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

STATE OF TENNESSEE, STATE OF MISSISSIPPI, STATE OF ALABAMA, STATE OF GEORGIA, STATE OF INDIANA, STATE OF KANSAS, COMMONWEALTH OF KENTUCKY, STATE OF LOUISIANA, STATE OF NEBRASKA, STATE OF OHIO, STATE OF OKLAHOMA, STATE OF SOUTH CAROLINA, STATE OF SOUTH DAKOTA, COMMONWEALTH OF VIRGINIA, AND STATE OF WEST VIRGINIA,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES 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; and CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services,

Defendants.

Civil Action No. 1:24cv161 LG-BWR

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

1. "[F]rom time immemorial," the States have maintained primary responsibility for regulating the medical field through their constitutionally reserved powers to protect their citizens' health and welfare. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889). But a new rule from the

U.S. Department of Health and Human Services ("HHS") seeks to supplant States' health regulations with a regime that sides with HHS's commitment to gender ideology over medical reality. *See* Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) ("2024 Rule") (Exhibit A). Purporting to implement the Affordable Care Act's prohibition on "sex" discrimination, HHS's 2024 Rule threatens States and healthcare providers with massive penalties for failing to align their policies, coverage decisions, and even medical care with patients' subjective gender identities rather than sex. The results of HHS's 2024 Rule will be radical: Hospitals and clinics that limit rooms to members of the same sex will be guilty of unlawful discrimination. So too will a surgeon who performs mastectomies to treat breast cancer yet declines to remove healthy breast tissue from a girl who identifies as a boy. Even a nurse who discusses health problems more prevalent in males risks liability if her patient is a male who identifies as a woman. States, for their part, must use taxpayer funds to pay for unproven and costly gender-transition interventions through Medicaid and state health plans—even for children, who may suffer irreversible harms. Courts have twice struck down similar HHS efforts to govern the Nation's health providers by administrative fiat. Plaintiffs now ask this Court to enjoin and invalidate the 2024 Rule's unlawful attempt to do the same.

INTRODUCTION

2. HHS's 2024 Rule is the latest effort by the Biden Administration to enshrine sweeping gender-identity mandates without congressional consent.

3. When Congress adopted the Affordable Care Act in 2010, it included a nondiscrimination provision known as Section 1557. *See* 42 U.S.C. § 18116. That provision in turn incorporates other longstanding civil rights laws to protect patients from unlawful

discrimination in the healthcare industry. Relevant here is Section 1557's incorporation of Title IX of the Educational Amendments Act, 20 U.S.C. § 1681 *et seq.*

4. Congress passed Title IX in 1972 to remedy historic and persistent mistreatment of women in education. The relevant portion of the statute prohibits recipients of federal educational funding from engaging in discrimination "on the basis of sex." *Id.* § 1681(a).

5. Federal courts across the country have recognized that the ordinary public meaning of "sex" at the time of Title IX's enactment referred to the biological distinction between male and female. *E.g.*, *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 817 (11th Cir. 2022) (en banc); *Neese v. Becerra*, 640 F. Supp. 3d 668, 683 (N.D. Tex. 2022); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 687-88 (N.D. Tex. 2016) (*Franciscan Alliance I*); *Texas v. United States*, 201 F. Supp. 3d 810, 832-33 (N.D. Tex. 2016). Accordingly, Title IX consistently treats "sex" as binary. For example, § 1681(a)(2) delays Title IX's application to an institution in the process of "changing from being an institution which admits only students of *one* sex" to being "an institution which admits students of *both* sexes." 20 U.S.C. § 1681(a)(2) (emphasis added). Other similar provisions appear throughout the statute.

6. Despite this clear meaning of "sex," the 2024 Rule reinterprets Section 1557 and Title IX to encompass protections for "gender identity" and other "sex characteristics" that appear nowhere in the text of either law. The upshot is a regime requiring providers to engage in—and health insurers to cover—so-called "gender-affirming care."

7. To reach this result, HHS relies heavily on the Supreme Court's decision in *Bostock v. Clayton County*, 590 U.S. 644 (2020), regarding Title VII's prohibition on discrimination "because of sex." But *Bostock* did not address Section 1557 or Title IX. Indeed, *Bostock* expressly

declined to "prejudge" any issues pertaining to bathrooms, healthcare, insurance, "or anything else of the kind" under any other nondiscrimination law. *Id*. at 681.

8. This is not the first time HHS has distorted the meaning of Section 1557. HHS in 2016 promulgated a similar rule that attempted to expand Section 1557's protections against sex discrimination to include "gender identity." A federal district court enjoined that attempt, noting that such a reading "conflict[ed] with Title IX, [Section 1557's] incorporated statute." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941-45 (N.D. Tex. 2019). A few years later, a federal district court enjoined HHS's similar 2021 guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" to be "arbitrary and capricious." *Texas v. EEOC*, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. 2022).

9. Like HHS's prior gender-identity mandates, the 2024 Rule represents a radical affront to the physician-patient relationship and States' sovereign interests.

10. Under the guise of "nondiscrimination," the 2024 Rule seeks to dictate the details of providers' medical practices and facilities as well as impose a new national standard of care for addressing gender dysphoria. Under the 2024 Rule, healthcare professionals must preference HHS's commitment to gender ideology over both the biological reality that the sexes are different in ways that affect health risks and their assessment of the proper approach to and scope of medical treatment. Even inquiring into a person's medical history and biological sex characteristics could be enough to trigger a discrimination claim and HHS investigation—even though understanding those issues is often critical to assessing and providing appropriate medical care.

11. More than that, the 2024 rule will force many doctors to provide controversial and potentially harmful medical intervention—like sterilizing hormones and sex-change surgeries—

on adults and children alike. So long as a doctor provides medication or surgeries to treat certain physical maladies, the doctor cannot refuse to provide HHS's list of gender-dysphoria-related interventions. Doing so, in HHS's view, would be "sex" discrimination—no matter that the procedures are different, that the conditions being treated are different, or whether providing interventions to individuals with gender dysphoria under those circumstances contradicts a doctor's reasonable medical judgment.

12. By setting out this mandate, the 2024 Rule overrides Plaintiff States' limitations on providing gender-dysphoria interventions to minors, which the States have permissibly adopted to further their longstanding and sovereign interests "'in protecting the integrity and ethics of the medical profession,' and 'preserving and promoting the welfare of the child.'" *L.W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 473 (6th Cir. 2023) (citations omitted).

13. Tennessee, for example, has "ban[ned] certain medical treatment for minors with gender dysphoria," including "'surgically removing, modifying, altering, or entering into tissues, cavities, or organs' and 'prescribing, administering, or dispensing any puberty blocker or hormone'" for the purpose of either "enabling a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or "treating purported discomfort or distress from a discordance between the minor's sex and asserted identity." *Id.* (citations omitted). Mississippi likewise prohibits the provision of certain "gender transition procedures" for minors, including "gender reassignment surger[ies]" and the "prescri[ption] or "administ[ration]" of "puberty-blocking drugs [or] … cross-sex hormones." Miss. Code Ann. § 41-141-3(d), (f)(1); *see id.* § 41-141-5. Many other States maintain similar laws. *See infra* pp. 37-40.

14. Yet the 2024 Rule would expose healthcare providers—including those employed by the States—to enforcement actions, the loss of patients who rely on federal financial assistance,

and civil liability simply for complying with state law. Indeed, at least one Mississippi pediatric clinic has already filed a pre-enforcement challenge seeking to shield its medical practice and its patients from HHS's unlawful new gender-identity mandate. *See McComb Children's Clinic, Ltd. v. Becerra*, 5:24-cv-48-KS-LGI (S.D. Miss.).

15. The 2024 Rule does not stop there. It goes on to require that States use taxpayer funds to *pay for* controversial sex-transition procedures under any state-operated plan that receives federal funding. This includes state Medicaid programs, Children's Health Insurance Programs, and health plans for state employees. In doing so, the 2024 Rule purports to outlaw as impermissible "sex discrimination" the choice by policymakers in Tennessee, Mississippi, and other States to exclude insurance coverage for risky and costly gender-transition surgeries, among other things.

16. In addition, the 2024 Rule subjects States to private suits by employees and patients for failing to follow these gender-identity mandates, even though neither Congress nor the States intended to waive the States' sovereign immunity in these areas.

17. Worse still, the 2024 Rule unlawfully coerces States' compliance by threatening to strip billions of dollars in federal funding that assists their most vulnerable populations. The Plaintiff States could not have foreseen that the Affordable Care Act's nondiscrimination provision would be wielded in such a way when they accepted these federal dollars from HHS and built extensive health programs—with annual budgets in the billions—in reliance on that funding.

18. With the 2024 Rule set to take effect on July 5, 2024, the Plaintiff States also face imminent, unrecoverable compliance expenses and the risk of liability in private suits. These compliance costs and efforts will be substantial—as the 2024 Rule itself acknowledges.

19. Tennessee and tens of thousands of other commenters opposed HHS's approach for these and other reasons. *See, e.g.*, Tenn. Comment Letter (Exhibit B). Yet in adopting the 2024 Rule, HHS failed to respond to many commenters' critiques—let alone with adequate explanations or supporting evidence. But basic administrative law principles make clear that agencies must offer well-reasoned decision-making to support their regulations, not dodge important aspects of the problem or draw arbitrary lines for political reasons. Nor has Congress vested HHS with authority—let alone using clear language—to resolve these highly controversial and localized issues.

20. Because HHS overreaches in its attempt to expand federal antidiscrimination law far beyond what the statutory text, the Administrative Procedure Act ("APA"), judicial precedent, and the U.S. Constitution permit, the 2024 Rule should be vacated and set aside.

21. Plaintiffs—the States of Tennessee, Mississippi, Alabama, Georgia, Indiana, Kansas, Kentucky, Louisiana, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Virginia, and West Virginia—accordingly bring this suit to seek preliminary and permanent relief. They ask this Court to stay the 2024 Rule's effective date and preliminarily enjoin enforcement pending judicial review. Plaintiffs further request that the Court ultimately declare unlawful, vacate, and set aside the 2024 Rule.

PARTIES

I. Plaintiffs

22. Plaintiff State of Tennessee is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. From "time immemorial," States have regulated the practice of medicine within their borders, *L.W.*, 83 F.4th at 475 (quoting *Dent*, 129 U.S. at 121-24), and Tennessee has the sovereign

authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Tennessee, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Tennessee's Medicaid and Children's Health Insurance Program ("CHIP") programs, which provide health insurance coverage for nearly 1.5 million Tennesseans with the help of a combined $10.3 billion in federal funding. Tennessee also has medical facilities that provide hormonal treatment for minors for various physical conditions, but not for the purpose of "gender transition" or treating gender dysphoria. Jonathan Skrmetti, the Attorney General and Reporter of Tennessee, is authorized by statute to try and direct "all civil litigated matters … in which the state … may be interested." Tenn. Code Ann. § 8-6-109(b)(1).

23. Plaintiff State of Mississippi is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Mississippi has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Mississippi, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Mississippi's Medicaid and CHIP programs, which are expected to provide health insurance coverage for nearly 752,000 Mississippians with the help of an approximate combined $6.3 billion in federal funding in State Fiscal Year 2024. Lynn Fitch, the Attorney General of Mississippi, is authorized to sue on the

State's behalf. Miss. Const. art. VI, § 173; Miss. Code Ann. § 7-5-1; *see Gandy v. Reserve Life Ins. Co.*, 279 So. 2d 648, 649 (Miss. 1973).

24. Plaintiff State of Alabama is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Alabama has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Alabama, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Alabama's Medicaid and CHIP programs, which provide health insurance coverage for nearly 1.07 million residents with the help of a combined $6.9 billion in federal funding. Steve Marshall, the Attorney General of Alabama, is authorized by statute to "institute and prosecute, in the name of the state, all civil actions and other proceedings necessary to protect the rights and interests of the state." Ala. Code § 36-15-12.

25. Plaintiff State of Georgia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Georgia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Georgia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Georgia's Medicaid and CHIP programs, Georgia Medicaid and Peachcare for Kids, which provide health insurance coverage for approximately 2.3

million (as of April 2024) residents with the help of approximately a combined $12.8 billion in federal funding in SFY 2023. That includes more than $12.2 billion for Georgia's Medicaid program and $543 million for the CHIP program.

26. Plaintiff State of Indiana is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Indiana has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Indiana, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). Indiana's Medicaid programs provide health insurance coverage for approximately 1,990,822 residents with the help of a combined $13.1 billion in federal funding. Indiana's CHIP program, which falls under the Hoosier Healthwise program, provides health insurance for approximately 137,681 children up to age 19 with the help of a combined amount of nearly $218 million in federal funding.

27. Plaintiff Commonwealth of Kentucky is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Kentucky has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Kentucky, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes the Kentucky Children's Health Insurance

Program ("KCHIP"), which provides health insurance coverage for nearly 1.8 million residents. Kentucky received approximately $12.3 billion in HHS funding for State Fiscal Year 2022, including more than $12.1 billion for its Medicaid program and $350 million for total CHIP funding.

28. Plaintiff State of Ohio is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Ohio has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Ohio, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Ohio's Medicaid and CHIP programs, which provide health insurance coverage for approximately 3.8 million residents. *See* Ohio Dep't of Medicaid, *Who We Served—Annual* (2023), available at https://tinyurl.com/3p2zn5n9. The Ohio Department of Medicaid received approximately $24.5 billion in HHS funding for State Fiscal Year 2022-2023.

29. Plaintiff Commonwealth of Virginia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. Virginia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. Virginia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes Virginia's Medicaid and CHIP programs,

run by the Virginia Department of Medical Assistance Services, which provide health insurance coverage for approximately 2 million residents with the help of a combined $17.2 billion in federal funding.

30. Plaintiff State of West Virginia is a sovereign State with the authority and responsibility to protect its public fisc, as well as the health, safety, and welfare of its citizens. West Virginia has the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by its employee health insurance policies. West Virginia, through its state-level agencies and political subdivisions, oversees and operates "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). That includes West Virginia's Medicaid and CHIP ("WVCHIP") programs, which provide health insurance coverage for nearly 530,000 residents with the help of roughly $4 billion in federal funding.

31. Plaintiff States of Kansas, Louisiana, Nebraska, Oklahoma, South Carolina, and South Dakota are likewise sovereign States with the authority and responsibility to protect their public fisc, as well as the health, safety, and welfare of their citizens. They also have the sovereign authority to promulgate standards of care for licensed physicians, to determine what medical procedures are reasonable for purposes of Medicaid coverage, and to decide what medical services should be covered by their employee health insurance policies. Through their state-level agencies and political subdivisions, these States oversee and operate "health program[s] and activit[ies]" that "receiv[e] Federal financial assistance" subject to Section 1557 and the 2024 Rule. 42 U.S.C. § 18116(a). Combined, these States receive many billions of dollars in federal funding from HHS, including funds to operate their respective Medicaid and CHIP programs.

II. Defendants

32. Defendant U.S. Department of Health and Human Services is an executive agency of the federal government charged with promulgating regulations under Section 1557 and with enforcing Section 1557 and related agency regulations and rules.

33. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services and is responsible for the agency's administration, including the effectuation of Section 1557 via rulemaking. 42 U.S.C. § 18116(c). He is sued in his official capacity only.

34. 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 only.

35. Defendant Centers for Medicare and Medicaid Services ("CMS") is an agency within HHS that participated in the promulgation of the 2024 Rule and will implement amendments to the CMS regulations.

36. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. She is sued in her official capacity only.

37. Collectively, Defendants are referred to as "HHS."

JURISDICTION AND VENUE

38. This Court has federal-question jurisdiction under 28 U.S.C. § 1331 because the Plaintiff States challenge HHS's actions under the Administrative Procedure Act's provision for judicial review of agency action, 5 U.S.C. § 702, and other federal laws.

39. This Court has jurisdiction under 28 U.S.C. § 1346 because this case involves claims against agencies and employees of the federal government.

40. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a).

41. This Court has the authority to grant Plaintiff States the relief they request under the APA, 5 U.S.C. §§ 705-06; the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02; the Constitution; and the Court's inherent equitable powers.

42. Venue is proper under 28 U.S.C. § 1391(e)(1) because Defendants are agencies of the United States and officers thereof sued in their official capacities, and Plaintiff State of Mississippi is a resident of every judicial district and division within its sovereign territory, including this judicial district and division. *See, e.g.*, *Texas v. Garland*, 2023 WL 4851893, at *3 (N.D. Tex. July 28, 2023) (noting 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)).

43. The Southern Division of the Southern District of Mississippi is a proper division for this action because a substantial part of the events giving rise to this action occurred in this division, the Mississippi Attorney General maintains a physical office in this division, and no Defendant resides in the State of Mississippi.

44. The 2024 Rule purposely regulates medical providers and health insurance plans across the country, including those located in the Plaintiff States. Therefore, this Court has personal jurisdiction over the HHS Secretary, OCR Director, and CMS Administrator for purposes of this action because their immunity has been abrogated by 5 U.S.C. § 702, and they have "submit[ted]" to such jurisdiction "through contact with and" regulatory "activity directed at" Plaintiff States and their respective medical providers and health plans. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881 (2011).

FACTUAL BACKGROUND

I. The Affordable Care Act's Prohibition on Sex Discrimination.

45. In 2010, Congress approved, and President Obama signed into law, the Patient Protection and Affordable Care Act ("ACA"). Pub. L. 111-148 (March 23, 2010). As relevant here, the ACA prohibits those receiving federal health funding from engaging in discrimination on the basis of several specified characteristics, including sex.

A. The ACA's Incorporation of Title IX.

46. Section 1557 of the ACA provides that an "individual shall not, on the ground[s] prohibited under" four existing federal civil rights laws—Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d, *et seq*.) (race, color, national origin); Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681, *et seq*.) (sex); the Age Discrimination Act of 1975 (42 U.S.C. § 6101, *et seq*.) (age); and Section 504 of the Rehabilitation Act (29 U.S.C. § 794) (disability)—"be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance …, 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).

47. Section 1557 does not create any new bases of prohibited discrimination. By referencing Title IX and three other well-established federal nondiscrimination provisions, "Congress incorporated the legal standards that define discrimination under each one." *Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 239 (6th Cir. 2019).

48. Section 1557 does not reference sexual orientation or gender identity.

49. Section 1557's sole basis for prohibiting sex discrimination is its cross-reference to "the ground prohibited under … title IX (20 U.S.C. § 1681 et seq.)." 42 U.S.C. § 18116(a).

50. Title IX states that "[n]o person in the United States shall, *on the basis of sex*, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681(a) (emphasis added).

51. "Reputable dictionary definitions of 'sex' from the time of Title IX's enactment [in 1972] show that when Congress prohibited discrimination on the basis of 'sex' … it meant biological sex, i.e., discrimination between males and females." *Adams*, 57 F.4th at 812 (collecting definitions).

52. Title IX's text and structure confirm its biological-binary understanding of sex. Title IX expressly states that it does not prohibit covered entities from "maintaining separate living facilities for the different sexes," i.e., for males and females. 20 U.S.C. § 1686. And many of Title IX's exclusions specifically preserve male-only or female-only spaces. *See, e.g.*, *id.* § 1681(a)(6) (college fraternity and sorority membership practices and sex-segregated voluntary service organizations like the Girl Scouts, Boy Scouts, and Camp Fire Girls); § 1681(a)(7) (boy or girl conferences); § 1681(a)(9) (scholarships for single-sex beauty pageants). Senator Bayh explained at the time of Title IX's enactment that "differential treatment by sex" was permissible in certain instances, such as "where personal privacy must be preserved." 118 Cong. Rec. 5807 (1972) (Statement of Sen. Bayh).

53. Indeed, Title IX consistently treats sex as a binary, using phrases such as "one sex," "the other sex," and "both sexes." *See* 20 U.S.C. § 1681(a)(2) (delaying Title IX's application to an institution in the process of "changing from being an institution which admits only students of *one sex* to being an institution which admits students of *both sexes*") (emphasis added); *id.* § 1681(a)(5) (excepting a public undergraduate institution with a historic "policy of admitting only

students of *one sex*") (emphasis added); *id.* § 1681(a)(6) (excepting certain organizations whose membership "has traditionally been limited to persons of *one sex*") (emphasis added); *id.* § 1681(a)(8) (excepting from Title IX's coverage "father-son or mother-daughter activities" so long as similar opportunities provided for "*one sex*" are provided for "*the other sex*") (emphasis added); *id.* § 1681(a)(9) (excepting scholarships associated with participation in a beauty pageant "limited to individuals of *one sex* only"); *id.* § 1681(b) (clarifying that Title IX does not require "preferential or disparate treatment to the members of *one sex*") (emphasis added).

54. This treatment of "sex" as a male-female binary reflects Title IX's linguistic context. "The phrase 'gender identity' did not exist" in 1972 "outside of some esoteric psychological publications." Ryan T. Anderson, Ph.D, & Melody Wood, *Gender Identity Policies in Schools: What Congress, the Courts, and the Trump Administration Should Do*, at 9, The Heritage Found. (2017). And the word "gender" had itself "been coined only recently in contradistinction to sex." *Id.* Indeed, "psychiatric literature" at the time "conflated sexual orientation with gender identity." *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 3 F.4th 1299, 1336 (11th Cir. 2021) (Pryor, C.J., dissenting) (citing Jack Drescher, *Transsexualism, Gender Identity Disorder and the DSM*, 14 J. Gay & Lesbian Mental Health 109, 111 (2010)), *rev'd on reh'g on banc*, 57 F.4th 791. "Even the early users of the term 'gender identity' recognized the distinction between 'sex' and 'gender identity.'" *Franciscan Alliance I*, 227 F. Supp. 3d at 688 (noting that the psychoanalyst who coined term "gender identity" believed "sex was biological but gender was social").

55. The original post-enactment regulations implementing Title IX, *see* C.F.R. pt. 86 (1975) (now codified at 34 C.F.R. pt. 106), likewise treat sex as binary, referring multiple times to "one sex," especially versus "the other sex"; using the phrase "both sexes"; referencing "boys and

girls" and "male and female teams"; and preserving certain sex-segregated spaces. *See, e.g.*, 34 C.F.R. §§ 106.33, 106.34(a)(3), 106.36(c), 106.37(a)(3), 106.41, 106.51(a)(4), 106.58(a), 106.60(b), 106.61.

56. In the decades after Title IX's enactment, the Department of Education consistently interpreted "sex" as a biological-binary classification—male and female—consistent with the statutory text, structure, and purpose and with the statute's implementing regulations.

57. Thus, it is unsurprising that when the ACA was enacted in 2010, "no federal court or agency had interpreted Title IX sex discrimination to include gender identity." *Franciscan Alliance I*, 227 F. Supp. 3d at 688.

58. 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).

B. The ACA's Application to States and Other HHS Funding Recipients.

59. Section 1557 applies to what HHS calls "covered entities," including 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 certain pharmacies and health insurance issuers.

60. An entity "any part of which" participates in HHS financial assistance programs is subject in all respects of its health programs and activities to Section 1557. 42 U.S.C. § 18116(a). That means that any hospital or doctor's 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.

61. 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).

62. If HHS finds a covered entity in noncompliance with Section 1557, the agency may require the entity to take remedial action or lose its federal funding.

63. Section 1557 also allows members of the public to sue covered entities to require compliance and seek damages through a private right of action. *See Cummings v. Premier Rehab Keller, PLLC*, 596 U.S. 212, 218 (2022).

C. The ACA's Reservation of States' and Providers' Authority.

64. The ACA maintains the States' power to regulate the medical field, as well as providers' power to practice medicine consistent with their ethical and evidence-based obligations to patients.

65. To begin, 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). Nor, the provision goes on, shall any implementation of the ACA "be construed to preempt any State or common law governing medical professional … actions or claims." *Id.* § 18122(3).

66. The ACA sets further limits on HHS's ability to promulgate regulations interfering with healthcare entities' and professionals' provision of medical care. Relevant here, a statutory section entitled "[a]ccess to therapies" states that "[n]otwithstanding any other provision" of the ACA, the agency "shall not promulgate any regulation" that, *inter alia*: "impede[s] timely access

to health care services"; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "restricts the ability of health care professionals to provide full disclosure of all relevant information to patients making health care decisions"; or "violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(2)-(5).

II. Background of Gender-Transition Medical Interventions

A. Sex, Gender Identity, and Gender Dysphoria.

67. Over the past several years, debates over the clash between sex and gender identity have divided policymakers, medical professionals, and the public.

68. As the Supreme Court has observed, and as Tennessee, Mississippi, and other Plaintiff States' laws set out, sex "is an immutable characteristic." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality opinion). It refers to "male or female according to their reproductive organs and functions assigned by the chromosomal complement." Comment of Ethics & Public Policy Center, at 12, HHS-OS-2022-0012-74097 ("EPPC Comment") (citing Institute of Medicine, *Exploring the Biological Contributions to Human Health: Does Sex Matter?* 1 (2001), https://doi.org/10.17226/10028)); *see, e.g.*, Tenn. Code Ann. § 1-3-105(c) (defining "sex" as "a person's immutable biological sex as determined by anatomy and genetics existing at the time of birth and evidence of a person's biological sex"); Miss. Code Ann. § 41-141-3(a) (defining "sex" as "the biological indication of male and female in the context of reproductive potential or capacity" as determined "at birth, without regard to an individual's psychological, chosen, or subjective experience of gender"); Ala. Code § 26-26-3 (defining "sex" as "[t]he biological state of being male or female, based on the individual's sex organs, chromosomes, and endogenous hormone profiles"); Kan. Stat. Ann. § 77-207(a) (defining "sex" as an "individual's

biological sex, either male or female, at birth," and further defining "male" and "female" based on their differing biological reproductive systems).

69. The "enduring" physical differences between men and women result in different health risks and conditions that necessitate distinct treatments based on biological reality. *United States v. Virginia*, 518 U.S. 515, 533 (1996). Indeed, in the medical field, sex is critical. Women have ovaries, and thus face risks of ovarian cancer, while men do not, so do not; the opposite goes for testicular cancer. *See, e.g.*, Nat'l Cancer Institute, *Reproductive System*, https://perma.cc/A9LT-PZEX. The same reality applies to many other sex-related or sex-correlated risks and conditions in areas ranging across mental health, autoimmune diseases, pain processing, and musculoskeletal health. *See generally* Nat'l Inst. of Health, *Sex and Gender Influences in Health and Disease*, https://perma.cc/92ND-DV5R. Biology also affects how patients' symptoms present and their proper drug dosage, among many other things. *See id.*; I. Zucker & B. Prendergast, *Sex Differences in Pharmacokinetics Predict Adverse Drug Reactions in Women*, Biology of Sex Differences (2020), https://perma.cc/6XH6-ADX8. These biological differences, by definition, mean there are "medical procedures unique to one sex or the other." *L.W.*, 83 F.4th 460 at 484.

70. In contrast, the term "gender identity" refers to "an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female." 81 Fed. Reg. 31,467. Unlike sex, gender identity is not ascertainable from observing human anatomy or chromosomes. Nor is it an immutable or stable characteristic. According to the World Professional Association for Transgender Health ("WPATH"), a prominent advocacy group that promotes so-called "gender-affirming care," a person's gender identity instead can "change … over time" and encompass "a huge variety of gender identities and expressions." WPATH,

Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, 28 Int'l J. of Transgender Health S15, S41 (2022) ("WPATH 8").

71. The term "transgender" describes people who "identify as a gender" different from their sex. 87 Fed. Reg. 47,831 n.75.

72. Sometimes, persons report experiencing a "persistent sense of discomfort" caused by an incongruence between their sex and gender identity. *L.W.*, 83 F.4th at 467 (citing Am. Psych. Ass'n, *Diagnostic and Statistcal Manual*, 261 (3d ed. 1980) ("DSM-3")). Initially, the American Psychiatric Association referred to this condition as "gender identity disorder." *Id.*

73. In 2013, the American Psychological Association replaced 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) ("DSM-5").

74. Not all transgender individuals experience "dysphoria." *Id*. at 451.

75. Historically, reported rates of gender dysphoria have been very low. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be between 0.0002% and 0.014%. *Id*. at 454. However, these numbers have increased dramatically in recent years, particularly in adolescent populations. Recent surveys estimate that between 2-9% of high school students identify as transgender or "gender non-conforming." Expert Report of Stephen B. Levine, M.D., 35 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192. Consistent with these surveys, gender clinics around the world have seen the number of referrals for gender dysphoria increase rapidly over the last decade. *Id*. at 35-36.

76. Like gender identity, gender dysphoria is not permanent. In children, gender dysphoria typically resolves over the course of puberty, so long as the child is not subjected to social transitioning. Levine, *supra*, at 40-42. And desistence has increasingly been observed among those who first manifest gender dysphoria during or after puberty. *Id*. at 42-45. "Watchful waiting" has thus long served as the "standard approach" for addressing gender dysphoria in minors. Levine, *supra*, at 17-19.

77. Many of the youth who present with gender dysphoria also present with mental health comorbidities. Levine, *supra*, at 13-14, 49.

B. Emergence of New "Gender-Transition" Protocols.

78. Physicians did not begin offering to minors "what the medical profession has come to call gender-affirming care" until the late 1990s. *L.W.*, 83 F.4th at 467.

79. Influential medical interest groups have since advocated for treating gender dysphoria in both adults and children by "affirming" their incongruence with sex through a protocol of social, chemical, and surgical transition designed to align their physical appearance and behavior with their internal sense of gender. *Id*. These groups assert that gender-transition interventions, referred to as "gender-affirming care," are medically necessary for many individuals—including minors going through puberty—even though these "treatments" can lead to infertility and other harmful side effects.

80. WPATH now publishes what it describes as "standards of care" for treating people with gender dysphoria in both children and adults. *See* WPATH 8, *supra*; *see also* WPATH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7 (2012), HHS-OS-2022-0012-4074 ("WPATH 7").

81. 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, Doc. 208, at 3 (M.D. Ala. Dec. 27, 2022). That label makes sense. Members of WPATH are required to show a commitment to "trans rights" and need not be medical professionals. Levine, *supra*, at 26-27. Contrary viewpoints "have been known to be shouted down and effectively silenced by the large number of nonprofessional adults who attend the organization's biennial meetings." *Id*. at 26. And WPATH has ardently opposed efforts to discover the bases for its "standards." *See Boe v. Marshall*, No. 2:22-cv-184-LCB, Doc. 263, at 1-3 (M.D. Ala. Mar. 27, 2023).

82. Another leading advocate for so-called "gender-affirming care" is the Endocrine Society, which has published recommendations for treating gender dysphoria in minors and adults. Those recommendations advocate for the use of both hormonal and surgical interventions as medically necessary "treatments"—all while the Society's members stand to financially benefit from the use of such treatments for gender dysphoria. Hembree, et al., *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"). Yet the Endocrine Society "makes no warranty, express or implied, regarding [its] guidelines," "nor do they establish a standard of care." *Id*. at 3895.

83. The gender-transition protocol embraced by these medical interest groups proceeds in four escalating steps: (1) social transition with mental health treatment; (2) puberty blockers (for those who have not completed puberty); (3) cross-sex hormones—*i.e.*, hormones associated with the physiological development of the opposite sex; and (4) gender-transition surgery. Jason Rafferty, et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse*

Children and Adolescents 6-7, 142 Pediatrics 4 (2018); *see* WPATH 7, *supra*, at 57; WPATH 8, *supra*, at S258, App'x E (non-exhaustive list of gender-transition surgeries).

84. Many of these medical interventions carry with them irreversible, lifelong consequences, including sterilization, loss of sexual function, decreased bone density, increased risks of cardiovascular disease and cancer, negative psychological consequences, and a lifelong dependence on hormone drugs. *See infra*, ¶¶ 87-104.

85. The medical guidelines advocated by WPATH and 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).

86. WPATH's latest set of "standards" removes *all* minimum-age requirements for cross-sex hormones and all gender-transition surgeries except for phalloplasty. WPATH 8, *supra*, at S43-79. These standards moreover devote an entire chapter to self-identified "eunuchs"—individuals "assigned male at birth" who "wish to eliminate masculine physical features, masculine genitals, or genital functioning"—and the recommendation of "castration to better align their bodies with their gender identity." *Id*. at S88-89. WPATH's recommendation for the castration of "eunuchs" was based on information it learned from a "large online peer-support community" with thousands of stories that "focus on the eroticization of child castration" and "involve the sadistic sexual abuse of children." *Id*. at S88; Genevieve Gluck, *Top Trans Medical Association*

Collaborated With Castration, Child Abuse Fetishists, REDUXX (May 17, 2022), https://perma.cc/5DWF-MLRU.

C. Risks of Gender-Transition Interventions.

87. "[N]o one disputes" that the above-mentioned interventions for gender dysphoria "carry risks or that the evidence supporting their use is far from conclusive." *L.W.*, 83 F.4th at 489.

88. The FDA may approve the marketing of drugs as safe and effective to treat a certain condition based on "adequate and well-controlled investigations"—typically a double-blind, randomized, clinical trial. 21 U.S.C. § 355(d). But 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.

89. Although the FDA has approved puberty blockers to rectify a hormonal imbalance in young children caused by precocious puberty, it has *not* approved their use as treatment for gender dysphoria in either children or adults. *L.W.*, 83 F.4th at 488. So, too, for cross-sex hormones. *Id*. Thus, the use of puberty blockers and cross-sex hormones for the purpose of treating gender dysphoria is considered "off label."

90. The known risks of hormonal gender transition are significant and well known. Risks associated with puberty-blocking drugs include "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. Recently, the FDA 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).

91. While some proponents say puberty blockers act merely as a "pause button," research shows that is not the case. Nearly *all* minors who start puberty blockers progress to sterilizing cross-sex hormones, and the majority of those individuals go on to have gender-transition surgery. Levine, *supra*, at 48-49 (UK study found 98% of adolescents who used puberty blockers progressed to cross-sex hormones); de Vries et al., *Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study*, 8 J. Sex Med. 8 (2011) (Dutch study found 100% of adolescents who took puberty blockers progressed to cross-sex hormones); de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 4 (2014) (follow-up study found most adolescents who received cross-sex hormones went on to have sex-reassignment surgery).

92. Conversely, without hormonal intervention, most children exhibiting gender dysphoria come to align their gender identity with their sex by the time they reach adulthood. Desistence is increasingly observed among teens and young adults who first manifest gender dysphoria during or after adolescence. Levine, *supra*, at 40-45; Paul Hruz, *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria* 36, 87 The Lineacre Quarterly 1 (Feb. 2020), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192 (noting most recent studies reported desistence in nearly 85% of children before the adoption of the "affirming" model).

93. 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).

94. Giving adolescent girls the high doses of testosterone needed for gender transition induces hyperandrogenism. According to WPATH 8, this causes "clitoral enlargement" (clitoromegaly), "vaginal atrophy" (atrophy of the lining of the vagina and uterus), "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). The Endocrine Society Guideline further advises that induced hyperandrogenism presents a "[v]ery high risk of" erythrocytosis, along with an increased risk of severe liver dysfunction, coronary artery disease, cerebrovascular disease, hypertension, and breast or uterine cancer. Endocrine Society Guideline, *supra*, at 3886-87.

95. Giving 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. WPATH 8, *supra*, at S254, App'x C, Tbl. 1. The Endocrine Society Guideline adds that this condition can also lead to a "[v]ery high risk of" thromboembolic disease and increased risk of macroprolactinoma, breast cancer, coronary artery disease, cerebrovascular disease, cholelithiasis, and hypertriglyceridemia. Endocrine Society Guideline, *supra*, at 3886.

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. The surgical removal of a person's reproductive organs, referred to as "bottom surgery," causes irreversible sterility. As WPATH acknowledges, these types of 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 groups assert that the significant physical side effects and increased health risks of medicalized gender-transition—including risks to fertility—are outweighed by the purported psychological benefits, including suicide prevention.

99. But no reliable studies demonstrate that medical gender transition lowers suicide rates, nor is there reliable evidence that medical transition improves long-term mental health relative to other treatments lacking medical risk. *See* Levine, *supra*, at 49-61; Hruz, *supra*, at 38 (citing 30-year study in Sweden that showed patients who had undergone medical gender transition had a completed suicide rate that was nineteen times higher than that of the general population). Some experts believe that this protocol may actually decrease mental wellbeing and increase suicide by, among other things, preventing desistance. *E.g.*, Levine, *supra*, at 70-71.

100. As the First and Fifth Circuits have concluded, "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); *see Kosilek v. Spencer*, 774 F.3d 63, 68-96 (1st Cir. 2014) (en banc). Recently leaked internal files from WPATH have only further demonstrated that the organization "is neither scientific nor advocating for ethical medical care." Environmental Progress, *The WPATH Files, Pseudoscientific Surgical and Hormonal Experiments on Children, Adolescents, and Vulnerable Adults* 3 (Mar. 4, 2024), https://perma.cc/4ZCW-FF23. WPATH-affiliated doctors have violated their "ethical requirement to obtain informed consent," with "members admitting that children and adolescents cannot comprehend the lifelong consequences"

of so-called "gender-affirming care." *Id*. Internal WPATH communications even revealed discussions about surgeons performing "non-binary" surgeries aimed at "creating bespoke anatomical features that do not exist in nature." *Id*. at 37, 51, 64.

101. In sum, the evidence supporting gender-transition interventions is weak, at best. HHS concluded as much in 2016 and again in 2020, when it remarked on the lack of "high quality evidence" to support the efficacy of gender-transition surgeries and other treatments. Tamara S. Jensen, et al., Decision Memo, CAG #00446N, Centers for Medicare & Medicaid Servs. (Aug. 30, 2016), https://perma.cc/R2ME-YQRA; 85 Fed. Reg. at 37,187; *see also* Endocrine Society Guideline, *supra* (acknowledging that most of its recommendations regarding gender-transition interventions are based on "low quality" or "very low quality" evidence); Levine, *supra*, at 22-33, 50-55.

102. The evidence of harm from gender-transition interventions, however, is apparent. *See* Levine, *supra*, at 56-71; The Cass Review, *Independent Review of Gender Identity Services for Children and Young People: Interim Report* 47 (Feb. 2022), HHS-OS-2022-0012-4075 (finding no consensus). Amplifying these concerns are the fact that adolescents often "lack the capacity to consent to such a significant and potentially irreversible treatment." *L.W.*, 83 F.4th at 488. With increasing frequency, detransitioners have come forward lamenting the harmful effects of these medical interventions and their regret for undergoing them. *Id*. at 487; Levine, *supra*, at 42-45.

103. Citing these concerning dynamics, "some of the same European countries that pioneered these treatments now express caution about them and have pulled back on their use." *L.W.*, 83 F.4th at 477. 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; *see* Levine, *supra*, at 31. To illustrate:

- ***Sweden:*** 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)*, Society for Evidence-Based Gender Medicine (Feb. 27, 2022), HHS-OS-2022-0012-10295, https://perma.cc/NWB6-3XEU.
- ***Finland:*** Finland's Council for Choices in Health Care has concluded that gender-transition 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:*** The United Kingdom has similarly restricted puberty blockers after finding the evidence inadequate to conclude that they are safe and effective to treat gender dysphoria. *B.P.J. by Jackson v. W. Va. State Bd. of Educ.*, 98 F.4th 542, 570 n.7 (4th Cir. 2024) (Agee, J., concurring in part and dissenting in part).

104. In July 2023, a group of respected clinicians from Finland, the UK, Sweden, Norway, Belgium, France, Switzerland, South Africa, and the United States published a letter in the *Wall Street Journal* reiterating that every systematic review to date "has found the evidence for mental-health benefits of hormonal interventions for minors to be of low or very low quality" and that there is "no reliable evidence to suggest that hormonal transition is an effective suicide-prevention measure." Kaltiala, et al., *Youth Gender Transition Is Pushed Without*

Evidence, Wall St. J. (July 14, 2023), https://perma.cc/P9GM-MHF7. Noting that "the risks are significant" and highlighting the growing international consensus that psychotherapy should be the "first line of treatment for gender-dysphoric youth," they urged American medical societies "to align their recommendations with the best available evidence—rather than exaggerating the benefits and minimizing the risks." *Id*.

D. States' Regulation of Gender-Transition Interventions.

105. Tracking the developing international consensus, more than twenty States have restricted access to gender-transition treatments for children. *L.W.*, 83 F.4th at 471 (collecting state statutes restricting the provision of gender-transition procedures for minors). Many States also have adopted limitations on the coverage of gender-transition interventions by their Medicaid and CHIP programs, as well as their state health plans.

1. Tennessee

106. In September 2022, the Tennessee public learned that Vanderbilt University Medical Center was engaged in a widespread and profit-motivated practice of prescribing hormones and conducting surgeries on children for the purpose of treating gender dysphoria. *See* Kruesi, *Social media posts spark calls to investigate Tenn.'s VUMC*, AP News (Sept. 21, 2022), https://perma.cc/K3DN-AV4Z. Vanderbilt was performing "top surgery" (i.e., double mastectomy) on gender dysphoric minors as young as 16. The founder of Vanderbilt's Transgender Health Clinic boasted that such surgeries would "make a lot of money" for Vanderbilt, as would "routine hormone treatment." Amanda Prestigiacomo, *'Huge Money Maker': Video Reveals Vanderbilt's Shocking Gender 'Care,' Threats Against Dissenting Doctors*, The Daily Wire (Sept. 20, 2022), https://perma.cc/M8YH-DLM3. Vanderbilt was giving hormone drugs to "children as young as 13." *Id*.

107. In response, and in an effort to "protect the health and welfare of minors" from unproven and risky gender-transition medical interventions, Tennessee legislators passed and Governor Lee signed SB1. *See* S.B.1, 113th Gen. Assem. (2023), codified at Tenn. Code Ann. § 68-33-101, *et seq*.

108. This law prohibits certain medical procedures on a minor "for the purpose of" either (1) "[e]nabling [the] minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or (2) "[t]reating purported discomfort or distress from a discordance between the minor's sex and asserted identity." Tenn. Code Ann. § 68-33-103(a)(1). Prohibited procedures include surgery and the use of puberty blockers and cross-sex hormones. *Id*. § 68-33-102(5).

109. In adopting these restrictions, the General Assembly noted that the prohibited procedures can lead to "life-altering consequences" for minors, including "becoming irreversibly sterile, having increased risk of disease and illness, or suffering from adverse and sometimes fatal psychological consequences." *Id*. § 68-33-101(b). It also determined that the harms of these treatments "are not yet fully known" and, in any case, outweigh any potential near-term benefits because they "are experimental in nature and not supported by high-quality, long-term medical studies." *Id*. And it found that "minors lack the maturity to fully understand and appreciate the life-altering consequences of such procedures." *Id.* § 68-33-101(h).

110. Tennessee also limits access to gender-transition interventions through the State's Medicaid program, which is the "primary federal program" though which States "provide medical care to indigents at public expense." *Mem'l Hosp. v. Maricopa Cnty*., 415 U.S. 250, 262 n.19 (1974); *see* 42 U.S.C. §§ 1396-1, 1396a. State Medicaid programs are administered jointly by the States and the federal government through a "contract[ual]" relationship. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

111. Tennessee's Medicaid program is administered by the Division of TennCare. Like all other insurance plans, TennCare expressly excludes coverage for dozens of categories of medical services, products, and supplies—even when considered medically necessary. Tenn. Comp. R. & Regs. 1200-13-13-.10(3). Among other things, TennCare does not cover treatments for infertility, sexual dysfunction, certain organ and tissue transplants, dental services, and certain pharmaceuticals. *Id.*

112. TennCare also does not cover "sex change or transformation surgery." *Id.* 1200-13-13-.10(3)(b)(72), -(86). And subject to exceptions for procedures that address defects caused by injury, physical disease, or a congenital condition, TennCare also excludes coverage for "cosmetic surgery or surgical procedures [performed] primarily for the purpose of changing the appearance of any part of the body to improve appearance or self-esteem." *Id.* 1200-13-13-.10(b)(22).

113. Tennessee's CHIP program, referred to as "CoverKids," maintains the same exclusions as TennCare. *See id.* 1200-13-21-.06(1).

114. Tennessee also provides healthcare benefits to thousands of State employees through its state health plan ("State Plan"). The statutorily created State Insurance Committee determines the Plan's premiums, benefits package, funding method, and eligibility provisions. Tenn. Code Ann. § 8-27-202. The State Plan is funded, in part, through contributions made by state-agency employers on behalf of their employees using federal funding received from HHS. For example, the Division of TennCare annually contributes approximately $11.6 million to the State Plan on behalf of its employees, including approximately $7.3 million in HHS funds.

115. The State Plan excludes over 50 categories of medical and mental health/substance abuse services from coverage, as well as coverage for dental expenses, on-the-job injuries, and

non-behavioral mental health/substance abuse expenses. *See* State Plan Document § 12.04 (2024), https://perma.cc/F3BB-2RHR.

116. The State Plan has long excluded coverage for "[s]urgery or treatment for, or related to, sex transformations … other than psychological treatment or counseling." *Id.* at § 12.04(A)(28). It also generally excludes "[c]harges incurred in connection with cosmetic surgery directed toward preserving or improving a patient's appearance." *Id.* at § 12.04(A)(16).

2. Mississippi

117. In 2023, Mississippi legislators passed, and Governor Reeves signed, the Regulate Experimental Adolescent Procedures Act. *See* H.B.1125, 2023 Reg. Sess., codified, in part, at Miss. Code Ann. § 41-141-1, *et seq*.

118. The law prohibits certain medical procedures on a minor "for the purpose of assisting [that] individual with a gender transition," defined as "the process in which a person goes from identifying with and living as a gender that corresponds to his or her sex to identifying with and living as a gender different from his or her sex" in certain circumstances. Miss. Code Ann. § 41-141-3(d)-(f); *id.* § 41-141-5. Prohibited procedures include certain surgeries and the use of puberty blockers and cross-sex hormones. *Id.* § 41-141-3(d), (f)(1); *id.* § 41-141-5.

119. Mississippi also limits access to gender-transition interventions through the State's Medicaid and CHIP programs.

120. Mississippi's Medicaid and CHIP programs are administered through the State's Division of Medicaid within the Office of the Governor. Like all other insurance plans, these programs expressly exclude certain coverage for dozens of categories of medical services, products, and supplies—even when those services are considered medically necessary. *See* 23 Miss. Admin. Code Pt. 200, R 5.1(C).

121. Mississippi's Medicaid and CHIP programs do not cover any "operative procedure, or any portion of a procedure, performed primarily to improve physical appearance and/or treat a mental condition through change in bodily form." *Id*. at Pt. 200, R. 2.2(A)(7). Mississippi's Medicaid and CHIP programs also exclude coverage if the service is "experimental, investigational, or cosmetic in nature." *Id.* at Pt. 200. R. 5.1(B)(7).

122. In addition, the Division of Medicaid is prohibited by statute from "reimburs[ing] or provid[ing] coverage" for certain "gender transition procedures" for minors. Miss. Code Ann. § 43-13-117.7; *see id.* §§ 41-141-3 (definitions), 41-141-7 (prohibition on use of "[p]ublic funds" and other resources for provision of certain "gender transition procedures" for minors).

123. Mississippi also provides healthcare benefits to thousands of State employees through its state health plan ("Mississippi State Plan"). The State School and Employees Health Insurance Management Board determines the Plan's premiums, benefits package, funding, and eligibility provisions. *Id*. §§ 25-15-5, 25-15-303.

124. The Mississippi State Plan limits or excludes coverage for dozens of categories of medical, dental, and other services and expenses. *See* Mississippi's State and School Employees' Life and Health Insurance Plan, Plan Document, at 33-38 (Rev. Jan. 2024), https://bit.ly/3X0oPQz.

125. The Mississippi State Plan excludes coverage for "[s]ex transformations" and "[p]uberty-blocking drugs." *Id*. at 36. It also generally excludes coverage for "cosmetic services," subject to narrow exceptions. *Id*. at 33; *see also* Miss. Code Ann. § 83-9-36.1 (excluding coverage for certain "gender transition procedures" for minors from coverage in Mississippi health-benefit plans).

3. Other Plaintiff States

126. Alabama law prohibits providers from performing certain gender-dysphoria-related medical procedures on minors. *See* Alabama Vulnerable Child Compassion and Protection Act, Act 2022-289, *codified at* Ala. Code § 26-26-4; *Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205 (11th Cir. 2023) (reversing preliminary injunction of law). Prohibited procedures include castration, vasectomy, hysterectomy, oophorectomy, orchiectomy, and penectomy, as well surgeries that artificially construct tissue with the appearance of genitalia that differs from the individual's sex, the removal of any healthy or non-diseased body part or tissue, except for a male circumcision, and the use of puberty blockers and cross-sex hormones. Ala. Code § 26-26-4. Moreover, Alabama Medicaid does not provide coverage for (i) sex-change surgeries or (ii) cross-sex hormones prescribed as transitioning treatments.

127. Georgia law prohibits providers from performing certain gender-transition medical interventions on minors, including "(1) sex reassignment surgeries, or any other surgical procedures, that are performed for the purpose of altering primary or secondary sexual characteristics; and (2) hormone replacement therapies." Ga. Code Ann. § 43-34-15.

128. Indiana law prohibits providers from knowingly performing certain "gender transition procedures" for minors. *See* Ind. Code § 25-1-22-13(a). Prohibited procedures include:

a. Genital Gender Reassignment Surgery, which includes but is not limited to: (1) penectomy, orchiectomy, vaginoplasty, clitoroplasty, or vulvoplasty for male sex patients, (2) hysterectomy, ovariectomy, phalloplasty, vaginectomy, scrotoplasty, or implantation of erection or testicular prostheses for female patients, and (3) urethral reconstruction with or without a metoidioplasty, and for a female patient. *Id*. § 25-1-22-6.

b. Non-Genital Gender Reassignment Surgery, which includes but is not limited to: (1) Mammoplasty, facial feminization surgery, liposuction, lipofilling, voice surgery, thyroid cartilage reduction, gluteal

augmentation, hair reconstruction for male patients, and (2) subcutaneous mastectomy, voice surgery, liposuction, lipofilling, or pectoral implants. *Id*. § 25-1-22-8.

c. Hormone Therapy, which includes any use of testosterone, estrogen, or progesterone given to an individual greater than would be produced endogenously by a healthy individual of that individual's age and sex. *Id*. § 25-1-22-4.

d. Puberty Blocking Drugs, which includes but is not limited to: gonadotropin releasing hormone analogues and synthetic antiandrogen drugs used to block the androgen receptors. *Id*. § 25-1-22-11.

129. Kansas' Medicaid and CHIPS programs are administered by the Kansas Department of Health and Environment ("KDHE") and the Kansas Department of Aging and Disability Services ("KDADS"). Kansas contracts with three managed-care providers ("MCOs") to provide healthcare plans to qualifying individuals: United, Sunflower, and Aetna. These MCOs provide medically necessary care to enrolled individuals, as described and covered by their respective healthcare plans. None of the MCOs that administer healthcare benefits under KanCare covers gender-transition surgeries. *See* United Healthcare Handbook (2024), https://perma.cc/X36H-U64B; Sunflower Health Plan Handbook (2024), https://perma.cc/8CX5-VF39; Aetna Better Health Handbook (2024), https://perma.cc/C6V9-2ME7. Additionally, Kansas state agencies, including KDHE and KDADS, which operate KanCare, must identify individuals by biological sex whenever they collect data on individuals "for the purpose of complying with anti-discrimination laws or for the purpose of gathering accurate public health, crime, economic or other data." Kan. Stat. Ann. § 77-207(c).

130. Kentucky law prohibits health care providers from performing certain gender-dysphoria-related medical procedures on minors. *See* Ky. Rev. Stat. § 311.372. Prohibited procedures include any surgery that would sterilize or artificially construct tissue having the

appearance of genitalia differing from the minor's sex, and the prescription or administration of drugs to delay or prevent normal puberty or to produce hormones in amounts greater than would be produced normally in a healthy minor of the same age and sex. *Id.* § 311.372(2).

131. Louisiana law prohibits providers from performing or administering certain medical interventions "that attempt to alter a minor's appearance in an attempt to validate a minor's perception of the minor's sex, if the minor's perception is inconsistent with the minor's sex." La. Stat. Ann. § 40:1098.2(A). That includes the prescription or administration of puberty-blocking drugs and cross-sex hormones, and the performance of gender-transition surgeries. *Id.*

132. Nebraska law generally prohibits (with narrow exception) providers from performing certain gender-altering medical procedures on minors. *See* Neb. Rev. Stat. § 71-7304, -7305. Prohibited procedures include surgery and the use of puberty blockers and cross-sex hormones. *Id.* § 71-7303(6)(a). Nebraska law further prohibits the use of State funds, directly or indirectly, for providing gender-altering procedures to minors. *See* Neb. Rev. Stat. § 71-7306. Additionally, Nebraska's Medicaid program excludes sex change procedures from coverage. *See* 471 Neb. Admin. Code § 18-006.01.

133. Ohio law prohibits providers from performing certain gender-transition medical services for minors. Ohio Rev. Code § 3129.02. Prohibited services include "gender reassignment" surgery and, subject to exceptions, prescribing cross-sex hormones and puberty-blocking drugs. *Id.* Additionally, Ohio's Medicaid program does not cover "gender transformation" medical services. Ohio Admin. Code Rule 5160-2-03(A)(2)(e); *see also* Ohio Rev. Code § 3129.06.

134. Oklahoma law prohibits healthcare professionals from providing "gender transition procedures" to any person under the age of 18. *See* Okla Stat. tit. 63, § 2607.1(B). That includes

(1) "surgical procedures that alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex," and (2) "puberty-blocking drugs, cross-sex hormones, or other drugs to suppress or delay normal puberty or to promote the development of feminizing or masculinizing features consistent with the opposite biological sex." *Id.* § 2607.1(A)(2)(a).

135. South Carolina law prohibits healthcare professionals from providing "gender transition procedures," including puberty-blocking drugs, cross-sex hormones, and gender-transition surgeries, to any person under the age of 18. *See* Help Not Harm Bill, H.B. 4624, 125th Leg. Sess. (S.C. 2024), *codified at* S.C. Code Ann. § 44-42-310, *et seq*. The law further prohibits the use of public funds for any such gender-transition procedures, and it expressly precludes the South Carolina Medicaid Program from reimbursing or providing coverage for the same. *Id.*

136. South Dakota law likewise prohibits healthcare professionals from performing or prescribing certain gender-transition medical interventions for minors. *See* S.D. Codified Laws § 34-24-34. Prohibited services include puberty-blocking drugs, cross-sex hormones, and gender-transition surgeries. *Id*.

III. HHS's Prior Failed Attempts to Use Section 1557 to Further Gender Ideology.

137. Since Congress enacted the ACA, HHS has twice tried and failed to use Section 1557's prohibition on sex-based discrimination as a mandate to provide and pay for gender-transition medical interventions.

A. The Obama Administration's Vacated 2016 Rule.

138. Well into President Obama's first term, federal regulators heeded the historical understanding of Title IX as limited to sex-based discrimination. In a 2010 "Dear Colleague Letter" on bullying, the Obama Department of Education acknowledged that Title IX did not cover

claims of sex discrimination by lesbian, gay, bisexual, and transgender students based on their "LGBT status" alone. U.S. Dep't of Educ., Off. for Civ. Rts., Dear Colleague Letter on Bullying, at 8 (Oct. 26, 2010) (marked "not for reliance"), https://perma.cc/3AGM-SB8P. Instead, the letter advised, any claims must overlap with allegations of "sexual harassment or gender-based harassment." *Id.*

139. Yet, a few years later, things began to shift. In 2014, the Department of Education performed an about-face by asserting that "Title IX's sex discrimination prohibition extends to claims of discrimination" based solely on "gender identity." U.S. Dep't of Educ., Off. for Civ. Rts., Questions and Answers on Title IX and Sexual Violence, at 5 (Apr. 29, 2014) (rescinded in 2017), https://perma.cc/Y7BD-XHFU.

140. In 2016, HHS followed suit with a rule that dramatically altered the agency's understanding of the scope of sex discrimination under Section 1557. Dep't of Health & Hum. Servs., Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) ("2016 Rule"). In particular, HHS defined Section 1557's prohibition of discrimination "on the basis of sex" to include discriminating against an individual "on the basis of … gender identity." *Id*. 31,467. The 2016 Rule defined "gender identity" 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.* And HHS defined "transgender individual" as "an individual whose gender identity is different from the sex assigned to that person at birth." *Id.*

141. The 2016 Rule required covered entities—including "almost all licensed physicians"—to perform or refer patients for sex-transition procedures. *See* 81 Fed. Reg. 31,445.

And it prohibited insurers from maintaining "explicit, categorical (or automatic) exclusion[s] or limitation[s] of coverage for all health services related to gender transition." *Id.* at 31,429.

142. The U.S. District Court for the Northern District of Texas preliminarily enjoined and later vacated HHS's rule insofar as it purported to prohibit "discrimination on the basis of gender identity." *Franciscan Alliance I*, 227 F. Supp. 3d at 696. The court concluded that "HHS's expanded definition of sex discrimination" that included gender identity "exceed[ed] the grounds incorporated by Section 1557" because "the meaning of sex in Title IX unambiguously refers to 'the biological and anatomical differences between male and female students as determined at their birth.'" *Id.* at 687, 689 (citation omitted); *accord Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941-45 (N.D. Tex. 2019).

143. The vacatur of the 2016 Rule remains "in effect." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 377 (5th Cir. 2022).

B. The Biden Administration's Vacated 2022 Guidance.

144. During President Trump's Administration, HHS issued a rule rescinding the failed 2016 Rule and returning the agency's interpretation of sex-based discrimination under Section 1557 to the plain, longstanding interpretation of Title IX. *See* Dep't of Health & Hum. Servs., Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) ("2020 Rule"). In so doing, the 2020 Rule specified that "the term 'on the basis of … sex' in Section 1557 does not encompass discrimination on the basis of gender identity." 85 Fed. Reg. 37,191.

145. Upon taking office, however, President Biden announced his administration's contrary view that all laws prohibiting sex discrimination—including Title IX—would

presumptively prohibit discrimination on the basis of gender identity or sexual orientation. *See* Exec. Order No. 13,988, 86 Fed. Reg. 7023-25 (Jan. 20, 2021).

146. As the basis for this view, President Biden's Executive Order and various agency pronouncements cited the Supreme Court's decision in *Bostock*. In that case, the Supreme Court held that Title VII's prohibition of discrimination "because of sex" prevents an employer from firing an employee simply "for being homosexual or transgender." *Id.* at 651-52. The Court explained that an employer who fires a male employee "for no reason other than the fact he is attracted to men … discriminates against him for traits or actions it tolerates in his female colleague," and vice versa. *Id.* at 660.

147. The *Bostock* Court, though, "proceed[ed] on the assumption that 'sex' … refer[s] only to biological distinctions between male and female." *Id.* at 655. It also expressly declined to "prejudge" whether its decision would "sweep beyond Title VII" to other nondiscrimination laws, such as Title IX, or affect policies and conduct—like access to bathrooms—other than the termination of employees simply for being homosexual or transgender. *Id.* at 681. Post-*Bostock* guidance issued by the Department of Education's Office of the General Counsel emphasized that *Bostock* did not affect the longstanding meaning of Title IX's reference to "sex." *See* Reed D. Rubinstein, Memo. for Kimberly M. Richey, Acting Assistant Secretary of the Office for Civil Rights, re: *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731 (2020) (Jan. 8, 2021), https://perma.cc/Q9YC-Q4Y2.

148. Notwithstanding these limits, in May 2021 HHS published guidance purporting to interpret Section 1557 "consistent with … *Bostock*" by reading the statute to prohibit "[d]iscrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." U.S. Dep't of Health & Human Servs., 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) ("*Bostock* Notification").

149. In March 2022, HHS doubled down on this view in a second Section 1557 guidance letter. U.S. Dep't of Health & Human Servs., Office for Civil Rights, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, (Mar. 2, 2022) ("March 2022 Guidance"), https://perma.cc/R4GJ-9CB3. This guidance reaffirmed the *Bostock* Notification's "interpretation" of Section 1557. *Id.* at 1-2. HHS further explained that efforts by covered entities to restrict access to "gender affirming care" may be treated as discrimination based on an individual's "gender identity," in violation of Section 1557. *Id.*

150. Shortly after HHS published its March 2022 guidance letter, an HHS sub-agency called the Office of Population Affairs released a two-page memorandum entitled "Gender-Affirming Care and Young People." *See* Office of Population Affairs, *Gender-Affirming Care and Young People*, https://perma.cc/H3CS-94KX. In this brief document, 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*. at 1. It 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*. HHS threatened to sue anyone who disagreed with this purported "standard of care." *See* March 2022 Guidance 1-2.

151. A federal district court later vacated and set aside as unlawful the March 2022 Guidance, finding HHS's conclusion that "denial of … care solely on the basis of a patient's sex assigned at birth or gender identity likely violates Section 1557" was "arbitrary and capricious."

Texas v. EEOC, 633 F. Supp. 3d 824, 838, 847 (N.D. Tex. Oct. 1, 2022). Among other things, the court held that the March 2022 Letter 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) (incorporating "section 794 of title 29")), failure to provide cross-sex hormones or gender-transition surgeries could amount to discrimination on the basis of a disability. *Id*. at 832-38. Other federal district courts enjoined similar efforts to extend *Bostock*'s reasoning to the Title IX context. *See, e.g.*, *Tennessee v. Dep't of Educ.*, 615 F. Supp. 3d 807, 839 (E.D. Tenn. 2022); *Neese*, 640 F. Supp. 3d at 675-78.

IV. HHS's New Attempt to Distort Section 1557 Through the 2024 Rule.

A. The Proposed Rule.

152. In August 2022, HHS published a Notice of Proposed Rulemaking for Section 1557. Dep't of Health & Human Servs., *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824 (Aug. 4, 2022) ("Proposed Rule").

153. The Proposed Rule was largely cribbed from the previously enjoined 2016 Rule. Like the 2016 Rule, the Proposed Rule interpreted Title IX's—and by implication Section 1557's—ban on sex discrimination to include "discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity." *Id.* at 47858.

154. According to HHS, *Bostock's* reasoning "support[ed] the interpretation that Title IX's prohibition of discrimination 'on the basis of' sex" extends to discrimination based on a "person's sexual orientation or transgender status." *Id.* at 47859.

155. The Proposed Rule broadly defined a "covered entity" as States and any other "recipient[s] of Federal financial assistance," HHS itself, and "an entity established under Title I

of the ACA." *Id.* at 47,912. Like the 2016 Rule, the Proposed Rule explicitly applied to health insurance issuers and administrators. *Id.* at 47,918.

156. The Proposed Rule stated that it would be unlawful for a covered entity to "deny[] or limit[] health services sought for the purpose of gender-affirming care that the covered entity would provide to a person for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded." *Id*. at 47,867.

157. In HHS's telling, this mandate meant that if a medical provider prescribes testosterone to treat a boy's hormone deficiency, the provider could not categorically refuse to prescribe testosterone to treat a gender dysphoric girl who identifies as a boy. In the same way, if a provider performs vaginoplasties to treat congenital defects or trauma to a woman's vagina, that provider could not refuse to perform a "vaginoplasty" on a gender dysphoric male who desires to have his genitals removed and replaced with repurposed tissue intended to replicate the appearance of a vagina. Similar logic would apply across a range of distinct procedures.

158. HHS asserted that the Proposed Rule would not "require[] the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity reasonably determines that such health service is not clinically appropriate for that individual." *Id.* at 47,867.

159. Yet at the same time, the Proposed Rule warned that "a provider's view that no gender transition or other gender-affirming care can ever be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate." *Id.* In other words, HHS proposed to override state laws prohibiting the provision of gender-transition drugs and surgeries to minors for the purpose of treating gender dysphoria.

160. HHS proposed a similar mandate for health insurers. Like the 2016 Rule, the Proposed Rule "prohibit[ed] a covered entity from having or implementing a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care"—regardless of the risks and costs. *Id.* at 47,871. And the Proposed Rule went on to instruct that exclusions deeming all "gender-affirming care for transgender people" as "'experimental' would result in prohibited discrimination on the basis of sex." *Id.* at 47,874.

161. The upshot is that HHS proposed to limit the ability of providers to exercise independent medical judgment about the medical necessity and appropriateness of sex-transition procedures, and to foreclose insurers from relying on concerns about the efficacy and long-term impacts of these treatments in assessing coverage.

162. HHS further proposed to enforce Section 1557's prohibition against sex-based discrimination using the "provisions applicable to Title VI to administrative enforcement actions." *Id.* at 47,828, 47,886. Noncompliance with HHS's Section 1557 mandates can result in the "suspension or termination" of federal funding or "other action authorized by law." *Id.* at 47919.

163. Consistent with the 2016 Rule, the Proposed Rule also included a private right of action against covered entities. *Id.* at 47885.

164. HHS also proposed to amend CMS regulations relating to Medicaid, CHIP, and the Program of All-Inclusive Care for the Elderly ("PACE").

165. HHS "propos[ed] to reinstate references to sexual orientation and gender identity in the Medicaid managed care regulation … that prohibits Medicaid managed care plans from discriminating against individuals eligible to enroll and from using any policy or practice that has the effect of discriminating on the basis of … sex." 87 Fed. Reg. 47,893. And HHS proposed to

"revise the term 'sex' in the current regulation text to 'sex (including sexual orientation and gender identity).'" *Id.*

166. The Proposed Rule also sought to amend the Medicaid and CHIP regulations to require that entities that deliver services must "promote the delivery of services in a culturally competent manner to all enrollees, … and regardless of sex which includes … gender identity." *Id.* at 47910.

167. The Proposed Rule also required State Medicaid and CHIP programs to "have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries … regardless of sex (including sexual orientation and gender identity)." *Id.*

168. With respect to its PACE regulations, HHS proposed to change the word "sex" to "sex (including sexual orientation and gender identity)." *Id.* at 47,894.

B. Commenters' Widespread Objections to HHS's Proposal.

169. Underlining the import of and opposition to HHS's redefinition of sex discrimination under Section 1557, the Proposed Rule generated more than 80,000 comments.[1]

170. The State of Tennessee and nineteen co-signing States submitted a public comment criticizing the Proposed Rule as unlawful. *See* Tenn. Comment Letter (Exhibit B).

171. The States explained that HHS's interpretation of "sex" to mean "gender identity" or "sexual orientation" does not comport with Title IX's text or plain meaning, and that "the Proposed Rule [is] an attempt to stretch HHS's power beyond the text of the statute Congress enacted." *Id.* at 1, 12. Further, Tennessee criticized HHS's reliance on *Bostock* as support for its interpretation of Section 1557 and Title IX because "the rule in *Bostock* extends no further than

[1] Comments on the Proposed Rule are available at https://www.regulations.gov/document/HHS-OS-2022-0012-0001/comment.

Title VII." *Id.* at 7. And, given that Title IX relies on a "biological binary of sex," the Proposed Rule ignored relevant statutory structure and historical practice. *Id.* at 8.

172. Tennessee also provided several reasons that the Proposed Rule violated Constitutional constraints. For example, the Proposed Rule encouraged regulated parties "to insert themselves into constitutionally protected family affairs," threatening families' Fourteenth Amendment Due Process rights. *Id.* Tennessee also reminded HHS of the limits on Congress's spending power, explaining that Section 1557 did not "unambiguously prohibit discrimination based on sexual orientation or 'gender identity.'" *Id.* at 12. For this reason, Tennessee explained, the Spending Clause would not allow HHS to impose a new condition on federal funds, including Medicaid funds. *Id.* at 12. Tennessee also argued that the Proposed Rule's condition on federal funding was unconstitutionally coercive. *Id.*

173. Commenters also objected to the Proposed Rule's approach of establishing national standards of medical care for gender-transition treatment. Commenters explained that it was arbitrary and capricious for HHS to fail to consider effects that innate sex differences have on health. *See* EPPC Comment, *supra*, at 14-16. And they objected to the lack of medical consensus regarding the appropriate means of treating gender dysphoria—particularly for minors—while noting the irreversible nature of certain treatments and the increased prospects of sterilization as well as other associated risks. *See, e.g.*, Comment of Florida Agency for Healthcare Administration, HHS-OS-2022-0012-69566; Comment of Society for Evidence-Based Gender Medicine, HHS-OS-2022-0012-73218; Comment of American College of Pediatricians, at 3-5, HHS-OS-2022-0012-74010; EPPC Comment, *supra*, at 24-34; ADF Comment, *supra*, at 17-27.

C. Final 2024 Rule.

174. On May 6, 2024, HHS finalized the 2024 Rule, which generally will take effect July 5, 2024. The 2024 Rule has two parts. First, HHS's Office of Civil Rights ("OCR") promulgated regulations purporting to set out funding recipients' nondiscrimination obligations under Section 1557. 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 Act ("PHA").

1. OCR Regulations.

175. The OCR regulations require that covered entities "provide individuals equal access to [their] health programs and activities without discriminating on the basis of sex." 89 Fed. Reg. at 37,770.

176. HHS declared that it was "not necessary to define 'sex'" for purposes of implementing this requirement. 89 Fed. Reg. at 37,575. HHS instead defined "[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." *Id.* at 37,699.

177. HHS's interpretation of this non-discrimination obligation will have immediate and industry-altering consequences. Under the 2024 Rule, no health facility may "[a]dopt or apply any policy or practice" that "prevents an individual from participating in a health program or activity consistent with the individual's gender identity." *Id.* at 37,701. That includes the use of sex-separated "intimate space[s]." *Id.* at 37,593. So, for example, a covered entity "will be in violation" of the 2024 Rule for refusing to place a transgender person "in facilities consistent with their gender identity." *Id.* That means covered entities will be compelled to allow men who

identify as women to share a room, bathroom, and other private facilities with women, and vice versa. 87 Fed. Reg. 47,866-67.

178. The OCR Regulations will also dictate the medical treatments and decisions of providers. Even while recognizing that sex-based characteristics are relevant to providing medical care, the 2024 Rule declares that "providers may use sex-based distinctions to administer individualized care, provided those distinctions do not cause more than *de minimis* harm." 89 Fed. Reg. at 37,594. But "*de minimis* harm" is a low bar: HHS suggests that merely "experiencing … distress" is enough to cross that threshold. *Id*. at 37,593.

179. HHS specifies that no covered provider—meaning most doctors across the nation—can "[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.* at 37,700.

180. So too, a provider cannot deny "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 of limitation is based on sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701.

181. To translate: HHS now deems it *sex discrimination* if a doctor or other medical entity declines to provide persons with gender dysphoria any (purportedly) similar treatments as those given to persons with cancer and other physical ailments. And this mandate has no age limit—meaning it applies equally to minors for whom such interventions are unproven, risky, and life altering.

182. The mandate in OCR's Regulations extends to all so-called "gender-affirming care," which "includes hormone therapy, surgery, and other related services." *Id.* So "a

gynecological surgeon may be in violation of the rule if they accept a referral for a hysterectomy but later refuse to perform the surgery upon learning" it was sought for purposes of "gender transition." 87 Fed. Reg. at 47,867. Or it would be presumptively discriminatory for a clinic to prescribe hormone replacement therapy to treat menopause but refuse to provide the same type of therapy for a "gender transition."

183. The OCR Regulations recognize that providers might have a "legitimate, nondiscriminatory reason for denying or limiting" a service, such as where the covered entity determines that a "health service is not clinically appropriate for a particular individual." 89 Fed. Reg. at 37,701. But HHS's view of this concept is narrow. As HHS puts it, 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.

184. Otherwise, HHS will evaluate a covered entity's decision not to provide services for gender-transition purposes based on "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. HHS signals that the "medical necessity standards" and "guidelines" it will use to evaluate these decisions come from WPATH and the Endocrine Society. *See* 87 Fed. Reg. at 47,868.

185. The OCR regulations require that a provider's decision not to provide gender-transition treatments "must not be based on unlawful animus or bias[] or constitute pretext for discrimination." 89 Fed. Reg. at 37,701. This means that a provider must rationalize why a gender-transition treatment "is not clinically appropriate *for a particular individual*." *Id.* (emphasis added).

186. Thus, decisions based on the lack of evidence of efficacy and safety of medical gender-transition interventions generally—as described by the comprehensive systematic reviews that have recently come out of Europe—"may be considered evidence of pretext for discrimination." *Id.* at 37,613. Along the same lines, a provider's determination that so-called "gender-affirming care" is "experimental or cosmetic would be considered evidence of pretext." 87 Fed. Reg. 47,874.

187. HHS likewise views "categorical exclusions for gender affirming care" as suggestive of pretext, even if required by state law. *Id.* As a result, a provider who declines treatment to minors under state laws prohibiting such treatment would engage in "prohibited discrimination on the basis of sex." *Id.*

188. HHS's enforcement decisions are also informed by "consideration of … whether [a] covered entity demonstrated a willingness to refer or provide accurate information about gender-affirming care." 89 Fed. Reg. at 37,598. But any provider who deviates from the WPATH script risks being found insufficiently willing to provide "accurate information." 87 Fed. Reg. 47,784 (citing WPATH to conclude that "[c]haracterizing [gender-transition treatments] as experimental or cosmetic … is not based on current standards of medical care"). HHS requires providers to parrot controversial positions of gender-transition advocates, even when doing so would give patients a false sense of certainty about the efficacy of these treatments.

189. The OCR regulations also apply to entities involved in federally funded health insurance and health-related coverage administered by HHS, such as Medicaid and CHIP. Such entities may not discriminate in healthcare coverage, in insurance benefit design, or in marketing practices. *See* 89 Fed. Reg. at 37,701. And HHS specifically prohibits limits or restrictions on

coverage or claims, including cost sharing, "based upon [an] individual's sex assigned at birth, gender identity, or gender otherwise recorded." *Id.*

190. HHS also prohibits covered entities from denying or limiting "coverage," denying or limiting "coverage of a claim," or imposing "additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or gender-affirming care if such denial, limitation, or restriction *results* in discrimination on the basis of sex." *Id.* (emphasis added). Thus, even facially neutral insurance policies that tend to screen out services used by transgender individuals may be found discriminatory, even if those policies are not motivated by sex or gender identity.

191. HHS purports to provide a safe harbor for insurers. "Nothing in [the rule] requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements." *Id.* But categorical exclusions of coverage for gender-transition interventions, including surgeries, would be considered unlawful sex discrimination.

192. Failing to comply with the OCR regulations puts the States' federal funding at risk, including their Medicaid funding. 45 C.F.R. §§ 80.8, 92.303.

2. CMS Regulations.

193. In addition to amending HHS's Section 1557 regulations, the 2024 Rule also amends CMS regulations relating to Medicaid, CHIP programs designed to provide healthcare for children and pregnant women, and PACE's program for providing elderly care. 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) (CHIP), and to PACE under 42 U.S.C. §§ 1395eee(f), 1396u-4(f) (PACE).

194. 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.

195. 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.*

196. Under the 2024 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.

197. 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." 89 Fed. Reg. at 37,669.

PLAINTIFFS' IMPENDING IRREPARABLE HARM

198. The 2024 Rule will inflict significant, irreparable harm on the Plaintiff States that only prompt judicial intervention can redress.

I. Nonrecoverable Compliance Costs.

199. *First*, Plaintiff States would suffer the "irreparable harm of nonrecoverable compliance costs." *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 194 (5th Cir. 2023) (citation omitted).

200. The 2024 Rule acknowledges as much. HHS 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.

201. Because TennCare's administrative rules for the State's Medicaid and CHIP programs exclude coverage for gender-transition surgeries, compliance with the 2024 Rule would require amending those rules through formal rulemaking. The rulemaking process is governed by the Tennessee Uniform Administrative Procedures Act and takes approximately nine months to complete. That process includes rule drafting, obtaining the review and approval of the offices of the Governor and Attorney General, posting for public comment, a rulemaking hearing, and a hearing before the Joint Government Operations Committee of the Tennessee legislature.

II. Derogation of Plaintiff States' Sovereignty.

202. *Second*, enforcement of the 2024 Rule would undermine Plaintiff States' sovereignty. "[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).

203. The State also "has an interest in protecting vulnerable groups … from mistakes," *Glucksberg*, 521 U.S. 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). It is also "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, 756-57 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

204. As discussed, Plaintiff States have adopted laws prohibiting healthcare providers from offering gender-transition treatments to minors. *See supra*, ¶¶ 107-09, 117-18, 126, 128, 130-36. Tennessee, Mississippi, and other Plaintiff States have likewise chosen not to cover certain gender-transition interventions—including sex-reassignment surgeries—through their Medicaid or state employee health programs. *See supra*, ¶¶ 112-13, 116, 121-126, 129, 132-35. Plaintiff States will be unable to enforce these duly enacted laws and longstanding policies without coming into conflict with the 2024 Rule.

205. States have "sovereign interests in enforcing their duly enacted state laws." *Tennessee*, 615 F. Supp. 3d at 841. Thus, "irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws." *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) (collecting cases).

III. Threatened Loss of Federal Funding and Civil Liability.

206. *Third*, enforcement of the 2024 Rule threatens to collectively strip Plaintiff States of tens of billions of dollars in federal HHS funds and to impose substantial penalties through private suits. This severe financial exposure endangers important health programs that serve some of the Plaintiff States' most vulnerable residents.

207. For example, TennCare administers Tennessee's Medicaid program, as well as CoverKids and its PACE program for the elderly. TennCare annually serves nearly 1.5 million Tennesseans, including low-income individuals, pregnant women, children, caretaker relatives of young children, older adults, and those with disabilities.

208. TennCare received approximately $10.3 billion in HHS funding for State Fiscal Year 2022-2023. That includes more than $10.2 billion for Tennessee's Medicaid program, $109.8 million for CoverKids (CHIP), and $10.8 million for the State's PACE program.

209. All are regulated by the 2024 Rule. Yet Tennessee's Medicaid and CHIP programs each categorically exclude coverage for gender-transition surgeries, which the 2024 Rule prohibits. *See* Tenn. Comp. R. & Regs. 1200-13-13-.10(a)(72), 1200-13-21-.06(1).

210. Tennessee thus faces a credible threat that HHS will enforce the 2024 Rule against it and terminate substantial federal financial assistance to noncomplying state entities. The 2024 Rule also subjects Tennessee to civil liability through Section 1557's private right of action.

211. The same goes for Mississippi and many of the other Plaintiff States. *See supra*, ¶¶ 23-31.

IV. Fiscal Costs of Covering Gender-Transition Interventions.

212. *Fourth*, the 2024 Rule's mandate that health insurers cover gender-transition drugs and surgeries will inevitably result in increased costs for each health plan.

213. According to WPATH 8, the purportedly medically necessary drug interventions for 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.

WPATH 8, *supra*, at S110.

214. According to WPATH 8, the purportedly "medically necessary" so-called "gender-affirming surgical procedures," *id*. 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 pubic bone, which is more pronounced in females);

w. "Nipple-areola tattoo;"

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

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

z. "Hair removal," including "laser epilation" (laser removal) or "electrolysis" (permanent removal by destroying hair follicles), "from the face, body and genital areas."

Id. at S258, App'x E (cleaned up). WPATH makes clear that the above list "is not intended to be exhaustive." *Id*.

215. According to one study used by HHS in its economic-impact analysis of the 2024 Rule, "the average cost of transition-related care (surgery, hormones, or both) per person needing treatment was $29,929 over 6.5 years," or approximately $4,600 per year. Aaron Belkin, *Caring for Our Transgender Troops—The Negligible Cost of Transition-Related Care*, 373 New Eng. J. Med. 1089 (2015).

216. According to the Williams Institute, 0.52% of adults and 0.74% of adolescents in Tennessee identify as transgender. *See* Williams Institute, *Transgender People*, https://perma.cc/2FNL-G3ZP (last visited May 30, 2024).

217. As of May 2024, approximately 670,000 adults were enrolled in Tennessee's Medicaid program, and approximately 824,000 minors were enrolled in Tennessee's Medicaid and CHIP programs. On top of that, roughly 115,000 adults and nearly 30,000 minors are enrolled in Tennessee's State Plan for state and higher education employees.

218. Mississippi's Medicaid and CHIP programs are expected to provide health insurance coverage for nearly 752,000 in Fiscal Year 2024. Thousands more are enrolled in Mississippi's State Plan.

219. As of May 2024, approximately 345,000 adults were enrolled in Alabama's Medicaid program, and approximately 719,000 minors were enrolled in Alabama's Medicaid and CHIP programs. Thousands more were enrolled in Alabama's State Plan.

220. As of April 2024, approximately 842,652 adults were enrolled in Georgia's Medicaid program, and approximately 1,452,001 minors were enrolled in Georgia's Medicaid and CHIP programs.

221. As of April 2024, more than 1 million adults were enrolled in Indiana's Medicaid program, and more than 800,000 minors were enrolled in Indiana's Medicaid and CHIP programs.

222. As of May 2024, approximately 1.5 million adults were enrolled in Kentucky's Medicaid program and almost 530,000 children were enrolled in Medicaid.

223. As of December 2023, approximately 3.6 million Ohioans were enrolled in the State's Medicaid program, with approximately 1.5 million children enrolled in Medicaid or CHIP.

224. As of May 2024, approximately 1,212,000 adults were enrolled in Virginia's Medicaid program, and approximately 782,000 minors were enrolled in Virginia's Medicaid and CHIP programs.

225. Covered plans of the remaining Plaintiff States collectively provide health benefits to millions more individuals.

226. Based on the demographic estimates from the Williams Institute, that means there are likely thousands of people enrolled across the Plaintiff States' covered plans who identify as transgender.

227. Thus, the 2024 Rule's gender-transition mandate will undoubtedly have a "substantial" fiscal effect on Plaintiff States. 89 Fed. Reg. at 37,683. And again, any monies the States expend as a result of the 2024 Rule could not later be recovered—even if the States ultimately prevail in their legal challenge.

V. Threat to the Health and Safety of Vulnerable Citizens.

228. *Finally*, the 2024 Rule will ultimately subject some of Tennessee's most vulnerable citizens to a gender-transition protocol that will leave them with irreversible side effects—including sterilization—and increased health risks for the rest of their lives.

229. The most recent systematic review of the available evidence, published in April 2024, only confirms prior concerns of leading national health authorities abroad and in many States at home regarding the lack of quality evidence supporting the safety and efficacy of medical gender transition, particularly for minors. *See* The Cass Review, *Independent review of gender identity services for children and young people: Final Report* (April 2024), *available at* https://cass.independent-review.uk/home/publications/final-report/.

230. This evidence review highlighted the "weak evidence" regarding the impact of puberty blockers on gender dysphoria and their still unknown effect on "cognitive and psychological development." *Id.* It further noted that the use of cross-sex hormones to treat gender dysphoria in minors "presents many unknowns" due to the "lack of long-term follow-up data," which leaves "inadequate information about the range of outcomes for this group." *Id.*

231. Clinicians are still unable to determine with any certainty which gender dysphoric youth will go on to have an enduring transgender identity. *Id.* That is alarming, given that gender dysphoria for most children naturally resolves by the time they reach adulthood if not subjected to transitioning interventions. Levine, *supra*, at 40-45.

232. Although a growing number of detransitioners have come forward to shed light on the permanent consequences they have endured because of the gender-transition protocol, public advocacy and delayed justice through private lawsuits against their medical providers cannot reverse their chemical or surgical sterilization or restore their lost adolescence.

CLAIM I
Violation of APA, 5 U.S.C. § 706(2)(A), (C)
The 2024 Rule Unlawfully Defines "on the Basis of Sex"

233. Plaintiffs incorporate by reference all preceding paragraphs.

234. HHS is a federal agency within the meaning of the APA. *See* 5 U.S.C. § 551(1).

235. The 2024 Rule is "final agency action" within the meaning of 5 U.S.C. § 704.

236. Plaintiff States lack another adequate remedy in court, and no rule requires that they appeal to a superior agency authority before seeking judicial review.

237. The APA requires courts to set aside and vacate agency action that is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C); *see Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 859 (5th Cir. 2022).

238. The 2024 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.

239. The text of neither Section 1557 nor Title IX mentions "sexual orientation" or "gender identity" as protected categories. Instead, Congress expressly limited Title IX's coverage to discrimination "on the basis of sex," and the ordinary public meaning of "sex" at the time of Title IX's enactment unambiguously excludes consideration of a person's gender identity. *See Adams*, 57 F.4th at 812. If the plain meaning of Title IX was not enough, the statute's structure, history, and purpose confirm that "sex" is limited to the traditional biological binary of male and female. Indeed, it makes perfect sense to import Title IX's understanding of "sex"—and sex discrimination—into Section 1557 because, much like in the educational context where differential treatment on the basis of sex may be warranted (e.g., facilities, sports teams), healthcare also

requires different treatment based on biological realities. Men and women have different health needs based on biological sex.

240. Other structural features of the statute confirm the invalidity of HHS's reading. The ACA elsewhere references "sexual orientation," *see* 42 U.S.C. § 294e-1(b)(2), signaling that if Congress wished to prohibit LGBTQ+ discrimination in Section 1557, it knew how to do so.

241. Section 1557, moreover, 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 that "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 do not have a disorder of sex development—a physical impairment—do not have a "disability" and are excluded from "section 792 of title 29."

242. The 2024 Rule nonetheless states that "sex" discrimination prohibited by Title IX—and incorporated by Section 1557—includes discrimination based on "sexual orientation" and "gender identity." 89 Fed. Reg. 37,698-99.

243. The 2024 Rule rests on *Bostock* for this result. But *Bostock* explicitly declined to "prejudge" whether other nondiscrimination laws—like Title IX—prohibit discrimination based on sexual orientation and transgender status, or whether its ruling affected common practices like maintaining sex-separated "bathrooms." 590 U.S. at 681. Thus, as many federal courts have held, "the rule in *Bostock* extends no further than Title VII." *Pelcha v. MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021) ("[T]he Court in Bostock was clear on the narrow reach of its decision and how it was limited only to Title VII itself."). And "it does not follow that principles announced

in the Title VII context automatically apply in the Title IX context." *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021).

244. Nor can *Chevron* deference save the 2024 Rule's misinterpretation of Title IX and Section 1557. For starters, HHS's reading falls outside the range of reasonable interpretations of the statutory text because it purports to resolve a policy issue of major political significance without clear congressional authority, *see West Virginia v. EPA*, 597 U.S. 697, 721-24 (2022), and fails to construe "on the basis of sex" "to avoid serious constitutional doubts," *Brawner v. Scott Cnty.*, 14 F.4th 585, 592 n.2 (6th Cir. 2021) (quoting *FCC v. Fox Tel. Stations, Inc.*, 556 U.S. 502, 516 (2009)); *see also infra* Claim III. And to the extent *Chevron* would permit HHS's interpretation, that decision should be reconsidered. *Cf. Loper Bright Enters. v. Raimondo*, No. 22-451 (U.S.) (argued Jan. 17, 2024) (presenting question "[w]hether the Court should overrule *Chevron*").

245. These problems all infect and render unlawful HHS's amendments to its OCR Regulations. They also preclude HHS's amendments to its regulations related to Medicaid, CHIP, and PACE to prohibit discrimination on the basis of gender identity under Section 1557 as well as provisions of the Social Security Act. For the reasons already discussed, Section 1557 does not warrant those changes to the CMS Regulations.

246. Neither does the Social Security Act. Section 1902(a) of the SSA, 42 U.S.C. § 1396a(a)(4)(A), requires 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." Non-discrimination rules are not "methods of administration." HHS's interpretation of Section 1902 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.

247. Section 2101(a) of the SSA, *id*. § 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.

248. 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.

249. Because the 2024 Rule's interpretation of Section 1557 and related provisions contravenes the statutory text and bedrock canons of statutory interpretation, it is not entitled to deference and exceeds HHS's legal authority. The 2024 Rule should thus be declared unlawful and "set aside"—meaning vacated. *See* 5 U.S.C. § 706(2); *see also Career Colls. & Sch. of Tex. v. U.S. Dep't of Educ.*, 98 F.4th 220, 255 (5th Cir. 2024) (collecting authorities).

CLAIM II
Violation of APA, 5 U.S.C. § 706(2)(A), (C)
The 2024 Rule Unlawfully Regulates the Practice of Medicine

250. Plaintiffs incorporate by reference all preceding paragraphs.

251. HHS further exceeds its statutory authority because the 2024 Rule pervasively regulates the practice of medicine—a matter within the traditional authority of the States and which Congress has not authorized the agency to regulate. This arbitrary expansion of HHS's authority

harms providers within Plaintiff States—including those health professionals the States employ directly.

252. Congress does not use "muffled hints" or "obscure" language to give federal agencies "authority to regulate areas traditionally supervised by the States' police power." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). Agencies possess that authority only when Congress grants it to them clearly.

253. "There 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. OSHA*, 595 U.S. 109, 121 (2022) (Gorsuch, J., concurring). HHS thus must point to "exceedingly clear language if it wishes to significantly alter the balance between federal and state power" in the field of medical regulation. *See U.S. Forest Serv. v. Cowpasture River Preservation Ass'n*, 590 U.S. 604, 622 (2020).

254. Applying that principle in *Gonzales*, the Supreme Court refused to read the federal Controlled Substances Act to give the U.S. Attorney General the power "to prohibit doctors from prescribing regulated drugs for use in physician-assisted suicide." 546 U.S. at 248-49, 275. Reading federal law otherwise would have allowed a federal agency "to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality"—without any clear grant of authority. *Id*. at 275.

255. These principles require invalidating the 2024 Rule, which prolifically directs (and hampers) health providers' practice of medicine and ousts States from their traditional role as regulators of the medical profession and medical ethics. Examples of HHS's improper overreach abound.

256. *First*, the 2024 Rule regulates how covered health entities run their facilities. That includes inhibiting entities from maintaining sex-separated "intimate space[s]." 89 Fed. Reg. at 37,593. According to HHS, covered entities will be guilty of sex discrimination if they "refuse to place [a transgender person] in facilities consistent with their gender identity," *i.e.*, if they maintain women's-only or men's-only spaces. *Id*. That mandate will undermine the medical treatment of those whose intimate spaces have been invaded.

257. *Second*, the 2024 Rule risks punishing doctors who decline to provide medically inappropriate care. The 2024 Rule declares that "providers may use sex-based distinctions to administer individualized care," but only if "those distinctions do not cause more than *de minimis* harm." *Id.* at 37,594. As discussed, "*de minimis* harm" is a low bar that HHS says even emotional "distress" would exceed. *Id*. at 37,593. Under the final rule, then, if a male patient seeks OBGYN services from a covered entity, and that entity declines to provide those services on the ground that they are inappropriate for a male, then the entity would face legal liability for sex discrimination if that male patient claims to have suffered "distress."

258. Likewise, the 2024 Rule risks deeming doctors guilty of sex discrimination simply for hewing to well-settled and scientifically grounded understandings about "sex" and the attendant medical consequences. The 2024 Rule pledges: "There is no part of section 1557 that compels clinicians to provide a service that they do not believe is medically appropriate for a patient or that they are not qualified to provide." *Id*. at 37,575. But that pledge is hollow, and the final rule elsewhere defies that promise. The 2024 Rule is clear: "Discrimination based on sex characteristics is a prohibited form of sex discrimination because discrimination based on anatomical or physiological sex characteristics is inherently sex-based." *Id*. at 37,576; *see id.* at 37,575 ("discrimination based on anatomical or physiological sex characteristics is inherently sex-

based"). Thus, if a doctor believes that removing cancerous breast tissue can be surgically appropriate and is willing to perform such a surgery in line with that medical judgment, the 2024 Rule requires him also to surgically remove the healthy breast tissue of a patient suffering from gender dysphoria—even if that procedure defies the doctor's medical judgment.

259. *Third*, the 2024 Rule also invades the doctor-patient relationship. HHS acknowledges that "[p]roviders often need to make inquiries about a patient's sex-related medical history, health status, or physical traits related to sex in the course of providing care." *Id*. at 37,595. Although HHS claims that "this rule does not prohibit or inhibit that," all the agency is willing to commit to is that such basic health-related inquiries "are not per se discriminatory." *Id*. If a patient "makes clear that further inquiries are unwelcome," however, "the inquiries may rise to the level of harassment on the basis of sex." *Id*. Suppose a doctor sees a patient seeking a life-altering and potentially dangerous gender-transition procedure, and the doctor responsibly asks the many questions needed to assess and inform the patient of the soundness of the procedure and dangers involved. If the patient declines that line of questioning but the doctor insists on doing her duty to assess and inform, the doctor risks liability for sex discrimination. Fears of that sort of liability will chill and undermine the doctor-patient relationship and resulting care.

260. *Fourth*, the 2024 Rule imposes a national standard of care for gender dysphoria without congressional authorization. The 2024 Rule mandates that nearly all doctors nationwide provide treatments pushed by an international organization recently shown to lack scientific and ethical rigor, *see* 87 Fed. Reg. at 47,834 n.139 (citing standards from WPATH). Providers are prohibited from exercising their own reasonable medical judgment about the appropriateness and safety of sex-transition procedures generally. Nor can they decline to provide sex-transition procedures based on the experimental nature of those procedures. Instead, to receive federal

funding from Medicaid, Medicare, and other programs, doctors—including employees of Plaintiff States—must perform sex-transition procedures even if those procedures are against their medical judgment and the subject of serious dispute in the medical community.

261. Making matters worse, the 2024 Rule's gender-transition-intervention mandate purports to nullify contrary state laws limiting the provision of gender-transition medical interventions to minors. The 2024 Rule openly deems preempted those 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 in minors. *See* 89 Fed. Reg. at 37,535, 37,598. These state laws permissibly reflect that the safety, efficacy, and appropriateness of "gender-transition" interventions are disputed matters on which policymakers may "reasonably exercise caution." *L.W.*, 83 F.4th at 477. Yet the 2024 Rule overrides those laws without demonstrating that this result was "the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citation omitted). General preemption principles foreclose this result.

262. In short, the 2024 Rule seeks to transform the practice of medicine across the country by dictating what treatments must be provided, how doctors must interact with patients, what doctors may say or not say, what doctors must affirm to be true or untrue, and more. But HHS's cited statutes fail to "effect" this "radical shift of authority from the States to the Federal Government" on sound medical practice. *Gonzales*, 546 U.S. at 275. And the 2024 Rule flouts the limits of Section 1554 of the ACA, which *prohibits* HHS from interfering with providers' practice of medicine. Section 1554 bars HHS from adopting any rule that "impede[s] timely access to health care services"; "interferes with communications regarding a full range of treatment options between the patient and the provider"; "restricts the ability of health care professionals to

provide full disclosure of all relevant information to patients making health care decisions"; or "violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(2)-(5). As discussed, HHS's 2024 Rule breaches all these limits, and then some.

263. Because the 2024 Rule's nationalization of medical care along HHS's preferred ideological lines exceeds HHS's authority, the 2024 Rule should be declared unlawful, "set aside," and vacated. *See* 5 U.S.C. § 706(2).

CLAIM III
Violation of APA, 5 U.S.C. § 706(2)(B)
The 2024 Rule Is Contrary to the U.S. Constitution

264. Plaintiffs incorporate by reference all preceding paragraphs.

265. 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); *Data Mktg. P'ship*, 45 F.4th at 859.

266. The 2024 Rule is unconstitutional, and thus unlawful, for several reasons.

267. *Spending Clause*. Congress passed Section 1557 under the Spending Clause of the United States Constitution. "[L]egislation enacted pursuant to the spending power is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions." *Adams*, 57 F.4th at 815 (quoting *Pennhurst*, 451 U.S. at 17). That framework means that "if Congress intends to impose a condition on the grant of federal moneys [under its Spending Clause authority], it must do so unambiguously." *Id.* (citation omitted). This "clear-statement rule" applies with special strength when a federal-funding condition "encroache[s] upon a traditional state power," such as the regulation of health care. *Kentucky v. Yellen*, 54 F.4th 325, 354 (6th Cir. 2022); *see also L.W.*, 83 F.4th at 473-74.

268. Nowhere in Section 1557, Title IX, the Social Security Act, or anywhere else has Congress permitted HHS to regulate "nondiscrimination" based on gender identity—let alone issue rules that contain the 2024 Rule's sweeping gender-identity mandates. *See supra* Claims I-II. Nor can HHS's 2024 Rule itself provide notice to satisfy the Spending Clause clear-statement rule. As the Fifth Circuit has held, the "needed clarity" to satisfy the Spending Clause "cannot be … provided" by "regulations clarifying an ambiguous statute." *Tex. Educ. Agency v. U.S. Dep't of Educ.*, 992 F.3d 350, 361 (5th Cir. 2021). Instead, it "must come directly from the statute." *Id.*

269. Independently, Congress is forbidden under the Spending Clause from wielding the Federal purse as "a 'weapon[] of coercion, destroying or impairing the autonomy of the states." *See NFIB*, 567 U.S. at 579 (quoting *Steward Machine Co. v. Davis*, 301 U.S. 548, 586 (1937)). Thus, Congress exceeds its Spending Clause authority when it offers a financial inducement that is "so coercive as to pass the point at which 'pressure turns to compulsion.'" *South Dakota v. Dole*, 483 U.S. 203, 211 (1987) (citation omitted).

270. HHS's 2024 Rule conditions hundreds of billions of dollars in federal funding for Plaintiff States—amounts representing large portions of their overall budgets, *see supra*, ¶¶ 22-31—on States' ceding their longstanding power to regulate permissible medical procedures and performing controversial treatments causing proven, life-long harms. Just as in *NFIB*, linking States' Medicaid funding to their following HHS's controversial federal mandate for gender-transition interventions is an unlawful "gun to the head" of States that violates the Spending Clause's anti-coercion limit. 567 U.S. at 581. That the "States, not the Federal Government, are the traditional source of authority over safety, health, and public welfare" further compounds the federalism harms inflicted by HHS's coercive regime. *Kentucky v. Biden*, 23 F.4th 585, 609 (6th Cir. 2022) (citation omitted).

271. *Nondelegation Doctrine*. To the extent HHS asserts authority to define new practices that violate Section 1557, it transgresses "the Constitution's rule vesting federal legislative power in Congress," not agencies acting by "pen-and-phone regulations." *West Virginia*, 597 U.S. 737, 753 (Gorsuch, J., concurring). Reading "sex" as a term capacious enough to encompass a controversial gender-identity mandate, among other novel ideas, would shift "unfettered" lawmaking power to the Department in a manner the nondelegation doctrine does not tolerate. *See Tiger Lily, LLC v. U. S. Dep't of Hous. & Urban Dev*., 5 F.4th 666, 672 (6th Cir. 2021).

272. Moreover, to the extent that HHS predicates its new regulations on the "medical necessity standards" and "guidelines" issued by WPATH and the Endocrine Society, they violate the private nondelegation doctrine. *See Carter v. Carter Coal Co*., 298 U.S. 238, 311 (1936). Handing off regulatory authority to private parties is "legislative delegation in its most obnoxious form; for it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business"—or the public welfare. *Id*.; *see also Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 60-64 (2015) (Alito, J., concurring).

273. *Eleventh Amendment*. The Eleventh Amendment provides that the "Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign States." U.S. Const. amend. XI. As a result of this limit, there are only two circumstances in which an individual may bring a suit against a State in federal court. *First*, a State may waive its sovereign immunity by consenting to being sued. *See College Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 670 (1999). *Second*, Congress may

abrogate a state's sovereign immunity through legislation enacted pursuant to its Section 5 enforcement power under the Fourteenth Amendment. *Id.*

274. Neither scenario applies here. As discussed, the statute does not condition—let alone do so clearly—States' HHS funding on their following the 2024 Rule's gender-identity mandates. *See supra* Claim I. Nor could HHS's attempt to apply 1557 to gender-identity discrimination pass Section 5 muster, including because gender identity is not a suspect characteristic and HHS has offered no evidence that the ACA was passed in response to a documented history of discrimination against transgender individuals. *See City of Boerne v. Flores*, 521 U.S. 507, 529-36 (1997). The 2024 Rule thus cannot constitutionally subject States to private suits for money damages.

275. Because the 2024 Rule is unconstitutional in the ways described above, it should be declared unlawful, "set aside," and vacated. 5 U.S.C. § 706(2)(B).

CLAIM IV
Violation of APA, 5 U.S.C. § 706(2)(A)
The 2024 Rule Is Arbitrary and Capricious

276. Plaintiffs incorporate by reference all preceding paragraphs.

277. 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).

278. A federal agency acts in an "arbitrary and capricious" manner when it (1) attempts to regulate based "on factors … Congress has not intended it to consider"; (2) "entirely fail[s] to consider an important aspect of the [regulatory] problem"; (3) "offers an explanation for" its conduct "that runs counter to the evidence before" it; or (4) reaches a determination that "is so implausible … it could not be ascribed to a difference in view or … agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

279. The 2024 Rule's gender-identity mandates are arbitrary and capricious.

280. *First*, HHS failed to offer a "reasoned explanation" of the 2024 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 2024 Rule are nothing more than "contrived reasons" offered to support a predetermined result. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2576 (2019).

281. *Second*, the 2024 Rule never defines "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "on the basis of" sex. HHS failed to adequately consider 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. at 37,189-90. But the 2024 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.* at 37,190.

282. *Third*, by requiring healthcare professionals to ignore the medical and biological differences between the sexes at the risk of causing "more than *de minimis* harm," 89 Fed. Reg. at 37,593-94, the 2024 Rule will prevent healthcare professionals from using their reasonable medical judgment and will damage the doctor-patient relationship, thus undermining the provision of sound medical treatment on a wide scale.

283. *Fourth*, 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 2024 Rule instead replaces science-based medicine with ideology-driven mandates.

284. *Fifth*, 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. HHS needs to consider that disadvantage.

285. *Sixth*, 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. 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.

CLAIM V
Relief Under the Declaratory Judgment Act, 28 U.S.C. § 2201, and 5 U.S.C. § 706
Claim for Declaratory Judgment Against Defendants

286. Plaintiffs incorporate by reference all preceding paragraphs.

287. The Declaratory Judgment Act provides that in the case of an "actual controversy within its jurisdiction … any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

288. This case presents an actual controversy. The 2024 Rule governs Plaintiff States, meaning its requirements affect their legal rights. Moreover, the imminent enforcement of HHS's

2024 Rule threatens to force recipients of federal HHS funding in the Plaintiff States to choose between violating state law and abandoning consistent policies or losing their federal funding.

289. The controversy arises in this Court's jurisdiction, as it relates to questions of federal law. Venue is proper, as the State of Mississippi resides in this District. 28 U.S.C. § 1391(e).

290. As set forth throughout this Complaint, the Plaintiff States have filed an appropriate pleading to have their rights declared. The Court can resolve this controversy by declaring that Plaintiff States have a right to receive HHS funding notwithstanding their respective state laws and administrative rules prohibiting gender-transition interventions for minors and excluding gender-transition interventions from their state-sponsored health insurance plans.

PRAYER FOR RELIEF

An actual controversy exists between the parties that entitles the Plaintiff States to declaratory and injunctive relief. Plaintiffs respectfully request that this Court:

a) Enter a stay of the Final Rule's effective date under 5 U.S.C. § 705 and a preliminary injunction enjoining Defendants, and any other agency or employee of the United States, from enforcing or implementing the portions of the 2024 Rule that exceed HHS's statutory authority, violate the APA, and violate the U.S. Constitution;

b) Enter a judgment declaring, pursuant to 28 U.S.C. § 2201 and 5 U.S.C. § 706, that: (i) the Final Rule's gender-identity mandates are unlawful; (ii) the Final Rule is arbitrary and capricious; and (iii) the Plaintiff States, their political subdivisions, and their resident healthcare providers may continue receiving federal financial assistance notwithstanding any failure to adhere to the 2024 Rule's unlawful requirements;

c) Set aside and vacate the Final Rule, pursuant to 5 U.S.C. § 706, on the basis that it exceeds HHS's statutory authority and violates the APA and the U.S. Constitution;

d) Permanently enjoin Defendants and their officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with Defendants from withholding federal financial assistance from the Plaintiff States, their political subdivisions, and their resident healthcare providers and health insurance issuers for refusing to comply with the Final Rule's unlawful requirements;

e) Grant any and all other relief the Court deems just and proper.

Date: May 30, 2024.

Respectfully submitted,

LYNN FITCH
Attorney General

/s/ *Scott G. Stewart*
SCOTT G. STEWART
Solicitor General
Bar No. 106359
JUSTIN L. MATHENY
Deputy Solicitor General
Bar No. 100754
MISSISSIPPI ATTORNEY GENERAL'S OFFICE
P.O. Box 220
Jackson, Mississippi 39205
(601) 359-3680
scott.stewart@ago.ms.gov
justin.matheny@ago.ms.gov

Counsel for Plaintiff State of Mississippi

JONATHAN SKRMETTI
Attorney General & Reporter

/s/ *Steven J. Griffin*
STEVEN J. GRIFFIN
Senior Counsel for Strategic Litigation
Bar No. 103218
WHITNEY HERMANDORFER*
Director of Strategic Litigation
HARRISON GRAY KILGORE*
Strategic Litigation Counsel and Assistant Solicitor General
OFFICE OF THE TENNESSEE ATTORNEY GENERAL
P.O. Box 20207
Nashville, Tennessee 37202
(615) 741-3491
steven.griffin@ag.tn.gov
whitney.hermandorfer@ag.tn.gov
harrison.kilgore@ag.tn.gov

*Motion for Pro Hac Vice admission under L.R. 83.1(d) forthcoming.

Counsel for Plaintiff State of Tennessee

STEVE MARSHALL
Attorney General

/s/ *A. Barrett Bowdre*
A. BARRETT BOWDRE*
Principal Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL
STATE OF ALABAMA
501 Washington Avenue
P.O. Box 300152
Montgomery, Alabama 36130-0152
(334) 242-7300
barrett.bowdre@AlabamaAG.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Alabama

CHRISTOPHER CARR
Attorney General

/s/ *Stephen Petrany*
STEPHEN PETRANY*
Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF GEORGIA
Georgia Department of Law
40 Capitol Square SW
Atlanta, Georgia 30334
(404) 458-3408
spetrany@law.ga.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Georgia

THEODORE E. ROKITA
Attorney General

/s/ *James A. Barta*
JAMES A. BARTA*
Solicitor General
INDIANA ATTORNEY GENERAL'S OFFICE
IGCS – 5th Floor
302 W. Washington St.
Indianapolis, Indiana 46204
(317) 232-0709
James.Barta@atg.in.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Indiana

KRIS W. KOBACH
Attorney General

/s/ *Jay Rodriguez*
JAY RODRIGUEZ*
Assistant Attorney General
OFFICE OF THE KANSAS ATTORNEY GENERAL
120 SW 10th Ave.
Topeka, Kansas 66612
(785) 296-4733
jay.rodriguez@ag.ks.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Kansas

RUSSELL COLEMAN
Attorney General

/s/ *Justin D. Clark*
JUSTIN D. CLARK*
Civil Chief
LINDSEY R. KEISER*
Assistant Attorney General
COMMONWEALTH OF KENTUCKY
OFFICE OF THE ATTORNEY GENERAL
700 Capital Avenue, Suite 118
Frankfort, Kentucky 40601
(502) 696-5300
justind.clark@ky.gov
lindsey.keiser@ky.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.5 forthcoming

Counsel for Plaintiff Commonwealth of Kentucky

ELIZABETH B. MURRILL
Attorney General

/s/ *J. Benjamin Aguiñaga*
J. BENJAMIN AGUIÑAGA*
Solicitor General
OFFICE OF THE LOUISIANA ATTORNEY GENERAL
1885 N. 3rd St.
Baton Rouge, Louisiana 70802
aguinagab@ag.louisiana.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Kansas

MICHAEL T. HILGERS
Attorney General

/s/ *Lincoln J. Korell*
LINCOLN J. KORELL*
Assistant Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF NEBRASKA
2115 State Capitol
Lincoln, Nebraska 68509
(402) 471-2682
lincoln.korell@nebraska.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Nebraska

DAVE YOST
Attorney General

/s/ T. Elliot Gaiser
T. ELLIOT GAISER
Solicitor General
OFFICE OF THE OHIO ATTORNEY GENERAL
30 East Broad Street, 17th Floor
Columbus, Ohio 43215
(614) 466-8980
Thomas.Gaiser@ohioago.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for the State of Ohio

GENTNER DRUMMOND
Attorney General

/s/ Garry M. Gaskins, II
GARRY M. GASKINS, II*
Solicitor General
OKLAHOMA OFFICE OF THE ATTORNEY GENERAL
313 NE 21st Street
Oklahoma City, Oklahoma 73105
(405) 312-2451
Garry.Gaskins@oag.ok.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for the State of Ohio

ALAN WILSON
Attorney General

/s/ *Thomas T. Hydrick*
THOMAS T. HYDRICK*
Assistant Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF SOUTH CAROLINA
1000 Assembly Street
Columbia, South Carolina 29201
(803) 734-4127
thomashydrick@scag.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of South Carolina

MARTY J. JACKLEY
Attorney General

/s/ *Clifton Katz*
CLIFTON KATZ*
Assistant Attorney General
OFFICE OF THE ATTORNEY GENERAL
STATE OF SOUTH DAKOTA
1302 E. Hwy. 14, Suite #1
Pierre, South Dakota 57501
(605) 773-3215
clifton.katz@state.sd.us

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of South Dakota

JASON S. MIYARES
Attorney General

/s/ *Kevin M. Gallagher*
KEVIN M. GALLAGHER*
Principal Deputy Solicitor General
BRENDAN T. CHESTNUT*
Deputy Solicitor General
VIRGINIA ATTORNEY GENERAL'S OFFICE
202 North 9th Street
Richmond, Virginia 23219
(804) 786-2071
kgallagher@oag.state.va.us
bchestnut@oag.state.va.us

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff Commonwealth of Virginia

PATRICK MORRISEY
Attorney General

/s/ *Michael R. Williams*
MICHAEL R. WILLIAMS*
Principal Deputy Solicitor General
OFFICE OF THE ATTORNEY GENERAL OF
WEST VIRGINIA
State Capitol Complex
Building 1, Room E-26
Charleston, WV 25301
(304) 558-2021
michael.r.williams@wvago.gov

*Motion for admission *Pro Hac Vice* under Local Rule 83.1(d) forthcoming

Counsel for Plaintiff State of Virginia