

NOT FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 25-12095
Non-Argument Calendar

STATE OF FLORIDA,
FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,
FLORIDA DEPARTMENT OF MANAGEMENT SERVICES,
CATHOLIC MEDICAL ASSOCIATION,
on behalf of its current and future members,

Plaintiffs-Appellants,

versus

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY, DEPARTMENT OF HEALTH AND HUMAN
SERVICES,
in his official capacity,
DIRECTOR, OFFICE FOR CIVIL RIGHTS,
in her official capacity,
CENTERS FOR MEDICARE AND MEDICAID SERVICES,
ADMINISTRATOR, CENTERS FOR MEDICARE AND
MEDICAID SERVICES,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida
D.C. Docket No. 8:24-cv-01080-WFJ-TGW

Before ROSENBAUM, JILL PRYOR, and GRANT, Circuit Judges.

PER CURIAM:

In 2024, the Department of Health and Human Services (“HHS”) issued a rule to address discrimination in health programs and activities. *See* Nondiscrimination in Health Programs & Activities, 89 Fed. Reg. 37522 (May 6, 2024) (the “2024 Rule”). The 2024 Rule added and amended regulations to, among other things, define sex discrimination to include discrimination based on gender identity and limit when covered entities could deny or limit gender-affirming health care services. The State of Florida, two related state entities, and the Catholic Medical Association filed a lawsuit challenging the 2024 Rule. After a change in presidential administrations, the district court dismissed the lawsuit as moot. The plaintiffs appealed. Even assuming that the lawsuit was not moot when the district court dismissed it, it has become moot while this appeal was pending. Accordingly, we dismiss the appeal.

I.

In 2010, Congress enacted the Patient Protection and Affordable Care Act (“ACA”). One ACA provision addresses sex-discrimination. Section 1557 of the ACA prohibits “any health program or

activity, any part of which is receiving Federal financial assistance” or “any program or activity that is administered by an Executive Agency” from engaging in discrimination that is prohibited by “[T]itle IX.” 42 U.S.C. § 18116(a). This provision thus incorporates the prohibition on sex discrimination set forth in Title IX. *See* 20 U.S.C. § 1681(a) (stating that no person “shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance”). In § 1557 of the ACA, Congress also authorized the Secretary of HHS to “promulgate regulations to implement” the ACA’s prohibition on sex discrimination. 42 U.S.C. § 18116(c).

In 2016, 2020, and 2024, the Secretary promulgated regulations to implement § 1557’s prohibition of sex discrimination. *See* Nondiscrimination in Health Programs & Activities, 81 Fed. Reg. 31376 (May 18, 2016); Nondiscrimination in Health & Health Education Programs or Activities, 85 Fed. Reg. 37160 (June 19, 2020); Nondiscrimination in Health Programs & Activities, 89 Fed. Reg. 37522 (May 6, 2024). Even before the 2024 Rule, HHS regulations generally prohibited covered entities from engaging in sex discrimination.¹ 45 C.F.R. § 92.2(a) (2023). Before the 2024 Rule, the regulations stated that “an individual shall not,” on the basis of sex, “be

¹ Under HHS regulations, “covered entities” include recipients of “Federal financial assistance,” HHS, and any “entity established under title I of the ACA.” 45 C.F.R. § 92.4 (2025).

excluded from participation in, be denied the benefits of, or be subjected to discrimination” under any health program or activity operated by a covered entity. *Id.* § 92.2.

The 2024 Rule continued to prohibit sex discrimination. *See* 45 C.F.R. § 92.101(a)(1) (2024). It moved the prohibition on sex discrimination to § 92.101(a)(1) and added detail about the types of acts that qualified as sex discrimination. The 2024 Rule added the following provision:

Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of:

- (i) Sex characteristics, including intersex traits;
- (ii) Pregnancy or related conditions;
- (iii) Sexual orientation;
- (iv) Gender identity; and
- (v) Sex stereotypes.

Id. § 92.101(a)(2); *see* 89 Fed. Reg. at 37699.

The 2024 Rule also added or modified other regulations to address what acts qualified as sex discrimination. For example, it added § 92.206, which required a “covered entity [to] provide individuals equal access to its health programs and activities without discriminating on the basis of sex.” 45 C.F.R. § 92.206(a) (2024); *see* 89 Fed. Reg. at 37700–01. This section further stated that in providing access to health programs and activities, covered entities could

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not “[d]eny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual’s sex assigned at birth, gender identity, or gender otherwise recorded.” 45 C.F.R. § 92.206(b)(1) (2024).

Section 92.206(b) also barred covered entities from adopting or applying a “policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subject[ed] any individual to more than de minimis harm.” *Id.* § 92.206(b)(3). As a result, a covered entity could not “prevent[] an individual from participating in a health program or activity consistent with the individual’s gender identity.” *Id.* This subsection also prohibited a covered entity from “[d]eny[ing] or limit[ing] health services sought for [the] purpose of gender transition or other gender-affirming care” when the covered entity would provide the same services “to an individual for other purposes” and the denial or limitation was “based on an individual’s sex assigned at birth, gender identity, or gender otherwise recorded.” *Id.* § 92.206(b)(4).

But under the regulations promulgated by the 2024 Rule, a covered entity was not always required to provide services related to gender transition or gender-affirming care. A covered entity was not required to provide these services if it had a “legitimate, non-discriminatory reason for denying or limiting that service.” *Id.*

§ 92.206(c).² In addition, a covered entity was not required to provide these services when doing so “would violate applicable Federal protections for religious freedom and conscience.” *Id.* § 92.3(c); *see id.* § 92.302(a) (“A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply.”); 89 Fed. Reg. at 37693, 37701–02.

The 2024 Rule also added § 92.207, which barred sex discrimination in “providing or administering health insurance coverage or other health-related coverage.” 45 C.F.R. § 92.207(a) (2024). Under this provision, a covered entity could not “[d]eny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage,” based on an “individual’s sex assigned at birth, gender identity, or gender otherwise recorded.” *Id.* § 92.207(b)(3). It also barred a covered entity from having a “categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care.” *Id.* § 92.207(b)(4). In addition, it prohibited a covered entity from taking any other action to “deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing

² The regulations explained that a covered entity had a legitimate, non-discriminatory reason if it “typically decline[d] to provide the health service to any individual” or it “reasonably determine[d]” that the health service was “not clinically appropriate for a particular individual.” 45 C.F.R. § 92.207(c) (2024).

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or other limitations or restrictions on coverage” for health services related to gender transition or gender-affirming care when the “denial, limitation, or restriction result[ed]” in sex discrimination. *Id.* § 92.207(b)(5). But a covered entity was not required to cover a health service if it had a “legitimate, nondiscriminatory reason for denying or limiting coverage of the health service” such as when it determined that the service “fail[ed] to meet applicable coverage requirements” because it was not medically necessary. *Id.* § 92.207(c). Furthermore, § 92.207 expressly stated that it did not “preclude a covered entity from availing itself” of the protections set forth in §§ 92.3 and 92.302 related to religious freedom and conscience. *Id.*; *see* 89 Fed. Reg. at 37701.

The 2024 Rule also added other regulations that required a covered entity to “implement written policies and procedures in its health programs and activities” that were designed to comply with the regulations prohibiting discrimination and to provide notice to participants and the public about these policies. 45 C.F.R. §§ 92.8(a), 92.10(a) (2024). Under the 2024 Rule, these policies and notices had to include statements that the covered entity did “not discriminate on the basis of . . . sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)).” *Id.* §§ 92.8(b)(1), 92.10(a)(1)(i); *see* 89 Fed. Reg. at 37696–98.

The Rule also modified Centers for Medicare & Medicaid Services (“CMS”) regulations regarding the standard contracts for Medicaid and Children’s Health Insurance Program (“CHIP”) managed care plans. 89 Fed. Reg. at 37691. Even before the 2024 Rule,

CMS regulations required that these contracts between a state and a managed care plan include a provision stating that the plan would not discriminate “against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability.” 42 C.F.R. § 438.3(d)(4) (2023). The 2024 Rule added language to this regulation specifying that sex discrimination included discrimination based on “sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.” 42 C.F.R. § 438.3(d)(4) (2024). It also required the contract to include a term that the plan would not use a “policy or practice” that had “the effect of” discriminating on these grounds. *Id.*

The 2024 Rule modified other CMS regulations related to Medicaid managed care plans. Even before the 2024 Rule, CMS regulations required each state to adopt “methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex.” 42 C.F.R. § 440.262 (2023). And Medicaid managed care plans were required to “participate[] in the State’s efforts to promote the delivery of services in a culturally competent manner to all enrollees.” *Id.* § 438.206(c)(2). The 2024 Rule amended the regulations regarding culturally competent care to add that the term “sex” included “sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity[;]

and sex stereotypes.” 89 Fed. Reg. at 37691–92; *see* 42 C.F.R. §§ 438.206(c)(2), 440.262 (2024).³

In addition, the 2024 Rule modified CMS regulations related to services provided by organizations under the Program of All-Inclusive Care for the Elderly (“PACE”). *See* 89 Fed. Reg. at 37692. PACE organizations operate programs that provide comprehensive health care for “frail, older adults” with the goal of enabling them to “live in the community as long as medically and socially feasible.” 42 C.F.R. § 460.4(b) (2025). Before the 2024 Rule, CMS regulations prohibited PACE organizations from discriminating against any participant “based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.” 42 C.F.R. § 460.98(b)(3) (2023); *see also id.* § 460.112(g)(1) (guaranteeing each participant a right to voice complaints to PACE staff “free of any . . . discrimination”). The 2024 Rule modified § 460.98(b) to add that the term “sex” as used in the prohibition on sex discrimination “include[d] sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.” 89 Fed. Reg. at 37692; *see* 42 C.F.R. § 460.98(b)(3) (2024).

³ The 2024 Rule amended a related regulation that required a State to have a plan describing how it would ensure that CHIP beneficiaries received quality and appropriate care. *See* 42 C.F.R. § 457.495 (2024). The 2024 Rule added to this regulation a provision stating that the plan must ensure that all beneficiaries had “[a]ccess to and delivery of services in a culturally competent manner . . . as described in 42 C.F.R. [§] 440.262.” 89 Fed. Reg. at 37692; *see* 42 C.F.R. § 457.495(e) (2024).

The Secretary issued the 2024 Rule on May 6, 2024. *See* 89 Fed. Reg. at 37522. He directed that it would begin to go into effect about two months later, on July 5, 2024. *Id.* at 37693. The Rule included a severability provision, which provided that if any portion of the Rule was “held to be invalid and unenforceable by its terms, or as applied to any person or circumstance,” the rest of the Rule would remain in effect. *Id.*; 45 C.F.R. § 92.2(c) (2024).

II.

The same day the Rule was issued, the State of Florida, the Florida Agency for Health Care Administration, the Florida Department of Management Services, and the Catholic Medical Association, which is an association of Catholic healthcare providers, filed a lawsuit in federal court in the Middle District of Florida challenging the Rule. They sued HHS, CMS, and several federal officials.⁴ In the section that follows, we describe the procedural history of this lawsuit. We then discuss developments that occurred while this appeal was pending.

A.

The plaintiffs brought claims against the Secretary under the Administrative Procedure Act (“APA”). They primarily challenged

⁴ For ease of reference, we refer to the defendants collectively as the “Secretary.”

portions of the 2024 Rule as an agency action that was not in accordance with law and was arbitrary and capricious.⁵ See 5 U.S.C. § 706(2)(A). They argued that in promulgating the Rule, the Secretary had exceeded his statutory authority in several ways.

To start, the plaintiffs asserted that the Secretary exceeded his authority when he defined sex discrimination to include discrimination based on gender identity. They did not dispute that § 1557 of the ACA prohibited “sex” discrimination and authorized the Secretary to promulgate regulations to implement this prohibition. But they argued that because the term “sex” referred only to “biological sex,” the Secretary exceeded his statutory authority when he defined discrimination on the basis of sex to include discrimination “based on gender identity.” Doc. 1 at 65.⁶

They argued that the Secretary similarly exceeded his authority when he amended the CMS regulations. They asserted that nothing in § 1557 permitted the Secretary to bar “Medicaid and CHIP managed care organizations from having policies or practices” that resulted in discrimination based on gender identity or to prohibit “PACE organizations from discriminating against any participant based on gender identity.” *Id.* at 73–74. Their arguments again rested on the premise that the ACA’s statutory prohibition on sex discrimination did not reach discrimination based on gender

⁵ The plaintiffs did not challenge every aspect of the 2024 Rule. For example, they did not challenge the portion of 45 C.F.R. § 92.101(a)(2) that defined sex discrimination to include discrimination based on pregnancy.

⁶ “Doc.” numbers refer to the district court’s docket entries.

identity. The plaintiffs acknowledged that the Secretary also promulgated the CMS regulations pursuant to the Social Security Act. *See* 42 U.S.C. §§ 1395eee, 1396u-4, 1396a, 1397aa. They similarly argued that nothing in the Social Security Act authorized the Secretary to “impose gender-identity non-discrimination rules.” Doc. 1 at 73.

The plaintiffs also asserted that the Secretary exceeded his statutory authority when he amended CMS regulations to require that states’ contracts with Medicaid and CHIP managed care plans include a term barring policies or practices that had a discriminatory effect. According to the plaintiffs, § 1557’s prohibition on sex discrimination barred only intentional discrimination, and thus the Secretary lacked the authority to define sex discrimination to include “facially neutral policies or practices” that had the “effect” of discriminating “on the basis of sex or gender identity.” *Id.* (citation modified).

The plaintiffs challenged the 2024 Rule on Spending Clause grounds. They explained that when Congress exercises its power under the Spending Clause to impose a condition on the grant of federal money to the states, it must do so unambiguously. They asserted that because at the time the ACA was passed in 2010 discrimination on the basis of sex was not understood to include discrimination based on gender identity, the Secretary could not condition a state’s receipt of ACA funds on the state’s agreement not to discriminate based on gender identity. They alleged that the Social Security Act, too, was a Spending Clause statute and that it did

not “clearly authorize CMS to impose rules against discriminating on the basis of gender identity” or to require the use of a patient’s preferred pronouns. *Id.* at 78.

The Catholic Medical Association brought additional claims. It challenged portions of the 2024 Rule as violating its members’ First Amendment rights to free speech by restricting them from engaging in speech that opposed gender-affirming care and “coercing” them to participate in healthcare related endeavors that “express[ed] messages” with which the members disagreed. *Id.* at 79.

The Catholic Medical Association also raised challenges to portions of the 2024 Rule under the First Amendment’s Free Exercise Clause and the Religious Freedom Restoration Act. It alleged that its members exercised “religious beliefs through providing healthcare and through expressing messages in their healthcare practices.” *Id.* at 80. The association asserted that requiring members to comply with portions of the 2024 Rule would “substantially burden their exercise of religion.” *Id.*

In the complaint, the plaintiffs requested several types of relief. They asked the district court to “[h]old unlawful, set aside, and vacate the 2024 Rule[]” and to issue injunctive relief by “enjoining [the Secretary] from enforcing” the 2024 Rule. *Id.* at 81. In addition, they sought a declaration that the 2024 Rule was “contrary to law.” *Id.* at 82. They also requested that the court declare that HHS could not require covered entities to provide gender affirming care, re-

frain from criticizing gender-affirming care, use a patient's preferred pronouns, or make statements that they would not discriminate based on gender identity.

Shortly after filing the complaint, the plaintiffs moved for a preliminary injunction. On July 3, before any part of the 2024 Rule went into effect, the district court granted the motion. It stayed the Rule in part, directing that the effective date for 45 C.F.R. §§ 92.101(a)(2)(iv), 96.206(b), and 92.207(b)(3)–(5), as well as 42 C.F.R. § 438.3(d)(4), would be “postponed pending the disposition of the complaint on the merits.” Doc 41 at 49. The court also enjoined the Secretary from instituting or pursuing any enforcement proceedings “based on the interpretation of discrimination ‘on the basis of sex’ to be codified at 45 C.F.R. §§ 92.101(a)(2)(iv), 92.206(b), or 92.207(b)(3)–(5).” *Id.* The court ordered that its injunction would “run[] throughout the State of Florida” and apply to all “covered entities within Florida.” *Id.* at 49–50.

The Secretary appealed the preliminary injunction order to this Court. While the appeal was pending, the district court stayed the underlying case.

In November 2024, after the presidential election, the district court directed the parties to submit supplemental filings that addressed “the likelihood of mootness given a pending change in administration.” Doc. 58. In their response, the plaintiffs reported that the incoming administration was “unlikely” to support the 2024 Rule and might seek “to repeal” it. Doc. 60 at 2. But they explained that this change “could take years” and the case was not

currently moot. *Id.* The Secretary likewise denied that the case was moot, stating that he could not “speculate about possible future actions by policymakers after the upcoming change in Presidential administration.” Doc. 61 at 1.

Shortly after Donald Trump took office as President of the United States, he issued an executive order stating that it was “the policy of the United States to recognize two sexes, male and female” and that the term “sex” referred to “an individual’s immutable biological classification as either male or female.” Exec. Order No. 14168, § 2(a), 90 Fed. Reg. 8615, 8615 (Jan. 30, 2025). He directed federal agencies to “remove all . . . regulations . . . that promote or otherwise inculcate gender ideology.” *Id.* § 3(e), 90 Fed. Reg. at 8616. But this order did not on its own rescind or amend any regulations related to gender identity or gender-affirming care.

A second executive order declared that it was the “policy of the United States” not to “fund, sponsor, promote, assist, or support, the so-called ‘transition’ of a child from one sex to another.” Exec. Order No. 14187, § 1, 90 Fed. Reg. 8771, 8771 (Feb. 3, 2025). It directed the Secretary to take “appropriate actions” to implement this policy, “including regulatory and sub-regulatory actions,” which could involve “section 1557” of the ACA. *Id.* § 5, 90 Fed. Reg. at 8772. But, again, this order did not itself rescind or amend any regulations.

In March 2025, the Secretary moved in our Court to dismiss his appeal of the district court’s preliminary injunction. We granted the motion and dismissed the appeal.

A few days after we dismissed the appeal, the district court, *sua sponte*, closed the underlying case. In a minute order, the court stated that after considering our dismissal, it was directing the clerk to lift the stay and close the case.⁷

The plaintiffs filed a motion seeking to reopen the case, arguing that the district court had acted prematurely in lifting the stay and closing the case. The court denied this motion in another minute order, stating, “[t]here is no case or controversy presently pending.” Doc. 76. It directed the clerk to dismiss the case without prejudice, stating that the case was moot and not capable of repetition within any reasonable time frame.

This is the plaintiffs’ appeal.

B.

While this appeal was pending, there were additional developments. This case was one of several lawsuits filed around the country challenging the 2024 Rule. Another lawsuit challenging the Rule was filed in the Southern District of Mississippi by Tennessee and fourteen other states. In October 2025, the district court

⁷ Even though the district court’s order had the effect of lifting the preliminary injunction it had previously imposed, the 2024 Rule did not go into effect in Florida. This is because in another case a district court had entered a nationwide stay of the challenged provisions in the 2024 Rule. *See Texas v. Becerra*, No. 6:24-cv-211, 2024 WL 4490621, at *2 (E.D. Tex. Aug. 30, 2024) (imposing nationwide stay to the portions of the 2024 Rule that modified 42 C.F.R. §§ 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), 460.112(a) and 45 C.F.R. §§ 92.101(a)(2), 92.206(b), 92.207(b)(3)–(5)). The Secretary acknowledges that this “stay remains in effect.” Appellees’ Br. 9.

in that case granted summary judgment to the plaintiffs on their challenge to the Rule under the APA. *See Tennessee v. Kennedy*, 807 F. Supp. 3d 613, 630 (S.D. Miss. 2025).⁸ It concluded that “HHS exceeded its authority by expanding” the definition of “sex discrimination to include gender-identity discrimination.” *Id.* at 622.

After concluding that there had been an APA violation, the district court considered the appropriate remedy. It concluded that universal vacatur, as opposed to vacatur only as to the specific plaintiffs in the case, was appropriate. *Id.* at 627. The court explained that “the APA does not limit the scope of vacatur to the parties.” *Id.*

It then addressed which portions of the 2024 Rule should be vacated. It explained that the Rule contained a severability provision and the parties had agreed that “the portions of the Rule that exceed HHS’s statutory authority [could] be severed from the remainder of the Rule.” *Id.* at 628. The court directed that “to the extent that they expanded [the statutory] definition of sex discrimination to include gender-identity discrimination,” the following provisions were vacated: 42 C.F.R. §§ 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(b)(3), and 460.112(a), as well as 45 C.F.R.

⁸ Before reaching the merits, the district court in *Tennessee* addressed mootness. After considering the change in presidential administration and the executive orders that addressed the definition of sex and gender-affirming care for minors, the court determined that the case was not moot because 2024 Rule had not been repealed or amended. *See Tennessee*, 807 F. Supp. 3d at 622.

§§ 92.101(a)(2)(iv), 92.206(b)(1)–(4), 92.207(b)(3)–(5), 92.8(b)(1), 92.10(a)(1)(i), and 92.208. *Id.* at 629.

In addition, the court in *Tennessee* granted declaratory relief. It declared that “HHS exceeded its statutory authority” when it (1) interpreted § 1557 “to prohibit discrimination based on gender identity” and (2) promulgated “regulations concerning gender identity and gender affirming care.” *Id.* (citation modified). The Secretary chose not to appeal in the *Tennessee* case.

In June 2026, HHS issued a notice to all covered entities regarding the *Tennessee* decision. It stated that so long as the provisions of the 2024 Rule remain vacated, “those provisions are legally void.” Notice of Vacatur, 91 Fed. Reg. 32887, 32888 (June 2, 2026). The notice further reported that HHS’s Office of Civil Rights “cannot and will not investigate or enforce compliance with[] the provisions of the 2024 Rule that were vacated.” *Id.*

III.

Article III of the Constitution limits the jurisdiction of the federal courts to the consideration of “Cases” and “Controversies.” U.S. Const. art. III, § 2. “If events that occur subsequent to the filing of a lawsuit or an appeal deprive the court of the ability to give the plaintiff or appellant meaningful relief,” the case no longer presents a case or controversy, is moot, and must be dismissed. *Al Najjar v. Ashcroft*, 273 F.3d 1330, 1336 (11th Cir. 2001). “No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, [a] case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs’

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particular legal rights.” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (citation modified). “Any decision on the merits of a moot case or issue would be an impermissible advisory opinion.” *Warren v. DeSantis*, 125 F.4th 1361, 1364 (11th Cir. 2025) (citation modified).

On appeal, the plaintiffs argue that the district court erred in concluding that the case was moot. They point out that at the time of the dismissal the only intervening events that could have affected the status of the case were the executive orders. And they say that the executive orders did not render the lawsuit moot. Because it was still possible for the district court to grant them meaningful relief at that time, they say, the district court erred in dismissing the case as moot.

We need not decide whether the case was moot when the district court dismissed it. This is because additional events that transpired while this appeal was pending—the district court’s grant of vacatur relief in the *Tennessee* case, which was not appealed—make this case moot now.

To understand why this case is moot, we must understand the nature of vacatur as a remedy under the APA. The APA directs that when a court finds that an agency action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” it must “hold unlawful and set aside [the] agency action.” 5 U.S.C. § 706(2). We have recognized that “vacatur is the ordinary APA remedy.” *Ins. Mktg. Coal. Ltd. v. FCC*, 127 F.4th 303, 317 (11th Cir. 2025) (citation modified).

When a district court orders vacatur, the agency action is “of no effect.” *Alabama v. Ctrs. for Medicare & Medicaid Servs.*, 674 F.3d 1241, 1244 (11th Cir. 2012). That is, the vacatur “retroactively undoes or expunges a past [agency] action.” *Driftless Area Land Conservancy v. Valcq*, 16 F.4th 508, 522 (7th Cir. 2021). Put another way, vacatur of an agency action “formally nullif[ies] and revoke[s]” it. *Data Mktg. P’ship, LP v. U.S. Dep’t of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022); *see also* Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 1014–16 (2018) (explaining the effect of vacatur of an agency decision under the APA).

Based on these principles, we conclude that the district court’s vacatur remedy in the *Tennessee* case had the effect of nullifying and revoking those provisions in the 2024 Rule that “expand[ed]” the statutory “definition of sex discrimination to include gender-identity discrimination.” *Tennessee*, 807 F. Supp. 3d at 629. That is, the *Tennessee* decision made void each provision of the 2024 Rule that the plaintiffs challenged in this case. Because these provisions never have been applied to the plaintiffs and now are void, we conclude that it is impossible for the plaintiffs to obtain “meaningful relief” in this lawsuit. *Al Najjar*, 273 F.3d at 1336; *see Covenant Christian Ministries, Inc. v. City of Marietta*, 654 F.3d 1231, 1243 (11th Cir. 2011) (recognizing that a lawsuit challenging a regulation becomes moot when “challenged features of the prior law” are removed). After all, any decision in this case in their favor would not grant them any meaningful relief because it would leave them in the exact same position that they are currently in with the

challenged provisions being void. We thus conclude that there is no live controversy in this case, and so the appeal is moot.⁹

The plaintiffs resist this conclusion. They argue that we should apply a more stringent standard to decide whether the appeal is moot and must ask whether it is “absolutely clear the allegedly wrongful behavior challenged here could not reasonably be expected to recur.” Reply Br. 9 (citation modified). This standard applies when a defendant asserts that its voluntary compliance has mooted a case. *See Already*, 568 U.S. at 92. We are not persuaded that this standard governs where the Secretary has not voluntarily ceased any challenged conduct. Instead, the Secretary was required to stop its challenged conduct of enforcing the 2024 Rule after the

⁹ On appeal, the plaintiffs question whether it was appropriate for the district court in the *Tennessee* case to grant universal vacatur and suggest that universal vacatur may not be “authorized by the [APA].” Reply Br. 2. But they cite no case law adopting their position that a district court lacks authority under the APA to grant universal vacatur when it concludes that an agency exceeded its statutory authority.

We acknowledge that the Supreme Court has held that federal courts “likely” lack equitable authority to issue “universal injunctions”—that is, injunctions that prohibit the enforcement “of a law or policy against *anyone*,” not just the plaintiff in the lawsuit. *Trump v. CASA, Inc.*, 606 U.S. 831, 837 (2025). But in *CASA*, the Supreme Court recognized that the question of whether a district court may grant universal vacatur under the APA presents an entirely “distinct question.” *Id.* at 847 n.10; *see also Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 603 U.S. 799, 827 (2024) (Kavanaugh, J., concurring) (rejecting the argument that the APA does not allow for universal vacatur as “both novel and wrong”).

district court in *Tennessee* found an APA violation and ordered the remedy of universal vacatur.

The plaintiffs press further. They say that this appeal is not moot because they sought more than just vacatur in their complaint, and that the district court could still grant them other forms of relief. Again, we are unconvinced.

To start, we acknowledge that the plaintiffs sought injunctive relief in this action. In their complaint, they asked the district court to “enjoin[] Defendants from enforcing the 2024 Rule[].” Doc. 1 at 81. And it is true that no injunctive relief was awarded in the *Tennessee* case. *See Tennessee*, 807 F. Supp. 3d at 618 n.1.

We nevertheless conclude that the plaintiffs’ request for injunctive relief here is moot. Injunctive relief “is a prospective remedy, intended to prevent future injuries.” *Adler v. Duval Cnty. Sch. Bd.*, 112 F.3d 1475, 1477 (11th Cir. 1997). “[F]or a claim for injunctive relief to remain a live controversy, there must exist some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive.” *Cambridge Christian Sch., Inc. v. Fla. High Sch. Athletic Ass’n, Inc.*, 115 F.4th 1266, 1283 (11th Cir. 2024) (citation modified). Because the district court in *Tennessee* granted vacatur and voided the challenged provisions of the 2024 Rule, the plaintiffs face no risk of being subjected to these provisions in the future. We thus conclude that their request for injunctive relief, too, is now moot. *See Aaron Priv. Clinic Mgmt. LLC v. Berry*, 912 F.3d 1330, 1335 (11th Cir. 2019) (concluding

that request for injunction to stop enforcement of statute that imposed a license moratorium on narcotic treatment programs was moot once the moratorium expired); *see also Monsanto Co. v. Geerston Seed Farms*, 561 U.S. 139, 165–66 (2010) (recognizing that when the remedy of vacatur redresses a party’s injury, injunctive relief is not warranted).

The plaintiffs also point out that they sought declaratory relief in their complaint. They say that there remains a live controversy about whether they are entitled to declarations that HHS may not “require covered entities to have policies of allowing males into female restrooms or saying that men can get pregnant and give birth.” Appellants’ Br. 55–56 (citation modified).

We disagree. “[A] claim for declaratory relief becomes moot when there is no longer a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Cambridge Christian Sch.*, 115 F.4th at 1283 (citation modified). After the *Tennessee* court order vacated the challenged provisions of the 2024 Rule, any controversy related to the vacated portions of the Rule no longer present a controversy of any immediacy. Thus, the fact that the plaintiffs also requested declaratory relief does not mean there is a live controversy. *See Burke v. Barnes*, 479 U.S. 361, 363–64 (1987) (concluding that a request for declaratory relief became moot when the challenged law “expired”).

Changing approaches, the plaintiffs argue that this case is not moot because they also raised non-APA claims in their complaint, and the district court in *Tennessee* did not address the merits of these claims. Certainly, the plaintiffs raised non-APA challenges to the 2024 Rule. Both Florida and the Catholic Medical Association claimed that the Rule was unenforceable because the underlying ACA provision prohibiting sex discrimination was enacted pursuant to the Spending Clause and there was no clear statement at the time the ACA was enacted that discrimination based on sex included discrimination based on gender identity. In addition, the Catholic Medical Association asserted that applying the portions of the Rule related to gender identity to its members would violate its members' First Amendment rights as well as the Religious Freedom Restoration Act.

Still, the case is moot for the same reason: The challenged provisions of the 2024 Rule never went into effect and have now been vacated. Given these developments, if we were to address the merits of the plaintiffs' non-APA claims, we "would be issuing a ruling that would have no effect in the world we now inhabit but would serve only to satisfy the curiosity of the litigants about a world that once was and is no more." *Wyoming v. U.S. Dep't of Interior*, 587 F.3d 1245, 1253 (10th Cir. 2009) (Gorsuch, J.). We thus conclude that the plaintiffs' non-APA claims are moot.

Lastly, the plaintiffs argue that the appeal is not moot because the 2024 Rule defines sex discrimination to include "[s]ex stereotypes," and the *Tennessee* decision did not vacate this portion of

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the Rule. *See* 45 C.F.R. § 92.101(a)(2)(v) (2024). They say that there remains a live dispute regarding whether HHS exceeded its statutory authority when it defined sex discrimination to include discrimination based on sex stereotypes. The problem with this argument is that the plaintiffs' complaint did not challenge the 2024 Rule's definition of sex discrimination to include sex stereotypes. In their complaint, they mentioned the portion of the 2024 Rule that defined sex discrimination to include discrimination based on sex stereotypes only in passing, without indicating that they were challenging this portion of the Rule. We will not consider this new challenge that was never raised in the district court. *See Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1331 (11th Cir. 2004) (refusing to consider new claim raised for the first time on appeal when plaintiffs did not raise the issue "in their initial complaint" and did not seek to amend their complaint in the district court).

Because we conclude that the plaintiffs' claims are moot, we dismiss the appeal. Usually, when we conclude that a case has become moot on appeal, we vacate the district court's judgment and remand with instructions to dismiss the case as moot. *See Al Najjar*, 273 F.3d at 1340. Because the district court previously dismissed the case as moot, albeit for different reasons than those we rely upon today, vacatur and remand is not required.

APPEAL DISMISSED.