UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPI
SOUTHERN DIVISION

STATE OF TENNESSEE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*,

Defendants.

No. 1:24-cv-00161-LG-BWR

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR § 705 RELIEF AND A PRELIMINARY INJUNCTION

INTRODUCTION

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. On May 6, 2024, the U.S. Department of Health and Human Services ("HHS") promulgated a new rule (the "Rule") that implements § 1557's nondiscrimination obligations and clarifies, pursuant to the rationale of prevailing Supreme Court precedent in *Bostock v. Clayton County*, 590 U.S. 644 (2020), that sex discrimination necessarily includes discrimination on the basis of gender identity. *See* Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024).[1]

Plaintiffs, by filing a motion for a stay and injunctive relief against all provisions of the Rule that touch on gender identity, seek to undo HHS's lawful attempt to codify that principle of nondiscrimination.[2] Yet Plaintiffs' arguments rest on fundamental misunderstandings of *Bostock* and what the Rule requires, as well as repeated invocations of standards of care that the Rule does not incorporate or reference. Indeed, most of Plaintiffs' arguments—including their unsupported claims of infringed sovereignty rights—suffer from the same fatal flaw: they ask this Court to enjoin a Rule that has not yet been applied by the agency. And they do so, despite the fact that the Rule makes clear that a covered entity does not violate § 1557 if it has a legitimate, nondiscriminatory reason for denying care or coverage to a transgender patient. *See* 45 C.F.R. §§ 92.206(c), 92.207(c). Because Plaintiffs have not established that any of the challenged provisions of the Rule violate § 1557, the Social Security Act, or the U.S. Constitution—let alone that they face any irreparable harm under the Rule—the Court should deny Plaintiffs' motion for a stay and preliminary injunction in its entirety.

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[1] Provisions of the Rule cited in this brief refer to those published at 89 Fed. Reg. at 37,691–703.

[2] Plaintiffs include the States of Tennessee, Mississippi, Alabama, Georgia, Indiana, Kansas, Louisiana, Nebraska, Ohio, Oklahoma, South Carolina, and South Dakota; and the Commonwealths of Kentucky and Virginia.

BACKGROUND

I. Section 1557 of the ACA and Its Statutory Enforcement Mechanisms

Section 1557 of the ACA provides that "an individual shall not, on the ground[s] prohibited under" various longstanding federal civil rights statutes—specifically, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, and § 504 of the Rehabilitation Act of 1973—"be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a).[3] In short, § 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities, any part of which receive federal funds. *Id.*

Section 1557 further provides that "violations" of its nondiscrimination requirements "shall" be addressed through the "enforcement mechanisms provided for and available under . . . title VI [and] title IX," *id.*—which allow for multiple layers of process and review, *see, e.g.*, 20 U.S.C. § 1682 (Title IX); 42 U.S.C. § 2000d-1 (Title VI).[4] That enforcement process works as follows. Upon receiving a complaint or "any other information indicat[ing]" a federal funding recipient's possible noncompliance with § 1557, HHS's Office for Civil Rights ("OCR") will first conduct an investigation, during which it will consider all factors and circumstances "relevant to a determination as to whether the recipient failed to comply" with the statute. 45 C.F.R. § 80.7(c). If OCR finds a "failure to comply," it must then "inform the recipient" of its noncompliance and seek to "resolve[]" the matter "by informal means." *Id.* § 80.7(d)(1); 20 U.S.C. § 1682. If "compliance cannot be secured by voluntary means," HHS may choose to "effect[]" such compliance by terminating or withholding federal funding. 20 U.S.C. § 1682. Any decision to

[3] Section 1557 also addresses discrimination occurring under "any program or activity that is administered by an Executive Agency or any entity established under" Title I of the ACA (*e.g.*, State-based marketplaces for healthcare coverage). 42 U.S.C. § 18116(a).

[4] Title VI's and Title IX's enforcement provisions are materially the same. *Compare* 42 U.S.C. § 2000d-1, *with* 20 U.S.C. § 1682. The enforcement procedures under both statutes are also governed by the same implementing regulations. *See* 45 C.F.R. § 86.71 (adopting and incorporating for purposes of Title IX the "procedural provisions applicable to Title VI"); 45 C.F.R. §§ 80.6–.11 (Title VI).

withhold federal funds, however, must be preceded by "an express finding on the record, after opportunity for hearing, of a failure to comply with" § 1557. *Id.* The required hearing is subject to robust procedural protections, *see* 45 C.F.R. §§ 80.9, 81.1–.86, and if a failure to comply is ultimately found, HHS must submit a "full written report" to congressional committees before any withholding of funds can take effect, 20 U.S.C. § 1682. Ultimately, any such withholding "shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found." *Id.* In addition to these procedural safeguards, § 1557's enforcement mechanism makes OCR's decisions to suspend or terminate federal financial assistance subject to judicial review. 20 U.S.C. § 1683. Accordingly, the ultimate arbiters of any violation of § 1557 are Article III courts.

II. HHS's 2024 Rule Implementing § 1557

On May 6, 2024, HHS published the Rule in the Federal Register. *See* 89 Fed. Reg. 37,522 (to be codified at 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 . . . [g]ender identity[.]" 45 C.F.R. § 92.101(a)(2)(iv). The Rule also addresses equal program access, 45 C.F.R. § 92.206, and insurance coverage, *id.* § 92.207, as described below.

§ 92.206—Equal Program Access. Section 92.206, which addresses equal access to health programs and activities on the basis of sex, applies primarily to those that provide direct healthcare services to patients, such as hospitals, physical and mental health care providers, and pharmacies. For example, § 92.206(b)(3) precludes covered entities 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.* That provision clarifies that the Rule does not prohibit "a covered entity from operating sex separated programs and facilities"—such as providing separate bathrooms labeled for men and women. 89 Fed. Reg. at 37,593. Section 92.206(b)(4) similarly precludes covered providers from denying or limiting 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 assigned at birth, gender identity, or

gender otherwise recorded." 45 C.F.R. § 92.206(b)(4). Importantly, the entirety of § 92.206 is subject to § 92.206(c), which makes clear that:

> Nothing in this section requires 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 other words, no § 1557 violation occurs where the denial of a service is based on "a legitimate, nondiscriminatory reason," and not "unlawful animus or bias" or "pretext for discrimination." *Id.*

§ 92.207—Insurance and Other Health-Related Coverage. Section 92.207 applies to covered entities that provide insurance or other health-related coverage. *Id.* Among other specific prohibitions, § 92.207(b)(3) prohibits insurance issuers from "deny[ing] or limit[ing] coverage" "based upon" an individual's "gender identity," while § 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)(3)–(4). Like § 92.206, § 92.207 makes clear that:

> Nothing in this 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); *accord id.* § 92.206(c). Thus, as HHS explains in the Rule's preamble, "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.

§ 438.3(d)(4)—Standard Contract Requirements. Finally, as relevant here, the Rule revises the nondiscrimination provisions of the regulations issued by the Centers for Medicare & Medicaid Services ("CMS"), which govern Medicaid and the Children's Health Insurance Program ("CHIP"). 89 Fed. Reg. at 37,691 (revising 42 C.F.R. § 438.3). These CMS regulations require contracts between States and Medicaid and CHIP managed care plans to include provisions

that preclude discrimination against enrollees. 42 C.F.R. § 438.3(d)(4). As relevant here, § 438.3(d)(4) adds discrimination on the basis of gender identity to the list of prohibited sex-based discrimination, *id.*, "based on Section 1557" and pursuant to HHS's separate statutory authority under 42 U.S.C. §§ 1396a(a)(4), 1396(a)(19), and 1397aa(a), Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824, 47,892 (Aug. 4, 2022).

PROCEDURAL HISTORY

Plaintiffs filed this lawsuit on May 30, 2024. Compl., ECF No. 1. Two weeks later, on June 13, 2024, Plaintiffs filed the instant motion for a delay of the effective date and for preliminary injunction of the Rule. ECF No. 20.

LEGAL STANDARDS

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008); *Anderson v. Jackson*, 556 F.3d 351, 360 (5th Cir. 2009) ("Injunctive relief is 'an extraordinary and drastic remedy[]' and should only be granted when the movant has clearly carried the burden of persuasion." (citation omitted)). Plaintiffs must—"*by a clear showing*"—establish that (1) they have a substantial likelihood of success on the merits; (2) they will suffer irreparable harm without an injunction; (3) the balance of equities tips in their favor; and (4) preliminary relief serves the public interest. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (citation omitted). The same standard applies to a plaintiff seeking to postpone the effective date of a rule pursuant to 5 U.S.C. § 705. *See Sampson v. Murray*, 415 U.S. 61, 68 n.15 (1974); *Career Colleges & Schs. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255–56 (5th Cir. 2024). A plaintiff's failure to demonstrate any one of these factors is sufficient to deny injunctive relief, *Allied Mktg. Grp., Inc. v. CDL Mktg., Inc.*, 878 F.2d 806, 809 (5th Cir. 1989), and "grant[ing] a preliminary injunction" represents "the exception rather than the rule[,]" *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ARGUMENT

Plaintiffs seek to postpone the effective date of, or enjoin enforcement of, all applications of provisions of the Rule that address gender identity discrimination during the pendency of this litigation. *See* ECF No. 20.[5] The Court should deny Plaintiffs' motion for sweeping relief because (1) they are not likely to succeed on the merits, (2) they have not established imminent, irreparable harm—let alone injury in fact, and (3) the equities and public interest weigh against enjoining the challenged portions of the Rule in all their applications.

I. Plaintiffs Are Not Likely to Succeed on the Merits of Their APA Claims.

To succeed on the merits of their APA claims, Plaintiffs must "establish that no set of circumstances exist under which the [Rule] would be valid." *Associated Builders & Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 220 (5th Cir. 2016) (citation omitted); *see also Reno v. Flores*, 507 U.S. 292, 301 (1993). Plaintiffs cannot meet that exacting standard because the gender identity discrimination provisions of the Rule flow directly from the text of § 1557 and the Supreme Court's reasoning in *Bostock*. Nor can Plaintiffs' hypothetical applications of the Rule carry the day, when "nothing in the [challenged] Rule itself speaks to" any of those applications. *Anderson v. Edwards*,

[5] Because Plaintiffs' briefing is limited to whether discrimination on the basis of sex includes discrimination on the basis of gender identity, the discussion that follows is limited accordingly. Although Plaintiffs seek to enjoin 45 C.F.R. § 92.101, *see* ECF No. 20, 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 (as a form of prohibited sex discrimination), 45 C.F.R. § 92.101. Plaintiffs' motion, ECF No. 20, also seeks to enjoin enforcement of a number of sections as "applied with respect to 'sex' discrimination encompassing gender identity.'" *Id.* at 2. That "as-applied" relief would apply to 45 C.F.R. § 92.5, which addresses assurances of nondiscrimination; § 92.6, which addresses remedial and voluntary actions by recipients; § 92.7, which addresses a § 1557 coordinator; § 92.8, which requires a written nondiscrimination policy; § 92.9, which governs training; § 92.10, which addresses notice of nondiscrimination; § 92.208, which addresses sex discrimination related to marital, parental, or family status; § 92.209, which addresses nondiscrimination on the basis of association; § 92.210, which addresses nondiscrimination in the use of patient care decision support tools; § 92.211, which addresses nondiscrimination in the delivery of health programs and activities through telehealth services; § 92.301, which restates the statutory text regarding enforcement mechanisms; §§ 92.303–04, which clarify procedures for processing complaints and administrative enforcement actions; 42 C.F.R. §§ 438.206, which addresses availability of services; § 440.262, which addresses access and cultural conditions; § 460.98, which addresses service delivery; and § 460.112, which addresses the rights to respect and nondiscrimination for participants. Plaintiffs' briefing does not raise any argument regarding the legality of these provisions, and thus, any such arguments are waived, and Defendants therefore do not address those provisions here.

514 U.S. 143, 155 n.6 (1995). Indeed, the Rule does not reflect a determination that any of Plaintiffs' particular laws or policies violate § 1557, and thus judicial review may be available only after final agency action and completion of the administrative procedures mandated by Congress. Thus, as Defendants explain below, the Court should deny the sweeping relief Plaintiffs seek because they fail to establish that the challenged provisions of the Rule—45 C.F.R. §§ 92.101(a)(2)(iv), 92.206, 92.207; 42 C.F.R. § 438.3(d)(4), *see supra* at 6 n.5—are contrary to § 1557, the Social Security Act, or the Constitution's Spending Clause.

A. The Rule's Prohibition of Discrimination on the Basis of Gender Identity Is Consistent with § 1557.

Plaintiffs' core arguments rest on the assertion that the Rule improperly shoehorns a prohibition of gender identity discrimination into § 1557's prohibition of sex discrimination. Not so. The prohibition of discrimination on the basis of gender identity is lawful because it flows directly from the text of § 1557 and the Supreme Court's reasoning in *Bostock*.

Bostock addressed whether Title VII's provision making it unlawful for an employer "to discriminate against any individual . . . because of such individual's . . . sex" prohibits an employer from firing someone "merely for being . . . transgender." *Bostock*, 590 U.S. at 683. The Supreme Court answered that question in the affirmative, concluding, in relevant part, that "[w]hen an employer fires an employee for being . . . transgender, it necessarily and intentionally discriminates against that individual in part because of sex." *Id.* at 665. "[P]roceed[ing] on the assumption that 'sex' . . . refer[s] only to biological distinctions between male and female," the Court explained that Title VII's "because of . . . sex" language plainly "incorporates the simple and traditional standard of but-for causation"—meaning, that the statute is violated whenever an employer "intentionally fires an individual employee based in part on sex." *Id.* at 655–56, 659 (citation omitted). The Court then concluded that firing an employee for being transgender violates Title VII as well, because "it is impossible to discriminate against a person for being . . . transgender" without also "discriminating against that individual based on sex." *Id.* at 660; *see also id.* at 660–61 ("[T]ransgender status [is] inextricably bound up with sex."). The Court

explained by way of illustration that if an employer fires a transgender woman for being transgender, that 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.* at 660. "[T]he individual employee's sex" thus "plays an unmistakable . . . role in the discharge decision." *Id.* And that "rel[iance] in part on an individual employee's sex," according to the Supreme Court, is precisely what Title VII prohibits. *Id.* at 659.

Bostock's reasoning applies with equal force to § 1557. The statute prohibits, in relevant part, "discrimination under[] any health program or activity" "on the ground prohibited under . . . [T]itle IX," 42 U.S.C. § 18116(a), which, in turn, prohibits discrimination "on the basis of sex," 20 U.S.C. § 1681. Thus, because "discrimination based on . . . transgender status necessarily entails discrimination based on sex," *Bostock*, 590 U.S. at 669, § 1557's prohibition on sex-based discrimination necessarily prohibits discrimination on the basis of gender identity as well. The latter form of discrimination, in short, "cannot happen without" the former. *Id.* Indeed, just like firing an employee for being transgender necessarily involves taking that employee's sex into account, a surgeon who refuses to perform a medically necessary procedure on a transgender man (*i.e.*, an individual who was assigned female at birth but has a male gender identity) that the surgeon would otherwise perform on a cisgender woman (*i.e.*, an individual who was assigned female at birth and has a female gender identity) "unmistakabl[y] and impermissibl[y]" denies an essential medical service based in part on a patient's sex. *Id.* at 660. The Rule's prohibition of gender identity discrimination is therefore wholly consistent with § 1557's nondiscrimination provision.

Plaintiffs assert that *Bostock* does not apply because it specifically addressed Title VII while § 1557 references Title IX, and they accuse the Rule of "conflating" the former statute's "because of . . . sex" language with the latter's "on the basis of sex" language. ECF No. 21 at 12–13. But Plaintiffs offer no explanation for how "because of . . . sex" is materially different from "on the basis of sex"—particularly when the Supreme Court in *Bostock* used those terms interchangeably. *See* 590 U.S. at 654, 662, 664, 666. Nor do they explain why *Bostock*'s textual

analysis of Title VII's nondiscrimination provision cannot inform the meaning of materially identical language used in another nondiscrimination statute like § 1557. Indeed, federal courts—including the Fifth Circuit—have routinely looked to interpretations of Title VII to inform Title IX. *See, e.g.*, *Franklin v. Gwinnett Cnty. Pub. Schs.*, 503 U.S. 60, 75 (1992) (explaining that "[w]hen a supervisor . . . harasses a subordinate *because of* the subordinate's sex," the supervisor "'discriminate[s]' *on the basis of sex*" under Title IX (emphases added) (citation omitted)); *Cardner v. Continental Airlines, Inc.*, 636 F.3d 172, 180 (5th Cir. 2011) ("[T]his court has interpreted Title IX as being intended to prohibit a wide spectrum of discrimination . . . in the same manner as Title VII."). And, relevant here, several other courts of appeals have expressly concluded that *Bostock*'s reasoning applies to § 1557. *See, e.g.*, *Kadel v. Folwell*, 100 F.4th 122, 163–64 (4th Cir. 2024); *Doe v. Snyder*, 28 F.4th 103, 113–14 (9th Cir. 2022).

Plaintiffs next attempt to narrow *Bostock*'s application by suggesting that "sex" in Title IX, and thus § 1557, refers only to "biological" sex. ECF No. 21 at 11. But in *Bostock*, the Court made clear that the parties' dueling definitions of "sex" were irrelevant to the discrimination analysis. *Bostock*, 590 U.S. at 655 ("[N]othing in our approach to these cases turns on the outcome of the parties' debate" over the definition of "'sex.'"). Here too, nothing in the Rule turns on whether "sex" "refer[s] only to biological distinctions between male and female." *Id.* Rather, as HHS explained in the preamble, the agency "determined it is not necessary to define 'sex' in this rule[.]" 89 Fed. Reg. at 37,575. Thus, even if "sex" refers to biological distinctions between males and females, HHS's inclusion of "'gender identity' in § 92.101(a)(2) is nonetheless consistent with the Supreme Court's reasoning in *Bostock*." *Id*. at 37,574.[6]

Plaintiffs' reliance on *Adams v. School Board of St. John's County*, 57 F.4th 791 (11th Cir. 2022), does not compel a different result. *See* ECF No. 21 at 11–12. Not only is that decision not binding on this Court, but nothing in *Adams* provides a reason to enjoin HHS from enforcing

[6] The Supreme Court also recognized that in 1964, shortly before Title IX's enactment, the term "sex" "bore a broader scope, capturing more than anatomy and reaching at least some norms concerning gender identity and sexual orientation." *Bostock*, 590 U.S. at 655.

§ 92.101(a)(2)(iv) or any other provision of the Rule that touches on gender identity. 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. *Adams*, 57 F.4th at 815. In so holding, the court relied on a safe-harbor provision of Title IX that is not incorporated in § 1557, *id.* at 791, and made clear that the *Adams* policy did "not depend in any way on how students act or identify[,]" *id.* at 809—unlike the sweeping set of policies that may be permitted under § 1557 if HHS's enforcement of § 92.101(a)(2)(iv) is enjoined in all applications. Nor did *Adams* 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). Indeed, the court went on to explain 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). That statement, however, is exactly what the Rule provides. *See* 45 C.F.R. § 92.101(a)(2)(iv) (explaining that discrimination on the basis of sex includes discrimination on the basis of gender identity).

Plaintiffs' attempt to narrow *Bostock*'s application through the non-incorporated provisions of Title IX that permit sex-based distinctions in the context of sports teams or living facilities fare no better. *See* ECF No. 21 at 11–13. That argument misreads the plain text of § 1557, which expressly incorporates only the "ground prohibited" and "enforcement mechanisms provided for" under Title IX. 42 U.S.C. § 18116(a). It did not purport, as Plaintiffs contend, to incorporate all other provisions within Title IX. *Cf. Schmitt v. Kaiser Found. Health Plan of Wash.*, 965 F.3d 945, 953 (9th Cir. 2020) ("Section 1557(a) incorporates only the prohibited 'ground[s]' and '[t]he enforcement mechanisms provided for and available under'" Title IX). But even if the Court were to credit Plaintiffs' strained reading of § 1557 to incorporate, for example, § 1686 of Title IX (separate living facilities for different sexes), ECF No. 21 at 13—nothing in the Rule would preclude courts from applying § 1686 in any particular case. In fact, the preamble clarifies that the Rule does not forbid what § 1686 permits. *See* 89 Fed. Reg. at 37,593 (The Rule does not prohibit "a covered entity from operating sex separated programs and facilities[.]").

B. 45 C.F.R. § 92.207—Which Governs Coverage of Gender-Affirming Care—Is Consistent with § 1557.

In addition to their generalized arguments that *Bostock* does not apply, Plaintiffs argue that the Rule "requires insurers," such as Plaintiffs, to cover gender-affirming care. *See* ECF No. 21 at 8, 15–16. Plaintiffs' fundamental error lies in viewing these provisions as imposing specific demands to cover particular health services, like puberty blockers or gender-affirming surgeries—when in fact, § 92.207 only requires insurers to act in a nondiscriminatory manner. *See* 89 Fed. Reg. at 37,607 ("We [] decline to state that any denial of [coverage of] gender-affirming care will necessarily be discriminatory regardless of context or rationale."). Section 92.207(c) of the Rule makes clear that "[n]othing in [Section 92.207] requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting" the coverage at issue. 45 C.F.R. § 92.207(c). That is because, "[w]hen OCR investigates claims of discrimination," 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. at 37,597. *See also id.* at 37,524 (explaining that § 92.207(c) operates the same as § 92.206(c)). Thus, § 92.207 does not determine whether any specific State's Medicaid coverage policy violates § 1557. The Rule merely sets up a framework that allows the agency to determine, on a case-by-case basis, whether discrimination has occurred—consistent with decades of precedent. *See, e.g.*, *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802–03 (1973) (establishing a similar framework for analyzing Title VII discrimination claims).

Indeed, Plaintiffs' hypothetical on this score illustrates the impropriety of their request for injunctive relief. They claim that insurers may refuse to cover gender-affirming surgeries due to the "high costs of these procedures." ECF No. 21 at 15. But so long as Plaintiffs, as insurance issuers, can demonstrate a "legitimate, nondiscriminatory reason" for a denial of coverage, 45

C.F.R. § 92.207(c)—such as, "high costs" for "top-of-the-line" procedures that they would not otherwise cover for other patients, ECF No. 21 at 15—they would not be in violation of § 1557.[7]

C. 45 C.F.R. § 92.206—Which Governs Equal Access to Care—Is Consistent with § 1557.

Plaintiffs' challenge to § 92.206 of the Rule—relating to equal access to care—fares no better. That claim fails on its merits because (1) nothing in the Rule imposes a national standard of care, (2) § 92.206(c) does not require a "similarly situated" analysis for determining discrimination, and (3) Plaintiffs have failed to establish that § 92.206(b)(3) is contrary to § 1557.

1. The Rule Does Not Impose a National Standard of Care.

Plaintiffs' first error lies in their assertion that the Rule "imposes a national standard of care." ECF No. 21 at 17–18. The Rule does no such thing. Contrary to Plaintiffs' repeated invocations of the notice of proposed rulemaking, nothing in the final rule mentions or even relies on World Professional Association for Transgender Health ("WPATH") Standards of Care. Nor does the Rule even attempt to impose a specific standard of care. Instead, the preamble makes clear that the Rule "does not (and cannot) require a specific standard of care or course of treatment for any individual, minor or adult." 89 Fed. Reg. at 37,596. That is because the Rule does not purport to override a clinician's medical judgment as to whether any healthcare service is medically necessary or appropriate for any particular patient. *See id.* at 37,595–96 ("[T]here 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."). Thus, so long as the refusal of care is not based on animus or bias, or a pretext for discrimination, the Rule cannot displace the independent judgment of providers as to the medical necessity of any specific gender-affirming care. 45 C.F.R. § 92.206(c).

Indeed, the revisions to Rule illustrate this point. Before the agency finalized the Rule, § 92.206(c) initially read as follows: "however, a provider's belief that gender transition or other

[7] Plaintiffs improperly rely on a dissenting opinion in *Lange v. Houston County*, 101 F.4th 793 (11th Cir. 2024)—which is certainly not binding here—and in any event, ignore several circuit court decisions that have concluded otherwise. *See Kadel*, 100 F.4th at 164; *Snyder*, 28 F.4th at 114.

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 37,598. In response to comments received during the notice-and-comment process, HHS replaced that provision with the current text, which now reads as follows: "[a] covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination." 45 C.F.R. § 92.206(c); *see also* 89 Fed. Reg. at 37,597 ("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."). In sum, nothing in the Rule displaces the medical judgment of providers or imposes a national standard of care.[8]

2. The Rule Does Not Require Plaintiffs' "Similarly Situated" Analysis.

Plaintiffs' request for a preliminary injunction rests in part on a hypothetical application of § 92.206 to the States' varying laws that "forbid[] hormonal treatments and surgeries for the purpose of gender transition." ECF No. 21 at 14. They argue that state laws forbidding *providers* from offering gender-affirming care cannot be discriminatory under § 1557, because removing breast cancer tissue from a cisgender woman is different in kind from removing breast tissue from a transgender man for the purposes of gender-affirming care. *See* ECF No. 21 at 14–15. In other words, Plaintiffs presume that their laws prohibiting gender-affirming care cannot be discriminatory because those two hypothetical patients are allegedly not "similarly situated." *Id.*

But § 92.206 does not require any such "similarly situated" analysis. Section 92.206 merely provides a framework that allows the agency to determine whether the specific denial of care was "based on unlawful animus or bias" or "pretext for discrimination." 45 C.F.R. § 92.206(c). *See also* 89 Fed. Reg. at 37,597 (explaining that "different methods of proof drawn from civil rights case law should be used in analyzing claims of discrimination"). The Rule simply does not prejudge the States' laws, as Plaintiffs suggest. Indeed, Plaintiffs' own example illustrates

[8] For the same reasons, Plaintiffs' claim that the Rule violates § 1554 of the ACA, 42 U.S.C. § 18114, because it "would require providers to cede their reasoned medical judgment" fails. ECF No. 21 at 19. Relatedly, Plaintiffs fail to explain how the Rule affects the "timely access to health care services" or "interferes with" doctor-patient "communications." *Id.*

this point. If a hypothetical provider refused to conduct a mastectomy on a transgender man but would otherwise do so for a cisgender woman, § 92.206(c) makes clear that the provider would not violate § 1557 if she demonstrates a "legitimate, nondiscriminatory reason for denying or limiting that service[.]" 45 C.F.R. § 92.206(c). In other words, whether that particular provider did in fact discriminate based on the patient's transgender status will depend on the provider's *reason* for denying treatment.

Plaintiffs' reliance on two out-of-circuit cases cannot save their flawed "not similarly situated" theory. *See* ECF No. 21 at 14 (citing *L. W. by & through Williams v. Skrmetti*, 83 F.4th 460 (6th Cir. 2023), *cert. granted sub nom. United States v. Skrmetti*, No. 23-477 (S. Ct. June 24, 2024) and *Eknes-Tucker v. Governor of Alabama*, 80 F.4th 1205 (11th Cir. 2023)). Not only are those cases not binding on this Court, but both decisions turned on the application of certain states' laws, and whether such applications violated the Equal Protection Clause based on evidence presented at a hearing on the merits. *See L. W.*, 83 F.4th at 480 (refusing to find an equal protection violation because the state laws "regulate[d] sex-transition treatments for all minors"); *Eknes-Tucker*, 80 F.4th at 1227 (explaining that the Alabama law "is best understood as a law that targets specific medical interventions for minors").[9] Those cases have no bearing on the question here, where the regulatory scheme seeks to understand the *reasons* why a particular individual was denied care. In the absence of any application of the Rule or enforcement action, Plaintiffs bring this case in the hopes that the Court will *presuppose* a provider's rationale for the denial of gender-affirming care. *See* ECF No. 21 at 16. But that is not the discrimination framework that the Rule prescribes.

[9] Even assuming that *Eknes-Tucker* is relevant here, it is difficult to see how the Rule runs afoul of that holding, as § 92.206(c) nearly mirrors the language there. *Compare Eknes-Tucker*, 80 F.4th at 1229–30 ("[T]he regulation of a course of treatment that only gender nonconforming individuals can undergo would not trigger heightened scrutiny *unless the regulation were a pretext for invidious discrimination against such individuals*." (emphasis added)) *with* 45 C.F.R. § 92.206(c) ("Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service . . . . A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination.").

3. 45 C.F.R. § 92.206(b)(3) Is Consistent with § 1557.

Plaintiffs likewise have not established that § 92.206(b)(3) is contrary to § 1557. They claim that § 92.206(b)(3) unlawfully "prohibits hospitals from maintaining sex-separated intimate space[s]" and "preferenc[es] [the] alleged harm to transgender patients over" cisgender patients that may share a hospital room with a transgender person who shares their gender identity. ECF No. 21 at 17 (citations omitted). But nothing in the Rule "prohibits a covered entity from operating sex separated programs and facilities." 89 Fed. Reg. at 37,593. The Rule instead 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[.]" 45 C.F.R. § 92.206(b)(3). And, as HHS clarified, the Rule explains that the covered entity should respect the dignity of, for example, a nonbinary transgender patient by "work[ing] with that individual" to determine "where they can benefit the most from the health program or activity" without experiencing, for example, "threats to their safety[.]" 89 Fed. Reg. at 37,593. Nor does the plain language of § 92.206(b)(3), as in *Bostock*, purport to resolve § 1557's application to specific claims involving "bathrooms, locker rooms, or anything else of the kind." 590 U.S. at 644. In the end, Plaintiffs never explain how intentionally disregarding any potential safety concerns of a transgender patient while simultaneously attending to any potential safety concerns of a cisgender patient who shares the same gender identity is consistent with the language of § 1557, or why such safety concerns cannot be addressed in the same manner any other safety concern among patients would be addressed. *See Bostock*, 590 U.S. at 660; 89 Fed. Reg. at 37,593 (explaining that "a provider generally may accommodate a patient's preferences about roommate assignments").

Nor do Plaintiffs explain how the de minimis harm standard set forth in the Rule is contrary to law. Rather, it is well-established that the concept of discrimination includes an element of injury or more than de minimis harm. *See, e.g.*, *Muldrow v. City of St. Louis*, 144 S. Ct. 967, 974 (2024) (Prohibitions on discrimination require not just different treatment, but different treatment that is "disadvantageous."); *Burlington N. & Santa Fe Ry. Co.*, 548 U.S. 53, 59 (2006) ("No one

doubts that the term 'discriminate against' refers to distinctions or differences in treatment that injure protected individuals."); *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 81 (1998) (Title VII does not reach nonharmful "differences in the ways men and women routinely interact with" each other.).

D. The Rule Does Not Violate the Social Security Act.

Plaintiffs have 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, violates the Social Security Act. Plaintiffs appear 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.[10] Plaintiffs are 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 HHS approval, States administer their plans, and the federal government provides funding to help defray costs.[11]

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[10] As explained above, *see supra* at 6 n.5, Plaintiffs appear to seek a stay of all Medicaid and CHIP regulations that touch on gender identity, *see* ECF No. 20 at 2, but fail to discuss or explain in their brief how the specific requirements of each of those regulations is somehow beyond the agency's authority. At best, Plaintiffs' brief can be read to refer, in part, to what § 438.3(d)(4) requires. *See* ECF No. 21 at 19 (citing 89 Fed. Reg. at 37, 691).

[11] CMS discussed the authorities for regulating managed care programs in detail in a final rule promulgated in 2016. *See* 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).

As relevant here, § 438.3(d)(4) does not impose improper "disparate-impact requirements" on covered entities, as Plaintiffs contend. ECF No. 21 at 20. Rather, the Rule 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.SC. § 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. In response, Plaintiffs largely ignore HHS's authority to regulate and approve state plans and conspicuously avoid any reference to HHS's authority to ensure that such plans operate in "the best interests" of patients under § 1396a(a)(19). *See* ECF No. 21 at 19–20. Nor do Plaintiffs cite any authority to support their argument that HHS lacked authority to impose the particular requirements in § 438.3(d)(4) as a condition of federal funding.

Moreover, to the extent Plaintiffs' argument suggests that HHS lacked authority to promulgate rules prohibiting policies or practices that have discriminatory effects, ECF No. 21 at 20, that 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, none of the Plaintiffs has ever 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, Plaintiffs' 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 a failure to comply with § 438.3(d)(4), Plaintiffs 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, 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. §§ 430.35–430.40; 42 U.S.C. § 1397gg(e)(2); 42 C.F.R. § 457.204–.208. In all events, Congress's "intent to allocate initial review of [Plaintiffs'] claims to CMS is 'fairly discernable in [42 U.S.C. § 1316],'" and therefore the Court lacks subject-matter jurisdiction over the claim. *Florida v. CMS*, 2024 WL 2803298, at *6 (M.D. Fla. May 31, 2024).

E. The Rule Does Not Violate the Spending Clause.

Plaintiffs rely on *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1 (1981), and its progeny, to suggest that § 1557 does not unambiguously condition federal funds on compliance with the Rule. *See* ECF No. 21 at 20–21. But both *Pennhurst* and the Fifth Circuit's decision in *Texas Education Agency v. United States Department of Education*, 992 F.3d 350 (5th Cir. 2021), are distinguishable, as those cases turned on ascertaining the scope of liability for private suits, typically involving claims of damages. *See, e.g.*, *Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 218–20 (2022) (explaining that "the scope of available remedies in actions brought to enforce Spending Clause statutes" is limited to suits of "money damages" (citations omitted)); *Texas Educ. Agency*, 992 F.3d at 356 (explaining that a statute's whistleblower program "lacks the clarity required for a knowing waiver" of sovereign immunity and suits for damages brought by private parties).[12]

But even assuming that *Pennhurst* requires a clear statement, there is no Spending Clause problem here, because "Congress has broad power under the Spending Clause of the Constitution to set the terms on which it disburses federal funds"—which includes the authority to "prohibit[] recipients of federal financial assistance from discrimination based on certain protected characteristics," *Cummings*, 596 U.S. at 216. Such conditions on federal funds are lawful so long

[12] The Supreme Court has also 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). Put differently, a statute imposing a "generalized duty" on a funding recipient cannot be 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, 281 (2002) (quoting *Suter*, 503 U.S. at 363).

as "a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds." *Nat'l Fed'n of Indep. Business v. Sebelius*, 567 U.S. 519, 578 (2012) ("*NFIB*"). Here, Plaintiffs have continued to accept funds from HHS since the ACA's enactment, all while knowing that § 1557 violations—including the statute's prohibition on sex-based discrimination—could potentially result in some of those funds being withheld. *See* 42 U.S.C. § 18116(a) (expressly incorporating Title IX's "enforcement mechanisms"); 20 U.S.C. § 1682. The Rule, which merely clarifies § 1557's scope in light of *Bostock*, and aligns CMS's regulations on nondiscrimination to that development, does nothing to change the essential terms of that choice. *See Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004) ("[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."); *see also Bostock*, 590 U.S. at 680 (explaining that the Court's holding that Title VII prohibits firing employees on the basis of transgender status "has never hidden in a mousehole; it has been standing before us all along").

Plaintiffs cite *NFIB*, the lone Supreme Court case to have found a condition on federal funds to be unconstitutionally coercive, as support for their claim that the Rule impermissibly requires Plaintiffs to provide gender-affirming care in violation of state laws. ECF No. 21 at 21. Yet the Rule does nothing of the sort. Nowhere does it require covered entities to provide specific types of care; it simply prohibits care and coverage decisions that are "based on unlawful animus or bias, or constitute a pretext for discrimination." 45 C.F.R. § 92.206(c); *id.* § 92.207(c). Nor does the Rule impose new conditions; indeed, before the Rule, § 1557 prohibited recipients of federal funds from discriminating on the basis of sex—which, as *Bostock* explained, necessarily encompasses discrimination on the basis of transgender status, 590 U.S. at 660–61, 669—and will continue to do so after the Rule becomes effective.[13] Thus, because § 1557's nondiscrimination

[13] To the extent Plaintiffs' "constitutional" claim alleging coercive funding conditions hinges on their argument that the Rule unlawfully applies *Bostock* to § 1557, such a claim is indistinguishable from their statutory APA claim and should therefore be rejected. *See Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 205 (2009) ("[I]t is a well-established principle . . . that normally the Court will not decide a constitutional question if there is some other ground upon which to dispose of the case.").

requirements, including its prohibition on gender identity discrimination, are nothing like the dramatic and atypical conditions at issue in *NFIB*, *see* 567 U.S. at 579, 584 (noting that the conditions in question were "far from the typical case" and were designed to "dramatically" transform the Medicaid program), that one-of-a-kind case is inapplicable here.

F. Plaintiffs Have Not Established That the Rule Is Arbitrary and Capricious.

Plaintiffs claim that the challenged provisions are arbitrary and capricious because the Rule purportedly mandates that medical professionals embrace WPATH guidelines and prevents healthcare professionals from using their reasonable medical judgment, which Plaintiffs allege could lead to tort liability. *See* ECF No. 21 at 22. But those arguments rest on fundamental misapprehensions about the Rule. As explained above, *supra* at 12–13, the Rule does not impose a national standard of care, let alone the standard of care proffered by WPATH. Nor does it attempt to supplant the medical judgment of healthcare professionals. Put simply, nothing that Plaintiffs point to establishes that HHS has engaged in the type of arbitrary and capricious decision-making that the APA protects against. *Cf. Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (An "[a]gency rule would be arbitrary or capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

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

Plaintiffs here seek to enjoin HHS from enforcing the gender identity discrimination provisions of the Rule as applied to all plausible factual scenarios they might encompass. But Plaintiffs' "hypothetical examples are not the stuff of ripe APA challenges." *Ass'n of Priv. Sector Colls. & 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 also Nat'l Ass'n of Regul. Util. Comm'rs v. FERC*, 964 F.3d 1177, 1185 (D.C. Cir. 2020). Indeed, any request for an order enjoining HHS from enforcing the Rule to preclude

particular policies would be inconsistent with the APA. That is because judicial review under 5 U.S.C. § 702, *see* Compl. ¶ 38, requires Plaintiffs to "direct [their] attack against some particular 'agency action[,]'" *Lujan v. Nat'l Wildlife Fed'n*, 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). In other words, 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. Put simply, 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); *Nat'l Wildlife Fed'n v. EPA*, 945 F. Supp. 2d 39, 44–47 (D.D.C. 2013).[14]

II. Plaintiffs Have Not Established Imminent Irreparable Harm.

Even if Plaintiffs could demonstrate likelihood of success on the merits, Plaintiffs cannot independently satisfy their "heavy burden of clearly establishing to the Court irreparable harm." *Watchguard Techs., Inc. v. Valentine*, 433 F. Supp. 2d 792, 794 (N.D. Tex. 2006). Whether for a preliminary injunction, *Google, Inc. v. Hood*, 822 F.3d 212, 227 (5th Cir. 2016), or Article III standing, injunctive relief requires a future "injury [that] proceed[s] with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all," *Lujan*, 504 U.S. at 564 n.2. Mere fear of future injury—even if "not fanciful, irrational, or clearly unreasonable"—is insufficient. *Clapper v. Amnesty Int'l 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 a [code's] actual or threatened"—not merely feared—"*enforcement*,

[14] Pre-enforcement review of any application of the Rule would also be inconsistent with § 1557 itself. Section 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. 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.

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 irremediable in damages, *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980).

Here, Plaintiffs cannot satisfy the requisite "heavy burden" of irreparable harm because they (1) face no credible threat of imminent enforcement under the Rule, let alone injury in fact, (2) have failed to establish that their purported financial losses are imminent and nonspeculative, and (3) lack standing to invoke the purported interests of their citizens.

A. Plaintiffs Face No Credible Threat of Imminent Enforcement Under the Rule.

Plaintiffs' purported harm—that the Rule would prevent States from effectuating their policy choices to prohibit or provide coverage for gender-affirming care, ECF No. 21 at 23—stems from events that have not happened, nor can be considered imminent. To put it concretely, Plaintiffs have "not been enjoined from establishing, enforcing, or effectuating any of [their] 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). *See also Google, Inc.*, 822 F.3d at 227 (finding no irreparable harm because "adjudicating whether federal law would allow an enforcement action" against Plaintiffs would "require [the court] to determine the legality of" Plaintiffs' actions "in hypothetical situations"). Nor can they allege that such purported harm is imminent. That is because the plain text of the Rule does not prejudge whether any particular State's policy is discriminatory. Rather, it provides a framework through which HHS can make a determination as to whether a covered entity has engaged in discrimination. And even under that framework, the covered entity is given the opportunity to demonstrate a legitimate, nondiscriminatory reason for a denial of care or coverage. Put simply, the fact that the Rule is merely on the books cannot itself be irreparable injury; rather, the injury must derive from "actual or threatened enforcement[.]" *Texas*, 593 U.S. at 670.[15]

[15] Plaintiffs' reliance on *Valentine v. Colloier*, 956 F.3d 797 (5th Cir. 2020), is similarly misplaced. *See* ECF No. 21 at 23. In *Valentine*, the Fifth Circuit granted a stay pending appeal of a preliminary injunction issued by the district court against state prison officials. In reaching that limited holding, the Fifth Circuit

Indeed, the fact that Plaintiffs do not actually face any irreparable, let alone imminent, harm is underscored by the very arguments they make with respect to the merits of their claim. Put differently, in order to establish irreparable harm, Plaintiffs would have to demonstrate, pursuant to the Rule, that the varying state laws are "based on unlawful animus or bias, or constitute a pretext for discrimination"—and thus violate §§ 92.206(c), 92.207(c). But while Plaintiffs, on the one hand, argue that their prohibitions on gender-affirming care are noncompliant with the Rule, ECF No. 21 at 23 (citing "conflicting" policies), they argue, on the other hand, that they have legitimate, nondiscriminatory reason for those polices, *id.* at 14–16 (arguing no intentional discrimination by the States). Plaintiffs cannot have it both ways.

In fact, Plaintiffs' challenge—insofar as they seek to enjoin the healthcare provider provisions of the Rule (45 C.F.R. § 92.206)—faces even greater hurdles for two distinct and independent reasons. *First*, Plaintiffs lack Article III standing to make such a challenge. Section 92.206's provisions apply to covered entities that "provid[e] access to health programs and activities," *i.e.*, healthcare providers, like hospitals, physical and mental healthcare providers, and pharmacies. *See* 45 C.F.R. § 92.206(a)–(b). Yet none of the Plaintiff-States (with the exception of Tennessee) allege that they actually provide any direct healthcare services to patients. *Compare* Compl. ¶¶ 23–31 (allegations for non-Tennessee Plaintiff-States) *with id.* ¶ 22 ("Tennessee also has medical facilities that provide hormonal treatment for minors for various physical conditions[.]"). In other words, Plaintiffs (with the exception of Tennessee) have not even alleged, let alone established, that HHS could bring any enforcement action against them pursuant to § 92.206. *See Lujan*, 504 U.S. at 559–62 (explaining that a plaintiff must establish that it has

recognized that the district court's injunction improperly imposed a series of demands on state officials, despite the fact that the administration of "prisons" lies almost exclusively with the State. *Valentine*, 956 F.3d at 803. The Fifth Circuit did not face the circumstances here, where Plaintiffs seek a sweeping injunction based on their perceived, not actual, claim that the Rule prejudges certain state laws.

suffered an injury in fact that is both (a) concrete and particularized and (b) actual or imminent, as opposed to conjectural or hypothetical).[16]

Second, even assuming that Plaintiffs operate the types of hospitals or clinics that may be covered by 45 C.F.R. § 92.206, any claim of imminent irreparable harm to those entities is foreclosed by the district court decision in *Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022), which is now pending on appeal, No. 23-10078 (5th Cir.).[17] In *Neese*, a putative class of healthcare providers challenged, under the APA, an HHS 2021 Notice of Interpretation, which notified the public that HHS "will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity." *See* Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984 (May 25, 2021). In November 2022, the *Neese* court certified the following class under Federal Rule of Civil Procedure 23(b)(2): "All health-care providers subject to Section 1557 of the Affordable Care Act." Ex. 1, Order Certifying Class Action, *Neese v. Becerra*, 21-cv-163, ECF No. 70 (N.D. Tex. Nov. 22, 2022). It then entered final judgment, providing the following declaratory judgment:

- Plaintiffs and members of the certified class need not comply with the interpretation of "sex" discrimination adopted by Defendant Becerra in his Notification of Interpretation and Enforcement of May 10, 2021; and
- Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of "sex" discrimination that

[16] To the extent the remaining Plaintiffs allege they have established third-party standing, that too fails. Plaintiffs have not established "a close relation to the third party" that is governed by § 92.206, *i.e.*, healthcare providers. Nor can they establish "some hindrance to the third party's ability to protect his or her own interests," *Powers v. Ohio*, 499 U.S. 400, 411 (1991), as evidenced by the complaint filed by McComb Children's Clinic, *see McComb Children's Clinic, Ltd. v. Becerra, et al.*, No. 5:24-cv-48-KS-LGI (S.D. Miss. May 13, 2024).

[17] 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 Mann Mfg. Inc. v. Hortex, Inc.*, 439 F.2d 403, 408 (5th Cir. 1971) (The issue is whether there is a "likelihood of substantial overlap between the two suits."); *accord Cadle Co. v. Whataburger of Alice, Inc.*, 174 F.3d 599, 606 (5th Cir. 1999) (second-filed court should determine only whether "the issues might substantially overlap").

> the Supreme Court of the United States adopted in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), is inapplicable to the prohibitions on "sex" discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA.

Ex. 2, Final Judgment, *Neese v. Becerra*, 21-cv-163, ECF No. 71 (N.D. Tex. Nov. 22, 2022). In sum, the *Neese* declaratory judgment undermines Plaintiffs' claims of standing and irreparable harm, because the Rule states that HHS "is not applying the challenged interpretation"—that is, that discrimination on the basis of sex in § 1557 includes discrimination on the basis of gender identity—"to members of the *Neese* class pending the appeal." 89 Fed. Reg. at 37,574 n.118. Thus, because the *Neese* class includes all healthcare providers subject to § 1557, any potential future application of the Rule's interpretation that sex discrimination includes gender identity discrimination to a healthcare provider could occur only if the *Neese* judgment is overturned on appeal. Any such potential future injury is not sufficiently "imminent," *Clapper*, 568 U.S. at 409, to establish standing or imminent irreparable harm. *See also FDA v. All. for Hippocratic Med.*, 602 U.S. ---, 2024 WL 2964140, at *6 (U.S. June 13, 2024) ("the injury must have already occurred or be likely to occur soon"); *Chacon v. Granata*, 515 F.2d 922, 925 (5th Cir. 1975) ("An injunction is appropriate only if the anticipated injury is imminent and irreparable.").

B. Plaintiffs' Purported Financial Harms Are Neither Imminent Nor Nonspeculative.

Plaintiffs' claims of purported loss of federal funds, ECF No. 21 at 23, fare no better, as those claims are both speculative and not imminent. Even assuming that OCR might, at some point, investigate whether Plaintiffs' health programs fail to comply with the Rule, the agency—before terminating federal funding—must follow an extensive (and often lengthy) process, which includes (1) a notice of a potential violation, (2) mandatory attempts to achieve voluntary compliance, (3) formal adjudication and administrative hearings, (4) notice to House and Senate committees, and (4) the opportunity for judicial review by an Article III judge. *See, e.g.*, 42 U.S.C. § 18116(a) (Section 1557 incorporates the "enforcement mechanisms provided for and available under" the referenced civil rights statutes, including Title IX.); 20 U.S.C. §§ 1682–83 (Title IX).

In other words, the purported termination of federal funds—which has typically taken years[18]—would be practically impossible "before a decision on the merits can be rendered." *Winter*, 555 U.S. at 22 (citation omitted). *See also Holland America Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985) (stating that "[s]peculative injury is not sufficient" to establish "a clear showing of irreparable harm"); *Flowers Indus. v. FTC*, 849 F.2d 551, 552–53 (11th Cir. 1988) (no imminent irreparable harm when agency lacked power to immediately effectuate harm).[19]

Indeed, if Plaintiffs were to stand on their good-faith representations about the bases for their state laws (or even on a good-faith belief that a provision of the Rule as applied to their state laws would be invalid), they cannot establish that their "good-faith conduct violating a grant condition would trigger an immediate funding cut-off, much less [a] retroactive penalty[.]" *Nat'l Fam. Plan. & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 829 (D.C. Cir. 2006). To the contrary, in § 1557, Congress sought "to obtain compliance and eliminate discrimination," not initiate "punitive measures[.]" 110 Cong. Rec. S7059 (daily ed. Apr. 7, 1964). Thus, compliance at any point in the putative enforcement process would preclude HHS from terminating any federal funding. *See* 45 C.F.R. § 80.7(d) (no funding loss proceedings if compliance can be achieved voluntarily after OCR investigation); *id.* § 80.10(f) (permitting recipient to "correct its noncompliance" to preclude future funding loss after decision by hearing examiner but before decision takes effect); *id.* § 80.10(g) (recipient "shall be restored to full eligibility" as soon as "it brings itself into compliance"). In other words, the States will not lose federal funding if at first they refuse to comply but then decide later that they will. Were that not enough, "Plaintiffs would

[18] *See, e.g.*, *Civ. Remedies Division The General Counsel v. San Agustin*, DAB No. CR2580, 2012 WL 3553101 (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.*, 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. 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).

[19] As discussed above, *supra* at 17–18, process protections also apply if CMS disallows or withholds federal Medicaid or CHIP funding.

be able to raise the same claims they now raise" "[a]t each point in any putative enforcement process." *Am. Coll. Of Pediatricians v. Becerra*, Case No. 1:21-cv-195, 2022 WL 17084365, at *15. Taken together, Plaintiffs cannot plausibly establish that they face any imminent irreparable harm from a termination of federal funds.

Nor can Plaintiffs bootstrap their hypothetical claims of "nonrecoverable compliance costs" to these already speculative claims of not-yet terminated federal funds. ECF No. 21 at 23. Without much context, Plaintiffs claim that they will suffer irreparable harm because they are likely to incur "nonrecoverable compliance costs." *Id.* But nowhere in their declarations do Plaintiffs actually allege that they have taken steps to make "changes" to their "administrative rules" in response to the Rule. Indeed, upon closer inspection of their declarations, those purported "compliance costs" are predicated on the wholly speculative theory that Plaintiffs actually face the imminent prospect of terminated federal funds. *See, e.g.*, ECF No. 20, Decl. of Stephen Smith ("Smith Decl.") ¶¶ 13–14 (stating that TennCare would need to "make changes to its administrative rules" on the *assumption* that "Tennessee risks losing significant funding"). Such speculative harm upon speculative harm lies in stark contrast to the Fifth Circuit case on which Plaintiffs rely, where the FDA specifically denied the petitioner's request to market a product, and thus there was no dispute that the petitioner would "incur substantial financial losses in annual revenue[.]" *R.J. Reynolds Vapor Co. v. Food & Drug Admin.*, 65 F.4th 182, 187–88, 194 (5th Cir. 2023).[20]

Plaintiffs' remaining claims of increased health-insurer costs for "medically necessary" procedures are similarly specious. *See* ECF No. 21 at 24. As explained above, the Rule does not endorse or impose a specific standard of care. Nor does the Rule require insurers to cover the alleged "non-exhaustive suite" of surgeries identified by WPATH. *See id.* So long as Plaintiffs,

[20] Nor do Plaintiffs demonstrate that such costs are traceable to the parts of the Rule they actually challenge. *Cf. California*, 593 U.S. at 678 (finding no standing where certain "additional costs" were imposed by statutory provisions other than the one the plaintiffs were challenging). For instance, even if Plaintiffs succeed on their claim that § 1557 does not prohibit discrimination on the basis of gender identity, they would still be obligated to implement written policies addressing other forms of discrimination and to provide training on those policies. *See* 45 C.F.R. §§ 92.8–.9.

as covered insurers, have a legitimate, nondiscriminatory reason for coverage denials, there is no § 1557 violation.

C. Plaintiffs Cannot Invoke Speculative Harms on Behalf of Third-Party Citizens.

As a last resort, Plaintiffs claim that they will suffer irreparable harm because the Rule will subject patients that reside within the Plaintiff-States to a "gender-transition protocol" with "irreversible side effects." ECF No. 21 at 24. But Plaintiffs cannot invoke the health and welfare of their citizens 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). In any event, the Rule does not, as Plaintiffs contend, subject individuals to a "gender-transition protocol." The Rule merely provides that covered entities may not deny care or coverage of gender-affirming care in a discriminatory manner. And nothing in the Rule purports to supplant the medical judgment of providers when it comes to determining what constitutes appropriate care for patients. *See supra* at 12–13.

III. The Equities and Public Interest Weigh Against Plaintiffs' Request for a Preliminary Injunction.

The balance of the equities and public interest plainly weigh against the relief Plaintiffs seek. Plaintiffs have not made any showing of any imminent, irreparable harm that would warrant such 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 United States v. Hayes Int'l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969). And 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, while inflicting, at the same time, the "irreparable harm of denying the public interest in the enforcement of its laws." *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 413 (5th Cir. 2013).

IV. Any Relief Should Be Limited to the Parties and the Provisions of the Rule Actually Challenged by Plaintiffs.

For the reasons explained above, no declaratory or equitable relief is warranted here. But in the event the Court were inclined to award any relief, such relief should be no broader than necessary to remedy any demonstrated harms Plaintiffs—insofar as they themselves qualify as covered entities—will suffer in this case. *Cf. Brackeen*, 599 U.S. at 95 (A "State does not have standing as parens patriae to bring an action against the Federal Government" (citation omitted)). "A plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 585 U.S. 48, 73 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 764 (5th Cir. 2018) (citation omitted).

Consistent with these principles, then, any preliminary relief here should be limited to Plaintiffs alone. The Fifth Circuit recently counseled that "judicial restraint" is warranted when crafting injunctive relief, and district courts should consider "whether one district court should make a binding judgment for the entire country." *Louisiana v. Becerra*, 20 F.4th 260, 263 (5th Cir. 2021). Since then, three Justices of the Supreme Court concluded that a "district court's universal injunction defied . . . foundational principles" that "a federal court may not issue an equitable remedy 'more burdensome . . . than necessary to [redress]' the plaintiff's injuries. *Labrador v. Poe ex rel. Poe*, 144 S. Ct. 921, 923 (2024) (Gorsuch, J., joined by Thomas, J. and Alito, J., concurring in the grant of the stay) (citation omitted). *See also Braidwood Mgmt., Inc. v. Becerra*, __ F.4th __, No. 23-10326, 2024 WL 3079340, at *15 (5th Cir. June 21, 2024) ("The parties recognize that [universal] injunctions are not 'required or even the norm,' and several [J]ustices on the Supreme Court have viewed them with conspicuous skepticism.").

Plaintiffs' invocation of § 705 of the APA does not change the inadvisability of a remedy that extends to non-parties. That section provides that "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. In limiting such

relief "to the extent necessary to prevent irreparable injury," 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. Indeed, the House Report for the APA indicates that relief under § 705 should "normally, if not always, be limited to the parties complainant." Administrative Procedure Act, S. Doc. No. 79–248, at 277 (1946).

In addition to being limited to the parties, any relief should be limited to the parts of the Rule that Plaintiffs "actually challenge[]" and that the Court determines are likely unlawful. *Career Colleges*, 98 F.4th at 255. Here, Plaintiffs' brief in support of their motion only meaningfully challenges the Rule's interpretation of § 1557's prohibition on sex discrimination to include discrimination on the basis of gender identity. *See* 45 C.F.R. § 92.101(a)(2)(iv). And Plaintiffs otherwise fail to explain why the Court should stay or enjoin the remaining provisions of the Rule that apply "'sex' discrimination" to encompass "gender identity." *Cf.* ECF No. 20 at 2 (asking the Court for declaratory relief and to stay enforcement of "42 C.F.R. §§ 438.3, 438.206, 440.262, 460.98, 460.112; 45 C.F.R. §§ 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206-211, 92.301, 92.303, 92.304; and any other provision of the 2024 Rule applied with respect to 'sex' discrimination that encompasses gender identity"). In light of that failure, and the Rule's severability provision, 45 C.F.R. § 92.2(c), any relief provided by the Court, at most, should be limited to § 92.101(a)(2)(iv) itself, "while leaving the remainder" of the Rule "intact," *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328–29 (2006).

CONCLUSION

Accordingly, Plaintiffs' motion for a delay of effective date and for preliminary injunction of the Rule should be denied.

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Respectfully submitted,

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