IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

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

Plaintiffs,

No. 8:24-cv-1080

DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as the Director of the Office for Civil Rights; CENTERS FOR MEDICARE AND MEDICAID SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid,

Defendants.

COMPLAINT FOR DECLARATORY RELIEF AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF

INTRODUCTION

1. Under the guise of federal non-discrimination rules, the Department of Health and Human Services ("HHS") seeks to redefine the practice of medicine. HHS's rules threaten the livelihood of doctors who refuse to provide experimental, sterilizing, "gender-change" interventions to persons suffering from psychological distress—including minor children. To do so, HHS purports to override the State of

Florida's laws and regulations protecting the health and safety of its residents. HHS further threatens the loss of federal funds for States and insurance issuers that refuse to cover these interventions. Plaintiffs bring this action to stop HHS's interference with the ethical practice of medicine and state police powers.

2. Section 1557 of the Affordable Care Act ("ACA") forbids covered entities, including States, from discriminating in health programs or activities "on the ground prohibited under … title IX of the Education Amendments of 1972." 42 U.S.C. § 18116(a). Title IX, in turn, prohibits discriminating "on the basis of sex." 20 U.S.C. § 1681(a).

3. On May 6, 2024, HHS and the Centers for Medicare and Medicaid Services ("CMS") promulgated rules purporting to implement Section 1557 (collectively, the "2024 Rules"). 89 Fed. Reg. 37,522 (May 6, 2024).

4. But the 2024 Rules go far beyond the limits of Section 1557 and Title IX. The 2024 Rules require Florida to allow and even fund drugs and surgeries for "gender-transition." The 2024 Rules do this through a series of missteps that are foreclosed by logic and Eleventh Circuit precedent.

5. First, the 2024 Rules define "[d]iscrimination on the basis of sex" to include discriminating based on "(i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). Despite this, HHS claims "it is not necessary to define 'sex' in this rule." 89 Fed. Reg. at 37,575.

6. Second, the 2024 Rules make it presumptively discriminatory for covered hospitals, clinics, residential treatment centers, medical practices, and pharmacies to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender transition," if covered entities provide those services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4). For example, under the final rule, a gynecological surgeon who performs a hysterectomy to treat endometrial cancer is presumptively required to remove a healthy uterus for a "gender transition." *Id.*; *see also* Notice of Proposed Rulemaking ("NPRM"), 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022).

7. A medical practice that refuses to assist a gender transition may avoid sanctions if HHS's Office for Civil Rights ("OCR") deems a refusal "clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added). OCR will review "medical necessity standards or guidelines" to ensure a clinical or ethical judgment is "bona fide" in a particular case, and not pretextual. 89 Fed. Reg. at 37,613.

8. Repeatedly, however, HHS emphasizes that covered entities must make an "*individualized* clinical judgment" for gender-change interventions. *Id.* at 37,575, 37,595–97 (emphasis added). OCR will review a "non-categorical denial[]" of a gender-change intervention "on a case-by-case basis." *Id.* at 37,607. The implied threat is clear: Any medical provider that categorically refuses to follow OCR's preferred "standards or guidelines" of care—*i.e.*, gender transition—risks crippling enforcement proceedings and punishment.

9. Third, on top of this, the 2024 Rules force States and insurance issuers to subsidize gender transitions. The 2024 Rules make it presumptively illegal for covered insurance providers and other entities—including States administering HHS programs such as ACA health-insurance exchanges, Medicaid, and a Childrens Health Insurance Program ("CHIP")—to set "limitations or restrictions" on claims "for specific health services related to gender transition" if doing so "results in discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5). Again, under the 2024 Rules, sex discrimination includes discriminating based on "gender identity," and does not distinguish between providing a service for one purpose as opposed to another. *Id.* at 37,699, 37,701. An insurer that covers a hysterectomy to treat endometrial cancer is presumptively required to cover the removal of a healthy uterus for a "gender transition."

10. An insurance issuer or a State may avoid sanctions by showing no "medical necessity" for a gender-transition intervention in a particular case. But the 2024 Rules prohibit a "categorical coverage exclusion … for all health services related to gender transition." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4), (c). In other words, HHS has already determined that "gender transition" is medically necessary and that disagreeing with HHS is a pretext for discriminating on the basis of sex. Indeed, according to HHS, merely referring to gender-change interventions as "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical care." NPRM, 87 Fed. Reg. at 47,874.

11. HHS's attempt to mandate gender-transition interventions and force States to subsidize the cost is unlawful under binding Eleventh Circuit precedent. To begin, the meaning of "sex" under Section 1557 extends no further than "sex" in Title IX. *See* 89 Fed. Reg. at 37,638 (admitting that "Section 1557 is best read to incorporate existing interpretations of what constitutes sex discrimination under title IX, including regulatory interpretations and case law"). In *Adams v. School Board of St. Johns County*, the Eleventh Circuit held that "sex" in Title IX *unambiguously* means "biological sex," *not* "sexual orientation" or "gender identity," 57 F.4th 791, 812–15 (11th Cir. 2022) (en banc).

12. Moreover, under *Adams*, the prohibition against discriminating "on the basis of sex" in Title IX must be read to permit some sex-based differences—including separate living facilities and bathrooms. *Id.* at 814 (citing 28 U.S.C. § 1686; 34 C.F.R. § 106.33). But reading Title IX to protect "'gender identity,' as [HHS does], would result in situations where an entity would be prohibited from" separating living facilities such as dual-occupancy hospital rooms based on sex whenever that comes "into conflict with a transgender person's gender identity." *Id.* That is wrong, and it is foreclosed by *Adams*. *Id.* "Whether [Section 1557] should be amended to equate 'gender identity' and 'transgender status' with 'sex'"—therefore—"should be left to Congress"—not an unelected administrative agency. *Id.* at 817. By purporting to do what may be done *only* by Congress, the 2024 Rules exceed HHS's statutory authority under Section 1557.

13. Further, a refusal to provide or subsidize these treatments is not "discrimination" anyway. 42 U.S.C. § 18116. *See Discriminate*, Webster's Third New International Dictionary 648 (1976) ("to make a difference in treatment or favor on a class or categorical basis in disregard of individual merit"); *Discrimination*, Black's Law Dictionary 534 (9th ed. 2009) ("failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored"). Refusing to provide interventions to anyone because of doubts about medical efficacy or ethical misgivings is not treating transgender individuals differently at all, much less on the basis of sex.

14. In medicine, therapeutic purpose matters. Removing organs with cancer is not "to [a doctor's mind], materially identical in all respects" to removing a healthy organ for a gender transition. *Bostock v. Clayton Cnty.*, 590 U.S. 644, 660 (2020). It is therefore not discriminatory for a State to prohibit interventions based on a clinical or ethical judgment that those interventions are not safe and effective or ethical to treat gender dysphoria, while allowing those interventions to treat materially *different* health conditions such as cancer.

15. HHS's false equivalency across treatments with different therapeutic purposes is foreclosed by logic and at odds with binding precedent. The Eleventh Circuit has held that a State does not discriminate or stereotype "on the basis of sex" (the exact same words used in Title IX) when it categorically forbids hormonal treatments or the removal of healthy organs for a gender transition. *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205, 1227–30 (11th Cir. 2023) (Equal Protection Clause);

see id. at 1233–34 (Brasher, J., concurring). By ignoring material differences in therapeutic purpose, the 2024 Rules would fundamentally redefine the practice of medicine and place OCR lawyers in the strange position of overseeing—and second-guessing—the clinical and ethical judgments of health care professionals and state medical boards across the country.

16. Section 1557 is an ordinary non-discrimination law, not a Trojan horse empowering OCR to play doctor and decree gender-transition interventions as the federal standard of care through threats of enforcement. Because the 2024 Rules are unauthorized by law, violate the clear-notice requirements of the Spending Clause, raise major questions and usurp traditional police powers without clear authority, fail to grapple with contrary evidence showing gender-transition interventions are not safe and effective, and depart from prior agency positions without explaining or considering reliance interests, this Court must set aside the 2024 Rules as contrary to law and arbitrary and capricious.

PARTIES

17. Plaintiff State of Florida is a sovereign State and has the authority and responsibility to protect its public fisc and the health, safety, and welfare of its citizens. Florida has the sovereign authority to regulate the practice of medicine within the State, promulgate standards of care for licensed physicians, determine what medical procedures are reasonable for purposes of Medicaid coverage, and decide what services and procedures should be covered by its employee health insurance policies. Florida has agencies and healthcare facilities that receive federal financial assistance

and participate in HHS health-related programs subject to Section 1557 and the 2024 Rules.

18. Ashley Moody, the Attorney General of Florida, has authority to sue in the name of the State. *See* Fla. Stat. § 16.01(4)–(5). That power is incredibly broad, and includes the power to vindicate injuries to the State at any governmental level. *See, e.g.*, *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1030 (M.D. Fla. 2021) (finding standing based on an injury to a state university); *Florida v. Becerra*, 544 F. Supp. 3d 1241, 1253–54 (M.D. Fla. 2021) (finding standing based on injuries to political subdivisions of the State).

19. Plaintiff Florida Agency for Health Care Administration ("AHCA") administers Florida's Medicaid and CHIP programs and assists CMS in regulating facilities that participate in Medicare. Exhibit 1, Kniepmann Decl. ¶¶ 1–2 ("Ex. 1").

20. Plaintiff Florida Department of Management Services ("DMS") is the business arm of Florida's government. DMS's primary mission is to support sister agencies as well as current and former state employees with workforce and business-related functions, including the provision of State Group Insurance. Exhibit 2, Sanders Decl. ¶ 3 ("Ex. 2").

21. Plaintiff Catholic Medical Association ("CMA") is the largest association of Catholic individuals in healthcare. CMA has 2,500 members nationwide in all fields of practice. CMA has a Florida statewide guild called the Florida Catholic Medical Association. CMA also has seven local Florida guilds, which are located in Gainesville, Miami, Orlando, Jacksonville, Palm Beach, Pensacola, and

St. Petersburg/Tampa Bay. CMA's 2024 national conference will be held in Orlando, Florida, as was CMA's 2021 national conference. CMA is organized as a Virginia nonprofit corporation.

22. Most CMA members provide medical care in health programs and activities that receive federal financial assistance and are subject to Section 1557. CMA seeks relief on behalf of its current and future members for all aspects of their practices.

23. CMA and its members hold the position that gender-transition procedures are unethical and dangerous. Providing, facilitating, referring for, or endorsing gender-transition efforts violates their medical views, their core religious beliefs, and their oath to "do no harm." CMA's members have medical and ethical positions contrary to the 2024 Rules' requirements, and they also have overlapping religious objections. It is within CMA's advocacy mission to advocate and litigate for its members' right to the conscientious and faithful practice of medicine.

24. The Executive Director of CMA is Mario Dickerson. Additional facts about CMA's membership are set forth in Mr. Dickerson's attached declaration ("Ex. 3") and in attached declarations from representative CMA members Dr. Michael S. Parker of Mansfield, Ohio ("Ex. 4"), and Dr. Quentin L. Van Meter of Atlanta, Georgia ("Ex. 5"). CMA's members are similarly situated to Drs. Parker and Van Meter.

25. Defendant Department of Health and Human Services is the agency of the United States that promulgated and now enforces the 2024 Rules.

26. Defendant Xavier Becerra is the Secretary of the Department of Health and Human Services. Plaintiffs sue Defendant Becerra in his official capacity only.

27. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights within HHS and now enforces the 2024 Rules. Plaintiffs sue Defendant Fontes Rainer in her official capacity only.

28. Defendant Centers for Medicare and Medicaid Services is an agency within HHS.

29. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Plaintiffs sue Defendant Brooks-LaSure in her official capacity only.

JURISDICTION AND VENUE

30. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1346, and 1361.

31. Plaintiffs are "entitled to judicial review" under 5 U.S.C. § 702.

32. The Court is authorized to award the requested declaratory and injunctive relief against Defendants under 5 U.S.C. §§ 703, 706, 28 U.S.C. §§ 1361, 2201–02, the Constitution, and the Court's equitable powers.

33. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412, and the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 1988(b).

34. Venue is proper under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a Defendant, and Plaintiff the State of Florida is a resident of every judicial district and division in its sovereign territory, including this judicial district

and division. *See Florida v. United States*, No. 3:21-cv-1066, 2022 WL 2431443, at *2 (N.D. Fla. Jan. 18, 2022) ("It is well established that a state 'resides at every point within its boundaries.'" (alteration omitted) (quoting *Atlanta & F.R. Co. v. W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892))); *see also California v. Azar*, 911 F.3d 558, 569–70 (9th Cir. 2018) ("[A] state with multiple judicial districts 'resides' in every district within its borders."); *Utah v. Walsh*, No. 2:23-cv-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023) ("Texas resides everywhere in Texas."); *Alabama v. U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005) ("[C]ommon sense dictates that a state resides throughout its sovereign borders.").

LEGAL BACKGROUND

I. The Affordable Care Act and Title IX

35. In March 2010, Congress passed, and President Obama signed, the ACA. Pub. L. No. 111-148, 124 Stat. 119.

36. Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under … title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) … be excluded from participating 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, or under any program or activity that is administered by an Executive agency or any entity established under [the ACA]." 42 U.S.C. § 18116(a).

37. Section 1557 does not reference sexual orientation or gender identity. Its sole basis for prohibiting sex discrimination is a cross-reference to "the ground prohibited under … title IX (20 U.S.C. 1681 et seq.)."

38. Title IX states: "No 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).

39. That general prohibition includes several sex-specific limitations and rules of construction. *Id.* Section 1686, for example, provides that nothing in Title IX "shall be construed to prohibit … maintaining separate living facilities for the different sexes." 20 U.S.C. § 1686.

40. Title IX furthermore does not apply to covered entities "controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." 20 U.S.C. § 1681(a)(3).

41. Section 1554 of the ACA provides that "notwithstanding 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).

42. Section 1557 applies to what HHS calls "covered entities," which includes recipients of federal financial assistance programs such as Medicaid and CHIP. Covered entities include hospitals, clinics, and doctors that accept patients

paying for services through these financial assistance programs, as well as pharmacies and insurance issuers.

43. An entity "any part of which" participates in HHS financial assistance programs is subject in all aspects of its health programs and activities to Section 1557. *Id.* § 18116(a). That means that any hospital or doctors' office that accepts a single Medicaid or CHIP patient must follow Section 1557 for *all* its patients, no matter how other patients pay for care.

44. The ACA incorporates Title IX's public and private enforcement mechanisms for Section 1557 and HHS's implementing regulations. 42 U.S.C. § 18116(a).

45. If OCR finds a covered entity in noncompliance, HHS may require providers to take remedial action or lose federal funding.

46. Section 1557 allows members of the public to sue covered entities to require compliance and seek damages. *See Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 218 (2022).

II. Prior 1557 Rules, Guidance, and Related Litigation

A. The 2016 Rules

47. On May 18, 2016, HHS published rules purporting to implement Section 1557. Those rules defined discriminating "on the basis of sex" to include discriminating against an individual "on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical

conditions, sex stereotyping, and gender identity." 81 Fed. Reg. 31,376, 31,467 (May 18, 2016). HHS defined the term "gender identity" in that rule as "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth." *Id.* at 31,467.

48. On December 21, 2016, the U.S. District Court for the Northern District of Texas vacated the 2016 rules and enjoined HHS from "enforcing the [rules] prohibition against discrimination on the basis of gender identity or termination of pregnancy." *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). On gender identity, the Court reasoned that "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical difference between male and female students as determined at their birth.'" *Id.* at 687. It then held that "HHS's expanded definition of sex discrimination exceeds the grounds incorporated by Section 1557." *Id.* at 689.

49. The Court's vacatur of the 2016 rules remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022) ("In short, Franciscan Alliance's APA claim is moot, its RFRA claim is not, and we leave the district court's vacatur of the 2016 Rule in effect."); *see also Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 609 (8th Cir. 2022) ("affirm[ing] the district court's grant of permanent injunctive relief against a requirement to provide 'gender-transition procedures' under Section 1557 on the ground that it violates the Religious Freedom Restoration Act").

B. The 2020 Rules

50. On June 12, 2020, HHS issued new rules rescinding the 2016 rules. 85 Fed. Reg. 37,160 (June 19, 2020) (the "2020 Rules").

51. The 2020 Rules repealed HHS's expansive definition of "on the basis of sex" and relied instead on the self-executing text of Section 1557, which speaks for itself. It also recognized the applicability of Title IX's religious exemption.

52. On June 15, 2020, three days after HHS issued its new rules, the U.S. Supreme Court decided *Bostock v. Clayton County*, 590 U.S. 644 (2020).

53. *Bostock* interpreted Title VII of the Civil Rights Act of 1964, which prohibits employers from discriminating "because of … sex." 42 U.S.C. § 2000e-2(a)(1). The Court in *Bostock* "proceed[ed] on the assumption that 'sex'" refers "only to biological distinctions between male and female." *Bostock*, 590 U.S. at 655. The Supreme Court then interpreted the text of Title VII to mean that "[a]n employer violates Title VII when it intentionally fires an individual employee based in part on sex." *Id.* at 659. "If the employer intentionally relies in part on an individual employee's sex when deciding to discharge the employee—put differently, if changing the employee's sex would have yielded a different choice by the employer—a statutory violation has occurred." *Id.* at 659–60.

54. Applying that rule to employers who fired their employees solely on the basis of the employee "being homosexual or transgender," the Supreme Court held the employers could be liable under Title VII. As the Court explained, when an employer fires a man who identifies as a woman solely for "traits or actions" it

tolerates in a female colleague, the employees "are, to the employer's mind, materially identical in all respects, except that one is a man and the other a woman." *Id.* at 660. The Court reasoned that biological sex is, therefore, a but-for cause of the employees' disparate treatment.

55. The Court, however, made clear its decision was limited to employment discrimination under Title VII. "The employers worry that our decision will sweep beyond Title VII to other federal or state laws that prohibit sex discrimination. … But none of these other laws are before us, we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today." *Id.* at 681.

56. After *Bostock*, "[t]wo courts entered nationwide injunctions preventing much of the 2020 Rule[s] from going into effect, effectively reinstating portions of the 2016 Rule[s]," even though the 2016 rules had already been vacated. *Franciscan All.*, 47 F.4th at 372 (citing *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60 (D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020)). These courts concluded that, "in light of *Bostock*, sex-stereotyping discrimination encompasses gender identity discrimination." *Id.* at 372–73.

C. The 2021 and 2022 Notices

57. The day he was sworn into office, President Biden issued an executive order asserting that "laws that prohibit sex discrimination … prohibit discrimination

on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

58. On May 25, 2021, pursuant to this executive order, HHS published a document titled "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). The May 2021 notice announced that "consistent with the Supreme Court's decision in *Bostock* and Title IX," HHS would "interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Id.* at 27,984.

59. Shortly thereafter a group of physicians challenged the notification on the grounds that it would force them to treat youth suffering from gender dysphoria in a manner that violated their clinical judgment and conscience. *Neese v. Becerra*, No. 2:21-cv-163-Z, 2022 WL 16902425, at *1–2 (N.D. Tex. Nov. 11, 2022). The U.S. District Court for the Northern District of Texas found the Notification to be "not in accordance with the law." *Id.* at 3. The Court entered a declaratory judgment declaring that "Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of 'sex' discrimination that the Supreme Court of the United States adopted in [*Bostock*] is inapplicable to the prohibitions on 'sex' discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA." Final Judgment, *Neese*, 2:21-cv-163-Z (N.D. Tex. Nov. 22, 2022), ECF No. 71.

60. In March of 2022, HHS published another document titled "Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy," https://perma.cc/LX26-59QR ("2022 Notice"). The 2022 Notice asserted that HHS "unequivocally" takes the position that restricting gender-change interventions even "for minors … is dangerous." HHS announced that its Office of Civil Rights would consider bringing enforcement actions against medical providers who comply with state laws that "restrict" the use of these interventions for minors. HHS also claimed that refusal to provide these interventions could be discriminating on the basis of disability. *Id.*

61. In *Texas v. Equal Employment Opportunity Commission*, the U.S. District Court for the Northern District of Texas vacated the 2022 Notice. 633 F. Supp. 3d 824, 847 (N.D. Tex. 2022). Among other things, the Court held that the 2022 Notice misread *Bostock*, and did not adequately explain how, despite the specific exclusion of gender identity disorders from the definition of disability in the Rehabilitation Act (and hence in Section 1557, *see* 42 U.S.C. § 18116(a) (including "section 794 of title 29"), failure to provide cross-sex hormones or surgeries to these individuals could be discriminating on the basis of a disability. *Id.* at 836–38.

FACTUAL BACKGROUND

I. Sex, Gender Dysphoria, and "Gender-Change" Interventions

A. Sex and Gender

62. As the Supreme Court and the Eleventh Circuit have observed, "sex … is an immutable characteristic." *Adams*, 57 F.4th at 807 (quoting *Frontiero v. Richardson*,

411 U.S. 677, 686 (1973) (plurality opinion)); *see also* Expert Report of Stephen B. Levine 8 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192.

63. Sex, therefore, is not arbitrarily "assigned at birth," as HHS's terminology implies. Rather, an individual's sex is male or female "according to [the individual's] reproductive organs and functions assigned by the chromosomal complement." Inst. of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter* 13 n.2 (2001) (*Does Sex Matter*); Levine, *supra*, at 8–9 (same); *see also* Fla. Stat. § 456.001(8) ("'Sex' means the classification of a person as either male or female based on the organization of the human body of such person for a specific reproductive role, as indicated by the person's sex chromosomes, naturally occurring sex hormones, and internal and external genitalia present at birth."); *Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male, by which most organisms are classified on the basis of their reproductive organs and functions.").

64. Sex should not be confused with "gender," which is increasingly understood by some to mean a person's "self-perception" as male, female, or perhaps something else. *Does Sex Matter*, *supra*, at 13 n.2. HHS, for example, claims that gender identity may be female, male, both, somewhere in between, or neither. 81 Fed. Reg. at 31,467. Unlike sex, gender cannot be reliably determined by inspecting reproductive organs or genetic testing. And unlike sex, gender is not an immutable characteristic. A person's gender identity may change over time.

65. Sex begins in the cells and the womb before anyone writes a birth certificate. "With some exceptions, individuals are either chromosomally XX and developmentally female or chromosomally XY and developmentally male." *Does Sex Matter*, *supra*, at 17. "It is the overriding presence of a gene on the Y chromosome (SRY) that results in development of the male gonadal pathway." *Id.* at 33. The testes start developing "by the 6th to 7th week of gestation." *Id.* at 55. By the 12th to 14th week, "male and female fetuses can be distinguished by inspection of the external genitalia." *Id.* at 61.

66. Physical differences between boys and girls become pronounced during puberty. This process of sexual maturation and growth is "primarily the consequence of testosterone secretion by the Leydig cells in boys and of estrogen secretion by the granulosa cells in girls." *Id.* at 66; *see also Adams*, 57 F.4th at 819–20 (Lagoa, J., specially concurring) (discussing some of the significant physical differences that develop during puberty).

67. Some individuals are born with disorders of sex development. These disorders may result in physiological traits that are inconsistent with chromosomal sex, and, in rare cases, a body that cannot be classified as male or female. These individuals are sometimes labeled "intersex." *See Adams*, 57 F.4th at 822–23 (Wilson, J., dissenting) (discussing "intersex people"). The prevalence of intersex individuals has been estimated at 1 in 5,000 per live birth. Leonard Sax, *How Common is Intersex? A Response to Anne Fausto-Sterling*, 39 J. Sex Res. 174 (2002). Intersex traits are caused

by congenital chromosomal, genetic, or hormonal abnormalities that prevent normal sexual development. *See* Levine, *supra*, at 9.

B. Gender Dysphoria

68. The American Psychological Association previously defined an incongruence between sex and gender as a "gender identity disorder." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 71 (3d ed. 1987).

69. In 2013, the American Psychological Association discontinued the term "gender identity disorder" and defined the psychological condition now known as "gender dysphoria" as a discomforting or distressing discordance between a person's biological sex and sense of "gender identity." Am. Psych. Ass'n, *Diagnostic and Statistical Manual* 451–53 (5th ed. 2013).

70. Not all transgender individuals experience "dysphoria." *Id.*

71. Gender dysphoria, like gender, is not necessarily permanent. In children, gender dysphoria usually resolves as the child undergoes puberty, as the child's gender identity may change. This is why "watchful waiting" became the standard approach for treating gender dysphoria in minors. Levine, *supra*, at 17–19.

C. The "Gender-Change" Protocol

72. "What the medical profession has come to call gender-affirming care was not available for minors until just before the millennium." *L.W. v. Skrmetti*, 83 F.4th 460, 467 (6th Cir. 2023). Over the past decade or so, influential interest groups in the United States have advocated for treating gender dysphoria by "affirming" a child or

adult's sense of incongruence with sex through a protocol of social, chemical, and surgical interventions aimed at changing a patient's physical characteristics and behavior to accord with his or her sense of "gender." *Id.* These groups claim these interventions, often labeled "gender-affirming care," are medically necessary for many, including minors undergoing puberty, even though the treatments may lead to infertility and other serious side effects.

73. One of these groups is the World Professional Association for Transgender Health ("WPATH"), which publishes what it styles as "standards of care" for treating gender dysphoria in both children and adults. *See* WPATH, *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8, 23 Int'l J. of Transgender Health S1 (2022) ("WPATH 8"); WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012), HHS-OS-2022-0012-4074 ("WPATH 7").

74. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,186–87. For good reason. WPATH members must show a commitment to "transgender rights" and need not be medical professionals. Levine, *supra*, at 26. "Contrary viewpoints have been known to be shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings." *Id.*

75. According to WPATH, psychological treatment or counseling "aimed at trying to change a person's gender identity and expression to become more congruent with [biological sex] … is no longer considered ethical." WPATH 7, *supra*, at 16;

WPATH 8, *supra*, at S53 (same). WPATH's guidelines instead steer health care professionals into a gender-change regimen.

76. Another organization is the Endocrine Society, an association of endocrinologists that stand to benefit from an increase in the prevalence of hormone therapy. The Endocrine Society has published a guideline with recommendations for treating gender dysphoria in minors and adults. Although its recommendations "do not establish a standard of care" for gender dysphoria, the Endocrine Society claims hormonal and surgical interventions are medically necessary to treat many children as well as adults suffering from dysphoria. *See* Wyle C. Hembree, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 10 J. Clin. Endocrinol Metab. 3869, 3896 (2017), HHS-OS-2022-0012-4060 ("Endocrine Society Guideline").

77. The gender-change protocol embraced by these groups proceeds in four escalating steps: (1) social transition and mental health treatment, (2) puberty blockers, (3) cross-sex hormones, and (4) sex-reassignment surgery. Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142 Pediatrics 1, 6–7 (2018) (Adults who have gone through puberty don't need puberty blockers.).

78. For pre-pubescent children, the protocol begins with "social transition"—that is, usually, encouraging a child to adopt the stereotypical behaviors, clothing, and hairstyle associated with members of the opposite sex, and allowing the child to adopt a name and pronouns used by the opposite sex. *Id.* at 6.

79. During the onset of puberty, the next step is administering a long-acting GnRH analogue, commonly known as a puberty blocker, to suppress the child's normal puberty, and hence the child's normal physical and sexual development. *Id.*

80. Most minors administered a puberty blocker for gender dysphoria are then prescribed supraphysiological levels of "cross-sex" hormones—hormones associated with the physiological development of the opposite sex: Estrogen for males, and testosterone for females. Levine, *supra*, at 48–49.

81. The last step is "gender-reassignment" surgery. That can include a double mastectomy to remove healthy breasts, "bottom surgery" to remove the healthy reproductive organs of either sex, and plastic surgery and cosmetic procedures to imitate the genitals and the physical appearance of the opposite sex. *See* WPATH 7, *supra*, at 57; WPATH 8, *supra*, at S258, App'x E (listing the procedures in a list that "is not intended to be exhaustive").

82. Gender-reassignment surgery cannot reassign sex. It does not change an individual's chromosomes or replace sexual organs with the functioning reproductive organs of the opposite sex. Rather, bottom-surgery renders an individual permanently infertile.

83. The medical guidelines of WPATH and the Endocrine Society have become more aggressive over time. "Today, these guidelines permit the use of puberty blockers or cross-sex hormones from the early stages of pubertal development. Therapy or time spent living as the desired gender is no longer required before or along with such treatments. Many surgical treatments initially restricted to adults have

become available to minors in the past six years, often without any prerequisites for therapy or cross-sex hormone treatments." *L.W.*, 83 F.4th at 467–68 (citations omitted).

84. Diagnoses for gender dysphoria have simultaneously increased. "In the last few years, the number of doctors prescribing sex-transition treatments and the number of children seeking them have grown." *Id.* at 468. At the same time, "[t]he percentage of youth identifying as transgender has doubled from 0.7% of the population to 1.4% in the past few years, while the percentage of adults (0.5% of the population) has remained constant." *Id.*

D. Health Risks of the Gender-Change Protocol

85. Although groups such as WPATH and the Endocrine Society claim these gender-change interventions have psychological benefits, "no one disputes that these treatments carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489.

86. The FDA may approve the marketing of drugs as safe and effective to treat a condition based on "adequate and well-controlled investigations"—typically a double-blind, randomized, clinical trial. 21 U.S.C. § 355(d). The FDA has approved puberty blockers to rectify a hormonal imbalance in young children caused by precocious puberty, but it has not approved marketing these drugs as part of a regimen to treat gender dysphoria in minors or adults. The use of these drugs for that purpose is therefore "off-label."

87. As WPATH 7 acknowledged, "[t]o date, no controlled clinical trials of any feminizing/masculinizing hormone regimen have been conducted to evaluate safety or efficacy in producing physical transition." WPATH 7, *supra*, at 47. That remains true today.

88. Even supporters acknowledge that puberty blockers have health risks. The Endocrine Society, for example, acknowledges that the "primary risks of pubertal suppression" are "adverse effects on bone mineralization," "compromised fertility if the person subsequently is treated with sex hormones, and unknown effects on brain development." Endocrine Society Guideline, *supra*, at 3882.

89. Although little is known about the long-term effects of puberty blockers used for a gender transition on brain function and brain development, the FDA recently required drug manufacturers to warn that puberty blockers may cause "pseudotumor cerebri, including headache, papilledema, blurred or loss of vision, diplopia, pain behind the eye or pain with eye movement, tinnitus, dizziness and nausea." FDA, *Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonist* (July 1, 2022).

90. Cross-sex hormones such as testosterone and estrogen have not been approved by the FDA to treat gender dysphoria. (Testosterone is a Class III controlled substance because it "may lead to moderate or low physical dependence or high psychological dependence," so it is not available over the counter. 21 U.S.C. §§ 802(41), 812(b)(3)(C), (c), Schedule III(e)).

91. Cross-sex hormone interventions also have physical side effects and increase serious health risks. *See L.W.*, 83 F.4th at 489 (listing side effects and potential health risks in detail).

92. Giving adolescent girls the high doses of testosterone needed for a gender-change induces hyperandrogenism. According to WPATH 8, this causes "clitoral enlargement" (clitoromegaly), "vaginal atrophy" (atrophy of the vagina's lining), "deepening of the voice," "facial/body hair growth" (hirsutism), "acne," and "scalp hair loss." WPATH 8, *supra*, at S254, App'x C, Tbl. 1 (cleaned up); *see also* WPATH 7, *supra*, at 37 (similar).

93. According to WPATH 8, induced hyperandrogenism in adolescent girls also, at a minimum, increases the risk of "polycythemia" (bone marrow producing too many red blood cells, which increases the risk of blood clots and heart attacks), "infertility," "weight gain," "acne," "sleep apnea," "androgenic alopecia" (balding), "hypertension" (high blood pressure), "decreased HDL ['good'] cholesterol and increased LDL ['bad'] cholesterol," "cardiovascular disease," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), and possibly of "type 2 diabetes," among other health risks. WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 40 (similar).

94. Giving adolescent boys high doses of estrogen induces hyperestrogenemia. According to WPATH 8, this causes "breast growth" "decrease

in muscle mass and strength," "softening of skin/decreased oiliness," and various forms of sexual dysfunction.

95. According to WPATH 8, induced hyperandrogenism in adolescent boys also, at a minimum, increases the risk of "venous thromboembolism" (life-threatening blood clots), "infertility," "cholelithiasis" (gallstones), "hyperkalemia" (high potassium levels that cause life-threatening heartbeat abnormalities, muscle weakness, or paralysis), "meningioma" (a primary central nervous system tumor), "polyuria/dehydration" (increased urine production), "weight gain," "hypertriglyceridemia" (high levels of triglycerides (fats) in the blood, leading to plaque buildup in arteries (atherosclerosis) which can result in heart attacks, strokes, blood clots, and similar complications), "cardiovascular disease," "cerebrovascular disease" (affecting the blood flow and blood vessels in the brain), and possibly "hypertension" (high blood pressure), "erectile dysfunction," "type 2 diabetes," "low bone mass/osteoporosis" (leading to weak and brittle bones), and "hyperprolactinemia" (high levels of the hormone prolactin, causing infertility and other issues). WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (cleaned up); *see also* WPATH 7, *supra*, at 38, 40 (similar).

96. By suppressing sexual development during puberty, a cross-sex hormone regimen for minors will likely cause lifelong sterility. Levine, *supra*, at 67; WPATH 8, *supra*, at S254, App'x C, Tbl. 2 (warning of a "clinically significant" risk of infertility). That is why WPATH and the Endocrine Society recommend warning "adolescents" seeking gender-change interventions about the "potential loss of fertility and available

options to preserve fertility." WPATH 8, *supra*, at S57, S156–57 (discussing the risk of infertility from hormone interventions); Endocrine Society Guideline, *supra*, at 3871 (similar).

97. Bottom-surgery (the removal of healthy reproductive organs) also causes irreversible sterility. As WPATH acknowledges, the surgeries also lead to an increased risk of infection and other serious and potentially lifelong medical complications. WPATH 7, *supra*, at 62–64.

98. WPATH, the Endocrine Society, and other interest groups nevertheless claim the side effects and downsides of gender-change interventions, including infertility, are often outweighed by the purported benefits of reduced psychological distress resulting from gender dysphoria, improved mental well-being, and allegedly reduced suicide risk.

99. But the evidence available to date is not robust enough to conclude these hormones and surgeries increase long-term mental health outcomes, and persons with gender dysphoria continue to commit suicide at vastly disproportionate rates even after all these interventions. *See* Levine, *supra*, at 49–61.

100. Some experts believe this protocol may actually decrease mental wellbeing and increase suicide by, among other things, preventing desistance. Some believe it to be an unethical experiment on humans, particularly on minors. There is no universal consensus on these clinical or ethical questions, but one thing is clear: the evidence of benefit is weak at best, and the evidence of harm is clear. *See* Levine, *supra*, at 22–30; The Cass Review, *Independent Review of Gender Identity Services for Children and*

You People: Interim Report 47 (Feb. 2022), HHS-OS-2022-0012-4075 (finding no consensus); Comment of the Society for Evidence Based Gender Medicine (Oct. 3, 2022), HHS-OS-2022-0012-73218 (arguing that the empirical evidence of a benefit is weak and is outweighed by clear evidence of harm); Comment of Florida AHCA (Oct. 28, 2022), HHS-OS-2022-0012-69566 (same).

101. In other words, as the Fifth Circuit has observed, "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson v. Collier*, 920 F.3d 212, 221 (5th Cir. 2019).

102. National public health authorities have taken a variety of views on the safety and efficacy of this protocol.

103. Start with HHS. In 2016, during the Obama Administration, HHS refused to require national coverage of gender-reassignment surgeries under Medicare, concluding in a thorough review that "[b]ased on an extensive assessment of the clinical evidence …, there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." Tamara S. Jensen et al., Decision Memo, CAG #00446N (Aug. 30, 2016), https://perma.cc/R2ME-YQRA. "Overall, the quality and strength of evidence were low due to mostly observational study designs with no comparison groups, subjective endpoints, potential confounding (a situation where the association between the intervention and outcome is influenced

by another factor such as a co-intervention), small sample sizes, lack of validated assessment tools, and considerable lost to follow-up." *Id.*

104. In 2020, HHS again concluded that there is "a lack of scientific and medical consensus to support" this gender-change regimen. 85 Fed. Reg. at 37,187. HHS expressly noted the "lack of high-quality scientific evidence supporting such treatments." *Id.*

105. But during the Biden Administration, HHS changed its tune. In 2022, the Office of Population Affairs released a two-pager entitled "Gender-Affirming Care and Young People." https://perma.cc/H3CS-94KX. In this two-pager, the Office of Population Affairs asserted that "[r]esearch demonstrates that" so-called "gender-affirming care improves the mental health and overall well-being of gender diverse children and adolescents." *Id.* HHS further asserted that "[f]or transgender and nonbinary children and adolescents, early gender-affirming care is crucial to overall health and well-being." *Id.* The two-pager prominently highlighted the treatment guidelines from the Endocrine Society and WPATH. *Id.* At the same time, in the 2022 Notice, HHS threatened to sue anyone who disagreed with this purported "standard of care."

106. HHS's change in position is more striking because the international trend is in the opposite direction. The "public healthcare entities of Sweden, Finland, France, Australia, New Zealand, and the United Kingdom have raised concerns about the risks associated with puberty blockers and cross-sex hormone treatment and

supported greater caution and/or more restrictive criteria in connection with such interventions." *Eknes-Tucker*, 80 F.4th at 1218; Levine, *supra*, at 31.

107. For example, the Swedish National Board of Health has stated that "the risks of hormonal interventions for gender dysphoric youth outweigh potential benefits." *Summary of Key Recommendations from the Swedish National Board of Health and Welfare (Socialstyrelsen/NBHW)*, SEGM.org (Feb. 27, 2022), HHS-OS-2022-0012-10295, https://perma.cc/NWB6-3XEU. Finland's Council for Health Choices has concluded that gender-change interventions in minors are "an experimental practice" and that "no irreversible treatment should be initiated" before adulthood. *Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors* (2020), https://perma.cc/PX74-4LBK. The United Kingdom has similarly restricted puberty blockers after finding the evidence inadequate to conclude they are safe and effective to treat gender dysphoria. *B.P.J. by Jackson v. W. Va. State Bd. of Educ.*, No. 23-1078, 2024 WL 1627008, at *18 n.7 (4th Cir. Apr. 16, 2024) (Agee, J., concurring in part and dissenting in part).

108. Plenty of governments are skeptical on this side of the Atlantic too. At least 21 states in the United States prohibit hormone treatment and surgery for minors suffering from gender dysphoria. *L.W.*, 83 F.4th at 471 (citing statutes).

II. Florida's Actions to Protect the Public from Experimental Treatments for Gender Dysphoria

109. Florida, for its part, has concluded that the alleged psychological benefits of gender-change interventions are far too speculative to justify the risks, particularly

in minors. Florida has accordingly acted to protect the health and safety of its citizens, protect the fertility and health of its youth, and promote the ethical practice of medicine.

A. Florida Guidance

110. "The purpose" of the Florida Department of Health ("DOH") "is to promote the health of all residents and visitors," by, among other things, "[r]egulat[ing] health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(1)(g).

111. On April 20, 2022, in response to the misleading two-pager published by the HHS Office of Population Affairs, DOH provided its own public guidance on the treatment of gender dysphoria in children. *Treatment of Gender Dysphoria for Children and Adolescents* (Apr. 20, 2022), https://perma.cc/BB4N-2QH4.

112. DOH noted 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." *Id.* Citing a "lack of conclusive evidence, and the potential for long-term, irreversible effects," the DOH concluded that "social gender transition" should not be recommended to youth, "puberty blockers or hormone therapy" should not be prescribed to children under 18, and that "gender reassignment surgery should not be a treatment option for children or adolescents." *Id.*

B. Florida Medicaid

113. Medicaid is a public assistance program that provides medical services for low-income individuals. 42 U.S.C. §§ 1396-1, 1396a. It is "the primary federal

program for providing medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 262 n.19 (1974). The program is administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

114. Florida Medicaid reimburses the "services and procedures" of a medical doctor when "medically necessary for the treatment of an injury, illness, or disease." Fla. Stat. § 409.905(9). But "clinically unproven" or "experimental treatments" are not reimbursed. *Id.* To qualify as medically necessary, AHCA rules require that the treatment be "consistent with generally accepted professional medical standards as determined by the Medicaid program, and not experimental or investigational." Fla. Admin. Code r. 59G-1.010(2.83).

115. Pursuant to its obligations, AHCA separately investigated the safety and efficacy of gender transition interventions to treat psychological distress. To make this determination, AHCA followed its regulatory process. *Id.* r. 59G-1.035.

116. As required by that process, on June 2, 2022, AHCA published a report, titled "Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria." https://perma.cc/7RZM-L3SN ("GAPMS Report").

117. The GAPMS Report included a lengthy review of the available evidence and literature, and the actions taken by public health authorities, and concluded that so-called "gender-affirming care" interventions are "experimental and investigational":

> Following a review of available literature, clinical guidelines, and coverage by other insurers and nations, Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety. In addition, numerous studies, including the reports provided by the clinical and technical experts listed above, identify poor methods and the certainty of irreversible physical changes. Considering the weak evidence supporting the use of puberty suppression, cross-sex hormones, and surgical procedures when compared to the stronger research demonstrating the permanent effects they cause, these treatments do not conform to GAPMS and are experimental and investigational. *Id.* at 3.

118. The GAPMS Report concluded that the "treatments pose irreversible consequences, exacerbate or fail to alleviate existing mental health conditions, and cause infertility and sterility." *Id.* at 38. Consequently, the GAPMS Report "does not recommend sex reassignment treatment as a health service that is consistent with generally accepted professional medical standards." *Id.*

119. The GAPMS Report also attached five assessments by subject-matter experts in the field. *Id.* at 2. One of those five assessments "examined the quality of 61 articles published between 2020 and 2022" purporting to support treatment for gender dysphoria. *Id.* at 27. The expert review concluded these articles were of "low quality" and do not permit an inference that hormonal or surgical treatments reduce distress or suicide rates. *Id.*

120. Following the recommendations of the GAPMS Report, AHCA went through a public notice-and-comment rulemaking process and held a public hearing on the topic.

121. Thereafter, on August 21, 2022, AHCA promulgated Rule 59G-1.050(7). Under Rule 59G-1.050(7), Florida Medicaid will not cover services related to gender

transition including puberty blockers, hormone and hormone antagonists, sex-reassignment surgeries, and "any other procedures that alter primary or secondary sex characteristics." Fla. Admin. Code r. 59G-1.050(7).

C. Florida Medical Ethics

122. Under Florida law, DOH has a duty to regulate "health practitioners for the preservation of the health, safety, and welfare of the public." Fla. Stat. § 20.43(g).

123. The Florida Board of Medicine ("Board") is the state agency responsible for the regulation of licensed physicians. The Board has authority to establish "standards of practice and standards of care" for licensed physicians. Fla. Stat. § 458.331(1)(v).

124. On July 28, 2022, DOH petitioned the Board to initiate rulemaking on treatment of gender dysphoria in children and adults. DOH Petition, https://perma.cc/97HK-Y4XS.

125. The Petition observed that the "lack of quality evidence in support of gender transition treatments" had caused "confusion" in the medical community and posed a danger to public health. *Id.* at 5. It further observed that "the use of such treatments for gender dysphoria should be considered experimental and should require fully informed consent of the risks and limitations." *Id.* at 5–6. In particular, the Petition observed that "[c]hildren do not possess the cognitive or emotional maturity to comprehend the consequences of these invasive and irreversible procedures." *Id.* at 6. The Petition asked the Board to adopt a standard of care prohibiting surgery, puberty blockers, and hormones to treat gender dysphoria for patients under 18 years of age

and requiring the use of pre-approved informed consent forms for adults receiving these treatments. *Id.* at 6–7.

126. Effective March 16, 2023, the Florida Board of Medicine published Rule 64B8-9.019 which prohibits "(a) [s]ex reassignment surgeries, or any other surgical procedures, that alter primary or secondary sexual characteristics; [and] (b) [p]uberty blocking, hormone, and hormone antagonist therapies" for treatment of gender dysphoria in minors, except for minors already being treated with these drugs. Fla. Admin. Code r. 64B8-9.019.

127. Effective March 28, 2023, the Board of Osteopathic Medicine published Rule 64B15-14.014, which is identical to Rule 64B8-9.019. Fla. Admin. Code r. 64B15-14.014.

D. Florida Health and Safety Laws

128. On May 17, 2023, Florida Governor Ron DeSantis signed into law SB 254. SB 254 prohibits "sex-reassignment prescriptions or procedures" for minors, requires informed consent in adults, and requires that sex-reassignment services for adults be performed by a licensed physician. *See* Fla. Stat. §§ 456.001 (definitions), 456.52 (restrictions). SB 254 also prohibits the use of state funds for sex-reassignment interventions. *Id.* § 286.311.

129. On May 17, 2023, Governor DeSantis also signed into law HB 1521. HB 1521 requires educational institutions, detention facilities, correctional institutions, juvenile correctional facilities, and public buildings with a restroom or changing

facility to designate separate facilities based on sex or to provide one-person unisex facilities. *See* Fla. Stat. § 553.865(5), (12).

III. The 2024 Rules

130. The 2024 Rules are comprised of two different sets of rules. HHS is promulgating one set of rules purporting to implement Section 1557, to be codified in Part 92 of Title 45 of the Code of Federal Regulations and enforced by OCR (the "OCR Rules"). CMS is also promulgating separate non-discrimination rules for specific aid programs, relying on both Section 1557 and provisions of the Social Security Act and the Public Health Service Act.

131. With some exceptions, the 2024 Rules will be effective on Friday, July 5, 2024. 89 Fed. Reg. at 37,522.

A. The OCR Rules

132. The OCR Rules generally provide: "Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of: (i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2).

133. Section 206 would require covered entities such as hospitals, clinics, and pharmacies receiving federal funds to ensure "equal access" without discriminating based on sex. 89 Fed. Reg. at 37,700, *to be codified at* 45 C.F.R. § 92.206(a).

134. According to Section 206, equal access means health care providers may not "[d]eny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.206(b)(1).

135. Section 206 further prohibits any policy or practice that separates or treats persons based on sex, including any policy or practice that prevents an individual from being treated "consistent with the individual's gender identity," if this causes the person harm—including emotional or dignitary harm—that is more than *de minimis*. *Id.* at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3). For example, HHS explains, a hospital that assigns patients to dual-occupancy rooms based on sex would be *required* to allow a man who identifies as a woman to share a room with a woman. *Id.* 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."); NPRM, 87 Fed. Reg. at 47,866–67.

136. Section 206 also specifically prohibits denying or limiting "health services sought for purpose of gender transition or other" so-called "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." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4) (emphasis added). That includes, according to HHS, "counseling, hormone therapy,

surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." NPRM, 87 Fed. Reg. at 47,834 n.139; *see* 89 Fed. Reg. at 37,596 ("gender-affirming care" includes "hormone therapy, surgery, and other related services").

137. For example, under Section 206, it would be presumptively discriminatory for a clinic to prescribe and administer puberty blockers to treat precocious puberty—an FDA-approved use—but not a "gender transition"—a non-FDA-approved use. It would similarly be presumptively discriminatory for a hospital to provide an orchidectomy to treat testicular cancer, but refuse to remove healthy testicles for a "gender transition."

138. Section 206(c) purports to provide a safe harbor. A covered entity need not provide such services when the covered entity typically declines to provide such services to any individual for any diagnosis or when they are "not clinically appropriate for a particular individual." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). Accordingly, HHS at least acknowledges that a doctor can refuse to perform a prostate exam on a person "who does not anatomically have a prostate." *Id.* at 37,607. And OCR would review whether the services are "clinically appropriate" for a particular individual in the first instance. When it comes to gender-change interventions, OCR indicates it would review "medical necessity standards or guidelines" and "the clinical, evidence-based criteria or guidelines relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination." *Id.* at 37,613. Decisions based on evidence or ethical and

moral reasoning that OCR deems insufficient "may be considered evidence of pretext for discrimination." *Id.*

139. Although OCR disclaims an attempt to mandate standards of care for gender-transition services in the final rule, the proposed rule mentioned the clinical "guidelines" it expects covered entities will follow: the guidelines of the WPATH and Endocrine Society, the entities discussed above at length. NPRM, 87 Fed. Reg. at 47,868 (asserting that covered entities "should follow clinical practice guidelines and professional standards of care," and citing WPATH 7 & Endocrine Society Guideline). OCR doesn't disavow that endorsement in the final rule or provide any examples of competing guidelines that would not require covered entities to support a "gender-transition."

140. The decision to refuse gender-change interventions "must not be based on unlawful animus or bias, or constitute a pretext for discrimination." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(c). This circular reasoning grants HHS wide discretion to decide who has "discriminated." HHS has made clear that it views a general or categorical refusal to provide gender-change interventions as "unlawful animus," even if required by state law. HHS repeatedly emphasizes that it might be permissible to refuse a gender-change intervention "*for a particular individual*," *id.*, *to be codified at* 45 C.F.R. § 92.206(c) (emphasis added), after exercising "*individualized* clinical judgment," *Id.* at 37,575, 37,595–97 (emphasis added). The negative implication is obvious: Any doctor who reviews the evidence above and decides that

a specific gender-change intervention is categorically too risky or unethical is a "discriminator."

141. OCR further announces that it will target any provider who does not hew to HHS's changed (and quite suspect) view of the evidence. OCR states its enforcement decisions will be informed by "consideration of … whether that covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. But a doctor who reviews the evidence and concludes, like 21 states and several Western European countries, that a gender-change protocol for minors or adults is dangerous and experimental medicine is not showing sufficient "willingness to … provide" HHS-approved "accurate information." *See* NPRM, 87 Fed. Reg. at 47,874.

142. Even providers that don't categorically rule out gender-change interventions can face enforcement at the whim of OCR under a malleable standard. If OCR concludes that a provider "reflect[ed] unlawful animus or bias" by "assert[ing]" a "judgment" that gender-change interventions are unwarranted in a particular case, *id.* at 37,598, then OCR can initiate enforcement proceedings, leading to a Star Chamber hearing in which HHS acts as prosecutor, judge, and jury. 45 C.F.R. §§ 80.8(c), 80.10; *see generally* HHS, *Guidelines—Civil Rights Reviewing Authority Review of Civil Rights Enforcement Decisions for HHS Programs*, https://perma.cc/D8RB-C654.

143. As the proposal made clear, in the view of HHS, claiming that gender-change interventions are "experimental or cosmetic would be considered evidence of pretext because this characterization is not based on current standards of medical

care," that is, the WPATH standards and the Endocrine Society Guideline discussed above. NPRM, 87 Fed. Reg. at 47,874. In other words, according to HHS, simply agreeing with the Florida Board of Medicine Standards of Medical Care, Finland's Council for Health Choices, or the Sixth Circuit, is evidence of animus. OCR seeks not just to coerce every covered entity to provide gender-transition interventions; it wants to chill any speech by covered entities that would discourage such interventions.

144. In response to First Amendment concerns about "what would be required of providers in terms of expressing support of transgender people who wish to access gender-affirming care, using the name and pronouns requested by patients, and speaking about gender-affirming care," OCR simply noted that whether "discrimination is unlawful or considered harassment is necessarily fact-specific" and that "conduct, including verbal harassment, that is so severe or pervasive that it creates a hostile environment on the basis of sex is a form of sex discrimination." 89 Fed. Reg. at 37,596.

145. As a result, under the OCR Rules, covered entities arguably cannot tell their patients that in their best medical opinions, gender-transition efforts or procedures are categorically experimental and dangerous. The OCR Rules arguably force covered entities to give patients the impression that "gender-transition" efforts can in some cases be clinically indicated or beneficial. They suggest that OCR may determine that a healthcare entity creates a hostile environment when it speaks in ways that categorically deny the medical legitimacy of gender transitions.

146. The OCR Rules likewise may consider it discrimination for a covered entity to categorically speak or write using a patient's pronouns that align with his or her sex according to the patient's biology if the patient prefers different pronouns that correspond to his or her gender identity. Under the OCR Rules, covered entities might need to refer to those persons using pronouns that are inconsistent with their sex.

147. Under the OCR Rules, covered entities may need to tell patients that males can get pregnant, give birth, and breastfeed. As HHS explains in the proposal, doctors are responsible for "'discrimination, stigma, and erasure'" if they speak or act in way that treats "pregnancy and childbirth … as something exclusively experienced by … women." NPRM, 87 Fed. Reg. at 47,865.

148. Section 207 applies to entities involved in federally funded health insurance and health-related coverage administered by HHS, such as Medicaid or CHIP. Section 207 generally prohibits discrimination in a variety of healthcare coverage and claim practices, in insurance benefit design, and in marketing practices. 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(a), (b)(1), (b)(2).

149. In addition, separate provisions within Section 207 specifically make it presumptively discriminatory for a covered entity to impose limits or restrictions on coverage or claims, including cost sharing, "based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*, *to be codified at* 45 C.F.R. § 92.207(b)(3). In the proposal, HHS suggested that denying "hormone therapy coverage" to a transgender person of color for a gender transition is, alone, evidence of "pervasive" "transphobia and racism." NPRM, 87 Fed. Reg. at 47,870.

150. Section 207 also makes it per se discriminatory to have a "categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4).

151. Section 207 further makes it presumptively discriminatory to "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 if such denial, limitation, or restriction *results in* discrimination on the basis of sex." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(5) (emphasis added). This results-oriented text doesn't appear to require a discriminatory motive, but would reach facially neutral insurance policies that tend to screen out services used by transgender individuals, even if those policies are not motivated by sex or gender identity. *See Brnovich v. Democratic Nat'l Comm.*, 141 S. Ct. 2321, 2332 (2021) (citing 52 U.S.C. § 10301(a)).

152. That is, apparently, the point: according to HHS, excluding coverage for gender-transition services is unlawful disparate treatment because "transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871. But by that logic, an issuer's refusal to cover vasectomies is discriminatory because only a male can get a vasectomy. *But see Eknes-Tucker*, 80 F.4th at 1229–30 ("[T]he regulation of a course of treatment that, by the nature of things, only transgender individuals would want to undergo" is not discrimination "on the

basis of sex" unless it were "mere pretext designed to effect an invidious discrimination" (cleaned up)).

153. Section 207(c) also purports to provide a safe harbor. It says it is not discriminatory to deny coverage "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." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(c). "Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination," *id.*, *to be codified at* 45 C.F.R. § 92.207(c), which OCR will assess based on the "guidelines" discussed above. But there is no safe harbor for categorical judgments of medical necessity.

154. Failure to comply with the prohibitions of Section 1557 may cause Florida to lose all federal funding, including Medicaid funding. 45 C.F.R. §§ 80.8, 92.303.

B. The CMS Rules

155. The 2024 Rules also amend regulations relating to Medicaid, CHIP, and the Program of All-Inclusive Care for the Elderly ("PACE") (collectively, "CMS Rules").

156. The CMS Rules amend three pre-existing Medicaid and CHIP rules to include HHS's new, expansive interpretation of sex discrimination. The first relates to contracts with entities that deliver services. Those contracts must now include a

promise that the entities "will not discriminate against individuals eligible to enroll on the basis of … 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 basis of …sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4). Under this rule, it would seem, any facially neutral policy or practice that has a discriminatory *effect* on transgender individuals, not just a discriminatory purpose, may violate the relevant contract.

157. In addition, those same entities must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.*, *to be codified at* 42 C.F.R. § 438.206(c)(2).

158. The other two rules require that States "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, … and regardless of *sex* which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." *Id.* at 37,692, *to be codified at* 42 C.F.R. §§ 440.262 (Medicaid), 457.495(e) (CHIP).

159. For these amendments, CMS relies not only upon its authority under Section 1557, but also upon Section 1902(a)(4) of the Social Security Act ("SSA") for Medicaid, 42 U.S.C. § 1396a(a)(4), and Section 2101(a) of the SSA for CHIP, *id.* § 1397aa(a).

160. "CMS interprets sections 1902(a)(4) and 2101(a) of the SSA as authorizing CMS to adopt regulations prohibiting discrimination on the basis of gender identity or sexual orientation because such prohibitions on discrimination are necessary for the proper and efficient operation of a state plan, are in the best interest of beneficiaries, and enable states to provide child health assistance in an effective and efficient manner." NPRM, 87 Fed. Reg. at 47,892.

161. Under this regime, HHS also serves as lawmaker, prosecutor, and jury. HHS can withhold payments from States for noncompliance with state-plan requirements after notice and a hearing. 42 U.S.C. § 1396c; 42 C.F.R. § 430.35. When a State challenges that decision in court, "[t]he findings of fact by the Secretary, if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 430.38(c)(1).

162. PACE is a Medicare and Medicaid program that helps people meet their health care needs in the community instead of going to a nursing home or other care facility.

163. In Florida, PACE is administered by AHCA in consultation with the Department for Elder Affairs.

164. The 2024 Rules amend two PACE regulations: 42 C.F.R. §§ 460.98(b)(3) and § 460.112(a). Section 460.98 regulates services provided by State PACE programs, while § 460.112 establishes the rights of PACE participants. The 2024 Rules change the word "sex" to "sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex

stereotypes)" in the PACE regulations. *See* 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98(b)(3), 460.112(a).

165. In addition to Section 1557, CMS relies upon the Public Health Service Act ("PSA") to promulgate the PACE-related statutory provisions, specifically Sections 1894(f)(A) and 1934(f)(A) of the SSA. 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f).

IV. Injury to Florida

166. AHCA and DMS administer health-related programs or activities that receive federal financial assistance or programs or activities administered by HHS as defined in the 2024 Rules, so they are subject to the 2024 Rules. They must comply with the rules or risk losing federal funds and being subject to private lawsuits for discrimination.

167. AHCA administers the state Medicaid, CHIP, and PACE programs, which are regulated by the 2024 Rules. Ex. 1 ¶ 2. Under state law, Florida Medicaid and CHIP currently do not cover or reimburse gender-transition hormonal or surgical interventions. *See* Ex. 1 ¶ 10–11.

168. In total, Florida Medicaid, CHIP, and PACE received $24,671,603,227 in federal funds from HHS in Fiscal Year 2022-2023. Ex. 1 ¶ 9.

169. DMS purchases and administers healthcare coverage plans for Florida's 310,750 active and retired state employees and their families. Specifically, the Division of State Group Insurance within DMS purchases and administers state employee and

retiree health insurance under the Florida State Group Health Insurance Program. DMS receives federal financial assistance from CMS through, for example, the Retiree Drug Subsidy. Ex. 2 ¶ 6. DMS is therefore a covered entity for this purpose under the OCR Rules.

170. For approximately 40 years, insurance coverage procured for the State Group Health Insurance Program has excluded gender-change interventions. Ex. 2 ¶ 7.

171. Florida law also requires generally excluding coverage for "sex-reassignment prescriptions or procedures" in "the state group health insurance program." Fla. Stat. § 286.311.

172. The 2024 Rules would purport to make that exclusion of coverage discriminatory. 45 C.F.R. § 92.207(b)(4). This would injure DMS and require the plan to incur additional claim costs. Ex. 2 ¶ 10.

173. Florida's Agency for Persons with Disabilities receives HHS funding and has a policy and practice of separating multiple-occupancy rooms in state hospitals on the basis of sex, regardless of gender identity.

174. Florida has also promulgated laws, rules, and standards of care restricting gender-change interventions and separating facilities based on sex to protect the health, safety, and fertility of Florida residents, particularly minors. *See supra* Part II. Florida has a sovereign interest in protecting these laws from conflicting federal agency rules that do not comply with federal law. *Florida v. Nelson*, 576 F. Supp. 3d 1017, 1032 (M.D. Fla. 2021) ("the state suffers sovereign injury when unlawful agency action

preempts state law"); *see also Texas v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) ("States have a sovereign interest in the power to create and enforce a legal code" (cleaned up)).

A. Florida's Medicaid and CHIP Program

175. Under the 2024 Rules, Florida may not refuse reimbursement or coverage for gender-change interventions on the ground that they are "experimental" and not medically necessary healthcare treatments. The 2024 Rules would therefore require covering puberty blockers, cross-sex hormones, surgeries, and related services to treat gender dysphoria under Florida Medicaid, CHIP, and other state programs subject to the 2024 Rules, contrary to Florida law. Fla. Admin. Code r. 59-1.050(7); Fla. Stat. § 286.311.

176. According to WPATH 8, the purportedly medically necessary drug interventions for a gender transition include:

a. Prescribing and administering puberty blockers off-label, and;

b. Prescribing supraphysiological levels of cross-sex hormones off-label and related visits and tests.

177. According to WPATH 8, the purportedly "medically necessary" so-called "gender-affirming surgical procedures," WPATH 8, *supra*, at S18, S128, include the following:

a. "Hysterectomy" (removal of healthy uterus);

b. "Mastectomy" (removal of healthy breasts);

c. "Salpingo-oophorectomy" (removal of healthy ovaries and fallopian tubes);

d. "Orchiectomy" (removal of healthy testicles);

e. "Phalloplasty" (constructing penis-like structure using tissue from skin), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

f. "Metoidioplasty" (constructing penis-like structure using tissue from a hormone-enlarged clitoris), including "urethral lengthening," "prosthesis," "colpectomy" (closure of healthy vagina), "colpoclesis" (shortening of healthy vagina), and "scrotoplasty" (creating new scrotums);

g. "Vaginoplasty" (constructing vagina-like structure), including methods of "[penile] inversion" (using combination of skin surrounding penis and scrotal skin), "peritoneal [flaps pull-through]" (pulling down peritoneum (inner lining of abdominal wall) into space between rectum and urethra/prostate), and "intestinal" technique (using section of terminal large intestine);

h. "Vulvoplasty" (constructing vulva-like structures)

i. "Hair line advancement and/or hair transplant;"

j. "Facelift/mid-face lift (following alteration of the underlying skeletal structures);"

k. "Platysmaplasty" (neck lift);

l. "Blepharoplasty" (eye and lid modification);

m. "Rhinoplasty" (nose reshaping);

n. "Cheek" surgery, including "implant[s]" and "lipofilling;"

o. "Lip" surgery, including "augmentation" and "upper lip shortening;"

p. "Lower jaw" surgery, including "augmentation" and "reduction of the mandibular angle" (cutting or shaving the corner of the lower jaw);

q. "Chin reshaping" surgery;

r. "Chondrolaryngoplasty" (shaving down Adam's apple);

s. "Vocal cord surgery;"

t. "Breast reconstruction" and "augmentation" (mammoplasty);

u. "Body contouring" surgeries, including "liposuction," "lipofilling," and "implants" (such as "pectoral, hip, gluteal, [and] calf");

v. "Monsplasty" (reduction of mons pubis tissue around the public bone, which is more pronounced in biological females);

w. "Nipple-areola tattoo;"

x. "Uterine transplantation" (uterus from donor);

y. "Penile transplantation" (penis from donor);

z. "Hair removal," including "laser epilation" (laser removal) or "electrolysis" (permanent removal by destroying hair follicles).

WPATH 8, *supra*, at S258, App'x E (cleaned up).

178. WPATH claims that "it is imperative to understand this list is not intended to be exclusive." WPATH 8, *supra*, at S258, App'x E.

179. The 2024 Rules will have a "substantial" fiscal effect on Florida. NPRM, 87 Fed. Reg. at 47,903. Although the total potential fiscal exposure is difficult to measure, covering gender-transition treatments under Florida Medicaid and CHIP could cost some $200,000,000 a year. Ex. 1 ¶ 21.

180. This cost, to be sure, pales in comparison with the human cost of aiding and abetting experimental interventions that could render thousands of Floridian minors infertile for life.

B. Florida's Standard of Care

181. "[T]he State has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). This includes "maintaining high standards of professional conduct" in the practice of medicine. *Barsky v. Bd. of Regents of Univ. of N.Y.*, 347 U.S. 442, 451 (1954).

182. The State also "has an interest in protecting vulnerable groups … from mistakes," *Glucksberg*, 521 U.S. at 731, and in "the elimination of particularly gruesome or barbaric medical procedures," *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301 (2022). Furthermore, "[i]t is evident beyond the need for elaboration that a State's interest in 'safeguarding the physical and psychological well-being of a

minor' is 'compelling.'" *New York v. Ferber*, 458 U.S. 747, 756 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

183. As described in Part II, Florida has enacted laws and promulgated rules delineating the proper standard of medical care as it relates to children suffering from gender dysphoria. Florida's Board of Medicine and Board of Osteopathic Medicine developed their standard of care after careful review of the available literature and studies. The Florida legislature and Surgeon General have also reached similar conclusions about health and safety and restricted cross-sex hormones and surgeries for minors more broadly.

184. Most medical providers in Florida, however, accept federal funds and are "covered entit[ies]" under the 2024 Rules. The 2024 Rules will therefore force healthcare providers in Florida to choose between accepting federal funds and complying with Florida law regarding treatments for persons suffering from gender dysphoria. Indeed, under the 2024 Rules, compliance with Florida's ethical requirements, laws, and regulations may be deemed a pretextual reason for discriminating, triggering an Office of Civil Rights investigation, and potentially, an enforcement proceeding.

V. Injury to Catholic Medical Association Members

A. The OCR Rules' New Policy and Training Requirements

185. The OCR Rules prohibit covered entities from having or applying policies not "consistent with" the OCR Rules' definition of sex discrimination or the

Rules' prohibitions. The OCR Rules require covered entities to adopt and publish policies that comply with the OCR Rules. 89 Fed. Reg. at 37,696–99, *to be codified at* 45 C.F.R. §§ 92.8(a), (b), & (h), 92.101.

186. The OCR Rules require covered entities to provide an updated notice of nondiscrimination to patients stating that they will not discriminate on the basis of gender identity. 89 Fed. Reg. at 37,697, *to be codified at* 45 C.F.R. § 92.10(a)(1)(i). The notice to patients must be provided annually and on request. *Id.* at 37,698, *to be codified at* 45 C.F.R. § 92.10(a)(2)(i)–(ii).

187. The notice must be posted "at a conspicuous location on the covered entity's health program or activity website" and "[i]n clear and prominent physical locations … where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice." *Id.*, *to be codified at* 45 C.F.R. § 92.10(a)(2)(iii)–(iv).

188. The OCR Rules require covered entities to train each relevant employee on the OCR Rules' required policies and procedures and document that training. *Id.* at 37,697, *to be codified at* 45 C.F.R. § 92.9(a)–(c).

189. Under the OCR Rules, covered entities must submit an assurance of compliance to HHS that they have adopted the OCR Rules' new policies as a contractual condition of receipt of federal funding, or else they will be unable to apply or maintain eligibility for federal funding. *Id.* at 37,696, *to be codified at* 45 C.F.R. § 92.5.

190. Every time a covered entity requests a federal health funding payment from HHS, it impliedly certifies to HHS that it follows governing regulations, and the

OCR Rules import the prohibition on gender identity discrimination into those implied certifications. Covered entities unwilling to agree to make such an assurance or certification of compliance cannot apply for or maintain eligibility for federal health funding from HHS unless an exception applies.

B. The OCR Rules' New Liability Risks

191. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations risks the burdens and costs of federal investigations and enforcement proceedings. It also risks disallowance, exclusion, suspension, and debarment from receipt of federal funding.

192. Failure to follow the OCR Rules and their interpretation of Section 1557, Title IX, and HHS regulations arguably risks liability under a cause of action in civil litigation, including in suits brought by the public.

193. CMA members care for all people without discrimination on the basis of sex or any other characteristic prohibited by law. They believe that a patient with medical needs should be given the best care possible, regardless of the patient's identity. But CMA members cannot harm or lie to patients.

194. Based on the Hippocratic Oath, on science, on medical ethics, on conscience, and on religious faith, CMA members like Dr. Parker and Dr. Van Meter hold the categorical position that providing, facilitating, referring for, or endorsing gender-transition efforts violates their core religious beliefs and their medical oath to "do no harm." CMA members hold the categorical view that gender-transition procedures harm patients—particularly children—and can result in infertility, heart

attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures. CMA members hold the categorical view that sex is a biological, immutable characteristic—a scientific reality, not a social construct. CMA members hold the categorical view that to eliminate sex-specific private spaces violates fundamental rights to privacy, dignity, safety, and security.

195. CMA members' categorical exclusion of providing, facilitating, or affirming gender transitions, and their commitment to state law, precludes CMA members from:

a. Prescribing puberty blockers, cross-sex hormone therapies, or other similar ongoing interventions to treat gender dysphoria or for transition efforts;

b. Performing surgeries to treat gender dysphoria or for transition efforts, including removing healthy organs from people who purport to identify as the opposite sex, nonbinary, or otherwise not as their sex;

c. Referring patients for any and all such interventions, procedures, services, or drugs, or affirming the same;

d. Saying in their professional opinions or through staff that these gender-transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

e. Refraining from expressing views, options, policies, and opinions critical of transition efforts;

f. Treating and referring to patients according to gender identity and not sex, such as using patients' self-selected pronouns according to gender identity in communications or in writing (rather than using no pronouns or using pronouns based on sex);

g. Saying that males can be pregnant or give birth;

h. Allowing patients to access single-sex programs and facilities, such as restrooms, by gender identity rather than sex;

i. Repealing or modifying policies, procedures, and practices against the above procedures, drugs, and interventions for transition efforts; and

j. Providing assurances of compliance, express or implied certifications of compliance, and notices of compliant policies as to the OCR Rules' gender-identity requirements.

196. CMA members like Dr. Parker and Dr. Van Meter are actively practicing medicine and seeing patients. They provide services to patients reimbursed by federal financial assistance.

197. The OCR Rules impact CMA members in their practice of medicine as individual physicians who are regulated by the OCR Rules. And the OCR Rules impact some of these members as corporate principals and owners of medical practices that are regulated by the OCR Rules—for example in their duty to create, implement, and train staff on policies and to ensure compliance with the OCR Rules in their businesses' medical practices.

198. The OCR Rules impose the following no-win choice on CMA members: (1) abandon or violate their convictions on gender and incur the costs of compliance with the OCR Rules; (2) maintain their positions and practices but arguably falsify their policies, notices, and assurances of compliance to HHS and then risk continuing liability and investigative demands from OCR with no promise they will be deemed categorically exempt from the loss of eligibility for participation in Medicaid, Medicare, and CHIP, and other federal financial assistance programs; or (3) exit the medical field and abandon their patients.

199. If CMA members were to comply with the OCR Rules, they would lose their integrity and reputation of practicing with sound judgment and good medical ethics, making patients less likely to trust them, and driving patients and employees away from their practices.

200. If CMA members do not comply with the OCR Rules, CMA members will have to defend themselves from investigations and enforcement actions, losing time, money, and resources that they could use for medical care.

201. If CMA members do not comply with the OCR Rules, CMA members will find it difficult to be employed in the field of medicine, as almost all medical practices receive federal financial assistance from HHS.

202. It is no answer to say that entities may seek a religious or conscience exemption. Seeking such an assurance of exemption from HHS will cost time and money—$987.70 per entity according to HHS estimates—for uncertain results: there

is no guarantee that HHS will issue an assurance of exemption or will do so in time to avoid irreparable harm. 89 Fed. Reg. at 37,684.

203. Many CMA members like Dr. Parker and Dr. Van Meter live in states that restrict gender-transition procedures. Without an exemption, the OCR Rules force these doctors to choose between (a) following state law and their consciences and violating the OCR Rules, or (b) following the OCR Rules and violating state law and their consciences. They will not violate state law.

204. Dr. Parker is a board-certified OB/GYN hospitalist serving female Medicare and Medicaid patients in labor & delivery and emergency room ("ER") settings at OhioHealth Mansfield Hospital in Mansfield, Ohio. He works as an OB Hospitalist employed by Pediatrix Medical Group of Ohio, part of Pediatrix Medical Group.

205. In his past OB/GYN practice for females, he regularly provided medically indicated hysterectomies and provided medically indicated estrogen and testosterone hormones. He is board-certified to provide these services again in future clinical settings, but he cannot provide these services for gender-transition purposes.

206. Dr. Parker routinely records all OB/GYN patients as female. He uses the correct biological and binary pronouns: she/her. He does not facilitate male access to hospital restrooms designated for females, or vice versa, based on gender identity.

207. Dr. Parker at times treats patients who identify as transgender, non-binary, or otherwise contrary to their sex. He has cared for such a patient who was in labor having a baby. He does not—and will not—call a woman giving birth "a man."

In the past, hospital colleagues have said men could get pregnant and said that a certain patient was a man who was pregnant. Dr. Parker corrected them: the patient was a woman who was pregnant. Every time he encounters this issue, he wants to be free to explain that only females can get pregnant and give birth.

208. Dr. Parker does not wish to attend required training from his hospital or his physician group to follow a "nondiscrimination" policy on gender identity. He will attend such training as required but he will not agree to follow such a policy. He would rather be fired than harm his patients.

209. Dr. Van Meter is a pediatric endocrinologist seeing Medicaid and CHIP pediatric patients at his independent practice, Van Meter Pediatric Endocrinology, P.C., in Atlanta, Georgia. About seven percent of his patients are Medicaid patients, and if his patients need hospitalization, he provides care at two local hospitals that receive Medicaid and CHIP funding.

210. Dr. Van Meter regularly provides puberty blockers and sex hormones for medical reasons. He regularly cares for patients who identify as transgender, non-binary, or otherwise contrary to their sex, as well as patients who struggle with gender incongruence. He regularly receives patient requests to provide puberty blockers and cross-sex hormones for gender-transition purposes, but as a matter of sound medical judgment and good conscience, Dr. Van Meter does not and will not provide puberty blockers or hormones for gender-transition purposes.

211. Dr. Van Meter regularly provides his medical opinion against starting gender-transition procedures. He regularly uses pronouns for patients that accord with

biological and binary sex in conversation and in writing. He cannot use pronouns contrary to biology, even though he is regularly asked to do so.

212. Dr. Van Meter provides access to male and female restrooms for patients and their visitors based on biological and binary sex. Because of safety, dignity, privacy, and conscience concerns, he does not and will not ensure access to these facilities by gender identity.

213. Dr. Van Meter has adopted an official policy statement on his website encompassing these policies, and he does not wish to change this policy statement to be consistent with the OCR Rules, although he will do so in compliance with the OCR Rules if not protected by judicial relief. He does not wish to adopt or share a contrary policy or notice with patients. He will not reeducate his staff to comply with the OCR Rules, nor will he attend such training if required by his hospital.

214. Dr. Parker and Dr. Van Meter have already spent time and resources to avoid non-compliance with the OCR Rules, and if the OCR Rules go into effect, they will have to spend even more time and resources. Neither wants to stop seeing patients receiving federal financial assistance or to stop being affiliated with hospitals, but each would rather stop seeing patients receiving federal financial assistance and lose local hospital affiliations than adopt a policy under which they would harm a patient. Were they to lose their eligibility to serve in practices that serve patients receiving federal financial assistance, it would threaten their livelihoods and harm their patients, who would lose their established providers.

215. The OCR Rules threaten to drive similarly situated healthcare providers out of the medical profession, and it will dissuade students from choosing to practice medicine, reducing care for underserved, low-income, and rural patients.

COUNT I
(OCR Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

216. Plaintiffs incorporate by reference paragraphs 1–215.

217. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

218. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

219. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

220. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

221. The OCR Rules define discriminating "on the basis sex" in a manner that is contrary to Section 1557 and Title IX.

222. The Eleventh Circuit has held that "sex" in Title IX "unambiguously" means "biological sex," not "sexual orientation" or "gender identity," *Adams*, 57 F.4th at 812–15, so the same is true under Section 1557, *see Sex*, American Heritage Dictionary 1605 (5th ed. 2011) ("Either of two divisions, designated female and male,

by which most organisms are classified on the basis of their reproductive organs and functions.").

223. Relying on the reasoning in *Bostock*, which interprets a different statute, the 2024 Rules nevertheless define "on the basis of sex" to necessarily include discriminating based on "sexual orientation and gender identity."

224. But *Bostock* cannot apply here.

225. *First*, as *Adams* holds, because Title IX, and hence Section 1557, expressly permits specific kinds of sex group separation, such as separate living facilities for each sex, discriminating based on gender identity is not necessarily prohibited discrimination based on sex under Title IX.

226. *Second*, Section 1557 specifically excludes from its scope "transsexualism" and a "gender identity disorder" "not resulting from physical impairments." 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under … section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing "transsexualism" and "gender identity disorders not resulting from physical impairments" are not a "disability" under section 794). Those terms at the time were synonymous with having a transgender identity, so transgender persons that don't have a disorder of sex development—a physical impairment—don't have a "disability" and are excluded from "section 792 of title 29." The specific exclusion of transgender identity governs the general prohibitions of Section 1557, so the general term "based on sex" cannot be read to include discriminating based on transgender identity in Section 1557.

227. But even if *Bostock* applied here, its reasoning wouldn't authorize the OCR Rules. *Bostock*'s reasoning, if it applies at all, applies when an individual is requesting a health care treatment that is "to the [covered entity's mind], materially identical in all respects, except that one" service is sought by one sex, and not the other. *Bostock*, 590 U.S. at 660. That doesn't authorize the OCR Rules. Removing a testicle or uterus with cancer is not "materially identical" to removing a healthy testicle or uterus to address a psychological condition. In both cases, the surgery is requested by one sex: only males have testicles removed, only females have a uterus removed. The thing that changes is the therapeutic purpose. A covered entity's refusal to remove healthy reproductive organs discriminates instead based on clinical purpose, not a patient's sex. *Eknes-Tucker*, 80 F.4th at 1233–34 (Brasher, J., concurring); *L.W.*, 83 F.4th at 481–82. Thus, as the Eleventh Circuit has held, a State does not discriminate or stereotype "on the basis of sex" (the text used in Title IX) when it forbids a hormonal overdose or the removal of healthy organs for a gender transition. *Eknes-Tucker*, 80 F.4th at 1227–30 (Equal Protection Clause).

228. Similarly, prescribing testosterone to treat abnormally delayed puberty or low levels of testosterone (in men or women) is not medically the same thing as prescribing supraphysiological levels of testosterone to embark a minor or adult in a gender transition protocol. The treatment (hormone levels), clinical purpose, and risks of the treatment are materially different.

229. Because HHS's definition of discriminating "on the basis of sex" exceeds the prohibition of Title IX as defined by binding Eleventh Circuit precedent and the

scope of Section 1557, the OCR Rules are contrary to law and in excess of statutory authority.

230. Several other provisions of law and principles confirm that HHS has exceeded its statutory authority.

231. *First*, HHS's departure from text is confirmed by Section 1554 of the ACA, which prohibits any HHS rules that "violate the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5). In Florida, and many other places, principles of informed consent and ethical standards forbid precisely the kind of medical interventions HHS seeks to compel. Under our federal system of government, state legislatures and medical boards, not HHS, decide the principles of informed consent and the ethical standards of health care professionals. Section 1554 confirms that Section 1557 doesn't alter the federal structure with regard to state laws requiring informed consent or setting ethical standards of care.

232. *Second*, Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *U.S. Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 622 (2020). States enjoy the "general power" of governing. *NFIB v. Sebelius*, 567 U.S. at 536. Moreover, "[t]here is no question that state and local authorities possess considerable power to regulate public health," and regulate the ethics and standards of medical professionals. *NFIB v. OHSA*, 595 U.S. 109, 121 (2022) (Alito, J., concurring). Vesting OCR with vast power to second-guess the judgments of state medical boards and determine what is "clinically

appropriate" seriously alters the balance of power between state and federal governments and intrudes upon the medical profession—an area traditionally regulated by the States.

233. *Third*, and relatedly, in areas traditionally regulated by the states, such as the medical profession, courts begin with the assumption "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009). The 2024 Rules openly seek to preempt state laws or regulations reflecting the judgment that gender-transition interventions such as hormones and surgeries are not clinically appropriate to treat psychological distress arising from gender dysphoria. 89 Fed. Reg. at 37,535, 37,598. Section 1557 is an ordinary discrimination law; it does not clearly and manifestly preempt laws regulating the standard of medical care. Indeed, the ACA contains an express savings clause, confirming no broad "obstacle" preemption applies. *See* 42 U.S.C. § 18041 ("Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.").

234. *Fourth*, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2022) (cleaned up). Section 1557 doesn't clearly authorize the OCR Rules.

235. *Fifth*, because Section 1557 is a Spending Clause statute, Congress had to prohibit gender identity discrimination and prohibit disparate impacts

"unambiguously." *Adams*, 57 F.4th at 815. No clear statement appears on the face of the statute.

236. *Sixth*, the 2024 Rules violate Title IX's religious exemption. 20 U.S.C. § 1681(a)(3). The 2024 Rules exceed HHS's authority as cabined by Title IX and incorporated into Section 1557 because Section 1557 does not apply when it would violate the religious tenets of a covered entity.

237. *Seventh*, the 2024 Rules violate the Church Amendments, 42 U.S.C. § 300a-7, which protect the right of healthcare entities that receive federal funding to refuse to participate, perform, or assist with gender-transition procedures, including when it would be contrary to his religious beliefs or moral convictions.

COUNT II
(OCR Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

238. Plaintiffs incorporate by reference paragraphs 1–215.

239. Defendants HHS and CMS are "agenc[ies]" under the Administrative Procedure Act ("APA"). 5 U.S.C. § 551(1).

240. The OCR Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

241. The OCR Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

242. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

243. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 44 (1983). An agency rule is also arbitrary and 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." *Id.*

244. The OCR Rules are arbitrary and capricious for several reasons.

245. *First*, the OCR Rules never define "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "based on" sex. HHS failed to adequately consider and find that, in medical practice as in education, sex is a biological reality.

246. *Second*, the OCR Rules' decision to embrace the WPATH and Endocrine Society Guideline runs counter to the evidence before the agency. Florida and other commenters put forth numerous studies and scholarly reviews showing these groups rely on weak evidence and that there is no consensus on gender-transition interventions.

247. *Third*, HHS failed to consider a significant aspect of the problem: the numerous negative side effects associated with "gender care." HHS never acknowledged, for example, that its preferred "standard of care" may render an untold

number of minors and adults infertile for life. HHS needs to consider that disadvantage.

248. *Fourth*, HHS arbitrarily departs from prior policy positions without adequate explanation. In the 2020 Rules, HHS said there was no medical or professional consensus that the benefits of gender-transition interventions outweighed the costs, as the evidence of a benefit was weak. HHS doesn't explain why the evidence is no longer weak.

249. *Fifth*, HHS improperly ignored the reliance interests of patients who want to keep receiving care from healthcare providers who object to gender transitions. HHS failed to adequately consider alternative policies.

250. Accordingly, the 2024 Rules' attempt to coerce covered entities into following a new federal standard of care for gender dysphoria is arbitrary and capricious and in violation of the APA.

COUNT III
(OCR Rules)

Violation of the Spending Clause

251. Plaintiffs incorporate by reference paragraphs 1–215.

252. Section 1557 is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "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." *Adams*, 57 F.4th at 815.

253. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

254. At the time that the ACA was passed in 2010, no federal courts or agencies interpreted "based on sex" in Title IX to include discrimination based on gender identity. *See Adams*, 57 F.4th at 815–17 (interpretation of Title IX that prohibits discrimination on the basis of gender identity cannot survive the Spending Clause's clear statement rule).

255. Nor does 1557 by its terms unambiguously prohibit refusals to provide medical interventions with a *different* clinical purpose.

256. Under the OCR Rules, Florida now faces the untenable choice of surrendering its power to protect the health and safety of Floridians or losing billions of dollars in federal funding without adequate notice that this would be part of the bargain.

257. Accordingly, the OCR Rules violate the Spending Clause.

COUNT IV
(CMS Rules)

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law, In Excess of Statutory Authority

258. Plaintiffs incorporate by reference paragraphs 1–215.

259. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

260. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

261. The 2024 Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

262. Under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law, in excess of statutory authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

263. The CMS rules prohibit Medicaid and CHIP managed care organizations from having policies or practices that result in discrimination based on gender identity. 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.3(d)(4).

264. These rules are not authorized by Section 1557. For the reasons given above (Count I), Section 1557 doesn't protect against "gender identity" discrimination.

265. Section 1557 also requires intentional discrimination on the basis of sex: It prohibits different treatment based on animus, not facially neutral policies or practices that have "*the effect* of discriminating" on the basis of sex or gender identity. The law, like Title IX, prohibits discriminatory intentions, not just discriminatory consequences or outcomes.

266. Section 1902(a)(4) of the SSA, 42 U.S.C. § 1396a(a)(4), also does not give HHS authority to impose gender-identity non-discrimination rules on the states and its managed-care organizations. Non-discrimination rules are not "methods of

administration"; they are civil rights regulations. CMS's limitless reading of "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

267. Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize this rule for CHIP. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate gender-identity non-discrimination rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

268. The CMS rules also prohibit PACE organizations from discriminating against any participant based on gender identity. 89 Fed. Reg. at 37,692, *to be codified at* 42 C.F.R. §§ 460.98, 460.112.

269. Sections 1894(f)(A) and 1934(f)(A) of the SSA, 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f), similarly do not give CMS authority to legislate gender-identity non-discrimination rules for PACE. CMS's limitless reading of these rulemaking grants is inconsistent with the statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

270. The CMS rules also require that Medicaid and CHIP managed care organizations "promote the delivery of services in a culturally competent manner to all enrollees … regardless of sex which includes … gender identity." 89 Fed. Reg. at 37,691, *to be codified at* 42 C.F.R. § 438.206(c)(2).

271. Similarly, the CMS rules require that States' fee-for-service Medicaid programs "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries … regardless of sex which includes … gender identity." *Id.* at 37,692, *to be codified at* 42 C.F.R. § 440.262.

272. Further, the CMS rules require that State CHIP plans include methods for assuring that "access to and delivery of services in a culturally competent manner to all beneficiaries, as described in [42 C.F.R. § 440.262]." *Id.*, *to be codified at* 42 C.F.R. § 457.495(e).

273. All the "cultural competence" provisions appear to be intended to require that states require that transgender persons be referred to by pronouns that do not align with their sex.

274. The Social Security Act does not authorize CMS to impose speech codes or require adherence to a specific view of how to address transgendered individuals. Instead, the statute authorizes Medicaid rules specifying "methods of administration" that the Secretary concludes are "necessary for the proper and efficient operation of the plan." 42 U.S.C. § 1396a(a)(4). Requiring the use of pronouns that differ from the individual's sex does not advance the goal of "efficient" "administration" of the Medicaid program—it's about prescribing what should be orthodox in public discourse. That's beyond the reach of CMS's authority to publish rules that increase efficiency. Moreover, CMS's limitless reading of the term "methods of administration" is inconsistent with both text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

275. For similar reasons, Section 2101(a) of the SSA, *id.* § 1397aa(a), also doesn't authorize the CHIP version of this rule. This vague statement of purpose doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this statement of purpose is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

276. Nor does Section 1902(a)(19) of the SSA, *id.* § 1396a(a)(19), authorize CMS to mandate the use of pronouns that differ from sex. That provision requires that State Medicaid plans contain safeguards that are "necessary to assure that" care and services are provided "in a manner consistent with simplicity of administration and the best interests of the recipients." *Id.* This general language doesn't grant any rulemaking authority or authorize CMS to legislate pronoun rules. CMS's limitless reading of this requirement of State Medicaid plans is inconsistent with text and statutory context, as well as the "clear notice" requirements for spending legislation and the major questions doctrine.

COUNT V
(CMS Rules)

Violation of the Administrative Procedure Act
Arbitrary and Capricious

277. Plaintiffs incorporate by reference paragraphs 1–215.

278. Defendants HHS and CMS are "agenc[ies]" under the APA. 5 U.S.C. § 551(1).

279. The CMS Rules are a "rule" under the APA. 5 U.S.C. § 551(4).

280. The CMS Rules are a "final agency action" subject to judicial review. 5 U.S.C. § 704.

281. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious." 5 U.S.C. § 706(2)(A).

282. An agency rule is arbitrary or capricious if it fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 44. An agency rule is also arbitrary and 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." *Id.*

283. The CMS Rules are arbitrary and capricious for several reasons.

284. *First,* they never define "sex." But without defining sex, CMS cannot reasonably explain what it means to discriminate based on sex or to provide "culturally competent" care regardless of sex.

285. *Second*, CMS relied on factors that Congress never intended it to consider. Congress authorized regulations to improve the efficiency of Medicaid and CHIP administration. Congress did not intend CMS to require "pursuing health equity"—*i.e.*, gender ideology. 89 Fed. Reg. at 37,668.

286. *Third*, CMS failed to consider a significant aspect of the problem when promulgating its "culturally competent" care requirements: the risk that providers will

leave the Medicaid and CHIP programs if required to use pronouns that differ from sex, creating a shortage of providers that harms Medicaid and CHIP recipients.

COUNT VI
(CMS Rules)

Violation of the Spending Clause

287. Plaintiffs incorporate by reference paragraphs 1–215.

288. The SSA is a Spending Clause statute. "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously," so "States [can] exercise their choice knowingly." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). "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." *Adams*, 57 F.4th at 815.

289. "States cannot knowingly accept conditions of which they are 'unaware' or of which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ.*, 548 U.S. at 296.

290. Neither the SSA nor the Public Health Service Act clearly authorize CMS to impose rules against discriminating on the basis of gender identity.

291. The SSA also does not clearly authorize CMS to impose rules requiring "culturally competent" care, especially when that appears to require the use of ungrammatical pronouns that differ from sex.

292. Accordingly, the CMS Rules violate the Spending Clause.

COUNT VII
(OCR Rules)

Violation of the First Amendment Guarantees of Free Speech and Association

293. Plaintiffs incorporate by reference paragraphs 1–215.

294. Under the First Amendment to the U.S. Constitution, "Congress shall make no law … abridging the freedom of speech … or the right of the people peaceably to assemble …." U.S. Const. amend. I.

295. CMA members' speech, association, and practice in healthcare are burdened in violation of the First Amendment.

296. The OCR Rules seek to restrict and compel speech and to regulate speech based on content and viewpoint. The OCR Rules require policies, opinions, referrals, and pronouns affirming gender-transition efforts, and they restrict speech taking a contrary view.

297. The OCR Rules violate CMA members' right of expressive association (or freedom of assembly) by coercing them to participate in facilities, programs, groups, and other healthcare-related endeavors that are contrary to their convictions and that express messages with which CMA members disagree.

298. The OCR Rules impose an unconstitutional condition on CMA members' receipt of federal funding.

299. The government lacks any compelling interest, and its mandates are not narrowly tailored to achieve any such interests.

300. If Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate the First Amendment of the U.S. Constitution as applied to CMA members and all similarly situated healthcare professionals.

COUNT VIII
(OCR Rules)

Violation of the Religious Freedom (First Amendment and Religious Freedom Restoration Act)

301. Plaintiffs incorporate by reference paragraphs 1–215.

302. RFRA prohibits the federal government from substantially burdening a person's exercise of religion unless the government demonstrates that the burden is the least restrictive means of furthering a compelling government interest. 42 U.S.C. § 2000bb-1(a).

303. Under the First Amendment to the U.S. Constitution, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof …." U.S. Const. amend. I.

304. RFRA and the Free Exercise Clause apply to the OCR Rules, the statutes underlying them, and HHS's enforcement of them.

305. CMA members exercise their religious beliefs through providing healthcare and through expressing messages in their healthcare practices, including to low-income and underserved populations in Medicaid, Medicare, and CHIP.

306. CMA members' provision of healthcare in accord with their religious beliefs does not prevent anyone from obtaining services from other providers.

307. The OCR Rules substantially burden their exercise of religion.

308. The OCR Rules are not neutral or generally applicable.

309. The OCR Rules observe other statutory and informal exemptions.

310. The OCR Rules contemplate the possibility of exemptions for some religious providers but not others. The OCR Rules thus may favor some religious beliefs over others.

311. The OCR Rules further no compelling or legitimate governmental interest and are not the least restrictive means of furthering any interests.

312. Defendants' actions promulgating and enforcing the OCR Rules violate CMA members' religious-exercise rights and hybrid free-speech and religious-exercise rights under RFRA and the First Amendment. In the alternative, if Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, these statutes violate RFRA and the First Amendment for the same reasons.

PRAYER FOR RELIEF

For these reasons, Plaintiffs ask the Court to:

a) Hold unlawful, set aside, and vacate the 2024 Rules;

b) Issue preliminary injunctive relief enjoining Defendants from enforcing the 2024 Rules during the pendency of this case, or, in the alternative, postpone the effective date of the 2024 Rules during the pendency of this case pursuant to 5 U.S.C. § 705;

c) Issue permanent injunctive relief enjoining Defendants from enforcing the 2024 Rules;

d) Declare that the 2024 Rules are contrary to law and arbitrary and capricious;

e) Declare that under any theory of Section 1557 and Title IX, Defendants may not require covered entities to:

i. Perform, provide, refer for, facilitate, affirm, or refrain from criticizing or from categorically rejecting "gender transition" interventions;

ii. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, writing, or conversation, or be forced to say that men can get pregnant and give birth;

iii. Allow members of one sex into the healthcare programs or private spaces of the other sex in their facilities, such as by allowing males into female restrooms; or

iv. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity.

f) Award Plaintiffs costs and reasonable attorneys' fees.

g) Award such other relief as the Court deems equitable and just.

May 6, 2024

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