IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC., *Plaintiff*, v. ROBERT F. KENNEDY JR., et al., *Defendants*,	Civil Action No. 26-cv-1190

PLAINTIFF ABBVIE INC.'S MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

This case asks a single, straightforward, and purely legal question: What does the word "patient" mean, as that term is used in the 340B statute's prohibition against the diversion of 340B-priced drugs? *See* 42 U.S.C. § 256b(a)(5)(B). The Court's answer to this question will decide whether the Health Resources and Services Administration (HRSA) may refuse to enforce the statute's anti-diversion safeguards simply because the agency prefers its own outdated and over-broad guidance over the statute's actual meaning.

Congress created the 340B drug discount program more than three decades ago as a carefully constructed bargain: Drug manufacturers offer low-priced drugs to select safety-net providers, known as covered entities, in exchange for participation in Medicare and Medicaid. Congress anticipated that the 340B program would apply to a relatively small number of hospitals and healthcare providers that treat vulnerable patients. *See* H.R. Rep. No. 102-384, pt. 2, at 12. But the program has since grown exponentially, transforming into an opportunity for more than 1,200 large hospital systems—often serving affluent populations—to generate billions in arbitrage "revenue." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Among Congress's most critical safeguards against abuse is a manufacturer's statutory right to audit covered entities for compliance with the statute's anti-diversion provision. *See* 42 U.S.C. § 256b(a)(5)(C). But Congress gave manufacturers no way to directly enforce the findings of those audits; instead, it entrusted that power to the Secretary of Health and Human Services (HHS). This case concerns the agency's refusal to exercise that authority consistent with the statute.

If the word "patient" means what the statutory text, structure, and history indicate—as AbbVie contends, and as the best reading of the statute confirms—then HRSA is required to allow AbbVie to audit these covered entities against that definition and to enforce audit findings from those audits. Indeed, Defendants do not seriously contest that this case turns on that question of

statutory interpretation. Instead, they ask the Court to avoid the merits altogether and to dismiss the suit on one of four threshold grounds, none of which withstands scrutiny.

First, Defendants contend that AbbVie—the direct object of HRSA's decision—lacks standing to bring this suit because its injury is purportedly not redressable. Defendants argue that AbbVie got what it wanted because HRSA authorized AbbVie to audit the covered entities *under HRSA's 1996 Guidelines*. But that argument ignores the relief that AbbVie actually seeks: a declaration of the *correct* statutory definition of "patient" and authorization to audit against *that* standard, rather than the agency's incorrect interpretation. AbbVie does not ask the Court to order any particular enforcement outcome; it asks only that its audit findings be evaluated under the law as Congress wrote it, not as HRSA rewrote it.

Second, Defendants argue that HRSA's refusal to allow AbbVie to proceed with audits against the proper patient definition is not "final agency action." But HRSA's response to AbbVie rested on a definitive, agency-wide position on the meaning of "patient"—a position that, under *Loper Bright*, is entitled to no deference. HRSA has also foreclosed any possibility that the audits could yield an enforceable remedy unless AbbVie abandons its (correct) statutory interpretation and instead follows the agency's (incorrect) interpretation. HRSA's decision thus consummated the agency's decision-making process, and it creates direct legal consequences for AbbVie.

Third, Defendants argue that AbbVie's claims are not ripe for review. But the merits question is purely legal and there is no future contingency left to await. HRSA has declared that the agency *will not* enforce findings based on anything but its own (incorrect) interpretation of Section 340B. No amount of further factual development—no audit, no ADR proceeding, no additional agency correspondence—could alter that legal position. Requiring AbbVie to march through a multi-step administrative process whose outcome the agency has already predetermined would be an exercise in futility, not a path to "further clarification."

Finally, Defendants contend that HRSA's decision constitutes an unreviewable exercise of enforcement discretion. But there is a strong presumption in favor of judicial review of agency actions, which nothing in Section 340B displaces or rebuts. Nor is this the rare scenario where a dearth of applicable law leaves a decision wholly up to agency discretion. To the contrary, AbbVie challenges HRSA's reading of a statutory term that the agency gets no deference in interpreting—precisely the kind of legal question that *Loper Bright* confirms belongs to this Court.

The motion to dismiss should be denied, and this Court should order Defendants to file a certified list of the contents of the administrative record.

BACKGROUND

A. Congress Creates the 340B Program to Help Providers of Underserved Populations

Section 340B of the Public Health Service Act 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. Compl. ¶ 30 (quoting *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011)). Before the 340B program, many drug manufacturers had adopted their own policies and practices to provide prescription drugs at discounted prices for the benefit of low-income and uninsured individuals. *Id.* ¶ 31 (citing H.R. Rep. No. 102-384, pt. 2, at 8-9 (1992)). Manufacturers would often provide these discounted drugs to the healthcare providers who served such individuals, and the providers in turn would pass on the discounts to their patients. *See id*.

In 1990, Congress unintentionally undermined these voluntary, patient-focused practices when it established the Medicaid Drug Rebate Program (MDRP). Under that statute, 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"). *Id.* ¶ 31; 42 U.S.C. § 1396r-8(c)(1)(C). This "best price" included the discounted prices that manufacturers had voluntarily offered to safety-net providers. As a result, because any discounts provided voluntarily by a manufacturer would now factor into a drug's "best price," the MDRP created an unintended "disincentive" for manufacturers to offer them. Compl. ¶ 31 (citing H.R. Rep. No. 102-384, pt. 2, at 9-10). In 1992, Congress solved this unintended consequence by enacting Section 340B, which, among other things, "exclude[s]" from the Medicaid best-price formula discounts to certain low-income and uninsured purchasers. *Id.* ¶ 32 (citing H.R. Rep. No. 102-384, pt. 2, at 11); *see* 42 U.S.C. 1396r-8(c)(1)(C)(i)(I).

In addition to fixing the "best price" problem, Congress required participating drug manufacturers to give certain safety-net providers access to the discounted prices that manufacturers had previously offered voluntarily for the benefit of patients. *Id.* ¶ 34. To accomplish this objective, 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). In return for granting covered entities this privilege, Congress's expectation was that they would continue the preexisting practice of passing on such discounts to their patients. *See* Compl. ¶ 66 (citing H.R. Rep. No. 102-384, pt. 2, at 10). As described below, however, today covered entities typically pocket the 340B discount themselves (or share it among their pharmacy and third-party administrator partners), transforming the 340B program into a price-arbitrage scheme that would be unrecognizable to the Congress that enacted it.

Congress thus created the 340B program as an exclusively federal program, overseen by the Secretary of HHS, and it gave manufacturers significant incentives to participate by making 340B program participation a condition of reimbursement for the manufacturers' drugs under Medicaid and Medicare Part B. *See* 42 U.S.C. § 256b(a)(1). These incentives are legally necessary

because Section 340B is Spending Clause legislation. *See* Compl. ¶ 35. Such incentives are also practically necessary: "If the costs of participating in these programs outstrip the benefits, . . . rational manufacturers can be expected to withdraw from them." Br. of United States as Amicus Curiae at 24, *AbbVie v. Drummond*, No. 25-6184 (10th Cir. Mar. 30, 2026), Dkt. No. 73.

Congress thus carefully crafted Section 340B to further the interest in increasing patient access to discounted drugs, without creating too strong a disincentive for manufacturers to participate. To that end, Congress carefully limited the program's reach by restricting which healthcare providers would qualify as "covered entities" and thus be granted the limited statutory privilege to purchase manufacturers' drugs at 340B prices. Compl. ¶ 38. Today there are fifteen delineated categories, including (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.*; *see* 42 U.S.C. § 256b(a)(4)(A)-(O). These entities range from small, geographically isolated organizations to some of the largest hospitals and healthcare centers in the country. Compl. ¶ 38. And, moreover, Congress made clear that, with respect to hospital covered entities, 340B program eligibility applies only to the "distinct part" of the hospital specified in the statute, which reinforces the narrow scope of program eligibility. *Id.* ¶ 88 (citing 42 U.S.C. § 256b(a)(6)).

B. The 340B Program Includes Mechanisms to Protect Program Integrity

As noted, Congress intended the 340B program to be used to benefit underserved communities and intended that covered entities would pass on the low prices that they are able to access under Section 340B, called "340B prices," to the "low-income and rural" patients for whom they offer care. Compl. ¶ 51 (quoting *Sanofi*, 58 F.4th at 699). And that is how the program worked for the first decade or so after enactment. But over time, covered entities realized that, if they *did not* pass on the 340B discount, they could use the program to generate arbitrage "revenue": Covered

entities "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi*, 58 F.4th at 699; *see* Compl. ¶ 52. Covered entities now use the program primarily to generate such arbitrage revenue—a "spread between the discounted price and the higher insurance reimbursement rate," Compl. ¶ 52 (quoting *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024))—which they euphemistically refer to as "340B savings" or "340B revenue." Pursuit of these arbitrage profits, and new schemes for generating them in ever-increasing amounts, now drives the 340B program.

The 340B program includes important safeguards to stay true to its required scope under the Spending Clause. As most relevant here, Section 340B specifies 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). To effectuate the Spending Clause bargain, the statute thus prohibits a covered entity from selling or transferring drugs acquired at federally discounted prices to anyone other than an individual who is prescribed the drugs in connection with the care he or she receives from the covered entity. Compl. ¶ 39. Providing drugs acquired at the federally discounted 340B price to "a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), is commonly known as "diversion." The 340B statute further provides that a covered entity may not obtain 340B pricing on units of drugs for which a manufacturer also pays a Medicaid rebate. Compl. ¶ 40 (citing 42 U.S.C. § 256b(a)(5)(A)). This forbidden practice, commonly known as "duplicate-discounting," could cause the manufacturer to incur a loss on the distribution of its products—taking into account both the 340B discount and the Medicaid rebate—thus exceeding constitutional limits on the conditions of 340B program participation. *Id.* A covered entity that "knowingly and intentionally" engages in diversion or duplicate-discounting is subject to civil monetary penalties. 42 U.S.C. § 256b(d)(2)(B)(v)(I).

C. HRSA's Guidance Facilitates Widespread Program Abuse

1. Although Congress prohibited the diversion of drugs "to a person who is not a patient of the entity," 42 U.S.C. § 256b(a)(5)(B), it did not define the term "patient." The Court accordingly must ascertain "the best reading of the statute," without affording deference to the agency's interpretation of the term. *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024).

In 1996, HRSA issued non-binding high-level guidance on the agency's interpretation of the word "patient" in Section 340B. Compl. ¶ 69 (citing 61 Fed. Reg. 55,156-58 (Oct. 24, 1996) (the 1996 Guidelines)). Under the 1996 Guidelines, an individual is a "patient of the entity" if: (1) the covered entity has established a relationship with the individual such that it maintains records of the individual's health care; (2) the individual receives health care services from a professional employed by, or under contract with, the covered entity such that responsibility for the individual's care remains with the entity; and (3) the individual receives services consistent with the scope of the entity's grant funding (unless the covered entity is a disproportionate share hospital). *Id.* Despite the fact that the 340B program has undergone massive growth and many changes during the three decades since 1996, HRSA has not updated this guidance. *Id.* ¶ 70. HRSA proposed a different definition in 2015, 80 Fed. Reg. 52,300, 52,306-07 (Aug. 28, 2015), but that guidance was never finalized. Compl. ¶ 70.

The 1996 Guidelines definition is not consistent with the best reading of the statutory term "patient." For a covered entity to claim an individual as its "patient"—and thus to be eligible for discounts for drugs dispensed to the patient—the 1996 Guidelines purport to require only that a covered entity maintain *some* "record" of its relationship with an individual. *Id.* ¶ 69 (citing 61 Fed. Reg. at 55,157). There is no requirement that the record must actually relate to the prescription for which the 340B discount has been claimed; nor is there any requirement that the underlying care must be substantive, recent, or ongoing. As a result, a covered entity can claim 340B discounts

on prescriptions written by an entirely *different* provider, including one who is not employed by *any* covered entity. Indeed, covered entities claim 340B discounts even where the drug has been dispensed to a wealthy, insured individual whose only "relationship" with the entity was a single short phone call, at some distant point in the past, wholly *unrelated* to the prescription at issue—so long as the entity kept a "record" of that call.

Unsurprisingly, this loose standard is easily, and frequently, exploited by covered entities. And the problem has been amplified substantially by the "replenishment model" that many covered entities and their contract pharmacies use today. *Id.* ¶ 59. As the D.C. Circuit has explained:

> While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis, 102 F.4th at 457-58. Under this model, a covered entity sells a drug to a customer at full price and only later—days, weeks, months, or even years after the sale—retroactively recharacterizes that customer as a 340B "patient" to justify replenishing its inventory at the discounted price. Compl. ¶ 59. Covered entities are incentivized to leverage the 1996 Guidelines, in combination with the replenishment model, to recharacterize as 340B-eligible as many prior sales as possible, often based on the most tenuous of connections between the entity and the patient.

2. The problems with HRSA's broad "patient" definition have been compounded by the agency's contract-pharmacy guidance. When enacting Section 340B, Congress anticipated that covered entities would dispense 340B-priced drugs to their own patients through their *own* in-

house pharmacies. *Id.* ¶ 54. But in 1996, HRSA issued guidance permitting covered entities without in-house pharmacies to contract with a single outside pharmacy for the distribution of 340B-priced drugs. *Id.* (citing 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996)). Then, in 2010, HRSA expanded that guidance to permit covered entities to use an *unlimited* number of contract pharmacies, with no geographic restriction. *Id.* ¶ 55 (citing 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010)). That meant a covered entity in New York could purchase 340B-priced drugs for dispensing to "patients" through contract pharmacies not only in New York, but also in California, Maine, Hawaii—and every State in between.

HRSA's 2010 contract-pharmacy guidance produced a "significant expansion" in the program, with covered entities dramatically increasing their ability to generate 340B revenues by transferring drugs to pharmacy customers (many of whom do not qualify as patients of the covered entity itself). *Id.* ¶ 56 (quoting *Novartis*, 102 F.4th at 457). When Congress created the 340B program, there were approximately 1,000 covered entities (approximately 90 of which were hospitals); by 2021, there were more than 50,000. *Id.* ¶¶ 6, 94. Discounts accessed under the program have also ballooned, increasing a hundred-fold in only a couple of decades—from around $1 billion in the early 2000s, *see* Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program* at 1, NIH Public Access (May 28, 2014), to more than $100 billion in 2025, HRSA, *2025 Covered Entity Purchases*, http://bit.ly/4fDhP3I (July 2026). As a result, the 340B program is now the nation's second-largest federal prescription drug program, behind only Medicare Part D—bigger even than the Medicare Part B and Medicaid programs it was designed to modify. Compl. ¶ 6. The tail is now wagging the dog.

Numerous government and independent examiners have concluded that the growth in the 340B program is substantially attributable to covered entities targeting wealthy, insured populations instead of the vulnerable populations the program was designed to help. In 2013,

Senator Chuck Grassley wrote to HRSA warning that contract pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients . . . in order to maximize their spread," and estimating that contract pharmacies retain up to $5 billion in annual profits from 340B sales. *Id.* ¶ 61. More recently, the Senate Committee on Health, Education, Labor, and Pensions published a report in April 2025 finding that covered entities, contract pharmacies, and third-party administrators have generated enormous profits from the program even as manufacturers continue to struggle to ensure program integrity. *Id.* ¶ 62.

Even the covered entities themselves have recognized the 340B program abuse fueled by contract pharmacy growth. In May 2026, for example, three covered entities—including Mount Sinai, one of the entities that AbbVie tried to audit in the events giving rise to this case—filed suit against CVS Health and its affiliates, alleging that CVS was retaining too large a share of 340B "profits," at the expense of covered entities. *See Mount Sinai Hosp., et al. v. CVS Health Corp., et al.*, No. 26-cv-4143 (S.D.N.Y.); *Univ. of Kan. Hosp. Auth. v. Caremark LLC, et al.*, No. 26-cv-2292 (D. Kan.); *Univ. of Mich. Hosps. & Health Ctrs., et al. v. CVS Health Corp., et al.*, No. 26-cv-11618 (E.D. Mich.). In these complaints,[1] the covered entities readily admit that they leverage the 340B program for profits, rather than sharing them with patients. *See, e.g.*, Compl. ¶ 15, *Mount Sinai*, No. 26-cv-4143 (S.D.N.Y. May 18, 2026), ECF No. 1 (covered entities were "deprived of much of the 340B Savings that *they* would otherwise have received") (emphasis added); ¶ 52 (covered entities can "pass on" savings "in theory," but are free to use them to "subsidize other … areas of their operations"); ¶ 151 (contract pharmacies receive 56% of 340B savings, covered entities get 44%, patients get 0%); ¶ 152 (340B "Savings" are intended to flow to covered entities).

[1] The Court should take judicial notice of these cases. *See, e.g.*, *Adeyemi v. Amazon.com Servs., LLC*, No. 24-cv-2887 (RDM), 2025 WL 2029758, at *1 n.1 (D.D.C. July 21, 2025) (courts "may properly take judicial notice of proceedings and filings in other courts").

These new lawsuits reinforce that contract pharmacies have transformed the 340B program into an arbitrage scheme in which covered entities and contract pharmacies now fight over their cut of the "340B profits" or "savings," each maneuvering for the largest percentage, and for many without much consideration for the patients that the 340B program was intended to benefit.

D. Section 340B Authorizes Enforcement through the Audit and ADR Processes

Recognizing that the 340B program's steep discounts create incentives for covered entities to push beyond the program's intended purpose, Congress built tools to safeguard program integrity. Congress directed the Secretary to provide oversight, required covered entities to maintain auditable records, and conferred on manufacturers a statutory right to audit covered entities when they suspect program abuse. 42 U.S.C. § 256b(a)(5)(C)-(D); *see* Compl. ¶ 42. Congress thus authorized both the agency 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).

The audit provision grants drug manufacturers an absolute right to conduct such audits—which occur "at the . . . manufacturer's expense"—subject only to procedures related to "the number, duration, and scope of audits." *Id.* Congress also made a covered entity's cooperation with the audit process a condition of its eligibility to participate in the 340B program. *See* § 256b(a)(4) ("the term 'covered entity' means an entity that meets the requirements described in paragraph (5)," which references the diversion and duplicate discounting provisions, as well as the audit requirement). Congress then directed HRSA to take action to remedy audit findings of misconduct

or abuse: "*If 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 the subject of the violation in an amount equal to the reduction in the price of the drug." *Id.* § 256b(a)(5)(D) (emphasis added). In other words, the statute makes enforcement mandatory once a violation is found.

In 1996, HRSA adopted audit guidelines that impose a number of non-statutory preconditions on a manufacturer's right to audit. Compl. ¶ 102 (citing 61 Fed. Reg. 65,406 (Dec. 12, 1996)). Under those guidelines, a manufacturer must notify the covered entity in writing of a suspected violation and attempt to resolve the matter in good faith. *Id.* ¶ 107 (citing 61 Fed. Reg. at 65,410). If the manufacturer and covered entity are not able to resolve the matter after at least 30 days of discussions, the manufacturer can then submit a formal audit workplan to HRSA describing "with sufficient facts and evidence" why it has "reasonable cause" to believe a statutory violation has occurred. *Id.* HRSA then has 15 days to respond "with an approval or denial of the submitted work plan." *Id.* ¶ 108 (quoting HRSA, *Clarification of Manufacturer Audits of 340B Covered Entities* (Nov. 21, 2011), https://bit.ly/4tpNuLw).

After completion of an approved audit, a manufacturer must submit an audit report detailing the audit's findings to the covered entity, which has an opportunity to respond. Compl. ¶ 45. If the covered entity agrees with the audit's findings, the 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.* (quoting 61 Fed. Reg. at 65,410). Conversely, a covered entity that does not agree with the audit findings—which is almost always the case—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.*

Critically, neither the statute nor HRSA's guidelines provide the manufacturer with any independent means of recovering from a covered entity for wrongdoing uncovered by an audit; instead, the manufacturer is dependent on the agency's authority to enforce findings against the covered entity. Congress required the Secretary 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 of the anti-diversion and duplicate-discounting prohibitions. 42 U.S.C. § 256b(d)(3)(A). This adjudicative process is known as the 340B administrative dispute resolution (ADR) process. The ADR panel is composed of HRSA staff. *See* 42 C.F.R. § 10.20.

After conducting audits, manufacturers may file ADR "claims" alleging "violations of" the 340B statute's anti-diversion and duplicate-discounting requirements. 42 U.S.C. § 256b(d)(3)(A). If the Secretary determines "that a covered entity is in violation" of the statute, the entity "shall be liable to the manufacturer" for the amount of the improper 340B discount. *Id.* § 256b(a)(5)(D). If the Secretary finds that the covered entity acted "knowingly and intentionally," the covered entity is required "to pay a monetary penalty to [the] manufacturer." *Id.* § 256b(d)(2)(B)(v)(I). And if the Secretary determines that the violation "was systematic and egregious as well as knowing and intentional," the Secretary may remove the covered entity from the program and disqualify it from re-entering the program for "a reasonable period." *Id.* § 256b(d)(2)(B)(v)(II).

E. AbbVie Engages with Barrio and Mount Sinai to Investigate Suspected Program Abuse

Against this backdrop, AbbVie—a longtime 340B-program participant—reviews its 340B purchasing data for signs of anomalous purchasing and prescribing activity by covered entities. In 2024, AbbVie's routine review identified concerning trends at multiple covered entities, including Barrio Comprehensive Family Health Care Center, Inc. (Barrio), a HRSA-funded health center in

San Antonio, Texas; and The Mount Sinai Hospital (Mount Sinai), a disproportionate share hospital located in New York City. Compl. ¶¶ 117-18, 148.

1. AbbVie's data showed that Barrio's 340B purchases of three AbbVie Immunology Products—Humira®, Skyrizi®, and Rinvoq®—had increased by more than 119% from 2021 to 2022, and by more than 53% from 2022 to 2023. *Id.* ¶ 119. Barrio was the *only* non-DSH covered entity among the top five national purchasers of these products, and it was the single largest purchaser among *all* health centers nationwide—an anomaly for an entity of its comparatively small size. *Id.* ¶ 120. AbbVie's review also found that, while 80% of other Texas covered entities' purchases of AbbVie products were dispensed through *in*-state pharmacies, 71% of Barrio's purchases were dispensed through pharmacies *outside* Texas. *Id.* ¶ 121.

On February 6, 2025, consistent with its routine oversight, AbbVie sent Barrio a letter describing these purchasing anomalies and requesting more information. *Id.* ¶ 119. The parties met on March 7, and Barrio explained that it does not require in-person visits to establish a "patient" relationship; that it considers an individual a "patient" for 24 months following any medical encounter; and that it treats prescriptions as 340B-eligible even when written by non-Barrio providers, so long as the prescription resulted from a referral by a Barrio provider, regardless of whether the referral related to the drug ultimately prescribed. *Id.* ¶¶ 122-25.

AbbVie followed up, requesting Barrio's written patient-eligibility policies and supporting documentation, and posing clarifying questions about Barrio's telehealth practices, out-of-state dispensing, and relationships with contract pharmacies and referral providers. *Id.* ¶ 127. In response, Barrio confirmed that it "follows HRSA's 1996 patient definition guidance," including by treating as a "patient" any individual with a "documented care relationship" with a Barrio-employed or contracted provider—without regard to whether that care relates to the prescription at issue, and without distinguishing between in-person and telehealth encounters. *Id.* ¶¶ 129-30.

Throughout the discussion period, AbbVie continued to monitor Barrio's purchasing data, which only reinforced AbbVie's concerns: In the first quarter of 2025 alone, a single Barrio nurse-practitioner wrote approximately 225 Skyrizi prescriptions claimed as 340B-eligible—the most out of 22,000 prescribers nationwide; and a Barrio physician assistant wrote nearly 250 Humira prescriptions—again, the most in the country. *Id.* ¶¶ 135-36 & figs. 1-2. These figures, combined with the fact that nearly three-quarters of Barrio's purchases were dispensed outside Texas, provided a strong indication that Barrio was extending 340B eligibility to individuals based on cursory telehealth contacts and out-of-state referrals, with little or no ongoing connection to Barrio itself. *Id.* ¶ 137. In short, AbbVie's good-faith communications with Barrio and its internal data suggested that the 1996 Guidelines were enabling Barrio to engage in conduct that constitutes diversion under the best statutory read of the term "patient."

2. AbbVie's data regarding Mount Sinai's 340B purchases likewise identified anomalous purchasing practices: Purchasing volume in the first three quarters of 2024 exceeded all of 2023 combined, and purchases of AbbVie's Immunology Products increased 63.9% year-over-year. *Id.* ¶¶ 149-50. Remarkably, voluntary claims data that Mount Sinai had previously shared with AbbVie revealed instances in which multiple, separately registered Mount Sinai covered entities each submitted 340B claims for reimbursement for sales bearing *the same* identical date of service, provider ID, prescription number, NDC, and quantity, differing only in which entity claimed the discount. *Id.* ¶¶ 151-52 & fig. 3. In one instance, The Mount Sinai Hospital, Mount Sinai West, and Mount Sinai Beth Israel—three unique covered entities under the Mount Sinai Health System—sought 340B discounts for the exact same claim (*i.e.*, Mount Sinai sought three discounts for a single prescription), apparently because their "patient" definitions allowed all three distinct entities to claim that *their* "patient" received that one prescription for 340B purposes.

On March 6, 2025, AbbVie sent Mount Sinai a good-faith inquiry letter describing these anomalies and requesting information about Mount Sinai's 340B compliance policies, including who it counts as a "patient" for purposes of the 340B program, its treatment of telehealth encounters, and the required nexus between a qualifying encounter and a 340B-eligible prescription. *Id.* ¶ 154. After initially failing to provide a substantive response, *id.* ¶ 155, Mount Sinai eventually reported that it follows "the HRSA patient definition for 'eligible patient,'" *id.* ¶ 156. And then, after denouncing AbbVie's follow-up questions as an "unwarranted fishing expedition," Mount Sinai stated that it treats as 340B-eligible all prescriptions (including those written following telehealth encounters) written within 18 months of a "qualifying encounter," and that some of its prescribers work only part-time at Mount Sinai. *Id.* ¶¶ 157-58. Further attempts by AbbVie to ask follow-up questions—including asking Mount Sinai to specify the criteria it uses for a "Mount Sinai provider"—were ignored or condemned as "an enterprise in harassment." *Id.* ¶¶ 159-61. In sum, AbbVie's good-faith communications with Mount Sinai and its internal data suggested that the 1996 Guidelines were enabling Mount Sinai to engage in conduct that constitutes diversion under the best statutory read of the term "patient."

F. HRSA Denies AbbVie's Request to Audit Barrio and Mount Sinai

Having developed reasonable cause to believe that Barrio and Mount Sinai were diverting 340B-priced drugs to pharmacy customers who are not "patients" of those entities under the best reading of the statute, AbbVie exercised its statutory right to seek authorization to audit each entity—only to have HRSA close the door on administrative relief. *Id.* ¶¶ 138, 163.

1. On June 27, 2025, AbbVie wrote to HRSA, submitting an audit request and workplan for Barrio that documented the substantial evidence described above and specifying the criteria—consistent with the proper interpretation of "patient" under the 340B statute—against

which AbbVie planned to audit Barrio's 340B compliance. *Id.* ¶ 139. In particular, AbbVie requested to audit Barrio against the following application of that term:

> 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.

Id. ¶ 140. AbbVie explained that this definition "accords with the best reading of that term in the 340B statute." *Id.*

On August 15, 2025, Chantelle Britton, Director of HRSA's Office of Pharmacy Affairs (OPA)—the subcomponent of HRSA that administers the 340B program—responded on the agency's behalf. *Id.* ¶ 142. She explained that the patient definition in AbbVie's workplan "goes beyond HRSA's 1996 Guidelines, which … [is] the currently operative standard for determining whether an individual is a 340B patient." *Id.* Director Britton informed AbbVie that HRSA would not "enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." *Id.* She then directed AbbVie to revise its workplan to remove a request for certain drug-order reports, and further declared that her letter "should not be viewed as an approval of AbbVie's interpretation of the term 'patient.'" *Id.* ¶¶ 142-43.

In response, AbbVie agreed to remove the drug-order report request but explained that AbbVie disagreed with HRSA's refusal to approve AbbVie's audit workplan as submitted. *Id.* ¶ 144. AbbVie reiterated that the patient definition set forth in its workplan reflected the best reading of "patient" under the statute. *Id*. Citing HRSA's own 2011 notice to 340B participants—stating that the agency will respond to workplans with either "an approval or denial" within 15 days—AbbVie asked HRSA to confirm, by September 19, 2025, whether it would approve AbbVie's workplan as it was submitted; absent such confirmation, AbbVie would understand the workplan to have been denied. *Id*.

On September 18, 2025, HRSA sent AbbVie another letter doubling down on its prior determination. *Id.* ¶ 145. HRSA insisted that the agency's 1996 Guidelines' interpretation of "patient" is "in accordance with section 340B(a)(5)(B) of the Public Health Service Act." *Id*. HRSA claimed that it was "not denying AbbVie the opportunity to audit Mt. Sinai or Barrio in accordance with the work plan submitted," but nevertheless reiterated that, to the extent any

findings resulted from AbbVie's application of a patient definition inconsistent with the 1996 Guidelines, "OPA will not be able to impose corrective actions." *Id.* Because HRSA made clear that it was refusing to approve AbbVie's workplan for Barrio, or to enforce findings made from evidence under that workplan, the letter constituted a denial of AbbVie's request to audit Barrio under the proper "patient" definition in the 340B statute.

2. On July 3, 2025, AbbVie submitted to HRSA a similar audit request and workplan for Mount Sinai, again setting out AbbVie's reasonable cause and the statutory patient definition against which it proposed to audit Mount Sinai's compliance. *Id.* ¶¶ 163-65. On July 22, HRSA notified AbbVie of its "concern[]" that the workplan reflected AbbVie's own definition of "patient," rather than the definition in the 1996 Guidelines, and the agency again directed AbbVie to revise the workplan to reflect the 1996 Guidelines' standard. *Id.* ¶ 167. AbbVie responded explaining its disagreement with HRSA's position that a manufacturer may audit a covered entity only using HRSA's own interpretation of "patient." *Id.* ¶ 168. AbbVie also highlighted why its definition more accurately captured instances of diversion, explaining that Mount Sinai's policies conferred 340B eligibility even where a Mount Sinai provider lacked direct oversight over the condition for which the drug was prescribed. *Id.* ¶¶ 168-69.

On August 15, 2025, HRSA reaffirmed its position in substantially the same terms as it did with respect to Barrio: HRSA informed AbbVie that the patient interpretation in its workplan "go[es] beyond" the 1996 Guidelines, and that HRSA would not "enforce corrective actions" for findings based on that interpretation. *Id.* ¶ 170. In response, AbbVie disagreed and asked the agency to confirm by September 19 whether it was approving or denying its audit workplan as submitted. *Id.* ¶ 171. On September 18, HRSA reiterated its determination that the patient definition that AbbVie articulated was inconsistent with HRSA's own interpretation, which HRSA described as being "in accordance with section 340B(a)(5)(B) of the Public Health Service Act."

Id. ¶ 172. HRSA again declared that "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*. As with Barrio, this letter denied AbbVie's request to conduct its requested audit.

LEGAL STANDARD

Defendants move to dismiss under both Rules 12(b)(1) and 12(b)(6). Where, as here, defendants "contest[] the legal sufficiency of the jurisdictional allegations contained in the complaint," the Court must "accept[] all well-pleaded factual allegations as true and draw[] all reasonable inferences from those allegations in the plaintiff's favor … In this sense, the Court must resolve the motion in a manner similar to a motion to dismiss under Rule 12(b)(6)." *Afanasieva v. Wash. Metro. Area Transit Auth.*, 588 F. Supp. 3d 99, 105 (D.D.C. 2022) (cleaned up). "In evaluating a Rule 12(b)(6) motion, the Court must first take note of the elements a plaintiff must plead to state the claim to relief, and then determine whether the plaintiff has pleaded those elements with adequate factual support to state a claim to relief that is plausible on its face." *Id.* (cleaned up). A complaint survives a 12(b)(6) motion as long as the facts alleged are "enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007).

ARGUMENT

I. The Agency's Refusals to Approve AbbVie's Audit Requests Constitute Final Agency Action

"To be final and thus reviewable, an agency action must (1) mark the consummation of the agency's decisionmaking process and (2) determine rights or obligations, or produce legal consequences." *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1235 (D.C. Cir. 2026) (cleaned up). Both requirements are readily satisfied here. AbbVie made multiple requests for

HRSA's approval of AbbVie's workplans to audit Barrio and Mount Sinai under the patient definition that best reflects the statutory text. HRSA declined each time, reiterating the agency's definitive view that the definition articulated in "HRSA's 1996 Guidelines"—*not* the one in AbbVie's workplans, which "goes beyond" HRSA's definition—is "the currently operative standard for determining whether an individual is a 340B patient." Compl. ¶ 142. HRSA also made clear 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.* The agency's decisions accordingly constitute final agency action reviewable under the APA. Defendants' arguments to the contrary rely on mischaracterizing the nature of AbbVie's requests, HRSA's response to those requests, and the relevant case law.

A. HRSA's Rejection of AbbVie's Workplans Marks the Consummation of the Agency's Decision-Making Process

Agency action "mark[s] the consummation of the agency's decisionmaking process" when it is definitive rather than "of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (citation omitted). HRSA's response to AbbVie's workplans reflects the agency's considered view on the legality and enforceability of the patient definition reflected there. The agency stated, in unqualified terms, that "the patient definition criteria outlined in the audit work plan[s]" for Barrio and Mount Sinai "go beyond HRSA's 1996 Guidelines." Compl. ¶ 182; *id.* Ex. 4. The agency conclusively determined that the definition in the 1996 Guidelines is the "currently operative standard" and that it "continues to guide HRSA's and manufacturers' audit activities." *Id.* ¶¶ 142, 182. And the agency declared that any audit "findings [that] result from AbbVie's application of a patient definition that is inconsistent with the longstanding 1996 Guidelines"—that is, any findings resulting 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.* ¶ 182 (emphasis added).

Those conclusions are firm and unequivocal, reflecting the agency's considered judgment, rather than being "of a merely tentative or interlocutory nature." *Bennett*, 520 U.S. at 178. They mark HRSA's "definitive" position, *FTC v. Standard Oil Co.*, 449 U.S. 232, 241 (1980), that the statutory interpretation of "patient" set forth in AbbVie's workplans is not consistent with the agency's view of the 340B statute and will not be given effect.

Nor is there any indication that HRSA intends to reconsider its position. In *Sackett v. EPA*, 566 U.S. 120 (2012), the Supreme Court confronted a similar argument that agency action was merely tentative: The government contended that an agency compliance order did not consummate the agency's decision-making process because it "invited the [plaintiffs] to engage in informal discussion" and to identify "inaccura[cies]" in the agency's response. *Id.* at 127 (cleaned up). The Court rejected that argument, holding that "[t]he mere possibility that an agency might reconsider . . . does not suffice to make an otherwise final agency action nonfinal." *Id.* Here, the case for finality is even stronger. HRSA did not invite AbbVie to discuss the patient definition or to identify errors in the agency's reasoning; it simply informed AbbVie that the 1996 Guidelines are "the currently operative standard" and that the agency "will not" enforce findings under any other interpretation. Compl. ¶¶ 142, 182. That is not a tentative position; it is a consummated one.

In arguing that HRSA's response was nevertheless nonfinal, Defendants attempt (at 16) to characterize the agency's response as a "threshold determination that further inquiry is warranted," because "[a]dditional steps are required before the Department can take any action regarding Barrio or Mt. Sinai's participation in the 340B Program or any other action based on the audits." That argument fundamentally misstates the nature of the agency action being challenged here. AbbVie does not challenge any future enforcement decision that might follow a completed audit. It

challenges HRSA's categorical legal determination—made *before* any audit had occurred—that the patient definition in AbbVie's workplans "goes beyond" the 1996 Guidelines and that any findings based on that definition "will not" be enforced. Compl. Ex. 4; *id.* ¶¶ 142, 182. On *that* question—the "operative" meaning of "patient" under Section 340B—HRSA's responses made crystal clear that no further inquiry was warranted. *Id.* ¶ 142. The fact that "additional steps" may remain in the audit process is beside the point; HRSA has already decided the legal standard that will govern those steps. The possibility that HRSA might "take . . . action" based on findings made under an *incorrect* legal standard (the 1996 Guidelines) does nothing to redress AbbVie's injury, which is the agency's refusal to enforce findings made under the *correct* standard (the patient definition articulated in AbbVie's workplans). *Id.* ¶ 182. There is no longer any question whether the agency will enforce findings made under the correct interpretation; it "will not." *Id.*

The cases on which Defendants rely (at 15-17) are easily distinguishable. Unlike *Sound-board Association v. FTC*, 888 F.3d 1261 (D.C. Cir. 2018), this is not a case where a "subordinate official" issued an informal letter that failed to reflect the view of "the full" agency. *Id.* at 1268 (cleaned up); *see id.* (challenged letter "explicitly and repeatedly states that it expresses the views of 'staff,' and it explains that such views do not bind the Commission"). To the contrary, the letters at issue here came from Chantelle Britton, the Director of OPA, and expressly made clear that they articulated "OPA's position." Compl. Ex. 4.

Nor is this case comparable to *Reliable Automatic Sprinkler Co., Inc. v. CPSC*, 324 F.3d 726 (D.C. Cir. 2003), where the Consumer Product Safety Commission's "compliance officials informed [the plaintiff] that they intended to make a preliminary determination that [its] sprinkler heads" were hazardous consumer products. *Id.* at 728-29. As the Court emphasized there, under the relevant statutory scheme, the definitive position of the Commission itself regarding the sprinklers could be articulated only in a formal "hearing," and "nothing in the record indicate[d] that

the outcome of [such] a hearing, where [the plaintiff] will have the opportunity to present its arguments to the agency, [wa]s preordained." *Id.* at 734. To the contrary, the Court recognized that the plaintiff "may be able to persuade an administrative law judge that the manner in which its sprinklers are produced and marketed, and the locations in which they are installed, demonstrate that they are not 'consumer products.'" *Id.* (cleaned up). Here, by contrast, HRSA's letters reflect the legal position of the agency itself—not its staff—that the agency "*will not* . . . enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines." Compl. ¶ 142 (emphasis added). Nor do Defendants claim that there is any other decision-maker within the agency that AbbVie must (or even can) "persuade."

Winter v. Cal. Med. Review, Inc., 900 F.2d 1322 (9th Cir. 1989), is even further afield. *Winter* involved a physician who received a "preliminary determination" from a peer review organization—not the agency itself—that he was violating Medicare Act obligations. *Id.* at 1324. The peer review group merely "informed him that it was considering recommending sanctions" to the agency's Office of Inspector General; no legal position (much less a definitive one) had been taken by the agency. *Id.* The physician then filed suit under the Medicare Act before seeking "resolution of [his] claim through established administrative channels." *Id.* at 1326. The Ninth Circuit dismissed his claim for failure to exhaust. *Id.*

This case is distinguishable from *Winter* in every material respect. First, unlike the preliminary finding of the third-party contractor there, HRSA's letters reflect the considered legal position of the agency itself—the entity with enforcement authority—and they leave no doubt about the agency's position or the outcome that AbbVie would face in any future proceeding. Second, unlike the physician in *Winter*, AbbVie does not seek to short-circuit an administrative process through which the agency might develop its position on the disputed issue; HRSA has already terminated the relevant inquiry by declaring that it "will not" enforce findings under the correct

statutory patient definition. Compl. ¶ 145. There are no further "established administrative channels" through which AbbVie could obtain a different answer to that legal question. Third, *Winter* was decided under the Medicare Act's exhaustion requirement—a requirement that has no analogue in the APA, which governs here. *See Darby v. Cisneros*, 509 U.S. 137, 146 (1993) (holding that the APA does not impose a freestanding exhaustion requirement). And nothing in Section 340B transforms otherwise final agency action into non-final agency action. *See Amgen, Inc. v. Kennedy*, No. 24-3571, 2025 WL 2206948, at *3 (D.D.C. Aug. 4, 2025) (holding that nothing in Section 340B "override[s] the APA" or alters its "default" rules of finality).

B. HRSA's Rejection of AbbVie's Workplans Determined AbbVie's Rights and Created Legal Consequences

1. HRSA's responses to AbbVie's workplans constitute agency "action by which rights or obligations have been determined, [*and*] from which legal consequences will flow." *Ipsen Biopharms., Inc. v. Azar*, 943 F.3d 953, 956 (D.C. Cir. 2019). Determining whether agency action meets this requirement requires a "pragmatic" inquiry, in which a court looks at "the concrete consequences [that] an agency action has or does not have as a result of the specific statutes and regulations that govern it." *Id.* (quoting *Cal. Cmtys. Against Toxics v. EPA*, 934 F.3d 627, 637 (D.C. Cir. 2019)). HRSA's rejection of AbbVie's workplans affected AbbVie's rights and created legal consequences for AbbVie under Section 340B, in at least three respects.

First, HRSA's response affects AbbVie's ability to pursue its audit rights. 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 is pointless if the agency has already decided it will not enforce diversion findings that are uncovered during it. HRSA's determination that the agency "will not" take action based on the audit as proposed in AbbVie's workplan, Compl. Ex. 4, thus effectively nullifies AbbVie's statutory right. In light of HRSA's decision, it would be

entirely futile for AbbVie to conduct its proposed audits, since the agency already decided that AbbVie does not have the right to recover from conduct that is consistent with the interpretation of "patient" in the 1996 Guidelines but inconsistent with the interpretation in AbbVie's workplans. That decision accordingly leaves AbbVie with no way to recover 340B discounts that it paid in connection with claims that, in its view, are statutorily ineligible for them.

These consequences are concrete in the context of this dispute. As Defendants do not dispute, AbbVie's complaint alleges that its audits of Barrio and Mount Sinai would uncover conduct that constitutes diversion under AbbVie's patient definition but *not* under the 1996 Guidelines definition. For example, Barrio told AbbVie that it follows the 1996 Guidelines interpretation, Compl. ¶ 129, and so (among other things) considers an individual to be a "patient" for 24 months after the date of a medical encounter, and would still deem a prescription 340B-eligible even if it was totally unrelated to the individual's medical encounter with Barrio, *id.* ¶ 123; *see id.* ¶ 124 (hypothetical explaining the breadth of these policy choices and how they can lead to diversion). The purchase data corroborate these concerns, showing specific transactions involving particular Immunology Products and prescribers that would constitute diversion under the correct statutory definition but are permissible under the 1996 Guidelines. *Id.* ¶¶ 134-37. This conduct violates the best reading of "patient" as used in the 340B statute and constitutes diversion under that definition; yet the conduct is permissible under the 1996 Guidelines. *Id.* ¶ 137.

Similarly, Mount Sinai follows "the HRSA patient definition," not the definition in AbbVie's workplans. *Id.* ¶ 156. Specifically, Mount Sinai told AbbVie that it allows patient visits to confer 340B eligibility even when the Mount Sinai provider does not have direct oversight over care for the condition for which the 340B-priced drug is prescribed; where the prescription was written by a non-Mount Sinai provider; and where the visit is not related to the 340B prescription written. *Id.* ¶¶ 158, 162. 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 over the patient's condition for which the 340B-priced drug is prescribed. *Id.* ¶ 158. AbbVie also identified specific "claims data" that confirms Mount Sinai is obtaining 340B discounts under circumstances that are authorized by the 1996 Guidelines *but not* under the best reading of "patient." *Id.* ¶¶ 151, 153.

Taken together, these allegations establish that AbbVie has paid—and continues to pay—340B discounts on transactions that are permissible under the 1996 Guidelines, yet constitute diversion under the correct statutory definition of "patient." HRSA's announcement that it "would not . . . enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines," *id.* ¶ 142, means that AbbVie has no path to a remedy for these violations. Any audit AbbVie might conduct under its workplans would be an exercise in futility: The agency has already declared that it will not act on the results. Critically, HRSA *did not dispute* that AbbVie had established reasonable cause to believe that Barrio and Mount Sinai were engaged in diversion under the correct statutory patient definition. The agency's sole basis for rejecting AbbVie's workplans was its legal conclusion that the interpretation reflected there "goes beyond" the 1996 Guidelines—a purely legal determination that, under *Loper Bright*, this Court reviews *de novo*. AbbVie has thus "plausibly allege[d] facts that establish that legal consequences will flow" from Defendants' categorical refusal to enforce audit findings under the correct statutory standard. *Young v. Dep't of Labor*, No. 17-cv-2428, 2020 WL 1557170, at *12 (D.D.C. Apr. 1, 2020).

Second, as a separate but related source of finality, HRSA's decision precludes AbbVie from benefitting 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 workplans. As noted, Section

340B's anti-diversion and duplicate discounting prohibitions are not self-enforcing. Rather, they depend on the Secretary's oversight and enforcement, including through three mechanisms that are no longer available to AbbVie:

> (1) "*If the Secretary finds, after audit* . . . that a covered entity is in violation of a requirement described in subparagraphs (A) or (B) [*i.e.*, the duplicate-discounting and diversion prohibitions], the 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" as provided by the statute. 42 U.S.C. § 256b(a)(5)(D) (emphasis added).
>
> (2) "[*I*]*n appropriate cases as determined by the Secretary* . . . [w]here a covered entity knowingly and intentionally violates subsection (a)(5)(B) [*i.e.*, the diversion prohibition], the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D)." *Id.* § 256b(d)(2)(B)(v)(I) (emphasis added).
>
> (3) "*Where the Secretary determines* a violation of subsection (a)(5)(B) [*i.e.*, the diversion prohibition] was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary. *Id.* § 256b(d)(2)(B)(v)(II) (emphasis added).

Because all three of these mechanisms depend on action by the Secretary, the agency's determination that it *will not* take such actions forecloses use of these statutory mechanisms—and hence constitutes final agency action.

That is precisely what happened here. Once HRSA determined that it "would not . . . enforce corrective actions for any findings resulting from AbbVie's application of a patient definition that exceeds the 1996 Guidelines," Compl. ¶ 142, it was no longer possible that the Secretary would find Barrio or Mount Sinai to be "in violation of" the diversion prohibition based on that definition, with the inevitable consequence that neither Barrio nor Mount Sinai will "be liable to [AbbVie]" for the amount of the contested 340B discounts, 42 U.S.C. § 256b(a)(5)(D). Similarly, HRSA's decision means that neither Barrio nor Mount Sinai will be "required to pay a monetary penalty to [AbbVie]," *id.* § 256b(d)(2)(B)(v)(I); and also that neither entity will be "remov[ed]"

from the program, which would have relieved AbbVie of the obligation to offer them its discounted drugs, *id.* § 256b(d)(2)(B)(v)(II).

Indeed, in some respects this case is the mirror image of *Sackett*. There, the Supreme Court found an agency warning letter issued to landowners to be final agency action even though it was "not self-executing, but must be enforced by the Agency" in an enforcement proceeding. 566 U.S. at 129. The letter was nevertheless final, the Court explained, because it "expose[d] the [landowners] to double penalties in [such] a future enforcement proceeding." *Id.* at 126. In this case, HRSA's rejection of AbbVie's workplans necessarily means that Barrio and Mount Sinai will face *no* "penalties in a future enforcement proceeding" as a result of their conduct constituting diversion under a proper reading of Section 340B. And AbbVie, in turn, will *receive* no such relief.

Third, Defendants' effective denial of AbbVie's audit also 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(d)(3)(A). But under HRSA's guidelines, AbbVie must audit the covered entity as a precondition to filing such a claim. 42 C.F.R. § 10.21(a)(2). Defendants' 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." Compl. Ex. 4. Or even if AbbVie were theoretically able to *file* such an ADR claim, the agency has already prejudged any claimed violation based on the definition of "patient" in AbbVie's workplans—violations that AbbVie is confident (and has evidence to suggest) it will find. Any ADR claim that AbbVie files would be decided by a panel "consisting of staff within OPA" that is chosen (and removable) by the OPA Director. 42 C.F.R.

§ 10.20. Given those circumstances, HRSA has cut off AbbVie's ability to use the ADR process to obtain "resolution of [its] claims" against Barrio and Mount Sinai. 42 U.S.C. § 256b(d)(3)(A).

2. Defendants' contrary argument rests on mischaracterizing the nature of HRSA's response and the relief that AbbVie seeks. According to Defendants, "nothing in the letter prohibits AbbVie from proceeding with its audits." Mot. 19. Yet any attempt by AbbVie to move forward with its audits *as presented in AbbVie's workplans* would be ineffectual, given HRSA's position that it "will not . . . enforce corrective actions" based on findings under those workplans. Compl. Ex. 4. Indeed, while Defendants attempt to frame HRSA's response as a decision "allowing the audits to proceed," such a *conditional* approval "has precisely the same impact on the rights of the parties as denial of relief," and HRSA "cannot preclude judicial review by casting its decision in the form of [an unreviewable approval] rather than in the form of an order denying relief." *Envtl. Def. Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (D.C. Cir. 1970). Defendants also argue that if the audits go forward, "AbbVie may find violations *under the Department's 1996 guidance*, or it may find no violations at all." Mot. 19 (emphasis added). Even if that were true, it would be beside the point. Tellingly, Defendants ignore the possibility—which AbbVie has substantiated with well-pleaded allegations—that AbbVie will find violations *under the proper interpretation*. HRSA's decision means that AbbVie has no remedy at all for such violations, which Defendants do not dispute.

Defendants rely heavily (at 18-19) on *Oregon Health & Science University v. Engels*, Nos. 24-cv-2184 *et al.*, 2025 WL 1707630 (D.D.C. June 17, 2025), but the consequences of HRSA's decision here easily distinguish this case from that one. In *Oregon Health & Science University*, HRSA had authorized a manufacturer to conduct several audits, and covered entities subject to the audits sought to challenge them under the APA, arguing that HRSA should not have authorized them because "the manufacturer failed to provide the required written notice." *Id.* at *3 (citation

omitted). The Court held that HRSA's audit approvals did not constitute final agency action for several reasons that have no application here; indeed, the reasons cited in that case underscore why HRSA's rejection of AbbVie's workplans in this case *is* final agency action.

First, the Court in the *Oregon* case determined that the audit approvals were "not the consummation of the agency's decision making because the pertinent question—whether Plaintiffs unlawfully benefitted from duplicate discounts or diversions—has not been definitively answered by anyone, let alone HRSA." *Id.* at *5. Here, by contrast, the "pertinent question" is not whether Barrio and Mount Sinai have "unlawfully benefitted" from *any* purchase, *id.*, but what is the correct definition of the term "patient" and the legal standard under which audits will be governed and enforceable, based on that correct definition. On *that* question, HRSA has provided a "definitive" response. *See, e.g.*, Compl. ¶¶ 142, 145.

Second, the *Oregon* court emphasized that the alleged "procedural deficiencies" could be raised "in potential future proceedings, including [alternative] dispute resolution with the Department." 2025 WL 1707630, at *7; *see id.* ("The fact that Plaintiffs will be able to make their points in subsequent proceedings before the Agency further supports that HRSA's actions thus far are not the consummation of its decision making."). Here, by contrast, HRSA's definitive rejection of AbbVie's audit workplans on purely legal grounds makes clear that any attempt by AbbVie to re-raise the definition of "patient" with HRSA "in potential future proceedings" would meet the same fate. *Id.* And notably, Defendants have not argued that HRSA's interpretation of "patient" can or will be reconsidered in any future administrative proceeding.

Third, the Court rejected the covered entities' argument that their "obligations to comply with [the] manufacturer audits" constituted a relevant legal consequence for finality purposes, because such "obligations . . . flow directly from the 340B statute," rather than "from HRSA's decision." *Id.* at *8 (citing 42 U.S.C. § 256b(a)(5)(C)). Here, by contrast, the consequences of

AbbVie's dispute with Defendants do not "flow directly" from the 340B statute; to the contrary, the very dispute is *about* the correct meaning of the 340B statute. *Id.*

Finally, the Court rejected the covered entities' argument that "complying with a manufacturer audit at the manufacturer's expense is a substantial burden." *Id.* Even if so, the Court explained, "'the burden of responding to the charges made against [oneself] is different in kind and legal effect from the burdens' that come with final agency action." *Id.* (quoting *Standard Oil*, 449 U.S. at 242). Here, by contrast, the relevant consequences of HRSA's decision to reject AbbVie's workplans are qualitatively different. They include: rendering AbbVie's audit rights meaningless, foreclosing its ability to obtain a remedy for unlawful diversion, and undermining its access to ADR proceedings. Those are precisely the type of "concrete consequences [that] an agency action has . . . as a result of the specific statutes and regulations that govern it." *Ipsen Biopharms.*, 943 F.3d at 956 (citation omitted).

II. AbbVie Has Standing to Challenge HRSA's Refusal to Permit the Requested Audits

To establish standing, a plaintiff must satisfy three elements: "injury in fact, causation, and redressability." *Siegel v. Dep't of Treas.*, 304 F. Supp. 3d 45, 49 (D.D.C. 2018). All three elements are met here, for reasons similar to those supporting final agency action.

As an initial matter, where a "plaintiff is himself an object of the action (or forgone action) at issue, . . . there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992). Such is the case here: AbbVie directly challenges HRSA's refusal to authorize its *own* audit workplans as they were submitted. In such a situation, AbbVie's "standing to seek review of administrative action is self-evident." *Sierra Club v. EPA*, 292 F.3d 895, 899-900 (D.C. Cir. 2002).

Defendants nevertheless claim AbbVie lacks standing because "its alleged injury is not redressable." Mot. 20 (capitalization altered). An injury is redressable if it is "remediable 'by a favorable decision.'" *Siegel*, 304 F. Supp. 3d at 50 (citing *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015)). AbbVie's injury here—its inability to meaningfully audit Barrio and Mount Sinai against the proper statutory definition of the term patient, and its inability to obtain redress for the 340B discounts improperly claimed by those entities—would be remedied by its requested relief. Namely, AbbVie asks the Court to "[a]uthorize 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*." Compl. at 70 (Prayer for Relief) (emphasis added). In claiming that AbbVie's injury is not redressable, Defendants tellingly omit the second half of this request. Mot. 20.

Defendants also argue that "a favorable ruling from the Court would do no more than return AbbVie to the beginning of an administrative process whose outcome remains entirely within the Department's discretion." Mot. 20. But that argument depends on the premise that HRSA enforcement decisions are "committed to agency discretion by law and . . . therefore unreviewable under the APA," Mot. 21, which is plainly incorrect for the reasons explained below. *See* Part IV, *infra*.

In any event, Defendants overstate what "discretion" means in this context. Where a statute provides that a covered entity "*shall be liable*" upon a finding of violation, 42 U.S.C. § 256b(a)(5)(D) (emphasis added), the agency retains no discretion to decline to impose liability; its only role is to determine whether a violation occurred, and that determination must be made under the correct legal standard, not one of the agency's own devising. Notably, Defendants' argument also exposes a fundamental contradiction in their position: Defendants' finality and ripeness arguments contend that judicial review is *premature*—that AbbVie should wait for later stages of the administrative process. But their standing and discretion arguments contend that "this

Court cannot [*ever*] compel" HRSA to act, Mot. 20, because the outcome is committed to agency discretion. If Defendants are right about the latter, then waiting would be pointless, because there would *never* be a right time for judicial review. The Court should not adopt a framework that renders AbbVie's statutory audit rights permanently unenforceable.

Defendants' other standing arguments rest on mischaracterizing AbbVie's position. Defendants argue that the agency "already" permitted AbbVie to audit Mount Sinai and Barrio. Mot. 20. But that simply ignores the crucial difference between being authorized to proceed under the *correct* reading of the law (under AbbVie's workplans), versus only under an *incorrect* reading of the law (under the 1996 Guidelines). AbbVie is entitled to the former, not the latter. Defendants similarly assert that AbbVie's injury is not redressable because the "outcome it actually wants [is] enforcement action against Barrio and Mt. Sinai." Mot. 20. Not so. What AbbVie wants is the ability to audit under the correct legal standard and to have any resulting findings *evaluated* under that standard—rather than prejudged as unenforceable before the audit has even begun. As things currently stand, AbbVie has no such option; but if this Court agrees with AbbVie on the merits, AbbVie will be able to audit, file claims, and seek recovery for misconduct measured against the statute's actual requirements. That is textbook redressability. *See Lujan*, 504 U.S. at 561 (where the plaintiff "is himself an object of the action . . . at issue," redressability requirement is ordinarily satisfied).

III. AbbVie's Claims Are Ripe for Review

"To determine whether a dispute is ripe for judicial consideration," the Court "evaluate[s] (1) 'the fitness of the issues for judicial decision' and (2) 'the hardship to the parties of withholding court consideration.'" *VanderKam v. VanderKam*, 776 F.3d 883, 888 (D.C. Cir. 2015) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). Both considerations strongly support that this case is ripe.

First, "[w]hen a petitioner raises a purely legal question," such as a "question[] of statutory interpretation that [is] legal rather than factual in nature," the Court "assume[s] the issue is suitable for judicial review." *Friends of Animals v. U.S. Bureau of Land Mgmt.*, 728 F. Supp. 3d 45, 68 (D.D.C. 2024) (quotation marks omitted). That is the case here: The parties' central dispute regarding Section 340B's meaning "presents a purely legal question of statutory interpretation, and would therefore not benefit from a more concrete setting." *PhRMA v. HHS*, 138 F. Supp. 3d 31, 42 n.7 (D.D.C. 2015) (quotation marks omitted). Since Congress did not give HRSA rulemaking authority with respect to the 340B statute (outside of three limited areas), *see PhRMA v. HHS*, 43 F. Supp. 3d 28, 37-45 (D.D.C. 2014), this dispute must be resolved based *solely* on "best reading" of the statute as interpreted 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). And that best reading was fixed by "the ordinary public meaning of its terms at the time of its enactment." *Bostock v. Clayton Cnty., Ga.*, 590 U.S. 644, 654 (2020).[2]

For similar reasons, the dispute is not contingent on—and would not "interfere with"—any "further administrative action." Mot. 14 (quoting *Nevada v. Dep't of Energy*, 457 F.3d 78, 84 (D.C. Cir. 2006)). This is not a case where the dispute will turn on how the agency "implement[s]" its views in future administrative proceedings. *Nevada*, 457 F.3d at 85. Nor is "further administrative action . . . needed to clarify the agency's position." *Id.* at 85-86 (cleaned up). Indeed, AbbVie and

[2] Amici assert that "[h]aving an actual record of patients that AbbVie does not believe should qualify as 'patients' under the statute would greatly assist the Court in evaluating … the single, best meaning of the term." Amici Br. 15. But "the whole point of having written statutes [is that] 'every statute's meaning is fixed at the time of enactment.'" *Loper Bright*, 603 U.S. at 400 (quoting *Wisc. Cent. Ltd. v. United States*, 585 U.S. 275, 284 (2018)). Amici's argument also proves too much: If amici were correct that judicial review of an agency's legal position must await "the *actual* results" of administrative proceedings, Amici Br. 15, no pre-enforcement suit would ever be possible. In any event, AbbVie's complaint includes extensive details about specific Barrio and Mount Sinai providers who made specific payment claims for specific drugs. *See* Compl. ¶¶ 134-37, 151-53.

HRSA exchanged *eight* letters before AbbVie brought this suit, *see* Compl. Exs. 1-8, and the agency's endorsement of the interpretation in the 1996 Guidelines remained unwavering throughout. Since "the agency has stated that the action in question *governs and will continue to govern* its decisions," therefore, "such action must be viewed as final in [the Court's] analysis of ripeness." *Pub. Citizen v. Dep't of State*, 276 F.3d 634, 642 (D.C. Cir. 2002). Nor do Defendants identify any "further administrative action" with which "judicial intervention" might "inappropriately interfere." *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)).

Defendants nevertheless argue that "AbbVie's feared harm, that the Department will decline to enforce audit findings based on its patient definition, depends on a chain of contingencies that may never materialize":

> The audit may find no violations. If violations are found, the Department may determine they are actionable under the 1996 Guidelines regardless of which patient definition is applied. If AbbVie initiates an alternative dispute resolution proceeding, that process may resolve in AbbVie's favor. At each step, the legal question AbbVie presses this Court to decide may become unnecessary.

Mot. 14. This argument conflates the ultimate outcome of the underlying audit with the threshold legal question that AbbVie asks this Court to decide.

The question here is not what an audit of Barrio or Mount Sinai will find; the question is which legal standard should govern those audits. That question is already fully crystallized: HRSA has declared, categorically, that it "will not" enforce findings under AbbVie's patient definition. Compl. ¶ 142. No future fact-finding will change that legal position. Indeed, Defendants' logic—that AbbVie must first complete the audit, file ADR claims, and exhaust a multi-step administrative process before a court may weigh in—would effectively eliminate pre-enforcement review of agency statutory interpretations, a result squarely at odds with *Abbott Laboratories*, 387 U.S. at 148-49, and with the D.C. Circuit's longstanding recognition that when "the agency has stated that

the action in question *governs and* will *continue* to *govern* its decisions, such action must be viewed as final." *Pub. Citizen*, 276 F.3d at 642.

Turning to Defendants' specific contentions, the possibility that "[t]he audit may find no violations" *under AbbVie's proposed definition* is refuted by AbbVie's extensive allegations, which properly allege conduct by Barrio and Mount Sinai that constitutes diversion under the definition of "patient" in AbbVie's workplans but not under the 1996 Guidelines. *See* pp. 26-27, *supra*. Notably, Defendants have not argued (or moved to dismiss on the ground) that such allegations are implausible. Nor did the agency dispute AbbVie's representations that it "had reasonable cause to believe that [Barrio and] Mount Sinai sought 340B discounts on AbbVie drugs that had been sold, transferred, and dispensed to individuals who do not qualify as patients" under the interpretation of patient in AbbVie's workplans. Compl. ¶ 162. To the contrary, the agency rejected AbbVie's workplans on the purely *legal* basis that the interpretation reflected there "go[es] beyond HRSA's 1996 Guidelines." *Id.* ¶ 170.

Defendants' remaining suggestion—that an audit might uncover conduct "actionable under the 1996 Guidelines," such that an ADR proceeding "may resolve in AbbVie's favor," Mot. 14—misses the point entirely. AbbVie does not dispute that an audit *might also* reveal violations under the 1996 Guidelines as well. But even if it did, that would not address the violations that are actionable only under the correct statutory definition—the very violations that prompted AbbVie to submit its workplans in the first place. AbbVie has established reasonable cause to believe that Barrio and Mount Sinai have engaged in conduct that constitutes diversion under the best reading of "patient" but that the 1996 Guidelines permit. *See* Compl. ¶¶ 137, 162. HRSA's refusal to enforce findings based on such conduct means AbbVie has *no remedy at all* for those specific violations, regardless of what else an audit might turn up. Defendants' argument amounts to telling AbbVie that the possibility of recovering for *some* violations allows the agency to evade judicial

review for precluding recovery for others—even though those other violations are just as unlawful under the statute. The APA does not require a plaintiff to accept partial relief as a substitute for the full remedy to which it is entitled.

Defendants rely on *Belmont Abbey College v. Sebelius* for the proposition that courts "refrain from intervening 'even if the issue presented is 'purely legal' and 'otherwise fit for review.'" Mot. 15 (quoting 878 F. Supp. 2d 25, 39 (D.D.C. 2012)). But *Belmont Abbey College* is readily distinguishable. There, the agencies had "issued an Advance Notice of Proposed Rulemaking (ANPRM) formally declaring their intention to amend the final regulations and soliciting input from interested parties and the public." 878 F. Supp. 2d at 31. The court found the dispute unripe because the "rulemaking process would provide the plaintiff with 'a chance to convince [the agency] to change its mind,'" such that "the Departments' position on the policy at issue remains indeterminate." *Id.* at 39 (citation omitted). Here, by contrast, Defendants have not claimed that HRSA intends to modify or otherwise reconsider the 1996 Guidelines; much less have they taken any concrete steps towards that end. HRSA's position is thus anything but "indeterminate": The agency has declared, repeatedly and unequivocally, that the 1996 Guidelines are "the currently operative standard" and that it "will not" enforce findings under any other interpretation. Compl. ¶¶ 142, 145. HRSA proposed to amend the Guidelines in 2015, but this proposed guidance was never finalized, and it has since lapsed. 80 Fed. Reg. 52,300, 52,306–07 (Aug. 28, 2015).

The fact that HRSA has no intention to stop relying on the 1996 Guidelines also distinguishes Judge Leval's concurring opinion in *Bronx Household of Faith v. Board of Education of City of N.Y.*, 492 F.3d 89, 114 (2d Cir. 2007). *See* Amici Br. 18-19 (discussing *Bronx Household*). In that case, a faith-based organization sought to challenge a proposed New York City rule that, they claimed, unconstitutionally excluded them from accessing City-owned school

buildings for church services. 492 F.3d at 106. But as Judge Leval emphasized, "[t]he proposed rule had never been invoked by the City as a basis for denying Bronx Household access to school facilities. Indeed it had not even been adopted, but was only a proposed rule that had been provisionally approved by City officials." *Id.* at 107. In light of "uncertain[ty]" about the basis for the City's future decision—including regarding "how the City will interpret its new criterion"—it was "impossible to know at this stage exactly how the process of Bronx Household's application and the City's ruling will play out." *Id.* at 117. Here, by contrast, there is no "uncertain[ty]" about the basis for HRSA's decision or about "how [the agency] will interpret" Section 340B. *Id.* Indeed, HRSA's interpretation of the statute *is* the basis for its decision.

Second, because "there are no institutional interests favoring postponement of review, [AbbVie] need not satisfy the hardship prong." *AT&T Corp. v. FCC*, 349 F.3d 692, 700 (D.C. Cir. 2003). Regardless, Defendants are wrong that delaying resolution would "cause[] AbbVie no cognizable hardship." Mot. 14. In light of HRSA's rejection of its workplans, AbbVie now has three options, each of which would impose its own hardship:

> (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.

Compl. ¶ 188.

Defendants attempt (at 14-15) to downplay AbbVie's Hobson's choice, but their argument only underscores why postponing review makes no sense. As to the first option—conducting a meaningless audit at AbbVie's own substantial expense—Defendants claim that undertaking an audit that HRSA will not enforce is "not futile because the audit may produce findings the Department could enforce *under the 1996 Guidelines*." Mot. 14 (emphasis added). But inherent in that argument is an admission that the audit *would be* futile as to all findings based on *the correct*

patient definition; and AbbVie already explained to HRSA why the agency's definition would not capture all the wrongdoing that AbbVie uncovered when gathering reasonable cause. *See, e.g.*, Compl. ¶ 141 (Barrio); *id.* ¶ 168 (Mount Sinai).

As to the second option—acquiescing to HRSA's unlawful interpretation—Defendants argue that being forced to conform to the 1996 Guidelines is "not a legal injury" because it is "how the program has operated for thirty years." Mot. 14-15. But this entire litigation is premised on the fact that HRSA, for thirty years, has been using a patient definition that is "not in accordance with law" and "in excess of statutory jurisdiction or authority." Compl. ¶ 197 (quoting 5 U.S.C. § 706(2)(A), (C)). Unlawful agency action becomes ripe for adjudication under the APA when "the plaintiff suffers the injury required to press her claim in court," *Corner Post, Inc. v. Bd. of Govs. of Fed'l. Res. Sys.*, 603 U.S. 799, 811 (2024), which occurred here when HRSA denied AbbVie's workplans. Indeed, there is an obvious irony in Defendants using the longstanding nature of HRSA's interpretation as an argument that AbbVie's claim is "not yet ripe." Mot. 13.

Finally, as to the third option—abandoning the audits altogether—Defendants assert that the hardship AbbVie faces is its "own choice, not a consequence the Department has imposed." Mot. 15. But an APA plaintiff can *always* just abandon its position and conform to the agency's contrary position. That fact obviously poses no ripeness concerns. *Cf. Friedman v. FAA*, 841 F.3d 537, 545 (D.C. Cir. 2016) (permitting APA review where "the only way out requires capitulation to the very requirement he seeks to challenge").[3]

[3] Amici argue that applying anything other than the 1996 Guidelines' interpretation of Section 340B to Barrio and Mount Sinai would violate the rule that "a regulation that changes legal rights adversely cannot be applied retroactively." Amici Br. 17 (citation omitted). But a decision by this Court is not "a regulation," and "[a] judicial construction of a statute is an authoritative statement of what the statute meant before as well as after the decision." *Rivers v. Roadway Exp., Inc.*, 511 U.S. 298, 312-13 (1994). Since HRSA gets no deference in its interpretation of "patient," moreover, the agency has always been bound to apply the statute faithfully as Congress wrote it. For the same reason, amici are incorrect that a ruling in AbbVie's favor would "strip covered entities of their due process rights." Amici Br. 16. There is no due process right to the application

IV. AbbVie Does Not Challenge Any Decision Committed to Agency Discretion

The APA creates a "basic presumption of judicial review [for] one 'suffering legal wrong because of agency action.'" *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967) (quoting 5 U.S.C. § 702). Defendants nevertheless argue that review is precluded here "because the enforcement determination [AbbVie] ultimately seeks (a particular enforcement outcome) is committed to agency discretion by law and is therefore unreviewable under the APA." Mot. 21. Defendants argue that AbbVie's claim runs afoul of the holding in *Heckler v. Chaney*, 470 U.S. 821, 831 (1985), that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." That argument fails several times over.

Defendants ignore the Supreme Court's admonition that the exception to APA review for issues committed to agency discretion must be construed "quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 586 U.S. 9, 23 (2018) (quotation marks omitted); *see Hi-Tech Furnace Systems, Inc. v. FCC*, 224 F.3d 781, 788 (D.C. Cir. 2000) (exception is "very narrow" and "reserved for . . . rare instances") (cleaned up). In *Weyerhaeuser*, the Court identified a "reason to be skeptical" of an agency's claim of unreviewable discretion that applies just as readily here:

> The few cases in which we have applied the . . . exception involved agency decisions that courts have traditionally regarded as unreviewable, such as the allocation of funds from a lump-sum appropriation, or a decision not to reconsider a final action. By contrast, this case involves the sort of routine dispute that federal courts regularly review: An agency issues an order affecting the rights of a private party, and the private party objects that the agency did not properly justify its determination under a standard set forth in the statute.

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of an incorrect interpretation of a statute. In any event, if this Court orders HRSA to authorize AbbVie to audit Barrio and Mount Sinai under its workplans, the entities would be able to contest liability on any ground in any further agency proceedings following the audits.

586 U.S. at 23-24 (citations omitted). An agency's interpretation of a statutory provision over which it has no rulemaking authority—and the agency's application of that interpretation to a regulated party—do not constitute the exercise of discretion. And judicial review of that interpretation is the "ordinary job" of an Article III court. *Loper Bright*, 603 U.S. at 403.

Indeed, *Heckler* specifically noted that it was *not* speaking to situations where the agency has "consciously and expressly adopted a general policy" that may be inconsistent with the statute. 470 U.S. at 833 n.4. And the D.C. Circuit has expressly held that "an agency's adoption of a general enforcement policy *is* subject to review." *OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998) (emphasis added). That accurately describes what happened here: HRSA did not merely reject AbbVie's workplans in a "single-shot nonenforcement decision" that was based on case-specific, discretionary considerations. *Id.* (cleaned up). Instead, the agency expressly relied on a generally applicable legal position that the 1996 Guidelines provide "the currently operative standard for determining whether an individual is a 340B patient." Compl. ¶ 142. The *Heckler* presumption rests on the premise that enforcement decisions involve "a complicated balancing of a number of factors" committed to agency expertise. 470 U.S. at 831. But there is no "balancing" here; HRSA adopted a categorical legal position that a particular reading of Section 340B is correct and will be applied universally. That is statutory interpretation, not enforcement discretion—and it is precisely the kind of legal question that *Loper Bright* confirms belongs to this Court, not the agency. For the same reasons, Defendants' argument that "[t]he 340B statute is silent on the standards governing the Secretary's enforcement discretion," Mot. 22, is a red herring. HRSA did not deny AbbVie's workplans as a matter of enforcement discretion. It denied them on the ground that the patient definition on which they were based "goes beyond HRSA's 1996 Guidelines." Compl. ¶ 142.

In any event, Defendants are quite wrong that "Congress has provided no law to apply." Mot. 22. *Heckler*'s exception applies only when a statute is "drawn in such broad terms that in a given case there is no law to apply." *Hi-Tech*, 224 F.3d at 788 (citation omitted). But here, both sides *agree* that Section 340B has a single correct, discernible meaning—albeit disagree about *whose* interpretation is better. *See* Compl. ¶ 172 (HRSA stating that the 1996 Guidelines are "in accordance with section 340B(a)(5)(B) of the Public Health Service Act"). To resolve this suit, the Court need only decide between the parties' competing interpretations.

Even Section 340B's enforcement provisions—though they are not at issue here because HRSA did not invoke them as a basis for denying AbbVie's workplans—provide adequate law to apply. The statute provides that "[i]f the Secretary finds, after audit … that a covered entity is in violation of" the prohibition against diversion and duplicate-discounting, "the covered entity *shall be liable* to the manufacturer" of the relevant drug "in an amount equal to the reduction in the price of the drug" under the statute. 42 U.S.C. § 256b(a)(5)(D) (emphasis added). In the case of a knowing and intentional violation, the statute further provides that a covered entity "*shall be required* to pay a monetary penalty" to the manufacturer "in the form of interest on sums for which the covered entity is found liable." *Id.* § 256b(d)(2)(B)(v)(I) (emphasis added). These provisions make compensation mandatory; they even specify the required *amount* of compensation. And while the agency does have some discretion where a violation "was systematic and egregious as well as knowing and intentional," *id.* § 256b(d)(2)(B)(v)(II), nothing in the statute indicates that such discretion is exclusively committed to the agency's judgment. If it were, the agency could deny a manufacturer compensation for a blatantly unlawful reason—or no reason at all—and the manufacturer would have no recourse.

Finally, the agency action that AbbVie challenges here makes this case quite different from *American Hospital Association v. Department of Health & Human Services*, No. 4:20-cv-8806,

2021 WL 616323 (N.D. Cal. Feb. 17, 2021). There, a group of covered-entity plaintiffs wrote letters to HRSA asking it to take enforcement action against manufacturers that had adopted policies restricting access to 340B pricing for contract pharmacy sales. *Id.* at *3. HRSA's communication director responded via email that the agency's "authority to enforce certain 340B policies [wa]s limited because Congress has not granted it comprehensive regulatory authority to develop enforceable policy that ensures clarity in program requirements." *Id.* (cleaned up). The covered entities then brought suit under the APA, but the court held that it lacked subject matter jurisdiction on three different grounds. *Id.* at *4-6.

As relevant here, the court held that "HHS cannot be ordered to prosecute or enforce certain requirements that are its absolute discretion." *Id.* at *7. In so ruling, the court noted that the plaintiffs had not specified "any request for th[e] Court to order what the contours of [its] enforcement policy should be, or what specific enforcement actions the Department should take against the drug companies." *Id.* at *8 (cleaned up). Instead, they had asked generally "for a sweeping, industry-wide enforcement 'policy' rather than specified injunctions directing the agency to take specific enforcement steps or actions." *Id.* The court also noted that the agency "continue[d] to contemplate [its] response to the recent actions by the drug companies." *Id.* Under those circumstances, the court concluded that, "[a]t this stage, given that the drug companies' actions are recent, an action brought against HHS on this ground is premature." *Id.*

This case is different from *American Hospital Association* in every relevant respect. Unlike the informal correspondence from the covered entities there, AbbVie submitted formal workplans to HRSA—asking "the agency to take specific . . . actions" with respect to specific covered entities based on specific violations—which the agency rejected based on its longstanding interpretation of Section 340B. AbbVie does not challenge the agency's enforcement priorities; it challenges the agency's reading of the statute. And here, the agency does not "continue to contemplate [its]

response" to AbbVie's position. The agency has made a definitive choice. And the 340B statute confers law to apply to analyze the correctness of that choice.

CONCLUSION

The Court should deny Defendants' motion to dismiss.

Dated: July 28, 2026

Respectfully submitted,

s/ Allon Kedem

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CERTIFICATE OF SERVICE

In accordance with LCvR 5.3, undersigned counsel hereby certifies that the above brief was filed via the Court's electronic filing system.

Dated: July 28, 2026

By: /s/ Allon Kedem
Allon Kedem

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ABBVIE INC.,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official capacity, et al.,

Defendants.

Civil Action No. 26-cv-1190-RDM

[PROPOSED] ORDER

Upon consideration of the Defendants' Motion to Dismiss, it is hereby ORDERED that the motion is DENIED.

SO ORDERED this _____ day of August _____, 2026.

_____
Randolph D. Moss
United States District Court Judge