UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMGEN, INC, *et al.*, **Plaintiffs,** **v.** **ROBERT F. KENNEDY JR., *et al.*,** **Defendants.**	**Civil Action No. 24-3571 (JEB)**

MEMORANDUM OPINION

Section 340B of the Public Health Service Act requires pharmaceutical companies to sell their drugs to certain healthcare providers at a hefty discount. Only a few kinds of providers may take advantage of this program, and the Secretary of Health and Human Services must certify — and periodically recertify — that a provider is eligible. In this case, three drug manufacturers — Amgen, Eli Lilly, and UCB — allege that the Secretary improperly certified a string of ineligible clinics, costing Plaintiffs millions of dollars in improper discounts. They have sued HHS and its component that administers Section 340B, as well as both entities' leaders, arguing that both the process and results of the Secretary's certification and recertification decisions are arbitrary and capricious.

Defendants now move to dismiss some parts of the Complaint. First, they say that Plaintiffs cannot bring one of their counts because they have not exhausted administrative remedies. Second, they argue that because the Secretary has decertified some of the disputed clinics, Plaintiffs' claims as to them are moot. The Court disagrees with both arguments and so will deny the Partial Motion to Dismiss.

I. Background

A. Section 340B

Section 340B offers drug manufacturers a deal: in exchange for Medicaid and Medicare Part B's covering a drug, its manufacturer must sell it at a discount to "covered entit[ies]" — such as hospitals with a high share of low-income patients, black-lung clinics, and (as relevant here) clinics receiving grants from state or local governments to treat sexually transmitted diseases. See 42 U.S.C. § 256b(a)(1), (a)(4)(F), (a)(4)(K)–(L); U.S. Gov't Accountability Off., GAO-11-836, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 10 (2011); Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 455 (D.C. Cir. 2024). These discounts are steep, typically knocking 20–50% off the drug's sticker price. See U.S. Gov't Accountability Off., *supra*, at 2. The discounts help uninsured patients, who can get cheaper drugs from covered entities. Sanofi Aventis U.S. LLC v. HHS, 58 F.4th 696, 699 (3d Cir. 2023). They also help covered entities themselves. The entities can buy drugs at a discount, get reimbursed by insurers for the drug's full price, and pocket the difference. See U.S. Gov't Accountability Off., *supra*, at 13–14.

To enroll in Section 340B, covered entities must get certified — and periodically recertified — by the Secretary of Health and Human Services. See 42 U.S.C. § 256b(a)(7). They also must agree to certain restrictions. For instance, they cannot "resell or otherwise transfer" a discounted drug "to a person who is not [their] patient," a practice known as diversion. Id., § 256b(a)(5)(B). If a drug manufacturer reasonably suspects that a covered entity has diverted drugs, it can audit the entity's records. Id., § 256b(a)(5)(C); Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65409 (Dec. 12, 1996). It can then file a claim for diversion with HHS, which an administrative panel decides. See 42 U.S.C.

§ 256b(d)(3)(A); 42 C.F.R. §§ 10.20, 10.21(a)(2). If the drug manufacturer is unhappy with the panel's decision, it can appeal to the Administrator of the Health Resources and Services Administration (HRSA) and, from there, to a court. See 42 C.F.R. § 10.24(a)–(b), (e).

B. This Case

Plaintiffs here suggest that the drug discounts may encourage providers to apply for Section 340B certification even if they are not eligible. See ECF No. 1 (Compl.), ¶ 21. They particularly object to the use of Section 340B by Sagebrush Health Services, which runs thirteen clinics across Nevada, Connecticut, and South Carolina. Id., ¶¶ 5, 35, 38. Sagebrush clinics claimed that they were eligible for 340B because they receive funding from state and local governments to treat sexually transmitted diseases. Id., ¶ 5; see also 42 U.S.C. § 256b(a)(4)(K) (including such clinics as covered providers). The Secretary certified and recertified them on that basis. See Compl., ¶¶ 1–6. But, according to the Complaint, these clinics were not eligible for the program and so bilked Plaintiffs — drugmakers Amgen, Eli Lilly, and UCB — out of millions of dollars in improper discounts. Id., ¶¶ 4–7. Those three companies have now sued the Department of Health and Human Services and its Secretary, as well as HRSA and its Administrator, seeking declaratory and injunctive relief. Id., ¶¶ 1, 15–18, pp. 41–42. They bring five separate counts under the Administrative Procedure Act, alleging that certifying and recertifying the clinics was arbitrary and capricious because:

(1) Although Sagebrush clinics were eligible for Section 340B discounts only because they received funding to treat STDs, they used their eligibility to get discounts on drugs that treat unrelated conditions, like diabetes and Alzheimer's, id., ¶¶ 44, 135–39;

(2) Sagebrush clinics thereby diverted drugs to people who were not truly "patient[s] of the entity," 42 U.S.C. § 256b(a)(5)(B); Compl., ¶¶ 141–44;

(3) The clinics purported to be eligible as "entit[ies] receiving funds . . . relating to treatment of sexually transmitted diseases . . . through a State or unit of local government," 42 U.S.C. § (a)(4)(K), but their funding was at best several steps removed from such governmental grants, see Compl., ¶¶ 147–49;

(4) Several clinics received only in-kind grants from state or local governments — say, boxes of condoms — which are not "funds," id. ¶¶ 153–55; and

(5) HRSA's certification and recertification process omitted safeguards required by statute. Id., ¶¶ 159–65.

As described in more detail below, Defendants now move to partially dismiss for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). See ECF No. 14 (MTD).

II. Legal Standard

To survive a motion to dismiss under Rule 12(b)(1), a plaintiff generally bears the burden of proving that the court has subject-matter jurisdiction to hear her claim. DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 342 & n.3 (2006); Arpaio v. Obama, 797 F.3d 11, 19 (D.C. Cir. 2015). A court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority," Grand Lodge of Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 13 (D.D.C. 2001), which includes the obligation to consider whether claims are moot. Mine Reclamation Corp. v. FERC, 30 F.3d 1519, 1522 (D.C. Cir. 1994). Unlike with other jurisdictional issues, however, the party asserting mootness — here, Defendants — bears the burden of establishing that the case is moot. Honeywell Int'l, Inc. v. NRC, 628 F.3d 568, 576 (D.C. Cir. 2010). Additionally, unlike with a motion to dismiss under Rule 12(b)(6), the court "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

III. Analysis

Defendants are not trying to dismiss the whole case; rather, they seek to prune it back slightly. In particular, they maintain that one count should be dismissed as unexhausted, and claims regarding certain decertified clinics should be jettisoned as moot. The Court considers each point separately.

A. Exhaustion

Count II alleges that it was arbitrary and capricious for Defendants to certify Sagebrush clinics because, when these clinics give discounted drugs to people seeking care unrelated to STDs, they are diverting drugs to people who are not patients of the covered entity. See Compl., ¶¶ 141–43. Recall that if drugmakers suspect that a covered entity is diverting drugs, they can audit it and then file a claim with an HHS panel. Yet Plaintiffs did not slog through the audit and review process, instead jumping straight to filing a Complaint. See MTD at 10; see also ECF No. 16 (Pl. Opp.) at 12 (conceding this fact). Defendants therefore argue that because Plaintiffs have not exhausted their administrative remedies, they cannot bring a claim grounded in diversion.

The Government is mistaken. Exhaustion requirements come in two forms: jurisdictional and prudential. Avocados Plus Inc. v. Veneman, 370 F.3d 1243, 1247 (D.C. Cir. 2004). Neither one bars Plaintiffs' claim.

Jurisdictional exhaustion must be met when a statute requires parties to exhaust administrative remedies before a court may hear their claim. Id. There is no jurisdictional-exhaustion requirement, however, for parties challenging final agency action. Darby v. Cisneros, 509 U.S. 137, 146, 154 (1993). That is because the APA allows parties to seek judicial review of final agency action and clarifies that, as a rule, agency action is final "whether or not" the

challenger has filed "an application for a declaratory order, for any form of reconsideration, or . . . for an appeal to superior agency authority." 5 U.S.C. § 704; see also Bennet v. Spear, 520 U.S. 154, 177–78 (1997) (agency action is final if it (1) is the consummation of the agency's decision-making process and (2) determines parties' rights or obligations). In other words, plaintiffs challenging final agency action need not exhaust administrative remedies.

That default can be changed by other statutes or rules that expressly add exhaustion requirements. Id.; Avocados Plus, 370 F.3d at 1248. But to override the APA, another provision must clearly mandate that plaintiffs first exhaust administrative remedies and must also clearly specify that the requirement is jurisdictional. Darby, 509 U.S. at 146; Avocados Plus, 370 F.3d at 1248. By contrast, merely creating an administrative remedy does not force parties to use it before they can sue. Avocados Plus, 370 F.3d at 1248. Having conferred jurisdiction in the APA, Congress must speak in "clear, unequivocal terms" to take it away. Id. (quotation marks omitted).

Defendants here do not point to any statute or rule that requires Plaintiffs to first exhaust the administrative process, let alone one that says such a requirement is jurisdictional. Instead, Defendants simply maintain that since an administrative process exists, Plaintiffs must exhaust it. See MTD at 10 (arguing that because "the 340B regulations outline an audit and [administrative review] process for manufacturers who believe a covered entity engaged in diversion" and because "Plaintiffs . . . have not engaged in this process," this Court lacks jurisdiction over any diversion-related claims). That process is certainly an option for Plaintiffs, but the APA also permits them to challenge right now the final agency action of certifying and recertifying clinics under Section 340B. No jurisdictional-exhaustion requirement stands in their way.

That leaves prudential exhaustion. Under this judicially created doctrine, courts sometimes decline to hear unexhausted challenges because giving agencies the first crack advances policy goals — "giving agencies the opportunity to correct their own errors, affording parties and courts the benefits of agencies' expertise, compiling a record adequate for judicial review, [and] promoting judicial efficiency." Marine Mammal Conservancy, Inc. v. Dep't of Agric., 134 F.3d 409, 414 (D.C. Cir. 1998). When it comes to APA challenges, however, Congress has already made the policy choice: if final agency action is injuring someone, she may skip nonmandatory agency processes and seek immediate judicial review. Darby, 509 U.S. at 146, 154. Courts may not revise that choice by adding exhaustion requirements that Congress has not. Id. In suits like this one, where Plaintiffs are aggrieved by final agency action and challenge it under the APA, prudential exhaustion is therefore irrelevant. Id.

As Plaintiffs need not exhaust administrative remedies, the Court will deny Defendants' request to dismiss Count II.

B. Mootness

Defendants next try mootness. Plaintiffs are admittedly seeking many types of relief: (1) a declaratory judgment that Defendants' certification process is unlawful, (2) a declaration that it is unlawful to certify or recertify a provider as eligible for Section 340B discounts when the provider flunks various eligibility requirements, (3) a declaration that certifying and recertifying nine specific Sagebrush providers was unlawful, (4) an order setting aside the certifications and recertifications of those nine providers, (5) an injunction requiring Defendants to decertify those nine providers, and (6) an injunction prohibiting Defendants from certifying or recertifying those nine providers. See Compl. at 41–42.

After Plaintiffs filed their Complaint, Defendants ended seven of the challenged providers' participation in Section 340B. See MTD at 11. Although the Government has since reinstated five of the seven, that leaves two clinics whose eligibility Plaintiffs are disputing even though they are no longer enrolled in the program. See ECF No. 19 (Notice of Factual Development) at 1. Defendants therefore argue that "most of Plaintiffs' claims are moot" as to those two. See MTD at 11.

The Court disagrees. For starters, Plaintiffs' requests for relief (1) and (2) challenge general certification criteria, not the certification of any particular clinic. Those challenges remain live regardless of whether any given clinic enters or exits the Section 340B program.

Request (6) seeks to bar Defendants from certifying clinics in the future. Although two clinics are not currently certified, they might reapply, regain certification, and once again force Plaintiffs to sell them drugs at a discount. See Notice of Factual Development at 1 (five terminated Sagebrush clinics reapplied and were reinstated). Enjoining Defendants from reinstating those clinics, then, will stave off financial harm to Plaintiffs and so "grant [them] effectual relief." Chafin v. Chafin, 568 U.S. 165, 172 (2013) (quotation marks omitted). This request is not moot.

That leaves requests (3), (4), and (5). Seven challenged clinics are currently certified, so the Court can grant Plaintiffs relief by declaring their certification unlawful, setting it aside, or ordering Defendants to decertify them. While the scope of those orders might expand or contract with the number of clinics involved, the requests for relief are still live.

Despite Defendants' framing, it is not true that "most" — or, indeed, any — "of Plaintiffs' claims are moot." MTD at 11.

IV. Conclusion

Plaintiffs need not exhaust administrative remedies, and none of their claims is moot. The Court therefore will deny Defendants' Partial Motion to Dismiss. An Order so stating shall issue this day.

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

Date: August 4, 2025