UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

SAGEBRUSH HEALTH SERVICES,

Plaintiff,

v.

Civil Action No. 25-915 (JEB)

ROBERT F. KENNEDY, JR., et al.,

Defendants.

MEMORANDUM OPINION

After several of its healthcare clinics were terminated from a federal drug-discount program, Sagebrush Health Services filed this suit against the Government, alleging that those clinics were wrongfully removed. It now seeks a preliminary injunction ordering the agencies to reinstate them. Because Sagebrush has not demonstrated that it is likely to succeed on the merits of its claim that the Government acted unreasonably, the Court will deny the Motion.

I. Background

The federal 340B Drug Pricing Program allows certain healthcare providers, known as "covered entities," to purchase prescription drugs at substantial discounts from participating drug manufacturers. See 42 U.S.C. § 256b; ECF No. 1 (Compl.), ¶ 1. As relevant here, one way for a provider to qualify as a covered entity, and thus become eligible to participate in the 340B Program, is to receive funds under Section 318 of the Public Health Service Act "through a State or unit of local government." Id. § 256b(a)(4)(K). That provision establishes the authority of the Department of Health and Human Services to provide "grants" to states. Id. § 247c(b)–(d). An entity receiving Section 318 funding, then, receives funding or in-kind support from a state or local government that was originally provided as a federal grant. See Compl., ¶¶ 13–15. The

340B Program is administered by the Health Resources and Services Administration (HRSA), a component of HHS, which is responsible for certifying covered entities for eligibility. <u>Id.</u>, ¶¶ 1, 16.

Sagebrush Health Services "is a Nevada nonprofit foundation that is affiliated with specialty care clinics in Nevada, Connecticut, and South Carolina." <u>Id.</u>, ¶ 31. Sagebrush operates sites in Nevada and Connecticut that provide sexual-healthcare services. <u>Id.</u>, ¶¶ 33–36. Some of those sites have participated in the 340B Program by way of receiving Section 318 funds. Id., ¶¶ 31–32, 38–39.

In February 2024, HRSA began a review of 53 Sagebrush sites' eligibility for and compliance with the 340B Program, id., ¶ 42, kicking off a tortuous series of events. After nearly a year of back-and-forth between the agency and Sagebrush, during which the provider attempted to prove eligibility, the Government determined that Sagebrush had not shown that 19 clinics in Nevada and one in Connecticut were receiving Section 318 funding. Id., ¶¶ 48, 50, 56. Consequently deeming those 20 sites ineligible, HRSA informed Plaintiff on December 20, 2024, that the clinics' participation in the 340B Program would be terminated within a week. Id., ¶ 48; ECF No. 4 (1st Guru Charan Decl.), Exh. G (Dec. 2024 Termination Letter) at 2. Following a protest from Sagebrush, which included additional documentation regarding the atrisk sites, HRSA paused the termination date pending further review. See Compl., ¶¶ 52–54. The agency decided again on January 13, 2025, however, that Sagebrush had still failed to demonstrate eligibility for the Program, id., ¶ 56, and terminated the 20 clinics the next day. Id., ¶ 61.

Plaintiff filed suit three days later, seeking a temporary restraining order and a preliminary injunction to prevent those terminations. Sagebrush Health Servs. v. Becerra, No.

25-127, ECF No. 2 (First Mot.) (D.D.C. Jan. 16, 2025). This Court denied that Motion on the ground that Sagebrush's legal arguments were unlikely to succeed. See Sagebrush, No. 25-127, ECF No. 27 (Jan. 31 Hr'g Tr.) at 27:2–27:3. That, however, was far from the last the Government (or the Court) would hear from Sagebrush. The company continued its *tête-à-tête* with HRSA by requesting reinstatement of the 20 sites in March of this year. See Compl., ¶ 62. In response, the agency not only declined to reinstate the sites but also terminated the only two Sagebrush clinics still participating in the 340B Program, also for not receiving Section 318 funding. Id., ¶ 63.

Sagebrush filed suit anew and once again sought a temporary restraining order, this time against the termination of those two sites from the 340B Program. See ECF No. 2 (TRO Mot.). After the Court denied Plaintiff's request, see Minute Order of Apr. 10, 2025, Sagebrush filed a Motion for a Preliminary Injunction seeking to return all of the terminated sites to the Program. See ECF No. 14 (PI Mot.) at 2. Over the course of two hearings on that Motion, the Court has narrowed this dispute. It now revolves solely around 18 Sagebrush sites in Nevada (the Sites) and whether HRSA knew or should have known that they were receiving Section 318 funding when it terminated them on January 14, 2025, thereby rendering the termination arbitrary and capricious. See ECF No. 18 (Apr. 25 Hr'g Tr.) at 19:18–19:20, 20:4–20:6. Lacking clarity on that issue, the Court ordered focused supplemental briefing, id. at 19:25–20:3, which the parties have now provided. They nevertheless remain at a stalemate.

II. Legal Standard

"A preliminary injunction is an extraordinary remedy never awarded as of right." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24 (2008). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to

suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." Sherley v. Sebelius, 644 F.3d 388, 392 (D.C. Cir. 2011) (alterations in original) (quoting Winter, 555 U.S. at 20). "The moving party bears the burden of persuasion and must demonstrate, 'by a clear showing,' that the requested relief is warranted." Hospitality Staffing Solutions, LLC v. Reyes, 736 F. Supp. 2d 192, 197 (D.D.C. 2010) (quoting Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 297 (D.C. Cir. 2006)).

Before the Supreme Court's decision in Winter, courts weighed these factors on a "sliding scale," allowing "an unusually strong showing on one of the factors" to overcome a weaker showing on another. Davis v. Pension Benefit Guar. Corp., 571 F.3d 1288, 1291–92 (D.C. Cir. 2009) (quoting Davenport v. Int'l Bhd. of Teamsters, 166 F.3d 356, 361 (D.C. Cir. 1999)). Both before and after Winter, however, one thing is clear: a failure to show a likelihood of success on the merits alone is sufficient to defeat the motion. Ark. Dairy Coop. Ass'n v. USDA, 573 F.3d 815, 832 (D.C. Cir. 2009) (citing Apotex, Inc. v. FDA, 449 F.3d 1249, 1253–54 (D.C. Cir. 2006)); Archdiocese of Wash. v. Wash. Metro. Area Transit Auth., 281 F. Supp. 3d 88, 99 (D.D.C. 2017), aff'd on other grounds, 897 F.3d 314 (D.C. Cir. 2018).

III. Analysis

Plaintiff seeks relief under the Administrative Procedure Act, claiming that HRSA acted arbitrarily and capriciously by terminating the Sites from the 340B Program. See Compl., ¶¶ 104–21; PI Mot. at 11–16. The parties agree that if the Sites received funding from the federal government through the Nevada Department of Health and Human Services (NHHS) (*i.e.*, Section 318 funding) at the time of termination, they were eligible to participate in the Program under the authorizing statute. See ECF No. 14-1 (PI Br.) at 5; ECF No. 16 (PI Opp.) at

2. (It bears mentioning, however, that in separate litigation, two drug companies are questioning whether Sagebrush can deem sub-entities, such as the Sites, eligible by passing Section 318 funding to them. See ECF No. 31 (Amgen Amicus); Amgen Inc. v. Becerra, No. 24-3571, ECF No. 1 (Compl.), ¶¶ 111-16 (D.D.C. Dec. 20, 2024); Genentech, Inc. v. Fink, No. 25-290, ECF No. 1 (Compl.), ¶¶ 110–15 (D.D.C. Jan. 31, 2025)). The parties also concur that Sagebrush was obligated to demonstrate that when HRSA terminated the Sites on January 14, 2025, "the Sites were at that time operating under" Section 318 funding. See ECF No. 19 (Pl. Supp. Br.) at 1; ECF No. 20-2 (3d Chantelle Britton Decl.), ¶¶ 19–20. The parties finally agree that the Sites did in fact receive such funding during the relevant time period. See Pl. Supp. Br. at 1; ECF No. 20 (Gov't Supp. Resp.) at 3.

The sole remaining question, then, is whether the Government knew or reasonably should have known that the Sites were receiving qualifying funding when it terminated them on January 14 — that is, whether its termination decision was reasonable in light of the information Plaintiff had provided. Simply asked, but apparently not so simply answered. Compare Pl. Supp. Br. at 1 ("The answer is yes."), with Gov't Supp. Resp. at 1 ("The answer to this question is no.").

Sagebrush points to three of its missives to HRSA, contending that each contains proof that it informed the Government of the Sites' funding prior to termination. After spelunking through the record in search of resolution, the Court concludes that HRSA reasonably terminated the Sites from the 340B Program. It takes each disputed communication in turn, then ties up some loose ends.

Plaintiff first insists that it provided a table to the agency on March 4, 2024, confirming that each Site was receiving eligible funding. See ECF No. 22 (Pl. Supp. Reply) at 2–4; ECF No. 22-2 (5th Charan Decl.), Exh. A (Mar. 2024 Table). That table, however, suffers from fatal

deficiencies. For each clinic listed there, "[s]upport" — *i.e.*, Section 318 funding — ends on December 31, 2023, or January 31, 2024. See Mar. 2024 Table at 2, 4, 6, 8, 10. When HRSA notified Sagebrush of the looming terminations on December 20, 2024, however, it specified that the Sites were ineligible because they did not receive "[S]ection 318 funding or support from NHHS" either after February 1, 2024, or "at any point in time." Dec. 2024 Termination Letter at 1. The March 2024 table, moreover, contains no verification of the funding from NHHS. It therefore does nothing to show, as Sagebrush must, that HRSA knew or should have known that the Sites were receiving Section 318 funding at the time the agency terminated them in January 2025.

Next, Sagebrush relies on a letter containing three tables that it sent to HRSA on August 2, 2024, five months before the agency's final termination decision. See Pl. Supp. Reply at 2, 4–5; ECF 14-2 (2d Charan Decl.), Exh. D (Aug. 2024 Letter). That information cannot save Plaintiff either. The tables list only Sagebrush sites that received direct or in-kind funding "during the time period from January 1, 2023, through January 31, 2024," and "since 2/1/2024." Aug. 2024 Letter at 5–6. The tables do not detail how long such funding would last or — as the Government points out, see Gov't Supp. Resp. at 5 — any information at all about the source of the funding besides that it was "approved by NHHS." Aug. 2024 Letter at 5–6. Sagebrush did not specify, for example, whether the funds had federal origins, NHHS's role in disbursing the funding, or the grant numbers for particular Sites. Id. at 16–22. The tables instead merely list clinics that Sagebrush purports receive Section 318 funding. The August 2024 submission, like the March 2024 table, also contains no corroboration from NHHS regarding the funding. It was thus reasonable for HRSA to conclude in January 2025 that those submissions did not adequately document that the Sites were then receiving Section 318 funding.

The final arrow in Sagebrush's quiver is a February 21, 2025, letter including an updated notice from NHHS. See 2d Charan Decl., Exh. N (Feb. 2025 Letter). That notice, which was created by the state agency and finalized on February 4, 2025, at last both names the 18 Sites and sets out the nature of their Section 318 funding. See ECF No. 17-1 (3d Charan Decl.), Exh. A (Feb. 2025 Notice) at ECF pp. 25–43; id. at ECF p. 30 (listing Sites). Those submissions, as the Government acknowledges, constitute "definitive documentation from Sagebrush establishing that the [S]ites were receiving [Section] 318 funding." 3d Britton Decl., ¶ 22. That proof, however, came too late. Recall, HRSA sought to terminate the Sites on December 27, 2024, following ten months of back-and-forth with Sagebrush. See Dec. 2024 Termination Letter at 2. The agency paused that termination at Sagebrush's request but, after "review[ing] the additional documentation provided by Sagebrush" and concluding that those documents contained "a number of . . . deficiencies," informed Plaintiff on January 13 that it stood by its original decision. See 1st Charan Decl., Exh. L (Jan. 2025 Termination Letter). The agency could not have considered in January a notice from NHHS that was not finalized until February.

Sagebrush does not attempt to resist that truism. It instead suggests that, rather than "forg[ing] ahead with termination," HRSA should have "simply wait[ed] for NHHS to issue the updated document that expressly confirmed the eligibility of the" Sites. See Pl. Supp. Br. at 5–6. To be sure, the Government could have waited for appropriate documentation and allowed Sagebrush additional chances to prove the Sites' eligibility. Given that HRSA had already been doing so for nearly a year when it finally terminated the Sites, however, the Court does not believe that the agency was under any obligation to continue biding its time. The February 21, 2025, letter therefore is no panacea.

Sagebrush, accordingly, has not pointed to any documentation demonstrating that it informed HRSA that the Sites were receiving Section 318 funding at the time of their termination. In a last-ditch effort to show otherwise, Plaintiff argues for the first time in its supplemental brief that the information it entered in the Office of Pharmacy Affairs Information System (OPAIS) database, HRSA's "340B covered entity tracking database," notified HRSA of the funding at the time of termination. See id. at 2-4. Even assuming Sagebrush has not forfeited that argument, see Jones Lang LaSalle Ams., Inc. v. NLRB, 128 F.4th 1288, 1296-97 (D.C. Cir. 2025), the information in OPAIS was provided by Sagebrush itself. See 3d Britton Decl., ¶ 25. The 340B statute obligates the Government to "develop and implement a process for the certification of entities" that receive state and local funds, see 42 U.S.C. § 256b(a)(7)(A); "require the recertification of entities," id. § 256b(a)(7)(E); and "require that such entities submit information to the Secretary" to assist with that determination. Id. The statute does not require HRSA to take 340B participants' self-reported information at face value or bar the agency from initiating its own inquiries to confirm compliance. See 3d Britton Decl., ¶¶ 6–7, 25. If HRSA has reason to doubt the entity's unverified self-attestations in OPAIS or otherwise wants to ensure eligibility, it appropriately may seek more formal documentation, such as funding-award documents or confirmation from the state agency.

To the extent that Sagebrush also attempts to revive its challenge to HRSA's termination of one Connecticut clinic, the Court has already denied Plaintiff's Motion for a TRO as to that site "for lack of likely success on the merits." Minute Order of Apr. 10, 2025. As Sagebrush offers no persuasive reason to disturb that conclusion, the Court will not do so.

In sum, Sagebrush has not demonstrated a likelihood of success on the merits for any of the Sites. The Court will consequently decline to order their reinstatement into the 340B

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Program. See Pl. Supp. Br. at 6–7. Although the Sites now appear to be eligible to participate in

the Program once more, Plaintiff did not demonstrate as much before the agency at the

appropriate time. See Butte Cnty. v. Chaudhuri, 887 F.3d 501, 506 (D.C. Cir. 2018) ("When

reviewing agency action, we generally consider only information that the agency had when it

made its decision. Thus, even if a party seeks to rely on evidence conflicting directly with an

agency decision, we will not invalidate the decision as arbitrary and capricious based on the

evidence if it was not in the record at the time of the decision.") (cleaned up). Because its Sites

were properly terminated, Sagebrush must follow the ordinary administrative process for re-

registration — as it has already begun to do for eight other Sites. See Pl. Supp. Br. at 6.

IV. Conclusion

For the foregoing reasons, the Court will deny Plaintiff's Motion for Preliminary

Injunction. A separate Order so stating will issue this day.

/s/ James E. Boasberg JAMES E. BOASBERG

Chief Judge

Date: June 27, 2025

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