Sanofi will analyze claims data to determine if there is a nexus between the health care services provided by the covered entity and the prescription.

56. Importantly, a covered entity will have the opportunity to rebut Sanofi's initial conclusion if it believes a credit was incorrectly denied.

IV. HRSA's Violation Letter

57. On November 1, 2024, Sanofi notified HRSA by letter of its intention to implement the Credit Model. *See* Exhibit A.

58. After detailing how the Credit Model would operate, Sanofi's letter explained that the Credit Model is consistent with Section 340B. As the letter

explained, Section 340B does not prohibit the use of post-purchase credits to effectuate the statutory discount. To the contrary, Section 340B expressly contemplates that 340B pricing can be implemented in this manner, because the statute concerns not what a covered entity may be initially charged, but rather "the amount required to be paid (*taking into account any rebate or discount*, as provided by the Secretary) to the manufacturer." 42 U.S.C. § 256b(a)(1) (emphasis added). Moreover, under the Credit Model, Sanofi will "offer drugs for purchase at the 340B price on terms that will provide a credit to effectuate the 340B price *after* a covered entity places an order with a wholesaler" and submits claims data but "*before* the wholesaler's invoice" becomes due. *See* Exhibit A at 4. As a result, Sanofi explained, the "covered entity should never pay out of pocket the full" undiscounted price. *Id.* at 3.

59. As to its proposed patient eligibility condition, Sanofi explained that providing the 340B credit only when a drug is provided to the covered entity's "patient," as HRSA's guidance defines the term, is also consistent with Section 340B because the statute does not obligate Sanofi to provide 340B pricing for drugs transferred to non-patients. *Id.* at 10.

60. Sanofi was aware that, in addressing similar proposals by other manufacturers, HRSA had taken the position that such initiatives required the agency's prior approval because Section 340B addresses the use of "any rebate or discount, *as provided by the Secretary*." 42 U.S.C. § 256b(a)(1) (emphasis added). Sanofi's letter to HRSA explained that this statutory language did not impose a pre-

approval requirement. Instead, as Sanofi explained, the statutory phrase "as provided by the Secretary," *id.*, merely reflects that the Secretary has the authority to specify in a Pharmaceutical Pricing Agreement *how*—not *whether*—"any rebate or discount" should be taken into account when manufacturers invoice the "amount required to be paid" by covered entities. The Secretary has not taken any such step or otherwise addressed the use of credits or rebates in Sanofi's Pharmaceutical Pricing Agreement. Exhibit A at 8–9. Sanofi also pointed out that this approach would be consistent with HRSA's past guidance and regulations, which provide for such rebates and discounts.

61. On November 12, 2024, HRSA sent Sanofi a letter determining that Sanofi's Credit Model "would be inconsistent with the statutory requirements for the 340B Program" because the Secretary had not approved Sanofi's proposed model. HRSA also posed a number of questions about how Sanofi's planned Credit Model would operate. *See* Exhibit B.

62. Sanofi responded to those questions on November 15. *See* Exhibit C. It also informed HRSA that it would proceed to announce its Credit Model publicly, as planned, on November 22 absent HRSA's determination that the Credit Model is substantively inconsistent with Section 340B. *See id.* On November 21, 2024, HRSA reaffirmed its position that pre-approval by the Secretary was required in order for Sanofi to implement its Credit Model. *See* Exhibit D. On November 22, 2024, Sanofi publicly announced its new Credit Model. *See* Exhibit E.

63. On December 13, 2024, HRSA sent Sanofi the Violation Letter determining that Sanofi's Credit Model violates Section 340B. *See* Exhibit F. After summarizing that Sanofi's Credit Model would both effectuate the 340B price through credits and implement a patient-eligibility condition, HRSA explained that Sanofi's Credit Model would violate Section 340B for two separate reasons. First, according to HRSA, because the "Secretary has not 'provided' that the credits described in Sanofi's notice should be 'tak[en] into account' in the 'amount required to be paid' for select Sanofi Products by certain covered entity types," Sanofi's Credit Model would violate the statute if launched "without Secretarial approval." *Id*. at 2. Second, separately, HRSA concluded that Sanofi's Credit Model "violates Section 340B(a)(1)" because "Sanofi's credit proposal would require certain covered entity types to purchase certain Sanofi products at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs." *Id.* In addition, HRSA objected "that the credit payment is subject to Sanofi's unilaterally imposed requirements for the timely submission of 'purchase and claims data' by a covered entity, as well as Sanofi's 'validation' of said data. In short, the notice makes clear that issuance of the '340B Credit' is conditioned on Sanofi's prior approval at Sanofi's sole discretion." *Id*. at 2 n.1.

64. After concluding that both components of Sanofi's Credit Model are unlawful, HRSA threatened enforcement action if Sanofi proceeds to implement its proposed model as announced. "Because Sanofi's credit proposal, if implemented, violates Sanofi's obligations under the 340B statute, it subjects Sanofi to potential

consequences, such as termination of Sanofi's Pharmaceutical Pricing Agreement (PPA)." *Id.* In addition, HRSA threatened to impose "sanctions in the form of civil monetary penalties." *Id.* HRSA accordingly demanded that Sanofi "cease implementation of its credit proposal immediately." *Id.*

65. The Violation Letter is the latest example of HRSA's regulatory capture. From contract pharmacies to rebate models, HRSA has ceased to be a neutral enforcer of Section 340B's requirements. Instead, HRSA has become an advocate for covered entities by acquiescing to their demands to sanction manufacturers for imposing limits on the delivery of 340B-priced drugs to contract pharmacies and now to quash manufacturers' attempts to limit waste and abuse in the 340B Program through credit and rebate models. All the while, HRSA has turned a blind eye to covered entities' systemic violations of Section 340B's prohibition on diversion.

66. Sanofi brings this suit to obtain confirmation that its Credit Model is consistent with Section 340B, and that it does not need HRSA's prior approval before launching the Credit Model, so that the company may pursue its business ends without the threats of crippling federal sanctions and expulsion from Medicare Part B, Medicaid, and the 340B program.

STANDING

67. Sanofi has standing to challenge the Violation Letter because it faces injuries traceable to the Letter and likely to be redressed by a favorable ruling.

68. The Violation Letter injures Sanofi. In the Violation Letter, HRSA determined that Sanofi's Credit Model is unlawful and that Sanofi cannot implement

its Credit Model without prior approval from the Secretary. HRSA warned Sanofi that it would face sanctions—such as termination of Sanofi's Pharmaceutical Pricing Agreement and civil monetary penalties—if it implements its Credit Model as planned. HRSA thus ordered Sanofi to "cease implementation of its credit proposal immediately." *Id.*

69. To proceed with its business plans in light of HRSA's enforcement threats, Sanofi would have to accept the risk of HRSA terminating its Pharmaceutical Pricing Agreement and HHS imposing many millions of dollars in civil monetary penalties, and to then vindicate the legality of the Credit Model after the fact. But the law does not put Sanofi to that choice, which is plainly designed by HRSA to scare Sanofi away from moving forward.

70. Sanofi's injuries are traceable to the Violation Letter. But for these enforcement risks, Sanofi would follow its stated intention to implement its new Credit Model in January 2025 without facing the risk of enforcement.

71. These injuries are redressable. The Court can resolve this controversy by vacating the Violation Letter, enjoining HRSA from taking enforcement action, and declaring that Sanofi's Credit Model does not violate Section 340B and that Sanofi thus may implement its Credit Model without need for prior approval from the agency and without risk of enforcement action.

FINAL AGENCY ACTION

72. The APA provides that "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704.

73. The Violation Letter is final agency action for which Sanofi has no other adequate remedy in court. The Violation Letter's definitive pronouncement that both components of Sanofi's Credit Model violate Section 340B represents the consummation of the agency's decision-making process with respect to the implementation of Sanofi's Credit Model. The Violation Letter's assertion that Sanofi cannot implement the Credit Model without prior approval from the Secretary likewise represents the consummation of the agency's decision-making process as to that question.

74. The Violation Letter also determines Sanofi's rights and legal obligations under Section 340B by declaring that the Credit Model violates the statute, and that Sanofi may not proceed without prior approval from the Secretary. And the Violation Letter carries legal consequences in the form of HRSA's enforcement threats—termination of Sanofi's Pharmaceutical Pricing Agreement, expulsion from Medicare Part B, Medicaid, and the 340B program, and exposure to enormous civil monetary penalties.

CLAIMS FOR RELIEF

Count I—Violation of Administrative Procedure Act (340B Credits)

75. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

76. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," as well as agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

77. HRSA's determination that the Credit Model violates Section 340B exceeds the agency's statutory authority because Section 340B does not prohibit Sanofi from using credits to effectuate the 340B price. Section 340B "merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount." *Novartis*, 102 F.4th at 460. Sanofi proposes to do just that by effectuating covered entities' purchases at the 340B price through a credit. HRSA's determination that Section 340B prohibits this practice exceeds the agency's statutory authority.

78. HRSA also failed to reasonably explain its determination that Sanofi's decision to use credits to effectuate the 340B price violates Section 340B. HRSA conceded nearly three decades ago that a manufacturer could effectuate the 340B price through a "rebate option" instead of a "discount mechanism." *See* 62 Fed. Reg. at 45,824. Indeed, as noted, HRSA has previously *permitted* the use of post-purchase rebates in certain circumstances. The Violation Letter is arbitrary and capricious

because it reverses that position without acknowledging, let alone explaining, the change.

79. HRSA's determination that using credits to effectuate the 340B price violates Section 340B on its face also is premature because HRSA lacks evidence that this approach results in overcharges in any particular case.

80. This Court should hold unlawful and set aside HRSA's determination that Sanofi may not effectuate the 340B price through credits because it is contrary to law and arbitrary and capricious.

81. Declaratory relief is also "appropriate" in this case because there is a controversy between the parties over whether Sanofi's proposed use of credits complies with Section 340B. 28 U.S.C. § 2201.

82. Declaratory relief is appropriate where it would "finally settle the controversy between the parties," resolve an issue of great "public importance," promote "the convenience of the parties," and be judicially manageable given "the degree of adverseness between the parties." *Morgan Drexen, Inc. v. Cons. Fin. Prot. Bureau*, 785 F.3d 684, 696–97 (D.C. Cir. 2015). All of those criteria are satisfied here.

83. Accordingly, the Court should declare that Sanofi's use of credits in the Credit Model complies with Section 340B.

Count II—Violation of Administrative Procedure Act (Patient Eligibility Condition)

84. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

85. HRSA's determination that the Credit Model violates Section 340B due to the patient eligibility condition exceeds the agency's statutory authority because the statute does not obligate Sanofi to provide 340B pricing for drugs dispensed to individuals who are not covered entities' patients.

86. HRSA also failed to reasonably explain its determination that Sanofi's decision to "unilaterally" implement a patient eligibility condition violates Section 340B.

87. HRSA also failed to provide a reasoned explanation for prohibiting Sanofi from enforcing the agency's own patient definition.

88. HRSA's determination that Sanofi's patient eligibility condition violates Section 340B on its face also is premature because HRSA lacks evidence that the condition results in overcharges in any particular case.

89. This Court should hold unlawful and set aside HRSA's determination that Sanofi may not implement a patient eligibility condition because it is contrary to law and arbitrary and capricious.

90. The Court should also declare that Sanofi's patient eligibility condition complies with Section 340B.

Count III—Violation of Administrative Procedure Act (Prior Approval)

91. Sanofi incorporates by reference the allegations contained in all of the preceding paragraphs as though set forth fully herein.

92. HRSA's determination that Sanofi must obtain the Secretary's approval before implementing the Credit Model exceeds the agency's statutory authority. Nothing in Section 340B requires manufacturers to obtain the Secretary's pre-approval before offering the 340B price through a credit or rebate. Section 340B permits the Secretary to specify in a Pharmaceutical Pricing Agreement *how* "any rebate or discount" should be taken into account when manufacturers invoice "the amount required to be paid" by covered entities. 42 U.S.C. § 256b(a)(1). But it does not give the Secretary authority to determine *whether* a rebate or discount could be used to effectuate the 340B price—and certainly does not allow the Secretary to take that step outside of a Pharmaceutical Pricing Agreement.

93. HRSA also failed to reasonably explain its determination that Sanofi was required to obtain the Secretary's prior approval of the Credit Model because HRSA failed to identify any portion of Section 340B or Sanofi's Pharmaceutical Pricing Agreement that requires such approval.

94. Even assuming Sanofi were required to obtain the Secretary's prior approval before implementing the Credit Model (it was not), HRSA's decision to withhold such approval is arbitrary and capricious because Sanofi's decision to use credits to effectuate 340B prices is consistent with Section 340B. In addition, HRSA has previously permitted the use of credits to effectuate the 340B price, but HRSA did not explain how Sanofi's Credit Model is materially different from these other circumstances.

95. This Court should hold unlawful and set aside HRSA's determination that Sanofi was required to obtain the Secretary's prior approval before implementing the Credit Model because it is contrary to law and arbitrary and capricious.

96. The Court should also declare that Sanofi was not required to obtain the Secretary's prior approval before implementing the Credit Model.

PRAYER FOR RELIEF

Wherefore, Sanofi prays for the following relief:

1. A declaration, order, and judgment holding unlawful, enjoining, and setting aside the Violation Letter;

2. A declaration, order, and judgment holding that Sanofi's Credit Model complies with Section 340B because the statute does not prohibit Sanofi from effectuating the 340B price through a credit or implementing its patient eligibility condition without the Secretary's prior approval;

3. An injunction prohibiting Defendants from terminating Sanofi's Pharmaceutical Pricing Agreement or otherwise taking any enforcement action against Sanofi for implementing the Credit Model, including without prior approval from the Secretary;

4. An award of all costs and attorney's fees pursuant to any applicable statute or authority; and

5. Any other relief this Court deems just and proper.

Dated: December 16, 2024

Respectfully submitted,

/s/ Brett A. Shumate

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