UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALBANY MED HEALTH SYSTEM, et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 23-cv-03252 (APM)**
HEALTH RESOURCES AND SERVICES ADMINISTRATION, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

It has been nearly six years since the start of the COVID-19 pandemic and at least one federal agency is still wrestling with its aftermath. In 2020, the Health Resources and Services Administration (HRSA), the agency in charge of administering the Section 340B discount drug program, posted a series of FAQ-style statements on its website to address various administrative concerns related to the pandemic. Among the offered guidance was that, during the public health emergency, HRSA would not require new offsite facilities of qualified hospitals to register with the agency before accessing 340B drug pricing. That signaled a change in policy; since 1994, the agency had required such facilities, known as "child sites," to be listed on the covered hospital's Medicare cost report and, upon agency certification, appear in the Office of Pharmacy Affairs Information System's (OPAIS) online database, which identifies entities eligible for 340B program participation. The agency "waived" this registration requirement during the pandemic.

In October 2023, HRSA announced that it was ending the "waiver" period and reverting to its pre-pandemic registration policy. This policy shift meant that, as before, child sites of covered hospitals no longer could immediately purchase or administer 340B drugs and would have to wait months as the registration process played out before qualifying for the program. In the meantime, those facilities would have to use drugs acquired at the higher non-340B price, thereby costing their parent hospitals more to deliver care.

Plaintiffs in this action are over 40 hospitals, health systems, and other medical facilities that participate in the 340B program. They challenge HRSA's return to its pre-pandemic registration requirement for child sites of otherwise covered entities through a host of claims under the Administrative Procedure Act. Before the court are the parties' motions for summary judgment.

For the reasons explained below, the court agrees that the registration requirement conflicts with the text of the 340B statute and therefore is contrary to law. Accordingly, the court grants Plaintiffs' motion for summary judgment and denies Defendants' cross-motion. The registration requirement will be vacated.

II. BACKGROUND

A. Statutory Framework and Regulatory History

1. The 340B Program

Section 340B of the Public Health Service Act "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities." *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011); *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992). The 340B program imposes as a condition of participation in Medicare Part B and Medicaid programs that drug manufacturers "offer

discounted drugs to covered entities at discounted rates, dominantly, local facilities that provide medical care for the poor." *Astra USA, Inc.*, 563 U.S. at 115. The 340B statute provides that participating drug manufacturers "shall enter into an agreement" with the Secretary of Health and Human Services (HHS) "under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed" a specified ceiling price. 42 U.S.C. § 256b(a)(1). "The ceiling price is fixed by a statutory formula strikingly generous to purchasers." *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456 (D.C. Cir. 2024) (citing 42 U.S.C. § 256b(a)(2); *id.* § 1396r-8(c)).

Only "narrow categories" of "covered entities" are statutorily permitted to purchase discounted drugs under the 340B program. *Id.* (citing 42 U.S.C. § 256b(a)(4)). Relevant to this case are so-called safety-net hospitals, which are entities primarily serving low-income and rural patient populations. *Novartis*, 102 F.4th at 456; *AbbVie, Inc. v. Murrill*, 166 F.4th 528, 534–535 (5th Cir. 2026). Among these types of entities are qualifying disproportionate share hospitals, free-standing cancer hospitals, and children's hospitals. *See* 42 U.S.C. § 256b(a)(4).

"Covered entities" that participate in the 340B program must adhere to certain statutory requirements to ensure program integrity. *See* 42 U.S.C. § 256b(a)(5); *Eli Lilly & Co. v. Kennedy*, No. 21-cv-02608 (DLF), 2025 WL 1423630, at *2 (D.D.C. May 15, 2025) (discussing § 256b(a)(5) limitations). A covered entity may not double dip: it cannot receive discounts under both the 340B program and the Medicaid drug rebate program for the same drug unit. 42 U.S.C. § 256b(a)(5)(A)(i). Nor can a covered entity divert 340B discounted drugs: it may not resell or transfer them to a person who is not a "patient of the entity." *Id.* § 256b(a)(5)(B). HRSA guidance states in relevant part that for an individual to qualify as a "patient" of a covered entity, the entity must have "established a relationship with the individual, such that the covered entity maintains

records of the individual's health care," and the health care professional providing care must either be employed by or under contract or arrangement with the entity "such that responsibility for the care provided remains with the covered entity." *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996). A person does not qualify as a 340B patient if the only care provided by the covered entity is "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *Id.* at 55158.

Congress also adopted measures to promote program transparency. The original legislation called on the Secretary to provide notice to "manufacturers of covered outpatient drugs and [certain state agencies] of the identities of covered entities" and of entities that no longer qualified to purchase discounted drugs. § 602, 106 Stat. at 4970 (codified at 42 U.S.C. § 256b(a)(9)). Then, in 2010, as part of the Patient Protection and Affordable Care Act, Congress amplified this requirement. It tasked the Secretary with the "establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs." Pub. L. No. 111-148, § 7102, 124 Stat. 119, 825 (2010) (codified at 42 U.S.C. § 256b(d)(2)(B)(iv)). Today, that identification system is the Office of Pharmacy Affairs Information System (OPAIS) and is available on HRSA's website. *See* HRSA, *Office of Pharmacy Affairs*, https://340bopais.hrsa.gov (last visited Mar. 3, 2026).

2. 1994 Notice

The Secretary of HHS "lacks rulemaking authority over the section 340B program." *Novartis*, 102 F.4th at 456. Still, from time-to-time, HRSA issues guidance documents

interpreting and implementing the 340B program. *Id.* At the center of the present dispute is one issued in 1994.

Some covered-entity hospitals deliver medical services at locations separate from their main campus to reach patients who face geographic, financial, or other barriers to receiving treatment at the primary hospital facility. *See* Pls.' Replacement Mem. in Supp. of Pls.' Mot. for Summ. J., ECF No. 27 [hereinafter Pls.' Mem.], at 5–6. An example is an off-campus infusion center that treats cancer patients and other patients that require medications delivered through intravenous injection. *See id.* These separate locations are known as "child sites."

In 1994, HRSA issued guidance acknowledging this reality. It determined that, "for purposes of section 340B drug discounts, a further interpretation of 'hospital' is needed" to ensure that covered hospitals' use of 340B drugs at child sites would not run afoul of the statutory non-transfer restriction. *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities*, 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994) [hereinafter 1994 Notice] ("Some disproportionate share hospitals offer outpatient services in off-site or satellite outpatient facilities."). To solve the problem, the 1994 Notice established that an outpatient facility "is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report." *Id.* at 47886. It further stated that off-site facilities would be able to "access [340B program] discount pricing" only after the "facilities are added to the master list of eligible and participating covered entities." *Id.*

The 1994 Notice thus established two preconditions to a child site's participation in the 340B program. First, the child site must be listed on the main hospital's Medicare cost report. And second, it must appear in the OPAIS covered-entities database. Only then can a child site

receive and administer 340B drugs to a patient of the covered entity. The court refers to these preconditions together as the "registration requirement."

This two-step process created a natural time lag between the time a child site was up and running and when it became 340B eligible. *See* Pls.' Mem. at 10–11. Medicare cost reports are submitted annually based on the covered entity's most recent fiscal year, *see* 42 C.F.R. § 413.20(b), and must be filed "on or before the last day of the fifth month following the close of the period covered by the report." *Id.* § 413.24(f)(2)(i). That is, the cost reports are due annually, five months after the close of a covered entity's fiscal year. Then, once on the cost report, the covered entity must seek approval from HRSA to add the child site to the covered-entity registry. *See* J.A., ECF No. 25, at 26 ("We require registration and approval for covered entities to participate in the 340B program"). HRSA limits when it accepts applications for registration to the first two weeks at the start of each quarter, e.g., January 1–January 15, April 1–April 15, etc. *Id.* Once approved, the child site's registration is effective at the start of the next quarter. *Id.* According to Plaintiffs, satisfying these two preconditions can delay a child site's participation in the 340B program by "at least 8 months, and potentially as long as 23 months." Pls.' Mem. at 11.

3. The 2020 FAQ

Fast-forward now to 2020. In response to the COVID-19 global pandemic, HRSA published online guidance stating that "[t]he circumstances surrounding this public health emergency may warrant additional flexibilities, especially to affected 340B covered entities." J.A. at 45. As part of that guidance, HRSA published eight FAQs and responses. *Id.* at 47–50. The FAQ at the heart of this case was as follows: "Are hospital covered entities able to register offsite, outpatient facilities before being listed as reimbursable on their Medicare Cost Report?" *See* Pls.'

Mem. at 12–13; J.A. at 47. The agency, in short, responded "no, but." It began by reiterating its longstanding policy:

> In order to register for the 340B Program and be listed on the 340B Office of Pharmacy Affairs Information System (340B OPAIS), HRSA must first verify that the offsite, outpatient facility is listed as reimbursable on the hospital's most recently filed Medicare cost report and has associated outpatient costs and charges as outlined in HRSA's 1994 Outpatient Hospital Facilities Guidelines. [PDF of guidelines.]

J.A. at 47. But then, it noted:

> [F]or hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. Learn more about HRSA's patient definition guidance. [PDF of guidance.]
>
> These situations should be clearly documented in the covered entity's policies and procedures. In addition, a covered entity is responsible for demonstrating compliance with all 340B Program requirements and ensure that auditable records are maintained for each patient dispensed a 340B drug.

Id. at 47–48.

Defendants acknowledge that this confusingly worded answer was intended to indicate a "waiver" of the registration requirement to 340B participation by child sites. *See* Combined Mem. of P. & A. in Supp. of Defs.' Cross-Mot. for Summ. J. & in Opp'n to Pls.' Mot. for Summ. J., ECF No. 20 [hereinafter Defs.' Mem.], at 7. A child site no longer would have to wait until it was listed on a Medicare cost report and registered in OPAIS to administer 340B drugs. They could do so upon starting operations.

The "waiver" was meant to be temporary. In contemporaneous communications with industry, the agency maintained that this was not a "new policy" or a change in policy. J.A. at 70, 72, 76. Yet, it also sent contradictory signals. An agency public affairs specialist advised an

industry publication in early June of 2020 that the registration requirement "flexibility" is "in place regardless of the COVID-19 pandemic." *Id.* at 74.

4. 2023 Notice

As the pandemic subsided, HRSA began to notify program participants that the 2020 FAQ "flexibility" would be no more. In response to an inquiry in May 2023, HRSA advised that it had "determined that we will be returning to pre-COVID policy regarding registration of outpatient facilities." *Id.* at 94. It warned that, starting on May 12, 2023, "hospital[s] should stop purchasing and using 304B drugs for [an] outpatient facility that is not yet registered . . . . The outpatient facility may begin purchasing and using 340B drugs once it is a reimbursable facility on the hospital's most recently filed Medicare cost report and registered on the 340B Office of Pharmacy Information System (340B OPAIS) as a child site." *Id.* at 94–95; *see also id.* at 85–93. HRSA also announced on its website that "the specific COVID-19 . . . flexibilities allowed under the 340B Program will expire on May 11, 2023." *Id.* at 53.

Apparently, informal communications and website posting were not enough to dispel industry uncertainty. So, on October 27, 2023, HRSA published a "Notice" to "inform and remind stakeholders of the registration requirements for off-site, outpatient hospital facilities to participate in the 340B Drug Pricing Program (340B Program)." *Registration Requirements in the 340B Drug Pricing Program*, 88 Fed. Reg. 73859, 73859 (Oct. 27, 2023). The agency formally announced that it was "ending the waiver" afforded in the 2020 FAQ. *Id.* at 73860. A child site of a covered entity hospital once more would have to be included on the most recent Medicare cost report and listed in OPAIS to be deemed eligible for 340B drug pricing. *Id.* at 73861. HRSA explained that ending the waiver promoted "its original policy goals." *Id.* at 73860. That included using the Medicare cost report to "determine hospital off-site, outpatient eligibility," and relying on a listing

in OPAIS to avoid "confusion" and promote "visibility into which sites are eligible to purchase 340B drugs." *Id.* at 73861. HRSA also reported, based on audit findings, that use of the "waiver" was widespread but that a large percentage of hospitals used 340B drugs at sites that they had not listed on their most recent Medicare cost report. *Id.*

The reversion to the 1994 Notice would not be immediate. Recognizing that "some covered entities believed the waiver would continue indefinitely," HRSA provided a transition period for hospitals to come into compliance with the registration requirement. *Id.* It afforded hospitals a "90-day grace period," after which a non-compliant entity could be "subject to audit and compliance action." *Id.* at 73862.

B. Procedural History

Four days after HRSA published the 2023 Notice, Plaintiffs filed this action challenging it under the Administrative Procedure Act (APA). Compl. for Declaratory and Injunctive Relief, ECF No. 1 [hereinafter Compl.]. They assert three APA claims. First, Plaintiffs allege that the 2023 Notice was a legislative rule that HRSA should have promulgated through notice and comment (Count I). *Id.* ¶¶ 172–78. Second, they maintain that the 2023 Notice was contrary to law because reviving the registration requirement created an extra-statutory eligibility precondition that the agency lacked the authority to impose (Count II). *Id.* ¶¶ 179–82. And third, Plaintiffs argue that HRSA's restoration of the 1994 Notice's requirements was arbitrary and capricious for a variety of reasons, including that it was not the product of reasoned decision-making and failed to take the industry's reliance interests into account (Count III). *Id.* ¶¶ 183–86. As relief, Plaintiffs ask the court to "[s]et aside and vacate HRSA's child-site limitation" and "[d]eclare that patients seen at child sites are patients of a covered entity for purposes of the 340B program as soon as the child sites qualify as part of the covered entity." *Id.* at 45.

Now before the court are the parties' motions for summary judgment. Pls.' Mot. for Summ. J., ECF No. 8 [hereinafter Pls.' Mot.]; Defs.' Cross-Mot. for Summ. J., ECF No. 21 [hereinafter Defs.' Mot.]. For the reasons explained below, the court concludes that the registration requirement imposes an extra-statutory term of eligibility that the agency lacked authority to impose as a condition of child-site 340B program eligibility. Because the court vacates the registration requirement on that ground, it does not reach Plaintiffs' other claims.

III. LEGAL STANDARD

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal" and must assess the "entire case" as "a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Generally, the court may consider only the administrative record in determining whether the agency acted contrary to law or arbitrarily or capriciously. *See* 5 U.S.C. § 706; *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006).

IV. DISCUSSION

A. Standing

Before turning to the merits, the court must first address subject matter jurisdiction, specifically standing. The familiar elements of standing are that a plaintiff "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). The party "invoking federal jurisdiction bears the burden of establishing these elements." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). A "deficiency on any one of the three prongs suffices to defeat standing." *U.S. Ecology, Inc. v. Dep't of the Interior*, 231 F.3d 20, 24 (D.C. Cir. 2000). At the summary judgment stage, the plaintiff "must 'set forth' by affidavit or other evidence 'specific facts,' which for purposes of the summary judgment motion will be taken to be true."

See Lujan, 504 U.S. at 561 (citing Fed. R. Civ. P. 56(e)). Where, as here, there are multiple plaintiffs, only one must have standing. *See Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017). As explained below, the court is satisfied that Plaintiff Glens Falls Hospital has met the jurisdictional requirement.[1]

1. Injury in Fact

An injury in fact can be, for example, a "physical injury, a monetary injury, an injury to one's property, or an injury to one's constitutional rights." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024). The injury must be "particularized" and may not be a generalized grievance. *See Lujan*, 504 U.S. at 560 & n.1. Further, it must be "actual or imminent, not speculative—meaning that the injury must have already occurred or be likely to occur soon" at the time the plaintiff files suit. *All. for Hippocratic Med.*, 602 U.S. at 381; *see also Equal Rts. Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1141 (D.C. Cir. 2011) ("[T]he existence of federal jurisdiction ordinarily depends on the facts as they exist when the complaint is filed." (alteration in original) (internal quotation marks and citations omitted)).

Glens Falls has suffered a financial injury. It received contingent approval from the New York State Department of Health to move forward with opening a second oncology extension clinic ("Oncology Clinic 2") on October 25, 2023. *See* Pls.' Mot., Decl. of Frances Spreer Albert, ECF 8-2 [hereinafter Albert Decl.], ¶ 14. Two days later, HRSA published the 2023 Notice and rescinded the "waiver." *Id.* Oncology Clinic 2 opened on December 19, 2023. Pls.' Notice of Suppl. Decls. in Supp. of Pls.' Mot., ECF No. 32, Suppl. Decl. of Frances Spreer Albert, ECF No. 32-1, ¶ 8. Thus, unlike under the COVID-era waiver regime, Glens Falls now had to

[1] After oral argument, the court asked Defendants to address whether a different Plaintiff, Lancaster General Hospital, had standing. Minute Order, Jan. 26. 2026. The court does not address Lancaster General Hospital's standing given its conclusion about Glens Falls.

register Oncology Clinic 2 with HRSA before it could receive and use 340B discounted drugs. Until such registration became final, Glens Falls had to purchase drugs at the steeper non-340B prices for use at Oncology Center 2. *Id.* ¶ 7. That came at a high cost. It took more than nine months after Oncology Center 2 opened to secure its registration. *Id.* During that period, Glens Falls paid $5.9 million more for non-340B drugs than if Oncology Center 2 had been 340B eligible once it began treating Glens Falls' patients. *Id.* ¶¶ 7–8. To be sure, Oncology Clinic 2 did not open until *after* Plaintiffs initiated this litigation on October 31, 2023, so Glens Falls was not incurring lost discounts on the date Plaintiffs filed suit. *See* Compl. But by that time, it had received contingent approval from the State of New York to move forward with the project, an indication that Oncology Clinic 2's opening—and attendant injury—was imminent. Albert Decl. ¶ 14. Glens Falls therefore has demonstrated that, at the time of filing, it had a "particularized" injury "likely to occur soon."

2. Causation

To show causation, the plaintiff must "establish that [its] injury likely was caused . . . by the defendant's conduct." *All. for Hippocratic Med.*, 602 U.S. at 382. That element is easily satisfied here. Because the 2023 Notice ended the COVID-era registration waiver policy, Glens Falls had to register with HRSA before Oncology Clinic 2 could participate in the 340B program. The resulting time delay of nine months between opening and registration caused financial loss because during those months Glens Falls had to purchase and administer only non-340B priced drugs to treat patients at Oncology Clinic 2.

3. Redressability

Glens Falls also has established redressability. "[B]ecause standing is assessed as of the time a suit commences," *Del Monte Fresh Produce Co. v. United States*, 570 F.3d 316, 324 (D.C.

Cir. 2009), a remedy of vacatur of the registration requirement as of October 31, 2023, would have allowed Glens Falls to avoid the financial loss it eventually incurred.

* * *

In sum, Glens Falls has "standing to seek review of [the] administrative action": it was injured and the "object of the action"; there is "little question" the 2023 Notice caused the injury; and "a judgment preventing . . . the action" would have redressed it. *See Corbett v. Transp. Sec. Admin.*, 19 F.4th 478, 483–84 (D.C. Cir. 2021) (quoting *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002)). The court therefore has subject matter jurisdiction to hear the parties' dispute.

B. Contrary to Law under the APA

1. The Merits

The court first addresses Plaintiffs' contrary-to-law claim before turning to their statute-of-limitations defense. Plaintiffs' contention, in essence, is that the registration requirement creates a condition of eligibility for covered hospitals' child sites that the 340B statute does not permit. As Plaintiffs put it, "[t]he statutory text compels the conclusion that child sites which meet the provider-based rules are eligible to participate in the 340B program . . . *regardless* of whether they have yet to appear on the covered entity's Medicare Cost Report." Pls.' Mem. at 22. The court agrees.

Following the Supreme Court's ruling overturning *Chevron*, courts are instructed 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). The court therefore cannot defer to HRSA's interpretation of section 340B. *See also Novartis*, 102 F.4th at 459. At most, the court "may follow the agency's interpretation of the statute only to the extent it has the 'power to persuade.'" *Id.* (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

As always, the court begins with the text of the statute, *Pac. Gas & Elec. Co. v. FERC*, 113 F.4th 943, 948 (D.C. Cir. 2024), and in construing the text, "look[s] to the ordinary meaning of its key terms," *Novartis*, 102 F.4th at 460.

Section 340B requires participating manufacturers to "offer each covered entity covered outpatient drugs" at or below a certain "ceiling price." 42 U.S.C. § 256b(a)(1). The statute defines a "covered entity" as "an entity that meets the requirements described in paragraph [(a)(5)] and is one of" 15 types of enumerated health care providers. *Id.* § 256b(a)(4). Thus, a provider must meet two criteria to qualify as a "covered entity." The second is not at issue here. The focus is on the first, which is to satisfy the "requirements" of subsection (a)(5). "Requirement" means "necessity" or "condition." Requirement, https://perma.cc/PJN8-DJ9E; *accord* Requirement, *Black's Law Dictionary* (12th ed. 2024) ("a requisite or essential condition"). Subsection (a)(5)'s "requirements" include: (1) not requesting a Medicaid rebate and the 340B program discount pricing for the same drug unit, (2) not "resell[ing] or otherwise transfer[ing] the drug to a person who is not a patient of the entity," and (3) permitting the Secretary or the drug manufacturer to audit the entity's records to assess compliance with (1) and (2). 42 U.S.C. § 256b(a)(5). Those are the only three "requirements" Congress specified. Put another way, Congress limited to three the "necessities" or "conditions" that a listed subsection (a)(4) entity must satisfy to be a "covered entity." The statute nowhere says that covered entities also must secure registration with HRSA as a "necessity" or "condition" of 340B program participation. Simply put, there is no statutory hook that grants the Secretary discretion to add additional "requirements," including registration.

Tellingly, Congress knew exactly how to make agency approval a precursor to 340B program eligibility—it expressly imposed that very requirement for certain listed health care entities. The 340B statute, from its inception, has provided that those entities listed in subsections

(a)(4)(J) and (a)(4)(K)[2] qualify as a "covered entity" "only if the entity is *certified* by the Secretary pursuant to paragraph [(a)(7)]." *Id.* § 256b(a)(4)(J), (K) (emphasis added); § 602, 106 Stat. at 4967–69. Subsection (a)(7) in turn directs the Secretary to "develop and implement a process for the certification" of the entities listed in "subparagraphs (J) and (K) of paragraph [(a)(4)]" of the statute, including a "requirement that an entity applying for certification under this paragraph submit information to the Secretary." *Id.* § 256b(a)(7)(A), (B). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). That general presumption is even stronger when, as here, the relevant text is omitted within a statutory list which continues with various types of hospitals. *Compare* 42 U.S.C. § 256b(a)(4)(J), (4)(K), *with id.* § 256b(a)(4)(L) (disproportionate-share hospitals), (4)(M) (children's hospitals), (4)(N) (critical access hospitals). Congress clearly understood how to impose agency certification as a precondition to 340B program participation. That it chose not to do so for hospital entities, like Plaintiffs, strongly suggests that Congress meant for there to be no such precondition.

The court also finds it significant that the 340B statute does not authorize the Secretary to create legislative rules. The D.C. Circuit recently observed that "[t]he Secretary lacks rulemaking authority over the section 340B program." *Novartis*, 102 F.4th at 456; *see also id.* at 459. Congress therefore constrained the Secretary's ability to adopt regulations that have the force of

[2] Subsection (a)(4)(J) pertains to certain entities delivering services for the treatment of HIV disease, 42 U.S.C. § 300ff, and subsection (a)(4)(K) concerns entities that treat sexually transmitted diseases, *id.* § 247c, or tuberculosis, *id.* § 247b(j)(2). (Subsection (a)(4)(K) cross-references § 247b(j)(2) as relating to entities that treat tuberculosis, but that provision concerns immunizations. *Id.* Section 247b-6 specifically relates to entities that treat tuberculosis. *See id.* § 247b-6.)

law. This denial of general rulemaking authority supports the conclusion that Congress did not mean for the Secretary to create extra-statutory hurdles to 340B participation.

Compare the 340B statute to the one at issue in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015). Under the Stark Act, Congress allows physicians to enter into equipment rental agreements with hospitals to whom they refer patients for treatment using such equipment if the agreement meets certain statutory conditions. *See id.* at 216, 219. The Secretary nevertheless adopted a regulation that barred rental agreements containing per-use fees, even if they otherwise conformed to the statutory requirements. The plaintiffs argued that "because the statute's text already lists specific requirements for rental charges, the Secretary cannot add further requirements related to rental charges." *Id.* at 219–20. The D.C. Circuit disagreed. It held that because Congress vested the "Secretary with the discretion to impose any additional requirements that she deems necessary 'to protect against program or patient abuse,'" the Secretary did not exceed her authority by banning per-use rental agreements, even if they otherwise met the statutory conditions. *Id.* at 219 (quoting 42 U.S.C. § 1395nn(e)(1)(B)(vi)). The 340B statute contains no similar authority. It lists as the only "requirements" those set forth in subsection (a)(5). That the Secretary lacks the power to create new "requirements" supports Plaintiffs' position that the registration requirement is contrary to law.

Defendants seek to avoid this conclusion in various ways. Primarily, they argue that the 340B statute itself makes eligibility verification a precondition to program participation. Defendants insist that, "under the statute," a covered entity "cannot access 340B discount pricing until it registers with HRSA." Defs.' Mem. at 23 (citing 42 U.S.C. § 256b(a)(9), (d)(2)); *see also* Tr. of Hr'g on Mots. Procs., ECF No. 31, at 55:14–56:10. But Defendants overread the provisions on which they rely.

Subsection (a)(9) requires the Secretary to "notify" manufacturers and certain state agencies "of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph [(a)(5)] or that are no longer certified pursuant to paragraph [(a)(7)]." 42 U.S.C. § 256b(a)(9). Subsection (d)(2), which Congress added in 2010, *see* § 7102, 124 Stat. at 825, tasks the Secretary with "the establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section." 42 U.S.C. § 256b(d)(2)(B)(iv). Taken together, these provisions require the Secretary to create and maintain a publicly available database by which market participants and regulators can identify both qualified and disqualified 340B program participants. According to Defendants, the agency cannot carry out that statutory obligation without using "verification to ascertain whether a purported child site is part of a 'covered entity.'" *See* Defs.' Reply Mem. of P. & A. in Supp. of Defs.' Mot., ECF No. 24 [hereinafter Defs.' Reply], at 17.

But subsections (a)(9) and (d)(2) only address the Secretary's obligation to *identify* entities qualified to purchase or administer 340B discounted drugs. They say nothing about an authority to determine *when* a "covered entity site" becomes so eligible. No one disputes that the Secretary can require a covered hospital to identify new child sites to HRSA. HRSA also can confirm 340B program eligibility of the child site before listing it in the OPAIS database. Establishing such process requirements is well within the agency's authority, and arguably is necessary, to carry out its obligations under subsections (a)(9) and (d)(2). *See* Pls.' Combined Reply Mem. in Supp. of Mot. & Opp'n to Defs.' Mot., ECF No. 22, at 25 (conceding that the agency can "require 'applications' as part of its record-keeping and enforcement functions"). But those provisions do

not allow HRSA to delay a statutorily qualified child site from 340B participation until the agency has signed off on eligibility. That is a precondition that finds no basis in the statutory text.

Defendants are dismissive of the fact that the 340B statute contains an agency certification requirement for those entities listed in subsections (a)(4)(J) and (K) but not others. They argue that "[w]hatever additional 'certification' and 'recertification' process may attach to specific types of entities whose eligibility may turn on the volume of discount purchases," "subsections 256b(a)(9) and (d)(2)(B) are separate and are not limited to particular covered-entity types." Defs.' Reply at 18. The court already has explained why those subsections do not help Defendants. The distinction they draw also makes the point. Congress reasonably could have determined that preclearance was needed only for entities "whose eligibility may turn on the volume of discount purchases." For all other covered entities, certification was not a hurdle that Congress deemed necessary.

The two primary cases on which Defendants rely do not help them. Defendants analogize this case to *Kessler v. FCC*, in which the D.C. Circuit agreed that the agency's temporary freeze on its acceptance of applications did not create "new allocation standards" that required notice and comment but instead was an "interim procedure controlling the time and order in which applications were to be considered under the existing rules pending conclusion of the rule making proceeding." 326 F.2d 673, 681 (D.C. Cir. 1963). But the temporary hold at issue in *Kessler* is a far cry from HRSA's registration requirement. The agency action in *Kessler* was "correctly viewed . . . as a matter of procedure and practice." *Id.* at 682. The registration requirement, by contrast, adds two substantive preconditions to program participation—(1) listing on a Medicare cost report and (2) agency verification and publication in the OPAIS database—neither of which are rooted in the statutory text. Defendants' citation to *Planned Parenthood of Metropolitan*

Washington, D.C. v. Horner is even further afield. There, the court concluded that the agency's prohibition on a certain manner of listing charities participating in the Combined Federal Campaign changed "*substantive* criteria," in violation of recently passed law that required that there be no change in eligibility unless otherwise allowed by the legislation. No. 88-cv-1751, 1988 WL 126240, at *3 (D.D.C. Nov. 15, 1988). Defendants do not explain the pertinence of that case here. *See* Defs.' Mem. at 22.

Defendants also try generally to place the 340B program in the same basket as various other federal programs that require an application or evidence to confirm eligibility to receive benefits. *See id.* (referencing reimbursement of Medicare provider claims, health care provided by the Department of Veterans Affairs, and student loan eligibility by the Department of Education). The court need not dwell on whether those examples are analogous. Defendants do not contend that, in enacting these public benefits programs, Congress withheld from the implementing agency either general rulemaking authority or specific statutory authority to collect information before making an eligibility determination. Congress did both in the 340B statute.

Lastly, Defendants emphasize the monitoring and enforcement challenges that HRSA would face if there is no registration requirement before program participation. They say that "Plaintiffs' position that access to 340B pricing should be automatic and self-fulfilling for any site they want would invite hospitals (and other entities) to access these valuable discounts based merely on say-so—vitiating Congress's careful delineation of eligible covered entities based on criteria [that] are not always self-evident." Defs.' Mem. at 23 (citation omitted). Defendants' argument is not without some force, but "policy concerns cannot trump the best interpretation of the statutory text." *Patel v. Garland*, 596 U.S. 328, 346 (2022). Again, the Secretary has no rulemaking authority with respect to the 340B program, and the governing statute does not require

registration before program eligibility. Congress instead chose to adopt various other monitoring and enforcement mechanisms: (1) a public database that identifies qualified and disqualified covered entities, 42 U.S.C. § 256b(a)(9), (d)(2)(B)(iv); (2) audits by HRSA and manufacturers, *id.* § 256b(a)(5)(C); (3) sanctions in the form of disgorgement, civil penalties, and program removal, *id.* § 256b(a)(5)(D), (d)(2)(B)(v); and (4) various other compliance measures directed at covered entities that Congress enacted as part of the Affordable Care Act, *id.* § 256b(d)(2)(B). Congress did not include agency certification among them. HRSA may believe that a registration requirement best promotes transparency and accountability, but that is not the law Congress enacted. *See Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 706 (2022) ("It is not [the court's] place to question whether Congress adopted the wisest or most workable policy, only to discern and apply the policy it did adopt."). Accordingly, the court concludes that the registration requirement is contrary to law.

2. Statute of Limitations

Before turning to the appropriate relief, the court must dispose of one last argument: that Plaintiffs' contrary-to-law claim is barred by the statute of limitations. Defs.' Mem. at 37; Defs.' Resp. to Pls.' Notice of Suppl. Decls. in Supp. of Pls.' Mot., ECF No. 34 [hereinafter Defs.' Suppl. Resp.], at 2–5. It is not.

The APA requires suits against the United States to be "filed within six years after the right of action accrues," unless the governing statute prescribes otherwise. 28 U.S.C. § 2401(a). After briefing in this matter concluded, the Supreme Court decided *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, 603 U.S. 799 (2024). *Corner Post* established that a claim brought under the APA accrues "when the plaintiff has a complete and present cause of action—*i.e.*, when she has the right to file suit and obtain relief." *Id.* at 809 (internal quotation marks and citation omitted). A plaintiff in an APA case "does not have a complete and present

cause of action until she suffers an injury from final agency action." *Id.* The statute of limitations thus "does not begin to run until she is injured." *Id.*

Here, for the reasons previously discussed in connection with standing, Plaintiff Glens Falls "suffere[d] an injury from" the 2023 Notice, *id.* at 809,[3] and that injury arose well within six years of its issuance. Glens Falls incurred impending financial harm due to HRSA's reversion to the registration requirement. *See supra* Section IV.A. It filed suit in late October 2023, only days after the Notice's publication. Plaintiffs' contrary-to-law claim therefore is timely.

C. Relief

Defendants urge the court to limit any relief to the plaintiffs before the court. Defs.' Mem. at 43. But Circuit precedent is clear that "vacatur is the normal remedy" for an APA violation, and the Supreme Court's recent decision in *Trump v. CASA* did nothing to disturb it. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014); *Trump v. CASA, Inc.*, 606 U.S. 831, 847 n.10 (2025) ("Nothing we say today resolves the distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action."). The court therefore vacates the 2023 Notice. It further declares the 2023 Notice unlawful insofar as it reverts to a regime that requires a child site of a covered hospital both to appear on the hospital's Medicare cost report and to secure certification from HRSA for listing in the OPAIS database before the child site becomes eligible to treat "patient[s] of the [covered] entity" using 340B discounted drugs. 42 U.S.C. § 256b(a)(5)(B).[4]

[3] Defendants do not argue that the 2023 Notice is not a final agency action. *See* Defs.' Suppl. Resp. at 3 (assuming "without conceding" that the 2023 Notice constitutes a final agency action).

[4] In their prayer for relief, Plaintiffs ask the court to declare that "patients seen at child sites are patients of a covered entity for purposes of the 340B program as soon as the child sites qualify as part of the covered entity." Compl. at 45. The court offers no opinion on when a child site "qualif[ies] as part of the covered entity," as that question is not before the court. *See* Pls.' Mem. at 8–9 (discussing when a satellite location is established as "provider-based" under the current version of the Medicare State Operations Manual).

V. CONCLUSION

For the reasons stated, the court grants Plaintiffs' Motion for Summary Judgment, ECF No. 8, and denies Defendants' Cross-Motion for Summary Judgment, ECF No. 21. A final, appealable order accompanies this Memorandum Opinion.

Dated: March 3, 2026

Amit P. Mehta
United States District Judge