UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, et al.,

Plaintiffs,

v. Case No. 8:24-cv-1080-WFJ-TGW

DEPARTMENT OF HEALTH
AND HUMAN SERVICES, et al.,

Defendants.
_____/

ORDER

Before the Court is Plaintiffs State of Florida, Florida Agency for Health Care Administration ("AHCA"), Florida Department of Management Services ("MS") (collectively, "Florida"), and Catholic Medical Association's ("CMA") Motion for Stay or Preliminary Injunction (Dkt. 12) of Final Rule. Defendants Department of Health and Human Services, Secretary of the Department of Health and Human Services (collectively "HHS"), Centers for Medicare and Medicaid Services, Administrator of the Centers for Medicare and Medicaid Services (collectively, "CMS"), and Director of the Office for Civil Rights have responded (Dkt. 33). Plaintiffs have replied (Dkt. 35). On June 21, 2024, the Court held a hearing on this matter. Upon careful consideration, and with the benefit of able argument by both sides, the Court grants Plaintiffs' Motion within the State of Florida. The subject

rules are stayed in Florida. Defendants are preliminarily enjoined within the State of Florida as follows.

BACKGROUND

The instant case is about Defendants' changed interpretation of the Affordable Care Act's ("ACA") prohibition on sex discrimination, and Defendants' attempt to enforce their new rules through the Final Rulemaking to be codified at 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See* 89 Fed. Reg. 37,522 (May 6, 2024). Specifically, Defendants interpret the ACA's proscription against discrimination *on the basis of sex* to include discrimination *on the basis of gender identity*. *Id.* at 37,699 (emphasis added). They now maintain, among other things, that ACA covered providers may not "[d]eny or limit health services sought for purpose of gender transition or other 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." *Id.* at 37701. Plaintiffs disagree with Defendants' interpretation of the ACA. They ask the Court to enjoin Defendants from enforcing it against them.

The Final Rules considered here are broad and significant in application. As HHS has noted, "almost all practicing physicians in the United States are reached by Section 1557 [the provision at issue] because they accept some form of Federal

remuneration apart from Medicare Part B." *Nondiscrimination in Health Programs and Activities,* 81 Fed. Reg. 31,375, 31,446 (May 18, 2016).

I. The ACA and Title IX

In 2010, Congress passed the ACA seeking to improve healthcare coverage for Americans. Pub. L. No. 111-148, 124 Stat. 119. Section 1557 of the ACA furthers this goal by mandating that no individual shall, "on the ground prohibited under . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . 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). Title IX then itself provides that "[n]o person in the United States shall, *on the basis of sex*, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance[.]" 20 U.S.C. § 1681(a) (emphasis added).[1]

[1] Title IX contains a number of sex-specific exceptions to this general language. 20 U.S.C. § 1686, for instance, provides that nothing contained within Title IX "shall be construed to prohibit any educational institution receiving funds under this Act, from maintaining separate living facilities for the different sexes." Further, § 1681(a) "shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." *Id.* at § 1681(a)(3). The ACA itself also states that, "[n]otwithstanding any other provision of [the ACA,] HHS "shall not promulgate any regulation that . . . violates the principles of informed consent and the ethical standards of health care professionals[.]" 42 U.S.C. § 18114(5).

In addition to borrowing Title IX's "on the basis of sex" language, section 1557 also incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). This essentially means that HHS's Office for Civil Rights ("OCR") may initiate investigations to determine whether "covered entities" have failed to comply with section 1557's anti-discrimination provision. *See* 20 U.S.C. § 1682; 45 C.F.R. §§ 80.7, 92.303(a). Where compliance cannot be secured voluntarily after an adverse finding, HHS must follow an administrative process before withholding federal funding. 20 U.S.C. § 1682. "[A]ny person aggrieved" by such action may also obtain judicial review. *Id.* at § 1683.

II. HHS's Implementation of Section 1557

On May 6, 2024, HHS issued a "final rule and interpretation" regarding section 1557 (the "Rule," "Rules," or "Final Rules"). *See generally* 89 Fed. Reg. 37,522. As relevant here, the Rules provide that discrimination "on the basis of sex includes, but is not limited to, discrimination on the basis of . . . [g]ender identity[.]" 45 C.F.R. § 92.101(a)(2)(iv) (effective July 5, 2024). The Rules expand on this interpretation through 45 C.F.R. §§ 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4).

At section 92.206 the Rule addresses covered entities' obligation to provide "equal access to its health programs and activities without discriminating on the basis of sex." 45 C.F.R. § 92.206(a) (effective July 5, 2024). According to HHS, this obligation specifically prohibits four things:

> (1) denying or limiting "health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;"
>
> (2) denying or limiting, "on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;"
>
> (3) adopting or applying "any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity;" and
>
> (4) denying or limiting "health services sought for purpose of gender transition or other 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."

Id. at § 92.206(b)(1)–(4). The Rule adds, "[n]othing 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 reasonably determines that such health service is not clinically appropriate for a particular individual." *Id.* at § 92.206(c). What ostensibly matters is that a "covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination." *Id.*

At section 92.207 the Rule focuses on "health insurance coverage and other health-related coverage." 45 C.F.R. § 92.207(a) (effective July 5, 2024). It provides that covered insurers must not "[h]ave or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care" or "[o]therwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender affirming care[.]" *Id.* at § 92.207(b)(4)–(5). Section 92.207(c) states that "reasonable medical management techniques such as medical necessity requirements" may provide a "legitimate, nondiscriminatory reason for denying or limiting coverage of" certain health services. *Id.* at § 92.207(c).

The final change concerns 42 C.F.R. § 438.3(d)(4).[2] Unlike the previously mentioned revisions, this one addresses "standard contract requirements" for entities that deliver services under Medicaid and CHIP.[3] 42 C.F.R. § 438.3(d)(4) (effective July 9, 2024). These contracts must now affirmatively state that the contracting

[2] Although Plaintiffs' complaint addresses a number of "CMS Rules," Dkt. 1 at 46–49, Plaintiffs' Motion for Stay or Preliminary Injunction only focuses on 42 C.F.R. § 438.3(d)(4). The Court will therefore largely limit its contracts analysis to 42 C.F.R. § 438.3(d)(4).

[3] Medicaid and CHIP are joint federal-state programs that enable states to extend medical coverage to 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 for approval. *Id.* § 1396a(b); *id.* §1397ff(a)–(c); 42 C.F.R. § 457.150(a)–(c). Upon approval, states administer and fund their plans, and the federal government provides funding to help defray costs.

entity will "not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating" on the same grounds. *Id.* In addition, participating states must ensure that these same entities "promote the delivery of services in a culturally competent manner to all enrollees . . . regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes[.]" 42 C.F.R. § 438.206(c)(2) (effective July 9, 2024).

III. Florida

Florida believes that gender-change interventions are "experimental" and risk irreversible damage. Dkt. 1 at 33. It has therefore "concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly in minors." *Id.*[4]

[4] In 2022, the Florida Department of Health ("DOH") released guidance to this effect. *See Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4. The DOH explained that "[s]ystematic reviews on hormonal treatment for young people show a trend of low-quality evidence, small sample sizes, and medium to high risk of bias. A paper published in the International Review of Psychiatry states that 80% of those seeking clinical care will lose their desire to identify with the non-birth sex." *Id.* The DOH also noted its belief that "encouraging mastectomy, ovariectomy, uterine extirpation, penile disablement, tracheal shave, the prescription of hormones which are out of line with the genetic make-up of the child, or puberty blockers, are all clinical practices which run an unacceptably high risk of doing harm." *Id.*

In line with this view, Florida has issued "standards of practice and standards of care" for licensed physicians. Fla. Admin. Code r. 64B8-9.019. The Florida Board of Medicine prohibits "[s]ex reassignment surgeries, or any other surgical procedures that alter primary or secondary sexual characteristics" as well as "[p]uberty blocking, hormone, and hormone antagonist therapies" in the treatment of minors with gender dysphoria. *Id.* The Florida Board of Osteopathic Medicine similarly prohibits such treatments. Fla. Admin. Code r. 64B15-14.014.

Florida has also passed a number of other laws and regulations that are relevant here. Rule 59G-1.050(7) provides that Florida Medicaid does not cover "puberty blockers, hormones and hormone antagonists, sex reassignment surgeries, or any other procedures that alter primary or secondary sexual characteristics" for the treatment of gender dysphoria. Fla. Admin. Code r. 59G-1.050(7). SB 254 prohibits "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same. Fla. Stat. §§ 286.311, 456.001, 456.52. And HB 1521 mandates that covered entities must generally provide both females and males "restrooms and changing facilities for their exclusive use, respective to their sex[.]" Fla. Stat. § 553.865(2), (5), (12).

Given the foregoing, Florida asserts that compliance with the Rules will require it to violate its own laws and regulations. Florida further asserts that non-compliance will result in a significant loss of funds as well as private lawsuits.

IV. Catholic Medical Association

Like Florida, "CMA and its members hold the position that gender-transition procedures are unethical and dangerous." Dkt. 1 at 9.[5] CMA's members also have "overlapping religious objections." *Id.* They believe that the Rules interfere with their right "to the conscientious and faithful practice of medicine." *Id.*

CMA focuses on aspects of the Rules that have not been previously mentioned but which ultimately depend on Defendants' interpretation of discrimination "on the basis of sex." Among other things, the Rules will require CMA members who qualify as "covered entities" to: (1) "submit an assurance . . . that the entity's health programs and activities will be operated in compliance with section 1557" as amplified by the Final Rules; (2) "implement a written policy" that "states the covered entity does not discriminate on the basis of" healthcare for gender-identity; (3) "train relevant employees of its health programs and activities on the civil rights policies" embodied in the Rules; and (4) "provide a notice of nondiscrimination" on the basis of gender-identity "to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public." 89 Fed. Reg. 37,696–98. Non-compliance may result in remedial action. *Id.*

[5] According to the Complaint, CMA is the largest association of Catholic individuals in healthcare with "2,500 members nationwide in all fields of practice." Dkt. 1 at 8. Additionally, "[m]ost CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557." *Id.* at 9.

CMA claims that these specific requirements, and the Rules as a whole, impose a "no-win" scenario for its members to: (1) "abandon or violate their convictions on gender and incur the costs of compliance"; or (2) "maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability"; or (3) "exit the medical field and abandon their patients." Dkt. 1 at 60. Ultimately, CMA maintains that its members' "categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from" complying with the Rules. *Id.* at 58.

CMA's approximately 2,500 members are nationwide. For reasons stated below, the undersigned believes a nationwide injunction issuing here is improvident. Thus, CMA's motion for a preliminary injunction will be denied, although its Florida members will be under this Court's order. CMA's other requested remedies must await a decision on the merits.

V. Procedural History

On May 6, 2024, Plaintiffs filed the instant lawsuit against Defendants. Plaintiffs generally assert that the Rules violate the Administrative Procedure Act ("APA"), the Spending Clause, the First Amendment's guarantee of free speech and association, and the First Amendment and Religious Freedom Restoration Act's ("RFRA") guarantees of religious freedom. *Id.* at 64–81.

Plaintiffs now move for a stay or preliminary injunction concerning 45 C.F.R. §§ 92.101, 92.206, 92.207 and 42 C.F.R. § 438.3(d)(4). *See generally* Dkt. 12. Defendants oppose such relief on the merits. *See generally* Dkt. 33. They also suggest that Plaintiffs lack standing and that Plaintiffs' claims are not ripe for review. *Id.* at 26–33.

LEGAL STANDARDS

To obtain a preliminary injunction concerning the Rules, Plaintiffs must show that: (1) they have "a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). "The first two factors are 'the most critical.'" *Swain v. Junior*, 958 F.3d 1081, 1088 (11th Cir. 2020) (quoting *Nken v. Holder*, 556 U.S. 418, 434 (2009)). Further, "the third and fourth factors [tend to] merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up) (citations omitted).

5 U.S.C. § 705 provides that, "[o]n conditions as may be required and to the extent necessary to prevent irreparable injury," a 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" a review. The showing required for stay under section 705 of the APA is not materially different than that required for a preliminary injunction. *Cook Cnty., Illinois v. Wolf*, 962 F.3d 208, 221 (7th Cir. 2020); *see also Purpose Built Fams. Found., Inc. v. United States*, No. 22-60938-CIV, 2022 WL 6226946, at *2–4 (S.D. Fla. July 29, 2022).

DISCUSSION

I. Justiciability

Defendants suggest that Plaintiffs lack standing, that Plaintiffs' claims are not ripe, and that implied preclusion issues exist. The Court will address each of these contentions before turning to consider the merits.

a. Standing

"Courts have jurisdiction to hear a case only when the plaintiff has standing to sue." *Baughcum v. Jackson*, 92 F.4th 1024 (11th Cir. 2024). Standing has three requirements: (1) "the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical"; (2) "there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court"; and (3) "it must be likely, as opposed to merely speculative, that the injury will be redressed by a

favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (cleaned up) (internal quotations and citations omitted). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Id.* at 561. CMA's standing is not relevant here.

Florida has shown that it faces an imminent injury in fact. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235, 2024 WL 2964140, at *7 (U.S. June 13, 2024). Here, among other things, the Rules force Florida to begin expending state funds on gender-transition healthcare in contravention of its own laws. *Compare* 45 C.F.R. § 92.207(a) (barring "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care") *with* Fla. Stat. §§ 286.311, 456.001, 456.52 (prohibiting "[s]ex-reassignment prescriptions or procedures" for "patients younger than 18 years of age," and the expenditure of state funds for the same). This alone represents an imminent injury to Florida's sovereign "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *State of Tennessee v. Dep't of Educ.*, No. 22-5807, 2024 WL 2984295, at *10 (6th Cir. June 14, 2024). And Florida "need not expose [itself] to liability to have standing to challenge the enforcement of [the Rules]." *W. Virginia by &*

through Morrisey v. U.S. Dep't of the Treasury, 59 F.4th 1124, 1137 (11th Cir. 2023) (internal quotations and citation omitted).

Having addressed injury in fact, the other questions of standing are causation and redressability. Defendants do not address these factors. *See generally* Dkt. 33. Still, it is worth noting that they are satisfied. Plaintiffs' alleged injuries are directly caused by Defendants' promulgation of the Rules and imminent (July 5, 2024) enforcement of the same. A preliminary injunction will delay this enforcement. The Florida Plaintiffs have standing.

b. Ripeness

The ripeness doctrine asks "whether there is sufficient injury to meet Article III's requirement of a case or controversy and, if so, whether the claim is sufficiently mature and the issues sufficiently defined and concrete, to permit effective decision-making by the court." *Elend v. Basham*, 471 F.3d 1199, 1211 (11th Cir. 2006) (internal quotations and citations omitted). "In cases involving pre-enforcement review, like this one, the standing and ripeness analysis tend to converge." *Baughcum*, 92 F.4th at 1036.

Florida has alleged sufficient injury to satisfy the constitutional component of ripeness for the same reason that it satisfied the injury in fact component of standing. "If, in a suit challenging the legality of government action, the plaintiff is himself an object of the action . . . there is ordinarily little question that the action or inaction

has caused him injury." *Texas v. EEOC*, 933 F.3d 433, 46 (5th Cir. 2019) (internal quotations and citations omitted). The "common-sense inquiry" called for to determine whether Florida and CMA are objects of the Rules "is easy here." *Id.* The Rules explicitly apply to "covered entities," such as the Florida Plaintiffs, and mandate assurances, notices, training, and healthcare work that they do not currently provide. *See* 89 Fed. Reg. 37,522–24, 37,696–98. Florida, moreover, is "trapped in a bind" between the Rules and Florida law, which categorically precludes gender transition procedures for minors with gender dysphoria. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) (explaining that "being pressured to change state law constitutes an injury"). There is simply no question that Plaintiffs face imminent injury where Defendants have expressed no intention to forego enforcement of the Rules.

This brings the Court to the prudential component of ripeness, which focuses on "both the *fitness* of the issues for judicial decision and the *hardship* to the parties of withholding judicial review." *Harrell v. The Fla. Bar*, 608 F.3d 1241, 1258 (11th Cir. 2010) (emphasis in original). In analyzing the fitness prong, courts are generally "concerned with questions of 'finality, definiteness, and the extent to which resolution of the challenge depends upon facts that may not yet be sufficiently developed.'" *Id.* (quoting *Ernst & Young v. Depositors Econ. Prot. Corp.,* 45 F.3d

530, 535 (1st Cir.1995)). "If a claim is fit for judicial decision, that is the end of the inquiry, and the matter is ripe, given that the absence of a hardship cannot tip the balance against judicial review under those circumstances." *Club Madonna, Inc. v. City of Miami Beach*, 924 F.3d 1370, 1380 (11th Cir. 2019) (cleaned up) (internal quotations and citation omitted).

Florida's claims are fit for judicial decision. "A facial challenge presenting a purely legal argument … 'is presumptively ripe for judicial review' because that type of argument does not rely on a developed factual record." *Id.* (quoting *Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301, 1308 (11th Cir. 2009)); *see Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014). Here, Plaintiffs' central challenge is purely legal in nature. They argue that the Rules are facially invalid because Defendants have erroneously interpreted the Title IX and ACA proscription against discrimination on the basis of sex to include discrimination on the basis of gender identity. There is no need for trial-like factual development at this stage. "The lines are drawn, the positions taken, and the matter is ripe for judicial review." *Florida v. Weinberger*, 492 F.2d 488, 493 (5th Cir. 1974).

The Court also notes that Plaintiffs would suffer hardship without judicial review. *See Club Madonna*, 924 F.3d at 1380. "Potential litigants suffer substantial hardship if they are forced to choose between foregoing lawful activity and risking substantial legal sanctions." *Cheffer v. Reno*, 55 F.3d 1517, 1524 (11th Cir. 1995).

In the instant case, the Rules force Plaintiffs to choose between foregoing ostensibly legal healthcare policies and practices or risking private lawsuits and the withholding of federal funds that are likely unrecoverable. This is sufficient hardship. *See Texas v. Brooks-LaSure*, 680 F. Supp. 3d 791, 804 (E.D. Tex. 2023) (finding that Texas faced sufficient hardship where it had to "comply" with a CMS bulletin or "face fund disallowance"); *U.S. Army Corps of Engineers v. Hawkes Co.*, 578 U.S. 590, 600 (2016) (Plaintiffs "need not assume such risks while waiting for [Defendants] to 'drop the hammer' in order to have their day in court"). Plaintiffs' claims are ripe.

c. Implied Preclusion

The final justiciability issue to consider is implied preclusion. District courts generally "have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Here the Administrative Procedure Act, 5 U.S.C. 706, assigns all legal interpretations to the courts. The prime issue here is whether the Final Rules are legally compliant with and covered by Title IX in the Eleventh Circuit. The APA mandates this task is not impliedly precluded.

In some circumstances "[a] special statutory review scheme . . . may preclude district courts from exercising jurisdiction over challenges to federal agency action." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023). Defendants suggest that section 1557 and 42 U.S.C. § 1316 represent such schemes.

Defendants are mistaken with respect to section 1557. The threshold implied preclusion issue is whether Congress has created a "comprehensive review process . . . that oust[s] district court jurisdiction[.]" *Axon Enter.*, 598 U.S. at 186 (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 208 (1994). Congress did no such thing through section 1557. As previously mentioned, section 1557 incorporates Title IX and Title VI's "enforcement mechanisms[.]" 42 U.S.C. § 18116(a). Neither contain a special statutory review scheme that vests review in the courts of appeal or provides a comprehensive review process. They instead provide that "[a]ny department or agency action . . . shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds." 20 U.S.C. § 1683; 42 U.S.C. § 2000d-2. There is consequently no implied preclusion of Plaintiffs claims concerning 45 C.F.R. §§ 92.101, 92.206, and 92.207. *See Louisiana v. U.S. Env't Prot. Agency*, No. 2:23-CV-00692, 2024 WL 250798, at *19 (W.D. La. Jan. 23, 2024) (finding that "42 U.S.C. § 2000d-2 is not a special statutory scheme"); *Tennessee*, 2024 WL 2984295, at *18 (6th Cir. June 14, 2024) (finding that Title IX does not "implicitly preclude[] the States from brining an APA pre-enforcement challenge").

Title 42 U.S.C. § 1316's interaction with the contracts provision of 42 C.F.R. § 438.3(d)(4) creates a closer question, but not by much. Unlike section 1557, section 1316 creates a valid and comprehensive review process. *See* 42 U.S.C. §

1316(a)–(e). But here, Plaintiffs' claims are not "of the type Congress intended to be reviewed within this statutory structure." *Thunder Basin Coal Co.*, 510 U.S. at 212. Section 1316 addresses determinations concerning whether state plans "submitted to the Secretary by a State for approval under subchapter I, X, XIV, XVI, or XIX . . . conform[] to the requirements for approval under such subchapter" and general item disallowance. 42 U.S.C. § 1316(a)–(e). These matters are wholly collateral to the review of managed-care-plan contracts which are reviewed under 42 C.F.R. § 438.3(a). Additionally, Plaintiffs' claims concerning 42 C.F.R. § 438.3(d)(4) ultimately present legal APA and constitutional issues that are outside of HHS and CMS's expertise. It is unclear how Plaintiffs could seek such administrative review without "betting the farm" through immediate and wholesale defiance of the Final Rule—something courts "normally do not require plaintiffs" to do and something courts "do not consider" to be "a meaningful avenue of relief." *Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 490–91 (2010).

In sum, Congress' intent to allocate initial review of Plaintiffs' claims to HHS or CMS is not "fairly discernable in [42 U.S.C. § 1316 or 42 U.S.C. § 18116(a)]." *Thunder Basin*, 510 U.S. at 207. The Court has subject matter jurisdiction over Plaintiffs' claims.

II. Injunctive Factors

a. Likelihood of Success on the Merits

HHS and the Final Rule interpret Title IX, and hence section 1557, to prohibit discrimination based on "gender identity." 89 Fed. Reg. at 37,699 (45 C.F.R. § 92.101(a)(2)). The Final Rule is stillborn and a nullity if Title IX does not prohibit discrimination on the basis of "gender identity." The Eleventh Circuit has spoken on this point, clearly: Title IX does not address discrimination on the basis of gender identity. *Adams v. Sch. Bd. of St. John's Cnty.*, 57 F. 4th 791, 812–15 (11th Cir. 2022) (*en banc*). Frankly, this ends the issue—the new Rule appears to be a dead letter in the Eleventh Circuit.

The plaintiff in *Adams*, like HHS here, contended that the Title VII employment case of *Bostock v. Clayton County*, 590 U.S. 644, 659–60 (2020), means that Title IX barred discrimination on gender identity grounds.[6] The Eleventh Circuit held otherwise. In Title IX, and hence in section 1557, "because of sex" unambiguously means "biological sex" (male and female), and not "gender identity." *Adams*, 57 F.4th at 812–13. And although *Bostock*, too, proceeded on the assumption that "sex" means biological sex, *Adams* said that "the statutory context of Title IX" requires a different result. *Id.* at 813. As the *Adams* Court noted, Title IX includes many sex-specific exceptions and instructs that the prohibition must be

[6] *Bostock* held that an employer discriminates "because of sex" under Title VII of the Civil Rights Act of 1964 when he fires a male for no reason other than identifying as a woman, but "retains an otherwise identical employee" who is a female, because in that case, the individual's sex is a but-for-cause of the disparate treatment. 590 U.S. at 659.

read to permit separating living facilities based on sex, which is inconsistent with protecting "gender identity." *Id.* at 814–15 & n.7; *see* 20 U.S.C. § 1686. If Title IX were read to protect "gender identity," the Court reasoned, Title IX's carve-outs "would be rendered meaningless" whenever they came "into conflict with a transgender person's gender identity." *Adams*, 57 F.4th at 813–14. This "would provide more protection against discrimination on the basis of transgender status under the statute . . . than it would against discrimination on the basis of sex." *Id.* at 814. "That conclusion cannot comport" with the text and context of Title IX. *Id.*

A further reasoning of the Eleventh Circuit was that Title IX, unlike Title VII, was enacted under the "Spending Clause." *Adams*, 57 F.4th at 815. "A safeguard of our federalist system is the demand that Congress provide the States with a clear statement when imposing a condition on federal funding." *Id.* That "clear-statement" rule required rejecting the plaintiff's argument, because Title IX does not clearly protect gender identity. The text of Title IX says nothing about gender identity.

Notably, the federal Government's argument here about Title IX, including its argument about the spending clause, is precisely the argument it made, and flatly lost, in *Adams*. Amicus Brief of United States, Dkt. 254, No. 18-1359, *Adams*, ecf.call.uscourts.gov/n/bean/serulet/TansportRoam, last consulted June 30, 2024. Repeating the same failed argument from *Adams* will likely render the same result.

In discussing its definition of "sex" under Title IX to include gender identity,

HHS cites the reversed District Court opinion in *Adams*. *Id*. at 37573 n.110. And when incorporating *Bostock* into Title IX, HHS cites the controlling *en banc Adams* decision but notes it is contrary, using the signal "But cf." *Id*. at 37574 n.116.

In the Final Rule, HHS recognizes that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under Title IX, including regulatory interpretations *and case law*." 89 Fed. Reg. at 37,638 (emphasis added). In the Eleventh Circuit, that case law includes *Adams*.

HHS argues the Court should limit *Adams* to its facts ("transgender restroom issues") and apply *Bostock*'s reasoning to uphold the Final Rule. But *Adams* rejected applying *Bostock*.

Respect for Executive Branch interpretation of a statute was previously "especially warranted when an Executive Branch interpretation was issued roughly contemporaneously with enactment of the statute and remained consistent over time." *Loper Bright Enters. v. Raimondo*, 603 U.S. — , No. 22-1219, 2024 WL 3208360, at *9 (June 28, 2024). In contrast the Executive Branch interpretation of Title IX now conjured comes decades after the enactment of Title IX and, as seen below, the interpretation has changed repeatedly over time.

As *Loper* states, the whole point of having a written statute is "every statute's meaning is fixed at the time of enactment." *Id*. at *16. *Adams* recognizes this. Title IX, decades old, did not change meaning in 2024. HHS's attempt to alter

prospectively the meaning of Title IX shows the wisdom of *Loper's* statement that "agencies have no special competence in resolving statutory ambiguities. Courts do." *Id*. at *16. The Administrative Procedures Act, § 706, which is the present guidepost, "demand[s] that courts exercise independent judgment in construing statutes administered by agencies." *Id*. at *19; 5 U.S.C. § 706.

Eknes-Tucker v. Governor of Ala., 80 F.4th 1205 (11th Cir. 2023), also suggests that Plaintiffs will likely prevail on the merits. *Eknes-Tucker* involved a challenge to an Alabama law prohibiting gender-transition interventions in minors, particularly puberty blockers and cross-sex hormones. *Id.* at 1210, 1227. Interpreting the Equal Protection Clause, the Eleventh Circuit held that "the statute does not discriminate based on sex." *Id.*

The Alabama law prohibited drugs used for a specific medical purpose of treating gender dysphoria. *Id*. The purpose of the treatment was to end the gender dysphoria by facilitating likely gender transition or at least enabling it. Any reference to sex or difference in treatment was due to the medical purpose of the drugs coupled with biological facts about the sexes, not stereotypes. *Id.* at 1229. Only females may take supraphysiologic levels of testosterone for a gender transition, and only males can take supraphysiologic levels of estrogen for a gender transition. *Id.* at 1213, 1228. The Court said prohibiting these treatments is not discriminating on the basis of sex under Equal Protection scrutiny. "[T]he regulation of a course of treatment

that only gender nonconforming individuals can undergo" was not stereotyping "based on sex" "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Id.* at 1228–30.

Like *Adams*, the *Eknes-Tucker* Court distinguished *Bostock*.[7] The Court emphasized the "different factual context" involved in *Eknes-Tucker* and *Bostock*—*Eknes-Tucker* involved a law regulating medical treatments, not a rule penalizing a transgender individual in employment for no reason other than being transgender. *Id.* at 1229. So too, here.

Eknes-Tucker held that a ban on gender-transition interventions does not intentionally discriminate "on the basis of sex." The same phrase is used in Title IX and imported into section 1557, increasing the likelihood that Plaintiff will prevail on the merits.

Section 206(b)(4) of the Rule makes it presumptively discriminatory for covered entities to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," so long as those entities provide the services for "other purposes." 89 Fed. Reg. at 37,701 (45 C.F.R. § 92.206(b)(4)).

[7] The Eleventh Circuit's recent decision in *Lange v. Houston County* does not govern here. 101 F.4th 793 (11th Cir. 2024). In that case, the Eleventh Circuit held that an employer violates Title VII when it denies health-insurance coverage for all gender transitions. But *Lange* (like *Bostock*) interprets Title VII, which is not a Spending Clause statute like section 1557. *Fitzpatrick v. Bitzer*, 427 U.S. 445, 458 (1976) (Brennan, J., concurring). So unlike section 1557, Title VII need not satisfy the requirement of clear and unambiguous notice. *Adams*, 57 F.4th at 815. *Adams* and *Eknes-Tucker* distinguished Title VII.

But this is insufficient to establish a prima face discrimination claim, as a patient seeking "gender transition" is not similarly situated to a patient seeking a drug or procedure to treat a different medical condition or diagnosis. *See Eknes-Tucker*, 80 F.4th at 1228; *id.* at 1233 (Brasher, J., concurring) (same); *L.W. v. Skrmetti*, 83 F.4th 460, 481–82 (6th Cir. 2023) (same in equal protection case).

To use *Bostock*'s language, HHS provides no reason to presume that a woman seeking a hysterectomy to treat cancer is "to [the doctor's mind], materially identical in all respects" to a woman seeking a hysterectomy for a gender transition. *Bostock*, 590 U.S. at 660. The diagnosis relevant to gender transition treatment—gender dysphoria—has a very different etiology and balance of risks. *See Eknes-Tucker*, 80 F.4th at 1233 (Brasher, J., concurring). Because the medical purpose is different, not similar, let alone "materially identical," intentional sex discrimination cannot be presumed. *Eknes-Tucker*, 80 F.4th at 1228; *Bostock*, 590 U.S. at 660.

One can envision many other factual scenarios showing that the Rule likely reaches well beyond "discrimination." For example, it is not actionable discrimination for a local hospital to provide an orchiectomy to a teenage boy with testicular cancer, yet refuse to even consider castrating a teenage gender dysphoric with healthy testicles. The diagnoses and medical purposes are not similarly situated.

Sections 207(b)(4) and (b)(5) prohibit a reimbursement policy or practice limiting gender-transition reimbursements if the policy or practice is "categorical"

or "results in sex discrimination." 89 Fed. Reg. at 37,701 (45 C.F.R. §§ 92.207(b)(4), (5)). HHS justifies this based on an argument that limiting coverage for a gender transition is a proxy for discriminating on the basis of gender nonconformity "because transgender individuals are the only individuals who seek transition-related care." Notice of Proposed Rule Making, 87 Fed. Reg. at 47,871. But *Eknes-Tucker* rejected that same argument: "the regulation of a course of treatment that only gender nonconforming individuals can undergo" is not discriminating "based on sex" (the same words used in Title IX) "unless the regulation [is] a pretext for invidious discrimination against such individuals." *Eknes-Tucker*, 80 F.4th at 1228–30. So *Eknes-Tucker* conflicts with these rules.

The Eleventh Circuit has concluded that limiting gender-transition treatments for minors such as pharmaceuticals or hormones is "rational." *Eknes-Tucker*, 80 F.4th at 1225. Surgery, which HHS addresses but *Eknes-Tucker* did not, would be all the more medically intrusive and "rational" to restrict.

Both *Eknes-Tucker* and the Final Rule forbid "pretext," but the Final Rule prohibits far more than "pretext," and its framework is the opposite of *Eknes-Tucker*'s. *Eknes-Tucker* requires a plaintiff to show "pretext" to establish that a state discriminated on the basis of sex. By contrast, under the Final Rule, a covered entity that bars coverage for gender-transition treatments would be presumed to discriminate based on sex, without any showing of pretext. Under the Final Rule, a

hospital's categorical denial of care ("no castration, hysterectomies, or mastectomies for gender transition") would be in violation of the Rule if the hospital provided those services for other reasons, like cancer.

The CMS contracts Rule would amend the standard contract requirements under Medicaid and CHIP to require prohibiting any policy or practice that has the "*effect of* discriminating" based on an individual's "gender identity." 89 Fed. Reg. at 37,691 (42 C.F.R. §§ 438.3(d)(4) (emphasis added), 457.1201(d)). But as explained above, section 1557 likely does not prohibit discriminating based on gender identity, and likely does not forbid the discriminatory effects that HHS defines. For additional statutory authority, HHS invokes the Social Security Act, which was also enacted under the Spending Clause and therefore likewise requires a "clear" statement of Congress. *See* 89 Fed. Reg. at 37,668.[8] But there is no clear statement. The Spending Clause failure was one of the salient points of the *Adams* opinion. 57 F.4th at 815.

In this regard, HHS defends the CMS contracts Rule by invoking its authority to adopt "methods of administration" for Medicaid that are "necessary for the proper

[8] HHS raises an affirmative defense. It argues that the claim is untimely under the Little Tucker Act's statute of limitations. 28 U.S.C. § 2401(a). This is meritless. The six-year statute of limitations "begins to run when the agency issues the final action that gives rise to the claim." *Alabama v. PCI Gaming Auth.*, 801 F.3d 1278, 1292 (11th Cir. 2015). To the extent earlier rules are implicated, HHS reopened them by vastly expanding them to gender identity medical services and contracting. *See Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1227 (D.C. Cir. 1996). These claims accrued upon issuance of the Final Rule. *See Corner Post, Inc. v. Bd. of Governors of the Fed. Rsrv. Sys.*, 2024 WL 3237691, at *7 (July 1, 2024).

and efficient operation of the [state Medicaid] plan." 42 U.S.C. § 1396a(a)(4). But imposing these vast duties and canceling Florida law is far afield from "methods of administration."

Congress offered examples of "methods of administration," giving "more precise content" to the term. *United States v. Williams*, 553 U.S. 285, 294 (2008). It includes setting "personnel standards," providing for "medical personnel in the administration … of the plan," and transporting "beneficiaries … to and from providers." 42 U.S.C. § 1396a(a)(4). That list of routine administrative tasks looks nothing like the power to declare new civil rights guarantees for groups of people. When the SSA was enacted, States had no "clear notice" from the face of the statute that HHS could force them to adopt very costly contracts expanding treatments due to alleged disparate impacts on transgender individuals. *Adams*, 57 F.4th at 815. The contract requirement "is markedly different from" other contract requirements HHS has imposed. *Ala. Ass'n of Realtors*, 594 U.S. 758, 764 (2021); *see generally* 42 C.F.R. § 438.3. The CMS contracts Rule, like the Title IX Rule, simply rewrites the statute. That is Congress' job alone. For the foregoing reasons, Plaintiffs have established a likelihood of success on the merits.

b. Florida Faces Irreparable Harm

For many of the same reasons they establish standing and hardship, Plaintiffs also show they will suffer "irreparable harm" absent a stay. *West Virginia*, 59 F.4th

at 1149.

If the Rule is implemented, on July 5, 2024, Florida will face irreparable harm. Florida's covered entities will have to file an assurance of compliance to avoid termination of funds. They must amend their policies and begin trainings on the new rules. 45 C.F.R. §§ 92.5, 99.8, 99.9.

The Plaintiff agencies and the healthcare providers they regulate must either clearly violate Florida law, or clearly violate the new Rule. To comply with the Rule, DMS would have to alter its policy against reimbursing managed care plan members for sex-change treatments. This is not possible because DMS cannot amend its self-funded insurance plan without permission from the Florida legislature, which is not is session and which has previously barred payment of tax dollars for gender transition treatment. DMS will clearly suffer irreparable harm if the Rule is not stayed.

Other Plaintiffs would be in a similar bind. Under current law AHCA cannot use state funds for these gender change services in state Medicaid. Fla. Admin. Code r. 59G-1.050(7). HHS lawyers have previously said this present Florida AHCA law violates the Rule.[9] Even if AHCA could violate state law by expanding coverage for

[9] Brief for the United States as Amicus Curiae at 26 n.10, *Dekker v. Fla. Agency for Health Care Admin.*, No. 23-12155 (11th Cir. Dec. 4, 2023), https://perma.cc/9UYG-SVPL.

these services it cannot print money. And the Rule provides nothing for the vast added, unallotted expense.

The federal government generally enjoys immunity from suit. *West Virginia*, 59 F.4th at 1149. So these costs can never be recovered. *See*, *e.g.*, *Odebrecht Const., Inc. v. Sec., Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013). Unrecovered monetary loss is irreparable harm. *Georgia v. President of the United States*, 46 F.4th 1283, 1302 (11th Cir. 2022).

Florida's Agency for Persons with Disabilities ("APD") also faces irreparable harm. Dkt. 12-2. APD has a policy of assigning dual-occupancy rooms in its residential living facilities on the basis of biological sex, regardless of an individual's gender identity. Presently, natal women have natal women roommates and natal males room with natal males. This makes sense given the residents APD serves. *See id*. But this would change.

The Rule would prohibit APD's room sharing policy if a biological male patient identified as a female, and refusing to lodge the natal male on the women's wing or with a female roommate would cause the natal male "more than de minimis harm." *See* § 206(b)(3) of Part 92; Dkt. 12, Ex. B; *see also* 89 Fed. Reg. at 37,593 ("A covered entity *will be* in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than de minimis harm."

(emphasis added)). HHS earlier explained its view that "a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman [meaning a natal male expressing the female gender] to share a room with a cisgender man [meaning a natal male who expresses a male gender], regardless of how her sex is recorded in her insurance or medical records." NPRM, 87 Fed. Reg. at 47,866–67. HHS reiterated in its brief that "refusing to place a transgender person 'in facilities consistent with their gender identity' would result in more than de minimis harm." Dkt. 33 at 17 n.9. Absent a stay, APD may likely violate Florida law. *See* Fla. Stat. § 553.865(5), (12). APD plausibly states it would have to redesign facilities and/or hire additional staff for safety, to accommodate the preferences of gender-divergent residents. *Id*. at 9.

Florida also plausibly asserts injury in its sovereign capacity. The Final Rule injures Florida's "interest in enforcing [its] duly enacted laws without contradiction from the federal government." *Tennessee*, 2024 WL 2984295, at *10. Florida "will continue to face pressure to change their laws to avoid legal consequences." *Id.* at *25; *see also Florida v. Nelson*, 576 F. Supp. 3d 1017, 1039 (M.D. Fla. 2021); *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) ("irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws"). Case law has recognized this type of injury as supporting a stay. *West Virginia*, 59 F.4th at 1149.

HHS argues that a pending class action before a different court negates the need for equitable relief. *See Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022). This case does not involve the Final Rule.

First, Florida, AHCA, DMS, and APD are not class members in *Neese*. Moreover, *Neese* did not provide equitable relief against Defendants. 640 F. Supp. 3d at 684–85. The judgment in *Neese*, now on appeal, does not stop HHS from enforcing the Final Rule against Plaintiffs.

Finally, the Court would note *Labrador v. Poe*, 601 U.S. — , 144 S. Ct. 921 (2024). Although arising in the context of a stay, the Supreme Court found that Idaho likely showed irreparable harm when a district judge struck down the state laws precluding puberty blockers and gender transition medical treatment for minors. *Id.*, 144 S. Ct. at 923–24 (concurrence). Here, of course, the Final Rule would similarly require repeal of substantive Florida statutes. *Labrador* suggests Florida faces irreparable harm.

c. The Balance of Harms and Public Interests Favor a Stay

The balance of harms and public interest factors "merge when, as here, the government is the opposing party." *Gonzalez v. Governor of Georgia*, 978 F.3d 1266, 1271 (11th Cir. 2020) (cleaned up). As discussed above, Plaintiffs will suffer harm and face unrecoverable, large monetary loss, legal jeopardy, and sovereign injury absent a stay.

Public Interest Requires a Lawful Rule

HHS and the public have an interest in HHS rules being legal. As noted, the Rule here appears to be contrary to the Eleventh Circuit's clear Title IX teachings in *Adams*; and *Eknes-Tucker* also teaches against the Rule indirectly. In the Eleventh Circuit, the Rule appears unlawful. "[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 766 (2021); *see BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) ("Any interest [the government] may claim in enforcing an unlawful [rule] is illegitimate."). In other words, the Rule invokes and relies on a Title IX that the Eleventh Circuit states does not exist.

Likewise, the reliance on the Social Security Act to impose costly new insurance/managed care contracts appears to be ultra vires to the Act. Neither is the Spending Clause requirement met, nor the stark changes permitted without a rewriting of that statute. The new Rules must be legal; and no deference on matters of legality need be shown the agency. *See Loper*, 2024 WL 3208360, at *22.

HHS's Rules Have Been Unstable, Ever-changing

A second reason why the public interest is furthered by a stay and injunction is that the Rule is ever-changing and unstable, buffeted by the prevailing political winds. The new Rule is the fourth version in the last eight years, which each version the opposite of the other. The repeated reversing of field by HHS presents large

compliance issues and costs for health care facilities and the states that regulate them; not to mention the stop-and-start effect on this sensitive area of health policy. This instability suggests that the public interest favors a preliminary pause to fully address on the merits this new, fourth version. And the instability shows little harm to HHS in keeping a steady hand rather than lurching change.

The stop/start timeline is illustrated in the case law. *See Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 589-591 (8th Cir. 2022). The first change was in 2016. Prior to 2016 the HHS rules did not require treatment and consideration of gender identity as part of healthcare nondiscrimination rules. This changed with a 2016 rule, *id.,* that stated "discrimination on the basis of sex includes discrimination on the basis of gender identity and sex stereotyping." *Id.* at 31,388; 31,467. The new rule barred providers from denying "transition-related care" based on explicit or categorical exclusions of services for purpose of gender transition. *Id.* at 31,439; 31,471. *See Religious Sisters,* 55 F.4th at 590.

After this change, though, HHS did another "180" and changed back again. *Id.* at 594; 85 Fed. Reg. 37,160 (June 19, 2020). In June 2020, HHS flatly repealed the 2016 rule, noting that it "repeal[ed] the 2016 Rule's definition of 'on the basis of sex'…" Instead, the 2020 HHS rule reverted to and relied upon the plain meaning of the term in Title IX. *Id.* at 37,178; *Religious Sisters,* 55 F.4th at 594. This change was the third rule within four years.

Now we have under review the fourth rule, as HHS has done one more about-face. Shortly after the Supreme Court issued its opinion in *Bostock,* President Biden issued an Executive Order stating that *Bostock's* reasoning meant that laws that prohibit sex discrimination, including Title IX, "prohibit discrimination on the basis of gender identity or sexual orientation," unless the laws contain sufficient indications to the contrary. *Executive Order No.* 13988, 86 FR 7023, 2021 WL 229396 (Jan. 20, 2021). The President thus ordered the head of each agency to rescind agency actions that were inconsistent with this definition he offered. Further, agencies were to promulgate new agency actions consistent with other laws including the APA, "as necessary to fully implement statutes that prohibit sex discrimination" as he defined it in the Order. *Id.* This fourth rule is the result: another 180-degree turn.

One need not be a cynic to predict that, if perchance there is a change in presidential administrations, we will have another sudden about-face by HHS and a fifth rule. This instability and repeated divergence is costly in many areas. It is entirely based upon national politics, and might support an argument that this sensitive issue of health and safety ought be left steady, or deferred to state medical regulators to decide in their public welfare role. In any event, this unstable regulatory regime does suggest there is little harm to a delay, and the public interest is here

served by a full decision on the factual merits and a preliminary stay, not to mention full development of real, hard science that was heretofore sparse in the field.

The Rule Requires Significant Alteration of Healthcare in Florida

The public has an interest in stable, orderly change in important public matters such as health care. The Final Rule would require covered entities to allow biological males who are transgender into female private spaces, including bathrooms, changing rooms, living facilities, dual-occupancy bedrooms, etc., if the natal males would otherwise suffer harm "more than de minimis." Unlike other more cautiously-worded provisions of HHS comments, HHS starkly stated, "[A] provider generally may accommodate a patient's preferences about roommate assignments. A covered entity will be in violation of this rule [Sec. 92.206] if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity because doing so would result in more than de minimis harm." 89 Fed. Reg. at 37,593. The Final Rule, moreover, allows no exceptions to this rule based on public safety or any similar rationales. That is not in the public interest, despite some minor harm that may be occasioned to gender-divergent patients by this injunction.

The Rule's commentary expressly declines to fully define the terms of "gender affirming care" or "gender identity" (other than to say it includes "transgender status") although the Rules are greatly about those subjects. 89 Fed.

Reg. 37,392; 37,596. HHS does say "gender affirming care generally refer[s] to a care designed to treat gender dysphoria that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other related sources." 89 Fed. Reg. 37,596.

Section 92.206 of the Rule clearly mandates availability of gender transition services if similar services (hormone therapy, mastectomies, hysterectomies, etc.) are available to patients for reasons other than gender transitions. This is because "[w]hen medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex." *Id.* at 37,671.

The Rule also seeks to make providers speak correctly about the subject to HHS's satisfaction, in addition to verbal assurance of compliance. The HHS commentary notes that in assessing a provider's good faith to avoid compliance sanctions the HHS will consider "whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care, or is otherwise engaging in good faith efforts to ensure patients are receiving medically necessary care." *Id.* at 37,598. HHS commented that the Rule clarifies "that while providers may exercise clinical judgment when determining if a particular service is appropriate for an individual patient, they may not refuse gender-affirming care

based on a belief that such care is never clinically appropriate." *Id.* at 37,597. This is contrary to the public interest, if public interest may be defined as the laws of Florida passed by the citizens' elected representatives.

Public Interest Supports Merits-Based Consideration of HHS's "Care" Regimen

HHS's brief, notably, does not argue that encouraging gender-transition treatments serves the public interest. This is a litigation strategy as both the Rule and HHS's clear public stance are entirely to the contrary. Given the uncertain benefit, the evidence of public health harms, and HHS's failure to defend the public health benefit of gender-transition treatments in its brief, the Court concludes that encouraging widespread access of "gender affirming care" is an issue that the public interest requires to be developed thoroughly on the merits. And such an examination brings no harm to HHS.

The Final Rule compels the State to make gender-transition services available in the Medicaid managed care plans, and compels all covered entities to not preclude gender-transition treatments when such services (like mastectomies for cancer, testosterone for hypogonadism, etc.) are provided for other medical reasons. Covered entities may not categorially refuse to perform gender transition. No hospital in Florida could have a categorical exclusion for gender-transition surgeries even for minors, if similar procedures were done for non-gender purposes.

If a hospital's outreach program sponsored a women-only support or counseling group, that group would have to admit a natal male who identified as female, if refusing to admit the natal male would cause that person more than de minimis harm. And no contractor such as the Florida Medicaid multi-billion-dollar managed care plans could omit a full panoply of gender transition coverage (surgery, hormone formulary, etc.) if those services were provided for non-transition maladies. This presents a *very* expensive regimen paid for by the taxpayers but unfunded by the Rule.

An honest appraisal of the Rule shows it imposes the availability of gender transition medicine upon all covered entities, wanted or unwanted. The public interest requires a merits-based analysis of this.

Although the task here is to undertake a "facial review" of the new Rules, some issues of "public interest and balanced harms" requires the further discussion. HHS's basis for a "gender affirming care" regimen appear to be long on ipse dixit[10] and short on real, hard science. *See generally* HHS Office of Population Affairs, G*ender-Affirming Care and Young People,* opa.hhs.gov/site/default/files/2022-03/gender-affirming-care-young-people-March-2022, last consulted June 29, 2024. In this March 2022 HHS "fact sheet" the HHS advocated the panoply of "gender

[10] **Ipse dixit**. L. He himself said it; a bare assertion resting on the authority of an individual. Black's Law Dictionary (5th ed. 1979).

affirming care" including counseling, pharmaceuticals, and stating that surgeries are "typically used in adult or case-by-case in adolescence." This "fact sheet" was immediately followed up by the Department of Justice Assistant Attorney General Kristin Clarke's letter of March 31, 2022, sent to State's Attorneys General, which fairly reads as a veiled threat to bring federal enforcement actions and litigation in pursuit of this trans-care agenda.[11]

At times the HHS position about "gender affirming care" seems to be political. It is no surprise to any observer that politics on both sides of this issue are prevalent. Concerning the parties here, HHS's Assistant Secretary Levine previously urged the medical/advocacy group World Professional Association for Transgender Health ("WPATH") to drop proposed age limits for minor transgender surgery. The age limits in the proposed WPATH guidelines were 15 for mastectomies, 16 for breast augmentation or facial surgeries, and 17 for hysterectomies. Levine's staff informed WPATH that Levine was "confident, based on the rhetoric she is hearing in D.C., and from what we have already seen, that these specific lists of ages, under 18, will result in devastating legislation for trans care. [Levine] wonder[s] if the specific ages can be taken out." Levine's staff went on to tell WPATH that Levine "was very concerned that having ages (mainly for surgery) will affect access to care for trans

[11] The letter may be found at ECF No. 193-3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023).

youth and maybe adults, too…" Levine's staff asked WPATH to remove the age limitations in the guidance for gender transition.[12] The WPATH has removed age limitations for minors on its guidance for transition surgeries.

It is in the public interest to address these issues with the benefit of a full record, substantively on the merits. The record now is sparse due to this "facial review"; further, the undersigned has no training in science or medicine. Despite this, several points are worth making.

A notable point about the Rule is that while it imposes significant "gender affirming care" and "transition treatment" requirements upon Florida, the HHS discounts, and in the commentary declares as "not germane to the proposed regulatory text," any uncertainty and lack of clarity concerning the safety and efficacy of the gender treatments HHS imposes. 89 Fed. Reg. 37672. HHS's boldness here is noteworthy and one might say brash, given that "[t]here are no large-scale population studies of gender dysphoria." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed. 2022 Text Revision)

[12]A. Ghorayshi, *Biden Officials Pushed to Remove Agent Limits for Trans Surgery, Documents Show* (N.Y. Times June 25, 2024), https://www.nytimes.com/2024/06/25/health/transgender-minors-surgeries.html. In response to this article the administration was reported to have stated that it opposed gender-affirming surgery for minors. Rabin, Rosenbluth, Weiland, *Biden Administration Opposes Surgery for Transgender Minors,* (N.Y. Times June 28, 20240, https://www.nytimes.com/2024/06/28/health/transgender-surgery-biden.html?pvid+kwDIVPqfjXyF_P9pkx7qMxSW&smid=url-share. This latter statement contrasts with the HHS "fact sheet" which states the "gender-affirming surgeries" are "typically used in adulthood or case-by-case- in adolescence. *Gender Affirming Care*, *supra* at 39-40, opa.hhs.gov.

("DSM-5") at 515. The Rule radically changes the law in Florida, as a matter of medicine and expense, concerning the treatment of gender dysphoria in minors. Yet the predominant psychiatric disorder "guidebook," DSM-5, tells us that "[n]o general population studies exist of adolescent or adult outcomes of childhood gender variance." *Id.* at 516.

After counseling, the starting point for physical intervention in the "gender affirming care" regimen for minors is puberty blockers, often followed by cross-sex hormones, meaning supra-physical doses of testosterone for transitioning natal females, and estrogen for transitioning natal males. The Food and Drug Administration has *never* approved any of these drugs as "safe and effective" for these treatments. The reason why is that studies about these pharmaceuticals in this application lack full, hard scientific rigor. The entire gender-transition drug regimen, is "off label." Off label drug use generally is not illegal and not infrequent, but before an entire formulary and medical practice in Florida is involuntarily devoted to off-label drugs, perhaps a pause to study these merits is in order.

When the FDA regulates a drug "on-label," that assurance means the FDA has conducted or supervised sufficient testing to determine that the drug is safe for its intended use. *See Food & Drug Admin. v. Brown & Williamson Tobacco Corp.* 529 U.S. 120, 142 (2000). This has not occurred with puberty blockers or cross-sex hormones used for gender dysphoria or transition. The FDA in 2022 required a

warning label on one GnRH agonist used as an off-label transition puberty blocker; this drug may cause or correlate to the brain disorder pseudotumor cerebri (idiopathic intercranial hypertension) in minor females. The Food and Drug Administration, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonists* (2022), https://publications.aap.org/aapnews/news/20636/Risk-of-pseudotumor-cerebri-added-to-labeling-for?autologincheck=redirected (last consulted Jul. 1, 2024).

Off-label use of drugs bypasses the consumer safety and efficacy purpose of the FDA approval process and is nearly impossible to track. New or novel off label use, such as would be imposed by the Rule, is unlikely to be supported by strong, hard scientific evidence, because such use has not undergone extensive clinical phase trials that would ordinarily be required for such use. *See generally* Gail A. Van Norman, *Off-Label Use vs Off-Label Marketing of Drugs: Part 1: Off-Label Use—Patient Harms and Prescriber Responsibilities,* 8 J. Am. Coll. Cardiol Basic Trans. Science 224–233 (Feb. 8, 2023), https://www.jacc.org/doi/full/10.1016/j.jacbts.2022.12.011 (last visited Jul. 1, 2024).

HHS's present view on "gender affirming care" is far from shared by other medical authorities. And the science seems to be trending the other way. *See also*

Labrador v. Poe, supra (reinstating most of the Idaho law barring transition medicine for minors).

If the British National Health Service ("NHS") were subject to the HHS Rule, the NHS would be in violation, as the NHS has stopped new, non-experimental prescriptions for puberty blockers for minor gender transition throughout the U.K., and indefinitely in England. Department of Health and Social Care, *New Restrictions on Puberty Blockers* (2024), https://www.gov.uk/government/news/new-restrictions-on-puberty-blockers?ref=world-weary.com (last consulted Jun. 29, 2024). This bar comes on the heels of a peer-reviewed survey entitled the "Cass Report," which reported on the scarce evidence showing puberty suppression was safe and effective for gender transition and further considering the scarce evidence and questionable safety and efficacy of cross-sex hormone treatment. Hilary Cass, *Independent Review of Gender Identity Services for Children and Young People* (2024), https://cass.independent-review.uk/home/publications/final-report/ (last consulted Jun. 29, 2024). Other authorities expressing doubts about the efficacy of

such treatments include Sweden,[13] Finland,[14] France,[15] and Australia/New Zealand.[16]

The reason for these concerns appears that, despite statements to the contrary, the science behind these programs is reasonably disputed, and does not appear to be yet proven to anywhere near a medical certainty. One example is a recent survey that the undersigned asked all counsel to comment upon: Jonas F. Ludvigsson *et al.*, *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and*

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[13] Sweden's National Board of Health and Welfare determined that "the risks of puberty blockers and gender-affirming treatment are likely to outweigh the expected benefits of these treatments," and determined that "[t]reatment with GnRH analogues, gender-affirming hormones, and mastectomy can be administered" only "in exceptional cases." Exhibit DX8 at 3, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-8); National Board of Health and Welfare, *Care of Children and Adolescents with Gender Dysphoria, Summary of National Guidelines December 2022* (2022), https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2023-1-8330.pdf (last visited June 26, 2022).

[14] Finland's Council for Choices in Healthcare urged extreme caution when providing gender transitioning services to children. It says that "[t]he reliability of the existing studies with no control groups is highly uncertain, and because of this uncertainty, no decisions should be made that can permanently alter a still-maturing minor's mental and physical development." Exhibit DX9 at 7, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-9); Council for Choices in Healthcare in Finland, *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf (last visited June 26, 2022).

[15] [The French National Academy of Medicine] concludes that "great medical caution" must be taken "given the vulnerability, particularly psychological, of this population [of younger people presenting with gender dysphoria] and the many undesirable effects, and even serious complications, that some of the available therapies can cause." Exhibit DX13 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-13); French National Academy of Medicine, *Medicine and Gender Transidentity in Children and Adolescents* (2022), https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en (last visited June 26, 2022).

[16] The Royal Australian and New Zealand College of Psychiatrists has said that there's a "paucity of evidence" on the outcomes of those presenting with gender dysphoria. Exhibit DX14 at 1, *Dekker v. Weida*, No. 4:22-cv-325-RH-MAF (N.D. Fla. 2023) (ECF No. 193-14).

Recommendations for Research, 112 Acta Paediatrica (Apr. 17, 2023), https://onlinelibrary.wiley.com/doi/10.1111/apa.16791 (last visited Jul. 1, 2024) ("Ludvigsson"). *See* Dkt. 38. Defendants dispute the value of the study, but its findings are worthy of a merits-based inquiry and full record.

Ludvigsson surveyed the major databases and identified nearly 10,000 potentially germane studies. After screening, 24 were found to be timely (within the last decade) and appropriate for further analysis. Dkt. 38 at 3. Eight address the use of puberty blockers, three addressed the use of cross-sex hormones, and the remainder addressed both. The results[17] appear to show how sparse the *actual hard*

[17] Ludvigsson concluded there was insufficient evidence to assess the therapeutic effects of hormone treatments on children with gender dysphoria. Ludvigsson at 2280. Studies that examined mental health outcomes suggested an improvement in global function and self-reported quality of life for children receiving puberty blockers, but no change in suicidal ideation, depression, or anxiety. *Id*. at 2286 & tbl. 2. Notably, the studies showed no change in children's experience of gender dysphoria following hormone treatment. *Id*. Other studies showed, albeit with low certainty, that puberty blockers slow bone densification in growing children, with mixed data on whether later CHST accelerates densification sufficiently to fully compensate. *Id*. at 2286–88 & tbl. 3. Ludvigsson emphasized that study weaknesses limit the conclusions that can reliably be drawn. None of the twenty-four studies were randomized controlled trials, the gold-standard in evidence-based clinical practice. *Id*. at 2287; *see*, *e.g.*, NIH, *Clinical Research: Benefits, Risks, and Safety*, https://www.nia.nih.gov/health/clinical-trials-and-studies/clinical-research-benefits-risks-and-safety ("The gold standard for testing interventions in people is called a randomized controlled trial"); E. Hariton & J.J. Locascio, *Randomized controlled trials—the gold standard for effectiveness research*, 125 BJOG 1635 (Dec. 2018), https://doi.org/10.1111/1471-0528.15199. Data related to mental health outcomes was such poor quality that the certainty of the evidence could not be assessed. *Id*. at 2282, 2286 tbl.2. The studies' short time frames (generally less than four years) and methodologies did not permit assessment of long-term outcomes or separation of psychological treatment effects. *Id*. at 2282, 2288. And analyses were performed at a group-level when assessing an individual over time would be more appropriate. *Id*. at 2288.

Ludvigsson's analysis is consistent with other independent, systematic reviews, which have similarly concluded that the evidence of benefit of medical gender transition in minors weak, while the evidence of harm is clear. *See id*. at 2290; Expert Report of Stephen B. Levine 51–52 (Feb. 23, 2022), HHS-OS-2022-0012-68192/attachment_12 at 165–66,

evidence is that lies behind the "gender affirming care" regimen that HHS embraces and for which the Final Rule compels availability in Florida.

One recent study (2024) of puberty suppression for gender dysphoria concluded:

> "In mammals, the neuropsychological impacts of puberty blockers are complex and often sex specific….There is no evidence that cognitive effects are fully reversible following discontinuation of treatment. No human studies have systematically explored the impact of these treatments on neuropsychological function with an adequate baseline and follow up. There is some evidence of a detrimental impact of pubertal suppression on IQ in children."[18]

The public interest favors a merits-based inquiry to address these matters.

III. The Court denies the Catholic Medical Association's Petition

The Catholic Medical Association is a group of some 2500 health professionals across the nation practicing the healing arts. CMA petitioned here for an injunction, which is denied. Without need to opine on CMA's representational standing, the Court simply believes that a nationwide injunction to cover all CMA members is improvident in this case for jurisprudential reasons. The CMA may

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https://www.regulations.gov/comment/HHS-OS-2022-0012-68192 at attachment 12 (last consulted Jul. 1, 2024). Even proponents acknowledge the health risks associated with gender transition in minors and the limited data addressing its safety and efficacy. These scientific assessments have led other countries to restrict, not expand, minors' access to medical gender transition.

[18]S. Baxendale, *The Impact of Suppressing Puberty on Neuropsychological function: A Review*, 113 Acta Paediatrica, (Feb. 9, 2024), https://onlinelibrary.wiley.com/doi/full/10.1111/apa.17150 (last visited Jul. 1, 2024).

remain in the case for the merits determination, and its Florida members will certainly be covered by this injunction.

First, the Court does not know who the CMA members are. Generally judges prefer to adjudicate disputes between the parties presenting before them. Although the Court has the power under Fed. R. Civ. P. 65 to enter such an injunction, how that rule intersects, if at all, with possible class action status under Rule 23 is now unclear. Also, a judge must not issue an injunction if he or she cannot enforce it. If, perchance, a CMA member in Oregon were told by her hospital administrator to follow the Final Rule in its entirety based upon Ninth Circuit precedent, enforcement of the undersigned's injunction could be problematic.

Much of this present injunction is based on the likely illegality of the Final Rule under the two specific Eleventh Circuit holdings discussed above. Those rulings do not bind outside of the Eleventh Circuit.

Several Supreme Court justices have recently criticized the modern spate of nationwide or universal injunctions from District Courts. *See, e.g., Labrador v. Poe*, 144 S. Ct. at 921, 925. The Eleventh Circuit has counseled similarly. *Georgia v. President*, 46 F.4th at 1304. Those admonitions seem condign: A nationwide injunction issuing from a District Court ought to be the rare exception, not routine.

CONCLUSION

Accordingly, it is hereby **ORDERED** and **ADJUDGED:**

(1) Plaintiffs' Motion for Stay and Preliminary Injunction (Dkt. 12) is **GRANTED** within Florida only.

(2) Pending trial on the merits, the Final Rule entitled "Nondiscrimination in Health Programs and Activities," Final Rule, 89 Fed. Reg. 37,522 (May 6, 2024) is stayed in part, in Florida. The effective date of 45 C.F.R. §§92101(a)(2)(iv), 92.206(b), 92.207(b)(3)-(5), 42 C.F.R. § 438.3(d)(4) is postponed pending the disposition of the complaint on the merits. 5 U.S.C. § 705. For the duration of this Order, an assurance of compliance with Part 92, *see* 45 C.F.R. § 92.5, shall not be construed to assure compliance with any provisions stayed by this Order.

(3) Defendants are preliminarily enjoined from instituting or pursuing any enforcement proceedings under Section 1557, 42 U.S.C. § 18116(a), based on the interpretation of discrimination "on the basis of sex" to be codified at 45 C.F.R. § 92.101(a)(2)(iv), 92.206(b), or 92.207(b)(3)-(5).

(4) This Order runs throughout the State of Florida, applying to all Plaintiffs, including the State of Florida, the Florida Agency for Health Care Administration, the Florida Department of Management Services, and their agents, agencies, contractors, and instrumentalities. Further, all

covered entities within Florida are covered by this stay and injunction.

(5) The Court waives any bond requirement found at Fed. R. Civ. P. 65(e). *City of Atlanta v. Metropolitan Atlanta Transp. Auth.*, 636 F.2d 1084, 1094 (5th Cir. Unit B 1981).

DONE AND ORDERED at Tampa, Florida, July 3, 2024.

/s/ William F. Jung
WILLIAM F. JUNG
UNITED STATES DISTRICT JUDGE