PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 20-1701

GENESIS HEALTHCARE, INC.,

Plaintiff - Appellant,

v.

XAVIER BECERRA, as Secretary of the United States Department of Health and Human Services; GEORGE SIGOUNAS, as Administrator of the Health Resources and Services Administration; KRISTA PEDLEY, as Captain in the United States Public Health Service and Director of the Office of Pharmacy Affairs in the Health Resources and Services Administration,

Defendants - Appellees.

Appeal from the United States District Court for the District of South Carolina, at Florence. R. Bryan Harwell, Chief District Judge. (4:19-cv-01531-RBH)

Argued: March 9, 2022 Decided: July 1, 2022

Before GREGORY, Chief Judge, and NIEMEYER and AGEE, Circuit Judges.

Reversed and remanded by published opinion. Judge Niemeyer wrote the opinion, in which Chief Judge Gregory and Judge Agee joined.

ARGUED: James Mixon Griffin, GRIFFIN DAVIS LLC, Columbia, South Carolina, for Appellant. Brian James Springer, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** Margaret N. Fox, GRIFFIN DAVIS LLC, Columbia, South Carolina; Daniel J. Westbrook, NELSON MULLINS RILEY & SCARBOROUGH LLP, Columbia, South Carolina, for Appellant. Jeffrey Bossert Clark,

Acting Assistant Attorney General, Abby C. Wright, Thais-Lyn Trayer, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Peter M. McCoy, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Columbia, South Carolina, for Appellees.

NIEMEYER, Circuit Judge:

This appeal by Genesis Healthcare, Inc. challenges the district court's order dismissing its action against the government as moot.

Genesis Healthcare is a healthcare provider participating in the federal "340B Program," which is designed to provide drugs to qualified persons at discounted prices. Under the Program, the Secretary of the Department of Health and Human Services ("HHS") enters into agreements with drug manufacturers to sell drugs at discounted prices to entities such as Genesis Healthcare, which can, in turn, sell the drugs to their patients at discounted prices. After Genesis Healthcare purchases the covered drugs from the manufacturers, it dispenses them to patients through its wholly owned pharmacies or contract pharmacies.

After the Health Resources and Services Administration ("HRSA"), an agency within HHS, conducted an audit of Genesis Healthcare in June 2017 for Program compliance, HRSA removed Genesis Healthcare from the 340B Program. The audit report found, among other things, that Genesis Healthcare dispensed 340B drugs to individuals who were ineligible because they were not "patients" of Genesis Healthcare. Genesis Healthcare protested HRSA's findings, objecting to its definition of "patient" as too narrow and not in conformance with the term in the governing statute. After HRSA rejected Genesis Healthcare's challenges, Genesis Healthcare commenced this action, seeking a declaratory judgment that it did not violate the requirements of the Program and injunctive relief requiring HRSA to reinstate it into the Program and to retract any notifications that

HRSA had provided to manufacturers stating that Genesis Healthcare was ineligible under the Program.

In response to the lawsuit, HRSA vacated its order removing Genesis Healthcare from the 340B Program, but it continued to insist that Genesis Healthcare comply with its requirement of serving only eligible "patients," as it had defined that term. Genesis Healthcare then filed an amended complaint to take into account HRSA's action. It alleged that even though it was returned to the 340B Program, HRSA continued to seek to enforce a definition of "patient" that Genesis Healthcare alleged contradicted "the plain language of the statute," to its detriment. For relief, Genesis Healthcare sought a declaratory judgment that "the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B)." It also sought injunctive relief requiring HRSA "to retract any notification it may have provided to manufacturers that Genesis is ineligible under the 340B program" and to "set aside HRSA's determinations."

In response to the amended complaint, HRSA (1) notified Genesis Healthcare by letter that it "ha[d] voided" all audit findings and that Genesis Healthcare "ha[d] no further obligations or responsibilities in regard to the audit" and (2) filed a motion to dismiss Genesis Healthcare's action as moot based on the letter.

The district court granted HRSA's motion, finding that the action was moot. The court concluded that while Genesis Healthcare may be challenging the "audit process," it was "not challenging the final result of the agency's process — the decision to void the audit and restore Plaintiff's eligibility to participate in the 340B Program." As a

consequence, it held that there was no final agency action for review under the Administrative Procedure Act ("APA"), 5 U.S.C. § 704. It also held that as to Genesis Healthcare's request for declaratory relief, there was "no case or controversy as required by Article III" because "the parties ceased to have a 'definite and concrete' controversy when the agency decided to void its audit findings."

Yet, while Genesis Healthcare's initial request for reinstatement was satisfied by HRSA's subsequent action voiding its audit findings, HRSA continues to have the ongoing duty to audit Genesis Healthcare, and the company continues to be obligated to comply with the 340B Program's requirements and is susceptible to removal from the Program if it rejects HRSA's continuing use of the definition of "patient." Thus, because Genesis Healthcare continues to be governed by a definition of "patient" that, it maintains, is illegal and harmful to it, we conclude that there remains a live controversy between the parties. Accordingly, we reverse the district court's judgment and remand for further proceedings.

I

Genesis Healthcare participates in the 340B Program from various locations in South Carolina, selling to patients discounted drugs that it purchases from manufacturers participating in the Program. Participating entities, such as Genesis Healthcare, must, among other things, maintain auditable records and, with those records, be able to demonstrate that they only sell or otherwise transfer the discounted drugs to persons who qualify as "patients." And HRSA conducts audits from time to time, as authorized by the governing statute, to ensure compliance with the Program's requirements.

In June 2017, HRSA conducted an audit of Genesis Healthcare over a two-day period. In its audit report and accompanying cover letter, dated February 14, 2018, it made a preliminary determination that Genesis Healthcare was no longer eligible to participate in the 340B Program and that it was liable to drug manufacturers for the drug discounts that it had received. The report found that Genesis Healthcare "failed to maintain auditable records" and that it "dispensed 340B drugs to ineligible individuals," i.e., any "person who is not a patient of the entity." In reaching that conclusion, the report stated that HRSA was enforcing "[p]atient eligibility requirements . . . defined in guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996))." Genesis Healthcare objected to the report, but HRSA, after assessing Genesis Healthcare's objections, adhered to its findings and issued a final audit report and cover letter dated June 26, 2018. The June 26 letter stated, "The documentation GHI [Genesis Healthcare] provided is *insufficient to show that all patient definition criteria were met* (61 Fed. Reg. 55156 (Oct. 24, 1996)). GHI has not shown that it met the applicable elements of *the current HRSA patient definition*." (Emphasis added). The attached report stated further that "[c]overed entities are prohibited . . . from reselling or otherwise transferring 340B drugs to a person who is not a patient of the entity. Patient eligibility requirements are defined in guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996))."

Promptly thereafter, on June 28, 2018, Genesis Healthcare commenced this action against HHS and HRSA and requested (1) an emergency stay that would halt implementation of HRSA's allegedly wrongful decision to remove Genesis Healthcare from the Program; (2) declaratory relief setting aside HRSA's determinations; and

(3) injunctive relief requiring HRSA to retract any notification of ineligibility that it had provided to manufacturers.

In response to the suit, HRSA sent a letter issuing a *revised* final audit report dated September 24, 2018, in which it vacated its sanction of removing Genesis Healthcare from the 340B Program and promptly reinstated the company. But this revised report contained the same findings that HRSA had made in its report of June 26, 2018. Again, the revised report included statements that "the documentation GHI provided [was] insufficient to show that all patient definition criteria were met (61 Fed. Reg. 55156 (Oct. 24, 1996))" and that certain "instances [did] not meet the patient definition guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996), . . . [and these] findings [were] not based upon withdrawn patient definition guidance and do not represent a new HRSA interpretation." The revised final report also continued requiring Genesis Healthcare to reimburse manufacturers for the drug discounts and to submit a corrective action plan ("CAP") within 60 days. Finally, the letter stated that failure to comply with the CAP requirements could lead to "termination from the 340B Program."

After Genesis Healthcare submitted a CAP, HRSA approved the plan by letter dated March 20, 2019. But in its letter, it again instructed Genesis Healthcare that "with respect to future implementation of the 340B Program," the company had to comply with its definition of "patient," dedicating an entire paragraph to restating the specific requirements. Without reiterating those requirements here, the letter stated that "HRSA would like to clarify that in order for an individual to qualify as a 340B patient, GHI must [comply with stated elements of the 1996 Guidelines definition of "patient"]. GHI must

be able [with respect to future implementation] to demonstrate [those elements], in order to meet *the patient definition guidelines*." (Emphasis added).

In response to HRSA's March 20, 2019 letter, Genesis Healthcare filed an amended complaint. While it acknowledged in its amended complaint that it had been "promptly reinstated into the 340B Program," it stated that it had not dismissed the action due to HRSA's failure to "vacate its findings that Genesis violated the program requirements." It alleged that HRSA's definition of "patient" has "never been promulgated by regulation" and, in any event, "contradicts the plain language of the statute" by "improperly focus[ing] on a patient's prescription, and who wrote it, rather than the existence of a patient relationship with Genesis [Healthcare] (or any other covered entity)." (Citing 42 U.S.C. § 256b(a)(5)(B)). For relief, Genesis Healthcare requested that the court (1) "declare that the only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in 42 U.S.C. § 256b(a)(5)(B)"; (2) "declare that the plain wording of 42 U.S.C. § 256b(a)(5)(B) requires that any prescription from any source is available to a patient of a covered entity"; and (3) "declare any and all interpretations or guidance of HRSA in contradiction of the plain wording of 42 U.S.C. § 256b(a)(5)(B) unlawful and unenforceable as a matter of law."

Finally, in response to Genesis Healthcare's amended complaint, HRSA issued a letter dated June 6, 2019, stating:

> This communication serves as notice that [HRSA] has voided the audit findings of the audit conducted . . . on June 21, 2017, through June 22, 2017 [including] the September 24, 2018 letter to GHI, the accompanying revised final audit report to GHI, also dated September 24, 2018, and the March 20, 2019 letter approving GHI's corrective action plan (CAP). As the audit

> findings have been voided, GHI has no further obligations or responsibilities in regard to the audit.

And based on this letter, it filed a motion with the court a few days later to dismiss the action as moot.

The district court granted HRSA's motion by order dated December 19, 2019, concluding that "the original final agency action" challenged by Genesis Healthcare was "the agency's determination that [Genesis Healthcare] was ineligible to continue participating in the 340B Program," which, the court noted, HRSA had "voided . . . in its entirety." As a result, the court concluded that "the parties ceased to have a 'definite and concrete' controversy," and it declined to "render . . . [an] impermissible advisory opinion" in the absence of a live controversy. The court also denied Genesis Healthcare's subsequent motion for reconsideration.

This appeal followed.

II

On mootness, Genesis Healthcare contends that "[a]lthough the audit findings were voided, a controversy still exists because HRSA's unlawful guidance and interpretation of the term 'patient' still exists," and "there is a 'substantial controversy' between Genesis and HRSA" over the point. It adds, "HRSA has the authority to conduct audits at any time." It could at any time "return to its old ways." (Citing *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)). It argues that a case becomes moot in this kind of circumstance only "if subsequent events made it absolutely clear that

the allegedly wrongful behavior could not reasonably be expected to recur." (Quoting *Laidlaw*, 528 U.S. at 189).

HRSA argues in response that because it voided the audit findings that were the subject of Genesis Healthcare's lawsuit, its "void notice therefore obviate[s] the basis for Genesis's lawsuit," and any judicial advice over the meaning of the term "patient" would only "'satisfy [a] demand for vindication or curiosity'" and "'advis[e] what the law would be upon a hypothetical state of facts.'" (Quoting *Norfolk S. Ry. Co. v. City of Alexandria*, 608 F.3d 150, 161 (4th Cir. 2010), then *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975)).

As is well understood, the Constitution limits the jurisdiction of federal courts to deciding "Cases" and "Controversies." U.S. Const. art. III, § 2. This requires a dispute that is both "definite and concrete, touching the legal relations of parties having adverse legal interests" and that is "real and substantial," seeking "specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)). Moreover, this requirement must be satisfied at all stages of a federal court proceeding, and if events subsequent to the commencement of the action resolve the dispute, the action should be dismissed as moot. *See Pashby v. Delia*, 709 F.3d 307, 316 (4th Cir. 2013). Federal courts have "no authority 'to give opinions upon moot questions or abstract propositions, or to declare principles or rules of law which cannot affect the matter in issue in the case before it.'" *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quoting *Mills v. Green*, 159 U.S. 651, 653 (1895)).

The question presented by the circumstances of this case is whether HRSA's *voluntary conduct* in voiding its audit findings rendered Genesis Healthcare's action against it moot. In the context of a voluntary cessation of conduct, the Supreme Court has set a high bar for finding the action moot, stating:

> [T]he standard we have announced for determining whether a case has been mooted by the defendant's voluntary conduct is stringent: A case might become moot if subsequent events made it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur. The heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again lies with the party asserting mootness.

Laidlaw, 528 U.S. at 189 (cleaned up). To address the question, we need to understand what Genesis Healthcare sought to achieve with its litigation and what HRSA's voluntary action taken during the litigation obviated.

Genesis Healthcare's complaint was filed fundamentally to challenge HRSA's final audit report of June 26, 2018, disqualifying Genesis Healthcare from the 340B Program because, in part, the company was allegedly selling discounted drugs to non-patients, as "patient" was defined by the "patient definition guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)." The report stated, "the documentation GHI provided [was] insufficient to show that all patient definition criteria were met (61 Fed. Reg. 55156 (Oct. 24, 1996)). GHI has not shown that it met the applicable elements of the current HRSA patient definition." In its complaint, Genesis Healthcare took issue with HRSA's action, alleging that it "disputes that it has wrongfully diverted covered outpatient drugs to any ineligible recipients." For relief, it sought declaratory and injunctive relief, challenging HRSA's position and seeking reinstatement.

Responding to the portion of Genesis Healthcare's complaint that challenged the termination sanction imposed by HRSA, HRSA reinstated Genesis Healthcare to the 340B Program. But it continued to enforce its definition of "patient," directing, "with respect to future implementation of the 340B Program," that "patient" means what its 1996 Guidelines provided. It essentially repeated that "HRSA would like to clarify that in order for an individual to qualify as a 340B patient, GHI must [comply with stated elements of the 1996 Guidance definition]. GHI must be able [with respect to future implementation] to demonstrate [those elements], in order to meet the patient definition guidelines."

Genesis Healthcare amended its complaint to recognize its reinstatement into the 340B Program, but it maintained its challenge to HRSA's definition of "patient" that would continue to control its compliance with the Program, seeking a declaratory judgment that "any and all interpretations or guidance of HRSA in contradiction of the plain wording of the [governing statute] [is] unlawful and unenforceable as a matter of law." It alleged that, absent court relief, HRSA's interpretation would "undermine[] the purpose of the 340B Program, endanger[] the health of the most vulnerable patient population, and force[] extreme limitations on the 340B program at the expense of Genesis and other 340B covered entities who provide medical care to those who can least afford prescription medications." It alleged also that the absence of court relief would require Genesis Healthcare to make changes to its own operations, materially affecting them. It alleged: "Genesis . . . will be forced to dismantle and reconfigure its 340B program. . . . [And] Genesis itself may not be able to survive."

In response to the amended complaint, HRSA sent another letter to Genesis Healthcare, which voided all of its audit findings with respect to its June 2017 audit. It then relied on that letter to support its motion to dismiss the action as moot.

It is decisive, however, that this HRSA letter voiding its audit findings said nothing about how Genesis Healthcare was to continue to conduct itself under the 340B Program, nor did it vacate or even address its 1996 Guidelines definition of "patient" that formed the basis for its enforcement action and Genesis Healthcare's lawsuit. Yet, Genesis Healthcare remains subject to audit and, as the record stands, would still have to comply with HRSA's 1996 Guidelines. Moreover, Genesis Healthcare has alleged that to comply with HRSA's definition of "patient," it would have to "dismantle and reconfigure" itself, to its severe disadvantage. The real issue thus remains, even after HRSA's final letter, whether the 1996 Guidelines are inconsistent with the statute, as Genesis Healthcare has alleged and with respect to which Genesis Healthcare sought a declaratory judgment.

We conclude that the ongoing disagreement over how "patient" is to be defined in the context of the 340B Program is a definite and concrete controversy touching the ongoing legal relations between HRSA, as regulator of the 340B Program, and Genesis Healthcare, as a participant in the Program. This is not a case where Genesis Healthcare is asking the federal courts for an advisory opinion on what the law is based on hypothetical facts, nor is it simply an effort to satisfy a curiosity on who is right in a now defunct controversy. HRSA has taken action against Genesis Healthcare based, in part, on its definition of "patient," and it can easily do so again in connection with its ongoing duty to audit Genesis Healthcare's compliance with the requirements of the 340B Program, as

Genesis Healthcare remains a Program participant. Thus, even though HRSA did void its audit findings, it has failed to carry its "heavy burden" of establishing "that the allegedly wrongful behavior could not reasonably be expected to recur." *Laidlaw*, 528 U.S. at 189 (citation omitted), *cf. Del Monte Fresh Produce Co. v. United States*, 570 F.3d 316, 321 (D.C. Cir. 2009) (recognizing that "a plaintiff's challenge will not be moot where it seeks declaratory relief as to an ongoing policy").

We thus conclude that the district court erred in dismissing this action as moot.

III

The parties also engage each other in a confusing debate on the question of whether Genesis Healthcare is challenging a "final agency action," as required by the APA, 5 U.S.C. § 704, and, if not, whether the absence of a final agency action renders the case moot. The confusion likely arises from the district court's ruling, but it continues on appeal.

With respect to the final-agency-action requirement, the district court concluded that "because there [was] no final agency action for Plaintiff to challenge under the APA, . . . this case is moot." It explained, "[T]he agency's decision to void the audit produced no 'appreciable legal consequences' and is not a final agency action subject to review under the APA." (Quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). It continued linking final agency action and mootness, stating that "because there is no final agency action, there is no case or controversy," leaving it only with the option to give "an impermissible advisory opinion." It is therefore apparent that the district court concluded that with

HRSA's withdrawal of its final audit report, HRSA eliminated any agency action *and that doing so rendered the case moot*.

On appeal, HRSA maintains that the district court was correct. It argues that given its withdrawal of the final audit report, Genesis Healthcare was left only with a challenge to the "audit process," and the audit process was "not a final agency action susceptible to judicial review" under the APA, suggesting that the court no longer had before it a live controversy, again linking "final agency action" with "mootness." And Genesis Healthcare's rebuttal does not undo the confusion, accepting the same analytical framework that links final agency action and mootness.

Unfortunately, the entire discussion confusingly mixes mootness and final agency action, proceeding from the assumption that the presence of a final agency action is necessary to maintain a live controversy. This assumption, however, is mistaken.

The role of the APA is to waive sovereign immunity for suits against the United States for relief other than monetary damages brought by persons "suffering legal wrong," "adversely affected," or "aggrieved by agency action." 5 U.S.C. § 702; *see also Nat'l Veterans Legal Servs. Program v. U.S. Dep't of Def.*, 990 F.3d 834, 839 (4th Cir. 2021); *City of New York v. U.S. Dep't of Def.*, 913 F.3d 423, 430 (4th Cir. 2019). It provides a cause of action to obtain judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704; *see also Lee v. U.S. Citizenship & Immigr. Servs.*, 592 F.3d 612, 619 (4th Cir. 2010) (noting that the APA "provide[s] a limited cause of action" (cleaned up)). The relief that can be given on such review is broad, and a reviewing court is directed to "decide all relevant questions of law, interpret . . . statutory

provisions, and determine the meaning . . . of the terms of an agency action." 5 U.S.C. § 706. But the APA does not confer subject-matter jurisdiction on a court. *See Califano v. Sanders*, 430 U.S. 99, 105 (1977) (holding that "the APA is not to be interpreted as an implied grant of subject-matter jurisdiction to review agency actions"). That must be demonstrated independently by statutory authority, such as by 28 U.S.C. § 1331 (conferring federal question jurisdiction). *See Lee*, 592 F.3d at 619.

The lack of a final agency action thus does not lead to a finding of mootness; rather, it goes to the statutory requirements for suing an agency in court pursuant to the APA. Once a plaintiff demonstrates to a court subject-matter jurisdiction and standing to challenge a qualifying final agency action, it may seek and obtain *any relief* from the court other than monetary damages. *See* 5 U.S.C. § 702; *Muniz-Muniz v. U.S. Border Patrol*, 741 F.3d 668, 672 (6th Cir. 2013). And this obviously includes declaratory relief that a term relied on by the agency in its action has a different meaning than the one that the agency gave to it. *See* 5 U.S.C. § 706. Mootness, on the other hand, can be found only when there is no longer a live controversy between the plaintiff and the agency.

In this case, Genesis Healthcare commenced an action against HRSA, invoking federal question jurisdiction under 28 U.S.C. § 1331 and challenging HRSA's action removing it from the 340B Program under the APA. Clearly, HRSA's action was a final agency action, as the district court noted:

> In this case, the original final agency action was the agency's determination that Plaintiff was ineligible to continue participating in the 340B Program. It "marked the consummation of the agency's decisionmaking process" and was one from which "legal consequences will flow." *Bennett*, 520 U.S. at 178. At the time this action was filed, this was the final agency action

> Plaintiff sought to challenge in this Court, and this Court had jurisdiction to review the agency's decision declaring Plaintiff ineligible for participation in the 340B Program.

Moreover, Genesis Healthcare's challenge to the 1996 Guidelines was also likely a challenge to a final agency action. *See U.S. Army Corps of Eng'rs v. Hawkes Co., Inc.*, 578 U.S. 590, 599–600 (2016) (explaining that the Court has "long taken" a "pragmatic approach" to finality by recognizing, for example, that an agency order that "give[s] notice of how the [agency] interpret[s] the relevant statute" is a final agency action even absent an enforcement action against a particular party (cleaned up)). Furthermore, Genesis Healthcare had standing to challenge the final agency action, as it was the party actually removed from the 340B Program under HRSA's final agency action enforcing the 1996 Guidelines and therefore suffered an adverse effect. And importantly, the agency did not assert in response to Genesis Healthcare's suit that its complaint had failed to challenge a final agency action. Accordingly, the court had the broad charter of 5 U.S.C. § 706 to not only grant injunctive relief for reinstatement but also to give declaratory relief with respect to defining terms employed by the agency in its action. Thus, Genesis Healthcare satisfied the requirements of the APA when it sued HRSA for both declaratory and injunctive relief.

The consequences of the agency's subsequent withdrawal of its order (its final agency action) during the course of litigation, however, are governed by the principles of mootness, not by whether sovereign immunity was waived or a final agency action was challenged. But the district court unfortunately blurred the distinction between the two concepts, contributing to the parties' confusion.

We conclude that Genesis Healthcare satisfied the requirements of the APA when it commenced this action against HRSA and that the disposition of this appeal — which concerns the consequences of HRSA's voluntary withdrawal of its order during the course of the litigation — is governed by principles of mootness, as discussed above, not by the APA's final agency action requirement.

* * *

The judgment of the district court is reversed, and the case is remanded for further proceedings.

REVERSED AND REMANDED