

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF FLORIDA**

<p><b>STATE OF FLORIDA, et al.,</b> Plaintiffs, v. <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,</b> Defendants.</p>
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Case No. 8:24-CV-01080-WFJ-TGW

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A  
STAY OR PRELIMINARY INJUNCTION**

Section 1557 of the Affordable Care Act (“ACA”), 42 U.S.C. § 18116, prohibits recipients of Federal financial assistance from excluding individuals from health programs or activities—or otherwise discriminating against them—on the basis of race, color, national origin, sex, age, or disability. The U.S. Department of Health and Human Services (“HHS”) promulgated a new rule that implements Section 1557’s nondiscrimination obligations (the “Rule”). As relevant here, the Rule provides that sex discrimination that violates Section 1557 includes discrimination on the basis of gender identity.

Plaintiffs the State of Florida, two Florida agencies, and the Catholic Medical Association (“CMA”) filed this lawsuit against HHS challenging the Rule. Their suit is premised on several misapprehensions regarding the Rule. For example, they say that the Rule establishes a federal standard of medical care and categorically requires the provision of particular treatments, like puberty blockers or hormones. ECF No. 12 at 3, 6. Not so. Contrary to Plaintiffs’ allegations, the “final rule does not promote any

particular medical treatment, require provision of particular procedures, mandate coverage of any particular care, or set any standard of care; rather, the final rule implements the nondiscrimination requirements of section 1557.” *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,533 (May 6, 2024). In fact, nothing in the Rule requires the provision of or insurance coverage for any particular health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting the service or coverage, such as, for example, a clinician’s medical judgment. 45 C.F.R. §§ 92.206(c), 92.207(c).<sup>1</sup> And although Plaintiffs repeatedly invoke the World Professional Association for Transgender Health (“WPATH”), the Rule does not mention WPATH, and nothing in the Rule mandates that any clinician follow any organization’s standards of care or clinical practice guidelines. Moreover, the Rule repeatedly makes clear that § 1557 does not apply insofar as any nondiscrimination obligation it creates would violate applicable Federal protections for religious freedom and conscience, including the Religious Freedom Restoration Act (“RFRA”). 45 C.F.R. § 92.3(c).

Plaintiffs’ motion for a stay or preliminary injunction should be denied. First, Plaintiffs have failed to establish likelihood of success on the merits. Plaintiffs claim the Rule’s statement that prohibited discrimination includes discrimination on the basis of gender identity, 45 C.F.R §92.101(a)(2)(iv), is contrary to § 1557. But § 1557 precludes discrimination on the basis of sex. Interpreting materially identical language

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<sup>1</sup> Provisions of the Rule cited in this brief refer to those published at 89 Fed. Reg. 37,691-703.

in Title VII, the Supreme Court held that “it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex.” *Bostock v. Clayton Cnty.*, 590 U.S. 644, 660 (2020). The Rule provides that discrimination on the basis of gender identity is prohibited sex discrimination under § 1557, 45 C.F.R. § 92.101(a)(2)(iv), for that same reason, 89 Fed. Reg. at 37,574. Plaintiffs’ arguments to the contrary ignore the statutory language and are rooted in hypothetical future disagreements with HHS about possible applications of the Rule that do not reflect anything in the Rule itself.

Second, Plaintiffs have failed to demonstrate imminent irreparable harm. The Rule does not include a determination that any of Plaintiffs’ particular laws or policies violate § 1557. And Congress required extensive procedures, culminating in judicial review, before HHS may terminate any entity’s federal funding. Thus, no Plaintiff or CMA member faces an imminent prospect of losing Federal financial assistance.

Finally, the public interest and the potential harms to third parties outweigh any hypothetical future injuries to Plaintiffs from specific applications of the Rule. At its core, the Rule precludes providers and insurance issuers from denying patients medically necessary care they typically provide—whether for, *e.g.*, a sore throat, a broken bone, or cancer—because of traits or actions that they would not have questioned in members of a different sex. There is a significant public interest in permitting HHS to enforce § 1557 to protect patients from discrimination in all of the programs and activities to which § 1557 applies, as Congress intended. For all these reasons, Defendants respectfully request that the Court deny Plaintiffs’ motion.

## BACKGROUND

### I. STATUTORY AND REGULATORY BACKGROUND

#### A. Section 1557 of the Affordable Care Act and its Statutory Enforcement Mechanisms

Through reference to longstanding civil rights statutes, such as Title VI of the Civil Rights Act of 1964 and Title IX of the Education Amendments of 1972, § 1557 prohibits discrimination on the ground of race, color, national origin, sex, age, or disability in any health program or activity any part of which is receiving Federal financial assistance. 42 U.S.C. § 18116(a).<sup>2</sup>

Section 1557 incorporates the “enforcement mechanisms provided for and available under” the referenced civil rights statutes. 42 U.S.C. § 18116(a). For administrative enforcement, those mechanisms provide layers of process and opportunities for congressional and judicial review before any entity faces a potential termination of any Federal financial assistance. *E.g.* 20 U.S.C. § 1682 (Title IX); 42 U.S.C. § 2000d-1 (Title VI). HHS’s enforcement is typically a complaint-driven process, though HHS’s Office for Civil Rights (“OCR”) has authority to initiate investigations on its own. *See, e.g.* 45 C.F.R. §§ 80.7 (Title VI); 86.71 (Title IX), 92.303(a) (Section 1557, incorporating by reference § 80.7). As part of an investigation, OCR considers all “factors relevant to a determination as to whether the recipient has failed to comply” with § 1557. *Id.* § 80.7(c) (incorporated by § 92.303(a)).

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<sup>2</sup> Section 1557 also addresses discrimination occurring under any program or activity administered by an Executive Agency or any entity established under Title I of the ACA.

If, following an investigation, OCR finds a “failure to comply,” first, HHS must advise the covered entity of a potential violation and make a good faith effort to come to a voluntary resolution without the need for administrative or judicial litigation. 20 U.S.C. § 1682. If that negotiation is unsuccessful, HHS, if it wishes to proceed further, must initiate the formal agency adjudication procedures of the Administrative Procedure Act (“APA”), which require an opportunity for a hearing and “an express finding on the record” of a failure to comply. *Id.*<sup>3</sup> And if that process results in a determination to withhold federal funding, HHS must submit a “full written report” to congressional committees before any funding withdrawal can take effect. *Id.*

Moreover, the statutory enforcement mechanism makes any HHS decision to terminate or suspend Federal financial assistance subject to judicial review. 20 U.S.C. § 1683. Any entity seeking judicial review can invoke the court’s power to postpone further the effective date of any termination of funding if such postponement is required to avoid irreparable harm. 5 U.S.C. § 705. Accordingly, the ultimate arbiters of any violation of § 1557 and the Rule are Article III courts.

### **B. HHS’s 2024 Rule Implementing § 1557**

HHS published the Rule in the Federal Register on May 6, 2024. *See* 89 Fed. Reg. 37,522 (codifying 45 C.F.R. pt. 92). As relevant here, the Rule provides that discrimination on the basis of sex includes discrimination on the basis of gender

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<sup>3</sup> Alternatively, HHS may refer the matter to the Department of Justice to secure compliance “by any other means authorized by law.” 20 U.S.C. § 1682. This alternative, however, also cannot take place until there has been a determination “that compliance cannot be secured by voluntary means.” *Id.*

identity. 45 C.F.R. § 92.101(a)(2)(iv).<sup>4</sup>

In § 92.206, addressing equal access to health programs and activities on the basis of sex, the Rule includes provisions that primarily relate to covered entities that are directly engaged in the provision of health care services, such as hospitals, physical and mental health care providers, and pharmacies. Among other specific provisions, § 92.206(b)(3) precludes providers from “treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm[.]” *Id.* § 92.206(b)(3). This provision clarifies that the Rule does not prohibit “a covered entity from operating sex separated programs and facilities[.]” 89 Fed. Reg. at 37,593. For example, merely providing separate bathrooms labeled for men and women is not discrimination on the basis of sex. “Although differential treatment on the basis of sex is generally prohibited, [HHS] acknowledges that there are certain circumstances in which § 1557 does not prohibit separation by sex or differential medical treatment on the basis of sex[.]” *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824, 47,866 (Aug. 4, 2022).

Section 92.206(b)(4) precludes providers from denying health services sought for the purpose of gender-affirming care “that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual’s sex

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<sup>4</sup> Because Plaintiffs seek to enjoin only 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4), ECF No. 12-5, the discussion that follows is limited accordingly. Although Plaintiffs seek to enjoin 45 C.F.R. § 92.101, most provisions of that section are not meaningfully challenged here, including those concerning discrimination on the basis of race, color, national origin, age, disability, and sexual orientation, 45 C.F.R. § 92.101.

assigned at birth, gender identity, or gender otherwise recorded.” But § 92.206 makes clear that this provision does not require

the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual.

*Id.* § 92.206(c).

In § 92.207, the Rule includes provisions governing nondiscrimination in health insurance coverage and other health-related coverage. *Id.* § 92.207. Among other specific prohibitions, § 92.207(b)(4) precludes insurance issuers from having or “implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care[.]” *Id.* § 92.207(b)(4). Section 92.207 makes clear that nothing in the section “requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements.” *Id.* § 92.207(c). For example, “a nondiscriminatory determination that care is not medically necessary based on a patient’s anatomy or medical need is permissible.” 89 Fed. Reg. at 37,607.

The Rule also includes revisions to nondiscrimination provisions of regulations issued by the Centers for Medicare & Medicaid Services (“CMS”) governing Medicaid and the Children’s Health Insurance Program (“CHIP”). 89 Fed. Reg. at 37,691 (revising 42 C.F.R. § 438.3). HHS revised those regulations “based on Section 1557”

as well as separate statutory authority under 42 U.S.C. §§ 1396a(a)(4), 1396(a)(19), and 1397aa(a). 87 Fed. Reg. at 47,892. These regulatory provisions require contracts between states and Medicaid and CHIP managed care plans to include provisions precluding those plans from discriminating against individuals eligible to enroll in these managed care programs. 45 C.F.R. § 438.3(d). The Rule’s revisions to that section, as relevant here, add discrimination on the basis of gender identity to the list of grounds of prohibited discrimination. 89 Fed. Reg. at 37,691.

## **II. Plaintiffs’ Incorrect Claims Concerning the Rule**

Plaintiffs misapprehend the Rule’s scope and what it requires. At the outset, two general points deserve emphasis. First, as HHS repeatedly emphasized in the preamble, the Rule does not set a standard of care or require the provision of any particular service. Nothing in the Rule overrides a clinician’s medical judgment as to whether a service is medically necessary or appropriate for any patient. *See* 89 Fed. Reg. at 37,595-96 (“There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide.”); *see also* 89 Fed. Reg. at 37,533; 37,596.

Second, and relatedly, Plaintiffs suggest that the Rule reflects an HHS determination “that ‘gender transition’ is medically necessary[.]” ECF No. 12 at 7. Not so. The Rule does not displace the judgment of providers as to the medical necessity of gender affirming care, so long as a refusal of care is not based on animus or bias or a pretext for discrimination. In response to comments, HHS eliminated a proposed provision of § 92.206(c), which read: “however, a provider’s belief that



gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate[.]” 89 Fed. Reg. at 37,597. In the Rule, HHS replaced it with “[a] covered entity’s determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination.” *Id.*; *see also id.* (“the [R]ule does not (and cannot) set a standard of care for gender-affirming care”); *id.* (“OCR understands that a provider may have a legitimate nondiscriminatory reason not to provide a health service, which the newly revised § 92.206(c) makes clear.”).

### **III. Procedural Background**

Plaintiffs filed this lawsuit on May 6, 2024. Compl. for Declaratory Relief and Prelim. and Permanent Inj. Relief (“Compl.”), ECF No. 1. Plaintiffs consist of the State of Florida, two Florida agencies, and CMA, a membership association suing on behalf of its 2,500 members. *Id.* ¶¶ 17-21. On May 15, 2024, Plaintiffs filed a motion for a stay or preliminary injunction. ECF No. 12.

### **LEGAL STANDARDS**

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To justify this “drastic remedy[.]” Plaintiffs must “clearly establish[] the burden of persuasion” on the following four elements: (1) a substantial likelihood of success on the merits; (2) a substantial threat that Movants will suffer irreparable injury absent an injunction; (3) the threatened injury to Movants outweighs the damage an injunction would cause

to Defendants; and (4) the injunction would not be adverse to the public interest. *Davidoff & CIE, S.A. v. PLD Int'l Corp.*, 263 F.3d 1297, 1300 (11th Cir. 2001). The same standard applies to a plaintiff seeking relief under 5 U.S.C. § 705. *Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974); *Va. Petrol. Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958).

A plaintiff seeking an order precluding enforcement of a regulation, or any “distinct provision” of a regulation, in all of its applications, must “meet an especially demanding standard.” *Am. Federation of State, County, and Mun. Employees Council 79 v. Scott*, 717 F.3d 851, 863, 865 (11th Cir. 2023) (“*AFSCME Council 79*”). Specifically, he “must establish that no set of circumstances exists under which the [regulation] would be valid.” *Id.* at 863 (citation omitted); see *Reno v. Flores*, 507 U.S. 292, 300 (1993).

## ARGUMENT

### I. Plaintiffs Are Not Likely to Succeed on the Merits.

Plaintiffs’ motion seeks to stay or enjoin enforcement of all applications of 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4) during the pendency of this litigation. ECF No. 12-5. That relief would authorize Florida and CMA members to deny health services, whether for a sore throat, a broken bone, or cancer, to transgender Americans on the basis of sex—for example, because of traits or actions that the provider would not have questioned in members of a different sex—in any conceivable circumstance. But the provisions of the Rule HHS promulgated are compelled by the Supreme Court’s reasoning in *Bostock*.

The relief Plaintiffs seek is not warranted by the arguments Plaintiffs raise and is not available under the “especially demanding” legal standard: that “no set of circumstances exists under which [each challenged provision of] the [regulation] would be valid.” *AFSCME Council 79*, 717 F.3d at 863 (citation omitted).<sup>5</sup> Rather than attempting to sustain their burden, Plaintiffs thrust several hypothetical applications of § 1557 before the Court—*i.e.*, hypotheticals about bathroom policies and policies governing puberty blockers. Plaintiffs then seek to force the Government to address those applications in litigation briefs in response to a purported challenge to the Rule. But “nothing in the [challenged] Rule itself speaks to” any of those applications. *Anderson v. Edwards*, 514 U.S. 143, 155 n.6 (1995).

Plaintiffs have not sought, and thus the Court should not entertain, entry of a preliminary injunction that would enjoin HHS from enforcing the Rule against particular policies or practices. The Rule does not reflect a determination that any of Plaintiffs’ particular laws or policies violate § 1557 and thus judicial review is only available after final agency action and completion of the administrative procedures mandated by Congress. *Florida v. CMS*, No 8:24-cv-317-WFJ-AAS, 2024 WL 2803298, at \*3-6 (M.D. Fla. May 31, 2024).<sup>6</sup>

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<sup>5</sup> *Reno v. Flores*, 507 U.S. 292, 301 (1993); *Children’s Health Def. v. FCC*, 25 F.4th 1045, 1052 (D.C. Cir. 2022); *Associated Builders and Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 220 (5th Cir. 2016); *Ass’n of Private Sector Colleges and Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012); *Sherley v. Sebelius*, 644 F.3d 388, 397 & n. \*\* (D.C. Cir. 2011).

<sup>6</sup> CMA is also unlikely to succeed on the merits of its claims in this action because, as another court already held, CMA lacks standing to press them. *Am. College of Pediatricians v. Becerra*, No. 1:21-cv-195, 2022 WL 17084365, at \*12-18 (E.D. Tenn. Nov. 18, 2022) (“ACP”). Compare *id.* \*10-11, with, Compl. ¶ 195. Although CMA has asked the Sixth Circuit to vacate that court’s decision, the Sixth Circuit has

### A. Section 92.101(a)(2)(iv)

Plaintiffs' claim that 45 C.F.R § 92.101(a)(2)(iv) is contrary to § 1557 fails. Again, § 92.101(a)(2)(iv) explains that discrimination on the basis of sex includes discrimination on the basis of gender identity. This provision is lawful because the Supreme Court's reasoning in *Bostock* that Title VII's prohibition against sex discrimination encompasses discrimination on the basis of gender identity applies to prohibitions against sex discrimination in Title IX and § 1557.

The Supreme Court explained in *Bostock* that "it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex." 590 U.S. at 660.<sup>7</sup> *Bostock* concerned Title VII's provision making it unlawful for an employer "to discriminate against any individual . . . because of such individual's . . . sex," 590 U.S. at 655 (quoting 42 U.S.C. § 2000e-2(a)(1)). The Court explained that Title VII's "because of" language "incorporates the 'simple' and 'traditional' standard of but-for causation." *Id.* at 656–57 (citation omitted). "[S]ex is necessarily a but-for cause" of discrimination on the basis of transgender status "because it is impossible" to discriminate against a person for being

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not resolved that request. Whether as a matter of issue preclusion, *Lewis v. Seneff*, 654 F. Supp. 2d 1349, 1359 (M.D. Fla. 2009), improper claim splitting, *Bongiovanni*, No. 3:22-cv-237-MMH-MCR, 2022 WL 1642158, at \*8-10 (M.D. Fla. May 24, 2022), or deferring to the *ACP* court's reasoning "as a matter of 'good sense and wise judicial practice,'" *id.* at \*14 (citation omitted), CMA should not be permitted to treat "an adverse judicial decision [as] little more than an invitation to take a mulligan[.]" *Entek GRB, LLC v. Stull Ranches, LLC*, 840 F.3d 1239, 1240 (10th Cir. 2016) (Gorsuch, J.). Nothing in the Rule, which only makes CMA members' alleged injuries more speculative due to its provisions protecting religious freedom, *see infra* at 30, has any bearing on the *ACP* court's reasoning.

<sup>7</sup> The terms "gender identity" and "transgender status" "are often used interchangeably." 89 Fed. Reg. at 37,556. *See Bostock*, 590 U.S. at 686 n.6 (Alito, J., dissenting).

transgender “without discriminating against that individual based on sex.” *Id.* at 660, 661 (emphasis omitted). If an employer fires a transgender woman but retains an otherwise identical cisgender woman, “the employer intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth.” *Id.* Thus, “the individual employee’s sex plays an unmistakable and impermissible role in the discharge decision.” *Id.* That is so even if “sex” in Title VII “refer[s] only to biological distinctions between male and female.” *Id.* at 655.

*Bostock’s* reasoning applies with equal force to § 1557. The statute incorporates Title IX’s prohibition on discrimination “on the basis of sex,” 20 U.S.C. 1681(a), which employs a causation standard indistinguishable from Title VII’s “because of . . . sex” language, 42 U.S.C. § 2000e-2(a)(1); *see also Bostock*, 590 U.S. at 650 (using the phrase “on the basis of” interchangeably with Title VII’s “because of” language). Courts consistently look to interpretations of Title VII to inform Title IX because both statutes prohibit discrimination on the basis of sex using nearly identical language. *E.g., GP by and through JP v. Lee Cnty Sch. Bd.*, 737 F. App’x 910, 916 n.5 (11th Cir. 2018). Indeed, other courts have concluded that the rationale of *Bostock* applies to § 1557. *E.g., Kadel v. Folwell*, 100 F.4th 122, 164 (4th Cir. 2024); *Doe v. Snyder*, 28 F.4th 103, 144 (9th Cir. 2022). That is because if a medical provider refuses to treat the broken bone of a transgender man because he presents as a man but was assigned female at birth, but would treat the broken bone of a similarly situated cisgender man, the provider is discriminating on the basis of sex. Indeed, Plaintiffs admit that there are circumstances in which discrimination on the basis of sex includes gender identity

discrimination. ECF No. 12 at 16 (admitting that where a doctor denies a transgender woman “an orchiectomy to treat testicular cancer” impermissible discrimination “may be afoot”). That admission undermines any claim that § 92.101(a)(2)(iv) is invalid in all of its applications.

Plaintiffs lean heavily on their view that sex is binary and “biological.” ECF No. 12 at 9, 14. But, as in *Bostock*, nothing in the Rule turns on whether “sex” is defined to “refer only to biological distinctions between male and female.” 590 U.S. at 655; *see also id.* at 660 (concluding that “it is impossible to discriminate against a person for being . . . transgender without discriminating against that individual based on sex”). Rather, as HHS explained in the preamble, the agency “determined it is not necessary define ‘sex’ in this rule.” 89 Fed. Reg. at 37,575. Even if “sex” refers to biological distinctions between male and female, including “‘gender identity’ in § 92.101(a)(2) is consistent with the Supreme Court’s reasoning in *Bostock*.” *Id.* at 37,574.

Plaintiffs devote much of their briefing to *Adams v. School Board of St. John’s County*, 57 F.4th 791 (11th Cir. 2022), ECF No. 12 at 8-13, but nothing in *Adams* provides a reason to enjoin HHS from enforcing § 92.101(a)(2)(iv). In *Adams*, the Eleventh Circuit held that a school’s restroom policy prohibiting a transgender male student from using the boys’ restroom did not violate Title IX. *See Adams*, 57 F.4th at 815. *Adams* did not hold that discrimination on the basis of sex excludes discrimination on the basis of gender identity, as would be necessary to find it irreconcilable with § 92.101(a)(2)(iv). The court explained that “[w]hile *Bostock* held that ‘discrimination based on . . . transgender status necessarily entails discrimination based on sex,’ . . .

that statement is not in question in this appeal.” *Id.* at 808-09 (quoting *Bostock*, 590 U.S. at 669). But that statement is what the Rule provides at § 92.101(a)(2)(iv).<sup>8</sup>

Plaintiffs’ reliance on *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205 (11th Cir. 2023), which addressed an Equal Protection Cause claim, is also misplaced. ECF No. 12 at 15-18. “Given the similarity in language prohibiting sex discrimination in Titles VII and IX,” *Doe*, 28 F.4th at 114, *Eknes-Tucker* provides no basis to conclude that § 92.101(a)(2)(iv) is invalid in all of its applications.

### **B. Section 92.206(b)(3)**

Plaintiffs likewise have not established that § 92.206(b)(3) is contrary to § 1557. That provision clarifies that not all practices of sex segregation or differing treatment based on sex—including practices preventing individuals from participating in a program or activity consistent with the individual’s gender identity—violate § 1557. Rather, only those that result in “more than de minimis harm” violate § 1557. *Id.* See 89 Fed. Reg. at 37,593-94 & n.162; see also, e.g., *Burlington N. and Santa Fe Ry. Co. v. White*, 548 U.S. 53, 68 (2006).

Plaintiffs do not dispute that the challenged provision can be validly applied in an overwhelming number of (if not all) circumstances. Most applications would have nothing to do with gender identity discrimination. Consider Florida’s operation of sex-segregated residential health care facilities. Bailey Decl. ¶ 35. There could be any

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<sup>8</sup> The *Adams* court also made clear that the policy at issue in that case did “not depend in any way on how students act or identify[.]” 57 F.4th at 809, unlike a sweeping set of policies that would be authorized by enjoining enforcement of § 92.101(a)(2)(iv) in all applications.

number of ways that Florida could treat their male residents differently than their female residents in the provision of health care that, for example, subjects a male resident to more than de minimis harm, potentially covered by § 92.206(b)(3), without any transgender individual being involved. Florida's arguments about the scope of discrimination on the basis of sex, ECF No. 12 at 9, would have no bearing on an overwhelming number of those applications. ECF No. 12-5.

The provision's explicit reference to gender identity is no less valid. As compelled by a natural reading of the statute, it precludes providers from engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity if it subjects the individual to more than de minimis harm. 42 C.F.R. § 92.206(b)(3).

Consider if Florida were to ban transgender individuals from participating as residents in its health facilities altogether because it considered those individuals to fail to comply with sex stereotypes given their sex assigned at birth, *Glenn v. Brumby*, 663 F.3d 1312, 1318 (11th Cir. 2018), and the ban caused an individual more than de minimis harm. Plaintiffs have not explained how the injunction they seek precluding enforcement in these circumstances could be justified. *See id.* at 1319.

Plaintiffs argue that Title IX "allows separating living facilities based on sex" and "separate bathrooms." ECF No. 12 at 12. Even if Plaintiffs are correct that § 1557 does not "*clearly* forbid separating private spaces based on sex," *id.*, the Rule expressly complies with, rather than violates, this interpretation. Section 92.206(b)(3) does not "prohibit[] a covered entity from operating sex separated programs and facilities." 89



Fed. Reg. at 37,593. And “the practice of assigning patients to dual-occupancy rooms . . . on the basis of sex is not, standing alone, a form of discrimination.” 87 Fed. Reg. at 47,866. The plain language of § 92.206(b)(3), as in *Bostock*, does not purport to resolve § 1557’s application to specific claims involving “bathrooms, locker rooms, or anything else of the kind.” 590 U.S. at 681.<sup>9</sup>

### C. Sections 92.206(b)(4) and 92.207(b)(4)-(5)

Plaintiffs similarly have not established that §§ 92.206(b)(4) and 92.207(b)(4)-(5), which address nondiscrimination related to gender-affirming care, are contrary to § 1557. Plaintiffs’ error lies in viewing these provisions as imposing specific demands to provide or cover particular health services, like puberty blockers or gender affirming surgeries, when in fact these provisions only require covered entities to act in a nondiscriminatory manner. *See* 89 Fed. Reg. 37,607 (“We [] decline to state that any denial of gender-affirming care will necessarily be discriminatory regardless of context or rationale.”). The Rule makes clear that “[n]othing in [§§ 92.206(b)(4) and

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<sup>9</sup> In responding to comments in the preamble, HHS stated that refusing to place a transgender person “in facilities consistent with their gender identity” would “result in more than *de minimis* harm,” 89 Fed. Reg. at 37,593—a conclusion that Plaintiffs do not dispute. That statement is consistent with federal court decisions. *E.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d at 617-18 (4th Cir. 2020); *Whitaker ex rel. Whitaker v. Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.*, 858 F.3d 1034, 1045-46 (7th Cir. 2017). Plaintiffs do not seek to enjoin enforcement of this preamble statement. ECF No. 12-5. While a Rule’s preamble may help determine whether an agency’s decision to adopt a particular approach was supported by adequate reasoning, it cannot render legally deficient otherwise legally permissible regulatory language. *See St. Francis Med. Ctr. v. Azar*, 894 F.3d 290, 297 (D.C. Cir. 2018); *Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). Insofar as Plaintiffs view the preamble statement as inconsistent with circuit precedent in some applications, absent a contrary “history of [] enforcement,” *Reno*, 507 U.S. at 301, the Court must assume that HHS would enforce the regulatory text in good faith consistent with caselaw that is binding in a particular circuit, *Hyatt v. Hecker*, 807 F.2d 376, 379 (4th Cir. 1986) (agencies must “follow the law of the circuit whose courts have jurisdiction over the cause of action”), given that the Court must presume that HHS “will act properly and according to law,” *FCC v. Schreiber*, 381 U.S. 279, 296 (1965).

92.207(b)(4)-(5)] requires the provision [or coverage] of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting” the service or coverage. 45 C.F.R. § 92.206(c); *accord id.* § 92.207(c). The Rule thus establishes a framework for determining whether any particular denial of care or coverage violates § 1557. “When OCR investigates claims of discrimination based on the denial of care, [it] will consider the covered entity’s rationale for such denial, any supporting information the covered entity offers for its position, and any evidence of unlawful animus, bias, or other discriminatory factors in the case.” 89 Fed. Reg. 37,597. The framework set forth in the Rule is consistent with decades of precedent. *See, e.g., McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802-03 (1973) (establishing same framework for analyzing Title VII discrimination claims); *Buckley v. Sec’y of Army*, 97 F.4th 784, 794 (11th Cir. 2024) (*McDonnell Douglas* framework appropriate for discrimination statutes that include “but-for causation” principles).

Consider Plaintiffs’ hypothetical involving a surgeon who routinely provides orchiectomies. ECF No. 12 at 16-17. Plaintiffs argue that a surgeon who treats a transgender woman seeking an orchiectomy because of testicular cancer but not a transgender woman who seeks an orchiectomy because of gender dysphoria is not discriminating on the basis of sex. *Id.* But whether that is true will depend on the surgeon’s reason(s) for denying treatment. For example, a determination that the service was “not clinically appropriate for [the] particular individual” would likely provide a legitimate, nondiscriminatory rationale for the denial. 45 C.F.R. § 92.206(c). In contrast, if the surgeon instead explained that they denied the orchiectomy because

of animus against transgender individuals for their sex-related traits, the surgeon would have engaged in impermissible sex discrimination. *Id.*; see *Glenn*, 663 F.3d at 1317; *Lange v. Houston County*, 101 F.4th 793, 798-99 (11th Cir. 2024) (holding that a health insurance provider can violate a statutory duty not to discriminate because of sex for denying coverage for gender-affirming care to a transgender employee because the employee is transgender). Plaintiffs have not established that the framework set forth in the Rule for assessing alleged legitimate, nondiscriminatory reasons for a denial of care or coverage is unlawful. *Bowers v. Bd. of Regents of Univ. Sys. of Ga.*, 509 F. App'x 906, 910 (11th Cir. 2013) (applying framework to Title IX claim).

**D. Plaintiffs' Arguments about 20 U.S.C. § 1686 are Unmoored from the Provisions of the Rule They Seek to Enjoin HHS from Enforcing.**

Plaintiffs argue that § 1557 incorporates 20 U.S.C. § 1686, which permits educational institutions to “maintain[] separate living facilities for the different sexes.” ECF No 12 at 10-11. It is far from clear that Plaintiffs' reading of § 1557 to incorporate § 1686 is the best one, given that § 1557 only explicitly refers to the “ground prohibited” and “enforcement mechanisms provided for” under Title IX. 42 U.S.C. § 18116. *Schmitt v. Kaiser Found. Health Plan of Wash*, 965 F.3d 945, 953 (9th Cir. 2020). But Plaintiffs never explain why their alleged entitlement to an injunction against enforcement of the provisions cited in their proposed order, ECF No. 12-5, turns on whether Congress incorporated § 1686 in § 1557. Even if Plaintiffs are correct that § 1686 governs the application of § 1557's bar on sex discrimination, nothing in the challenged Rule precludes the agency or courts from applying § 1686 when addressing

particular cases. Relatedly, the Rule does not forbid what § 1686 permits. Insofar as this argument is related to Plaintiffs' request to enjoin enforcement of § 92.206(b)(3), again, that provision only requires that sex separation not "subject[] any individual to more than de minimis harm." 45 C.F.R. § 92.206(b)(3). Insofar as this argument is related to Plaintiffs' request to enjoin enforcement of § 92.101(a)(2)(iv), a determination that § 1686 governs § 1557 in some contexts would not mean that § 1557 never prohibits discrimination on the basis of gender identity. *See supra* at 12-15.

**E. No Motion to Enjoin or Stay Any Application of the Rule to Plaintiffs' Particular Policies is Properly Before the Court.**

Plaintiffs' heavy reliance on *Adams* and *Eknes-Tucker* to support their motion to enjoin portions of the Rule in all of their applications is misplaced. In addition to the reasons discussed *supra* at 14-15, both of those cases addressed various antidiscrimination provisions "as applied to a particular factual scenario," *Eknes-Tucker*, 80 F.4th at 1229, *i.e.*, one where a school district employed a particular bathroom policy, *Adams*, 57 F.4th at 811-17, and another where a state employed a particular policy restricting minors from accessing specific medical treatments, *Eknes-Tucker*, 80 F.4th at 1230. "That is not the scenario presented here." *Id.* at 1229. Rather, Plaintiffs here seek to enjoin HHS from enforcing general rules as applied to all plausible factual scenarios they might encompass. Plaintiffs' "hypothetical examples are not the stuff of ripe APA challenges." *Ass'n of Priv. Sector Colleges & Univs. v. Duncan*, 110 F. Supp. 3d 176, 196 (D.D.C. 2015), *aff'd*, 640 F. App'x 5 (D.C. Cir. 2016). *See Nat'l Ass'n of Regul. Util. Comm'rs v. FERC*, 964 F.3d 1177, 1185 (D.C. Cir. 2020).

Any request for an order enjoining HHS from enforcing the Rule to preclude particular policies would be inconsistent with the APA. Plaintiffs invoke judicial review under 5 U.S.C. § 702. Compl. ¶ 31. That provision requires Plaintiffs to “direct [their] attack against some particular ‘agency action[,]’” *Lujan v. National Wildlife Federation*, 497 U.S. 871, 890 (1990), as opposed to “an abstract decision apart from [the] specific agency action” that they challenge, *Biden v. Texas*, 597 U.S. 785, 809 (2022). Plaintiffs cannot invoke the APA to have the Court review an agency decision about whether their particular policies violate the Rule before the agency analyzes any legitimate, nondiscriminatory justifications for each policy, as the Rule requires, and generates a reviewable agency action. *Supra* at 17-18; *infra* at 27-29. “It is a tautology that [a plaintiff] may not challenge [an agency’s] regulations as applied until [the agency] applies the regulations[.]” *Dunn-McCampbell Royalty Int., Inc. v. Nat’l Park Serv.*, 112 F.3d 1283, 1288 (5th Cir. 1997); *see also Reno*, 507 U.S. at 300-01 (challenging application of a newly promulgated Rule would be impossible); *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1255 n.20 (11th Cir. 2012); *Nat’l Wildlife Fed. v. EPA*, 945 F. Supp. 2d 39, 44-47 (D.D.C. 2013).<sup>10</sup>

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<sup>10</sup> Pre-enforcement review of any application of the Rule would also be inconsistent with § 1557 itself. As described above, *supra* at 4-5, § 1557 incorporates the administrative enforcement mechanisms of Title IX, including its detailed judicial review provision, permitting an Article III court to determine whether any application of the Rule is consistent with § 1557 and the Rule. 20 U.S.C. § 1683. Permitting pre-enforcement injunctions against hypothetical applications of the Rule would undermine the comprehensive review process established by Congress. *See Thunder Basin*, 510 U.S. at 207-18; *Florida*, 2024 WL 2803298, at \*3-6.

**F. 42 C.F.R. § 438.3(d)(4)**

Florida also has not established that 42 C.F.R. § 438.3(d)(4), which requires contracts between states and managed care plans to include provisions that prohibit discrimination on the basis of gender identity, is unlawful.<sup>11</sup> Florida appears to claim that HHS lacked statutory authority to promulgate regulations prohibiting discrimination in enrollment as part of HHS's oversight of the Medicaid and CHIP programs and requiring contract terms in managed care plans that prohibit discrimination in enrollment by those plans. Florida is incorrect.

Medicaid and CHIP are joint federal-state programs that enable states to extend medical coverage to certain low-income individuals under Title XIX (Medicaid) and Title XXI (CHIP) of the Social Security Act. 42 U.S.C § 1396, *et. seq.*; *id.* § 1397aa, *et. seq.* To participate in either, each state must create a specific plan that fulfills the conditions specified in 42 U.S.C. § 1396a(a) or 42 U.S.C. §§ 1397aa-1397bb and submit the plan to HHS for approval. *Id.* § 1396a(b); *id.* § 1397ff(a)-(c); 42 C.F.R. § 457.150(a)-(c). Upon approval, states administer their plans, and the federal government provides funding to help defray costs.<sup>12</sup>

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<sup>11</sup> CMA does not allege any injury to its members from this provision. *See* Compl. ¶¶ 185-215 (alleging harm only from the “OCR Rules”). Accordingly, CMA lacks standing to obtain injunctive relief against this provision. *See Mack v. USAA Casualty Insurance Co.*, 994 F.3d 1353, 1356 (11th Cir. 2021) (“[S]tanding is not dispensed in gross.” (quoting *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996))).

<sup>12</sup> CMS discussed the authorities for regulating managed care programs in detail in a final rule promulgated in 2016. *Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability*, 81 Fed. Reg. 27,498, 27,500-01 (May 6, 2016).

The challenged provision does not “impose[] effects-based liability on contractors,” as Florida claims. ECF No. 12 at 20. Rather, it establishes a condition of federal funding, and it is beyond dispute that HHS—through CMS—may establish requirements for state Medicaid and CHIP plans by regulation, including for the proper and efficient operation of state Medicaid plans, 42 U.S.C. § 1396a(a)(4), to ensure that such plans operate in the “best interests of recipients[,]” *id.* § 1396a(a)(19), and to provide for the “effective and efficient” provision of child health assistance, *id.* § 1397aa(a). *See* 42 U.S.C. § 1302(a). That is precisely what HHS did here. *See* 89 Fed. Reg. at 37,668. Florida largely ignores HHS’s authority to regulate and approve state plans, and it conspicuously avoids any reference to HHS’s authority under § 1396a(a)(19). *See* ECF No. 12 at 19-20. Nor does Florida cite any authority to support its argument that HHS lacked authority to impose the particular requirements in § 438.3(d)(4) as a condition of federal funding. *See, e.g., W. Virginia v. Thompson*, 475 F.3d 204, 209-14 (4th Cir. 2007) (deferring to CMS’s interpretation of the Medicaid statute even in the absence of notice-and-comment rulemaking). *Compare Adams*, 57 F.4th at 815 (addressing notice requirements in the context of a private suit for damages under § 1983).

Moreover, to the extent Florida’s argument is that HHS lacked authority to promulgate rules prohibiting policies or practices that have discriminatory effects, ECF No. 12 at 19-20, Florida’s claim comes too late. CMS regulations have proscribed such policies and practices with respect to race, color, and national origin since 2002, *see Medicaid Program; Medicaid Managed Care: New Provisions*, 67 Fed. Reg. 40,989,

41,098 (June 14, 2002), and discrimination based on sex was added in 2016, *see* 81 Fed. Reg. at 27,856. In all that time, Florida has never challenged CMS's authority to prohibit discriminatory effects, and the statute of limitations for questioning that authority has now passed. *See* 28 U.S.C. § 2401(a).

In any event, Florida's challenge to § 438.3(d)(4) is not properly before this Court. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 208 (1994). If CMS were to disallow federal financial participation on the basis of failure to comply with § 438.3(d)(4), Florida would be entitled to notice and, upon request, to receive a reconsideration of the disallowance and appeal to the Departmental Appeals Board, and could then seek judicial review if dissatisfied. 42 U.S.C. §§ 1316(e), 1397gg(e)(2); 42 C.F.R. § 430.42. Similarly, were CMS to seek to withhold or defer federal financial participation on Florida's payments to its managed care plans, there are procedural protections in place and a right to seek further review in the court of appeals. 42 U.S.C. §§ 1316(a)(3), 1396c; 42 C.F.R. §§ 430.35 through 430.40. In all events, Congress's "intent to allocate initial review of Florida's claims to CMS is 'fairly discernable in [42 U.S.C. § 1316]," and therefore the Court lacks subject-matter jurisdiction over the claim. *Florida*, 2024 WL 2803298, at \*6.

#### **G. The Rule Does Not Violate the Spending Clause.**

Section § 92.101(a)(2)(iv) is not impermissibly ambiguous under *Pennhurst State Sch. & Hosp. v. Halderman*, 541 U.S. 1, 18 (1981). ECF No. 12 at 11-12. Even assuming



*Pennhurst* requires a clear statement,<sup>13</sup> there is no Spending Clause problem because the relevant provision in the Rule merely explains the scope of § 1557’s unambiguous prohibition on sex discrimination, based on the statutory language’s plain meaning. *Bostock*, 590 U.S. at 674. In *Bostock*, the Supreme Court explained that Title VII’s “message” on this score was “simple.” *Id.* at 644. “Given the similarity in language prohibiting sex discrimination in Titles VII and IX,” *Doe*, 28 F.4th at 114, the same clear statement exists in Title IX and § 1557; *see also Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 953 (D. Minn. 2018).<sup>14</sup> “[S]o long as a spending condition has a clear and actionable prohibition of discrimination, it does not matter that the manner of that discrimination can vary widely.” *Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004). Moreover, the statutory provisions cited above clearly put states on notice that CMS will impose regulatory requirements for operation of programs.

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<sup>13</sup> The *Pennhurst* analysis is most frequently invoked in the context of ascertaining the scope of liability in a private lawsuit (typically for damages). *See, e.g. Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218-219 (2022); *Adams*, 57 F.4th at 815. In those case, the *Pennhurst* analysis does not result in an unenforceable statutory or regulatory spending condition, but instead a conclusion that enforcement must be at the hands of the federal government seeking prospective compliance as a condition of continued funding rather than private individuals seeking damages for past conduct. In applying *Pennhurst*, the Supreme Court has explained that the consequence of a statute “not unambiguously confer[ring] an enforceable right upon the Act’s beneficiaries” is the unavailability of a private cause of action to enforce the provision either in its entirety or in certain applications. *Suter v. Artist M.*, 503 U.S. 347, 363 (1992). A statute imposing a “generalized duty on [the] State” is not invalid, but is “to be enforced by the Secretary in the manner [of reducing or eliminating payments].” *Gonzaga Univ. v. Doe*, 536 U.S. 273, 381 (2002) (quoting *Suter*, 503 U.S. at 363).

<sup>14</sup> Plaintiffs seemingly argue that the Spending Clause would preclude reading § 1557 to bar separate living facilities or separate bathrooms based on sex. ECF No. 12 at 12-13. But, as explained above, the Rule does not determine whether any particular practice violates § 1557; thus, particular applications of the Rule are not at issue here.

## II. Plaintiffs Cannot Establish Imminent Irreparable Injury.

Whether for a preliminary injunction, *Siegel v. LePore*, 234 F.3d 1163, 1176-77 (11th Cir. 2000), or Article III standing, *Corbett v. TSA*, 930 F.3d 1225, 1233 (11th Cir. 2019), “injunctive relief requires [a] future injury [that] ‘proceed[s] with a high degree of immediacy,’” specifically, “within some fixed period of time in the future[,]” *id.* at 1233, “to reduce the possibility of deciding a case in which no injury would have occurred at all.” *Lujan v. Defs of Wildlife*, 504 U.S. 555, 564 n.2 (1992). Mere fear of future injury—even if “not fanciful, irrational, or clearly unreasonable”—is insufficient. *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 416 (2013) (citation omitted). Rather, a plaintiff alleging injury due to a legal code must “assert an injury that is the result of the [code’s] actual or threatened”—not merely feared—“enforcement, whether today or in the future.” *California v. Texas*, 593 U.S. 659, 670 (2021). Consistent with the “characterization” of injunctive relief as “extraordinary[,]” *Winter*, 555 U.S. at 22, not all Article III injuries constitute irreparable harm, even if they cannot be redressed in damages, *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980).

Here, Plaintiffs’ allegations of possible future harm do not establish imminent injury. This Court thus lacks jurisdiction whether analyzed as a matter of standing, *Nat’l Fam. Plan. and Reprod. Health Ass’n v. Gonzales*, 468 F.3d 826, 829-31 (D.C. Cir. 2006), ripeness, *Colwell v. HHS*, 558 F.3d 1112, 1123-29 (9th Cir. 2009), or statutory preclusion of pre-enforcement jurisdiction, *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207-18 (1994). But for purposes of the present motion, it is most speculative that

Florida or CMA members will experience an irreparable injury “before a decision on the merits can be rendered,” *Winter*, 555 U.S. at 22 (citation omitted)—which is the purpose of a preliminary injunction.

Plaintiffs’ failure to show irreparable injury that will occur before the Court decides this case is premised on the combination of three points: (1) Florida and CMA members’ insistence in their briefing and elsewhere that they have legitimate, nondiscriminatory bases for their policies, which is all that the Rule requires, (2) Plaintiffs’ failure to show that “good-faith” reliance on a belief that policies are nondiscriminatory “would trigger” irreparable consequences, like “an immediate funding cut-off, much less the sort of retroactive penalty that was involved in *Abbott Labs [v. Gardner]*, 387 U.S. 136 (1967),” *Gonzales*, 468 F.3d at 829, and relatedly (3) the attenuated procedures required before any loss of Federal financial assistance.

First, neither Florida nor CMA members allege that their policies are “based on unlawful animus or bias, or constitute a pretext for discrimination.” *E.g.*, 45 C.F.R. § 92.207(c). For example, while Florida must comply with the Rule, Florida is pre-judging that its policies are noncompliant while arguing elsewhere that it has a legitimate, nondiscriminatory reason for those policies, ECF No. 12 at 5, *see also* ECF No. 12-3 at 2 (CMA members “care for all patients with respect and without unlawful discrimination”), which is what § 1557 and the Rule requires, *see* 45 C.F.R. §§ 92.206(c), 92.207(c); 89 Fed. Reg. at 37,535.

Second, if Florida or CMA members were to stand on their good-faith representations about the bases for their policies (or even on a good-faith belief that a

provision of the Rule as applied would be invalid), they do not establish that they would suffer a “retroactive penalty” at the hands of HHS, *Gonzales*, 468 F.3d at 829, for reliance on those representations or views after the Rule’s effective date. To the contrary, in § 1557, Congress sought “to obtain compliance and eliminate discrimination [and did] not wish to use punitive measures[.]” 110 Cong. Rec. S7059 (daily ed. Apr. 7, 1964).<sup>15</sup> Compliance at any point in any putative enforcement process would thus preclude HHS from terminating funding. 45 C.F.R. §§ 80.7(d) (no funding loss proceedings if compliance can be achieved voluntarily after OCR investigation); 80.10(f) (permitting recipient to “correct its noncompliance” to preclude future funding loss after decision by hearing examiner but before decision takes effect), 80.10(g) (recipient “shall be restored to full eligibility” as soon as “it brings itself into compliance”). In other words, Florida won’t lose its funding if it first refuses to comply but then decides later that it will.

Finally, the extensive procedures, culminating in judicial review, required by § 1557 before HHS could terminate any Federal financial assistance for noncompliance make any loss of “federal financial assistance from HHS,” ECF No. 12 at 20, practically impossible “before a decision on the merits can be rendered[.]” *Winter*, 555 U.S. at 22 (citation omitted). *see also Flowers Industries v. FTC*, 849 F.2d 551, 552-53 (11th Cir. 1988) (no imminent irreparable harm when agency lacked

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<sup>15</sup>One reason that Congress precluded any funding termination decision from taking effect until after a review process by congressional committees, *supra* at 5, was to provide a “further opportunity to end the discrimination without the necessity of cutting off Federal funds[.]” 110 Cong. Rec. S7060.

power to immediately effectuate harm). “At each point in any putative enforcement process, Plaintiffs would be able to raise the same claims they now raise.” *ACP*, 2022 WL 17084365, at \*15. Previously, the required steps have taken extensive time.<sup>16</sup>

Together, all this means that Plaintiffs have not shown imminent irreparable injury. *Sch. Dist. of City of Saginaw v. HEW*, 431 F. Supp. 147, 154 (E.D. Mich. 1977) (no irreparable harm from being required to present claims following completion of Title VI proceedings). Florida claims that it “will face an untenable choice”—stop enforcing its policies “or lose federal financial assistance[,]” ECF No. 12 at 20. Even if any “choice” alone “would be sufficiently great” to justify drastic injunctive relief, *Petrol. Exploration v. PSC of Ky.*, 304 U.S. 209, 220 (1938), neither Florida nor any CMA member faces one until after they are “requested” to “correct [any charge of noncompliance], and thus hopefully achieve ‘voluntary compliance[,]’” *see Cook*, 1979 U.S. Dist. LEXIS 14572, at \*3. In *Cook*, for example, it took HHS’s predecessor agency over two years of investigation before even a preliminary finding of noncompliance. *Id.* And “[a]t the moment it also remains speculative whether such an [investigation] may be forthcoming” at all. *See Siegel*, 234 F.3d at 1177. Moreover, informal

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<sup>16</sup> *E.g., See, e.g., Civ. Remedies Div. the Gen. Couns.*, DAB No. CR2580 (2012) (H.H.S. Aug. 2, 2012) (terminating funding in 2012 after 3 years of investigation, 2 months of ignored repeated attempts to secure voluntary compliance, and more than 2 additional years had passed); *Freeman v. Cavazos*, 939 F.2d 1527, 1528 n.1, 1530 (11th Cir. 1991) (terminating funding in 1990 after investigating for 2 years and beginning funding termination procedures in 1986); *Cook v. Ochsner Found. Hosp.*, C.A. No. 70-1969, 1979 U.S. Dist. LEXIS 14572, at \*3 (E.D. La. Feb. 7, 1979) (3 years and 5 months between initiation of investigation and initiation of formal administrative adjudication proceeding); *Bd. of Pub. Instruction of Taylor Cnty, Fla. v. Finch*, 414 F.2d 1068 (5th Cir. 1969) (19 months between initiation of mandatory voluntary mediation efforts (after completion of investigation) and final order terminating funds).

cooperation with HHS during that process would not itself constitute irreparable injury. *Standard Oil*, 449 U.S. at 244; *see also Petrol. Exploration*, 304 U.S. at 220-21 (same).

The harm alleged by CMA members—who fear enforcement of § 1557 requiring conduct that would violate their “core religious beliefs[.]” Compl. ¶ 23—is even more remote and speculative. The Rule’s protections for religious freedom are robust. CMA members may rely on religious freedom and conscience protections, including RFRA, without obtaining a religious exemption under §§ 92.3(c), 92.302(a), which provide that application of the Rule’s provisions “to specific contexts, procedures, or health care services” shall not be required where RFRA or other protections apply, *id.* § 92.302(a). Separately, the Rule establishes a process whereby CMA members can seek assurances from OCR that federal law protecting religious freedom and conscience exempts them from any of those applications. 45 C.F.R. § 92.302(b).<sup>17</sup> CMA members thus face no injury at all, let alone irreparable injury, *at least* until after “the exemption [request] is finally denied.” *Navy SEAL 1 v. Biden*, 574 F. Supp. 3d 1124, 1143 (M.D. Fla. 2021).

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<sup>17</sup> CMA members can seek such assurances even before any administrative complaint is filed and “before an[y] investigation is initiated.” *Id.* Where members avail themselves of this option in advance and obtain an assurance, they will face no threat of investigation or enforcement. *Id.* § 92.302(d). Even if they did not proactively seek an assurance, if any administrative complaint is filed regarding their conduct or any investigation is otherwise initiated, CMA members “may, during the pendency of that investigation, similarly notify OCR of their belief they are entitled to an exemption under the process provided at § 92.302(b).” 89 Fed. Reg. at 37,658. And a member can appeal any adverse determination by OCR regarding an exemption within HHS and can seek judicial review in the event of a final adverse decision from the agency. 45 C.F.R. § 92.302(e)-(f).

Plaintiffs' arguments to the contrary lack merit. Florida cannot invoke the "health and welfare of [its] citizens," ECF No. 12 at 21 (citation omitted), as an interest in a suit against the Federal Government. *Haaland v. Brackeen*, 599 U.S. 255, 294-95 (2023); *Florida v. HHS*, 19 F.4th 1271, 1291-93 (11th Cir. 2021). And even if it could, Florida never explains how denying patients medically necessary care because of traits or actions that it would not have questioned in members of a different sex advances those interests.

Similarly, Florida cannot show imminent irreparable injury based on interests it may have in enforcing state statutes or rules that (1) it has represented to the *Dekker v. Weida*, No. 4:22-cv-00325-RH-MAF (N.D. Fla.) court that it is not enforcing or that (2) the *Doe v. Ladapo* court has enjoined Florida from enforcing against a class. --- F. Supp. 3d ---, 2024 WL 2947123 (N.D. Fla. June 11, 2024). ECF No. 32 at 4-7.<sup>18</sup>

That Florida is a State does not entitle it to a special "'presumption' of irreparable harm." See *Blue-Grace Logistics LLC v. Fahey*, 340 F.R.D. 460, 466 (M.D.

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<sup>18</sup> Florida's reliance on the Government's amicus brief in *Dekker* to suggest it faces imminent irreparable harm due to the Rule's enforcement is misplaced. ECF No. 12 at 21. In *Dekker*, the district court's findings that Florida's policies violated § 1557 occurred after a trial where plaintiffs proved that Florida's justifications for the policies were pretext for discrimination on the basis of sex. For HHS to terminate Federal financial assistance due to the same policies under the new Rule's provisions would require resource-intensive trial-type administrative proceedings that would be largely duplicative of the *Dekker* proceedings. 45 C.F.R. § 92.207(c). If Florida loses *Dekker* on appeal, presumably Florida will comply with the Eleventh Circuit's judgment and there will be no need for any administrative adjudication, let alone termination of funding. If the Eleventh Circuit reverses, Florida cannot explain why the Eleventh Circuit's opinion would not inform HHS enforcement discretion. In any event, the mere fact that Florida might need to defend itself against an administrative complaint would not itself constitute irreparable harm. *Standard Oil*, 449 U.S. at 244. And whatever harm Florida currently faces from § 1557 enforcement in cases like *Dekker* is not redressable through enjoining enforcement of the Rule in this case.

Fla. 2022) (citation omitted). Florida invokes *Abbott v. Perez*, 585 U.S. 579 (2018). But in *Abbott*, the court held that enjoining a state from enforcing a statute imposed irreparable injury, 585 U.S. at 602 n.17; here, “[Florida] has not been enjoined from establishing, enforcing, or effectuating any of its statutes,” *N.M. Dep’t of Game and Fish v. U.S. Dep’t of the Interior*, 854 F.3d 1236, 1255 (10th Cir. 2017). The point is that the mere existence of a statute or rule on the books cannot itself be irreparable injury; the injury must derive from “actual or threatened enforcement.” *California*, 593 U.S. at 670. And as explained, irreparable injury from enforcement is not imminent. Plaintiffs’ evidence therefore does not connect the dots so as to demonstrate that its ostensible sovereign injury will occur before a decision on the merits. Any chilling effect on Florida’s interests associated with a potentially invalid rule being on the books is insufficient. *Whole Woman’s Health v. Jackson*, 595 U.S. 30, 50 (2021).

Finally, a class-wide declaratory judgment precludes a finding of imminent irreparable harm. ECF No. 32 at 1-2. It already addresses any fear of enforcement against healthcare providers. As long as that judgment remains good law, OCR will not investigate class members alleged to have engaged in the kind of gender identity discrimination addressed in that case. *Id.* Thus, there is no risk of harm to the members of Plaintiff CMA or to the healthcare facilities that Plaintiff Florida has identified. *See* Compl. ¶ 17 and ECF 12-2 (Decl. of Kevin Bailey).<sup>19</sup> Courts have declined to find

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<sup>19</sup> Plaintiffs’ membership in the *Neese* class may have broader implications for their ability to pursue the relief they seek in this case insofar as it is “within the subject matter of the class action.” *Green v. McKaskle*, 770 F.2d 445, 447 (5th Cir. 1985); *see also, e.g., Roth v. Austin*, 62 F.4th 1114, 1117-18 (8th Cir. 2023) (“[P]roper remedy is to dismiss the duplicative claims”).



imminent irreparable harm in similar contexts. *See Bongiovanni*, 2022 WL 1642158, at \*10; *Faust v. Vilsack*, No. 21-C-548, 2021 WL 2806204, at \*3 (E.D. Wis. July 6, 2021); *see also Sanchez-Espinoza v. Reagan*, 770 F.2d 202, 208 n.8 (D.C. Cir. 1985).

### **III. The Equities and Public Interest Weigh Against a Preliminary Injunction.**

The balance of the equities and public interest plainly weigh against the drastic relief Plaintiffs request. Plaintiffs have not made any showing of substantial, imminent, and irreparable injury of the nature that would warrant extraordinary intervention by a court of equity. Against this non-existent showing of harm weighs the significant public interest in permitting enforcement of the Rule to combat discrimination in health programs and activities receiving federal funds. It is well-established that violations of federal civil rights statutes constitute irreparable harm. *See Rogers v. Windmill Pointe Vill. Club Ass'n*, 967 F.2d 525, 528 (11th Cir. 1992); *United States v. Hayes Int'l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969). A patient who is denied basic medical care just because a provider or insurer wants to intentionally penalize them for their sex-related traits suffers “irreparable injury.” *Lange*, 101 F.4th at 801. Issuing Plaintiffs’ injunction would authorize that behavior. Moreover, there is “inherent harm” in preventing HHS from enforcing statutes. *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). *See Abbott*, 585 U.S. at 602 n.17.

Plaintiffs assert that “staying or enjoining enforcement of the 2024 Rules won’t interfere with HHS’s legitimate law-enforcement interests” and that “HHS will be able to continue enforcing Section 1557 to prevent actual intentional sex discrimination.”

ECF No. 12 at 23. That is not the import of their proposed order.<sup>20</sup> Insofar as Plaintiffs suggest that the Court should issue an order that precludes HHS from taking enforcement actions against Florida or CMA members by citing the provisions of the Rule but leaves HHS “free to engage in the [same]” enforcement actions “that the plaintiffs say injures them” by citing the statute alone, their motion should be dismissed on standing grounds. *See Support Working Animals, Inc v. Governor of Fla*, 8 F.4th 1198, 1205 (11th Cir. 2021). An order permitting HHS to take the same enforcement actions it would take under the Rule by instead citing the statute could not plausibly redress any threat of enforcement they purport to face. *See id.*

**IV. The Court Should Not Enjoin Defendants from Enforcing Any Provision of the Rule Against Nonparties or Unharmful, Unidentified CMA Members.**

Any preliminary injunction or stay should be limited in scope. The Eleventh Circuit has confirmed that entry of a nationwide injunction will typically be an abuse of discretion. *See Georgia v. Pres. of the U.S.*, 46 F.4th 1283, 1306 (11th Cir. 2022).

Here, Plaintiffs fail to show that nationwide relief is necessary to redress the alleged injuries of Florida or CMA members. An order appropriately limited to enjoining Defendants from enforcing specific provisions of the Rule against Florida or CMA members insofar as they have shown individualized imminent irreparable injury from enforcement of those provisions (and otherwise persuaded the court that

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<sup>20</sup> In the context of agency rules, a § 705 stay operates to “stay enforcement” of the stayed provisions. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 156 (1967); *see also Nken v. Holder*, 556 U.S. 418, 428 (2009) (stays and injunctions have the same “practical effect”).

preliminary injunctive relief is appropriate) would suffice to redress that showing of irreparable harm. Plaintiffs offer no legitimate reason consistent with Article III to extend an injunction to others. *See Gill v. Whitford*, 585 U.S. 48, 73 (2018). Nor does CMA’s representation of its identified members mean that CMA may seek an injunction on behalf of nonparty CMA members that CMA has not shown face imminent irreparable harm. CMA cannot “circumvent” Rule 23’s class-action “mechanisms in the name of providing injunctive relief only for nonparties’ benefit” and for whom it has not shown irreparable harm. *Georgia*, 46 F.4th at 1306.<sup>21</sup>

## CONCLUSION

Accordingly, the motion for a preliminary injunction should be denied.<sup>22</sup>

Dated: June 13, 2024

Respectfully submitted,

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<sup>21</sup> Plaintiffs “lightly assume that Congress has intended to depart from [these] established [equitable] principles[,]” *see Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982), when it enacted 5 U.S.C. § 705. ECF No. 12 at 24. But that provision does not change the inadvisability of a universal remedy. It was designed “to reflect existing law . . . and not to fashion new rules of intervention for District Courts.” *Sampson*, 415 U.S. at 68 n.15. Its plain language requires the Court to consider relief that merely “preserve[s] status or rights pending conclusion of the review proceedings.” 5 U.S.C. § 705. In tailoring any relief only “to the extent necessary to prevent irreparable injury[,]” *id.*, the statute directs courts to apply traditional equitable principles, which include tailoring relief to be no more intrusive than necessary to prevent irreparable harm to the parties. *Georgia*, 46 F.4th at 1303-04. Indeed, the House Report for the APA indicates that relief under § 705 should “normally, if not always, be limited to the parties complainant.” H.R. Rep. No. 79-1980, at 43 (1946).

<sup>22</sup> Plaintiffs have not established that venue is proper in this district. To the extent Plaintiffs' complaint raises RFRA claims on behalf of CMA members, this Court is not a proper venue for those claims. *See* 28 U.S.C. § 1391(e); *Tucker v. U.S. Dep’t of Army*, 42 F.3d 641 (5th Cir. 1994). Moreover, the RFRA claims and any (premature) as-applied challenges of individual CMA members asserted in the complaint should be severed. *See Crosby v. Austin*, No. 8:21-cv-2730-TPB-CPT, 2022WL 19236177, at \*2 (M.D. Fla. Feb. 22, 2022). The Court need not address these issues in resolving the instant motion, however, because Plaintiffs' motion relies solely on their APA and Spending Clause claims to challenge provisions of the Rule in all their applications. Defendants note these issues here solely to ensure that they are not inadvertently forfeited. *See Order, U.S. Navy SEALs 1-26 v. Biden*, No. 4:21-cv-01236-O (N.D. Tex. May 7, 2022), ECF No. 150, at 7.

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