IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., a Delaware corporation,
1 N. Waukegan Road
North Chicago, IL 60064

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official capacity, and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

and

THOMAS J. ENGELS, in his official capacity, and HEALTH RESOURCES AND SERVICES ADMINISTRATION,
5600 Fishers Lane
Rockville, MD 20857,

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. At its core, this suit seeks to restore integrity to the federal 340B drug discount program—which, as one court recently described it, is "the most important drug pricing scheme virtually no one has heard of." *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1270 (W.D. Okla. 2025). Plaintiff AbbVie Inc. (AbbVie) seeks judicial review of an effective denial by the Health Resources and Services Administration (HRSA) of AbbVie's audit rights under the program based on an overly broad interpretation of the statutory term "patient." As the allegations described herein demonstrate, HRSA's incorrect interpretation facilitates widespread 340B program abuse, which is the opposite of what Congress tasked HRSA to do.

2. Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to offer certain outpatient medicines at deeply reduced prices to a specified list of healthcare providers known as "covered entities." Recognizing that access to these steep discounts is so valuable for covered entities—and costly for manufacturers—Congress has strictly limited the circumstances in which they must be made available. Key among those safeguards for maintaining program integrity, the statute forbids a covered entity from "resell[ing] or otherwise transfer[ring] the [340B-discounted] drug to a person who is not a *patient of the entity*." *Id.* § 256b(a)(5)(B) (emphasis added). This provision ensures that covered entities access 340B discounts only for drugs that they provide to *their own* "patients"—a restriction necessary to ensure that the 340B statute's intrusion on manufacturers' private rights serves a valid public purpose.

3. AbbVie, a longtime participant in the 340B program, has seen firsthand how an overly permissive interpretation of "patient" can lead to program abuse. AbbVie recently discovered that a small, federally funded health center in San Antonio was issuing the vast majority

of its drug prescriptions to pharmacy customers *outside* of Texas. Equally troublingly, a prescriber at this relatively small entity writes more prescriptions for AbbVie drugs, by tremendous margins, than any other prescriber in the nation. In another example of abuse, AbbVie discovered that three separate covered entity hospitals—all part of the same healthcare system—were each claiming 340B discounts on the *same* units of drugs prescribed to the *same* individuals.

4. After communications with these covered entities confirmed that their anomalous practices stemmed from their overly broad interpretation of "patient," AbbVie sought to audit these entities in accordance with Section 340B's dispute-resolution procedures. But HRSA, the agency that administers the 340B program, effectively denied AbbVie's audit workplans. In fact, HRSA informed AbbVie that it *agreed* with these entities' interpretation of "patient," and that the agency accordingly would not enforce any audit findings inconsistent with that definition.

5. In reaching that conclusion, HRSA relied on the agency's outdated, overly expansive, and erroneous definition of the term "patient" under Section 340B. HRSA's definition is not the "best reading" of the statutory term, *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 400 (2024), and it undermines Congress's intent to ensure that drug manufacturers are obligated to provide steep discounts under the 340B program only in limited situations. AbbVie asks this Court to confirm the governing standard and to restore integrity to the 340B program by directing HRSA to authorize and enforce audits based on the proper statutory definition of the term "patient," rather than the erroneous definition that HRSA has been using.

6. Congress designed the 340B program as a means of assisting a narrow class of safety-net providers in giving their low-income and vulnerable patients access to lower-cost prescription drugs and more-comprehensive healthcare services. But in the years since its enactment, sophisticated participants have developed ways to exploit the program for profit,

causing it to grow exponentially. In 1992, when the program was created, there were approximately 1,000 covered entities. By 2021, there were over 50,000. *See* Ryan P. Knox, et al., *Outcomes of the 340B Drug Pricing Program*, JAMA Health Forum (Nov. 22, 2023), https://bit.ly/4m8NBsq. The volume of discounts accessed under the program has similarly exploded—from approximately $6.6 billion in 2010 to $43.9 billion in 2021. *See* Congressional Budget Office, *Growth in the 340B Drug Pricing Program* (Sept. 2025), https://bit.ly/3NWj2cw. Today, the 340B program is the nation's second-largest federal prescription drug program, after only Medicare Part D.

7. At its core, the 340B program offers a tradeoff to participating drug manufacturers: They receive coverage and reimbursement for their drugs under Medicaid and Medicare Part B; in exchange, they must "offer each covered entity covered outpatient drugs for purchase" at steeply discounted prices. 42 U.S.C. § 256b(a)(1). This offer is set out in a Pharmaceutical Pricing Agreement signed between participating manufacturers and the Secretary of Health and Human Services (HHS).

8. Congress recognized that these steep discounts could incentivize abuse of the program, however, and it accordingly imposed program-integrity safeguards. The 340B statute prohibits a practice commonly referred to as "duplicate-discounting"—*i.e.*, where a manufacturer is required to provide multiple discounts on the *same* unit of a drug, for instance because a covered entity has submitted requests for payment both under Section 340B and under Medicaid. *See id.* § 256b(a)(5)(A). And as particularly relevant here, the statute also prohibits a practice known as "diversion," by specifying that a "covered entity shall not resell or otherwise transfer [a 340B-discounted drug] to a person who is not a ***patient of the entity***." *Id.* § 256b(a)(5)(B) (emphasis added).

9. Though the 340B statute prohibits the diversion of drugs to "a person who is not a patient of the [covered] entity," it does not define the term "patient." But in 1996, HRSA, the sub-agency of HHS that administers the 340B program, issued non-binding guidance outlining the agency's interpretation of the word. 61 Fed. Reg. 55,156–58 (Oct. 24, 1996). HRSA's guidance on this subject has not been updated since, despite nearly 20 years of explosive growth in the program and substantial evidence of abuse.

10. The 340B statute allows drug manufacturers to defend program integrity by investigating suspected violations. Covered entities "shall permit" drug manufacturers to audit any records of the covered entity that "directly pertain to the entity's compliance with" the prohibitions on duplicate-discounting and diversion. 42 U.S.C. § 256b(a)(5)(C).

11. Under HRSA's guidelines for manufacturer audits, however, a manufacturer must submit an audit workplan to HRSA prior to auditing a covered entity; and before the agency will approve the audit, the manufacturer must provide reasonable cause that the entity is engaging in duplicate-discounting or diversion. *See* 61 Fed. Reg. 65,406–12 (Dec. 12, 1996). Moreover, only HRSA has authority to impose sanctions or otherwise enforce the findings of an audit, *see* 42 U.S.C. §§ 256b(a)(5)(D), (d)(2)(B)(v), and manufacturers can access HRSA's administrative dispute-resolution system (ADR) only "after the conduct of audits as authorized," *id.* § 256b(d)(3)(A). Agency permission is thus essential to any effort by a manufacturer to investigate, prosecute, and remedy suspected violations of program rules by covered entities.

12. AbbVie is a biopharmaceutical company and longtime participant in the 340B program, giving it a front-row seat to the rapid rise in the 340B program's size—and, unfortunately, to the proliferation of program abuse. AbbVie is committed to helping maintain

program integrity, which includes review of 340B data for anomalous purchasing activity by covered entities.

13. In 2024, AbbVie identified concerning purchase data for multiple covered entities, including: Barrio Comprehensive Family Health Care Center, Inc. (Barrio) and The Mount Sinai Hospital (Mount Sinai).

14. After identifying abnormal purchase trends from these two covered entities, AbbVie requested more information from both. Following months of good-faith discussions, AbbVie developed reasonable cause to believe that both entities are engaging in diversion—meaning they have sold or otherwise transferred drugs purchased at 340B prices to individuals who were *not* patients of the entity.

15. AbbVie's reasonable cause is based on the term "patient," as that term is used in the 340B statute's anti-diversion provision. Applying traditional tools of statutory construction, AbbVie interpreted the 340B statute's prohibition on selling or transferring 340B-priced drugs to anyone who is not "a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), in a manner that identifies the "single, best meaning" of that phrase, *Loper Bright*, 603 U.S. at 400.

16. The best reading of the term "patient," however, differs from the one that HRSA set forth in its 1996 Guidelines. HRSA's reading is overly inclusive, capturing individuals who may have had only a cursory encounter with the covered entity a long time ago. It also fails to account for technological developments since 1996, such as the advent of telehealth and virtual medicine. As a result, HRSA's interpretation is so loose and broad that it permits, for example, two or more *different* covered entities to each claim that the *same* prescription was written for its own patient.

17. So when AbbVie submitted proposed audit workplans to HRSA, seeking to audit Mount Sinai and Barrio, it told HRSA that it intended to conduct the audits using the best meaning of the statutory term "patient"—not the interpretation from HRSA's 1996 Guidelines. This included a non-exhaustive list of the essential elements of what it means to be a "patient of the entity," including:

- **Direct Connection Between Prescription and Care from Covered Entity**: The drug for which a 340B discount is claimed has been prescribed to the patient as a direct result of a healthcare encounter with a professional who provides services at the covered entity (*i.e.*, not because of a healthcare encounter unrelated to the prescription or from a provider outside the covered entity);

- **Substantive Medical Care**: The healthcare encounter is sufficient to allow the professional to meet clinical practice standards for diagnosing and treating the condition for which the drug is prescribed (*i.e.*, not a superficial healthcare encounter that is inadequate in time or substance to properly diagnose and treat the condition for which the drug was provided);

- **Direct Provider Oversight**: The healthcare professional who provides this service has direct oversight of, and maintains responsibility for, the individual's care, including the condition for which the drug has been prescribed (*i.e.*, not a referral from another, primarily responsible healthcare provider that is made merely to "launder" the prescription through a covered entity for purposes of obtaining a 340B discount); and

- **Timely Care Relationship**: The healthcare service takes place no more than 12 months prior to the dispensing or administration of the drug prescribed (*i.e.*, not healthcare services that were rendered so long ago that the covered entity is no longer responsible for the individual's care related to the drug prescribed).

18. HRSA has effectively denied AbbVie's workplans by *rejecting* the correct statutory interpretation of "patient" as set forth in those workplans, and making clear that the agency *will not* enforce any audit findings based on that interpretation, rendering AbbVie's statutory audit rights futile. The agency initially asked AbbVie to modify its proposed workplans to conform to the 1996 Guidelines' understanding of the term "patient." When AbbVie reiterated that the Guidelines do not reflect the best meaning of the statute, HRSA responded that any attempt by

AbbVie to use the interpretation of patient set forth in its workplans—rather than the Guidelines definition—would not be enforceable by the agency.

19. An audit serves no purpose if the agency has already made clear that it will not enforce diversion findings that arise from it; nor can a manufacturer successfully pursue a diversion claim using an ADR system administered by an agency that has already decided that the claim is legally invalid.

20. AbbVie brings this action to challenge HRSA's decision not to enforce audit findings for Barrio and Mount Sinai under the proper "patient" interpretation. That decision is based on an incorrect reading of the term "patient" in Section 340B. The correct reading of the term "patient," as set forth in AbbVie's audit workplans, is the best reading of the statute, and the workplans accordingly should have been approved.

21. AbbVie seeks a declaration that, as demonstrated by the "patient" interpretation in AbbVie's proposed workplans, the interpretation in HRSA's 1996 Guidelines does not accord with the 340B statute. AbbVie also asks the Court to set aside HRSA's decisions not to enforce AbbVie's audits for Barrio and Mount Sinai, which were based on the agency's flawed Guidelines definition.

JURISDICTION AND VENUE

22. This action arises under, and asserts violations of, the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*., and Section 340B of the Public Health Service (PHS) Act, 42 U.S.C. § 256b. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, and the APA, 5 U.S.C. §§ 705–06.

23. HRSA's decisions refusing to enforce findings from AbbVie's requested audits of Barrio and Mount Sinai each constitute final agency action; each is inconsistent with the statute; and each is subject to challenge under the APA. *See* 5 U.S.C. §§ 704, 706.

24. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because this action seeks relief against federal agencies and officials acting in their official capacities; at least one defendant is located in this district; and a substantial part of the events or omissions giving rise to the claim occurred in this district.

PARTIES

25. Plaintiff AbbVie Inc. is a corporation organized under the laws of the State of Delaware with its headquarters in North Chicago, Illinois. AbbVie is a biopharmaceutical company focused on advancing medical science and addressing complex and serious diseases worldwide. AbbVie and its predecessors have participated in the federal 340B drug discount program since the program's inception in the 1990s. AbbVie has signed 340B Pharmaceutical Pricing Agreements (PPAs) with the Secretary of HHS and is the successor-in-interest to executed PPAs, and AbbVie is accordingly subject to regulation by HRSA, a division of HHS. Through the 340B program, AbbVie helps certain safety-net healthcare providers access medications at a lower cost, in hopes that the providers will pass those savings on to uninsured, underprivileged, and vulnerable patients.

26. Defendant Robert F. Kennedy Jr. is the Secretary of HHS. Secretary Kennedy oversees the activities of HRSA, including the administration of the 340B program and the actions complained of herein. Secretary Kennedy is being sued in his official capacity. He maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

27. Defendant HHS is an executive department of the United States government. It is responsible for HRSA and the 340B program, including the administration of the 340B program, the authorization of manufacturer audits, and the actions complained of herein. HHS is headquartered in Washington, D.C.

28. Defendant Thomas J. Engels is the Administrator of HRSA. He is being sued in his official capacity. Administrator Engels maintains an office at 5600 Fishers Lane, Rockville, MD 20852. Administrator Engels is responsible for HRSA's Office of Pharmacy Affairs (OPA) and its administration of the 340B program.

29. Defendant HRSA is an administrative agency of the United States government within HHS. It is the division of HHS charged with administering the 340B program. HRSA is headquartered in Rockville, Maryland.

BACKGROUND

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations and Imposes Safeguards Against Program Abuse

30. Section 340B of the Public Health Service Act, enacted in 1992, established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold [under the Program] to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

31. Before the establishment of the 340B program, many drug manufacturers had adopted their own voluntary policies and programs to provide prescription drugs at discounted prices for the benefit of low-income and uninsured individuals (often by providing the discounted drugs to the healthcare providers who served them). But in 1990, Congress established the Medicaid Drug Rebate Program (MDRP), under which manufacturers were required to provide

rebates to states on their Medicaid utilization based on the lowest price that the manufacturer's drugs were offered to any eligible purchaser (commonly known as the manufacturer's "best price"). 42 U.S.C. § 1396r-8(c)(1)(C). This "best price" included the prices manufacturers had voluntarily provided to the safety net. Because the federal Medicaid program "purchases basic health care and long-term care services on behalf of [millions of] low-income women, children, and elderly and disabled individuals" and had long been the nation's single largest purchaser of prescription drugs, H.R. Rep. No. 102-384, pt. 2, at 8–9 (1992), the MDRP created an unintended "disincentive" for manufacturers to offer safety net discounts, *id.* at 9–10.

32. In 1992, Congress solved this unintended consequence created by the MDRP by enacting Section 340B, which, among other things, "exclude[s]" discounts to such low-income and uninsured purchasers from the Medicaid best-price formula. *Id.* at 11.

33. At the same time, Congress made clear that manufacturers would not be required to offer *both* a 340B discount *and* a Medicaid rebate on the same unit of a drug. *Id.* at 14-15. This provision became known as the 340B statute's "duplicate discount prohibition."

34. Going further than simply fixing the "best price" problem, Congress mandated that participating drug manufacturers *must* give safety-net providers access to the discounted medications that the manufacturers had previously offered voluntarily for the benefit of patients. Section 340B requires participating manufacturers—those who have "enter[ed] into an agreement" with the Secretary of HHS—to provide reduced prices on covered outpatient drugs to certain eligible healthcare providers, called "covered entities." 42 U.S.C. § 256b(a)(1).

35. The Takings and Due Process Clauses generally prohibit the government from forcing a private company to transfer its property to another private entity. They also prohibit the government from imposing non-market prices on sellers without adequate safeguards. Congress

could not force manufacturers to transfer their drugs to covered entities for the financial benefit of the covered entities themselves, as the government has no valid interest in enriching covered entities at the expense of manufacturers. The program is permissible only if it is structured for the benefit of uninsured and indigent patients. Congress thus took several steps to ensure that the 340B program did not violate the Constitution.

36. ***First***, Congress gave manufacturers significant incentives to participate in the 340B program by requiring a manufacturer to participate in the program as a condition of receiving reimbursement for its drugs under Medicaid and Medicare Part B. *See* 42 U.S.C. § 256b(a)(1). As a condition of participation, the 340B program must be interpreted and implemented to ensure that it retains a close nexus to Medicaid and Medicare Part B, which are designed to assist uninsured and indigent patients and provide patients with medically necessary care. In other words, Congress struck a "bargain between the federal government and private drug manufacturers." *Pharm. Rsch. & Mfrs. of Am. v. McCuskey*, No. 25-1054, --- F.4th ----, 2026 WL 898259, at *1 (4th Cir. Mar. 31, 2026).

37. ***Second***, Congress created the 340B program as an exclusively federal program, overseen by HRSA, a subcomponent of HHS. *See id.*, at *11; *see also Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011); Br. of United States as Amicus Curiae at 15–16, *AbbVie v. Weiser*, No. 25-1439 (10th Cir. Feb. 25, 2026), Dkt. No. 30.

38. ***Third***, in line with constitutional limitations, Congress made sure the 340B program was narrowly drawn to further its interest in increasing patient access to discounted drugs without creating too strong a disincentive to keep manufacturers from participating in Medicaid. To that end, Congress carefully designed the program for the benefit of needy patients, reaching only the healthcare entities that predominantly serve such patients. Congress identified with

particularity the types of entities that are considered "covered entities" under the 340B program, and thus are eligible to be offered discounted drugs. Today there are fifteen delineated categories of covered entities. *Id.* § 256b(a)(4)(A)-(O). Those fifteen categories include, among others, federally qualified health centers, critical access hospitals, freestanding cancer hospitals, and hospitals that serve a high volume of low-income patients (known as "disproportionate share hospitals" or "DSHs"). *Id*. They range from small, isolated organizations to some of the largest hospitals and healthcare centers in the country, but all of them are entities that typically serve low-income populations and individuals who lack insurance. Under the 340B program, the drugs that the entity purchases at a 340B discount are supposed to be only for patients of an entity that meets one of these fifteen statutory categories.

39. ***Fourth***, Congress included additional safeguards to prevent overreach and to adhere to constitutional requirements. As most relevant here, Section 340B specifies in broad terms that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). The statute thus prohibits a covered entity, among other things, from selling drugs acquired at federally discounted prices to any individual who receives the drugs for a reason unrelated to the care he or she received from the covered entity. Providing drugs acquired at the federally discounted 340B price to "a person who is not a patient of the entity" is commonly known as "diversion." Engaging in diversion "knowingly and intentionally" is grounds for the imposition of civil monetary penalties on covered entities. *Id.* § 256b(d)(2)(B)(v)(I).

40. The 340B statute also provides that covered entities may not obtain 340B pricing on units of drugs for which a manufacturer also pays a Medicaid rebate. *Id.* § 256b(a)(5)(A). This forbidden practice, commonly known as "duplicate-discounting," would result in manufacturers

taking a loss on the distribution of their products (taking into account both the 340B discount and the Medicaid rebate), thus exceeding constitutional limits on the conditions of 340B program participation.

41. Despite the prohibitions on diversion and duplicate-discounting, the 340B statute does not require covered entities to report their 340B sales data to manufacturers (or, for that matter, to anyone). As a result, manufacturers who want such information must *ask* covered entities to provide it. But even where manufacturers have adopted express policies of asking for such information, they often are unable to obtain the type of claim-specific data necessary to identify diversion and duplicate-discounting, including information about the relationship between the individual to whom the 340B-priced drug was prescribed and the covered entity.

42. ***Fifth***, Congress directed HRSA to provide oversight and conferred on manufacturers a statutory right to audit covered entities when they suspect program abuse. *Id.* § 256b(a)(5)(C)-(D); *see Drummond*, 808 F. Supp. 3d at 1272 (describing the audit provision as Congress's "respon[se]" to the "lack of transparency in the process by which" covered entities and their third-party administrators were submitting 340B claims); *McCuskey*, 2026 WL 898259, at *11 ("Recognizing that manufacturers were incentivized to guard against diversion and duplicate discounts, Congress required covered entities to permit manufacturer-led audits."). Congress authorized both HRSA and participating manufacturers to audit covered entities regarding their compliance with the program:

> A covered entity *shall permit* the Secretary and *the manufacturer* of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

42 U.S.C. § 256b(a)(5)(C) (emphases added).

43. This audit provision thus grants drug manufacturers an absolute right to conduct such audits, subject only to procedures related to "the number, duration, and scope of audits." *Id.* Congress did not place any other conditions on a manufacturer's right to audit a covered entity, which occurs "at the . . . manufacturer's expense." *Id.*

44. The statute also specifies that, "[i]f the Secretary finds, after [an] audit," that a covered entity has engaged in diversion or duplicate discounts, "the covered entity shall be liable to the manufacturer of the covered outpatient drug that is subject of the violation in an amount equal to the reduction in the price of the drug." *Id.* § 256b(a)(5)(D).

45. HRSA's 1996 manufacturer audit guidelines provide the process for how, exactly, the Secretary can "find" wrongdoing post-audit. *See* 61 Fed. Reg. at 65,410. The manufacturer must submit an audit report detailing the audit's findings to the covered entity, and the covered entity has an opportunity to respond to the report. If the covered entity agrees with the audit's findings, the covered entity "shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations." *Id.* But if the covered entity does not agree with the audit findings—as is almost always the case—the covered entity must provide its "rationale for the disagreement" to the manufacturer. *Id.* If the parties do not agree on the audit findings, the manufacturer can then file a claim using the 340B program's ADR process. *Id.* Neither the statute nor HRSA's guidelines provide the manufacturer with any power to independently enforce the findings of its audit; the manufacturer is dependent on HHS's authority to find wrongdoing and impose punishment or implement corrective measures.

46. ***Sixth***, Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities

that they have been overcharged for drugs purchased under . . . section [340B], and claims by manufacturers . . . of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A).

47. Under that authority, HRSA has established "requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. 80,632, 80,632 (Dec. 14, 2020). The ADR Rule authorizes panels of federal officers to resolve claims for "monetary damages," as well as other unspecified "equitable relief" sought by claimants. *Id.* at 80,635; *see* 42 C.F.R. § 10.21(a). HRSA administers the ADR program, and the ADR panel is composed of HRSA representatives, meaning the panelists can be expected to adhere to and reflect the agency's views.

48. The ADR Rule provides that a manufacturer may file an ADR claim "that the covered entity has violated section 340B(a)(5)(A) of the PHS Act, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHS Act, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity." 42 C.F.R. § 10.21(a)(2). But, importantly, a manufacturer may file such a claim only "*after* it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHS Act." *Id.* (emphasis added). As a result, under HRSA's regulations, auditing a covered entity is a precondition for a manufacturer to file an ADR claim and thereby obtain enforcement of diversion or duplicate discounting findings.

49. Thus, while Section 340B provides covered entities with access to prescription drugs at below-market prices for the benefit of the uninsured and indigent patients that visit their facilities and seek treatment, H.R. Rep. No. 102-384, pt. 2, at 10-11, Congress recognized the risk of program abuse and took concrete steps to mitigate it, consistent with constitutional requirements. Indeed, precisely because of the risk that covered entities would take advantage of

the program for their own benefit—and not for the benefit of indigent and uninsured patients—Congress recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

The 340B Program Has Experienced Rampant Growth and Abuse

50. The 340B program is currently the second-largest federal prescription drug program in the United States—larger than even the Medicaid Drug Rebate Program from which it was created. Indeed, the 340B program has grown exponentially in the three decades since its creation, in ways that would render the program unrecognizable to the Congress that created it.

51. At the time of enactment, Congress intended for covered entities to continue passing on the below-market prices required by Section 340B, commonly referred to as "340B prices," to the "low-income and rural" patients for whom they often care. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). That is how the program worked originally.

52. But over time, covered entities realized that if they *did not* pass on the full 340B discount, they could use the program to generate arbitrage "revenue." *Id.* They do so by purchasing manufacturers' drugs at deep 340B discounts, reselling them at full prices to patients (and their insurance carriers), "and pocket[ing] the difference." *Drummond*, 808 F. Supp. 3d at 1270. Since there is no requirement that covered entities share any part of their discount with patients or their insurers, every unit resold by a covered entity at full price generates a "spread between the discounted price and the higher insurance reimbursement rate." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 459, 457–58 (D.C. Cir. 2024); *see* Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), https://bit.ly/4s8zS6b (Grassley Letter). Nor is there any income limitation on the patients to whom a covered entity might dispense drugs purchased at the 340B discount. Indeed, the wealthier the population to which the drugs are dispensed, the greater the capacity for that population to absorb full-priced

drugs. Thus, the larger and wealthier a covered entity's "patient" population, the greater the "spread" that the covered entity can generate for itself. This arbitrage model presents a serious risk to the integrity of the 340B program and makes enforcement of the program's integrity requirements all the more important. It has also led to a sharp growth in the size of the program and its growth into wealthy communities.

53. A related part of the 340B program's explosive growth has stemmed from changes in HRSA guidance regarding the use of so-called "contract pharmacies."

54. When Congress enacted the 340B statute, it expected that covered entities would dispense drugs to patients who visited their facilities through their own in-house pharmacies. But in 1996, HRSA issued non-binding guidance authorizing covered entities that did not have their own in-house pharmacies to contract with a *single* outside pharmacy to provide services for 340B-priced drugs—commonly referred to as "contract pharmacies." 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996); *see Novartis*, 102 F.4th at 455 (describing contract pharmacy arrangements). The contract pharmacy would effectively operate as an outsourced in-house pharmacy for the benefit of the indigent and uninsured patients who seek treatment from the covered entity and its providers.

55. In 2010, HRSA revised its guidance to allow covered entities to "use multiple pharmacy arrangements"—meaning an *unlimited* number of contract pharmacies, without any geographic limits. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). This meant, for example, that a small rural hospital in Texas could now contract with hundreds of Walgreens locations across the country to dispense 340B-priced drugs to people around the country. That expansion increased the risk that covered entities would attempt to increase their own profits by selling manufacturers' drugs acquired at discounted prices not to their own patients in connection with services provided by the covered entity itself, but to *any* pharmacy customer despite having only limited or attenuated

connections to the covered entity. HRSA must have recognized the abuses that this expansion caused, because it made clear that covered entities would have to "comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." *Id.*

56. The 2010 Guidance triggered a "significant expansion" in the 340B program, especially in terms of the number of contract pharmacies receiving and distributing 340B-priced drugs. *Novartis*, 102 F.4th at 457. In 2018, the Government Accountability Office reported that the number of 340B contract pharmacies had multiplied from 1,300 in 2010, to nearly 20,000 in 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Report), https://bit.ly/3O8UZHz. These numbers have continued to rise, even while the number of indigent and uninsured patients has decreased. By mid-2023, more than 33,000 different pharmacies participated in the 340B program, with more than 194,000 individual contracts with pharmacies—an increase of more than 2,400% in just thirteen years. Adam J. Fein, Drug Channels Inst., *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), https://bit.ly/4ciOWcA.

57. Experts have determined that this massive growth in 340B program sales is due, at least in significant part, to covered entities targeting affluent, insured communities—rather than the vulnerable, needy populations that the 340B Program was intended to benefit. *See*, *e.g.*, Berkeley Rsch. Grp., *340B Covered Entity Acquisitions of Physician-based Oncology Practices* (Apr. 22, 2014) (*Covered Entity Acquisitions*), https://bit.ly/3zqMOz8; Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, 33 Health Affs. 1786 (2014), https://bit.ly/3ZFC9uP.

58. In 2023, for instance, researchers estimated that 65% of DSH covered entities were not located in HRSA-designated "medically underserved areas"—the areas that the 340B program was designed to help. AIR340B, *340B - A Missed Opportunity To Address Those That Are Medically Underserved: 2023 Update* 4 (2023), https://bit.ly/4eDzyG1. Part of this expansion is due to covered entities designating so-called "child sites" as eligible for 340B-pricing, many of which are "not located in socioeconomically challenged areas." *Drummond*, 808 F. Supp. 3d at 1271 (noting that, "[a]s of 2023, only 30% of 340B-eligible child sites are located in counties with either poverty rates higher than Oklahoma's statewide poverty rate or with median incomes lower than the state's median income").

59. The 340B program's expansion can also be attributed to covered entities' increased use of contract pharmacies and the "replenishment model." Under this model, a covered entity and its contract pharmacies will purchase a 340B drug at its normal commercial price, *without* a 340B discount, and will dispense that drug to a pharmacy customer at full price. Later—after the customer and his or her insurance have already paid for the drug— the covered entity may retroactively claim the customer as a 340B-eligible "patient," even if there has been no recent or direct healthcare relationship between the entity and the patient that relates to the dispensed drug. The covered entity and its contract pharmacy will then make a subsequent purchase from the manufacturer at a 340B-discounted price in order to "replenish" their stock, even if that replacement drug will not be sold to a 340B patient. Contract pharmacies almost always maintain a single inventory of intermingled drugs, from which they fill prescriptions both for 340B and for non-340B patients. *See, e.g.*, *Novartis*, 102 F.4th at 457–58 (describing "replenishment model"). This process allows covered entities (and their contract pharmacies) to profit from the price difference, even when the discounted drug is not provided to a qualifying patient.

60. Despite the 340B program's goal of helping vulnerable patients, as the 340B program has grown, patients have fallen to the wayside—with covered entities and contract pharmacies focusing instead on their own profits. For instance, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* 340B discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. The GAO noted that the remaining 55% of entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. And the HHS Office of Inspector General found in 2014 that some contract pharmacies do not offer 340B-discounted prices to uninsured customers *at all*. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), https://bit.ly/4bLKqU0. As a result, even uninsured pharmacy customers "pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.*

61. This exploitation of the 340B program is well-documented and well-recognized. In 2013, Senator Chuck Grassley wrote to HRSA expressing concern that for-profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Grassley Letter at 3. This "spread" means that contract pharmacies—entities who are not identified as intended beneficiaries of the 340B program— retain up to $5 billion in annual profits from 340B sales.

62. Twelve years after Senator Grassley expressed concern over the 340B program and contract pharmacies' profits, the Senate Committee on Health, Education, Labor, & Pensions published a report titled "Congress must act to bring needed reforms to the 340B drug program." *See* Majority Staff Report, Senate Comm. on Health, Educ. Labor, & Pensions (Apr. 2025), https://bit.ly/4cmIpN9. The report found that covered entities, contract pharmacies, and third-party

administrators generated enormous profits from their participation in the 340B program. *See id.* Despite providing billions of dollars in discounts, however, manufacturers still struggled to ensure 340B program integrity. *Id.* at 31–32. Academics studying the 340B program have observed similar trends. *See, e.g.*, Neal Masia, *340B Drug Pricing Program: Analysis Reveals $40 Billion in Profits in 2019*, Alliance for Integrity & Reform 2 (May 2021), http://bit.ly/4bM7sHE; Rory Martin et al., IQVIA, *Unintended Consequences: How the Affordable Care Act Helped Grow the 340B Program* 5 (Aug. 30, 2024) (*Unintended Consequences*), https://bit.ly/4e7XHDX ("From 2013 to 2021, while the size of the vulnerable population [was] almost halved (due to greater access to insurance), 340B drug discount revenue [for covered entities] grew by 374% . . . .").

63. The increased use of contract pharmacies does not only lead to greater pharmacy profits. It also substantially increases the risk of diversion. Diversion allows "covered entities [to] achieve arbitrage at scale, undercutting manufacturers' ability to sell at a profit." *McCuskey*, 2026 WL 898259, at *2. Among other things, when a single covered entity uses multiple contract pharmacies, the volume of drugs distributed at 340B prices—including to insured individuals, to individuals who live in affluent communities far from the covered entity, and to individuals whose relationship with the covered entity consists only of perfunctory telehealth visits rather than ongoing or regular care—multiplies as well. And as studies have shown, under the replenishment model, drugs sold at 340B prices are more likely to end up in the hands of pharmacy customers who do not qualify as proper patients of a 340B entity.

64. This is not mere speculation: Government-published reports confirm that widespread use of contract pharmacies has led to rampant 340B program abuse. For example, in 2020, the GAO reported that 1,242 HRSA-conducted audits of covered entities from 2012 through 2019 showed 546 instances of diversion and 429 instances of duplicate discounts with the

Medicaid Program. U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 13 (Dec. 14, 2020), https://perma.cc/7GS2-HDT2. In other words, over 40% of HRSA's audits found that covered entities were allowing 340B-priced drugs to end up in the hands of individuals who were not "patients" of the covered entities. Without these audits, this abuse likely would have gone undiscovered.

The Best Reading of "Patient" in the 340B Statute

65. As noted, the 340B statute prohibits covered entities from reselling or otherwise transferring 340B-discounted drugs "to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B),

66. Congress did not define the term "patient." That is likely because, at the time of its enactment, all involved parties understood that the 340B program was meant to help indigent and uninsured individuals get access to low-priced drugs. *See, e.g.*, H.R. Rep. No. 102-384, pt. 2, at 10 (discussing impact on Department of Veterans' Affairs hospitals and other healthcare providers who serve "low-income and uninsured patients"). Congress thus anticipated that covered entities would use 340B discounts to help those patients, rather than to generate arbitrage revenue.

67. Especially in light of the dramatic growth of the 340B program, the definition of "patient" is of critical importance to manufacturers like AbbVie. The term is central to determining whether covered entities are in compliance with 340B program requirements, and whether manufacturers are providing discounts only in accordance with Congress's intentions. Manufacturers like AbbVie also elect to participate in the program—and periodically renew their participation agreements—after carefully weighing the benefits and obligations of participation. They thus need to know the full scope of their obligations as 340B participants in order to make an informed decision.

68. Congress did not expressly give HRSA authority to define the term "patient," nor did it give the agency rulemaking authority with respect to the statute generally. *See PhRMA v. HHS*, 43 F. Supp. 3d 28, 37–45 (D.D.C. 2014). As a result, any dispute about the "best reading" of the statute ultimately must be resolved by "'the reviewing court'—not the agency whose action it reviews." *Loper Bright*, 603 U.S. at 400, 398 (quoting 5 U.S.C. § 706).

69. Nevertheless, in 1996, HRSA issued non-binding guidance setting forth the agency's purported understanding of key terms in the 340B statute, including the meaning of "patient" as it is used in the prohibition on diversion. *See* 61 Fed. Reg. at 55,156–58. The 1996 Guidelines provide, in relevant part, that an individual is a 340B-eligible "patient of the [covered] entity" if:

> 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
>
> 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
>
> An individual will not be considered a "patient" of the entity for purposes of 340B if 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 55,157–58.

70. HRSA has not updated its proposed interpretation of the term "patient" since issuing the 1996 Guidelines. However, in a tacit acknowledgment that its 1996 Guidelines were too broad, HRSA proposed a new interpretation of the term in 2015, but this proposed guidance was never finalized. 80 Fed. Reg. 52,300, 52,306–07 (Aug. 28, 2015).

71. As the Supreme Court has explained, legislative enactments must be interpreted to "effectuate the will of Congress subject to constitutional limits." *Loper Bright*, 603 U.S. at 395. Where, as here, Congress has been silent on the meaning of a statutory word or phrase, interested parties and courts must accordingly identify the "best meaning" of the text. *Id*. at 400.

72. The text, structure, and the history of the 340B statute make clear that HRSA's interpretation of "patient," as set forth in the 1996 Guidelines, is *not* the "single, best meaning" of "patient" as that term is used in the 340B statute. *Id.* at 400. Rather, HRSA's 1996 Guidelines stray from the statutory text, facilitating program abuse and other consequences that Congress never intended.

73. Consider, as just a single example, the fact that HRSA's 1996 Guidelines require only that a "covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care." 61 Fed. Reg. at 55,156. That means the covered entity can collect a 340B discount (and can generate arbitrage revenue) on a prescription from *another* provider that was dispensed to a wealthy, insured individual who only had a single 10-minute telephone call with the covered entity at some point in the past—even if that call had nothing to do with the prescription—so long as the covered entity maintains some form of a "record" of that previous, unrelated encounter. In this example, such a prescription would have arisen from the health care provided by a *different* provider, which could be a non-340B entity. Yet under HRSA's guidance, the covered entity would *still* be able to claim this prescription as 340B-eligible, since the covered entity "has established a relationship" with the individual and "maintains records of the individual's health care." This absurd result—allowing the covered entity to claim 340B discounts based on a brief, unrelated phone call— is inconsistent with the most textually faithful reading of the term "patient" and demonstrates that HRSA's definition enables

exactly the kind of program abuse Congress sought to prevent. And HRSA's definition makes this sort of abuse even more likely when it is coupled with the replenishment model used by most covered entities, because the model relies on recharacterizing prior pharmacy sales as 340B-eligible based on records showing a relationship (however attenuated) between the pharmacy sale and the covered entity.

74. HRSA's 1996 Guidelines misinterpret the term "patient" as the term is used in the 340B statute and its anti-diversion provision. The best reading (and the one put forward to HRSA in AbbVie's audit plans) is that the following elements must be met for an individual to qualify as a "patient" of a covered entity:

(I) **Legitimate Healthcare Service from Covered Entity:** The individual receives an outpatient healthcare service from a covered entity site that is registered and listed in the 340B Office of Pharmacy Affairs Information System (OPAIS) database—HRSA's database for 340B participant registration—and that service meets all of the following requirements:

(a) **Direct Connection Between Prescription and Care from Covered Entity:** The covered outpatient drug is prescribed as a direct result of the healthcare encounter by a healthcare professional who is acting pursuant to an employment or contractual agreement under which the healthcare professional provides services at the covered entity site;

(b) **Substantive Medical Care**: The healthcare encounter is sufficient to allow the healthcare professional to meet clinical practice standards for diagnosing and treating the condition for which the covered outpatient drug is prescribed;

(c) **Timely Care Relationship**: The healthcare service takes place no more than 12 months prior to the dispensing or administration of the covered outpatient drug; and

(d) **Compliant with Funding**: For covered entities other than Disproportionate Share Hospitals, the healthcare service is consistent with the services for which grant funding or federally qualified health center look-alike status has been provided to the entity.

(II) **Direct Oversight**. The healthcare professional who provides the service described above has direct oversight of the individual's care, which means that:

(a) **Prescriber Oversees Condition for which 340B Priced Drug Is Prescribed**: The healthcare professional is personally responsible for diagnosing and directly managing the patient's condition for which the covered outpatient drug is prescribed as part of a provider-patient relationship that is sufficient to meet clinical practice standards for diagnosing and treating the condition for which the covered outpatient drug is prescribed; and

(b) **Covered Entity Manages Patient's Care**: The covered entity maintains primary responsibility for care for the patient's condition for which the covered outpatient drug is prescribed.

75. As explained further below, this understanding of "patient" is based on the best reading of the text, structure, and history of the 340B statute. It best "interpret[s] the statute and effectuate[s] the will of Congress" and represents the "single, best meaning" of the 340B statute. *Loper Bright*, 603 U.S. at 395, 400.

Text

76. The 340B statute provides that "a covered entity shall not resell or otherwise transfer [a 340B] drug to a person who *is not a patient* of the entity." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). Congress used the present tense in defining "patient," indicating that a qualifying individual must have a current, active relationship with both the covered entity and with a specific prescribing healthcare professional at that entity.

77. The use of the present tense excludes former or inactive patients from Congress's intended "patient" population, indicating that Congress intended "patient" to refer to individuals who had recent interaction with the covered entity. This supports the "Timely Care Relationship" requirement that healthcare services occur within 12 months of drug dispensing.

78. The text also indicates that (1) there must be a direct connection between the prescription and the care provided by the covered entity, and (2) that there is substantive medical care such that the healthcare service is sufficient to ensure that the 340B-priced drug is appropriately prescribed—not merely a perfunctory interaction.

79. Congress's use of present tense supports that there must be a substantive connection between the healthcare visit the "patient" received from the covered entity and the drug prescribed subject to 340B program requirements.

80. Similarly, the provision of substantive medical care from "the [covered] entity" follows from the ordinary meaning of "patient," as it ensures the covered entity actually manages the patient's care for the condition for which the drug is prescribed. Indeed, a common thread across dictionary definitions of the term "patient" is that the individual in question is actively being cared for by a medical professional. *See, e.g.*, *Patient*, Merriam Webster's Dictionary ("[A]n individual awaiting or under medical care and treatment."). Common to this definition and others is that the individual be presently receiving medical care or treatment from a specific health care professional. *See, e.g.*, *Patient*, Cambridge English Dictionary ("a person who is receiving medical care, or who is cared for by a particular doctor . . . when necessary"); *Patient*, Collins Dictionary ("[A] patient is a person who is receiving medical treatment from a doctor or hospital."); *Patient*, Oxford English Dictionary ("A person receiving or . . . registered to receive medical treatment, esp. at a particular establishment or from a particular practitioner."); *Patient*, Black's Law Dictionary ("A person under medical or psychiatric care."). This ordinary meaning supports the "Substantive Medical Care Required" element of the proper patient definition.

81. The Supreme Court has repeatedly held that such plain meaning readings of statutory terms are required, as "those whose lives are governed by law are entitled to rely on its ordinary meaning." *Feliciano v. Dep't of Transp.*, 605 U.S. 38, 45 (2025).

82. These dictionary definitions demonstrate that the ordinary meaning of "patient" is someone actively receiving medical care—*i.e.*, someone who had a recent interaction that led to the prescription—from a healthcare provider. The American Medical Association's Code of

Medical Ethics supports this reading, as that definition also utilizes the present tense when describing when a patient-physician relationship exists. *See* AMA, *Opinion 1.1.1: Patient-Physician Relationships*, https://perma.cc/G9ZC-ZZL7 ("A patient-physician relationship exists when a physician serves a patient's medical needs.").

83. This interpretation of the term patient also makes sense in the context of the 340B statute. The 340B program is about the purchase of covered outpatient drugs for a "patient of the entity," so the care or treatment provided to "the patient" by "the entity" should be related to the 340B-priced drug being prescribed. The care and treatment inherent in the meaning of patient and the present-tense language means that a *de minimis* encounter—one that may pass muster under HRSA's 1996 definition—lacks the provision of substantive medical care for a patient and cannot therefore meet the standard of a patient-professional relationship under the 340B statute.

84. The requirement that the provider have oversight over the condition for which the 340B-priced drug is prescribed is also inherent in the statute's requirement of a patient-provider relationship, the common understanding of which requires such oversight and continuing care. For example, the American Medical Association explains that providers have an obligation to ensure that "the care patients receive is safe, effective, patient centered, timely, efficient, and equitable," AMA, *Opinion 1.1.6: Quality*, https://perma.cc/A78W-84T4, a feat that would not be possible without regular, ongoing encounters that are sufficient to allow the provider to accurately oversee, diagnose, and treat a particular condition. By contrast, a brief one-time 10-minute telehealth visit solely for the purpose of qualifying a particular prescription as 340B-eligible in order to obtain 340B revenue is not a proper application of the statutory term "patient," as such a superficial encounter does not allow the prescriber to "oversee the condition for which 340B priced drug is

prescribed" or allow the covered entity to "manage the patient's care" under the proper patient definition.

Structure

85. The structure of Section 340B further demonstrates that the interpretation of "patient" set forth in AbbVie's audit work plans reflects the best meaning of the term.

86. The 340B statute creates a highly reticulated scheme, open only to a small set of narrowly defined categories of beneficiaries and the individuals they serve. Congress specifically provided that drug manufacturers participating in the 340B program are only obligated to offer their covered outpatient drugs at discounted 340B prices to specific types of entities, and only obligated to provide one discount for a particular drug unit.

87. There are currently fifteen types of covered entities under the 340B program, all of which meet specific statutory criteria or receive specific grants of federal funds. *See* 42 U.S.C. § 256b(a)(4)(A)-(O). For example, the list includes federally qualified health centers as defined by a specific provision of the Social Security Act, state-operated AIDS drug purchasing assistance programs receiving financial assistance under federal law, black lung clinics receiving funds under a specific provision of federal law, critical access hospitals as determined under section 1820(c)(2) of the Social Security Act and that meet certain requirements, Native Hawaiian Health Centers receiving funds under the Native Hawaiian Health Care Act of 1988, and Disproportionate Share Hospitals (as described above). Each of these categories was narrowly drawn with exacting precision; Congress was extremely specific as to what entities qualified as covered entities.

88. The universe of qualifying covered entities is further narrowed beyond those fifteen categories: If a "distinct part of a hospital" may qualify as a covered entity, the rest of the hospital does *not* automatically qualify as a covered entity; the hospital as a whole must independently

qualify as a covered entity under the 340B statute. *See* 42 U.S.C. § 256b(a)(6). The presence of a qualifying black lung *clinic* on the grounds of a for-profit hospital complex, for instance, does not entitle the *hospital* to discounted 340B pricing.

89. Further, Congress's prohibitions on duplicate discounts and diversion codify that the 340B program was in fact limited in scope. Congress intentionally did not require that drug manufacturers offer 340B prices for *every* covered outpatient drug purchased by a covered entity; it instead said that a "covered entity shall not request" 340B pricing on a unit of a drug "if the drug is subject to the payment of a rebate to the State" under the MDRP. *Id.* § 256b(a)(5)(A)(i). Similarly, Congress barred covered entities from "resell[ing] or otherwise transfer[ring covered outpatient] drug[s] to a person who is not a patient of the entity," *id.* § 256b(a)(5)(B), ensuring that 340B prices are limited to patients who are actually receiving bona fide medical care at the covered entity.

90. These carefully crafted structural features demonstrate that Congress took steps to strictly delimit the scope of the 340B program. These narrow limitations, along with Congress's concern with—and its express prohibition of—diversion, supports that Congress rejected the kind of freewheeling approach to statutory terms embraced by HRSA and by many covered entities. *See AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021), *aff'd sub nom. Sanofi Aventis*, 58 F.4th 696; *Novartis*, 102 F.4th at 456.

91. The specificity and meticulousness used throughout the 340B statute carries over into the best reading of the meaning of the term "patient." As shown by the hypothetical in ¶ 73, *supra*, and the real-world examples and in ¶¶ 135, 136, 152, *infra*, a loose, malleable definition like HRSA's in the 1996 Guidelines permits the same individual to be claimed as a "patient" by more than one covered entity with respect to a particular prescription. Surely nothing in the statute

can be read to obligate a manufacturer to provide 340B discounts to multiple different covered entities on a single unit of drug, the absurd (yet presently occurring) result of the application of HRSA's malleable patient definition. Further, it allows an individual to be deemed a "patient" after just one superficial or cursory encounter with the covered entity, even if that interaction was not recent and even if neither the covered entity nor the prescriber actively oversees and manages the patient's care. Those results cannot be squared with the structure of the statute in which that term is found. Indeed, the presence of a highly reticulated list in a statute sheds light on Congress's intended narrow scope of other terms used in the same statutory provision. *See Fischer v. United States*, 603 U.S. 480, 493-94 (2024). Just as the statute was interpreted narrowly in *Fischer*, the term "patient of the entity" in Section 340B should be read narrowly in light of the highly defined scope of the 340B program and the anti-diversion and duplicate discount provisions.

Purpose and History

92. While the text (including the structure) of Section 340B definitively establishes that "patient" should be defined specifically, the purpose and history of the statute further corroborate that understanding.

93. Congress struck a balance between increasing patient access and "assur[ing] the integrity of the drug price limitation program." H.R. Rep. No. 102-384, pt. 2, at 16. While a key House report states that the 340B program was created to help covered entities to "stretch scarce Federal resources as far as possible," that statement was expressly tied to reaching "more *eligible patients* and providing more comprehensive *services*"—language further confirming that the statute requires a direct connection between the prescription and the care from covered entity. *Id.* at 12 (emphases added).

94. The legislative history confirms that the 340B program was targeted in scope. Congress designed the 340B program to benefit patients by restoring the reduced pricing that manufacturers had *voluntarily* provided to safety-net providers before 1990 to help indigent and uninsured patients. *See id; see also* ¶ 31, *supra.* At the time of the 340B statute's passage, only approximately 90 DSHs existed in the entire United States. H.R. Rep. No. 102-384, pt. 2, at 13. Congress accordingly anticipated that its inclusion of DSHs as covered entities would apply to approximately the same number of covered entities. But today there are nearly *1,200* DSHs nationwide—a more-than twelvefold increase. Congress could have never anticipated this exponential growth.

95. Even after narrowly defining the universe of covered entities, Congress placed additional safeguards against program abuse. The legislative history shows that Congress recognized that covered entities "would be prohibited from obtaining payment for these drugs under Medicaid or from reselling or transferring the drugs to individuals other than their patients, and they would be subject to audit to verify compliance with these requirements." *Id.* at 12. Congress intended this to be a meaningful limit on the scope of the statute.

96. Section 340B's prohibition on diversion (and its related prohibition on duplicate discounts) are not only sound policy judgments that Congress made and reflected in the statute, but they are also essential to ensure that the statute remains within constitutional bounds. As discussed, Congress has no authority to force manufacturers to transfer unlimited drugs at discounts of up to 99.99% to covered entities and commercial pharmacies for their own private financial benefit. Such a scheme would violate the Takings Clause. *See Drummond*, 808 F. Supp. 3d at 1279–80 (finding that a state law requiring 340B discounts for unlimited contract pharmacy sales violates the Takings Clause). To satisfy constitutional requirements, therefore, the

obligations imposed by the 340B statute must have a close nexus to a valid governmental purpose and must be proportional to the benefits that manufacturers receive in return for participating in the 340B program and Medicaid. Drug manufacturers can then weigh the costs *and benefits* of participating in these federal programs in deciding whether or not to agree to participate. Indeed, as the costs of 340B participation have grown in recent years, some drug manufacturers have determined that the burdens outweigh the benefits and have opted out of 340B participation.

97. Congress intended the 340B program to be a limited program that would restore the previously voluntary discounts that drug manufacturers offered to certain safety net providers. In recognition of the potential for abuse in offering such steep discounts, Congress included safeguards that would preserve the program's narrow scope. But, in the absence of a meaningfully circumscribed interpretation of the term patient, a covered entity can characterize a broader range of customers—including individuals who receive prescriptions from a provider not employed by the covered entity or unrelated to the care they receive from the covered entity—as its own "patients." More 340B patients means more 340B discounts, generating more arbitrage profit for covered entities and the commercial pharmacies with which they contract. This is why the requirements that there be direct oversight by the prescribing physician and management of care by the covered entity are clearly included in the appropriate meaning of "patient" under the limited 340B program that Congress created.

98. Congress did not anticipate the unchecked growth of the 340B program over the past three decades.

99. Nor did Congress anticipate the emergence of contract pharmacies and covered entities' increasing targeting of affluent, insured communities.

100. The legislative history and context of the 340B statute demonstrate that Congress was aiming to create a narrowly defined benefit for a narrow group of entities providing care to the indigent and uninsured, which both the government and manufacturers could readily police to ensure compliance. The meaning of "patient" adopted by AbbVie and listed above is consistent with that understanding.

FACTUAL ALLEGATIONS

HRSA Creates Guidelines for Manufacturer Audits

101. Congress directed HRSA to protect the 340B program's integrity and ensure that the program is used for the benefit of uninsured and indigent patients by implementing improvements necessary to ensure that covered entities comply with their statutory obligations. Rather than comply with Congress's commands, however, HRSA has refused to enforce the statute and has instead weakened its essential protections against diversion and duplicate-discounting. Instead of allowing manufacturers to help police program abuses, as Congress intended, HRSA has erected barriers that have made it difficult for manufacturers to obtain the remedies that Congress provided.

102. Congress provided that covered entities "shall permit" manufacturers to conduct audits, subject only to "procedures established by the Secretary relating to the number, duration, and scope of audits," 42 U.S.C. § 256b(a)(5)(C). In 1996, HRSA adopted guidelines for manufacturer audits. *See* 61 Fed. Reg. at 65,406–410. Among other things, the guidelines require manufacturers to submit an audit workplan to HRSA prior to auditing a covered entity. They further require that the auditor be an independent public accountant employed by the manufacturer, that the auditor follow current Government Auditing Standards, and that the auditor prepare an audit report "[a]t the completion of the audit." *Id.* at 65,409.

103. HRSA's audit guidelines also impose an additional threshold requirement that manufacturers must satisfy before they can exercise their statutory audit right. In a subsection titled "Number of Audits," the guidelines assert that a "manufacturer shall conduct an audit only when it has documentation which indicates that there is reasonable cause" to "believe that a covered entity may have violated a requirement of section 340B(a)(5)(A) or (B)" (*i.e.*, is engaging in diversion or collecting duplicate discounts). *Id.*

104. Also in the "Number of Audits" section, HRSA created a guideline that "[o]nly one audit of a covered entity will be permitted at any one time." *Id.*

105. In a subsection titled "Scope of Audits," the guidelines require a manufacturer to submit an audit workplan to HRSA for review. HRSA will "review the workplan for reasonable purpose and scope." *Id.* The guidelines then specify which records may be accessed during the audit.

106. In a section regarding the "Duration of Audits," the guidelines state that "[n]ormally, audits shall be limited to an audit period of one year," but also that they must be performed in the "minimum time necessary." *Id.* at 65,410.

107. The guidelines further require that (1) a manufacturer must notify a covered entity in writing that it believes the entity has violated Section 340B; (2) the manufacturer and covered entity must attempt in good faith to resolve the matter for "at least 30 days;" and (3) the manufacturer must file a work plan with HRSA that sets forth "a clear description of why it has reasonable cause to believe" a violation of 340B has occurred, with "sufficient facts and evidence." *Id.*

108. The guidelines set forth the types of information that must be included in a manufacturer's workplan. Upon receiving the workplan, HRSA has 15 days to review the

workplan. If HRSA has concerns, it "will work with the manufacturer to incorporate mutually agreed-upon revisions to the plan." *Id.* In 2011, HRSA clarified that, per these guidelines, upon receiving a proposed audit workplan, OPA "will work with manufacturers in its consideration of submitted audit work plans, and will respond within 15 calendar days with *an approval or denial* of the submitted work plan." HRSA, *Clarification of Manufacturer Audits of 340B Covered Entities* (Nov. 21, 2011) (emphasis added), https://bit.ly/4tpNuLw.

109. After the audit is complete, the manufacturer must provide a copy of an audit report both to the covered entity and to HRSA. If the covered entity disagrees with any of the audit's findings, the guidelines set forth a procedure for the covered entity to raise those disagreements. *Id.*

110. In sum, although the 340B statute provides a manufacturer with an almost unconditional right to audit covered entities, HRSA's guidelines require the manufacturer to seek HRSA's permission prior to initiating an audit (among various other requirements). Manufacturers thus must follow HRSA's guidelines before they can conduct an audit; and if HRSA *does not* grant such permission, the manufacturer will be prevented from conducting the audit—and will accordingly be unable to seek HRSA's enforcement of the statute's diversion and duplicate-discounting prohibitions. In that situation, the manufacturer will not have any ability to recover for 340B discounts that were improperly obtained because its drugs were "transfer[red] . . . to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The integrity of the 340B program will thus be damaged, and covered entities will be incentivized to abuse the patient definition to generate a "spread."

AbbVie Seeks to Limit Covered Entity 340B Statute Violations

111. AbbVie has been a participant in the 340B program for more than three decades. Over the course of its time in the program, AbbVie has had a front row seat to the program's massive growth—and the corresponding emergence of systemic program abuse.

112. As a longtime 340B program participant, AbbVie is invested in maintaining program integrity. AbbVie believes the 340B program should function the way that Congress intended: increasing access to 340B-priced drugs for the benefit of underserved communities and individuals in need, rather than generating arbitrage revenue for the benefit of for-profit pharmacies and hospitals. Because AbbVie has participated in the 340B program since the 1990s, AbbVie is very familiar with its statutory obligations and restrictions—and is also familiar with the obligations and restrictions that Congress placed on covered entities in service of program integrity. AbbVie regularly monitors 340B buying activity, one of its only windows into monitoring for potential program abuse.

113. Over the last decade, AbbVie observed a rapid rise in the number of contract pharmacies that covered entities were using to purchase 340B-priced drugs. This enabled large pharmacy chains—and sophisticated hospital systems—to pocket windfall profits while patients continued to pay full commercial prices for the drugs that covered entities (and their contract pharmacies) were buying at 340B-discounted pricing, sometimes just pennies on the hundreds-of-dollars.

114. In an effort to combat this program abuse, in February 2022, AbbVie implemented a policy of providing a hospital covered entity 340B pricing through a single contract pharmacy of its choosing. The U.S. Court of Appeals for the Third Circuit upheld such policies in 2023, *see Sanofi Aventis*, 58 F.4th at 699, and the D.C. Circuit agreed in 2024, *see Novartis*, 102 F.4th at 461.

115. Notwithstanding AbbVie's contract pharmacy policy, the exponential growth in 340B-drug purchases by covered entities continued unabated. This substantial growth trend raised suspicions about whether covered entities were complying with the statute's anti-diversion provision—and the best understanding of "patient of the entity," as used in that provision—as discussed above. In light of these suspicions, AbbVie began to take a closer look at covered entities' claims data and purchasing patterns.

116. As noted, the anti-diversion provision makes clear that, "[w]ith respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to *a person who is not a patient of the entity*." 42 U.S.C. § 256b(a)(5)(B) (emphasis added). Thus, the rapid growth in 340B sales—more than triple the growth of drug sales generally, *see* IQVIA, *The 340B Drug Discount Program Grew to $124B in 2023*, at 2 (2024), https://bit.ly/47zKdRe—suggests potential diversion. In other words, if 340B-priced drugs are transferred to ineligible patients, then covered entities will be purchasing more drugs at the 340B price than if they were only going to eligible patients.

AbbVie Seeks to Audit Covered Entities Due to 340B Program Abuse

117. AbbVie regularly reviews 340B purchase data for behavior suggestive of potential diversion or duplicate-discounting. In 2024, AbbVie identified anomalous trends for multiple covered entities, including: Barrio Comprehensive Family Health Care Center, Inc. (Barrio) and The Mount Sinai Hospital (Mount Sinai).

Barrio

118. Barrio (340B ID: CH062360) is a HRSA-funded health center based in San Antonio, Texas.

119. On February 6, 2025, AbbVie sent Barrio a letter reporting that, as part of routine oversight, AbbVie had identified unusual and atypical buying activity by Barrio from January 1,

2021, through December 31, 2024. Specifically, Barrio's 340B purchases of three AbbVie Immunology Products (Humira®, Skyrizi®, and Rinvoq ®) had increased by over 119% from 2021 to 2022, and over 53% from 2022 to 2023.

120. AbbVie's data also revealed that Barrio was the only covered entity in the top five purchasers of the Immunology Products in the United States that was not a DSH. Further, Barrio was the top purchaser of the Immunology Products among *all* Health Centers and Federally Qualified Health Centers nationwide. Unlike DSHs, which are large hospital facilities serving substantial patient populations, Barrio is a comparatively small health center that would not ordinarily be expected to generate purchasing volumes of this magnitude.

121. AbbVie compared Barrio's purchasing behavior to that of other covered entities in Texas and found further anomalies. Although 80% of 340B purchases of AbbVie products (by all Texas covered entities) were dispensed through pharmacies located in Texas, 71% of Barrio's purchases utilized pharmacies located *outside* of Texas. Given the requirement that 340B-priced drugs must be used only by "patients" of the entity, this high number of out-of-state transactions raised a serious red flag: How could so many "patients" of Barrio be purchasing products outside of the State in which Barrio is located?

122. In light of this data, AbbVie asked Barrio to answer a number of questions relating to Barrio's 340B policies. Barrio met with AbbVie on March 7, 2025, to address these questions.

123. At the March 7 meeting, Barrio explained aspects of its approach to determining whether a prescription is 340B-eligible. Among other things, Barrio said that it *does not* require its "patients" to have in-person visits with Barrio; that an individual is considered a "patient" for 24 months after the date of a medical encounter; and that a prescription would still be deemed 340B eligible even if it was totally unrelated to the individual's medical encounter with Barrio. In

other words, so long as an individual had *some* medical encounter with Barrio within the preceding 24 months, Barrio would qualify *any* prescription written by *any* prescriber to whom a Barrio provider made a referral as 340B eligible—even if the prescriber is not connected to Barrio at all.

124. An example illustrates the point. Consider an individual who goes to Barrio a single time for a brief (20-minute) physical exam for stomach pain, at which his Barrio general practitioner refers him to a non-Barrio gastroenterologist. Over time, the individual and the non-Barrio gastroenterologist establish a doctor-patient relationship. A year and a half after the Barrio physical, the non-Barrio gastroenterologist diagnoses the individual with ulcerative colitis and prescribes Humira. Even though the individual has had no further contact with Barrio after leaving the initial consultation a year-and-a-half earlier, under Barrio's policy, the individual would nevertheless *still* be a "patient" of Barrio, because the physical occurred within the preceding 24 months. Barrio would accordingly submit a claim to AbbVie associated with the individual's Humira prescription, seeking 340B pricing on that unit, even though the prescription was written by a non-Barrio prescriber and even though no Barrio provider had oversight over the individual's ulcerative colitis for which Humira was prescribed.

125. Indeed, Barrio further acknowledged that it does not even require *any* in-person visit before an individual was considered a "patient." In its view, a short telephone or video call was all that was necessary to establish a patient relationship for 340B purposes. In other words, according to Barrio, a provider could visually assess a serious skin condition through a 10-minute video call and, as a result, would be eligible to obtain a 340B discount for an AbbVie covered outpatient drug—despite not ever seeing the condition in person.

126. Barrio was also unable to answer why so many of their 340B contract pharmacies were located outside of Texas.

127. On March 19, 2025, AbbVie sent a communication to Barrio memorializing AbbVie's understanding of the March 7 meeting and asking additional follow-up questions. Specifically, AbbVie requested a copy of Barrio's policies regarding patient eligibility, qualified providers, and referrals, as well as a copy of the HRSA-approved Form 5 detailing the scope of Barrio's federal grant. Each of these documents would provide AbbVie with more insight into whether Barrio was violating Section 340B's diversion prohibition by reselling AbbVie products to individuals who are not properly considered "patients" of Barrio. AbbVie also asked clarifying questions about how prescriptions sent to out-of-state pharmacies were relevant to Barrio patients; about Barrio's requirements for qualifying telehealth visits as 340B eligible; and about the relationship between Barrio and its contract pharmacies.

128. On April 3, 2025, Barrio notified AbbVie that it needed "some more time" to provide AbbVie with additional information about its patient interpretation and 340B activity. Ex. 1, Reasonable Cause Letter for Barrio Comprehensive Family Health Care Center, Inc. (CH062360) (June 27, 2025), at 43. AbbVie agreed to extend the time period within which Barrio was to provide rolling responses and production of information until April 30, six weeks from the date of AbbVie's follow up letter.

129. On April 30, Barrio informed AbbVie that it "follows HRSA's 1996 patient definition guidance." Ex. 1 at 63. In particular, Barrio said that it defines a "340B eligible patient" as someone who has: "a documented care relationship and receive[s] care from a [Barrio]-employed or contracted provider that is consistent with the scope of [Barrio's] health center project. Further [Barrio] must maintain records of the individual's health care." *Id.*

130. Barrio further explained that, under its patient definition, a "patient" need only receive health care services within two years preceding a prescription to qualify for 340B eligibility

under its definition. Barrio also admitted that it did not distinguish between in-person and telehealth visits. Barrio attributed its increased 340B purchases to a "rising patient volume" and increased telehealth capabilities. *Id.* at 62. Although consistent with HRSA's 1996 patient definition, Barrio's responses are *not* consistent with the best reading of "patient" under the statute.

131. Moreover, the information from Barrio only heightened AbbVie's concerns about diversion. Barrio had not provided any information about the criteria that it uses to qualify an individual for 340B eligibility through a telehealth visit, such as the required relationship (if any) between Barrio and the telehealth provider and the nature of the healthcare encounter. This lack of responsiveness raised serious questions about how Barrio was finding this new patient population, where those patients were located, and whether they qualified as "patients" under the 340B statute. Moreover, AbbVie's own information revealed that Barrio was treating prescriptions written by non-Barrio providers as 340B-eligible whenever the prescription resulted from a referral from Barrio to the provider, which is yet another way that Barrio's patient eligibility criteria do not conform with the best reading of the statutory text. *Id.* at 7–8. Yet Barrio did not provide information explaining what standards Barrio was applying to document those referrals, or how it was determining that the individuals seen by those non-Barrio providers were "patients" of Barrio. With the intent of getting answers to these open questions, AbbVie sent follow-up questions to Barrio on May 7, 2025.

132. On May 30, 2025, Barrio "decline[d] to provide additional information" in response to AbbVie's inquiries. Barrio attempted to justify its refusal to engage further on the ground that it could not "devote significant leadership time to responding to multiple inquiries from a single manufacturer." Ex. 1 at 131.

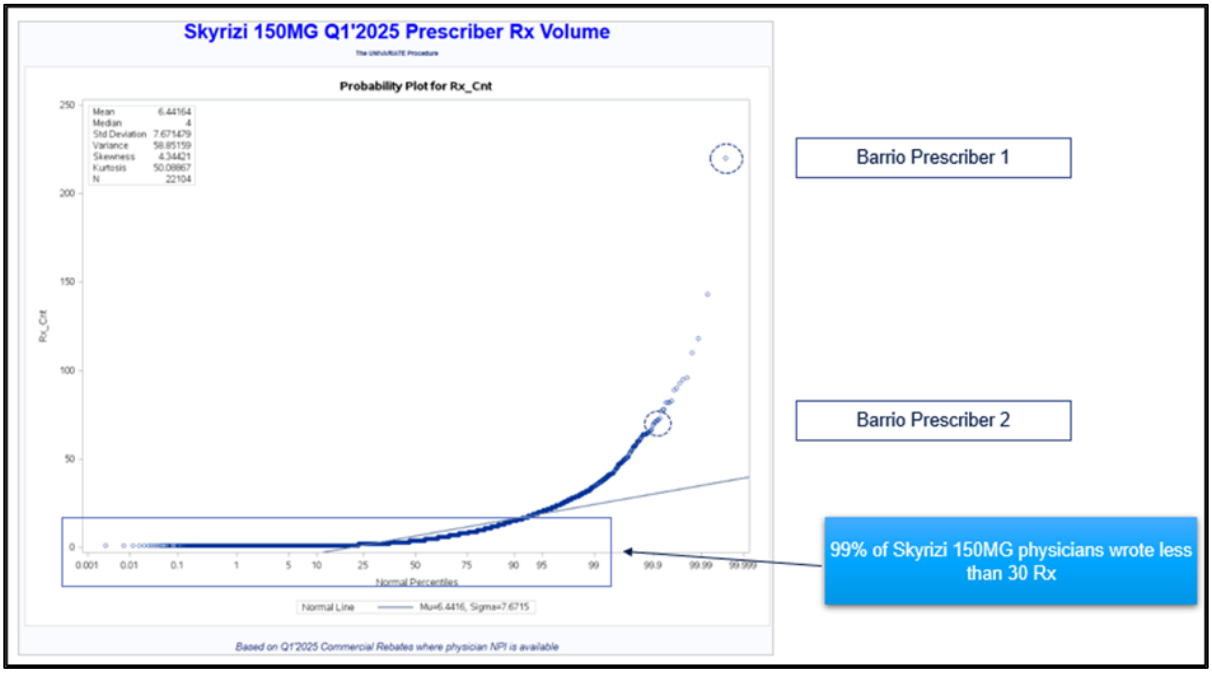
133. Barrio's answers to AbbVie's inquiries gave AbbVie significant cause to believe that Barrio was seeking discounts on AbbVie drugs that have been sold, transferred, and dispensed to individuals who do not qualify as "patient[s] of the entity" in violation of 42 U.S.C § 256b(a)(5)(B). In particular, as noted, Barrio only requires that patients be seen sometime in the *two years* preceding the prescription for the 340B-priced drug, and the 340B-priced drug does not need to relate to that prior medical encounter. Moreover, Barrio purports to allow telehealth referral to count as 340B eligible, even if the telehealth visit does not involve a bona fide medical encounter. And Barrio apparently claims 340B discounts on prescriptions written by *non*-Barrio providers, so long as the prescription resulted from a "referral" from Barrio. Those practices are directly at odds with the best reading of the 340B statute.

134. Indeed, Barrio's 340B purchase data for AbbVie's Immunology Products, which AbbVie continued to monitor during the course of its correspondence with Barrio, strongly indicates that Barrio is applying HRSA's overly expansive definition of "patient of the entity," rather than the best reading of that term.

135. For example, AbbVie's data shows that, in the first quarter of 2025, 99% of all 22,000 prescribers nationwide who wrote prescriptions for Skyrizi (150MG) wrote fewer than 30 prescriptions over the course of the quarter. However, the top prescriber in the country was a nurse practitioner at Barrio who, in a single quarter, wrote approximately 225 prescriptions claimed by Barrio as 340B eligible—and this number could be even higher, if additional claims are later

submitted by Barrio as 340B eligible. Another nurse practitioner at Barrio was in the top 99.9% of Skyrizi prescribers nationwide.

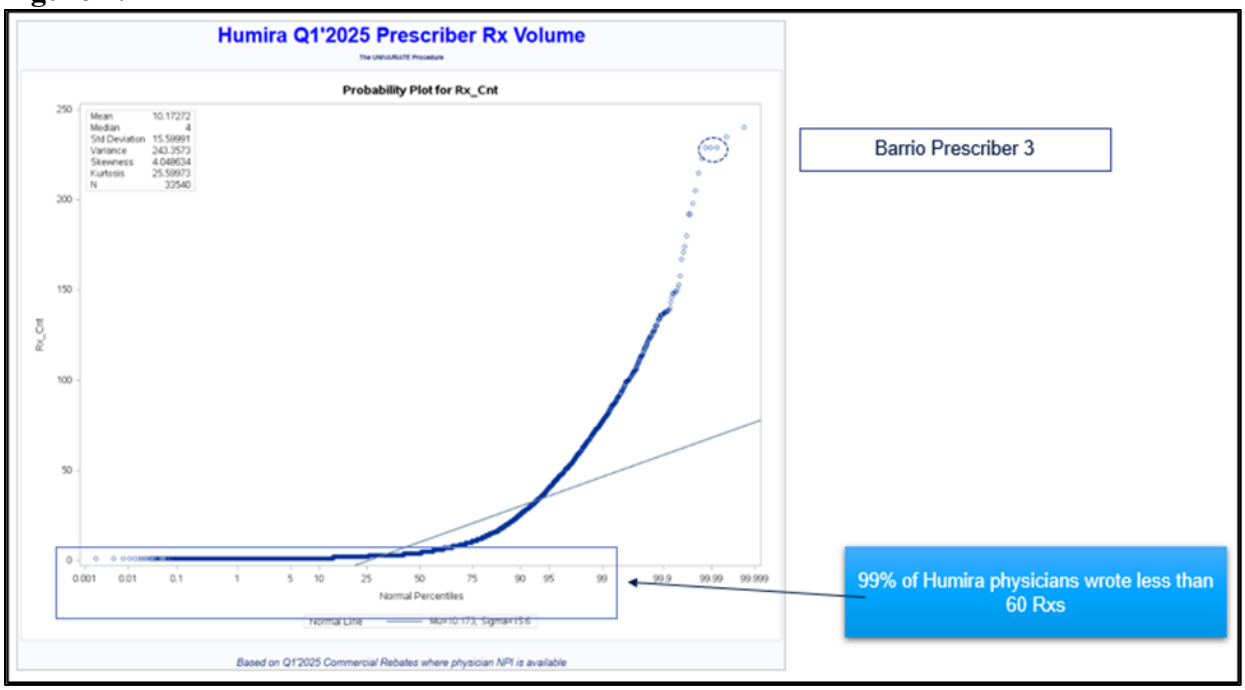
Figure 1:



136. Similarly, in the first quarter of 2025, 99% of 33,500 nationwide prescribers who wrote prescriptions for Humira wrote fewer than 60 prescriptions over the quarter. One of the top prescribers however, was a physician assistant at Barrio, who wrote nearly 250 prescriptions for

Humira claimed by Barrio as 340B eligible—and this number could be even higher, if additional claims are later submitted by Barrio as 340B eligible.

Figure 2:



137. Barrio is not a large hospital, but rather a *single* HRSA-funded health center, part of a San Antonio-based health system. Yet somehow its providers were *by far* some of the top prescribers for two different AbbVie 340B-priced drugs. When these findings are combined with previous data showing that nearly three-quarters of Barrio 340B purchases were dispensed *outside of Texas*, *see* ¶ 121, *supra*, they strongly suggest that Barrio is purchasing 340B-discounted drugs based solely on cursory telehealth visits on referrals from providers in other States, a practice that is not prohibited under the vague standards of HRSA's 1996 definition of the term "patient" but is completely at odds with the text, structure, and history of the 340B statute.

138. The information supplied by Barrio during AbbVie's good-faith inquiries, along with Barrio's refusal to answer AbbVie's additional questions, established more than just reasonable cause; they established that diversion under the 340B statute *is* actually occurring. This

prompted AbbVie to seek approval to audit, as it was clear that the data likely revealed the tip of the iceberg of such misconduct. Only an audit would present the full picture.

139. On June 27, 2025, AbbVie submitted an audit request, consistent with HRSA's guidelines, seeking HRSA's authorization to allow AbbVie to audit Barrio in accordance with its workplan. AbbVie's audit request documented the substantial evidence that AbbVie had obtained, which as noted provided reasonable cause to believe that Barrio was violating the 340B statute's anti-diversion provision and attached a corresponding audit workplan. *See* Ex. 1.

140. In particular, AbbVie specifically requested to audit Barrio against the following interpretation, which as noted above accords with the best reading of that term in the 340B statute:

> An individual is a "patient" of a covered entity when, at minimum, the following criteria are met:
>
> (I) **Legitimate Healthcare Service from Covered Entity:** The individual receives an outpatient health care service from a covered entity site that is registered and listed in the 340B Office of Pharmacy Affairs Information System (OPAIS) database—HRSA's database for 340B participant registration—and that service meets all of the following requirements:
>
> (a) **Direct Connection Between Prescription and Care from Covered Entity:** The covered outpatient drug is prescribed as a direct result of the health care encounter by a health care professional who is acting pursuant to an employment or contractual agreement under which the health care professional provides services at the covered entity site;
>
> (b) **Substantive Medical Care**: The health care encounter is sufficient to allow the health care professional to meet clinical practice standards for diagnosing and treating the condition for which the covered outpatient drug is prescribed;
>
> (c) **Timely Care Relationship**: The health care service takes place no more than 12 months prior to the dispensing or administration of the covered outpatient drug; and
>
> (d) **Compliant with Funding**: For covered entities other than Disproportionate Share Hospitals, the health care service is consistent with the services for which grant funding or federally qualified health center look-alike status has been provided to the entity.

(II) **Direct Oversight**. The health care professional who provides the service described above has direct oversight of the individual's care, which means that:

(a) **Prescriber Oversees Condition for which 340B Priced Drug Is Prescribed**: The health care professional is personally responsible for diagnosing and directly managing the patient's condition for which the covered outpatient drug is prescribed as part of a provider-patient relationship that is sufficient to meet clinical practice standards for diagnosing and treating the condition for which the covered outpatient drug is prescribed; and

(b) **Covered Entity Manages Patient's Care**: The covered entity maintains primary responsibility for care for the patient's condition for which the covered outpatient drug is prescribed.

141. AbbVie explained to HRSA that Barrio's responses to AbbVie's good-faith inquiry demonstrated that Barrio was not complying with this patient interpretation in a number of respects.

a. First, Barrio does not require that the 340B-priced drug prescribed be related to the healthcare service provided, in violation of the statute's requirement that there be a direct connection between the prescription and the care received from a qualifying healthcare professional of the covered entity.

b. Second, Barrio refused to provide information about the level of care needed for a healthcare encounter to qualify, providing reasonable cause to believe Barrio treats perfunctory and non-*bona fide* telehealth visits as qualifying encounters, despite the statutory requirement that a covered entity must provide substantive medical care to diagnose and treat the patient's condition.

c. Third, the 340B statute requires that, for an individual to be a "patient of the entity," the health care professional who provides the service leading to the 340B-priced prescription must have direct oversight over the individual's healthcare. But Barrio considers individuals patients even when a Barrio-affiliated provider has little to no

oversight over the individual's care—including where a prescription was written by non-Barrio providers—so long as the prescription resulted from a "referral" from Barrio.

142. On August 15, 2025, after previously informing AbbVie that it was not permitted to audit Barrio because another manufacturer was finishing an audit of Barrio, Chantelle Britton, Director, OPA, on behalf of HRSA, sent AbbVie a letter in which it notified AbbVie that the patient interpretation in its audit workplan "goes beyond HRSA's 1996 Guidelines, which . . . the currently operative standard for determining whether an individual is a 340B patient." Ex. 2, Letter from C. Britton, Director, OPA, to J. Colvin, Vice President, Legal Strategy, AbbVie (Aug. 15, 2025), at 1. HRSA further informed AbbVie that the agency would not "enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id.* HRSA also noted that its "letter should not be viewed as an approval of AbbVie's interpretation of the term 'patient.'" *Id.*

143. In addition to clearly rejecting the best interpretation of the statutory term "patient," which was the basis of AbbVie's audit workplan, HRSA's response asked AbbVie to revise its audit workplan to remove its request for drug order reports from WAC and GPO accounts. *Id.*

144. On September 4, 2025, AbbVie responded to HRSA's August 15 letter. Per HRSA's request, AbbVie agreed to remove from its workplan its request for drug order reports from WAC and GPO accounts. AbbVie then informed HRSA that it disagreed with HRSA's broader refusal to approve AbbVie's audit workplans for both Barrio and Mount Sinai (another covered entity discussed in further detail below). *See* Ex. 3, Letter from J. Colvin, Vice President, Legal Strategy, AbbVie, to C. Britton, Director, OPA (Sept. 4, 2025). AbbVie explained that the interpretation submitted in its workplans reflected the best reading of the term "patient" as used in the 340B statute, and that its workplans were tailored to verify that Barrio and Mount Sinai were

in compliance with the 340B statute's program integrity requirements. AbbVie noted that, based on HRSA's rejection of the statutory patient interpretation on which the workplans were based, and in light of the agency's declaration that enforcement and corrective actions would be unavailable to AbbVie if it conducted its audit based on the statutory patient interpretation, AbbVie understood HRSA's August 15 letters regarding Barrio and Mount Sinai as rejecting AbbVie's workplans. AbbVie cited HRSA's 2011 guidance on manufacturer audits, which states that the agency will respond to a submitted audit workplan "within 15 calendar days with an **approval or denial** of the submitted work plan." AbbVie thus asked HRSA to inform AbbVie by September 19, 2025, if it would approve AbbVie's audit workplans for Barrio and Mount Sinai and authorize AbbVie to proceed with its audits consistent with the statutory patient interpretation contained in those workplans, with full remedies available in the event that the audit identified a violation. AbbVie notified HRSA that if it did not hear from the agency by that date confirming approval, it would proceed consistent with its understanding that HRSA had denied the workplans.

145. On September 18, 2025, HRSA responded reiterating the position set forth in its August 15 letter. *See* Ex. 4, Letter from C. Britton, Director, OPA, to J. Colvin, Vice President, Legal Strategy, AbbVie (Sept. 18, 2025). HRSA told AbbVie that the patient interpretation set forth in its audit workplan go beyond its 1996 Guidelines' interpretation of "patient," and that HRSA's interpretation is "in accordance with section 340B(a)(5)(B) of the Public Health Service Act." *Id.* HRSA then stated it was "not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan submitted, however, to the extent findings result from AbbVie's application of a patient definition that is inconsistent with the longstanding 1996 Guidelines and the 340B statute, *OPA will not be able to impose corrective actions*." *Id.* (emphasis added).

146. HRSA's determination that the agency "will not" take corrective action based on the audit as proposed in AbbVie's workplan effectively renders AbbVie's statutory audit rights meaningless, as an audit serves no purpose if the agency will not enforce diversion findings that arise from it. As discussed in ¶¶ 45–49, *supra*, AbbVie lacks power to enforce the findings of its audits on its own and instead must rely on HRSA to enforce any diversion findings. In light of the information that AbbVie received in its good-faith discussions with Barrio, the difference between the correct statutory reading of "patient" (which formed the basis of AbbVie's workplan) and the definition in HRSA's 1996 Guidelines is material and outcome-determinative: AbbVie is confident it will identify diversion under the correct statutory interpretation of "patient."

147. HRSA's rejection of the interpretation of "patient" in AbbVie's workplan, and its refusal to enforce diversion findings based on that interpretation, are prejudicial to AbbVie, given that: (1) AbbVie had reached an impasse with HRSA, (2) HRSA only had the authority to "approve or deny" an audit, (3) HRSA stated that it would not take corrective actions stemming from anticipated findings from AbbVie's proposed audit, thus defeating the purpose of conducting such an audit, and (4) proceeding with the audit under these circumstances would be futile.

Mount Sinai

148. Mount Sinai (340B ID: DSH330024) is a DSH located in New York, New York, with associated child sites throughout New York City.

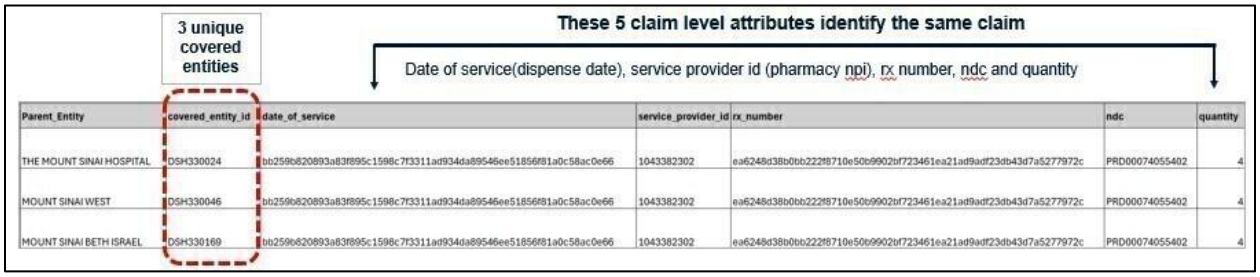
149. On March 6, 2025, AbbVie sent Mount Sinai a good-faith inquiry letter noting that, as part of its routine oversight, AbbVie had observed significant growth in Mount Sinai's 340B-priced drug purchases from the fourth quarter of 2021 through the third quarter of 2024. Specifically, AbbVie identified that Mount Sinai's purchasing volume in the first three quarters of 2024 was 35% higher than in all of 2023 combined.

150. Further, Mount Sinai had an unusual and atypical increase in 340B purchases of three Immunology Products (Humira®, Skyrizi®, and Rinvoq®). Mount Sinai's purchase of these products increased significantly and anomalously. For instance, purchases in the first three quarters of 2024 exceeded purchases made during the entirety of 2023; and purchases of some products had increased by as much as 63.9% in the first three quarters of 2023, as compared to the entire prior year.

151. Voluntary claims data received prior to 2023 (AbbVie has not received data from Mount Sinai since then) further revealed a high number of instances where Mount Sinai had claimed 340B discounting on a specific unit of a drug that was *also* claimed by another covered entity—sometimes even two other covered entities. The majority of such duplicate-dispense claims were requested by other 340B covered entities under Mount Sinai Health System.

152. For example, as shown in the below figure, The Mount Sinai Hospital, Mount Sinai West, and Mount Sinai Beth Israel—three unique covered entities under the Mount Sinai Health System—all submitted the exact same claim for reimbursement. The three submissions bear the same date of service, same provider ID, same prescription number, same NDC, and same quantity. The only difference is the Mount Sinai covered entity claiming the 340B discount.

Figure 3:



Parent_Entity	covered_entity_id	date_of_service	service_provider_id	rx_number	ndc	quantity
THE MOUNT SINAI HOSPITAL	DSH330024	bb259b820893a83f895c1598c7f3311ad934da89546ee51856f81a0c58ac0e66	1043382302	ea6248d38b0bb222f8710e50b9902bf723461ea21ad9adf23db43d7a5277972c	PRD00074055402	4
MOUNT SINAI WEST	DSH330046	bb259b820893a83f895c1598c7f3311ad934da89546ee51856f81a0c58ac0e66	1043382302	ea6248d38b0bb222f8710e50b9902bf723461ea21ad9adf23db43d7a5277972c	PRD00074055402	4
MOUNT SINAI BETH ISRAEL	DSH330169	bb259b820893a83f895c1598c7f3311ad934da89546ee51856f81a0c58ac0e66	1043382302	ea6248d38b0bb222f8710e50b9902bf723461ea21ad9adf23db43d7a5277972c	PRD00074055402	4

153. This data reinforced AbbVie's concerns that Mount Sinai covered entities are using HRSA's overly broad definition of "patient"—one that permits multiple covered entities within

the Mount Sinai system to treat the same individual as their patient with respect to the same single prescription solely because each entity keeps "records" on the individual, but where the entity does not manage the patient's care and maintain *primary* responsibility for care of the patient's condition for which the 340B-priced drug is prescribed.

154. In light of this troubling data, in its March 6 letter, AbbVie asked Mount Sinai to answer a number of questions to aid its understanding of Mount Sinai's purchases, including explaining: the policies and procedures that Mount Sinai uses to govern its 340B program compliance; the reasons for the increase in Mount Sinai purchases during the relevant time period; Mount Sinai's definition of the term "patient," including the level of care and type of service an individual must receive to be considered a 340B-eligible patient, whether telehealth appointments qualified for 340B eligibility, whether health care encounters were required to occur at a certain cadence for an individual to remain a 340B-qualifying patient; and whether a 340B-eligible prescription must be related to the health care service provided by Mount Sinai.

155. On April 4, 2025, AbbVie met with Mount Sinai to discuss the questions raised in the March 6 letter. On that call, Mount Sinai refused to provide AbbVie with its patient definition. On April 11, AbbVie followed up by email, reiterating its request for Mount Sinai's patient definition and asking Mount Sinai to send written answers to a streamlined list of its questions. Those included questions about Mount Sinai's record keeping requirements for referrals to 340B-eligible facilities; the time period between an encounter with a provider and the dispensing of a prescription that Mount Sinai uses to evaluate whether the prescription is 340B-eligible; how Mount Sinai determines 340B eligibility when a provider is affiliated with multiple entities; the documentation that Mount Sinai requires to substantiate that a medical encounter is sufficient to

establish a patient relationship; Mount Sinai's controls for differentiating between inpatient and outpatient prescriptions; and Mount Sinai's controls for mitigating duplicate-discounting.

156. On April 12, 2025, Mount Sinai responded generally that it followed "the HRSA patient definition for 'eligible patient.'" Ex. 5, Reasonable Cause Letter for The Mount Sinai Hospital (DSH330024) (July 3, 2025), at 40. It also provided written responses to two of AbbVie's questions but objected to AbbVie's other inquiries. Mount Sinai stated that its increased purchases were due to the growth of its specialty pharmacy and AbbVie's own marketing initiatives. Mount Sinai also provided further information about its process for reviewing and reprocessing 340B claims. *Id.* at 47–48.

157. On April 28, 2025, AbbVie noted with concern that Mount Sinai had responded only to *two* of the questions posed in AbbVie's good-faith inquiry letter, despite AbbVie narrowing its requests in a show of good faith. AbbVie noted that its questions were within the scope of a good-faith inquiry under HRSA's audit guidance and explained the relevance of each of its questions to AbbVie's inquiry into whether Mount Sinai was violating the 340B statute's anti-diversion provision. AbbVie also reiterated its outstanding questions to Mount Sinai. *Id.* at 55–56.

158. On May 21, 2025, Mount Sinai responded that AbbVie's questions were an "unwarranted fishing expedition" that "exceed[ed] the scope of any reasonable 'good faith inquiry.'" *Id.* at 65. Mount Sinai nevertheless provided some further information about its administration of the 340B program. Among other information, Mount Sinai reaffirmed that it followed HRSA's patient definition; that all prescriptions written within 18 months of an eligible encounter were treated as eligible for 340B discounts; that telehealth visits could be a qualifying encounter if the visit met Mount Sinai's unspecified criteria; and that some Mount Sinai providers are part-time providers. In response to AbbVie's question about Mount Sinai's record-keeping

requirement—to establish that a provider is sufficiently affiliated with Mount Sinai such that individuals seen by that provider are 340B-eligible patients—Mount Sinai responded only that its credentialing team "maintains a file of all eligible providers which is updated on a monthly basis," without providing detail about how Mount Sinai confirms sufficient affiliation. *Id.* at 66. As with Barrio's responses, Mount Sinai's responses demonstrated that Mount Sinai is not compliant with the statute's anti-diversion requirement under the best reading of the term "patient."

159. Moreover, Mount Sinai's responses raised additional questions. On May 30, 2025, AbbVie asked Mount Sinai: what criteria would qualify a healthcare professional as a "Mount Sinai provider" with "privileges within the Mount Sinai Health system;" what frequency of work was required for a provider to qualify as a Mount Sinai provider when he or she is affiliated both with Mount Sinai and with a non-340B entity; whether all Mount Sinai child sites were considered eligible locations for patient encounters; and when do virtual encounters qualify as patient encounters sufficient to establish 340B eligibility. *Id.* at 70–71.

160. On June 9, 2025, Mount Sinai responded that it "define[s] specific visit types . . . as substantive encounters," but it did not provide a full list of qualifying substantive encounters. *Id.* at 93. Mount Sinai also noted that it has some providers who work at both Mount Sinai and other entities, and that Mount Sinai does not require a provider to practice a minimum amount of time at Mount Sinai versus that other entity to be considered a Mount Sinai provider. Relatedly, Mount Sinai confirmed that it employs providers who maintain private practices in addition to working at Mount Sinai and that it will recognize virtual visits as bona fide medical encounters with Mount Sinai—but it did not provide specific information on the criteria it uses to make this determination. *Id.* at 93–95.

161. Mount Sinai's responses left AbbVie with significant questions regarding Mount Sinai's views on which of its providers are eligible to prescribe 340B-priced drugs; which patients it considered to be 340B-eligible; and what healthcare encounters are sufficient to create a "patient" relationship for 340B purposes. In a continuation of the good-faith inquiry and discussions, therefore, AbbVie sent a few limited follow-up questions on June 13, 2025. *Id.* at 97–98. Mount Sinai responded that AbbVie's questions were "an enterprise in harassment sent on Friday nights" that had "gone far afield from the essence of the issue of diversion." *Id.* at 125. Mount Sinai provided limited answers to AbbVie's follow-up questions.

162. Upon reviewing all the information in its possession, including the answers that Mount Sinai had provided, AbbVie had reasonable cause to believe that Mount Sinai sought 340B discounts on AbbVie drugs that had been sold, transferred, and dispensed to individuals who do not qualify as patients of a 340B entity in violation of 42 U.S.C § 256b(a)(5)(B). In particular, Mount Sinai defines "patient" more broadly than the 340B statute allows. Mount Sinai allows patient visits to confer 340B eligibility even when the Mount Sinai provider does not have direct oversight over the care of the patient's condition for which the 340B-priced drug is prescribed; where the prescription was written by a non-Mount Sinai provider; and, potentially, where the visit is not related to the 340B prescription written. Mount Sinai also employs part-time physicians, a practice that raises concerns about whether the provider writing the prescription and seeing the patient has a sufficiently close connection with Mount Sinai such that *Mount Sinai itself* manages the patient's care and maintains primary responsibility for care for the patient's condition for which the 340B-priced drug is prescribed. Although Mount Sinai states that its policies are consistent with the 1996 Guidelines, they violate the proper interpretation of "patient" required by the 340B statute, as set forth above, *see* ¶ 74, *supra*.

163. On July 2, 2025, consistent with the 340B statute and HRSA's audit guidelines, AbbVie sent a letter to HRSA setting forth reasonable cause that Mount Sinai is violating the 340B statute's anti-diversion provision. AbbVie followed up with a revised request on July 3, 2025. *See* Ex. 5.

164. AbbVie explained that Mount Sinai applies a "patient" definition that is broader and more inclusive than the statute allows. AbbVie's letter explained that the 340B statute requires that (1) the covered outpatient drug be prescribed only as a direct result of a healthcare encounter with a healthcare professional who is acting pursuant to an employment or contractual relationship with the covered entity site; (2) the healthcare encounter that results in the prescription and establishes 340B patient eligibility must meet clinical practice standards for diagnosing and treating the condition for which the covered outpatient drug is prescribed; and (3) the healthcare professional who provides the service must have direct oversight over the individual's care with respect to the condition for which he or she was prescribed the 340B-priced drug, such that the covered entity retains primary responsibility for care for that condition.

165. AbbVie further explained that Mount Sinai confers 340B eligibility on encounters that *do not* meet these criteria, including where Mount Sinai providers *do not* have direct oversight over the individual's care. Mount Sinai uses HRSA's 1996 Guidelines' purported definition of "patient," which requires only that the covered entity has a "record" of relationship with the patient and that the patient receives healthcare services from a Mount Sinai provider. As Figure 3, shows, this definition allows multiple Mount Sinai entities to claim the exact same prescription, merely because each entity maintains a "record" on that particular patient.

166. On July 8, 2025, HRSA notified AbbVie that it would respond to the audit request and workplan by July 25, 2025.

167. On July 22, 2025, HRSA sent a letter to AbbVie expressing the agency's "concern[]" that the audit workplan reflects AbbVie's own patient interpretation and does not follow the HRSA 1996 patient guidelines. HRSA requested that AbbVie "revise the audit work plan to reflect a review for alleged diversion based on . . . the standards set forth in HRSA's 1996 Guidelines." Ex. 6, Letter from C. Britton, Director, OPA, to E. Scheidler, Head of 340B Center of Excellence, AbbVie, Inc. (July 22, 2025).

168. On August 1, 2025, AbbVie responded to HRSA, noting its disagreement with HRSA's position that a manufacturer may conduct an audit of a covered entity only using HRSA's interpretation of the term "patient." Ex. 7, Letter from J. Colvin, Vice President, Legal Strategy, AbbVie, to C. Britton, Director, OPA (Aug. 1, 2025). AbbVie explained that HRSA's interpretation was overinclusive. Specifically, AbbVie pointed out that Mount Sinai's policies seemingly confer 340B patient eligibility on encounters where a Mount Sinai provider does not have direct oversight over the individual's care, so long as the provider performs a "medical evaluation related to" the prescription. *Id.* Though that policy would be permissible under HRSA's definition, AbbVie explained, it is not permissible under the best reading of the statute: For a patient to qualify as Mount Sinai's "patient," a Mount Sinai provider must oversee the condition for which the drug is prescribed. *Id.*

169. AbbVie accordingly asked HRSA to reconsider its position and to authorize AbbVie to audit Mount Sinai against the interpretation of "patient" set forth in its reasonable cause letter. *Id.*

170. On August 15, 2025, HRSA responded with a letter reaffirming its July 22 concerns. Ex. 8, Letter from C. Britton, Director, OPA, to J. Colvin, Vice President, Legal Strategy, AbbVie (Aug. 15, 2025). HRSA told AbbVie that the patient interpretation in its audit workplan

"go[es] beyond HRSA's 1996 Guidelines, which . . . contains the currently operative standard for determining whether an individual is a 340B patient." *Id.* HRSA then informed AbbVie that the agency would not "enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id.* HRSA also noted that its "letter should not be viewed as an approval of AbbVie's interpretation of the term 'patient.'" *Id.*

171. On September 4, 2025, as noted above, AbbVie responded to HRSA's August 15 letter. Ex. 3. AbbVie explained that its workplans reflected the best reading of the term "patient" as used in the 340B statute, and that its workplans were tailored to verify that Barrio and Mount Sinai were in compliance with the patient interpretation as articulated in AbbVie's reasonable cause letter. AbbVie noted that, based on HRSA's rejection of the statutory patient interpretation on which the workplans were based, and the agency's declaration that enforcement and corrective actions would be unavailable to AbbVie if it conducted its audit based on that interpretation, AbbVie understood HRSA's August 15 letters regarding Barrio and Mount Sinai as denying AbbVie's workplans. AbbVie cited HRSA's 2011 guidance on manufacturer audits. As noted, that guidance states that the agency will respond to a submitted audit workplan "within 15 calendar days with an **approval or denial** of the submitted work plan." Because the agency could only approve or deny the audit, HRSA's August 15 letter was a denial. AbbVie thus asked HRSA to inform AbbVie by September 19, 2025, if it would approve AbbVie's audit workplans for Barrio and Mount Sinai and allow AbbVie to proceed with its audits consistent with the statutory patient interpretation contained in those workplans, with all statutory remedies available in the event the audits identified a violation. AbbVie notified HRSA that if it did not hear from the agency by that date confirming approval of the audit consistent with the interpretation set forth in AbbVie's

reasonable cause letter, AbbVie would proceed consistent with its understanding that HRSA had denied the workplans.

172. On September 18, 2025, HRSA responded reiterating the position set forth in its August 15 letter. Ex. 4. HRSA told AbbVie that the company's patient interpretation is inconsistent with HRSA's interpretation, and that HRSA has concluded that the Guidelines are "in accordance with section 340B(a)(5)(B) of the Public Health Service Act." *Id.* HRSA then claimed it was "not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan submitted, however, to the extent findings result from AbbVie's application of a patient definition that is inconsistent with the longstanding 1996 Guidelines and the 340B statute, *OPA will not be able to impose corrective actions*." *Id.* (emphasis added).

173. As above with respect to Barrio, HRSA's determination that it "will not" take action based on the Mount Sinai audit as proposed in AbbVie's workplan renders AbbVie's statutory audit rights meaningless. Based on the information that AbbVie received in its good-faith discussions with Mount Sinai, the difference between the correct statutory reading of "patient" (which formed the basis of AbbVie's workplan) and the definition in HRSA's 1996 Guidelines is material and outcome-determinative: AbbVie is confident it will identify diversion under the correct statutory interpretation of "patient."

174. HRSA's rejection of the interpretation of "patient" in AbbVie's workplan, and its refusal to enforce diversion findings based on that interpretation, are prejudicial to AbbVie, given that: (1) AbbVie had reached an impasse with HRSA, (2) HRSA only had the authority to "approve or deny" an audit, (3) HRSA stated that it would not take corrective actions stemming from anticipated findings from AbbVie's proposed audit, thus defeating the purpose of conducting such an audit, and (4) proceeding with the audit under these circumstances would be futile.

LEGAL ALLEGATIONS

HRSA's Refusal to Enforce AbbVie's Requested Audits Rests on a Misinterpretation of Law

175. In refusing to enforce any findings from AbbVie's audit requests, HRSA applied a reading of "patient" that conflicts with the statutorily required interpretation of that term. HRSA's 1996 Guidelines articulate an improperly broad reading of "patient" that is contrary the statute, confirming that HRSA's treatment of AbbVie's audit requests was attributable to its unlawful interpretation.

176. AbbVie's request to audit Barrio established reasonable cause that Barrio was dispensing 340B-priced drugs using an overly broad definition of "patient," such that it was allowing 340B-priced drugs to go to individuals who do not meet the best statutory reading of the word "patient." Figures 1 and 2 in paragraphs 135–36 above provide illustrative examples of how Barrio's reliance on the 1996 Guidelines definition of "patient" facilitates 340B program abuse, in violation of the statute. Among other things, the definition does not require that the drug prescribed must be related to the healthcare service provided, and it allows providers to prescribe 340B-priced drugs after only superficial healthcare encounters. Nor does it require a covered entity to exercise sufficiently direct oversight over 340B-priced drug recipients' care: Barrio's anomalous claims data shows that Barrio is claiming an individual as its "patient" after the most cursory of telehealth visits, or after the individual was only referred to Barrio for the purpose of obtaining a prescription. A definition of the term "patient" that allows such rampant abuse from a single covered entity cannot be the best reading of the term, as Congress intended for the term to be understood.

177. Because Barrio defines "patient" in an overly broad manner that conflicts with the statute, AbbVie has reasonable cause to believe that Barrio is violating Section 340B's anti-diversion provision. HRSA accordingly acted contrary to law when it announced that it would not enforce findings from AbbVie's audit request of Barrio.

178. AbbVie's request to audit Mount Sinai similarly established reasonable cause to believe that Mount Sinai dispensed 340B-priced drugs using an overly broad definition of the word "patient," such that it was allowing 340B-priced drugs to go to individuals who do not meet the best interpretation of that statutory term. AbbVie had every reason to ask Mount Sinai for information following the observance of anomalous buying behavior, but Mount Sinai refused to provide full answers to AbbVie's good-faith inquiries. Mount Sinai did reveal, however, that it applies the 1996 Guidelines to define "patient," including HRSA's overly broad concept of when a healthcare encounter can create a "patient" relationship. *See* 61 Fed. Reg. at 55,157 (indicating such a relationship exists so long as the "covered entity maintains records of the individual's health care" and "the care provided remains with the covered entity"). For the reasons discussed, that definition is overinclusive and inconsistent with the 340B statute.

179. As illustrated by the example in Figure 3 in paragraph 152 above, use by Mount Sinai covered entities of HRSA's "patient" definition has led multiple covered entities under the Mount Sinai Health System to collect multiple 340B discounts on the *same* prescription. HRSA's overly inclusive definition of the term "patient" allows this because it lacks a requirement that only the covered entity with *direct* oversight over and *primary* responsibility for the care of the patient's condition for which the 340B-priced drug is prescribed may claim that individual as its "patient" for the purposes of a single prescription. Only one Mount Sinai entity can actually claim to have written the prescription and have primary care responsibility for the condition for which the drug was prescribed; yet under HRSA's definition, which lacks such a requirement, more than one Mount Sinai covered entity can claim a single individual as its "patient" at the same time for the same prescription. A definition of the term "patient" that allows such duplicate claim submissions from multiple covered entities within the same hospital system cannot be the best reading of the

term, as Congress intended for it to be understood. But the best reading of that term—as it is used in the 340B statute and as set forth in AbbVie's proposed audit workplan—would preclude such duplicate claims. Under the proper reading, only the single covered entity with direct oversight over and primary responsibility for the individual's care may claim the individual as its "patient."

180. Because Mount Sinai defines "patient" in an overly broad manner that conflicts with the statute, AbbVie has reasonable cause to believe that Mount Sinai is violating Section 340B's anti-diversion provision. HRSA acted contrary to law when it determined that it would not enforce findings from AbbVie's audit request of Mount Sinai.

HRSA's September 18 Letter Is Final Agency Action Subject to Judicial Review

181. HRSA's September 18 letter is final agency action reviewable by this Court. The letter represents "the consummation of the agency's decisionmaking process," and it is action by which "rights . . . have been determined" or from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quotation marks omitted).

182. ***First***, the September 18 letter consummates HRSA's decision-making process. The letter states, in definitive terms, that "the patient definition criteria outlined in the audit work plan[s]" for Barrio and Mount Sinai "go beyond HRSA's 1996 Guidelines," and that the definition in the 1996 Guidelines "continues to guide HRSA's and manufacturers' audit activities." Ex. 4. The letter further states that any audit "findings [that] result from AbbVie's application of a patient definition that is inconsistent with the longstanding 1996 Guidelines"—that is, that result from the patient interpretation that forms the basis for AbbVie's proposed workplans—will *not* be recognized by the agency: "OPA will not be able to impose corrective actions" on the basis of such findings. *Id.*

183. Those conclusions are firm, reflecting the agency's considered judgment, and they are "not . . . of a merely tentative or interlocutory nature." *Bennett*, 520 U.S. at 178. They mark

HRSA's "definitive" position that the statutory interpretation of "patient" set forth in AbbVie's workplans is not consistent with the agency's view of the 340B statute. *FTC v. Standard Oil Co.*, 449 U.S. 232, 241 (1980).

184. ***Second***, the September 18 letter also determines AbbVie's rights and creates legal consequences, in multiple respects.

185. Only HRSA has authority to impose sanctions or otherwise enforce the findings of an audit, *see* 42 U.S.C. § 256b(a)(5)(D); *id.* § 256b(d)(2)(B)(v), so an audit serves no purpose if the agency will not enforce diversion findings that arise from it. HRSA's determination that the agency "will not" take action based on the audit as proposed in AbbVie's workplan effectively nullifies AbbVie's statutory audit. In light of HRSA's decision, it would be entirely futile for AbbVie to conduct its proposed audits.

186. Moreover, the agency's refusal to expressly reject the workplans, while *also* refusing to enforce any findings from the audits, at best "place[s] [AbbVie] in a holding pattern—preventing [AbbVie] from obtaining any explicitly final determination on [its proposed audit workplans] and thwarting the Court's interest in reviewing" such a decision. *Friedman v. FAA*, 841 F.3d 537, 542 (D.C. Cir. 2016). HRSA thus "has clearly communicated it will not reach a determination on" AbbVie's audit workplans due to AbbVie's adherence to its patient interpretation, yet the agency "simultaneously refuses to deny [AbbVie's workplans] on those grounds." *Id*. "[I]n practical effect if not formal acknowledgement," that message "constitute[s] 'the consummation of the agency's decisionmaking process' and determine[s] 'rights or obligations.'" *Id.* (quoting *Bennett*, 520 U.S. at 177–78).

187. As a separate source of finality, HRSA has affected AbbVie's rights under the 340B statute through its decision that the agency "will not be able to impose corrective actions" as a

result of any audit findings based on the patient interpretation in AbbVie's workplans. Ex. 4. The agency has thus made clear that any such findings will be given no effect. Important "legal consequences will flow" from that determination: AbbVie will be categorically unable to benefit from the agency's enforcement authority with respect to findings under the best reading of the statutory term "patient," as set forth in AbbVie's work plans. *Bennett*, 520 U.S. at 178. For example, under Section 340B, a "covered entity *shall be* liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug" provided by the statute. 42 U.S.C. § 256b(a)(5)(D) (emphasis added). Moreover, the Secretary is authorized to impose additional sanctions on covered entities who violate their program integrity obligations, including civil monetary penalties, termination from the 340B program, and potential referral to other enforcement authorities. *Id.* § 256b(d)(2)(B)(v). In light of HRSA's September 18 letter, however, none of those remedies would be available for violations of the patient interpretation in AbbVie's audit workplans.

188. In addition, the September 18 letter leaves AbbVie with no practical alternative for enforcing the "patient" interpretation in its audit workplans. AbbVie submitted workplans for Barrio and Mount Sinai on June 27 and July 2, 2025, respectively. It then spent several months working in good faith with HRSA to come to an agreement. Based on the September 18 letter, AbbVie now has three options: (1) undertake the time, resources, and expense to conduct audits that HRSA will not enforce, since any findings of those audits will not lead to corrective action; (2) revise the workplans to abandon the best interpretation of "patient," and instead incorporate the flawed definition in the 1996 Guidelines that enables covered entities to circumvent the diversion prohibition; or (3) abandon its attempt to audit Barrio and Mount Sinai altogether.

189. This Hobson's choice is no choice at all. Congress specifically afforded manufacturers a right to audit covered entities if the manufacturer believes the covered entity is violating a provision of Section 340B. Audits are time- and resource-intensive, and their purpose is thwarted if the audit cannot result in the correction of any violations that are uncovered. HRSA's refusal "to impose corrective actions" if "findings result from AbbVie's application of" the best-meaning of the term "patient," Ex. 4, negates the purpose of the audit, rendering AbbVie's statutory audit right a nullity. In practical effect, therefore, HRSA has "demand[ed]" that AbbVie must "compl[y] with [the agency's] announced position" and must abandon its own. *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986).

190. As a third independent source of finality, HRSA's effective denial of AbbVie's audit undermines AbbVie's access to the ADR process. As explained, the 340B statute gives drug manufacturers, like AbbVie, the right to file ADR claims seeking to recover losses after a covered entity has engaged in diversion or duplicate-discounting. 42 U.S.C. § 256b(b)(3)(A). But under HRSA's guidelines, AbbVie must audit the covered entity as a precondition to filing an ADR claim. 42 C.F.R. § 10.21(a)(2). HRSA's position that the "patient" interpretation in AbbVie's workplans is "inconsistent with" the agency's definition—and therefore "will not be" enforced by the agency—makes clear that AbbVie will not be permitted to file an ADR claim on the basis of "findings result[ing] from AbbVie's application of [its] patient definition." Ex. 4. Or even if AbbVie were theoretically able to *file* such an ADR claim, the agency has already definitively indicated that it will *reject* any claim based on violations of the best reading of the statutory term "patient," which forms the basis of AbbVie's audit workplan—violations that AbbVie is confident (and has evidence to suggest) it will find. Under those circumstances, filing an ADR claim (to be heard by HRSA representatives who have already determined that the interpretation of the term

"patient" set forth in AbbVie's workplans is not enforceable) would be futile, and AbbVie need not await the inevitable rejection before seeking to vindicate its rights.

191. For similar reasons, HRSA's final letter is ripe for review: AbbVie's claims are "fit for judicial decision" because they involve final agency action "and because 'judicial intervention' would not 'inappropriately interfere with further administrative action.'" *Bellion Spirits, LLC v. United States*, 7 F.4th 1201, 1209 (D.C. Cir. 2021) (quoting *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998)). Precluding review would also impose "hardship" to AbbVie, *id.*, by depriving AbbVie of its statutory right to conduct audits and, consequently, its ability to protect its own and the public's interests.

192. Finally, AbbVie clearly has standing to challenge HRSA's 1996 Guidelines' interpretation of "patient" because AbbVie was the "object of [these] action[s]," such that its standing is "self-evident." *Sierra Club v. EPA*, 292 F.3d 896, 899–900 (D.C. Cir. 2002).

CLAIMS FOR RELIEF

COUNT 1
(Declaratory/Injunctive Relief – Violation of the Administrative Procedure Act As To Barrio Refusal to Enforce Letter)

193. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

194. The APA requires courts to "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), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C).

195. The 340B statute provides that covered entities "shall not resell or otherwise transfer the [340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). It also expressly allows drug manufacturers to audit covered entities when the manufacturer has

reasonable cause to believe the covered entity is violating this statutory provision. *Id.* § 256b(a)(5)(C).

196. AbbVie has reasonable cause to believe Barrio Comprehensive Family Health Care Center, Inc. (Barrio) is violating the 340B statute's anti-diversion provision because it is applying a definition of "patient" that is broader than the 340B statute allows.

197. Despite this reasonable cause, HRSA stated that if AbbVie audits Barrio in accordance with the patient interpretation that forms the basis of its workplans, the agency will not enforce any audit findings based on that interpretation. That determination was contrary to law, as HRSA based its decision on an incorrect interpretation of the 340B statute—namely, the agency's erroneous determination that the "patient" interpretation in AbbVie's workplan was inconsistent with the 340B statute. That refusal to enforce any findings from AbbVie's proposed audit of Barrio is a final agency action that is not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of statutory jurisdiction or authority, *id.* § 706(2)(C).

198. AbbVie is entitled to a judgment declaring the patient interpretation set forth in its Barrio audit request letter is the best reading of the term "patient" as used in the 340B statute.

199. The Court should order HRSA to authorize AbbVie's request to audit Barrio using the patient interpretation set forth in its audit request letter.

COUNT 2
(Declaratory/Injunctive Relief – Violation of the Administrative Procedure Act As To Mount Sinai Refusal to Enforce Letter)

200. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

201. The APA requires courts to "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), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C).

202. The 340B statute says covered entities "shall not resell or otherwise transfer the [340B] drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). It also expressly allows drug manufacturers to audit covered entities when the manufacturer has reasonable cause to believe the covered entity is violating this statutory provision. *Id.* § 256b(a)(5)(C).

203. AbbVie has reasonable cause to believe The Mount Sinai Hospital (Mount Sinai) is violating the 340B statute's anti-diversion provision because it is using a definition of "patient" that is broader than the 340B statute allows.

204. Despite this reasonable cause, HRSA stated that if AbbVie audits Mount Sinai in accordance with the patient interpretation that forms the basis of its workplans, the agency will not enforce any audit findings based on that interpretation. That determination was contrary to law, as HRSA based its decision on an incorrect interpretation of the 340B statute—namely, the agency's erroneous determination that the "patient" interpretation AbbVie's workplan was inconsistent with the 340B statute. That refusal to enforce findings from AbbVie's requested audit of Mount Sinai is a final agency action that is not in accordance with law, 5 U.S.C. § 706(2)(A), and in excess of statutory jurisdiction or authority, *id.* § 706(2)(C).

205. AbbVie is entitled to a judgment declaring that the patient interpretation set forth in its Mount Sinai audit request letter is the best reading of the term "patient" as used in the 340B statute.

206. The Court should order HRSA to authorize AbbVie to audit Mount Sinai using the patient interpretation set forth in its audit request letter.

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff AbbVie Inc. requests a judgment in its favor against Defendants as follows:

1. Declare that HRSA's determination regarding what constitutes a "patient of the entity," as reflected in its September 18 letter refusing to enforce findings from AbbVie's audit requests as proposed, and as that determination applies to Barrio Comprehensive Family Health Care Center, Inc. and The Mount Sinai Hospital, is unlawful under the APA and the 340B statute;

2. Declare that HRSA's refusal to enforce findings from AbbVie's proposed audits as to Barrio Comprehensive Family Health Care Center, Inc. and The Mount Sinai Hospital are unlawful under the APA and the 340B statute;

3. Set aside HRSA's September 18 letter;

4. Enjoin Defendants from implementing or enforcing their determination reflected in HRSA's September 18 letter regarding what constitutes a "patient of the entity";

5. Declare that the interpretation of "patient of the entity" set forth in AbbVie's audit requests reflects the best meaning of the term as it is used in the 340B statute;

6. Authorize AbbVie to audit Barrio and Mount Sinai using the correct statutory understanding of "patient of the entity," as set forth in AbbVie's audit requests;

7. Award Plaintiff reasonable attorneys' fees and costs; and

8. Grant such other and further relief as the Court may deem appropriate.

Dated: April 8, 2026

Respectfully submitted,

/s/ Allon Kedem

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

/s/ Allon Kedem

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