UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TYLER DIVISION

STATE OF TEXAS, STATE OF MONTANA *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; MELANIE FONTES RAINER, in her official capacity as Director of the Office for Civil Rights; CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants.*	Case No.

COMPLAINT

1. The Biden Administration is attempting to exact radical social change by defunding States and healthcare providers across the country who refuse to provide or pay for dangerous and experimental "gender-transition" medical activities. Through a sweeping new rule promulgated under the Affordable Care Act (ACA), those who do not conform to the Biden Administration's gender-ideology regime stand to lose all federal healthcare funds, including Medicaid and Medicare dollars. Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) (Final Rule). The Final Rule purports to override and preempt all State laws to the contrary, ensuring that the Biden Administration's assumption of control over the States' regulation of health and safety is complete. The Final Rule is unlawful and violates the Constitution, and the Court should set it aside and issue injunctive relief.

2. The Biden Administration cites Section 1557 of the ACA as a basis for this mandate. But Section 1557 does not authorize—and has never authorized—the federal government to compel anyone to perform or pay for these procedures. Defendants' mandate is wholly contrary to law.

3. Section 1557 of the ACA prohibits any federally funded health program from discriminating "on the grounds 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). In other words, federally funded health programs are prohibited from engaging in any practices that would treat men better than women, or vice versa.

4. In the Final Rule, the Department of Health and Human Services (HHS) interprets Section 1557 far more broadly by equating "sex" discrimination with discrimination based on "gender identity." *See generally* 89 Fed. Reg. 37,522.

5. In doing so, the Final Rule requires Texas and Montana to allow, and to even to expend taxpayer dollars to *pay for*, controversial drugs and experimental surgeries for those seeking to "transition"—notwithstanding the States' sovereign interests in protecting citizens from risky and experimental procedures that inflict permanent harm.

6. Under the Final Rule, HHS requires healthcare providers like Texas Tech University's Health Science Centers to fill prescriptions for puberty blockers—even when doing so would violate State law—or risk losing millions of dollars in federal healthcare funding.

7. This is not the first time the federal government has attempted to effect devastatingly drastic social change under Section 1557. First, the United States District Court for the Northern District of Texas set aside a 2016 regulation, promulgated under the Obama-Biden Administration, that interpreted Section 1557 the same way this Rule does. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016). Later, the same court set aside an effort by HHS to reimpose the same result by way of a 2021 Notification

on Section 1557. *Neese v. Becerra*, 640 F. Supp. 3d 668 (N.D. Tex. 2022). Finally, it set aside another such effort in the form of HHS's 2022 Guidance on Section 1557. *Texas v. EEOC*, 633 F. Supp. 824 (N.D. Tex. 2022).

8. The fourth time is not the charm. HHS's latest attempt to refashion the medical profession to match its views on "gender identity" and "gender-affirming care" again exceeds its authority under Section 1557, Title IX, and the United States Constitution, and it must be set aside.

Parties

9. Texas is a sovereign State of the United States.

10. Montana is a sovereign State of the United States.

11. Defendant Xavier Becerra is the Secretary of Health and Human Services. He is sued in his official capacity.

12. Defendant Melanie Fontes Rainer is the Director of the Office for Civil Rights within HHS and is responsible for bringing enforcement actions under Section 1557. She is sued in her official capacity.

13. Defendant Centers for Medicare & Medicaid Services (CMS) is an agency within HHS that participated in the promulgation of the Final Rule and will implement the amendments to the CMS regulations.

14. Defendant the United States Department of Health and Human Services is the executive agency of the federal government that promulgated and now enforces the challenged Final Rule.

Jurisdiction and Venue

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

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

17. The Court is authorized to award the requested declaratory and injunctive relief under 5 U.S.C. §§ 702, 703, and 706, and 8 U.S.C. §§ 1361, 2201, and 2202, and the Court's inherent equitable powers.

18. Venue lies in this district under 28 U.S.C. § 1391(e)(1) because an agency of the United States is a defendant, and because Texas resides in every judicial district and division within its borders, including this one. *See, e.g.*, *Utah v. Walsh*, 2:23-cv-016-Z, 2023 WL 2663256, at *3 (N.D. Tex. Mar. 28, 2023) ("Texas resides everywhere in Texas.").

Legal Background

I. The Affordable Care Act and Title IX.

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

20. The ACA maintains the States' power to regulate the medical field.

21. The ACA sets out a specific "[r]ule of construction regarding health care providers." 42 U.S.C. § 18122. That rule specifies that "the development, recognition, or implementation of any guideline or other standard under any Federal health care provision"—including any provision of the ACA—"shall not be construed to establish the standard of care or duty of care owed by a health care provider to a patient in any medical malpractice or medical product liability action or claim." *Id.* § 18122(1), (2)(A).

22. The ACA sets further limits on HHS's ability to promulgate regulations interfering with healthcare entities' and professionals' provision of medical services. 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).

23. Section 1557 applies to what HHS calls "covered entities," which includes recipients of federal financial assistance, including the joint federal/state Medicaid and the

Children's Health Insurance Program (CHIP) like those administered by Texas and Montana.

24. 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.

25. Section 1557 applies to virtually every healthcare entity in America. According to CMS, 98% of healthcare providers participate in Medicare.[1]

26. Any 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. 42 U.S.C. § 18116(a). That means that any hospital or doctors' office that accepts a single Medicaid of CHIP patient must follow Section 1557 for *all* its patients, no matter how other patients pay for care.

27. Through Medicare, Medicaid, and CHIP, the federal government is the single largest source of spending on healthcare—providing 33% of all U.S. health spending in 2022.[2]

28. Notably, Section 1557 does not add a new non-discrimination provision to the United States Code, but merely incorporates by reference pre-existing provisions under Title VI, Title IX, the Americans with Disabilities Act, and the Rehabilitation Act.

29. Section 1557 states that an individual shall not be denied, among other things, certain federally funded health benefits on the grounds prohibited under Title VI of the Civil Rights Act of 1965, Title IX of the Education Amendments of 1972, the Age Discrimination Act, or section 504 of the Rehabilitation Act of 1973, namely because of the individual's race, color, national origin, sex, age, or disability. 42 U.S.C. § 18116.

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[1] Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *Annual Medicare Participation Announcement*, https://www.cms.gov/medicare-participation.

[2] Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *National Health Expenditures 2022 Highlights* 3, https://www.cms.gov/files/document/highlights.pdf.

30. Section 1557 thus does not independently define the term "sex" and does not reference sexual orientation or gender identity. Its sole basis for prohibiting sex discrimination is based on its reference to Title IX, 20 U.S.C. § 1681 *et seq.*

31. 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).

32. That general prohibition under Title IX 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.

33. In addition to incorporating Title IX's "on the basis of sex" language, the ACA incorporates Title IX's public and private enforcement mechanisms for Section 1557. 42 U.S.C. § 18116(a).

34. If the Office for Civil Rights (OCR) finds a covered entity in noncompliance, HHS may require providers to take remedial action or lose federal funding.

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

36. When the ACA was enacted in 2010, no federal court or federal agency interpreted "sex" in Title IX to include gender identity.

37. In fact, Section 1557 specifically excludes from the scope of its nondiscrimination rule "transsexualism" and any "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 that "transsexualism" and "gender identity disorders not resulting from

physical impairments" are not a "disability" under section 794); *see also* 29 U.S.C. § 705(20)(E) (excluding "homosexuality" and "bisexuality" from protected categories).

38. And tellingly, Congress has repeatedly rejected attempts to expand the term "sex" in Title IX. Lawmakers have also rejected multiple attempts to amend the Civil Rights Act to add the new categories of "sexual orientation" and/or "gender identity." The first attempt to amend the Civil Rights Act to include sexual orientation as a protected class was in 1974, and there have been dozens of such attempts since then. All have failed.

II. Prior 1557 Rules, Guidance, and Related Litigation

A. The 2016 Rule

39. HHS issued its first Section 1557 rule in 2016 during the Obama-Biden Administration.[3] 81 Fed. Reg. 31,376 (May 18, 2016) (the "2016 Rule"). That rule defined "on the basis of sex" to include, inter alia, "gender identity." *Id.* at 31,467. Given this definition, HHS asserted that covered entities were required to perform (or refer for) medical transition procedures if they offer analogous services in other contexts. *See id.* at 31,455 ("A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.").

40. The 2016 Rule also prohibited certain employers, health programs, and insurance plans (again, including State Medicaid and CHIP programs) from excluding transition procedures from their health plans. As the rule stated: "[A]n explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face." *Id.* at 31,429.

41. The 2016 Rule also defined "on the basis of sex" to include "termination of pregnancy," pressuring covered entities to perform and insure abortions. *Id.* at 31,467.

[3] *See, e.g.*, *The Obama administration just took another step to protect trans people—in health care*, Vox (May 13, 2016), https://tinyurl.com/Obama1557.

42. In October 2016, the State of Texas, alongside a Catholic hospital system and a membership organization of Christian healthcare professionals, sued HHS, claiming that the 2016 Rule's definition of "sex" was inconsistent with Section 1557 and that forcing the religious plaintiffs to perform and/or provide coverage for gender-transitions and abortions violated RFRA. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016).

43. The *Franciscan* court agreed. The court explained that "[t]he text of Title IX indicates Congress's binary definition of 'sex;'" that the definition did not include "gender identity;" and that "HHS's expanded definition of sex discrimination exceeds the grounds incorporated by Section 1557." *Id.* at 687–89. Further, the 2016 Rule "place[d] substantial pressure on Plaintiffs to perform and cover transition and abortion procedures," and the government had not satisfied strict scrutiny, violating RFRA. *Id.* at 691–93; *see also Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941–44 (N.D. Tex. 2019) (summary judgment on RFRA claims). The court therefore vacated the portions of the 2016 Rule covering "gender identity" and "termination of pregnancy" and enjoined HHS from enforcing Section 1557 against the religious plaintiffs to force them to perform or insure gender-transitions or abortions. *See Franciscan*, No. 7:16-cv-00108-O, Dkt. Nos. 182, 211.

44. HHS did not appeal the vacatur. And when HHS appealed the injunction, a unanimous panel of the Fifth Circuit affirmed, also explaining that the vacatur remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022).

B. The 2020 Rule and *Bostock*

45. HHS next issued a new Section 1557 rule on June 12, 2020. *See* 85 Fed. Reg. 37,160 (June 19, 2020) (the 2020 Rule).

46. HHS noted that the 2020 Rule was promulgated in part in response to the *Franciscan* court's orders. *See, e.g.*, *id.* at 37,164–65; *id.* at 37,168. Agreeing with *Franciscan*, the 2020 Rule repealed the 2016 Rule's definition of discrimination "on the basis of sex," concluding that "the 2016 Rule's extension of sex-discrimination protections to encompass

gender identity was contrary to the text of Title IX." *Id.* at 37,167–68. The 2020 Rule declined, however, to provide a definition of "sex" discrimination of its own.

47. Three days later, the Supreme Court decided *Bostock v. Clayton County*, 590 U.S. 644 (2020).

48. There, the Court held that when "an employer . . . fires someone simply for being homosexual or transgender," the employer has "discriminated against that individual 'because of such individual's sex'" within the meaning of Title VII. *Id.* at 681.

49. The Court cautioned, however, that its opinion did not "prejudge" the proper interpretation of "other federal or state laws that prohibit sex discrimination," *id.* (majority opinion), including Section 1557 and Title IX, *see also id.* at 726–32 & n.57 (Alito, J., dissenting).

50. Following *Bostock*, plaintiffs in multiple jurisdictions sued HHS, challenging the 2020 Rule in light of *Bostock* and seeking restoration of the 2016 Rule, in whole or in part. In that litigation, "[t]wo courts entered nationwide injunctions preventing much of the 2020 Rule from going into effect," purporting to "reinstat[e] portions of the 2016 Rule" that had been vacated in *Franciscan*. *Franciscan*, 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)).

C. The 2021 Notification and 2022 Guidance

51. From the day the Biden Administration took office, HHS has been seeking to reinstate the 2016 Rule's redefinition of "sex" discrimination under Section 1557 to include "gender identity." But again, these efforts have repeatedly been recognized as contrary to law.

52. First, on January 20, 2021, 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).

53. Pursuant to the President's executive order, HHS then issued a "Notification of Interpretation and Enforcement" addressing Section 1557 (2021 Notification). 86 Fed. Reg. 27,984 (May 25, 2021). The 2021 Notification stated 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.

54. As with the 2016 Rule, the United States District Court for the Northern District of Texas held the 2021 Notification unlawful. In *Neese v. Becerra*, two physicians challenged the 2021 Notification, claiming it forced them to perform gender-transitions on minors contrary to their medical judgment and conscience. 640 F. Supp. 3d 668, 673 (N.D. Tex. 2022). The Court held that the 2021 Notification was "not in accordance with law" because (1) "*Bostock* does not apply to Section 1557 or Title IX" and (2) "Title IX's 'on the basis of sex' language does not include 'sexual orientation' or 'gender identity' status." *Id.* at 676, 684-85; *see also* Final Judgment, *Neese*, No. 2:21-cv-163-Z (N.D. Tex. Nov. 22, 2022), Dkt. No. 71 (declaratory judgment stating same).

55. Despite this, HHS next issued a document titled "Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy," https://perma.cc/LX26-59QR ("2022 Guidance"). In that Guidance, HHS "unequivocally" took the position that restricting gender-transition procedures even "for minors . . . is dangerous." *Id.* HHS said OCR would consider enforcement actions against healthcare providers who comply with state laws "restrict[ing]" the performance of those procedures on minors. *Id.*

56. This Guidance was issued "in direct response" and opposition to an order issued by the Governor of Texas. *Texas v. EEOC*, 633 F. Supp. 3d 824, 828 (N.D. Tex. 2022). On February 22, 2022, Governor Abbott had issued a directive to Texas's Department of Family and Protective Services, instructing it that "a number of so-called 'sex change' procedures constitute child abuse under existing Texas law," and directing it

"to conduct a prompt and thorough investigation of any reported instances of these abusive procedures." Gov. Abbott Letter, https://gov.texas.gov/uploads/files/press/O-MastersJaime202202221358.pdf.

57. In response to the Guidance, Texas sued HHS, explaining that the Guidance (like the 2016 Rule and 2021 Notification before it) was inconsistent with Section 1557 and therefore unlawful under the APA. The court again agreed, holding that the Guidance "exceeds Section 1557's requirements and is not justified by *Bostock*." *Texas v. EEOC*, 633 F. Supp. 3d at 840. The court therefore vacated the Guidance. *Id.* at 847.

D. The 2024 Final Rule

58. Undeterred by the previous holdings, HHS and CMS promulgated the Final Rule. 89 Fed. Reg. 37,522 (May 6, 2024); *see* Notice of Proposed Rulemaking ("NPRM"), 87 Fed. Reg. 47,824 (Aug. 4, 2022). This Final Rule is set to take effect on July 5, 2024.

59. The Final Rule has two parts. First, OCR promulgated regulations purporting to set out funding recipients' nondiscrimination obligations under Section 1557, which are to be codified in Part 92 of Title 45 of the Code of Federal Regulations and enforced by OCR. Second, CMS promulgated amendments to separate regulations for specific aid programs under both Section 1557 and provisions of the Social Security Act (SSA) and the Public Health Service Act (PHSA).

60. Broadly speaking, the Final Rule expands "[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). And it expands this definition all while claiming that "it is not necessary to define 'sex' in this rule." 89 Fed. Reg. at 37,575.

61. According to HHS, this expanded concept of discrimination mandates the performance of gender-transitions and prohibits the exclusion of transition procedures in insurance plans even when such exclusions apply equally to both sexes.

1. Section 1557 Regulations

a. Gender-transition and abortion

62. Amendments to 45 C.F.R. § 92.206 require covered entities to "provide individuals equal access" to their "health programs and activities without discriminating on the basis of sex." 89 Fed. Reg. at 37,701. It then sets forth in detail a number of "specific forms of discrimination" that are prohibited under HHS's sweeping view of what "sex" includes. 89 Fed. Reg. at 37,701.

63. First, under Section 92.206(b)(1), "a covered entity must 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." 89 Fed. Reg. at 37,700.

64. For example, a healthcare provider apparently cannot decline to provide a lactation consultation on the basis that the individual requesting it is a biological male.

65. Second, under Section 92.206(b)(3), "a covered entity must not . . . [a]dopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity." *Id.* at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(3).

66. HHS explains that, under this provision, it is a "violation" for a hospital with dual-occupancy rooms to prevent 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."); *see also* NPRM, 87 Fed. Reg. at 47,866–67.

67. Third, under Section 92.206(b)(4), "a covered entity must not . . . [d]eny or limit health services sought for purpose of gender transition or other gender-affirming care

that the covered entity *would* provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701 (emphasis added), *to be codified at* 45 C.F.R. § 92.206(b)(4).

68. In other words, if a covered entity would perform a hysterectomy for the purpose of treating uterine cancer, it must be willing to remove a healthy uterus for the purpose of facilitating a gender-transition. Or if a covered entity would prescribe puberty blockers to treat precocious puberty, it must be willing to prescribe them to a minor girl seeking to live as a boy. And this reasoning applies across the full range of treatments that could be sought for a gender-transition—including "counseling, hormone therapy, surgery," and more. NPRM, 87 Fed. Reg. at 47,834 n.139; *see* 89 Fed. Reg. at 37,596.

69. The Final Rule further makes 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). Again, for example, the Final Rule presumptively requires that a gynecological surgeon who performs a hysterectomy to treat endometrial cancer must remove a healthy uterus for a "gender-transition." *Id.*; *see also* NPRM, 87 Fed. Reg. 47,824, 47, 867.

70. And a medical practice that refuses to assist a gender-transition may only avoid sanctions if HHS's 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.

71. 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), and OCR will conduct a review of a "non-categorical denial[]" of a gender-change intervention "on a case-by-case basis," *id.* at 37,607.

72. Because of the Final Rule's emphasis on "individualized" assessment, the threat is clear: Any medical provider that *categorically* refuses to follow OCR's preferred "standards or guidelines" or care—*i.e.*, gender-transition—risks crippling enforcement proceedings and punishment.

73. The Final Rule forces States to subsidize gender-transitions. Indeed, the Final Rule makes it presumptively illegal for covered insurance providers and other entities—including States administering HHS programs such as ACA health-insurance exchanges, and joint federal/state programs such as Medicaid and 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. 37,701, *to be codified* at 45 C.F.R. § 92.207(b)(5). Again, under the Final Rule, 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.

74. A State may avoid sanctions by showing that there is no "medical necessity" for a gender-transition intervention in a particular case. But the Final Rule prohibits 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, 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.

75. Section 92.206(c) goes on to provide that a covered entity need not provide such services "where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service

is not clinically appropriate *for a particular individual*." 89 Fed. Reg. at 37,701 (emphasis added), *to be codified at* 45 C.F.R. § 92.206(c). But HHS's explanation of this concept is narrow. Section 1557's nondiscrimination mandate would not require a doctor to provide "a prostate exam for a transgender man who does not anatomically have a prostate." *Id.* at 37,607. As this language itself indicates, HHS contends that *categorical* refusals to perform procedures sought for purpose of a gender-transition *are* discriminatory in violation of the Rule. *See id.* at 37,575, 37,595–97 ("individualized clinical judgment").

76. HHS views "categorical exclusions for gender affirming care" as suggestive of pretext, even if required by state law. 87 Fed. Reg. 47,874. Accordingly, a provider who follows State law and declines to perform "gender-transition" procedures on minors would engage in "prohibited discrimination on the basis of sex." *Id.*

77. In explaining how it would distinguish a lawful refusal from an unlawful one, HHS states it would review "medical necessity standards or guidelines; the clinical, evidence-based criteria or guidelines relied upon to make the medical necessity determination; and the medical substantiation for the medical necessity determination." 89 Fed. Reg. at 37,613. And it makes clear the particular "guidelines" it has in mind, citing those issued by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society—leading proponents of "what the medical profession has come to call gender-affirming care." *L.W. by and through Williams v. Skrmetti*, 83 F.4th 460, 467 (6th Cir. 2023); *see* NPRM, 87 Fed. Reg. at 47,868 n.423.

78. HHS has previously described WPATH as an "advocacy group." 85 Fed. Reg. at 37,198. So has WPATH itself. *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Dkt. 208 at 3 (M.D. Ala. Dec. 27, 2022). And WPATH has adamantly opposed efforts to discover the bases for its "standards." *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Dkt. 263 at 1–3 (M.D. Ala. Mar. 27, 2023).

79. Similarly, the Endocrine Society "makes no warranty, express or implied, regarding [its] guidelines," "nor do they establish a standard of care." Hembree, et al.,

Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, 10 J. Clin. Endocrinol Metab. 3895 (2017).

80. The Final Rule also includes, in the prohibition of "sex" discrimination, discrimination based on "Pregnancy or related conditions." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). According to the commentary, HHS agrees that "termination of pregnancy" is a "pregnancy-related condition[]." *Id.* at 37,634 ("OCR affirms that under section 1557, covered entities may not discriminate against individuals for their pregnancy-related decisions, past, present, or future.").

81. On the same reasoning it uses to require the performance of gender-transition procedures, the Final Rule arguably requires abortions too. For example, if a provider would perform a dilation and curettage for a miscarriage, it must be willing to do so for an abortion, or else face liability for "sex" discrimination. To do otherwise would be "discriminat[ing]" because of a "pregnancy-related decision." *Id.*

82. The Final Rule is clear that it preempts State "laws impacting health programs and activities that are contrary to the final rule's nondiscrimination protections." 89 Fed. Reg. 37,535.

83. And while the Final Rule disclaims an interpretation of Section 1557 that would preempt State laws regulating and prohibiting abortions, it does not disclaim an interpretation of its own terms that would require covered entities and providers to violate regulations and prohibitions on abortion.

84. The Rule also mandates revisions to covered entities' written policies, requiring express affirmance that transition-related procedures will be provided. 89 Fed. Reg. at 37,696, *to be codified* at 45 C.F.R. § 92.8(b). They must do so even if such revisions do not reflect their medical judgment, values, beliefs, or compliance with State law.

85. There is no exception or protection for entities who fail to "implement a written policy" or "provide a notice of nondiscrimination to participants, beneficiaries, . . . and

members of the public" that the entity does not discriminate on the basis of "termination of pregnancy." *See* 89 Fed. Reg. 37,696–97, *to be codified at* 42 C.F.R. §§ 92.7, 92.10.

86. In effect, the Final Rule compels entities to represent that they perform abortions—even when State law would prohibit them from performing abortions.

87. Section 1557 is an ordinary non-discrimination law. It does not confer sweeping authority on OCR to decree gender-transition interventions or abortions as the federal standard of care through threats of putting States' federal funding at risk. *See* 45 C.F.R. §§ 80.8, 92.203.

b. Insurance coverage for transition procedures

88. The Final Rule also governs the provision of health insurance by entities involved in federally funded health insurance and joint federal/state health insurance programs, such as Medicaid or CHIP. Under Section 206, "[a] covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(a).

89. Like Section 92.206, Section 92.207 then provides several specific examples of prohibited discrimination.

90. First, Section 92.207(b)(4) says a covered entity may not "[h]ave or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care." *Id.*, *to be codified at* 45 C.F.R. § 92.207(b)(4).

91. Second, Section 92.207(b)(5) provides that a covered entity may not "[o]therwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for *specific health services* related to gender-transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex." *Id.* (emphasis added); *to be codified at* 45 C.F.R. § 92.207(b)(5). According to HHS, such exclusions are themselves unlawful discrimination, even if they are not motivated by sex or gender identity, because

"transgender individuals are the only individuals who seek transition-related care." NPRM, 87 Fed. Reg. at 47,871.

92. Taken together, these provisions mean a covered entity can't exclude all transition procedures (subsection (b)(4)) and can't exclude any particular one of them either (subsection (b)(5)). In other words, gender-transition procedures are given "an unconditional most-favored-nation status." *Young v. UPS*, 575 U.S. 206, 222 (2015). Now, health plans can exclude coverage for all kinds of things (from weight-loss surgery to cancer treatments), but any gender-transition procedure cannot be excluded.

2. CMS Regulations

93. In addition to amending HHS's Section 1557 regulations, the Final Rule also amends CMS regulations relating to the Medicaid and CHIP programs designed to provide healthcare for children and pregnant women, and PACE's program for all-inclusive care for the elderly. In addition to relying on its authority under Section 1557, CMS claimed authority to make these changes to Medicaid under 42 U.S.C. § 1396a(a)(4), to CHIP under 42 U.S.C. § 1396aa(a), and to PACE under 42 U.S.C. §§ 1395eee(f), 1396u-4(f).

94. Under CMS's revised Medicaid and CHIP regulations, contracts with entities that deliver services 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 (emphasis added). Thus, a managed care organization's facially neutral policies or practices that lack any discriminatory purpose that nonetheless have a discriminatory *effect* on transgender individuals may now violate its contract.

95. Entities that deliver services also must "promote the delivery of services in a culturally competent manner to all enrollees, . . . and regardless of sex which includes . . . gender identity." *Id.*

96. And under the Final Rule, States' Medicaid and CHIP programs "must 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.

97. With respect to its PACE regulations, CMS likewise revised the regulatory language's reference to "sex" to include "sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." *See* 89 Fed. Reg. at 37,669.

98. The SSA does not authorize Defendants to fundamentally transform the practice of medicine.

99. Section 1902(a)(4) of the SSA (codified at 42 U.S.C. § 1396(a)(4)) merely authorizes the adoption of "methods of administration necessary for the proper and efficient operation of the Medicaid State plan."

100. Section 1902(a)(19) of the SSA (codified at 42 U.S.C. 1396a(a)(19)) simply "requires the Medicaid State plan to provide safeguards as necessary to assure that covered services are provided in a manner consistent with the best interests of the recipients." 89 Fed. Reg. 37,668. And section 2101(a) of the SSA (codified at 42 U.S.C. 1397aa(a)) only "permits provision of funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low income children in an effective and efficient manner,." 89 Fed. Reg. 37,668

101. Defendants' contention that the SSA authorizes Defendants to impose a "gender-identity" mandate on healthcare providers across the United States lacks any limiting principle and is wholly unsupported by the statute.

III. The Vigorous Debate over the Proper Treatment of Gender Dysphoria

102. The Final Rule attempts to impose a new, nationwide standard of care on the medical profession: transition procedures are "medically necessary," NPRM, 87 Fed. Reg. at 47,981, and contrary views are discrimination, *see id.* at 47,480 (uninsured transition procedures evince "pervasive" "transphobia"). This is wrong.

103. The proper treatment of gender dysphoria—a condition defined to involve distress from a discordance between a person's perceived gender and his or her biological sex—"remains one of the most hotly debated topics within the medical community today." *Gibson v. Collier*, 920 F.3d 212, 217, 224 (5th Cir. 2019).

104. On one side are proponents of the "gender-affirming" approach, exemplified by WPATH (and now HHS). According to this approach, the only proper approach to gender dysphoria is to "affirm" the perceived "gender" by changing the body to match it.

105. "Gender-affirming" care is typically a multi-step process. In a child, for example, the process often begins with puberty blockers to stop the natural onset of puberty; then progresses to cross-sex hormones aimed at triggering the development of the other sex's secondary sex characteristics; and continues on to surgery designed to alter the body's physical characteristics. Such surgeries can include, for example, a double mastectomy to remove healthy breasts, "bottom surgery" to remove healthy reproductive organs, and plastic surgery and cosmetic procedures to imitate the genitals and physical appearance of the opposite sex. *See* WPATH Standards of Care, Version 8, *available at* https://tinyurl.com/WPATHSoCV.

106. But "the WPATH Standards of Care reflect not consensus, but merely one side in a sharply contested medical debate." *Gibson*, 920 F.3d at 221.

107. On the other side are those who recognize the "affirming" approach's certain and irreparable harms, which contrast sharply with its uncertain and unproven benefits. For one, "[b]ottom surgery" renders its recipients permanently infertile, as does

the successful blocking of puberty in tandem with cross-sex hormones.[4] The "affirming" protocol also turns recipients into lifelong medical patients, with a continuous hormone regimen to maintain, surgically altered body parts requiring ongoing treatment or repair, and ever more surgeries potentially around the corner. *See* WPATH, *supra*, at S18, S2128, S258 (listing 30+ "medically necessary" "gender-affirming surgical procedures").

108. Puberty blockers and cross-sex hormones also come with ample risks of their own. For example, puberty blockers cause decreased bone density, "'associated with a high risk of osteoporosis.'"[5]

109. As for hormones, for women and girls, WPATH-recommended levels of testosterone "induc[e] severe hyperandrogenism," a state "associated with multiple risks to . . . physical and mental health," including clitoromegaly, atrophy of the lining of the uterus and vagina, irreversible vocal-cord changes, hirsutism, erythrocytosis, myocardian infarction, severe liver dysfunction, coronary artery disease, hypertension, and breast or uterine cancer.[6] And for men and boys, WPATH-recommended levels of estrogen induce "the medical condition of hyperestrogenemia," causing sexual dysfunction and increased risk of thromboembolic disease, macroprolactinoma, breast cancer, coronary artery disease, cerebrovascular disease, cholelithiasis, and hypertriglyceridemia.[7]

110. Meanwhile, the evidence purporting to show the benefits of these procedures is woefully inadequate. Indeed, "every systematic review to date" has concluded that "the evidence base for the life-altering interventions of puberty

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[4] *E.g.*, Stephen B. Levine, Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, 44 J. Sex & Marital Therapy 29 (2018), https://pubmed.ncbi.nlm.nih.gov/28332936/

[5] Soc'y for Evidence Based Gender Medicine, *The Effect of Puberty Blockers on the Accrual of Bone Mass* (May 1, 2021), https://tinyurl.com/SocyEvid.

[6] Expert Declaration of Michael K. Laidlaw, M.D., *Skrmetti*, No. 3:23-cv-00376 (M.D. Tenn. May 19, 2023), ECF No. 113-7, at ¶¶ 117–44.

[7] *Id.* ¶¶ 145–54.

suppression, cross-sex hormones, and surgeries is low quality."[8] As a recent, yearslong independent study commissioned by England's National Health Service recounts, such reviews have shown "no evidence that puberty blockers improve body image or dysphoria," no evidence "that hormone treatment reduces the elevated risk of suicide" for those suffering from gender dysphoria, and the "single Dutch study" initially responsible for the spread of the affirming approach was marred by potential sources of bias and confounding factors. *The Cass Review: Independent Review of Gender Identity Services for Children and Young People* (April 2024), https://tinyurl.com/CassRev24 at 33, 68, 178.

111. This combination of unproven benefits and guaranteed, irreversible harms is especially intolerable for children, given that the vast majority of children who experience gender dysphoria desist on their own before adulthood. *See* WPATH Standards of Care (7th ed. 2012), https://tinyurl.com/WPATHv7 at 11 (studies alternatively showing up to 88% or 94% desistance rate).

112. Even HHS has previously recognized as much. In 2016, HHS, under the Obama Administration, refused to require national coverage of "gender reassignment surgery" under Medicare, concluding 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." CMS, Final Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (Aug. 30, 2016), https://perma.cc/R2ME-YQRA. "There were conflicting (inconsistent) study results—of the best designed studies, some reported benefits while others reported harms." *Id.*

113. More recently, countries across the globe have begun to retreat from the "affirming" model—including the European nations that once pioneered it. The "public

[8] Mia Hughes, *The WPATH Files: Pseudoscientific Surgical and Hormonal Experiments on Children, Adolescents, and Vulnerable Adults* (March 2024) https://tinyurl.com/MHughesWPATH 40.

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 v. Gov. of Ala.*, 80 F.4th 1205, 1218 (11th Cir. 2023). NHS England has halted the use of puberty blockers "as a routine commissioning treatment option for treatment of children and young people who have gender incongruence/gender dysphoria." NHS England, *Clinical policy: puberty suppressing hormones* (Mar. 12, 2024), https://tinyurl.com/NHSclinicalpolicy.

114. Twenty-five States, including Texas and Montana, have enacted laws barring the performance of gender-transition procedures on minors (including drug regimens and surgical procedures).[9] These laws are consistent with the States' "abiding interest 'in protecting the integrity and ethics of the medical profession' and 'preserving and promoting the welfare of the child,'" *Skrmetti*, 83 F.4th at 473—and have accordingly been upheld against constitutional challenges in both the Sixth and Eleventh Circuits, *id.* (upholding Kentucky's and Tennessee's laws); *see also Eknes-Tucker*, 80 F.4th at 1225 (upholding Alabama's).

IV. Impact on Plaintiffs

A. Impact on Texas

115. "[T]he State has a significant role to play in regulating the medical profession." *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007). This includes "an interest in

[9] *See* Ala. Code § 26-26-4; Ariz. Stat. § 32-3230; Ark. Code § 20-9-1502(a); Fla. Admin. Code R.64B8-9.019; Ga. Code § 31-7-3.5; Idaho Code § 18-1506C; Ind. Code § 25-1-22-13; Iowa Code § 147.164; Ky. Stat. § 311.372; La. Stat. § 40:1098 (effective Jan. 1, 2024); Miss. Code § 41-141-1-9; Mo. Stat. § 191.1720; S.B. 99, 68th Leg., 2023 Sess. (Mont. 2023); Neb. Stat. § 71-7301–7307; H.B. 808, 2023 Sess. (N.C. 2023); N.D. Cent. Code. § 12.1-36.1-02; Ohio Code § 3129.01-06; Okla. Stat. tit. 63, § 2607.1; H.B. 4624, 125th Leg. Sess. (S.C. 2024); H.B. 1080, 98th Leg. Sess. (S.D. 2023); Tenn. Code § 68-33-101. S.B. 14, 88th Leg. Sess. (Tex. 2023); Utah Code § 58-68-502(1)(g); W. Va. Code § 30-3-20 (effective Jan. 1, 2024); Wyo. Stat. § 35-4-1001 (effective July 1, 2024).

regulating the medical treatments offered to children suffering from gender dysphoria." *Skrmetti*, 83 F.4th at 468.

116. Texas prohibits medical organizations from interfering with, controlling, or directing "a physician's professional judgment," Tex. Occ. Code § 162.0021, and mandates that physicians exercise "independent medical judgment when providing care to patients," *id.* § 162.0022.

117. In furtherance of these objectives, Texas hospitals must appoint a chief medical officer who is responsible for adopting policies to ensure that physicians can exercise independent medical judgment. Tex. Health & Safety Code § 311.083(d). Texas law requires the chief medical officer to report to the Texas Medical Board any action or event that constitutes a compromise of the independent medical judgment of a physician in caring for a patient. *Id.*

118. Under Texas law, a physician or healthcare provider may not knowingly perform a sterilizing surgery or mastectomy, or provide puberty blockers or cross-sex hormones, to minors "[f]or the purpose of . . . affirming the child's perception of the child's sex if that perception is inconsistent with the child's biological sex." Tex. Health & Safety Code § 161.702.

119. Texas also excludes these same procedures from its CHIP program. Tex. Health & Safety Code § 62.151(g).

120. But the Final Rule requires the State to pay for these medical activities. 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4)–(5).

121. Similarly, Texas excludes "Sex change operations" from its Medicaid program. Tex. Health & Human Servs., Tex. Medicaid Provider Procedures Manual § 1.11 (May 2024), available at https://tinyurl.com/TxPPM. The Final Rule stipulates that such exclusions are "discrimination." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.207(b)(4)–(5).

122. The majority of Texas's Medicaid recipients are children.[10]

123. The Final Rule requires Medicaid providers to violate State law by prescribing puberty blockers and performing surgeries like mastectomies on minors. And it requires the State to pay for those experimental treatments.

124. The Final Rule also arguably requires covered entities in Texas to violate Texas's regulations and prohibitions on abortion.

125. Under Texas's Human Life Protection Act, "[a] person may not knowingly perform, induce, or attempt an abortion." Tex. Health & Safety Code § 170A.002. That prohibition does not apply if the woman on whom the abortion is performed "has a life-threatening physical condition" arising from a pregnancy that places her "at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed." Tex. Health & Safety Code § 170A.002(b)(2). Texas law imposes criminal and civil penalties for violation of this law. *See* Tex. Health & Safety Code §§ 170A.004–.005; Tex. Penal Code § 12.32–.33.

126. In addition to the Human Life Protection Act, Texas statutes predating *Roe v. Wade* also address the subject of abortion. *See* Tex. Rev. Civ. Stat. arts. 4512.1–.4, .6. Under those statutes, any person who causes an abortion is guilty of an offense and shall be confined in a penitentiary. *Id.* at 4512.1. Moreover, an individual may not act as an accomplice to abortion or an attempted abortion. *Id.* at 4512.2.–.3. However, it is not an offense if the abortion is performed under "medical advice for the purpose of saving the life of the mother." *Id.* ta 4512.6.

127. The Texas pre-*Roe* statutes also impose felony criminal liability on any person who engages in conduct in Texas that "procures" an abortion, as well as any person who aids or abets this procuring conduct. *See* Tex. Rev. Civ. Stat. arts. 4512.1.

[10] *Facts About Medicaid in Texas*, Pharmaceutical Research & Manufacturers of America, https://tinyurl.com/MedFctsPhRMA.

128. The Final Rule is clear that it preempts State "laws impacting health programs and activities that are contrary to the final rule's nondiscrimination protections." 89 Fed. Reg. 37,535. And while the Final Rule disclaims an interpretation of Section 1557 that would preempt State laws regulating and prohibiting abortions, it does not disclaim an interpretation of its own terms that would require covered entities and providers to violate Texas's regulations and prohibitions on abortion.

129. The Final Rule purports to preempt Texas's sovereign interests in the health and safety of its residents. In doing so, it threatens Texas's "sovereign interest in the power to create and enforce a legal code" and threatens substantial economic injury on Texas. *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015) (cleaned up).

130. Under the Final Rule, Texas healthcare providers must violate State law to retain federal funding. *See* NPRM, 87 Fed. Reg. at 47,867 ("[A] provider's view that no gender-transition or other gender-affirming care can ever be beneficial for such an individuals (*or its compliance with a state or local law that reflects a similar judgment*) is not a sufficient basis for a judgment that a health service is not clinically appropriate." (emphasis added)).

131. Texas receives billions of dollars in federal financial aid administered by HHS every year. The Final Rule places unlawful conditions on that funding, penalizing Texas for attempting to protect its citizens from harmful medical procedures and for declining to insure those procedures in its health plans.

132. For example, Texas Tech University Health Science Center (TTUHSC) and Texas Tech University Health Science Center (TTUHSC EP) both participate in Medicaid and Medicare. For the 12-month period that ended on August 31, 2023, TTUHSC received total Medicaid and Medicare revenue of $98,571.70, and TTUHSC EP received total Medicaid and Medicare revenue of $32,991,046. If TTUHSC and TTUHSC EP do not comply with the Final Rule, they stand to lose millions of dollars in federal funding.

133. The Final Rule acknowledges the enormous economic impact it will have on the States. HHS itself estimates that the cost of revising relevant policies and procedures to comply with the 2024 Rule will result in a one-time cost of $65 million across all covered entities. 89 Fed. Reg. at 37,680. It predicts the initial cost of training employees on the 2024 Rule across all covered entities will be more than $927 million, with ongoing annual training estimated to cost another $309 million per year. *Id.* at 37,679, 37,680. And it estimates that required annual recordkeeping will cost millions more. *Id.* at 37,682. TTUHSC and TTUHSC EP are among the covered entities who will incur these costs.

B. Impact on Montana

134. In 2023, Montana enacted SB 99, which provides that a person may not knowingly provide surgical procedures, supraphysiologic doses of testosterone or other androgens, or puberty blockers to a female minor to address the minor's perception that her gender or sex is not female or to a male minor to address the minor's perception that his gender or sex is not male. Mont. Code. Ann. § 50-4-1004(1). Among other things, SB 99 also prohibits the use of public funds for the purpose of providing such medical treatments and specifically prohibits Montana Medicaid and CHIP (and other insurers) from reimbursing or providing coverage for such treatments. *Id.* §§ 50-4-1004(3), (6), 50-4-1006, 53-6-135. Although SB 99 has been preliminary enjoined by a state district judge, Montana has appealed that ruling.

135. Under the Final Rule, however, Montana healthcare providers must violate state law to retain federal funding. *See* NPRM, 87 Fed. Reg. at 47,867 ("[A] provider's view that no gender-transition or other gender-affirming care can ever be beneficial for such an individuals (*or its compliance with a state or local law that reflects a similar judgment*) is not a sufficient basis for a judgment that a health service is not clinically appropriate." (emphasis added)).

136. Montana did not pay for gender transition procedures for minors, such as chest mastectomies, prior to SB 99 and still does not pay for those procedures. The Final Rule would force the state to pay for those procedures.

137. "[T]he State has a significant role to play in regulating the medical profession." *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007). This includes "an interest in regulating the medical treatments offered to children suffering from gender dysphoria." *Skrmetti*, 83 F.4th at 468. The Final Rule nullifies Montana's efforts to vindicate that interest.

138. Montana receives approximately $2 billion in federal financial aid administered by HHS every year. The Final Rule places unlawful strings on that aid, penalizing Montana for attempting to protect its citizens from harmful medical procedures and for declining to insure those procedures in its health plans.

Claims

Count I

The Final Rule Exceeds Statutory Authority and Is Not in Accordance with Law 5 U.S.C. § 706

139. Plaintiffs incorporate by reference all preceding paragraphs.

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

141. The Final Rule exceeds HHS's statutory authority because it defines discrimination "on the basis of sex" in a manner contrary to Section 1557 and Title IX.

142. Congress has not delegated to Defendants the authority to prohibit gender-identity discrimination under Section 1557.

143. The Final Rule defines prohibited "sex" discrimination to include discrimination based on "gender identity." 89 Fed. Reg. at 37,699. But "the meaning of sex in Title IX"—and thus in Section 1557—"unambiguously refers to 'the biological and anatomical differences" "between males and females"—not to "gender identity." *Franciscan*, 227 F. Supp. 3d at 685–89. "Accordingly, HHS's expanded definition of sex discrimination exceeds the grounds incorporated by Section 1557." *Id.* at 689.

144. The Final Rule cites *Bostock* to support its conclusion that "sex" discrimination includes "gender identity." 89 Fed. Reg. at 37,574. But "*Bostock* does not apply to Section 1557 or Title IX." *Neese*, 640 F. Supp. 3d at 675. *Bostock* addressed Title VII, not Title IX, and the "overall statutory scheme and purpose of Title IX" make clear that "'sex'" is "based on biology and reproductive function." *Adams v. Sch. Bd. of St. John's Cnty.*, 57 F.4th 791, 813 (11th Cir. 2022) (en banc).

145. Even if *Bostock* did apply to Section 1557, the Final Rule's prohibitions still would not follow because, under *Bostock*, it is not "sex" discrimination to decline to perform or pay for gender-transition procedures for individuals of either sex.

146. *Bostock* held that an employer's firing an employee "simply for being . . . transgender" is "sex" discrimination because the firing is based on "actions or attributes it would tolerate in an individual of another sex." 590 U.S. at 650–52, 658. In other words, sex is a but-for cause of such a firing because "changing the employee's sex would have yielded a different choice." *Id.* at 649–50.

147. But this reasoning doesn't apply to refusals to perform or pay for gender-transitions. If a healthcare provider would provide (for example) puberty blockers to treat precocious puberty, but not to facilitate a gender-transition, then "changing the [patient]'s sex" wouldn't "yield a different choice." The but-for cause of the decision isn't the patient's sex (or even gender identity) but the fact that the patient lacks the diagnosis that calls for the procedure. *See Texas v. EEOC*, 633 F. Supp. 3d at 829–36 ("the State of Texas may *not* discriminate against an employee '*for being* homosexual,' [or] '*for being*

transgender' . . . but may regulate correlated conduct via sex-specific dress, bathroom, pronoun, and healthcare policies").

148. The SSA does not authorize HHS's gender-identity mandate either.

149. Section 1902(a) of the SSA, 42 U.S.C. § 1396a(a)(4), requires Medicaid State plans to provide "such methods of administration . . . as are found by the Secretary to be necessary for the proper and efficient operation of the plan."

150. Defendants' reliance on 42 U.S.C. § 1302 fares no better. That section of the SSA provides that the Secretary "shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary for the efficient administration of the functions with which each is charged under his chapter."

151. Nondiscrimination rules are not "methods of administration." HHS's interpretation of the SSA as providing carte blanche authority to impose requirements on State Medicaid plans is inconsistent with the statutory text and violates the "clear notice" requirements for Spending Clause legislation and the major questions doctrine.

152. Section 2101(a) of the SSA, 42 U.S.C. § 1397aa, also does not authorize HHS's gender-identity mandate for CHIP. This provision does not grant HHS rulemaking authority or otherwise support HHS's interpretation of "sex" discrimination to include sexual orientation and gender identity. HHS's interpretation of this section is inconsistent with the text and statutory context, as well as the "clear notice" required by the Spending Clause and the major questions doctrine.

153. Section 1894(f)(A) and 1934(f)(A) of the SSA, 42 U.S.C. § 1395eee(f); *id.* § 1396u-4(f), similarly do not give HHS authority to impose its gender identity mandate. HHS's reading of these provisions to afford near limitless rulemaking authority is contrary to statutory text and context, as well as the "clear notice" required by the Spending Clause and the major question doctrine.

154. That the Final Rule exceeds Defendants' authority is confirmed by the principle that agencies must be able to point to "clear congressional authorization" when

they claim power to make decisions of vast "economic and political significance." *West Virginia v. EPA*, 597 U.S. 697, 721–23 (2022). Prohibiting discrimination on the basis of gender identity throughout the nation's healthcare system, as a condition of receipt of federal funding from HHS, is an issue of vast economic and political significance for which Congress did not give HHS clear authority.

155. The proper treatment of gender dysphoria is one of the most hotly debated issues in American life today—a debate exemplified by the fact that exactly half the States have barred certain gender-transition procedures from being performed on minors. Yet HHS attempts to enact the "gender-affirming" approach as a new, nationwide standard of care in a regulation it admits will apply to "almost all practicing physicians" in the country. 89 Fed. Reg. at 37,685. Far from being able to identify "clear congressional authorization" for that decision, Section 1557 cuts against it.

156. Further, the Final Rule is contrary to Section 1554 of the ACA, 42 U.S.C. § 18114. By requiring covered entities to represent that they perform abortions, even when performing such an abortion would violate State law, the Final Rule "restricts the ability of health care providers to provide full disclosure of all relevant information to patients," 42 U.S.C. § 18114(4), and "interferes with communications . . . between the patient and the provider." 42 U.S.C. § 18114(3).

157. The Final Rule is also contrary to Section 1303 of the ACA, 42 U.S.C. § 18023. That section provides that nothing in the ACA "shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions," but the Final Rule purports to require covered entities to perform abortions even when doing so would violate State law.

158. The Final Rule also conflicts with the terms of the ACA by imposing a national standard requiring the provision of "gender-affirming" treatment that prevents providers from warning patients about the risks and dangers of such procedures. *See* 42

U.S.C. § 18114(5) ("Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that— (5) violates the principles of informed consent and the ethical standards of health care professionals.").

159. The Final Rule is therefore not in accordance with law within the meaning of the APA, 5 U.S.C. § 706(2)(A).

COUNT II

The Final Rule is Arbitrary and Capricious 5 U.S.C. § 706

160. Plaintiffs incorporate by reference all preceding paragraphs.

161. The APA requires courts to set aside agency action that is "arbitrary, capricious," or an "abuse of discretion." 5 U.S.C. § 706(2)(A).

162. "Normally, an agency rule would be 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." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

163. "[A]gency action" is "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent thereof, or failure to act." 5 U.S.C. § 551(13). An agency "rule" is defined as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." *Id.* at § 551(4).

164. An agency action is arbitrary or capricious if it fails to "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.*, 463 U.S. at 43. Under

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

165. The Final Rule's gender-identity mandates are arbitrary and capricious.

166. *First*, HHS failed to offer a "reasoned explanation" of the Final Rule's departure from the historic understanding of "sex" as used in Title IX. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). If anything, HHS's history of shifting positions on the meaning of "sex" demonstrates that HHS's purported *Bostock*-based justifications for the Final Rule are nothing more than "contrived reasons" offered to support a predetermined result. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019).

167. *Second*, the Final Rule never defines "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, differences between the sexes are a biological reality. HHS's 2020 Rule previously conceded as much: It explained that preferencing ideology over science "risk[s] masking clinically relevant, and sometimes vitally important, information"—like potential pregnancy in a transgender male. 85 Fed. Reg. 37,189–90. But the Final Rule does not engage with the biological and medical realities that sex has in medical care, or the "life-and-death" risks associated with ignoring them. *Id.*

168. *Third*, HHS's decision to embrace the WPATH Standards and Endocrine Society Guideline runs counter to the evidence before the agency. Commenters presented numerous studies and scholarly reviews showing that the "standards" advocated by these medical interest groups are based on weak evidence and that there is no consensus on gender-transition interventions. The Final Rule instead replaces science-based medicine with ideology-driven mandates.

169. *Fourth*, HHS "entirely failed to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, namely the numerous negative side effects associated with "gender-affirming care." HHS never acknowledged, for example, that its preferred

"standard of care" may render an untold number of minors and adults infertile for the rest of their lives and dependent on a life-long drug regimen. HHS needs to consider that disadvantage.

170. *Fifth*, HHS failed to consider whether requiring providers to "affirm" gender ideology and to use patients' preferred pronouns instead of ones that are biologically accurate will drive providers out of Medicaid and CHIP—and possibly out of the profession completely. The potential shortage of providers and its harm to Medicaid and CHIP recipients is an "important aspect of the problem" that HHS failed to consider. *State Farm*, 463 U.S. at 43.

171. *Finally*, Defendants ignored the reliance interests of covered entities on the absence of a "gender-transition" mandate under Section 1557.

Count III

The Final Rule is Contrary to the U.S. Constitution 5 U.S.C. § 706(2)(A)

172. Plaintiffs incorporate by reference all preceding paragraphs.

173. The APA requires courts to set aside and vacate agency action that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B); *see also id.* § 706(2)(A).

174. Congress passed Section 1557 under the Spending Clause of the United States Constitution.

175. When Congress exercises its Spending Clause power against the States, principles of federalism require that conditions on Congressional funds given to States must enable a state official to "clearly understand," from the language of the law itself, what conditions the State is agreeing to when accepting the federal funds. *Arlington Cent. Sch. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

176. "The legitimacy of Congress's exercise of the spending power 'thus rests on whether the [entity] voluntarily and knowingly accepts the terms of the

'contract.'" *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 577 (2012) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)).

177. Here, Defendants' *ex-post* Final Rule does not accord with the understanding that existed when the States chose to participate in the Medicaid and CHIP programs and when covered entities, like TTUHSC and TTUHSC EP, began accepting Medicare and Medicaid as payment for medical services provided. *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985) (providing that a state's obligation under cooperative federalism program "generally should be determined by reference to the law in effect when the grants were made").

178. The text employed by Congress does not support understanding the term "sex" in the manner put forth by Defendants. While Congress has expressed its intent to cover "gender identity" as a protected class in *other* pieces of legislation, *see, e.g.*, 18 U.S.C. § 249(a)(2)(A); 42 U.S.C. § 13925(b)(13)(A), it has not done so regarding Title IX. In *other* legislation, Congress included "gender identity" along with "sex," thus evidencing its intent for "sex" in Title IX to retain its original and only meaning—one's immutable, biological sex as acknowledged at or before birth.

179. The Final Rule was adopted under the authority Congress delegated to HHS in Section 1557 of the ACA. Section 1557 does not add a new nondiscrimination provision to the federal code, but merely incorporates by reference preexisting provisions under Title VI, Title IX, the Age Discrimination Act, and section 504 of the Rehabilitation Act. Section 1557 does not independently define terms such as "sex."

180. At the time that the ACA was passed in 2010, no federal courts or agencies had interpreted "sex" in Title IX to include gender identity.

181. No State could fathom, much less "clearly understand," that the ACA—or the SSA—would impose on it the conditions created by HHS's new Final Rule.

182. Coercing States to abandon their laws—and healthcare providers to violate State laws—or sacrifice federal funding is beyond the government's Spending Clause

power. It amounts to a "gun to the head" for the States and covered entities. *Sebelius*, 567 U.S. at 581. It is "economic dragooning that leaves the States with no real option but to acquiesce." *Id.* at 582.

183. The Spending Clause violations articulated herein provide the Court with an additional basis to set aside the new Rule under the APA.

Declaratory Judgment

184. The federal Declaratory Judgment Act authorizes federal courts to declare the rights of litigants. 28 U.S.C. § 2201. The issuance of a declaratory judgment can serve as the basis for an injunction to give effect to the declaratory judgment. *Steffel v. Thompson*, 415 U.S. 452, 461 n.11 (1974).

185. For the reasons described above, Plaintiffs are entitled to a declaration that Defendants are violating the law and the Final Rule is unlawful, unconstitutional, and unenforceable.

Prayer for Relief

Plaintiffs pray the Court:

a. Enter a stay of the Final Rule's effective date under 5 U.S.C. § 705, and hold unlawful and set aside (*i.e.*, vacate) the Final Rule under 5 U.S.C. §706(2);

b. Declare that the Final Rule is unlawful;

c. Issue a temporary restraining order, preliminary injunction, and permanent injunction prohibiting Defendants from interpreting or enforcing Section 1557 of the Affordable Care Act, 42 U.S.C. §18116(a), or any implementing regulations thereto, or the Social Security Act, as barring discrimination based on sexual orientation or gender identity or as requiring performance of (or insurance or other coverage of) abortions or gender-transition procedures or treatments—including by denying federal financial assistance or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions—

and from enforcing, implementing, or relying on the Final Rule against the Plaintiffs (including any of their instrumentalities, agencies, and political subdivisions and resident healthcare providers and health insurance issuers) for refusing to comply with the Final Rule; and

d. Award such other and further relief as the Court deems equitable and just.

Dated: June 10, 2024.

Respectfully submitted.

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