UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SAGEBRUSH HEALTH SERVICES, **Plaintiff,** **v.** **ROBERT F. KENNEDY, JR., *et al.*,** **Defendants.**	**Civil Action No. 25-915 (JEB)**

MEMORANDUM OPINION

Plaintiff Sagebrush Health Services runs a stable of clinics that participate in Section 340B, a federal program that allows certain providers to buy drugs from pharmaceutical companies at a discount. More than a year ago, the Health Resources and Services Administration — housed in the U.S. Department of Health and Human Services — concluded that several Sagebrush clinics were ineligible for the program and so kicked them out. Thus began a blizzard of challenges by Plaintiff to HRSA's actions. Those challenges have now reached their final stage, as both sides have moved for summary judgment. Plaintiff argues that HRSA lacked statutory authority to remove its clinics, that the removals were arbitrary and capricious and procedurally improper to boot, and that the Administration unlawfully ordered it to repay drug manufacturers for any improper discounts. On all three issues, the Court sides with HRSA. It will therefore grant summary judgment to the Government.

I. Background

A. Statutory Background

Section 340B lets certain healthcare providers — called "covered entities" in the statute's lingo — buy prescription drugs from manufacturers at a discount. See 42 U.S.C. § 256b(a)(1).

Qualifying entities include hospitals with a high share of low-income patients, black-lung clinics, and (relevant here) clinics receiving grants from state or local governments to treat or prevent sexually transmitted diseases. Id., § 256b(a)(4)(F), (K)–(L). The discounts are steep, typically knocking 20–50% off the drug's sticker price. See U.S. Gov't Accountability Off., GAO-11-836, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 2 (2011). They benefit uninsured patients, who can visit a covered entity and get cheaper drugs. Sanofi Aventis U.S. LLC v. HHS, 58 F.4th 696, 699 (3d Cir. 2023). They also benefit covered entities themselves. Those entities can buy drugs at a discount, get reimbursed by insurers for the drug's full price, and pocket the difference. Id.; U.S. Gov't Accountability Off., supra, at 13–14.

To enroll in Section 340B, clinics must get certified as eligible by the Health Resources and Services Administration. See 42 U.S.C. § 256b(a)(7); 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, 89 Fed. Reg. 64468, 64468 (Aug. 7, 2024) (while relevant statute says that Secretary of Health and Human Services will certify and recertify covered entities, "[t]he Secretary . . . has delegated the authority to administer the 340B" program to HRSA's Administrator). They must then get recertified "on a not more frequent than annual basis." 42 U.S.C. § 256b(a)(7)(E). If an entity is no longer eligible for the program, then HRSA can refuse to recertify it and so end its participation. See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52304 (Aug. 28, 2015).

Between recertifications, HRSA can kick providers out in one specific circumstance. Covered entities may not "resell or otherwise transfer" a discounted drug "to a person who is not [their] patient," a practice known as diversion. See 42 U.S.C. § 256b(a)(5)(B). If HRSA finds that a covered entity engaged in diversion that "was systematic and egregious as well as knowing

and intentional," then it may "remov[e] the covered entity from the drug discount program." Id., § 256b(d)(2)(B)(v)(II).

Put it together, and HRSA may kick a covered entity out of Section 340B at two points: at annual recertification, if the Administration finds that the entity is ineligible; or at any time, if HRSA finds that the entity diverted drugs.

B. Factual Background

Enter Sagebrush Health Services. The company runs a string of clinics across Nevada, Connecticut, and South Carolina, many of which are enrolled in Section 340B as providers that receive state funding to treat or prevent STDs. See Sagebrush Health, https://perma.cc/39CT-HGTL; ECF No. 54 (J.A.) at 36. In February 2024, HRSA informed Sagebrush that it had spotted "a significant increase in 340B purchases" at most of its clinics — which, the Administration said, often signals that a clinic is violating program rules. Id. HRSA therefore opened an investigation into whether Sagebrush's clinics were eligible for Section 340B and whether they had been diverting discounted drugs. Id. at 36–37, 191–92.

While the review was playing out, fifteen of those clinics' annual recertifications rolled around in June 2024. See ECF Nos. 61 (Pl. Suppl. Br.) at 1; 60 (Def. Suppl. Br.) at 3. That same month, three more Sagebrush clinics applied to be certified for the first time. See Pl. Suppl. Br. at 1; Def. Suppl. Br. at 3. One might think that since HRSA was investigating Sagebrush clinics' eligibility, it would closely scrutinize those applications. Certification and recertification, however, are rather cursory. Covered entities upload documentation and assert that it shows they are eligible, and HRSA basically takes their word for it. As the Government explained at a hearing before this Court, "[T]he entities self-attest that they meet the statutory requirements," ECF No. 53 (Mar. 25, 2026, Hr'g Tr.) at 17:25–18:1, and "[i]t's somewhat automatic that after

you attest that the information is correct and accurate, the certification goes through." Id. at 12:23–25. Sure enough, the Administration certified the three new applicants and recertified the fifteen incumbents. See Pl. Suppl. Br. at 1; Def. Suppl. Br. at 3.

At the same time, however, HRSA's review of Sagebrush clinics was proceeding. For almost a year, HRSA and Plaintiff plodded through a long and fruitless palaver: the Administration would ask Sagebrush for proof that its sites were eligible, Sagebrush would send over documents, and HRSA would respond that they did not prove eligibility. See J.A. at 36–37, 42–56, 87–91, 98. Finally, in December 2024, the Administration sent Sagebrush a letter announcing that the three newly certified and fifteen recertified clinics were all ineligible. Id. at 106–07. Some of those clinics had not received qualifying funding since January 1, 2023; others had not received such funding since February 1, 2024; and still others had never received it at all. Id. at 106; Pl. Suppl. Br. at 2; Def. Suppl. Br. at 4–5. The letter advised that "[i]t is Sagebrush's responsibility to determine the full scope of non-compliance and repay affected [drug] manufacturers . . . for the period of time that" these clinics had bought discounted drugs while ineligible. See J.A. at 107. While HRSA noted that it did not take any position on "the amounts owed to the affected manufacturers," it warned that Plaintiff could not re-enroll the clinics until it could show "that it [had] determined the full scope of noncompliance" and had "repaid affected manufacturers." Id. Sagebrush protested HRSA's findings, asked for a 30-day pause, and sent over more documents. Id. at 108–09. The Administration responded with a letter in January 2025 confirming its decision and reiterating that, "[a]s stated in [the December] letter, it is Sagebrush's responsibility to determine the full scope of non-compliance and repay affected manufacturers . . . for the period of time that the Sagebrush sites" had been ineligible. Id. at 169.

Fast forward to today, and nine of the eighteen at-issue clinics have been readmitted to the program. See Pl. Suppl. Br. at 3. Despite what HRSA's letters said, those clinics never had to reimburse drug manufacturers as a condition of re-enrollment. Id. The other nine clinics remain exiled from the drug-discount program. Id. at 4.

C. Procedural History

Days after HRSA removed its clinics, Sagebrush filed a motion for a temporary restraining order and preliminary injunction to keep its clinics enrolled. Sagebrush Health Servs. v. Becerra, No. 25-127, ECF No. 2 (First TRO Mot.) (D.D.C. Jan. 16, 2025); Sagebrush, No. 25-127, ECF No. 2-3 (Proposed TRO Order) at 2. This Court held that Sagebrush was unlikely to succeed on the merits of its claim and so denied its motion. Sagebrush, No. 25-127, ECF No. 27 (Jan. 31, 2025, Hr'g Tr.) at 27:2–3.

Undaunted, Sagebrush filed a fresh Complaint two months later, along with a new motion for a TRO. See ECF Nos. 1 (Compl.); 2 (Second TRO Mot.). That new attempt met the same result, as the Court denied relief. See Minute Order of Apr. 10, 2025. Sagebrush then filed a motion for a preliminary injunction, see ECF No. 14 (PI Mot.), which the Court also denied. Sagebrush Health Servs. v. Kennedy, 2025 WL 1784436, at *4 (D.D.C. June 27, 2025).

With emergency relief off the table, both parties have now moved for summary judgment. See ECF Nos. 44 (Pl. MSJ); 46 (Def. MSJ). Plaintiff asks the Court to vacate HRSA's expulsion of the eighteen sites and to order them reinstated. See ECF No. 44-1 (Pl. Proposed MSJ Order) at 1–2. It also seeks to vacate what it calls HRSA's "demands" that it repay drug manufacturers for improper discounts. Id. at 1. For its part, Defendant asks the Court to rebuff Sagebrush's requests. See Def. MSJ at 14.

II. Legal Standard

Although styled as Cross-Motions for Summary Judgment, the submissions in this case seek the Court's review of an administrative decision. The summary-judgment standard set forth in Federal Rule of Civil Procedure 56 does not apply to Administrative Procedure Act claims because of the limited role of a court in reviewing the administrative record. See Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89–90 (D.D.C. 2006). "[W]hen a party seeks review of agency action under the APA, . . . the district judge sits as an appellate tribunal." Rempfer v. Sharfstein, 583 F.3d 860, 865 (D.C. Cir. 2009) (quotation marks and citation omitted). The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). It also obligates courts to "exercise their independent judgment in deciding whether an agency has acted within its statutory authority." Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412 (2024).

III. Analysis

Sagebrush launches a barrage of arguments against HRSA's actions, which fall into three clusters. First, it asserts that HRSA may not remove clinics for ineligibility between annual recertifications. Second, even if HRSA could remove its clinics during that period, Plaintiff thinks that the Administration did so in a way that was arbitrary and capricious and procedurally improper. Finally, even if HRSA properly removed Sagebrush's clinics, Plaintiff contends that

(at least under these facts) the Administration could not order it to repay drug manufacturers. The Court takes those three arguments in turn.

A. Mid-Year Removals

Sagebrush's request to vacate the removal of its clinics is moot for the nine clinics that have already reenrolled in Section 340B. For the other nine who remain expelled, however, vacating their removal and ordering their reinstatement would provide effectual relief, preserving a live case for this Court's review. The question is thus whether HRSA could lawfully remove them.

The relevant statute authorizes the HHS Secretary — and thus his subdelegate HRSA — to remove a clinic from Section 340B by (1) declining to recertify it or (2) expelling the clinic after finding that it committed systematic, egregious, knowing, and intentional diversion. See Pl. MSJ at 11–12; 42 U.S.C. § 256b(a)(7)(E), (d)(2)(B)(v)(II). As Plaintiff reads the statute, those routes are available at different times. Since recertification must happen "on a not more frequent than annual basis," 42 U.S.C. § 256b(a)(7)(E), Sagebrush concludes that HRSA may check a provider's eligibility and — if the provider is ineligible — remove it from the program only at those one-year intervals. See Pl. MSJ at 11–16. By contrast, Plaintiff concedes that the Administration can kick a provider out for diversion at any time. Here, however, HRSA removed Sagebrush's clinics because they were ineligible — and it did so between annual recertifications. That route, Plaintiff thinks, is one that the statute does not allow.

Sagebrush reads the statute's basic structure right but misses a key point: when Congress authorizes an agency to make a decision, it implicitly authorizes the agency to reconsider. Mazaleski v. Treusdell, 562 F.2d 701, 720 (D.C. Cir. 1977); Ivy Sports Med., LLC v. Burwell, 767 F.3d 81, 86 (D.C. Cir. 2014); see also Albertson v. FCC, 182 F.2d 397, 399 (D.C. Cir. 1950)

("The power to reconsider is inherent in the power to decide."). The D.C. Circuit used to call this an "inherent" power of agencies. E.g., Mazaleski, 562 F.2d at 720. It has since clarified that because agencies have only the powers that Congress gives them, "the term 'inherent' is misleading." Nat. Res. Def. Council v. Regan, 67 F.4th 397, 401 (D.C. Cir. 2023). The more precise explanation is that when Congress authorizes an agency to decide, that authorization implicitly includes the power to reconsider. Id.

Applying that rule here, when the statute authorizes HRSA to certify or recertify a provider as eligible for Section 340B, it impliedly permits the Administration to revisit that decision. That is what HRSA did here. It initially certified and recertified these clinics with hardly any scrutiny. See Mar. 25, 2026, Hr'g Tr. at 12:22–25 ("It's somewhat automatic that after [providers] attest that the information is correct and accurate, the certification goes through."). It then reexamined whether these eighteen sites were really eligible, found that its previous decision had been erroneous, and reversed course. When the statute authorized the Administration to certify or recertify Sagebrush's clinics, it implicitly authorized such reconsiderations.

What about the fact that HRSA recertified the clinics and then reconsidered less than a year later? Does that not violate the statute's rule that the Administration must recertify clinics "on a not more frequent than annual basis"? 42 U.S.C. § 256b(a)(7)(E). No. That is because reconsidering the last recertification decision is different from making a new one. When HRSA reconsiders its prior recertification, it asks whether a clinic was eligible at the time of that decision. The inquiry looks backward and is limited to assessing eligibility at one — and only one — date each year: the date when the clinic was last recertified. By contrast, a new

recertification focuses on the present, asking whether — regardless of the clinic's previous eligibility — it is eligible for the program now.

To see the difference, contrast HRSA's two actions here. First, it recertified fifteen of the eighteen at-issue clinics in June 2024. See Pl. Suppl. Br at 1; Def. Suppl. Br. at 3. Those decisions asked whether the clinics were eligible then — as of the date when the agency was acting. They thus illustrate the hallmarks of a recertification: accepting the previous recertification as given, asking whether subsequent changes have affected a clinic's eligibility, and deciding whether it is eligible currently. If, several months later, the Administration had asked for proof that the clinics were still eligible, then it might well have been opening a new recertification process within the same year. But it did not do that here. Instead, in December 2024 and January 2025, HRSA looked back to its June certifications and recertifications and asked whether Sagebrush's clinics had been eligible at that time. It found that some of the clinics had not qualified for Section 340B since January 2023, others had not since February 2024, and still others had never qualified at all. See J.A. at 106; Pl. Suppl. Br. at 2; Def. Suppl. Br. at 4–5. It therefore decided that its previous determinations had been wrong at the time when they were made — *i.e.*, June 2024 — and so undid them. It was thus reconsidering its first round of recertifications, not starting a second round.

At times, Sagebrush seems to argue that even if HRSA was merely reconsidering, Congress has barred it from doing so. Plaintiff insists that because Congress created a mechanism for mid-year removals — expelling an entity for diversion — that mechanism must be "exclusive." Pl. MSJ at 11–14. Plaintiff is right that Congress can limit an agency's ability to reconsider. Regan, 67 F.4th at 401. But it has not done that here.

The D.C. Circuit holds that Congress has ousted an agency's power to reconsider only when the statute "provides statutory authority to rectify the agency's mistakes" through some alternative mechanism. Ivy Sports Med., 767 F.3d at 86. Take Ivy Sports Medicine. In that case, the statute explicitly created a procedure for the agency to undo a previous action, which required the change to first undergo notice and comment. Id. at 84. The agency instead tried to revise its choice by simply reconsidering — thereby skipping the notice and comment that Congress had intended. Id. at 85–86. Because the statute had laid out a procedure that the agency "could have used" "to correct the same mistake," and because reconsideration would "short-circuit or end-run th[at] carefully prescribed statutory . . . process," the circuit held that Congress had displaced the agency's implicit reconsideration authority. Id. at 87. In general, statutes displace that authority when they "provide[] a mechanism capable of rectifying mistaken actions." Am. Methyl, 749 F.2d at 835; accord New Jersey v. EPA, 517 F.3d 574, 583 (D.C. Cir. 2008). Put differently, courts are "unwilling[] to imply revocation authority" where Congress has created an alternative scheme that would address "precisely the evil an implied revocation authority would remedy." Am. Methyl, 749 F.2d at 837.

The statute here provides no such mechanism. It lets HRSA boot a provider because it diverted drugs, but that does not allow the Administration to remove a provider who is ineligible for the program entirely. The diversion provision therefore does not "provide[] statutory authority to rectify the agency's mistakes," Ivy Sports Med., 767 F.3d at 86, does not "provide[] a mechanism capable of rectifying mistaken" certifications, Am. Methyl, 749 F.2d at 835, and so does not overcome the default presumption that Congress authorized HRSA to reconsider erroneous certifications. The statute therefore authorized HRSA to remove Sagebrush's long-ineligible clinics mid-year.

B. Other Challenges to Removal

Even if HRSA could remove the clinics in the middle of the year, Sagebrush still challenges how the Administration did so. First, Plaintiff claims that HRSA removed several sites from Section 340B while letting one site (number STD891132) remain, even though that site and the removed ones had "identical funding streams and documentation." Pl. MSJ at 17. Sagebrush thus argues that the Administration treated similarly situated clinics differently without explaining why and so acted arbitrarily and capriciously. Id.

The Court disagrees. When HRSA asked Sagebrush to prove its clinics' eligibility, it specifically asked for documents showing that each site was receiving qualifying funding, complete with awards bearing each clinic's name and address. See J.A. at 36. HRSA says that Sagebrush submitted such documentation for STD891132 — in the form of a grant from the Nevada Department of Health and Human Services to screen for, treat, and prevent STDs at that site — but not for the clinics that the Administration found ineligible. See Def. MSJ at 6 (citing J.A. at 80), 12; ECF No. 51 (Def. Reply) at 4 (citing J.A. at 80). That difference in documentation was the basis for the Administration's decision: its letter expelling Sagebrush's clinics explained that Plaintiff had "failed to provide documentation" showing that they were eligible, see J.A. at 106 — while, again, it had provided such documentation for STD891132. The Administration thus explained why it treated the clinics differently.

To be fair, while the record supports HRSA's contention that one grant listed STD891132 but not the other clinics, the grant that Defendants cite is too laconic to offer definitive proof that this was the case. See id. at 80. Matching it to the Government's Section 340B records, however, appears to support Defendant's assertion. Compare id. (grant to Sagebrush clinic located at 8379 W Sunset Rd., Suite 210, in Las Vegas), with STD891132, 340B OPAIS,

https://perma.cc/BQ26-P8Y3 (Section 340B records listing STD891132 at that address). But Sagebrush does not even contest the Administration's account. It just keeps intoning that "HRSA left [STD891132] active while terminating other Nevada sites supported by the same State funding stream, without explanation." ECF No. 48 (Pl. Reply) at 8; see also id. at 11. As support, it cites only an email that it sent HRSA restating that same assertion, while providing no record evidence that might back it up. Id. at 8 (citing J.A. at 188). Weighing HRSA's explanation supported by the record against Sagebrush's assertion supported by nothing, the Court must side with the Administration. Indeed, by not even attempting to rebut HRSA's account, Sagebrush has conceded it. Wilkins v. Jackson, 750 F. Supp. 2d 160, 162 (D.D.C. 2010). Once the Court accepts the premise that a grant listed STD891132 but not the other clinics, then it follows that the Administration's choice was both "reasonable and reasonably explained." Dep't of Com. v. New York, 588 U.S. 752, 776 (2019).

Next, Sagebrush takes issue with the documentation requirement itself. It argues that no statute or rule required it to produce grants showing each clinic's name and address; by requiring that documentation, HRSA was thus (Plaintiff thinks) promulgating a substantive rule that had to go through notice and comment. See Pl. MSJ at 19. That argument makes a basic category error. Agencies must use notice and comment for rulemaking. Pub. Serv. Comm'n v. FCC, 906 F.2d 713, 717 (D.C. Cir. 1990). They do not need it for their actions during informal adjudications. Int'l Internship Program v. Napolitano, 718 F.3d 986, 988 (D.C. Cir. 2013); Everett v. United States, 158 F.3d 1364, 1368 (D.C. Cir. 1998).

What is the difference between the two? Rulemaking involves issuing a general policy that binds parties prospectively, "rather than case-specific individual determinations." Neustar, Inc. v. FCC, 857 F.3d 886, 893 (D.C. Cir. 2017); see also 5 U.S.C. § 551(4) (defining "rule" as

"an agency statement of general or particular applicability and future effect"). By contrast, informal adjudication determines a party's rights or obligations (and does so without the strictures of formal adjudication). Elec. Energy, Inc. v. EPA, 106 F.4th 31, 45 (D.C. Cir. 2024) ("Unlike rulemaking, which typically announces generally applicable legal principles and governs only the future, adjudication involves case-specific determinations that immediately bind parties by retroactively applying law to their past actions.") (quotation marks omitted); see also Matlovich v. Sec'y of the Air Force, 591 F.2d 852, 861 (D.C. Cir. 1978) (contrasting "written rules" with "case-by-case decision making"). Of course, adjudicating a party's rights and obligations requires interpreting the law. Those decisions, however, do not turn the adjudication into a rulemaking and so do not require notice and comment, even if they set a precedent that will govern a host of similarly situated parties. ITServe All., Inc. v. U.S. Dep't of Homeland Sec., 71 F.4th 1028, 1035 (D.C. Cir. 2023).

HRSA's actions here took place during what was plainly an informal adjudication. The Administration was applying the law in a one-off decision to determine whether Sagebrush's clinics were eligible for a government program. Its legal interpretations made in the course of that decision — including what documents Sagebrush needed to show eligibility — did not need to undergo notice and comment. If Sagebrush thinks that the documentation requirement was unlawful, then it should have challenged it as arbitrary and capricious. See U.S. Postal Serv. v. Postal Regul. Comm'n, 785 F.3d 740, 755 (D.C. Cir. 2015) (arbitrary-and-capricious review governs informal adjudications). It did not, however, so its challenge fizzles.

Finally, Plaintiff returns to its original theory that HRSA acted arbitrarily and capriciously — this time, because it expelled Sagebrush clinics without waiting for documentation that Plaintiff says would have proven their eligibility. Before HRSA removed Sagebrush's clinics,

Plaintiff sent it a letter from the Nevada Department of Health and Human Services promising to update its grants to show that those clinics qualified for Section 340B. See Pl. MSJ at 17; J.A. at 200 (letter asserting that Department was "amending the current award" to satisfy HRSA requirements). Instead of waiting for this forthcoming proof of eligibility, however, HRSA "pressed ahead with termination." Pl. MSJ at 17.

Plaintiff's promise to prove eligibility at some time in the future, however, did not solve the fundamental problem: it had no current proof that its clinics were eligible. Swearing to get that proof later does not suffice, and the Administration did not have to take it on trust that the amended documents — which did not yet exist and which it could not see — would meet its requirements. It was hardly arbitrary to remove clinics that still could not show eligibility months after such documentation was due. See Sagebrush, 2025 WL 1784436, at *4 (holding similarly when denying PI motion).

C. Repayment

Finally, Sagebrush disputes whether it must reimburse drug makers for any ill-gotten discounts. Recall that when HRSA removed Plaintiff's clinics from the program, it admonished, "It is Sagebrush's responsibility to determine the full scope of non-compliance and repay affected [drug] manufacturers . . . for the period of time that" its clinics were ineligible. See J.A. at 107; see also id. at 169 (reiterating this position). Until Sagebrush "determined the full scope of noncompliance" and "repaid affected manufacturers," HRSA warned, its expelled sites would not be let back into Section 340B. Id. at 107. Sagebrush argues that these "repayment demands" were unlawful and asks the Court to vacate them. See Pl. MSJ at 21.

The Court will not, since the letter's statements are not final agency action. See 5 U.S.C. § 704 (Administrative Procedure Act creates cause of action to challenge only such step). An

agency's action is final if (1) it is the "consummation of the agency's decisionmaking process," and (2) it determines a party's "rights or obligations" or "legal consequences will flow" from it. Bennett v. Spear, 520 U.S. 154, 177–78 (1997) (quotation marks omitted). Even if the challenged action meets one of those prongs, it is unreviewable if it fails the other. Sw. Airlines Co. v. U.S. Dep't of Transp., 832 F.3d 270, 275 (D.C. Cir. 2016). The statements here flunk both.

Start with whether they represent the consummation of HRSA's decisionmaking process. The letter contains two statements that could be construed as final action: a putative order that Sagebrush must repay affected manufacturers and an alleged decision that Plaintiff's clinics would not be let back into Section 340B until it had paid up. Neither one satisfies Bennett's first prong.

The first statement — that Sagebrush must repay improper discounts — specified that HRSA "does not endorse any specific methodology to determine the scope of 340B non-compliance" or "the amounts owed to the affected manufacturers." J.A. at 107. The Administration thus had not decided whether Sagebrush owed $1 million, $1 billion, or nothing. Instead, it would make that decision later — when any expelled clinics reapplied and HRSA would have to decide whether Sagebrush had adequately "determined the full scope of noncompliance[and] repaid affected manufacturers." Id. Until then, the challenged statement merely told Sagebrush and the drug manufacturer to take the first cut. Because these statements never resolved how much the clinics owed or even whether they owed anything at all, they were not a decision either way — let alone a final one.

Moving to the assertion that clinics would not be allowed back until they had paid, it was also non-final. Even when an agency's statement appears definitive on its face, it is not final if

the agency subsequently does not treat it as binding. Sw. Airlines, 832 F.3d at 275–76. Take Southwest Airlines, where the Department of Transportation sent parties a letter with statements that appeared conclusive: it announced that federal policy "requires" certain action, that "it is [the agency's] position that" an entity would be "entitled" to a right and "should not be" deprived of it, and that a party "must" do something because a federal plan "requires" it. Sw. Airlines, No. 15-1036, ECF No. 28 (J.A.) at 2 & n.1 (D.C. Cir. 2016). Months later, however, the agency instituted a proceeding to decide the issues that its prior letter had seemed to resolve. Sw. Airlines, 832 F.3d at 274. The D.C. Circuit held that the earlier letter's statements were therefore non-final. Id. at 277. Whether an action is final, the circuit explained, depends on "the way in which the agency subsequently treats the challenged action," and this agency treated the letter as if it did not bind the regulated parties. Id. at 275–77; see also Nat'l Mining Ass'n v. McCarthy, 758 F.3d 243, 253 (D.C. Cir. 2014) ("Our cases . . . have looked to post-guidance events to determine whether the agency has applied the guidance as if it were binding on regulated parties."); Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457, 479 (2001) (looking to agency's "own behavior" to evaluate finality). That rule makes sense: if the agency does not treat its prior action as its final word, then the action cannot have been the consummation of the agency's decisionmaking process.

Here, HRSA did not treat the challenged statements as final and binding. Its letter might have declared that it would not re-register clinics until they paid back manufacturers, but the Administration later re-enrolled those very clinics without requiring payment. See Pl. Suppl. Br. at 3. It therefore did not treat the prior letter as if it had conclusively determined Sagebrush's obligations, so that letter's statements were non-final.

For the reasons discussed above, both sets of statements also fail Bennett's second prong: they imposed no legal consequences. The statement that Sagebrush should repay affected manufacturers left open the possibility that Plaintiff might owe nothing at all, so it created no binding obligation. Meanwhile, the assertion that Sagebrush's clinics would be denied readmission until they paid had no legal effect whatsoever. Both statements were merely advisory, and Sagebrush safely could — and apparently did — ignore them both. Sagebrush therefore lacks a cause of action to challenge these statements, and the Court will not vacate them.

IV. Conclusion

HRSA had statutory authority to remove Sagebrush's clinics, the removals were procedurally and substantively proper, and Plaintiff cannot challenge the Administration's non-final statements about repaying improper discounts. The Court will therefore grant summary judgment to HRSA. An Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
Chief Judge

Date: April 27, 2026