UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, *et al.*,

Plaintiffs,

v. **Case No.** 8:24-CV-01080-WFJ

DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*

Defendants.

NOTICE OF PENDENCY OF OTHER ACTIONS

In accordance with Local Rule 1.07(c), I certify that the instant action:

_X_ IS related to pending or closed civil or criminal case(s) previously filed in this Court, or any other Federal or State court, or administrative agency as indicated below:

I. *Neese et al. v. Becerra et al.*, No. 2:21-cv-00163-Z (N.D. Tex.), appeal pending, No. 23-10078 (5th Cir.)

Neese involves a challenge, under the Administrative Procedure Act (APA), to a 2021 Notice of Interpretation issued by HHS. *See Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972*, 86 Fed. Reg. 27,984 (May 25, 2021). The defendants in *Neese* are Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services (HHS), and the United States of America.

On November 22, 2022, the *Neese* court certified the following class under Federal Rule of Civil Procedure 23(b)(2): "All health-care providers subject to Section

1557 of the Affordable Care Act." ECF No. 70 (attached as Exhibit (Ex.) 1).[1]" On the same date, the *Neese* court entered final judgment. ECF No. 71 (attached as Ex. 2). The *Neese* judgment declares:

- Plaintiffs and members of the certified class need not comply with the interpretation of "sex" discrimination adopted by Defendant Becerra in his Notification of Interpretation and Enforcement of May 10, 2021; and

- Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of "sex" discrimination that the Supreme Court of the United States adopted in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), is inapplicable to the prohibitions on "sex" discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA.

Id. The *Neese* court declined to enter injunctive relief and instead granted summary judgment for defendants insofar as the certified class sought injunctive relief. *Id*. Defendants appealed the district court's judgment to the United States Court of Appeals for the Fifth Circuit, and the appeal was assigned Docket Number 23-10078. The Fifth Circuit heard argument on January 8, 2024, and Defendants' appeal remains pending.

HHS Office for Civil Rights (OCR) will not take enforcement action against healthcare facilities identified by Florida in Compl. ¶ 17 and ECF 12-2 (Decl. of Kevin Bailey), or against CMA members insofar as they engage in the kind of gender identity discrimination addressed in *Neese* in any health care provider capacity, as long as the *Neese* judgment is in effect. *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522, 37,574 n.118 (May 6, 2024).

[1] Citations to ECF docket entries in this notice are citations to the docket entries in the relevant related action unless the context provides otherwise.

II. *American College of Pediatricians, Catholic Medical Association, and Jeanie Dassow, M.D. v. Becerra, et al.*, No. 1:21-cv-00195-TRM-SKL (E.D. Tenn.), appeal pending, No. 23-5053 (6th Cir.)

In *American College of Pediatricians* (*ACP*), several plaintiffs filed suit on behalf of their members challenging a purported "Section 1557 gender identity mandate" as violating the APA, the First Amendment, the Religious Freedom Restoration Act, structural principles of federalism, the Spending Clause, and the Tenth Amendment. ECF No 1. CMA is a plaintiff in both *ACP* and this suit. Defendants in *ACP* are Defendants in this action as well.[2] On November 10, 2021, CMA filed an amended complaint in *ACP* seeking some of the same relief on behalf of its members that it is seeking on their behalf in this suit. ECF No. 15 (attached as Ex. 3) In the amended complaint, among other relief, CMA seeks a

> preliminary and permanent injunction against implementation, enforcement, or application of a gender identity nondiscrimination mandate under Section 1557 of the ACA, by Defendants, . . . including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities because of the failure to perform, offer, endorse, proscribe or refer for gender interventions, or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions

Id., Prayer for Relief ¶ A(3). CMA also requests a

> declaratory judgment that Section 1557 of the ACA does not prohibit discrimination on the basis of gender identity.

Id., Prayer for Relief ¶ A(5).

[s] The Centers for Medicare & Medicaid Services (CMS) and the Administrator of CMS are Defendants in this suit but not in *ACP*.

On November 18, 2022, the *ACP* district court issued a Memorandum Opinion and Order dismissing the case for lack of Article III standing. ECF Nos. 61, 62 (attached as Ex. 4). CMA appealed the decision to the United States Court of Appeals for the Sixth Circuit. ECF No. 63. CMA's appeal was assigned Docket Number 23-5053. The Sixth Circuit heard argument in the appeal on December 6, 2023.

On May 8, 2024, the Sixth Circuit requested supplemental briefing addressing the import of the Final Rule promulgated by HHS that CMA also challenges in this action. *Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2022). Defendants and CMA filed supplemental briefs on May 29, 2024. ECF Nos. 43, 44 (attached as Ex. 5). Defendants explained that the Final Rule makes even clearer that CMA's members face no imminent threat of enforcement by Defendants given new provisions the Final Rule has established for providers to rely upon conscience and religious freedom protections for specific conduct and to prospectively seek written assurances of those exemptions if they wish. Ex. 5 at 23-38. CMA's appeal remains pending before the Sixth Circuit.

III. *Dekker v. Weida*, No. 4:22-cv-00325-RH-MAF (N.D. Fla.), appeal pending, No. 23-12155 (11th Cir.)

In *Dekker*, plaintiffs contend that Florida violates Section 1557 by enforcing Florida Statutes § 286.311(2) and Florida Administrative Code rule 59G-1.050(7) because the provisions draw lines based on sex and the State's proffered nondiscriminatory justifications for the provisions are pretextual. ECF No. 246 at 30-31, 37-38, 51. Jason Weida, in his official capacity as Secretary of the Florida Agency

for Health Care Administration ("AHCA"), and AHCA itself, are defendants. The district court found that the plaintiffs are entitled to prevail on their Section 1557 claim. *Dekker v. Weida*, 679 F. Supp. 3d 1271, 1298 (N.D. Fla. 2023). Among other relief, the district court entered a declaratory judgment as follows:

> It is declared that Florida Statutes [§ 286.311(2)[3]] and Florida Administrative Code rule 59G-1.050(7) are invalid to the extent they categorically ban Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria.

ECF No. 247 (attached as Ex. 6). Florida has appealed the district court judgment to the United States Court of Appeals for the Eleventh Circuit. ECF No. 248. Florida's appeal has been assigned Docket Number 23-12155. On December 4, 2023, the United States submitted an amicus brief in support of plaintiff-appellees and urging affirmance. The appeal remains pending before the Eleventh Circuit and has not yet been orally argued.

On October 4, 2023, the *Dekker* plaintiffs filed a Motion to Enforce the Court's Judgment or, Alternatively, to Clarify the Court's Judgment. In the motion, the *Dekker* plaintiffs alleged that AHCA had continued to enforce provisions that the court had declared invalid. ECF No. 258. In their opposition, Secretary Weida and AHCA stated that they had not sought a stay of the district court's judgment pending appeal "and have otherwise complied with the Final Judgment." ECF No. 259 (attached as

[3] As the district court later explained, the court's orders and judgment refer to Florida's statutory ban on Medicaid payment for puberty blockers and cross-sex hormones as Florida Statutes § 286.31(2) because the bill adopting the provision sought to codify the provision there. However, the Florida Reviser of Statutes ultimately codified the provision as § 286.311(2) after the Legislature enacted two provisions that both were to be codified at § 286.31(2). ECF No. 266 at 8.

Ex. 7). Quoting an earlier e-mail to Plaintiffs' counsel, Florida represented to the court that it "'will not enforce [§ 286.311(2)'s] prohibition on 'managed care plan[s] providing services under part IV of chapter 409' because '[t]he best and most obvious reading of this statutory provision is that it serves as a categorical ban on the use of puberty blockers and cross-sex hormones.'" *Id*. at 3. Florida further represented to the court that the State "'will enforce rule 59G-1.050(7) to bar the use of puberty blockers and cross-sex hormones unless someone submits [a petition for] and obtains a [] variance or waiver under § 120.542 of the Florida Statute[s].'" *Id*. Florida argued that, given the availability of waivers, the State was "not enforcing Rule 59G-1.050(7) as a categorical ban on Medicaid coverage of hormonal treatment for gender dysphoria." *Id*. at 5.

In this action, AHCA is a Plaintiff. ECF No 1. The Complaint includes allegations referring to the same statutory and regulatory provisions declared invalid by the *Dekker* court and that Florida has represented to the *Dekker* court it is not enforcing. *Id*. ¶¶ 8, 114, 115, 121, 128, 171, 175. Those allegations are incorporated by reference into every count in the Complaint. *Id*. ¶¶ 216, 238, 251, 258, 277, 287, 293, 301. Among other relief, AHCA seeks a judgment declaring "that under any theory of Section 1557 and Title IX, Defendants may not require [AHCA] to . . . refrain from . . . categorically rejecting 'gender transition' interventions" under Florida Statutes § 286.311(2) and Florida Administrative Code rule 59G-1.050(7). *Id*., Prayer for Relief ¶ e(i).

IV. *Doe v. Ladapo*, No. 4:23-cv-00114-RH-MAF (N.D. Fla.)

On June 11, 2024, the district court in *Doe v. Ladapo* entered classwide declaratory and injunctive relief in a case involving several Florida statutes and agency regulations, including Florida Statutes §§ 456.52(1), 456.52(3), 456.52(5), and Florida Administrative Code rules 64B8ER23-7, 64B15ER23-9, 64B8ER23-11, and 64B15ER23-12. *Doe v. Ladapo*, --- F. Supp. 3d ---, 2024 WL 2947123, at *39-41 (N.D. Fla. June 11, 2024). Official capacity Florida defendants are enjoined from enforcing these statutes and rules in many applications. *Id.* at *40. In this action, the Complaint includes allegations referring to the same provisions. Compl. ¶ 128.

V. *McComb Children's Clinic, LTD. v. Becerra, et al.*, No. 5:24-cv-00048-KS-LGI (S.D. Miss.)

On May 13, 2024, plaintiff McComb Children's Clinic, LTD. (MCC) filed a complaint against the same parties named as Defendants in this action to challenge the same Final Rule challenged here. ECF No. 1 (attached as Ex. 8). Among other relief, MCC is seeking an order under 5 U.S.C. § 705 that the court enjoin and declare the rule unenforceable on a preliminary basis and delay its effective date. *Id.*, Prayer for Relief ¶ D. MCC is also seeking a declaratory judgment "that Section 1557 of the ACA, Title IX of the Education Amendments Act of 1972, and Section 504 of the Rehabilitation Act as incorporated therein do not prohibit discrimination on the basis of gender identity under the ACA." *Id.*, Prayer for Relief ¶ E.

VI. *Catholic Benefits Association, et al. v. Becerra, et al.*, No. 3:23-cv-203-PDW-ARS (D.N.D.)

On May 30, 2024, plaintiffs the Catholic Benefits Association (CBA), Sisters of St. Francis of the Immaculate Heart of St. Mary; St. Anne's Guest Home; and St. Gerard's Community of Care filed an amended complaint against the Secretary of HHS and HHS itself—two Defendants in this suit—as well as the United States Equal Employment Opportunity Commission (EEOC) and the Chair of the EEOC. ECF No. 46 (attached as Ex. 9). Among other relief, the *CBA* plaintiffs are seeking an injunction prohibiting HHS from interpreting or enforcing Section 1557 against CBA members in a manner that would require them to perform gender-transition procedures. *Id.*, Prayer for Relief ¶ C(a). Both CBA and CMA allege to be organizations consisting of Catholic members. CBA alleges that its membership includes hospitals, medical clinics, physicians medical practice groups, skilled nursing facilities, and other healthcare entities. *Id.* ¶ 57. At least as of several years ago, CMA itself was alleged to be a member of CBA. *See Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 597, 602 (8th Cir. 2022). Because Defendants otherwise lack specific information about the membership of CBA and CMA, Defendants do not know whether the membership of CBA and CMA overlap in additional ways.

VII. *State of Tennessee, et al. v. Becerra, et al.*, No. 1:24-cv-00161-LG-BWR (S.D. Miss.)

On May 30, 2024, the following states filed a complaint in the U.S. District Court for the Southern District of Mississippi: Tennessee, Mississippi, Alabama,

Georgia, Indiana, Kansas, Kentucky, Louisiana, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Virginia, and West Virginia. ECF No. 1 (attached as Ex. 10). Defendants are the same as the Defendants in this action. *Id.* Among other relief, the *Tennessee* plaintiffs seek a "stay of the Final Rule's effective date under 5 U.S.C. § 705 and a preliminary injunction enjoining Defendants, . . . from enforcing or implementing [certain] portions of the 2024 Rule." *Id.*, Prayer for Relief, (a).

VIII. *State of Texas, et al. v. Becerra, et al.*, No. 6:24-cv-00211-JCB (E.D. Tex.).

On June 10, 2024, the States of Texas and Montana filed a complaint in the U.S. District Court for the Eastern District of Texas. ECF No. 1 (attached as Ex. 11). Defendants in that action are also Defendants in this case. *Id.* Among other relief, the *Texas* plaintiffs seek a "stay of the Final Rule's effective date under 5 U.S.C. § 705" and a preliminary injunction enjoining Defendants "from interpreting or enforcing Section 1557" to bar discrimination based on gender identity." *Id.*, Prayer for Relief.

_____ IS NOT related to any pending or closed civil or criminal case filed with this Court, or any other Federal or State court, or administrative agency.

Dated: June 13, 2024

Respectfully submitted,

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Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

SUSAN NEESE, *et al.*,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	2:21-CV-163-Z
	§	
XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services, *et al.*,	§	
	§	
	§	
	§	
Defendants.	§	

ORDER

On October 14, 2022, the Court granted Plaintiffs' Motion for Class Certification. *See* ECF Nos. 44, 65. The Court certifies the following class under Federal Rule of Civil Procedure 23(b)(2): All health-care providers subject to Section 1557 of the Affordable Care Act ("ACA"). Plaintiffs Susan Neese and James Hurly are appointed class representatives. The Court appoints Jonathan F. Mitchell to serve as class counsel under Rule 23(g).

The class claims are:

1. Whether Defendant Becerra's interpretation of Section 1557 of the ACA, which appears in his Notification of Interpretation and Enforcement of May 10, 2021, is inconsistent with the statutory definition of "sex" discrimination; and

2. Whether the prohibition on "sex" discrimination in Section 1557 of the ACA encompasses only situations in which a provider would have acted differently toward an identically situated member of the opposite biological sex.

SO ORDERED.

November 22, 2022

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE

Exhibit 2

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

SUSAN NEESE, *et al.*,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	2:21-CV-163-Z
	§	
XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services, *et al.*,	§	
	§	
Defendants.	§	

FINAL JUDGMENT

On November 11, 2022, the Court issued an Opinion and Order (ECF No. 66) **GRANTING IN PART** Plaintiffs' Motion for Summary Judgment and **GRANTING IN PART** Defendants' Motion for Summary Judgment. The Court issues the following relief consistent with that Opinion and Order.

1. The Court awards Plaintiffs and the certified class relief under 5 U.S.C. § 706(2). The Court **HOLDS UNLAWFUL** and **SETS ASIDE** Defendant Becerra's Notification of Interpretation and Enforcement of May 10, 2021.

2. The Court awards Plaintiffs and the certified class declaratory relief under 28 U.S.C. § 2201. The Court **DECLARES**:

   - Plaintiffs and members of the certified class need not comply with the interpretation of "sex" discrimination adopted by Defendant Becerra in his Notification of Interpretation and Enforcement of May 10, 2021; and

   - Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of "sex" discrimination that the Supreme Court of the United States adopted in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), is inapplicable to the prohibitions on "sex" discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA.

3. The Court **GRANTS** summary judgment for Defendants insofar as Plaintiffs and the certified class seek injunctive relief on any claim.

This final judgment fully and finally resolves all remaining claims in this suit and is appealable. The Court **DENIES** all other relief not expressly granted herein.

Judgment is rendered accordingly.

November 22, 2022

MATTHEW J. KACSMARYK
UNITED STATES DISTRICT JUDGE

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself and its members; **CATHOLIC MEDICAL ASSOCIATION**, on behalf of itself and its members; and **JEANIE DASSOW, M.D.,** *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**; **LISA J. PINO**, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services; and **OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**, *Defendants.*	No. 1:21-cv-00195-TAV-SKL **FIRST AMENDED COMPLAINT** **Jury Trial Demanded**

PLAINTIFFS' FIRST AMENDED COMPLAINT

Plaintiff American College of Pediatricians, on behalf of itself and its members; Plaintiff Catholic Medical Association, on behalf of itself and its members; and Plaintiff Jeanie Dassow, M.D. (collectively, Plaintiffs), for the first amended complaint against Defendants, state as follows:

INTRODUCTION

1. This case challenges whether the federal government can make medical doctors perform gender-transition surgeries, prescribe gender-transition drugs, and speak and write about patients according to gender identity, rather than biological reality—regardless of doctors' medical judgment or conscientious objections.

2. The U.S. Department of Health and Human Services (HHS) has re-interpreted Section 1557 of the Affordable Care Act (ACA), which prohibits sex discrimination, to require doctors to perform such interventions by prohibiting discrimination on the basis of gender identity. Under the government's overreaching interpretation, doctors now face an untenable choice: either act against their medical judgment and deeply held convictions by performing controversial and often medically dangerous gender interventions, or succumb to huge financial penalties, lose participation in Medicaid and other federal funding, and, as a practical matter, lose the ability to practice medicine in virtually any setting. HHS has also imposed a gender identity mandate through its overarching grants regulation, 45 C.F.R. § 75.300, which partly overlaps and partly surpasses the Section 1557 mandate in many health contexts.

3. Federal statutes do not support the imposition of this gender identity mandate. As a result, the mandate violates the Administrative Procedure Act, and is also a violation of the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb-1, the First Amendment's Free Speech and Free Exercise of Religion Clauses, and other constitutional doctrines. Nor may HHS ignore procedures that protect doctors against these mandates, such as opportunities for agency repeal of these rules under the Regulatory Flexibility Act and chances for public participation to bring attention to these burdens under the SUNSET Rule.

4. Plaintiffs are two medical associations, which together represent approximately three thousand physicians and health professionals, and one medical doctor in Chattanooga, Tennessee. Unless the court issues injunctive and declaratory relief halting this mandate, they will incur irreparable harm to their practices.

5. Two courts have already recognized that the Section 1557 mandate is illegal and enjoined it in favor of plaintiffs in those cases. *Franciscan Alliance, Inc. v. Becerra*, No. 7:16-cv-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021), as amended

(Aug. 16, 2021); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1139 (D.N.D. 2021). But both injunctions protect only the plaintiffs in those cases, not the members of the medical associations here. And injunctive relief is needed to shield physicians from the gender identity mandate in HHS's Grants regulation. Therefore a preliminary and permanent injunction under the Administrative Procedure Act and the Religious Freedom Restoration Act are needed to shield plaintiffs from the federal government's penalties that threaten to drive thousands of doctors out of practice.

JURISDICTION & VENUE

6. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.[1]

7. This Court also has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

8. Additionally, this Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

9. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the APA, 5 U.S.C. §§ 553, 701–706, and the Regulatory Flexibility Act, 5 U.S.C. § 611.

10. This Court has inherent jurisdiction to review and enjoin ultra vires or unconstitutional agency action through an equitable cause of action. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–71 (1949).

11. This case seeks declaratory and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 5 U.S.C. § 705 & 706, Federal Rule of Civil Procedure 57, and the Court's inherent equitable powers.

[1] Under 28 U.S.C. § 1331, the district courts have jurisdiction over all claims in this case because the vast majority of the regulations at issue, including those affected by the SUNSET Rule, fall under statutory provisions that have no specific direct-review provision elsewhere.

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

13. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of the action is situated here, because this district is where Plaintiffs American College of Pediatricians and Dr. Jeanie Dassow are situated and are regulated by Defendants' actions. Defendants are United States agencies or officers sued in their official capacities. A substantial part of the events or omissions giving rise to the Complaint occur within the Eastern District of Tennessee.

PARTIES

I. American College of Pediatricians (ACPeds)

14. Plaintiff American College of Pediatricians (ACPeds) is a national organization of pediatricians and other healthcare professionals.

15. ACPeds is a nonprofit organization founded in 2002, is incorporated in the State of Tennessee, and has its registered agent in Tennessee.

16. ACPeds' membership includes more than 600 physicians and other healthcare professionals drawn from 47 different States across the nation.

17. ACPeds has members within this judicial district and elsewhere in the State of Tennessee.

18. Most ACPeds members provide medical care in health programs and activities receiving federal financial assistance from HHS under 42 U.S.C. § 18116.

19. Some ACPeds members provide medical care in programs or entities receiving grants from HHS governed by 45 C.F.R. § 75.300.

20. ACPeds seeks relief on behalf of itself and its current and future members.

21. The President of ACPeds is Quentin Van Meter, M.D.

22. Additional facts about ACPeds and Dr. Van Meter are set forth in Dr. Van Meter's declaration attached as Exhibit 1.

II. Catholic Medical Association

23. Plaintiff the Catholic Medical Association (CMA) is the largest association of Catholic individuals in healthcare.

24. CMA is a nonprofit organization incorporated in Virginia, and its registered agent is in Virginia.

25. CMA has three member guilds in Tennessee: in Clarksville, the Immaculate Conception Catholic Medical Guild; in Memphis, the Catholic Medical Association of Memphis Guild; and in Nashville, the Nashville Guild. It hosted its annual national conference in 2019 in Nashville.

26. CMA has individual members in Tennessee.

27. Most CMA members provide medical care in health programs and activities receiving federal financial assistance under 42 U.S.C. § 18116.

28. Some CMA members provide medical care in programs or entities receiving grants from HHS governed by 45 C.F.R. § 75.300.

29. CMA seeks relief on behalf of itself and its current and future members.

30. The Executive Director of CMA is Mario Dickerson.

31. Additional facts about CMA are set forth in Mr. Dickerson's declaration attached as Exhibit 2.

III. Jeanie Dassow, M.D.

32. Plaintiff Jeanie Dassow, M.D., is a board-certified obstetrician and gynecologist in Chattanooga, Tennessee, and practices medicine in this judicial district.

33. Dr. Dassow provides medical care in health programs and activities receiving federal financial assistance under 42 U.S.C. § 18116, and in programs and

activities receiving grants from Defendant U.S. Department of Health and Human Services governed by 45 C.F.R. § 75.300.

34. Additional facts about Dr. Dassow a are set forth in her declaration attached as Exhibit 3.

IV. Defendants

35. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services. Defendant Becerra is sued in his official capacity. Defendant Becerra is responsible for the overall operations of HHS, including the Department's administration of Section 1557 of the ACA. *E.g.*, 42 U.S.C. § 18116. His address is 200 Independence Ave SW, Washington, DC 20201.

36. Defendant U.S. Department of Health and Human Services (HHS) is a federal cabinet agency within the executive branch of the U.S. government and is an agency under 5 U.S.C. § 551 and 701(b)(1). Its address is 200 Independence Ave SW, Washington, DC 20201. HHS is responsible for implementing and enforcing 42 U.S.C. § 18116.

37. Defendant Lisa J. Pino is the Director of the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services. As head of OCR, Defendant Pino is responsible for enforcing 42 U.S.C. § 18116 on behalf of HHS. Her address is 200 Independence Ave SW, Washington, DC 20201.

38. Defendant the Office for Civil Rights is a component of the U.S. Department of Health and Human Services. Its address is 200 Independence Ave SW, Washington, DC 20201. OCR is responsible for implementing and enforcing 42 U.S.C. § 18116 on behalf of HHS.

FACTUAL ALLEGATIONS

39. This case challenges three regulatory actions that limit the ability of healthcare professionals to use their best medical judgment and stay faithful to their religious beliefs.

a. *First*, this case challenges HHS's gender identity mandate under Section 1557 of the Affordable Care Act, which forces doctors to endorse or perform gender interventions if they participate in federal financial assistance programs, such as Medicaid or the Children's Health Insurance Program (CHIP).

b. *Second*, this case challenges HHS's 2016 Grants Rule, which imposes a second gender identity mandate on doctors who work in programs that receive grants from HHS, such as community health centers.

c. *Third*, this case challenges HHS's "Delay Rule," by which it engaged in a sudden withdrawal and delay of its "SUNSET Rule," which provided important procedural protections for those affected by HHS regulations, such as doctors, and gave them opportunities to comment on and rescind these gender identity mandates.

I. Section 1557 of the Affordable Care Act

40. Section 1557 of the Affordable Care Act (ACA), 42 U.S.C. § 18116, states in paragraph (a) that:

> Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29, 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, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms

> provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

41. None of the anti-discrimination statutes mentioned in Section 1557 prohibit discrimination on account of gender identity.

42. Among the statutes cited in Section 1557, the only one that prohibits discrimination on the basis of sex is Title IX of the Education Amendments of 1972 (Title IX).

43. Title IX states, *inter alia*, 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.

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

45. Title IX states it cannot be construed to require any person or entity to "provide or pay for any benefit or service, including the use of facilities, related to an abortion." 20 U.S.C. § 1688.

46. To the extent an action is encompassed by the religious exemption or abortion neutrality language in Title IX, it is not prohibited under the sex discrimination ban of Section 1557.

47. Many provisions in the ACA show that Congress understood "sex" to mean the biological binary of male and female, and not to encompass the concept of gender identity. *See, e.g.*, 124 Stat. at 261, 334, 343, 551, 577, 650, 670, 785, 809, 873, 890, 966. For example, the ACA requires the provision of "information to women and health care providers on those areas in which differences between men and women exist." *Id*. at 536–37.

48. Likewise, language throughout Title IX reflects that Congress understood "sex" as a biological binary and not as including gender identity. *See, e.g.*, 20 U.S.C. §§ 1681(a)(2); 1681(a)(8), 1686.

49. Paragraph (c) of Section 1557 states, "The Secretary may promulgate regulations to implement this section."

II. Effects of the 2016 ACA Rule

50. In 2016, HHS used its rulemaking authority under Section 1557 to promulgate a final rule entitled Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) (codified at 45 C.F.R. pt. 92) (referred to here as the 2016 ACA Rule).

51. The 2016 ACA Rule interpreted discrimination "on the basis of sex" to include discrimination on the basis of gender identity and sex stereotypes, and its preamble specified multiple ways by which this meant the rule would require medical providers to offer gender identity interventions and procedures, and to engage in speech affirming gender identities and interventions. 81 Fed. Reg. at 31,467–68 (45 C.F.R. § 92.4).

52. The 2016 ACA Rule forbade "discrimination" based on "gender identity," which HHS defined to mean an individual's "internal sense of gender, which may be male, female, neither, or a combination of male and female." *Id*. HHS said, "The way an individual expresses gender identity is frequently called 'gender expression,' and may or may not conform to social stereotypes associated with a particular gender." *Id*. The "gender identity spectrum includes an array of possible gender identities beyond male and female," and individuals with "non-binary gender identities are protected under the rule." *Id*. at 31,375, 31,392, 31,384. The 2016 ACA Rule mandated that "a covered entity shall treat individuals consistent with their gender identity." *Id*. at 31,471 (formerly codified at 45 C.F.R. § 92.206).

53. The 2016 ACA Rule preamble specifies that its prohibition on gender identity discrimination apply in various specific ways, including but not limited to:

a. a prohibition on categorizing transition-related treatment as experimental, outdated, or not based on current standards of care, 81 Fed. Reg. at 31,429, 31,435;

b. a prohibition on imposing a binary view of gender, *id.* at 31,350 n.263;

c. a requirement that doctors to perform (or refer for) sex or gender-transition procedures, including hysterectomies, mastectomies, hormones, drugs, and plastic surgery, if the doctor performs analogous services in other, non-transition medical practices, for example, to biological females seeking cancer treatment, even if those procedures are not strictly identified as medically necessary or appropriate," *id.* at 31,429, *Id.* at 31,455;

d. a requirement to apply "neutral, nondiscriminatory criteria that it uses for other conditions when the [insurance] coverage determination is related to gender transition" whether or not "the services are medically necessary or medically appropriate." 81 Fed. Reg. at 31,435.

e. a prohibition on the "explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition, *id.* at 31,429, 31,456, 31,472 (45 C.F.R. § 92.207(b)(4)).

f. a prohibition on denying or limiting care or coverage for a person who identifies contrary to his or her biological sex to "health services that are ordinarily or exclusively available to individuals of one sex," *id.* at 31,471 (45 C.F.R. § 92.206).

g. the range of transition-related services required by the rule "includes treatment for gender dysphoria, is not limited to surgical treatments and may include, but is not limited to, services such as hormone therapy

and psychotherapy, which may occur over the lifetime of the individual," *id.* at 31,435–36.

A. Requirements to offer and recommend gender interventions

54. Under the 2016 ACA Rule, a doctor must offer, recommend, refer for, and engage in advice in favor of gender interventions.

55. The 2016 ACA Rule similarly requires a provider to prescribe, offer to prescribe, or refer for puberty blocking drugs and cross-sex hormones to patients with gender dysphoria.

56. The 2016 ACA Rule requires that providers not raise concerns about gender-transition regret *or* about permanent, irreversible damage, and instead, requires them to affirm patients' state gender identities and to provide gender interventions on demand.

57. The 2016 ACA Rule compels doctors to say that transition-related procedures and interventions are medically necessary and appropriate. 81 Fed. Reg. at 31,429. Under the 2016 ACA Rule, healthcare providers may not offer a view contrary to HHS in their medical advice to patients, or even to other healthcare providers in their practices or at medical conferences.

58. The 2016 ACA Rule bans a policy, procedure, and practice of not performing, offering, or referring these interventions.

59. The 2016 ACA Rule mandates revisions to healthcare professionals' written policies, censoring speech declining to provide transition-related interventions and requiring policies to expressly affirm that transition-related procedures will be provided, even if these policies would not reflect their medical judgment or ethical, conscientious, and religious positions. 81 Fed. Reg. at 31,455.

60. The 2016 ACA Rule not only requires providers to perform these interventions but to offer them or provide them whether or not requests have been made.

61. The 2016 ACA Rule requires that covered entities, "as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the entity's health programs or activities will be operated in compliance with section 1557 and this part," meaning the HHS regulations including the operative portions of the 2016 ACA Rule. 45 C.F.R. § 92.4(a); 81 Fed. Reg. at 31,392, 31,442, 31,468.

62. Covered entities must post notices about compliance with the 2016 ACA Rule in conspicuous locations, and HHS provided a sample notice to be posted. 81 Fed. Reg. at 31,472, 45 C.F.R. § 92, App. A.

63. OCR can also demand that covered entities record and submit compliance reports. 81 Fed. Reg. at 31,439, 31,472.

B. Compelled speech affirming gender identity as sex

64. The 2016 ACA Rule requires providers to use gender-transition affirming language in all situations, regardless of circumstance. *Id*. at 31,350.

65. The 2016 ACA Rule states that "refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth constitutes illegal sex discrimination if such conduct is sufficiently serious to create a hostile environment." *Id*.

66. The 2016 ACA Rule requires healthcare providers to use documentary codes and make medical records consistent with a patient's gender identity even if it differs from a patient's biological sex.

67. The 2016 ACA Rule punishes healthcare providers for expressing to patients or to fellow healthcare providers their medical, ethical, or religious views concerning gender identity, gender-transition interventions, or biological differences between men and women. This could include the provision of books, pamphlets, or other written materials, or the posting of messages or pictures, alleged to contribute to a hostile environment.

68. Under the 2016 ACA Rule, a medical provider's objection to referring a patient for a procedure for gender-transition purposes would constitute unlawful discrimination.

69. The 2016 ACA Rule then provides for liability in any of these areas on theories of harassment, hostile environment, and disparate impact. *See, e.g.*, *id.* at 31,470 (then codified at 45 C.F.R. § 92.101(b)(3)(ii)).

C. Prohibition on single-sex programs and facilities

70. The 2016 ACA Rule prohibits single-sex spaces, such as single-sex medical rooms and single-sex restrooms or communal shower rooms unless access is allowed based on a person's stated gender identity, even when that identity does not align with the person's biological sex.

71. The 2016 ACA Rule directs that any "shower facilities" offered by providers may not exclude anyone "based on their gender identity." 81 Fed. Reg. at 31,409.

72. HHS denied that any "legal right to privacy" could be violated "simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity." *Id.*

73. The 2016 ACA Rule required sex-specific health programs to admit patients based on gender identity. It stated that sex-specific health programs or activities are unlawful unless a covered entity can "supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex," and in "no case will [HHS] accept a justification that relies on overly broad generalizations about the sexes. *Id.*

III. Current status of gender identity under HHS's Section 1557 Rule

74. In December 2016, a district court issued a preliminary injunction against the gender identity mandate under the 2016 ACA Rule, as well as against similar language requiring abortions and abortion advocacy. *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 695–96 (N.D. Tex. 2016).

75. In October 2019, the court issued final judgment declaring that the 2016 ACA Rule violated the APA and RFRA, vacating the gender identity language (and other termination of pregnancy language) from the 2016 ACA Rule, and remanding the rulemaking to HHS. *Franciscan Alliance, Inc. v. Burwell*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019).

76. In 2020, HHS issued a final rule substantially revising the 2016 ACA Rule, removing its gender identity language and stating that HHS interprets Section 1557 and Title IX to not prohibit discrimination on the basis of gender identity. Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority." 85 Fed. Reg. 37,160 (June 19, 2020) (to amend and be codified at 45 C.F.R. pt. 92) (the "2020 ACA Rule").

77. The 2020 ACA Rule stated that the 2016 ACA Rule "exceeded its authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, and imposed unjustified and unnecessary costs." *Id*. at 27,849. In particular, HHS stated that its prior position declining to provide these procedures or interventions is "'outdated and not based on current standards of care'" was "erroneous" and lacked a "scientific and medical consensus to support" it. *Id*. at 37,187 (quoting 81 Fed. Reg. at 31,429).

78. Two courts, however, issued injunctions not only preventing parts of the 2020 ACA Rule from going into effect, but also declaring that the gender identity language from the 2016 ACA Rule is still in effect, and one of those courts also blocked HHS from putting the Title IX religious exemption language in HHS's 1557 regulations. *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020), *modified by* 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020); *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020).

79. As the result of *Walker* and *Whitman-Walker Clinic*, the 2016 ACA Rule's gender identity language, and the implications of that language described in the 2016

ACA Rule's preamble, remain in effect, including as discussed above, and its lack of incorporation of the religious exemption from Title IX.

80. The U.S. District Court for the District of North Dakota essentially agreed with other plaintiffs that the gender identity mandate from the 2016 ACA Rule is in effect as of January 2021. *See Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1139 (D.N.D. 2021).

81. Plaintiffs contend in the alternative that, if the *Walker* and *Whitman-Walker Clinic* orders are interpreted by this Court to not have actually restored the 2016 ACA Rule's gender identity language, HHS has nevertheless concluded that those courts did so, and HHS is engaging in enforcement accordingly, under a presidential directive and a subsequent announcement HHS made on May 10, 2021.

82. This complaint proceeds under the assumption that the *Walker* and *Whitman-Walker Clinic* orders did restore the 2016 ACA Rule's gender identity language, consistent with *Religious Sisters of Mercy*, but preserves Plaintiffs' right to present an alternative argument regarding that issue, so that plaintiffs have an avenue for protection from HHS's Section 1557 gender identity mandate whether its source is determined to be the 2016 ACA Rule, HHS's May 10, 2021 announcement, or Section 1557 itself.

83. On January 20, 2021, immediately upon taking office, President Biden signed an executive order requiring that Section 1557 and Title IX be interpreted to include gender identity as a protected trait, as well as requiring similar interpretations of all other federal civil rights laws and promoting related policies.[2]

84. On May 10, 2021, HHS announced that its Office for Civil Rights (OCR), effective immediately, "will interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual

[2] Executive Order 13,988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7023 (Jan. 20, 2021).

orientation; and (2) discrimination on the basis gender identity." 86 Fed. Reg. 27,984, 27,985 (May 25, 2021) (May 10, 2021 Notice of Enforcement).

85. HHS also announced, in the same notice and in a press release, that it interprets the term sex in Title IX of the Education Amendments of 1972 ("Title IX"), 20 U.S.C. § 1681, to include gender identity.[3]

86. Regarding Section 1557, HHS stated its enforcement activity would comply with RFRA "and all other legal requirements," including the various district court injunctions related to Section 1557 regulations, but it did not specify how it would or would not respect religious or other objections. 86 Fed. Reg. at 27,985.

87. For ease of reference, the gender identity provisions in effect from the 2016 ACA Rule, and the May 10, 2021 Notice of Enforcement, and the penalties set forth in the 2020 ACA Rule for violating HHS's Section 1557 regulations related to the ACA, are referred to herein as the "Section 1557 gender identity mandate," or the "gender identity mandate."

88. Upon information and belief, OCR is now actively investigating, enforcing, and implementing an interpretation of Section 1557 and HHS regulations under which sex discrimination includes gender identity and sex stereotyping.

89. Upon information and belief, Defendants do not believe that RFRA or other laws require any exemptions from the Section 1557 gender identity mandate.

90. HHS has not publicly recognized any RFRA exemption under its interpretation of Section 1557 except those ordered by a court, and even in some of those cases HHS takes the position that RFRA provides no exemption.

91. HHS filed a Statement of Interest in which it cited its Section 1557 authority as grounds for preempting a state law that protected children from gender

[3] Press Release, HHS OCR, HHS Announces Prohibition on Sex Discrimination Includes Discrimination on the Basis of Sexual Orientation and Gender Identity (May 10, 2021), https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html.

interventions and that protected healthcare providers from providing them. Statement of Interest of the United States, *Brandt v. Rutledge*, No. 4:21-cv-00450-JM (E.D. Ark. June 17, 2021), ECF. No. 19.

IV. Court Orders Against HHS's Section 1557 Gender Identity Mandate

92. In *Religious Sisters of Mercy v. Azar*, the district court acknowledged that a gender identity mandate under Section 1557 exists after *Walker* and *Whitman-Walker Clinic*, and it issued final injunctive relief from that mandate for plaintiffs in that case, including named health care providers and a nonprofit association, some of whose members are health care providers. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1139 (D.N.D. 2021), *judgment entered sub nom. Religious Sisters of Mercy v. Cochran*, No. 3:16-CV-00386, 2021 WL 1574628 (D.N.D. Feb. 19, 2021).

93. In another case, on August 9, 2021, the *Franciscan Alliance* district court added to its previous rulings by issuing a permanent injunction against HHS under RFRA to stop enforcement of this gender identity mandate, but only in protection of the plaintiffs in that case, including named health care providers and the Christian Medical & Dental Associations and their members. *Franciscan Alliance, Inc. v. Becerra*, No. 7:16-cv-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021), as amended (Aug. 16, 2021).

V. HHS's Separate Gender Identity Mandate for Grants

94. In addition to HHS's Section 1557 gender identity mandate, in 2016 HHS separately imposed an overarching gender identity mandate on all of its grants programs. See 45 C.F.R. § 75.300.

95. This mandate consequently includes healthcare providers who work in programs that accept federal HHS grants, such as doctors practicing at community health centers or institutions receiving HHS grants.

96. HHS awards grants under more than 300 programs, making it the largest grant-awarding agency in the Federal government.[4]

97. 45 C.F.R. § 75.300(c) & (d) was added by Health and Human Services Grants Regulation, 81 Fed. Reg. 89,393 (Dec. 12, 2016) (hereinafter, § 75.300(c) & (d) is referred to as "the 2016 Grants Rule"); *see also* Health and Human Services Grants Regulation, 81 Fed. Reg. 45,270 (July 13, 2016) (the proposed 2016 grants rule).

98. The 2016 Grants Rule applies to all "grant agreements and cooperative agreements" unless the program is specifically exempted. 45 C.F.R. § 75.101.

99. The 2016 Grants Rule prohibits discrimination on the basis of gender identity.

100. HHS understands the gender identity nondiscrimination provisions of the 2016 Grants Rule to require the same things from healthcare providers encompassed by that rule that the 2016 ACA Rule requires of them where it applies, including the mandates outlined above imposing the objectionable practices.

101. The 2016 Grants Rule relied as its sole source of authority on the multi-agency "housekeeping statute" 5 U.S.C. § 301, which is written to govern internal agency operations, and on HHS's claim that it can impose the mandate as a matter of public policy.

102. The 2016 Grants Rule does not state that any religious exemption applies to relieve persons of its gender identity nondiscrimination requirement.

103. However, the 2016 Grants Rule is subject to a long-standing, more general discretionary provision that authorizes the Department to grant "[e]xceptions on a case-by-case basis for individual non-Federal entities." 45 C.F.R. § 75.102(b).

104. From 2017–2020, the previous administration granted three exemptions to the 2016 Grants Rule under § 75.102(b) and/or RFRA, specifically to foster care

[4] HHS, HHS Grants Policy Statements at I-1 (Jan. 1, 2007), https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf (describing grant policies and programs).

programs administered in South Carolina, Texas, and Michigan, and funded by HHS grants.

105. In 2019, HHS issued a notice of non-enforcement, declaring it would not enforce the 2016 Grants Rule because the Grants Rule violated the Regulatory Flexibility Act. Notification of Non-enforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809, 63,809-11 (Nov. 19, 2019) (the 2019 Notification of Nonenforcement).

106. Simultaneously HHS published a proposed rule to remove the gender identity nondiscrimination mandate from § 75.300(c) & (d).

107. A challenge is pending to HHS's 2019 Notification of Nonenforcement. *Family Equality v. Azar*, No. 1:20-cv-2403 (S.D.N.Y.).

108. HHS is not bound to retain the 2019 Notification of Nonenforcement for any time period, and could withdraw it at any moment.

109. Upon information and belief, HHS is not committed to retaining the 2019 Notification of Nonenforcement or the previous administration's RFRA exemptions granted to the 2016 Grants Rule.

110. HHS began and is still currently evaluating rescinding the 2019 Notification of Nonenforcement. *See Family Equality v. Azar*, No. 1:20-cv-2403, ECF 52 (S.D.N.Y. Feb. 16, 2021).

111. HHS may enforce the 2016 Grants Rule at any time despite the 2019 Notification of Non-Enforcement.

112. Upon information and belief, HHS accepts and investigates complaints from the public for investigation about grantee practices prohibited by the 2016 Grants Rule.

113. Upon information and belief, Defendants do not believe that RFRA or other religious-freedom or conscience laws require any exemptions from their enforcement of this gender identity mandate on grants.

114. In 2021, in the waning days of the previous administration, HHS published a final rule to remove the 2016 Grants Rule's language on gender identity. Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257, 2,257 (Jan. 12, 2021) (the 2021 Grants Rule). That rule was not set to go into effect until February 11, 2021.

115. The 2021 Grants Rule's preamble explains that HHS lacked statutory authority to promulgate the 2016 Grants Rule, that the 2016 Grants Rule ignored RFRA, and that the 2016 Grants Rule discouraged faith-based entities from participating in HHS programs. 86 Fed. Reg. at 2,257, 2,262-63.

116. HHS acknowledged that the 2016 Grants Rule created several known RFRA violations, as well as an unknown number of other "circumstances where these requirements create similar problems under RFRA." *Id*. at 2,263.

117. HHS also expressed concern that the 2016 Grants Rule could deter participation and thus "undermine the effectiveness" of its grants programs by reducing the number of service providers. *Id*. at 2,259, 2,263, 2,269, 2,273.

118. After President Biden took office, a lawsuit was filed against the 2021 Grants Rule, and HHS swiftly stipulated to an order prior to February 11, 2021, delaying implementation of the 2021 Grants Rule before it went into effect. Order, *Facing Foster Care in Alaska v. HHS*, No. 21-cv-00308, ECF No. 17 & 18 (D.D.C. Feb. 2, 2021) (order postponing effective date to August 11, 2021); Order, *Facing Foster Care*, No. 21-cv-00308, ECF No. 23 (D.D.C. Aug. 5, 2021) (order postponing effective date to November 9, 2021); Joint Status Report and Motion for Stay, *Facing Foster Care*, No. 21-cv-00308, ECF No. 25 & 26 (D.D.C. Nov. 2–3, 2021) (request to postpone effective date to January 17, 2022 granted by unnumbered minute order). The 2021 Grants Rule thus has yet to take effect.

119. HHS did not conduct any briefing, public participation, or judicial findings on the merits before stipulating to delay of the 2021 Grants Rule.

120. HHS stated that it would review the 2021 Grants Rule during the period of postponement. *Id*.

121. Upon information and belief, HHS does not intend to defend the 2021 Grants Rule in court at all, let alone on the merits.

122. Upon information and belief, HHS intends to indefinitely delay the effective date of 2021 Grants Rule, through judicial orders or otherwise, and eventually withdraw it.

123. With no current replacement of the 2016 Grants Rule by an effective 2021 Grants Rule, the 2016 Grants Rule remains on the books, and it currently imposes a gender identity mandate on grant recipients, in addition to and separate from the Section 1557 gender identity mandate that HHS announced under Section 1557, including as it impacts doctors working for a grantee or sub-grantee.

124. If any other source of authority is interpreted (incorrectly) to impose the same gender identity mandate contained in the 2016 Grants Rule, this complaint against Defendants' enforcement encompasses it as well.

125. For ease of reference, Defendants' enforcement of a gender identity mandate under the 2016 Grants Rule is referred to as the "Grants gender identity mandate."

VI. The Effect of HHS's 1557 and Grants Gender Identity Mandates and Other Rules on Plaintiffs

126. Plaintiffs provide high-quality medical services to all people, regardless of their "internal sense of gender."

127. For Plaintiffs, demand nothing less.

128. Based on the Hippocratic Oath, their commitment to the medical profession, and for religious plaintiffs, their faith, Plaintiffs believe that a patient with medical needs, such as a broken bone, an infection, or cancer, should be given the best medical care possible, regardless of their identity.

129. But the gender identity mandates require doctors to provide gender interventions, treat patients as if their sex is their gender identity and not their actual biological sex, and engage in speech affirming gender identity regardless of the doctors' medical judgment and religious or ethical objections.

130. The Section 1557 gender identity mandate imposes tangible, concrete harm for ACPeds and CMA members, and the parallel Grants gender identity mandate imposes like harm on Dr. Dassow as well as members of ACPeds and CMA who work at facilities receiving HHS grants.

131. Plaintiffs have medical, ethical, or religious objections to the following activities and speech that HHS requires of them:

a. Prescribing puberty blockers off-label from the FDA-approved indication to treat gender dysphoria and initiate or further transition in adults and children;

b. Prescribing hormone therapies off-label from the FDA-approved indication to treat gender dysphoria in all adults and children;

c. Providing other continuing interventions to further gender transitions ongoing in both adults and minors;

d. Performing hysterectomies or mastectomies on healthy women who believe themselves to be men;

e. Removing the non-diseased ovaries of healthy women who believe themselves to be men;

f. Removing the testicles of healthy men who believe themselves to be women;

g. Performing a process called "de-gloving" to remove the skin of a man's penis and use it to create a faux vaginal opening;

h. Remove vaginal tissue from women to facilitate the creation of a faux or cosmetic penis;

i. Performing or participating in any combination of the above mutilating cosmetic procedures, or similar surgeries,[5] to place a patient somewhere along the socially constructed gender identity spectrum;

j. Offering to perform, provide, or prescribe any and all such interventions, procedures, services, or drugs;

k. Referring patients for any and all such interventions, procedures, services, or drugs;

l. Ending or modifying their policies, procedures, and practices of not offering to perform or prescribe these procedures, drugs, and interventions;

m. Saying in their professional opinions that these gender intervention procedures are the standard of care, are safe, are beneficial, are not experimental, or should otherwise be recommended;

n. Treating patients according to gender identity and not sex;

o. Expressing views on gender interventions that they do not share;

p. Saying that sex or gender is nonbinary or on a spectrum;

q. Using language affirming any self-professed gender identity;

r. Using patients' preferred pronouns according to gender identity, rather than using no pronouns or using pronouns based on biological sex;

s. Creating medical records and coding patients and services according to gender identity not biological sex;

t. Providing the government assurances of compliance, providing compliance reports, and posting notices of compliance in prominent

[5] Similar objectionable surgeries include orchiectomy and penectomy (removal of testicles and penis); clitoroplasty, labiaplasty, and vaginoplasty (creation of a clitoris, labia, and vagina); vulvectomy and vaginectomy (removal of vulva and vagina); and metoidioplasty and phalloplasty (creation of penis).

physical locations, if the 2016 ACA Rule's interpretation of the term sex governs these documents;

u. Refraining from expressing their medical, ethical, or religious views, options, and opinions to patients when those views disagree with gender identity theory or transitions; and

v. Allowing patients to access single-sex programs and facilities, such as mental health therapy groups, breastfeeding support groups, post-partum support groups, educational sessions, changing areas, restrooms, communal showers, and other single-sex programs and spaces, by gender identity and not by biological sex.

For ease of reference, the items in this list will be referred to as the "objectionable practices."

132. Plaintiffs will never abandon a patient and they will discuss procedures and interventions used for altering biological sex characteristics under informed consent, but they oppose engaging in the objectionable practices.

133. Defendants now require Plaintiffs to provide the objectionable practices that Defendants deem to be within the scope of their medical practice, as well as other gender identity related interventions to be articulated by HHS in the future.

A. Effect on American College of Pediatricians and its members.

134. Most ACPeds members are board-certified pediatricians with active practices.

135. Most ACPeds' members participate in health programs and activities receiving federal financial assistance, and thus are encompassed by the Section 1557 gender identity mandate.

136. Most ACPeds members treat patients who are members of federal healthcare programs such as Medicaid, Medicare, and CHIP, and are thus subject to Section 1557.

137. Many ACPeds members also work in hospitals that receive HHS grants and are thus subject to the 2016 Grants Rule, and some provide services in clinics serving rural or underserved populations.

138. Most hospitals and children's hospitals, for example, receive HHS grants of various kinds covered by the 2016 Grants Rule, such as from HHS components NIH, SAMHSA, HRSA, or ACF,[6] and many clinics serving rural and underserved populations receive grants from HRSA.

139. Upon information and belief, the hospitals where ACPeds members provide care receive grants from HHS, as do the clinics serving rural or underserved populations.

140. Consistent with the Hippocratic Oath, ACPeds' mission is to enable all children to reach their optimal physical and emotional health and well-being from the moment of conception.

141. ACPeds and its members are dedicated to caring for all children regardless of their family structure, race, ethnicity, religion, ideology, sexual attractions, and gender identity. That commitment extends to caring for LGBTQ+ youth, parents, and families, to include children who identify as a gender other than their biological sex.

142. ACPeds members care for youth who identify contrary to their biological sex in many ways ranging from setting broken bones, to conducting physicals, to treating acute and chronic illnesses. ACPeds is unaware of any of its members denying this type of ordinary, accepted, and critical care to youth who identify contrary to their biological sex. Anything less would be violation of the Hippocratic Oath and would also cause ACPeds to expel those members for not meeting the organization's ethical standards.

[6] Respectively: National Institutes of Health, Substance Abuse and Mental Health Services Administration, Health Resources and Services Administration, and Administration for Children and Families.

143. ACPeds and its members sincerely believe that sex is a biological, immutable characteristic—a scientific reality, not a social construct.

144. ACPeds and its members have deep, substantial, science-based concerns about gender interventions, such as surgery and drug regimens such as puberty-blockers and hormone administration to facilitate a patient's "transition" from their biological sex to the opposite sex or to another gender (or genders) with which the patient identifies.[7]

145. ACPeds and its members believe that the gender identity interventions described herein can be harmful to patients, particularly children, resulting in infertility, heart attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures and interventions.

146. Because ACPeds' members are dedicated to the health and well-being of children, they oppose participating in the objectionable practices on medical and ethical grounds.

147. Some ACPeds members also have religious objections to such participation. As a secular, scientific medical association, ACPeds' views are not religious as such, although some ACPeds members have religious beliefs consistent with their and ACPeds' scientific and medical ethics beliefs. ACPeds is welcoming both towards members who hold religious beliefs and towards those who do not.

148. The Section 1557 gender identity mandate limits or prohibits the ability of ACPeds members to engage in speech advising patients of their medical judgment about gender-transition procedures, it forces them to offer services or facilities to further gender transitions, and it requires them to inaccurately refer to a patient's sex orally and in medical records.

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[7] For more information, see the many resources at ACPeds, Gender Confusion and Transgender Identity, https://acpeds.org/topics/sexuality-issues-of-youth/gender-confusion-and-transgender-identity (last visited Oct. 29, 2021), & Family Watch International, Transgender Issues Videos, https://familywatch.org/transgenderissues/#.YRl6kohKg2x (last visited Oct. 29, 2021).

149. ACPeds members cannot perform or refer patients to other healthcare providers who will perform the objectionable practices. ACPeds members believe it would violate their obligation to their patients as expressed in the Hippocratic Oath.

150. ACPeds has members who have treated or currently treat individuals who identify contrary to their biological sex, and these members would be liable for failure to engage in the objectionable practices under the Section 1557 gender identity mandate.

151. ACPeds also believes that to eliminate sex-specific private spaces violates fundamental rights of all persons to privacy, safety, and a secure environment.

152. Defendants' Section 1557 and Grants gender identity mandates, if not enjoined, would cause ACPeds members to violate their oaths, their conscience, and cause them to engage in a course of procedures and interventions which is manifestly not in the best interests of patients.

153. ACPeds members are predominantly pediatricians and specialists, including but not limited to pediatric surgeons, family medicine physicians, and pediatricians who are dual certified in pediatrics and adult internal medicine. ACPeds members thus seek relief for all aspects of their practices.

154. ACPeds members practice in each of these various situations, and each would suffer the harm identified if the Section 1557 gender identity mandate is fully enforced.

155. Some ACPeds members are self-censoring out of fear of enforcement of the Section 1557 gender identity mandate.

156. Some ACPeds members continuing to practice consistent with their views and therefore face the danger of enforcement penalties as the result of the Section 1557 gender identity mandate.

157. The Section 1557 gender identity mandate jeopardizes virtually every member of ACPeds, including, for example, the following specific and representative ACPeds members:

158. For example, ACPeds has a member who practices in Tennessee, referred to herein as Dr. Jane Doe 1. Dr. Jane Doe 1 is a member of ACPeds and shares ACPeds' views.

159. Dr. Jane Doe 1 is a pediatrician and has a private practice where she currently sees patients. Dr. Jane Doe 1 provides services to patients reimbursed by Medicaid and CoverKids Tennessee.

160. If her patients need hospitalization, Dr. Jane Doe 1 provides care in a hospital that receives federal financial assistance from HHS.

161. Dr. Jane Doe 1 is not a member of the Catholic Medical Association or the Christian Medical & Dental Associations.

162. Dr. Jane Doe 1 is therefore directly affected by the Section 1557 gender identity mandate in her practice but opposes engaging in the objectionable practices with respect to her patients.

163. Dr. Jane Doe 1 wishes to remain anonymous due to serious concerns of liability and harassment.

164. Dr. Jane Doe 1 has practiced and wishes to practice medicine consistent with the principles concerning gender identity she shares with ACPeds, but she fears liability from the Section 1557 gender identity mandate if she continues to practice and speak consistent with those principles.

165. As another example, Dr. Jane Doe 2 practices in Kentucky. Dr. Jane Doe 2 is a member of ACPeds and shares ACPeds' views.

166. Dr. Jane Doe 2 is a pediatrician who currently sees patients. Dr. Jane Doe 2 provides services to patients reimbursed by Medicaid.

167. Dr. Jane Doe 2 is not a member of the Catholic Medical Association or the Christian Medical & Dental Associations.

168. Dr. Jane Doe 2 is therefore directly affected by the Section 1557 gender transition mandate in her practice but opposes engaging in the objectionable practices with respect to her patients.

169. Dr. Jane Doe 2 wishes to remain anonymous due to serious concerns of liability and harassment.

170. Dr. Jane Doe 2 has practiced and wishes to practice medicine consistent with the principles concerning gender identity she shares with ACPeds but fears liability from the Section 1557 gender identity mandate if she continues to practice and speak consistent with those principles.

171. As another example, Dr. Jane Doe 3 practices in Ohio. Dr. Jane Doe 3 is a member of ACPeds and shares ACPeds' views.

172. Dr. Jane Doe 3 is a pediatrician who currently sees patients. Dr. Jane Doe 3 provides services to patients reimbursed by Medicaid.

173. Dr. Jane Doe 3 is not a member of the Catholic Medical Association or the Christian Medical & Dental Associations.

174. Dr. Jane Doe 3 is therefore directly affected by the Section 1557 gender transition mandate in her practice but opposes engaging in the objectionable practices with respect to her patients.

175. Dr. Jane Doe 3 wishes to remain anonymous due to serious concerns of liability and harassment.

176. Dr. Jane Doe 3 has practiced and wishes to practice medicine consistent with the principles concerning gender identity she shares with ACPeds but fears liability from the Section 1557 gender identity mandate if she continues to practice and speak consistent with those principles.

177. As another example, Dr. John Doe 1 practices in Michigan. Dr. John Doe 1 is a member of ACPeds and shares ACPeds' views.

178. Dr. John Doe 1 is a full-time pediatrician who currently sees patients. Dr. John Doe 1 provides services to patients reimbursed by Medicaid.

179. Dr. John Doe 1 is not a member of the Catholic Medical Association or the Christian Medical & Dental Associations.

180. Dr. John Doe 1 is therefore directly affected by the Section 1557 gender transition mandate in his practice but opposes engaging in the objectionable practices with respect to his patients. Dr. John Doe 1 wishes to remain anonymous due to serious concerns of liability and harassment.

181. Dr. John Doe 1 has practiced and wishes to practice medicine consistent with the principles concerning gender identity he shares with ACPeds but fears liability from the Section 1557 gender identity mandate if he continues to practice and speak consistent with those principles.

182. The President of ACPeds, Dr. Quentin Van Meter, practices in Georgia. As the President of ACPeds, Dr. Van Meter is member of ACPeds and shares ACPeds' views.

183. Dr. Van Meter is a pediatric endocrinologist who currently sees patients. Dr. Van Meter runs Van Meter Pediatric Endocrinology, P.C., in Atlanta, Georgia.

184. Dr. Van Meter provides services to patients reimbursed by Georgia Medicaid and PeachCare for Kids.

185. If his patients need hospitalization, Dr. Van Meter provides care in a hospital that receives federal financial assistance from HHS.

186. Dr. Van Meter is also an adjunct associate professor of Pediatrics at Emory School of Medicine at Emory University, and an Associate Clinical Professor of Pediatrics at Morehouse School of Medicine.

187. Emory School of Medicine at Emory University receives grants from HHS.

188. Morehouse School of Medicine receives grants from HHS.

189. Dr. Van Meter is a member of the Catholic Medical Association but not of the Christian Medical & Dental Associations.

190. Dr. Van Meter is therefore directly affected by the Section 1557 gender transition mandate in his practice, and practices in hospitals covered by the 2016 Grants Mandate, but he opposes engaging in the objectionable practices with respect to his patients.

191. Dr. Van Meter has been campaigning around the world to educate health care professionals about the harm of affirmation of gender incongruences. His objections to these practices include non-religious bases, such as the scientific fact, which informs his medical judgment, that "Puberty blockers and cross-sex hormones combined will sterilize many youth and cause them to develop serious chronic illnesses such as diabetes, heart disease, stroke and cancers that they otherwise would have never experienced."

192. Dr. Van Meter has practiced and wishes to practice medicine consistent with the principles concerning gender identity he shares with ACPeds but fears liability from the Section 1557 gender identity mandate if he continues to practice and speak consistent with those principles.

193. Further information about ACPeds' views, its members, and the effect of the gender identity mandates on them, are set forth in Dr. Van Meter's declaration attached as Exhibit 1.

B. Effect on Catholic Medical Association and its members.

194. The Catholic Medical Association (CMA) is a national, physician-led community that includes about 2500 physicians and health providers nationwide.

195. CMA's mission is to inform, organize, and inspire its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the principles of the Catholic faith in the science and practice of medicine.

196. CMA's members are healthcare providers who object on grounds of science and medical ethics, as well as on religious grounds, to providing, offering, participating in, referring for, or paying for the objectionable practices.

197. Most of CMA's members treat patients within federal healthcare programs such as Medicaid, Medicare, and CHIP, and are thus subject to Section 1557.

198. Many CMA members also work in hospitals that receive HHS grants and are thus subject to the 2016 Grants Rule, and some provide services in clinics serving rural or underserved populations.

199. Most hospitals and children's hospitals, for example, receive HHS grants of various kinds covered by the 2016 Grants Rule, such as from HHS components NIH, SAMHSA, HRSA, or ACF, and many clinics serving rural and underserved populations receive grants from HRSA.

200. CMA has many members who receive federal funds and who provide medical services that may be used as part of attempted medical gender transitions.

201. CMA is committed to handing on a Catholic and Hippocratic approach to medicine.

202. CMA seeks to pursue its mission in conformity to Christ the Divine Physician. Its members are challenged to be a voice of truth spoken in charity, to show how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

203. CMA builds communities of support through local guilds (chapters) covering every region of the country and the military. Guilds provide fellowship, education, and service to the local Church, the community, and peers in healthcare.

204. CMA represents faithful Catholics in the healthcare field so that its members can grow in faith, maintain ethical integrity, and provide excellent healthcare in accordance with the teachings of the Roman Catholic Church. CMA's

mission is forming and supporting current and future physicians to live and promote the principles of the Catholic faith in the science and practice of medicine. CMA's vision is inspiring physicians to imitate Jesus Christ.

205. For CMA and its members, both medical ethics (beginning with a respect for the dignity of the human person as an embodied true male or female) as well as science, not cultural ideologies or political correctness, serve as the basis of all true healthcare.

206. CMA believes that the rights of conscience and religious freedom are integral to each person's dignity.

207. CMA and its members sincerely believe that sex is a biological, immutable characteristic.

208. CMA and its members believe that the norm for human design is to be conceived either male or female.

209. CMA follows the teachings of the Catholic Church, believing that faith and reason work together to inform how to love and care for community members.

210. CMA and its members believe that healthcare that provides gender-transition procedures and interventions is neither healthful nor caring; it is dangerous.

211. CMA and its members believe that gender-transition procedures and interventions can be harmful, particularly to children, resulting in infertility, heart attacks, strokes, and other chronic illnesses, and that medical science does not support the provision of such procedures or interventions.

212. CMA and its members believe providing or referring patients for the provision of gender identity interventions violates their core beliefs and their oath to "do no harm."

213. CMA and its members believe that the controversial and complex issues addressed in the Section 1557 and Grants gender identity mandates must be

thoroughly discussed among the medical community, and no government mandates would be appropriate while this discussion is ongoing or in a way that violates conscience rights.

214. CMA has adopted an official resolution stating, "the Catholic Medical Association does not support the use of any hormones, hormone blocking agents or surgery in all human persons for the treatment of Gender Dysphoria."

215. CMA has adopted an official resolution stating, "Catholic Medical Association and its members reject all policies that condition children to accept as normal a life of chemical and surgical impersonation of the opposite sex" as well as "the use of puberty blocking hormones and cross-sex hormones."

216. CMA has adopted an official resolution stating, "the Catholic Medical Association, in recognition of the dignity of the person, supports the continuation of gender-specific facilities in all public and private places; and further resolves that a reasonable accommodation is a single-occupancy facility available for all persons who are uncomfortable with the standard arrangement of gender-specific facilities."

217. CMA's members seek to avoid any limits or prohibits their ability to engage in speech advising patients of their medical judgment about gender-transition procedures or to offer services or facilities to further gender transitions.

218. CMA has members who have treated or currently treat individuals who identify contrary to their biological sex, and these members would be liable for failure to provide, offer, or refer for medical transition procedures, were the Section 1557 or Grants gender identity mandates enforced against them. Their ability to discuss their medical opinions with their patients and offer medical advice freely has been chilled by this agency action.

219. CMA's members share the non-religious medical and ethical positions described and referenced above, and they also have overlapping religious objections to engaging in the objectionable practices.

220. Some CMA members are self-censoring out of fear of enforcement of the Section 1557 gender identity mandate.

221. Some CMA members continuing to practice consistent with their views and therefore face the danger of enforcement penalties as the result of the Section 1557 gender identity mandate.

222. The Section 1557 gender identity mandate jeopardizes virtually every member of CMA, including the above-discussed CMA member, Dr. Van Meter, and the following specific and identified representative CMA members.

223. These CMA members are subject to a risk of harm because they continue to practice medicine without performing the Section 1557 and Grants gender identity mandates' objectionable practices.

224. Another example of a CMA member affected by these gender identity mandates is Dr. Rachel Kaiser, who practices medicine in Nashville, TN.

225. As a past president of the Nashville Guild of the Catholic Medical Association and the current Tennessee State Director for the CMA, Dr. Kaiser is member of CMA and shares CMA's views.

226. Dr. Kaiser is an emergency room doctor who currently sees patients.

227. Dr. Kaiser works at Ascension Saint Thomas Hospital West.

228. She provides services to patients reimbursed by federal financial assistance programs. Her hospital accepts all insurance, including TennCare, Medicare, etc., and she sees patients who have no insurance at all.

229. The kinds of patients and situations handled by Dr. Kaiser are wide ranging.

230. Dr. Kaiser is a dedicated medical professional and recently performed significant and admirable actions in the battle against the COVID-19 virus.[8]

[8] Andy Telli, Nashville doctor serving on COVID front lines in Texas, *Tennessee Register* (Aug. 26, 2020), https://tennesseeregister.com/nashville-doctor-serving-on-covid-front-lines-in-texas/.

231. When Dr. Kaiser creates a chart for a patient, she lists the patient by their biological sex but if applicable would also note that the patient refers to himself or herself by another gender.

232. Dr. Kaiser has encountered patients who have said that their gender identity differs from the patient's sex. In one case, she cared for one patient who identified as a female and the diagnosis was a prostate issue. In another case, a patient came into the ER and was treated by one of the other doctors. That case involved a mother who came in with a female child taking testosterone and wanted a continuation of the prescription for testosterone. Had Dr. Kaiser been taking care of that patient, she would not have filled the prescription request, based on medical and moral implications.

233. Dr. Kaiser is a member of the Catholic Medical Association but not of the Christian Medical & Dental Associations.

234. Dr. Kaiser is therefore directly affected by the Section 1557 gender transition mandate in her practice, but she opposes engaging in the objectionable practices with respect to her patients.

235. Dr. Kaiser has practiced and wishes to practice medicine consistent with the principles concerning gender identity she shares with CMA but fears liability from the Section 1557 gender identity mandate if she continues to practice and speak consistent with those principles.

236. In particular, Dr. Kaiser shares CMA's objections to providing interventions that assist gender transitions, she wishes to be free to use patient pronouns consistent with biological sex, she wishes to be able to chart patients based on biological sex, and she wishes to be able to counsel patients about the flaws of gender transition practices and affirmation of gender ideology.

237. As another example, the President of CMA, Dr. Michael S. Parker, practices in Ohio. As the President of CMA, Dr. Parker is member of CMA and shares CMA's views.

238. Dr. Parker is an OBGYN in the Columbus, Ohio area.

239. Dr. Parker provides services to patients reimbursed by Medicaid, and is a member of a private practice of physicians.

240. Dr. Parker serves as the Medical Director for Employed Obstetricians at Mount Carmel St. Ann Hospital, and that hospital receives patients through programs such as Medicaid and Medicare.

241. Dr. Parker helped establish the Order of Malta Center of Care in Columbus, which provides free medical care to the homeless and underserved.

242. Dr. Parker is not of the Christian Medical & Dental Associations.

243. Dr. Parker is therefore directly affected by the Section 1557 gender transition mandate in his practice, but he opposes engaging in the objectionable practices with respect to his patients.

244. Dr. Parker has practiced and wishes to practice medicine consistent with the principles concerning gender identity he shares with CMA but fears liability from the Section 1557 gender identity mandate if he continues to practice and speak consistent with those principles.

245. Further information about CMA's views, its members, and the effect of the gender identity mandates on them, are set forth in Mr. Dickerson's declaration attached as Exhibit 2.

C. Effect on Dr. Dassow

246. Dr. Dassow earned an M.D. with highest distinction from the University of Kentucky College of Medicine in 1987. She completed an obstetrics and gynecology internship and an obstetrics and gynecology residency at the Washington University School of Medicine in 1991.

247. Along with a general ambulatory OBGYN care, Dr. Dassow has a special interest in pediatric and adolescent gynecology, including complex medical problems, along with premenstrual syndrome and menopause.

248. Dr. Dassow receives referral patients with puberty issues. She also cares for the gynecology needs of pediatric patients with complex medical disorders. Another practice focus of Dr. Dassow is the care of perimenopausal and post-menopausal women. In this capacity, she often prescribes hormone therapy.

249. Dr. Dassow provides medical services for reasons other than gender transition intervention, but those same services are ones that other doctors provide for the purpose of engaging in gender transitions or interventions affirming gender identity.

250. Dr. Dassow is compelled by her religious faith to provide healthcare to all patients she encounters, including patients who have undergone gender transitions. Even so, based on her best medical judgment, Dr. Dassow does not believe that gender-transition procedures or interventions for pre-transition or mid-transition patients, especially minors, serve their best interests. She thus objects to providing, participating in, offering, or referring for medical transitions.

251. Dr. Dassow provides care for and respects all female patients, irrespective of gender identity, sexual orientation, religious belief, political position affiliations, and reproductive health history.

252. Dr. Dassow's individual-centric and compassionate view of healthcare extends to her significant practice in the prescription of hormones and puberty blockers. She understands that, for many women, hormone therapy is medically indicated when, at a patient's wish, it helps manage menopause. She also understands that for precocious puberty, such as menstruation beginning in five-year-old girls, puberty blockers are a proven and safe treatment and can be medically indicated, provided patients' parents provide the appropriate consent.

253. Dr. Dassow also understands that differences exist between adults who underwent a gender-transition process decades ago and patients who have not done so or who are in the middle of this process, a difference heightened between older adults and minors. One key difference is that an adult whose interventions occurred decades ago has been on hormones for a significant period of time, which means that the hormones' effects have long since nearly entirely occurred, including many permanent changes.

254. For Dr. Dassow, prescribing hormones to this category of older adult patients involves causing relatively little effect compared to prescribing the same hormones for non-transitioned or mid-transition patients, especially non-transitioned or mid-transition minors, who lack adult maturity and autonomy and who should have parental involvement for major medical decisions. Dr. Dassow has thus, on a case-by-case basis, and when her clinical judgment favors it, prescribed hormones to long-transitioned adult patients when the continued use of hormones would not have a significant effect or change on the status quo of their health.

255. Dr. Dassow has not provided hormones to pre-transition or mid-transition patients, given the significant and permanent damaging effects of these therapies, which are especially significant for minor patients.

256. Dr. Dassow also understands that times occur when the use of puberty blockers is appropriate for minors with parental consent. She does not prescribe puberty blockers to older minors in adolescence to delay the natural onset of puberty, given the unproven safety of this course of puberty blockers.

257. Dr. Dassow wishes to retain and not modify her current policies and practices of not offering, prescribing, or performing these interventions. Dr. Dassow thus objects to any coercion of her to offer and perform the interventions described above, especially on patients who are minors or who are considering whether to

transition, and she also has religious objections to the provision of gender-transition procedures and interventions in such cases.

258. Compelling Dr. Dassow to perform, offer, or refer for the performance of gender-transition procedures, drugs, or interventions for pre-transition or mid-transition patients, especially minors, would violate her medical judgment and her religious beliefs.

259. Dr. Dassow's medical care is provided in health programs and activities subject to Section 1557, including Medicaid or CHIP.

260. Dr. Dassow is, however, a member of the Christian Medical & Dental Associations (CMDA), and so upon information and belief would be protected from the Section 1557 gender identity mandate by the current permanent injunction issued in the *Franciscan Alliance* case, although if Defendants reverse that injunction on appeal, she would again be subject to the Section 1557 gender identity mandate unless this Court issues relief protecting her.

261. Dr. Dassow is nevertheless subject to the Grants gender identity mandate, because through her practice she participates in health programs and activities that receive federal grants from HHS.

262. Dr. Dassow's employer Erlanger Health System receives millions annually in HHS grants.

263. Erlanger Health System is incorporated as the Chattanooga-Hamilton County Hospital Authority.

264. In FY2021, HHS granted Erlanger $7.41 million, including $3.4 million in grants under the American Rescue Plan Act funding for health centers.[9]

[9] Recipient Profile, Chattanooga Hamilton County Hospital Authority, USASpending.Gov (accessed Oct. 28, 2021), https://www.usaspending.gov/recipient/71acf772-17cf-2ee8-2e03-89b2ec336d80-P/latest; Award Profile, Grant Summary FAIN H8F41319 USASpending.gov, (accessed Oct. 28, 2021), https://www.usaspending.gov/award/ASST_NON_H8F41319_7526.

265. Erlanger receives grants from HHS's Health Resources and Services Administration (HRSA).

266. Dr. Dassow practices in a health clinic of Erlanger that receives HRSA grants.

267. The Grants gender identity mandate requires Dr. Dassow to engage in the objectionable practices in violation of her medical judgment and her religious beliefs.

268. Dr. Dassow has treated or currently treats individuals who identify contrary to their biological sex, and she would be liable for failure to provide, participate in, offer, or refer for medical transition procedures under the Grants gender identity mandate.

269. The Grants gender identity mandate limits or prohibits Dr. Dassow's ability to engage in speech advising patients of her medical judgment about gender-transition procedures and it forces her to offer services or facilities to further gender transitions regardless of her medical judgment or religious beliefs.

270. Dr. Dassow's ability to discuss her medical opinions with her patients and offer medical advice freely has been chilled by the 2016 Grants Rule, which could be enforced against her at any time if HHS decides to do so, including retroactively.

271. Through her membership associations, including CMDA and the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), Dr. Dassow participates in public advocacy, and her interests are represented in comments submitted to agencies like HHS on rules that burden her ability to practice in accord with her medical judgment, conscience rights, and religious freedom.

VII. Effect of Threatened Enforcement

272. The Section 1557 and Grants gender identity mandates, as applicable, impose three choices on the Plaintiffs: (1) not comply with the government's mandates, and risk significant government enforcement and penalties, likely driving them out of much of the healthcare field and market; or (2) comply with the

government's mandates, abandoning their medical, conscientious, and religious beliefs, and accept the dangers and burdens of compliance; or (3) exit most healthcare fields entirely, a penalty in and of itself.

273. If ACPeds and CMA members do not abide by the Section 1557 gender identity mandate, they face losing access to federal healthcare program funds, potential civil lawsuits from plaintiffs, and being investigated by HHS's Office for Civil Rights or the Attorney General. 18 U.S.C. 3486; 45 C.F.R. §§ 80.6 to 80.11; 45 C.F.R. Pt. 81; 45 C.F.R. §§ 92.5, 92.301.

274. If ACPeds and CMA members or Dr. Dassow do not abide by the Grants gender identity mandate, they face getting kicked out of programs receiving federal funds, and therefore loss of employment.

275. The burdens of being investigated for alleged or suspected violations of Section 1557, or reviews concerning such compliance, are severe, imposing significant costs of time, money, attorney's fees, and diversion of resources that Plaintiffs could use to continue providing quality medical care and receive compensation for the same.

276. Violators can be subjected to private lawsuits for damages under Section 1557's enforcement mechanisms, which can include awards of attorney's fees (42 U.S.C. 1988(b)), and they risk federal false-claims liability, including civil penalties, treble damages, and the possibility of "up to five years' imprisonment," 45 C.F.R. §§ 86.4, 92.4, and civil penalties up to $11,000 per false claim plus treble damages, 31 U.S.C. § 3729(a)(1).

277. The Section 1557 gender identity mandate expose ACPeds and CMA members to criminal penalties for their current speech and conduct if they do not comply but have participated or continue to participate in federal programs. 18 U.S.C. §§ 287, 1001, 1035, 1347; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c).

278. Plaintiffs also face potential criminal liability if they fail to provide affirmative evidence of compliance, as required by the government in an investigation. 18 U.S.C. §§ 1516, 1518.

279. Plaintiffs risk expulsion from participation in Medicaid, Medicare, and CHIP, and from receiving, or participating in other programs receiving, federal financial assistance or HHS grants.

280. Failure to comply with the gender identity mandates threatens Plaintiffs with loss of income and employment.

281. ACPeds and CMA members and Dr. Dassow will incur increased costs from the investigation and enforcement of claims against them, and significant burdens of time and resources to plan for how they must comply or face penalties.

282. Many Plaintiffs cannot continue their healthcare practices if they are not eligible to participate in federal healthcare programs like Medicare, Medicaid, and CHIP or HHS grant programs.

283. The Section 1557 gender identity mandate has already necessitated that ACPeds and CMA members spend time and money training staff, issuing guidance, and engaging in public education campaigns to mitigate the confusion caused by the mandate.

284. If Plaintiffs were to comply with the Section 1557 gender identity mandate or the Grants gender identity mandate, they would suffer the loss of their integrity and reputation, making patients less likely to trust them, and driving patients away from their practices.

285. If Plaintiffs comply with the Section 1557 gender identity mandate or the Grants gender identity mandate by performing gender transition interventions, they take on increased malpractice liability due to the risks and harms of those interventions, and of patients later regretting the decision to undergo those interventions.

286. At the same time the Section 1557 gender identity mandate and the Grants gender identity mandate constrict Plaintiffs' ability to warn patients about the risks and harms of gender transition interventions, increasing their liability if they were to actually succumb to the gender identity mandate and perform such interventions in violation of their consciences.

287. Compliance with the Section 1557 gender identity mandate and the Grants gender identity mandate leads to medically unnecessary procedures, harming patients, wasting the time and money of providers, patients, and insurers, and draining resources that could be better spent elsewhere, especially during a pandemic.

288. Compliance with the Section 1557 gender identity mandate and the Grants gender identity mandate presents risks to Plaintiffs' patients, including life-threatening risks, by requiring that necessary procedures and inquiries be omitted by Plaintiffs because those are associated with the patient's biological sex not the patient's gender identity.

289. Imposing the Section 1557 gender identity mandate or the Grants gender identity mandate on Plaintiffs will deprive Plaintiffs' patients, who want to receive care from them because of their ethical and religious beliefs, of their chosen doctor.

290. Imposing the gender identity mandates on Plaintiffs and their members will harm patients in low-income and underserved communities cared for by those doctors.

291. The Section 1557 gender identity mandate and the Grants gender identity mandate will drive thousands of doctors out of the medical profession, and it will dissuade students from choosing to practice medicine, exacerbating shortages of medical professionals nationwide, placing intense strain on the healthcare system, and causing immense human suffering and higher medical costs.

292. In contrast, as HHS has acknowledged, interpreting federal laws to not impose a gender identity mandate will "protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve." 85 Fed. Reg. at 37, 206.

VIII. HHS's SUNSET Rule and Delay Rule

A. The Regulatory Flexibility Act and HHS's SUNSET Rule

293. Under Section 610(a) of the Regulatory Flexibility Act (RFA), HHS must "publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities." 5 U.S.C. §§ 602, 605, 610(a).

294. HHS has said that it is not—and likely has never been—in compliance with the RFA. Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5,694, 5,695–97 (Jan. 19, 2021) (the SUNSET Rule).

295. HHS "has roughly 18,000 regulations, the vast majority of which it believes would need to be [a]ssessed" for whether they affect small entities and then reviewed to bring HHS into compliance with the RFA. *Id*. at 5,740.

296. Earlier this year, HHS published in the Federal Register a final rule to enforce the RFA entitled "Securing Updated and Necessary Statutory Evaluations Timely." 86 Fed. Reg. 5,694 (Jan. 19, 2021) (the SUNSET Rule).

297. The SUNSET rule requires HHS to "assess" its regulatory corpus to determine whether its rules have a significant economic impact on a substantial number of small entities. 45 C.F.R. § 8.1(b)(1). The SUNSET Rule provides for a public notice-and-comment process, subject to judicial review, at the assessment and review phases, so that no regulation is subject to rescission or modification arbitrarily or unlawfully. *Id*. at 5,750–64; *see* Securing Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70,096, 70,106-07, 70,110 (proposed Nov. 4, 2020).

298. The SUNSET Rule requires HHS to engage in periodic review of the 2016 and 2020 ACA Rules, the 2016 Grants Rule, and various rules implementing health care conscience rights that affect Plaintiffs in this case,[10] including soliciting public notice and comment subject to judicial review—and if HHS failed to do so, those regulations would automatically expire. 86 Fed. Reg. at 5,756 (amending 45 C.F.R. Pt.8 and citing 42 U.S.C. § 18116 as authority).

299. The SUNSET Rule thus provided important procedural rights for small entities with conscience objections to these federal mandates.

B. HHS's Unilateral Delay Rule

300. The SUNSET Rule was set to go into effect on March 22, 2021, which would start the deadlines for HHS to review regulations that govern health insurance, hospitals, clinics, Medicare, Medicaid, CHIP, grants, health care rights of conscience, and more.

301. On March 9, 2021, entities filed a complaint in federal court against the SUNSET Rule. *County of Santa Clara v. HHS*, No. 5:21-cv-01655-BLF (N.D. Cal. filed Mar. 9, 2021).

302. Ten days later, on March 19, 2021, and with no further developments in the case, HHS announced that it would issue a final rule to delay the SUNSET Rule for one year, with immediate effect. This new delay rule was then published in the Federal Register four days later on March 23, 2021—one day *after* the SUNSET Rule took effect. Securing Updated and Necessary Statutory Evaluations Timely; Administrative Delay of Effective Date; Correction, 86 Fed. Reg. 15,404 (the Delay Rule).

303. The Delay Rule thus did not go into effect in time to stay the SUNSET Rule's effective date before it occurred—yet HHS acts if it did.

[10] See 73 Fed. Reg. 78,072 (Dec. 19, 2008); 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011) (the 2011 Conscience Rule); 84 Fed. Reg. 23,170 (May 21, 2019).

304. HHS claims that it stayed the SUNSET Rule's effective date on March 19, 2021 when it uploaded the Delay Rule to its website, three days before the Delay Rule was published in the Federal Register. *Id.*

305. Moreover, with no finding of good cause, the Delay Rule could not go into effect until a further 30 days from March 23, 2021, which would be April 22, 2021.

306. The Delay Rule thus improperly and ineffectively seeks, without notice or comment, not only to delay the SUNSET Rule's effective date but also to change the compliance dates of the final SUNSET rule, already in effect.

307. The Delay Rule also made other changes to the SUNSET Rule that purported to "correct" various errors in the SUNSET Rule. *Id.*

308. HHS cited as its authority 5 U.S.C. § 705, which provides that "[w]hen an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review."

309. But nothing in the litigation challenging the SUNSET Rule required the Delay Rule—that case has had no action since its filing on March 9, 2021, and it is now stayed by stipulation until November 1, 2021 and potentially longer, not for litigation purposes, but purely to grant HHS's request for time to prepare to rescind the SUNSET Rule.

310. HHS has proposed to repeal the SUNSET Rule,[11] but that proposal is not yet in effect and does not retroactively justify the Delay Rule.

C. Effect of the SUNSET Rule and the Delay Rule on Plaintiffs

311. The SUNSET Rule's holistic retrospective review allows agencies to take account of new developments in science and medicine, better respect legal rights of

[11] HHS, Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal, 86 Fed. Reg. 59,906 (Oct. 29, 2021).

conscience and religion, and perform more accurate cost-benefit analyses, which would yield significant economic benefits and save lives.[12]

312. By categorically refusing to enforce the SUNSET Rule—no matter how egregious the RFA violation—HHS removed these substantive benefits and altered the regulatory obligations on healthcare providers and grant recipients for the length of the delay and by HHS's own judicial admissions permanently.

313. The Delay Rule is tantamount to amending or revoking the SUNSET Rule because it is a modification of the standards for the entire period of time that the delay is imposed, HHS does not intend to reconsider this decision for delay or to vacate the grant of a delay.

314. The Delay Rule unlawfully withholds agency action by rescinding, without adequate replacement, the plan mandated by the RFA to review regulatory burdens on small entities and its implementation.

315. The SUNSET Rule subjects to assessment, including to review for amendment or rescission, the Section 1557 gender identity mandate including the 2016 ACA Rule, the Grants gender identity mandate including the 2016 Grants Rule, the 2011 Conscience Rule, and thousands of other HHS rules governing federal financial assistance and grants, such as those under Medicaid, CHIP, and HRSA, or that govern the private purchase of health insurance, that apply to Plaintiffs.

316. If HHS were to comply with SUNSET Rule, Plaintiffs would submit comments on HHS's assessment and review of the 2016 or 2021 ACA Rules, the 2016 Grants Rule, the 2011 Conscience Rule, and other HHS rules applicable to Plaintiffs.

317. And there is a reasonable probability that in its review HHS would reconsider and rebalance the effects of these rules to better address Plaintiffs'

[12] *See, e.g.*, James Broughel, The Benefits of HHS's SUNSET Regulation (Jan. 2021) https://www.mercatus.org/system/files/broughel_-_policy_brief_-_the_benefits_of_hhss_timely_sunset_regulation_-_v1.pdf.

concerns about regulatory burdens. These regulatory burdens are particularly acute during a pandemic, as HHS acknowledged in its preamble to the SUNSET Rule.

318. Without any lawful or effective replacement plan in place for RFA review, Plaintiffs lack any guarantee that HHS will complete retrospective review for its regulations, and Plaintiffs must assume that under HHS's deficient 2011 RFA plan any, or all, of the regulations that affect them and other small entities will *never* be reviewed or rescinded for legal validity, outdatedness, or other defects.

319. Under the Delay Rule, Plaintiffs and the public will have no opportunity to participate in review of these regulations, whereas under the SUNSET Rule, Plaintiffs and the public will have robust rights for participation and for judicial review.

320. The Delay Rule will harm the public, including the elderly, children, doctors, and other healthcare workers, because outdated regulations will cause them worse outcomes in terms of health and well-being. These regulatory burdens will increase the economic costs to Plaintiffs, who will need to devote more time, energy, and resources to finding ways to help individuals.

321. The lack of regulatory review and recission for the rules affecting Plaintiffs will also cost them time and money, including in their personal review for regulatory compliance, in their advocacy for regulatory reform on these conscience protections and in their education and advice to fellow members about regulatory compliance with various unlawful mandates.

322. The Delay Rule adversely affects and aggrieves ACPeds and CMA, as membership and advocacy organizations who comment on rules that would have been reviewed but for the Delay Rule, because of the effect of those rules.

323. ACPeds and CMA are small entities under the Regulatory Flexibility Act, specifically, small organizations. 5 U.S.C. § 601(4).

324. Many members also practice medicine in businesses or non-profit organizations that are small entities themselves.

325. These burdens do and will continue to divert significant resources from the primary goal of ACPeds and CMA and their members of providing healthcare to patients.

IX. The Propriety of Prompt Judicial Relief

A. HHS's actions are subject to judicial review

326. Defendants HHS and OCR are federal agencies subject to the APA. 5 U.S.C. § 701(b); 5 U.S.C. § 551(1).

327. The APA allows a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" to seek judicial review of that action. 5 U.S.C. § 702. Plaintiffs suffer legal wrong and adverse effects from HHS's regulatory actions.

328. HHS and the Defendants are government agencies and officials under 42 U.S.C. § 2000bb-2.

329. Plaintiffs have no adequate or available administrative remedy. In the alternative, any effort to obtain an administrative remedy would be futile.

330. Plaintiffs have no adequate remedy at law.

331. Absent injunctive and declaratory relief, Plaintiffs have been and will continue to be harmed.

332. All the acts of the Defendants described above, and their officers, agents, employees, and servants, were executed and are continuing to be executed by Defendants under the color and pretense of the policies, statutes, ordinances, regulations, customs, and usages of the United States.

333. The gender identity language from the 2016 ACA Rule, including as set forth above in related regulatory instruments, is in effect, is final agency action, is a legislative rule, and is subject to judicial review under the APA.

334. HHS's May 10, 2021 Notice of Enforcement is likewise subject to review under the APA.

335. The Section 1557 gender identity mandate is definitive and determines the rights of persons; the government declares the mandate to be treated as if it has the full force of law; and Defendants have done so.

336. Under 5 U.S.C. § 701(a), no statute precludes judicial review of the gender identity mandate, and this mandate is not committed to agency discretion by law.

337. The gender identity language from the 2016 Grants Rule, including as set forth above, is in effect, is final agency action, is a legislative rule, and is subject to judicial review under the APA.

338. The Grants gender identity mandate is definitive and determines the rights of persons; the government declares the mandate to be treated as if it has the full force of law; and Defendants have done so.

339. Under 5 U.S.C. § 701(a), no statute precludes judicial review of the Grants gender identity mandate, and this mandate is not committed to agency discretion by law.

340. The Delay Rule is subject to judicial review under the APA and RFA. It is in effect, is final agency action, is a legislative or substantive rule, 5 U.S.C. § 551(4), and constitutes "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court," *id.* § 704.

341. The Delay Rule is definitive and determines the rights of persons; the government declares the mandate to be treated as if it has the full force of law; and Defendants have done so.

342. Under 5 U.S.C. § 701(a), no statute precludes judicial review of the Delay Rule, and this Delay Rule is not committed to agency discretion by law.

343. The Delay Rule cites as its authority 5 U.S.C. § 705, which says that "[w]hen an agency finds that justice so requires, it may postpone the effective date of action

taken by it, pending judicial review." Section 705 stays or other agency actions that delay rules are not "committed to agency discretion by law" under 5 U.S.C. § 701(a) and are therefore reviewable.

344. The delay affects the rights or obligations of the agency, the regulated parties, and the public by suspending the SUNSET Rule and delaying its review or replacement of agency rules, its assessments of agency rules, its deadlines for the review or expiration of agency rules, and its opportunities for public comment in that process. Removing the possibility of forced compliance with regulations, as well as leaving in place legal obligations, creates legal consequences.

B. Plaintiffs face imminent irreparable harm

345. The Section 1557 gender identity mandate is irreparably harming the members of Plaintiffs ACPeds and CMA, and the Grants gender identity mandate is irreparably harming their members as well as Dr. Dassow, by exposing them to legal penalties for practicing medicine in keeping with their best judgment and religious beliefs, and for even speaking those beliefs to their patients.

346. ACPeds and CMA members are susceptible to risk under the Section 1557 gender identity mandate at any moment.

347. Unless the Court provides protection from the Section 1557 gender identity mandate, including the 2016 ACA Rule's gender identity language, HHS's May 10, 2021 notice of enforcement of the gender identity mandate, and (to the extent they are deemed to require the mandate) the 2020 ACA Rule and Section 1557 itself, ACPeds and CMA members will continue to suffer from this ongoing violation of law.

348. ACPeds and CMA members and Dr. Dassow are susceptible to risk under the Grants gender identity mandate at any moment of their practice in a program funded by HHS grants.

349. Unless the Court provides protection from the Grants gender identity mandate, including the 2016 Grants Rule, ACPeds and CMA members and Dr. Dassow will continue to suffer from this ongoing violation of law.

350. Unless the Court provides protection from the Delay Rule and makes clear that the SUNSET rule remains in effect, Plaintiffs will continue to suffer irreparable harm from HHS's ongoing violation of law. Every day that goes by is a day that HHS continues to ignore the APA and the RFA, fails to comply with deadlines, and continues to impose burdensome and outdated regulations.

CLAIMS FOR RELIEF

CLAIM ONE
ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)
SECTION 1557 GENDER IDENTITY MANDATE
(ACPEDS AND CMA)

351. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

352. In this claim, as above, the gender identity language from the 2016 Rule, as set forth above, and the May 10, 2021 Notice of Enforcement are referred to as "the Section 1557 gender identity mandate." Plaintiffs ACPeds and CMA, on behalf of their present and future members, challenge enforcement of them together, and each of them separately.

353. This APA challenge to the Section 1557 gender identity mandate also includes the enforcement mechanisms and penalties that HHS has attached to Section 1557, so long as the Section 1557 gender identity mandate is in effect and is not enjoined, because the Section 1557 gender identity mandate triggers those penalties. Those are set forth in HHS's final 2020 ACA Rule, and they are also subject to APA review.

354. This APA challenge also includes any action or publication by HHS to enforce the Section 1557 gender identity mandate against ACPeds and CMA members.

A. Not in Accordance with Law, In Excess of Statutory Jurisdiction, Authority, and Limitations, and Contrary to Right, Power, Privilege, and Immunity

355. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "contrary to constitutional right, power, privilege, or immunity" under 5 U.S.C. § 706(2)(A)–(C).

356. The Section 1557 gender identity mandate is not in accordance with law, and is in excess of statutory jurisdiction, authority, and limitations, and contrary to constitutional rights and power.

357. Congress has not delegated to the Defendants the authority to impose this gender identity mandate under Section 1557.

358. This gender identity mandate exceeds the authority of Section 1557, the Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended, all of which limit discrimination on the basis of sex and do not encompass discrimination on the basis of gender identity.

359. This gender identity mandate exceeds the authority of Title IX, as incorporated into Section 1557, which does not apply where it would violate the religious tenets of an organization.

360. The Section 1557 gender identity mandate is contrary to the ACA's provision that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding (i) conscience protection." 42 U.S.C. § 18023(c)(2); *see* Executive Order 13535, Enforcement and Implementation of Abortion Restrictions in [ACA], 75 Fed. Reg. 15599 (Mar. 29, 2010).

361. *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), did not interpret the ACA or Title IX, and does not require the Section 1557 gender identity mandate.

362. The Section 1557 gender identity mandate is contrary to Section 1554 of the ACA, 42 U.S.C. § 18114; specifically: parts (1)–(2) and (6) because it pressures ACPeds and CMA members out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires ACPeds and CMA members to speak in affirmance of gender identity and refrain from speaking in accordance with a patient's biological sex and related medical needs; part (5) because it requires ACPeds and CMA members to deprive patients of informed consent by preventing them from warning patients of the dangers of gender transition interventions; and also part (5) because it forces ACPeds and CMA members to violate their ethical and conscientious standards as healthcare professionals.

363. The Section 1557 gender identity mandate violates 42 U.S.C. § 300a-7(d) because it compels ACPeds and CMA members, within health service programs funded by HHS, to provide gender identity procedures, interventions, and information, including sterilizations, in violation of their religious beliefs and moral convictions.

364. The Section 1557 gender identity mandate violates the Medicare statute's restriction that it may only pay for items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(1)(A), and it removes the authority of states to declare that gender transition interventions are not covered under Medicaid and Medicaid Expansion CHIP programs, in violation of 42 U.S.C. § 1396d(r)(5).[13]

[13] *See, e.g.*, Nat'l Academy for State Health Policy, State Definitions of Medical Necessity under the Medicaid EPSDT Benefit, NASHP (April 23, 2021), https:// www.nashp.org/medical-necessity/ (reporting a 50-state survey of state laws defining medical necessity under Medicaid's benefit for Early

365. The Section 1557 gender identity mandate is contrary to the Religious Freedom Restoration Act, because it substantially burdens the exercise of religion by CMA's members, and the religious members of ACPeds, and is not the least restrictive means of advancing a compelling government interest.

366. For the reasons discussed below in Claims Two through Five, the Section 1557 gender identity mandate violates constitutional protections for free speech, association, and assembly, free exercise of religion, structural protections of federalism, the Spending Clause, the clear notice canon, and the Tenth Amendment.

B. Without Procedure Required by Law

367. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "without observance of procedure required by law," 5 U.S.C. § 706(2)(D).

368. Plaintiffs bring this argument in the alternative, if the court were to rule that the 2016 ACA Rule's gender identity language is *not* in effect as the result of *Whitman-Walker* and *Walker*.

369. In that case, HHS's May 10, 2021 Notice of Enforcement was a substantive and legislative rule that required to be promulgated by notice and comment under the APA, but was not so promulgated. Likewise, 45 C.F.R. §§ 1.2, 1.3, 1.4 would have required notice and comment of that document.

370. Moreover, under this argument HHS lacks authority to enforce the gender identity provisions from the 2016 ACA Rule because such language was vacated by the *Franciscan Alliance* court.

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and Periodic Screening, Diagnostic and Treatment services, which is part of Medicaid Expansion CHIP programs).

C. Arbitrary, Capricious, and an Abuse of Discretion

371. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "arbitrary," "capricious," or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

372. In promulgating the Section 1557 gender identity mandate, Defendants failed to adequately consider that in medical practice, sex is a biological reality, and there is an evolving state of medical knowledge concerning gender transition interventions that the federal government should not circumvent by rulemaking.

373. The Section 1557 gender identity mandate unlawfully requires ACPeds and CMA members to treat patients and to provide objectionable practices.

374. The Section 1557 gender identity mandate relied on facts and studies only from one side of the issue, and it ignored other experts who said there is not enough evidence to require the provision of gender transition procedures.

375. Defendants failed to adequately consider the Section 1557 gender identity mandate's impact on doctors and medical associations with medical, ethical, conscientious, and religious objections to it, or their reliance interests in not being subject to such a mandate.

376. Defendants failed to adequately consider the Section 1557 gender identity mandate's harm to patients, either in general, or to those patients who want to continue receiving care from ACPeds and CMA members.

377. HHS's May 20, 2021 notice is internally contradictory by promising both to abide judicial opinions holding that Section 1557 does not prohibit gender identity discrimination, and to abide by other judicial opinions holding that it does.

378. In issuing the Section 1557 gender identity mandate, Defendants failed to consider alternative policies that respect the interests of doctors and medical associations with medical, ethical, conscientious, and religious objections to the mandate.

379. The Section 1557 gender identity mandate is arbitrary and capricious because it relies on the erroneous legal view that Section 1557, Title IX, and *Bostock* require Section 1557 to be interpreted to prohibit gender identity discrimination, and without that view would not or had a reasonable possibility of not being issued.

380. The Section 1557 gender identity mandate's rationale is contrived for the President's policy convenience, set forth in his sweeping and mandatory Executive Order 13,988, rather than based on law and necessary considerations under the APA. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019).

381. Therefore, the Section 1557 gender identity mandate must be enjoined and set aside under 5 U.S.C. § 706 and the Court's inherent equitable power to enjoin ultra vires and unconstitutional actions.

382. The Section 1557 gender identity mandate should also be enjoined and declared unenforceable under 5 U.S.C. § 705 pending review of this Court to preserve status and rights pending review of this Court.

383. In the alternative, to the extent that the prohibition of discrimination on the basis of sex under the 2020 ACA Rule or any other is interpreted to impose the Section 1557 gender identity mandate as set forth in the 2016 ACA Rule and the May 10, 2021 Notice of Enforcement, the 2020 ACA Rule is invalid under the APA for the same reasons, and the same remedies against it are required and appropriate.

CLAIM TWO
FREEDOM OF SPEECH AND ASSOCIATION
(FIRST AND FIFTH AMENDMENTS)
SECTION 1557 GENDER IDENTITY MANDATE
(ACPEDS AND CMA)

384. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

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

386. Under the Fifth Amendment to the U.S. Constitution, "No person shall be . . . deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

387. Defendants must comply with the First Amendment in engaging in the actions alleged herein.

388. ACPeds and CMA members' speech in the context of healthcare is protected under the First Amendment.

389. ACPeds and CMA bring this claim against the gender identity language in the 2016 ACA Rule and the May 10, 2021 Notice of Enforcement.

390. This challenge also includes the enforcement mechanisms and penalties that HHS has attached to Section 1557, so long as the Section 1557 gender identity mandate is in effect and is not enjoined, because the Section 1557 gender identity mandate triggers those penalties. Those are set forth in HHS's final 2020 ACA Rule, and they are also subject to review.

391. In the alternative, to the extent the 2020 ACA Rule's prohibition on discrimination on the basis of sex, or Section 1557 itself, are interpreted to prohibit discrimination on the basis of gender identity, ACPeds and CMA, on behalf of their members, seek relief against those requirements.

392. In this claim, the term "Section 1557 gender identity mandate" refers to the requirements of the Section 1557 gender identity mandate as set forth in the factual allegations, to the extent they are derived from any of these four sources, together or separately.

393. Plaintiffs ACPeds and CMA, on behalf of their members, also challenge any actions of Defendants, their officers, or their agents, to enforce the Section 1557 gender identity mandate, including under any other source of authority.

394. The Section 1557 gender identity mandate both restricts the speech of members of ACPeds and CMA and compels their speech.

395. Plaintiffs ACPeds and CMA, on behalf of their members, oppose the Section 1557 gender identity mandate's requirements of, and restrictions on, their speech, including: having to offer and refer for gender interventions; the use of pronouns; medical screening questions; medical coding and record keeping; referrals; policies governing speech and information at their medical practices; assurances of compliance with Section 1557; and mandatory notices of compliance with Section 1557.

396. Defendants lack authority under Section 1557 to interfere in what doctors can and cannot say about and concerning the debated topic of gender identity in the context of the patient-physician relationship.

397. Families have a right to know certain facts regarding documented harms associated with gender interventions as well as the permanence of a decision to follow through with a gender transition.

398. In the past, ACPeds and CMA members have conveyed medical views and concerns, in appropriate and patient-sensitive ways, to their patients and their families in the context of their clinical practice, but under the Section 1557 gender identity mandate, HHS would consider this speech to harassment, hostile environment, or discrimination on the basis of gender identity.

399. The Section 1557 gender identity mandate prevents conversations between ACPeds and CMA members and their patients, and it casts a credible threat of government prosecution over those conversations.

400. The Section 1557 gender identity mandate chills the speech of a health care professional of ordinary firmness, and it chills the speech of ACPeds and CMA members from (1) full and frank conversations on alternatives to gender procedures and interventions; (2) from using proper descriptions of sex in coding and medical records according to biological sex; and (3) from the spoken and written use of biologically correct pronouns.

401. ACPeds and CMA members' sincere medical, ethical, religious, and conscientious beliefs prohibit them from offering or referring for gender identity interventions described in the factual allegations above.

402. ACPeds and CMA members' views also prohibit them from telling patients that they should have healthcare treatments based on gender identity, rather than on biological sex.

403. ACPeds and CMA members' medical judgment is that, in general, it is harmful to encourage a patient to undergo gender transition procedures, and so referring for or providing information affirming medical transition procedures is contrary to ACPeds and CMA members' best medical and ethical judgment.

404. The Section 1557 gender identity mandate, both facially and as-applied, restricts speech and imposes mandates on speech in violation of the First Amendment of the U.S. Constitution.

405. The Section 1557 gender identity mandate regulates speech based on its content and viewpoint, by requiring messages, information, referrals, and pronouns affirming any self-professed gender identity, and by prohibiting speech taking a different view.

406. The Section 1557 gender identity mandate prohibits ACPeds and CMA members from engaging in speech that affirms a policy that healthcare is based on biological sex, and that patients are treated based on what their biological sex is. At the same time the mandate requires speech saying the opposite.

407. The Section 1557 gender identity mandate prohibits the ACPeds and CMA Members from expressing their religious or conscientious viewpoint on gender identity interventions to their patients.

408. ACPeds and CMA members wish to keep using their best medical, ethical, and religious judgments in speaking and giving information to patients, but the Section 1557 gender identity mandate does not allow this.

409. But for the Section 1557 gender identity mandate, the members would continue to speak freely on these matters in healthcare each day in each clinical situation as they deem appropriate, as they have done throughout their careers until this mandate.

410. Defendants intrude upon the right to expressive association (or freedom of assembly) of the members of ACPeds and CMA by requiring them to participate in facilities, programs, and other healthcare-related endeavors contrary to their religious beliefs and expressive identities and to associate with messages on these topics they disagree with.

411. The Section 1557 gender identity mandate's speech regulations are not justified by a compelling governmental interest.

412. The Section 1557 gender identity mandate's speech regulations are not narrowly tailored to achieve the government's interests.

413. Section 1557 of the ACA does not prohibit discrimination on the basis of gender identity, and therefore does not support any governmental interest to sustain the speech regulations of the gender identity mandate.

414. In the alternative, if Section 1557 is deemed to prohibit discrimination on the basis of gender identity as set forth in the Section 1557 gender identity mandate, Section 1557 violates the First Amendment of the U.S. Constitution as applied to ACPeds and CMA members and all similarly situated health care professionals, for the reasons explained in this claim.

415. The Section 1557 gender identity mandate is an overbroad restriction of speech, and it sweeps within its ambit a substantial amount of First Amendment-protected speech and expression.

416. This overbreadth chills the speech of healthcare providers who engage in private speech or religious expression through statements, notices, and other means in healthcare on the basis of sex.

417. The Section 1557 gender identity mandate imposes an unconstitutional condition on ACPeds and CMA members' receipt of federal funding.

418. Defendants' administrative requirements that incorporate the Section 1557 gender identity mandate by reference or implication, such as HHS's Form 690 requirement to assure compliance with Section 1557, or statements required to be made in award applications, notices of awards, or applications to qualify as providers in Medicaid, Medicare, or CHIP, compel speech in violation of the First Amendment.

419. Therefore, Defendants' enforcement and implementation of the Section 1557 gender identity mandate must be enjoined and set aside under 5 U.S.C. §§ 705–06 and the Court's inherent equitable power to enjoin *ultra vires* and unconstitutional actions.

420. The Court should therefore declare that the Section 1557 gender identity mandate, whether through the 2016 ACA Rule, the May 10, 2021 Notice of Enforcement, the 2020 ACA Rule, or Section 1557 itself, or any other source of authority, imposes unconstitutional regulations of speech.

CLAIM THREE
RELIGIOUS FREEDOM RESTORATION ACT
(42 U.S.C. § 2000bb, et seq.)
SECTION 1557 GENDER IDENTITY MANDATE
(ACPEDS AND CMA)

421. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

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

423. RFRA applies to Section 1557, Title IX, and HHS's implementing regulations, notices, and actions to implement those statutes.

424. Defendants' enforcement of the Section 1557 gender identity mandate, whether from the 2016 ACA Rule, the May 10, 2021 Notice of Enforcement, the 2020 ACA Rule, Section 1557, any other source of authority, or any other action by Defendants, is subject to RFRA.

425. CMA asserts this claim on behalf of its members, and ACPeds brings it on behalf of its religious members. Collectively, these are referred to as the Religious Members.

426. The Religious Members' sincerely held religious beliefs prohibit them providing, offering, facilitating, or referring for gender transition interventions.

427. The CMA members' sincerely held religious beliefs in particular prohibit them performing, offering, facilitating, or referring for intentional sterilization procedures.

428. The Religious Members' sincerely held religious beliefs prohibit them from engaging in or facilitating in the "objectionable practices" as defined in the factual allegations incorporated above.

429. The Religious Members exercise their religious beliefs through providing healthcare and through expressing messages in the course of their healthcare practices.

430. The Religious Members exercise their religious beliefs through providing healthcare to low-income and underserved populations in health programs and

activities funded by HHS, such as Medicaid, Medicare, CHIP, and federally qualified health centers.

431. The Religious Members' compliance with these beliefs is a religious exercise.

432. The Religious Members' speech about these beliefs is a religious exercise.

433. The Section 1557 gender identity mandate substantially burdens the Religious Members' exercise of religion by requiring them to engage in the objectionable practices in violation of their beliefs.

434. The Section 1557 gender identity mandate exerts significant pressure on the Religious Members to violate their beliefs to continue providing healthcare in federally funded health programs and activities or else face exclusion from those programs, loss of funding, loss of livelihood, and investigatory burdens by Defendants.

435. The Section 1557 gender identity mandate exposes the Religious Members to civil liability and penalties, described above, as well as criminal penalties under 18 U.S.C. §§ 287, 1001, 1035, 1516, 1518; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c).

436. The Section 1557 gender identity mandate substantially burdens the Religious Members' free exercise of religion.

437. If the Religious Members continue to provide healthcare, they will have to either violate the Section 1557 gender identity mandate or violate their sincere religious beliefs.

438. The Religious Members' provision of healthcare in accord with their religious beliefs prevents no one from obtaining gender transition interventions from other providers.

439. The Section 1557 gender identity mandate furthers no compelling governmental interest and is not the least restrictive means of furthering Defendants' purported interests.

440. Therefore, Defendants' actions promulgating and enforcing the Section 1557 gender identity mandate violate RFRA.

441. In the alternative, if Section 1557 of the ACA is deemed to prohibit discrimination on the basis of sexual orientation or gender identity, Section 1557 itself and Defendants' enforcement thereof violate RFRA for the same reasons.

442. Therefore, Defendants' enforcement and implementation of the Section 1557 gender identity mandate must be declared illegal and enjoined under RFRA, 42 U.S.C. § 2000bb-1(c).

CLAIM FOUR
FREE EXERCISE OF RELIGION
(FIRST AND FIFTH AMENDMENTS)
SECTION 1557 GENDER IDENTITY MANDATE
(ACPEDS AND CMA)

443. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

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

445. Under the Fifth Amendment to the U.S. Constitution, "No person shall be * * * deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

446. The Section 1557 gender identity mandate, whether from the 2016 ACA Rule, the May 10, 2021 Notice of Enforcement, the 2020 ACA Rule, Section 1557, another source of authority, or any other action by Defendants to enforce gender identity nondiscrimination against plaintiffs under Section 1557, are subject to the First Amendment.

447. For the same reasons outlined in Claim Three above under RFRA, Defendants' actions, and in the alternative Section 1557 itself and Defendants'

actions, burden the exercise of religion by the members of CMA and the religious members of ACPeds ("the Religious Members").

448. Upon information and belief, the Section 1557 gender identity mandate specifically and primarily burdens religious conduct.

449. Upon information and belief, the Section 1557 gender identity mandate favors some religious beliefs over others.

450. Upon information and belief, Defendants permit exceptions to and engage in non-enforcement of nondiscrimination requirements in the ACA and other similar statutes for numerous secular and non-secular reasons, while denying faith-based providers an exception to the Section 1557 gender identity mandate for religious reasons.

451. Upon information and belief, Defendants' laws and policies have not been evenly enforced, showing that Defendants' application of the Section 1557 gender identity mandate is not neutral or generally applicable.

452. The Section 1557 gender identity mandate is not neutral or generally applicable.

453. The Section 1557 gender identity mandate furthers no compelling or legitimate governmental interest.

454. The Section 1557 gender identity mandate is not the least restrictive means of furthering Defendants' purported interests.

455. By promulgating and enforcing the Section 1557 gender identity mandate without including the religious exemption set forth in Title IX, Defendants have targeted the Religious Members' religious beliefs and practices and shown hostility toward them.

456. The Section 1557 gender identity mandate, and Defendants' enforcement of it, violates Plaintiffs' hybrid free speech and religious exercise rights under the First Amendment.

457. Therefore, Defendants' actions promulgating and enforcing the Section 1557 gender identity mandate violate the Free Exercise Clause.

458. In the alternative, if Section 1557 of the ACA is deemed to prohibit discrimination on the basis of sexual orientation or gender identity as set forth in the agency action, Section 1557 violates the Free Exercise Clause for the same reasons set forth in this claim.

459. The Court should thus declare that the Section 1557 gender identity mandate, whether from the identified agency actions or Section 1557 itself, and Defendants' enforcement thereof, violates the Religious Members' rights secured to them by the Free Exercise Clause, and enjoin its application or enforcement application under the APA, 5 U.S.C. §§ 705–06, and/or the Court's inherent equitable power to enjoin *ultra vires* and unconstitutional actions, *Larson*, 337 U.S. at 689-91.

CLAIM FIVE
STRUCTURAL PRINCIPLES OF FEDERALISM AND LACK OF ENUMERATED POWERS
SECTION 1557 GENDER IDENTITY MANDATE
(ACPEDS AND CMA)

460. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

461. Any application or enforcement of Section 1557 or its regulations to discrimination because of gender identity exceeds Congress's Article I enumerated powers and transgresses on the reserved powers of the State under the federal constitution's structural principles of federalism and the Tenth Amendment. U.S. CONST. art. I, § 8, cl. 1; *id.* amend. X.

462. Plaintiffs ACPeds and CMA, on behalf of their members, challenge any actions of Defendants, their officers, or their agents, to enforce the Section 1557 gender identity mandate, including the 2016 ACA Rule, the May 10, 2021 Notice of

Enforcement, the 2020 ACA Rule, Section 1557, or under any other source of authority.

463. A "clear and manifest" statement is necessary for a statute to preempt "the historic police powers of the States," *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), to abrogate state sovereign immunity, or to permit an agency to regulate a matter in "areas of traditional state responsibility," *Bond v. United States*, 134 S. Ct. 2077, 2089 (2014).

464. The federal Constitution limits the States and the public's obligations to those requirements "unambiguously" set forth on the face of any Spending Clause statute.

465. A clear contemporaneous statement is necessary both to make a statute apply to the States and to show that the statute applies in the particular manner claimed.

466. The U.S. Constitution's clear-notice rule governs any interpretation of federal law in this area because the federal officials displaced traditional state authority over healthcare and constitutional liberties, with a possible abrogation of state sovereignty from suit, and under a statute that is enacted under the Spending Clause, to extend federal law to ACPeds and CMA members.

467. Defendants expressly and impliedly, but improperly, sought to preempt the prerogative of States not only to regulate the healing professions, but also to maintain standards of care that rely on the medical judgment of health professionals as to what is in the best interests of their patients.

468. Defendants also subject States to private lawsuits for damages and attorney's fees on these new theories, even though States did not know of these liabilities and could not have known or consented to this waiver of their sovereign immunity.

469. Section 1557 does not prohibit, let alone clearly and unmistakably prohibit, discrimination on the basis of gender identity, and therefore does not support any clear notice to justify the burden the Section 1557 gender identity mandate imposes on ACPeds and CMA members, the public, or the States.

470. The Section 1557 gender identity mandate is not in accord with the understanding that existed among the public or the courts at the passage of Title IX or the ACA, or when the States and ACPeds and CMA members chose to begin accepting Medicare, Medicaid, and CHIP as payment for medical services provided.

471. No State could unmistakably know or "clearly understand" that the ACA would impose on it the conditions created by HHS—namely, a new "gender identity" requirement, let alone a requirement that applies in the objectionable ways described above.

472. The public and the States thus unconstitutionally lacked clear notice when the Act was passed or the grants were made that the Act would apply in this way.

473. Because Defendants have violated these constitutional standards of clear notice, any application or enforcement of Section 1557 to discrimination on the basis of gender identity violates the structural principles of federalism, the Spending Clause, and the Tenth Amendment.

474. These structural principles protect citizens, not just states.

475. Therefore, Defendants' enforcement of the Section 1557 gender identity mandate must be enjoined and set aside under 5 U.S.C. §§ 705–06 and/or the Court's inherent equitable power to enjoin *ultra vires* and unconstitutional actions.

476. The Court should thus declare that the Section 1557 gender identity mandate is unconstitutional and enjoin its enforcement or application.

CLAIM SIX
GRANTS GENDER IDENTITY MANDATE
(ALL PLAINTIFFS)

477. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

478. Plaintiff Dr. Dassow, and ACPeds and CMA on behalf of their members, challenge the Grants gender identity mandate, that is, Defendant's promulgation, implementation, and enforcement of the gender identity language in the 2016 Grants Rule, 81 Fed. Reg. 89,393, 89,395 (Dec. 12, 2016) (codified at 45 C.F.R. § 75.300), and related agency actions and publications, as described in the factual allegations.

A. Not in Accordance with Law, In Excess of Statutory Jurisdiction, Authority, and Limitations, and Contrary to Right, Power, Privilege, and Immunity

479. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," and "contrary to constitutional right, power, privilege, or immunity" under 5 U.S.C. § 706.

480. The Grants gender identity mandate is not in accordance with law, and is in excess of statutory jurisdiction, authority, and limitations, and contrary to constitutional rights and power.

481. Congress has not delegated to the Defendants the authority to impose the Grants gender identity mandate.

482. The Grants gender identity mandate exceeds the authority of the housekeeping statute, 5 U.S.C. § 301, as well as any other source of authority, such as Section 1557, the Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended.

483. The housekeeping statute does not allow HHS to regulate anything outside a department's internal functions.

B. RFRA and the Free Exercise Clause

484. The Grants gender identity mandate conflicts with statutory and constitutional protections for Plaintiffs' religious freedom under RFRA and the Free Exercise Clause of the First Amendment.

485. The religious beliefs of CMA's members, the religious members of ACPeds, and Dr. Dassow (in this section, the "Religious Plaintiffs"), do not allow them to perform the objectionable practices, yet the Grants gender identity mandate requires such performance where they practice in programs receiving HHS grants.

486. The Religious Plaintiffs' opposition to engaging in the objectionable practices is an exercise of religion.

487. The Grants gender identity mandate substantially burdens the religious exercise of the Religious Plaintiffs, and exerts significant pressure on them to violate their beliefs or abandon participation in a program receiving HHS grants.

488. The Grants gender identity mandate has not been evenly or consistently enforced.

489. HHS's Notice of Nonenforcement of the Grants gender identity mandate demonstrates that its enforcement is subject to and has been applied under the unbridled discretion of federal officials.

490. The Grants gender identity mandate specifically and primarily burdens religious conduct, and favors some religious beliefs over others.

491. The Grants gender identity mandate is enforced in a manner that targets religious speech and permits federal officials or courts to arbitrarily decide what speech and exercise is permitted and what speech and exercise is not permitted.

492. The Grants gender identity mandate is subject to the discretionary granting of case by case and program-wide exemptions by federal officials. *See* 45 C.F.R. § 75.102.

493. The Grants gender identity mandate is not neutral or generally applicable.

494. The Grants gender identity mandate burdens the Religious Plaintiffs' hybrid free speech and religious exercise rights under the First Amendment.

495. The Grants gender identity mandate is subject to strict scrutiny under RFRA and the Free Exercise Clause.

496. The Grants gender identity mandate substantially burdens the exercise of religion by the Religious Plaintiffs.

497. Using the Grants gender identity mandate to coerce the religious beliefs of the Religious Plaintiffs advances no compelling government interest.

498. Using the Grants gender identity mandate to coerce the religious beliefs of the Religious Plaintiffs is not the least restrictive means of advancing a compelling government interest, and the mandate is not narrowly tailored.

499. The Court should enjoin application of the Grants gender identity mandate to the Religious Plaintiffs under RFRA, the Free Exercise Clause, and the APA.

C. Free Speech Clause

500. Dr. Dassow's speech and that of members of CMA and ACPeds (in this section, "the Plaintiffs") in the context of healthcare is protected under the First Amendment.

501. Plaintiffs oppose the Grants gender identity mandate's requirements of, and restrictions on, their speech, including: having to offer, affirm, and refer for gender interventions; the use of pronouns; medical screening questions; and using proper descriptions of sex in medical coding and record keeping.

502. But for the Grants gender identity mandate, the Plaintiffs would speak freely on these matters.

503. The Grants gender identity mandate, both facially and as-applied, restricts speech and imposes mandates on speech in violation of the First Amendment of the U.S. Constitution.

504. The Grants gender identity mandate regulates speech based on its content and viewpoint.

505. The Grants gender identity mandate's speech implications are not justified by a compelling governmental interest, are not narrowly tailored to achieve the government's interests, and are overbroad, for Plaintiffs and all similarly situated health care professionals.

506. The Grants gender identity mandate imposes an unconstitutional condition on receipt of federal grants.

507. The Court should enjoin the Grants gender identity mandate under the Free Speech Clause of the First Amendment

D. Federalism, Tenth Amendment, and Clear Notice

508. Any application or enforcement of the Grants gender identity mandate exceeds Congress's Article I enumerated powers and transgresses on the reserved powers of the State under the federal constitution's structural principles of federalism, the Spending Clause, and the Tenth Amendment, and violates the clear notice rule. U.S. CONST. art. I, § 8, cl. 1; id. amend. X.

509. No statute authorizes the Grants gender identity mandate, and so Congress did not prohibit, let alone clearly and unmistakably prohibit, discrimination on the basis of gender identity.

510. The Grants gender identity mandate effectively coerces or commandeers the public and the States, including in grant conditions.

C. Arbitrary, Capricious, and an Abuse of Discretion

511. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "arbitrary," "capricious," or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

512. In promulgating the gender identity language in the Grants gender identity mandate, Defendants failed to examine important aspects of the problem, let alone adequately consider that in medical practice, sex is a biological reality, and there is an evolving state of medical knowledge on experimental gender transition interventions.

513. The Grants gender identity mandate unlawfully requires healthcare providers to treat patients according to gender identity and not sex, in action and speech, under the objectionable practices described above.

514. Defendants failed to adequately consider the Grants gender identity mandate's impact on doctors and medical associations with medical, ethical, conscientious, and religious objections to it, or their reliance interests in not being subject to such a mandate.

515. Defendants failed to adequately consider the Grants gender identity mandate's harm to patients.

516. Defendants failed to consider alternative policies.

517. The Grants gender identity mandate violates the APA because it relies on the erroneous legal view that HHS has statutory authority to issue it.

E. Relief

518. The Court should therefore declare the Grants gender identity mandate to be unlawful and enjoin it under the APA, RFRA, the Free Exercise Clause, and the Free Speech Clause, and the Court's equitable power to enforce constitutional provisions against *ultra vires* agency action.

519. Plaintiffs also seek to "compel agency action unlawfully withheld" under 5 U.S.C. § 706, that is, HHS's refusal to repeal the Grants gender identity mandate by allowing the 2021 rule amending that mandate to go into effect.

CLAIM SEVEN
INVALID DELAY OF THE SUNSET RULE
(ALL PLAINTIFFS)

520. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–350 of this complaint.

521. Plaintiffs ACPeds and CMA, on behalf of themselves and their members, and Plaintiff Dr. Dassow challenge Defendants' promulgation, implementation, and enforcement of the Delay Rule, which purports to delay the SUNSET Rule that provides for agency review of the gender identity mandates, conscience rules, grants rules, and many other regulations applicable to Plaintiffs.

522. All Plaintiffs contend the Delay Rule is arbitrary and capricious, contrary to law and statutory authority, and without observance of required procedure under 5 U.S.C.§ 706.

523. Plaintiffs also bring an equitable cause of action under the Court's inherent equitable power to enjoin *ultra vires* and unconstitutional actions.

524. Plaintiffs ACPeds and CMA also bring this claim under the judicial review provision of the RFA as well. 5 U.S.C. § 611.

A. Without Procedure Required by Law

525. First, the Delay Rule violates 5 U.S.C. § 706(2)(D) because it violated the publication requirement that an agency "shall separately state and currently publish in the Federal Register" its rules, and that all "substantive rules of general applicability adopted as authorized by law" must be published in the Federal Register, 5 U.S.C. § 552(a)(1), and that, without good cause, the "required publication" of a rule may not be less than 30 days before a rule's effective date, *id.* § 553(d).

526. HHS purported to make the Delay Rule effective before its publication in the Federal Register, and before 30 days after publication in the Federal Register.

527. Second, the Delay Rule is a legislative or substantive rule that unlawfully skipped notice and comment under the APA. The Delay Rule prescribes "law or policy," 5 U.S.C. § 551(4), and thus under the APA is a substantive or legislative rule subject to notice and comment. The Delay Rule was also required to undergo notice and comment under 45 C.F.R. §§ 1.2, 1.3, 1.4**.**

528. HHS never undertook notice and comment for the Delay Rule.

529. HHS never made a finding of good cause for omitting these procedures.

B. Regulatory Flexibility Act

530. ACPeds and CMA contend the Delay Rule violates section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 610, because it purported to repeal or delay the SUNSET Rule without otherwise providing for HHS compliance with the RFA, and HHS admitted that it did not comply with the RFA.

531. HHS did not identify any other "plan" for periodic review which meets the requirements of 5 U.S.C. 610(a).

532. HHS failed to consider its compliance with statutory duties to review regulations under the Regulatory Flexibility Act, and HHS failed to explain why its actions during the delay complied with its RFA obligations.

533. The Delay Rule rested on an incorrect position about the RFA, Section 705, and the actual nature of pending litigation, rather than on the full consideration of relevant factors.

C. In excess of statutory authority

534. The Delay Rule is "not in accordance with law" and "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" under 5 U.S.C. § 706.

535. First, the Delay Rule lacks authority under 5 U.S.C. § 705. HHS may not use any stay power under 5 U.S.C. § 705 to delay the compliance dates of a prior, already-effective, already-published rule.

536. Second, HHS issued the Delay Rule without satisfying the standard under 5 U.S.C. § 705 that "justice so requires" the agency to "postpone the effective date of action taken by it, pending judicial review." The Delay Rule is not grounded on the existence or consequences or tailored to the litigation but on general reasons to halt the SUNSET Rule, which does not satisfy 5 U.S.C. § 705.

537. Claiming that a delay was required for judicial review of the SUNSET Rule was a pretext not tailored to any actual delays needed for litigation deadlines, as shown by the government's desire for extensions in the litigation so that it could just repeal the SUNSET Rule.

D. Arbitrary, Capricious, and an Abuse of Discretion

538. The Delay Rule is "arbitrary, capricious, [or] an abuse of discretion" under 5 U.S.C. § 706.

539. The reasons offered by HHS in the Delay Rule are insufficient to satisfy this requirement of reasoned decision making.

540. HHS's rationale for the Delay Rule amounts to mere disagreement with the rule and the raising of serious questions concerning its issuance, which is an insufficient reason under 5 U.S.C. § 705.

541. HHS failed to specifically address the inconsistency between its current view that the SUNSET Rule stands on a legally questionable footing, and its prior conclusion that it was legally sound.

542. HSS offered no new reason to change course and therefore did not have a sufficient basis to issue the Delay Rule.

543. HHS failed to consider the disruption that the Delay Rule would have on the agency and on public participation in the review process, or the diminution of the benefits that the SUNSET Rule brings, or of the need for the immediate implementation of the SUNSET Rule.

544. HHS failed to consider other important aspects implicated by the Delay Rule, in particular the First Amendment, liberty, and privacy interests of healthcare providers like the Plaintiffs who would benefit from the on-time implementation of the already-final SUNSET Rule to rules like the gender identity mandates.

545. HHS did not consider the degree of regulatory uncertainty that the Delay Rule creates, especially due to the uncertain time that a delay may be in effect or the time it will take HHS to undergo new rulemaking to rescind the SUNSET Rule.

546. HHS improperly failed to consider any alternative to the Delay Rule that respects the interests of healthcare providers like Plaintiffs, such as by allowing and expediting the pending litigation, allowing notice and comment on the Delay Rule before it was issued, having a plan in place for compliance with the Regulatory Flexibility Act while the SUNSET Rule was delayed, or only applying the Delay Rule to some but not all HHS regulations to which the SUNSET Rule applied.

E. Relief

547. Because the Delay Rule violates the APA and the RFA, the Court should enjoin it, hold it unlawful, and set it aside under 5 U.S.C. §§ 705–06 and 611(a) and the Court's inherent equitable power to enjoin *ultra vires* and unconstitutional actions.

548. Alternately, the Court should delay the effectiveness of the Delay Rule as to the effects on small entities under 5 U.S.C. § 611(a)(4), leaving the SUNSET Rule's provisions in place as to rules affecting such entities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court enter judgment against Defendants, and provide Plaintiffs with the following relief:

A. With respect to the Section 1557 gender identity mandate, Plaintiffs ACPeds and CMA, on behalf of their current and future members, ask:

1. That this Court declare unlawful, set aside, and vacate the 2016 ACA Rule's gender identity language, and the May 10, 2021 notice of enforcement of a gender identity discrimination prohibition;
2. That, if the 2020 ACA Rule is interpreted to prohibit gender identity discrimination, this Court declare unlawful, set aside, and vacate that rule to that extent;
3. That this Court issue a preliminary and permanent injunction against implementation, enforcement, or application of a gender identity nondiscrimination mandate under Section 1557 of the ACA, by Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office; including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities because of the failure to perform, offer, endorse, proscribe, or refer for gender interventions, or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;
    i. In the alternative, if Section 1557 or Title IX is deemed to prohibit discrimination on the basis of gender identity in the way identified in the Section 1557 gender identity mandate, Plaintiffs ACPeds and CMA, on behalf of their current and future members, ask for the

relief described above with respect to enforcement of such a requirement.

4. That this Court render declaratory judgment that agency actions imposing or enforcing a gender identity mandate under Section 1557 violate the Administrative Procedure Act and the ACA; and, with respect to Religious Members of Plaintiffs ACPeds and CMA, violates the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment; and, with respect to Plaintiffs ACPeds' and CMA's current and future members, and all similarly situated individuals, institutions, or religious entities, violates the First and Fifth Amendments of the U.S. Constitution, the constitutional principles of federalism, the Spending Clause, the Tenth Amendment, and Congress's enumerated powers; and
5. That this Court render declaratory judgment that Section 1557 of the ACA does not prohibit discrimination on the basis of gender identity;

B. With respect to the Grants gender identity mandate, Plaintiffs Dr. Dassow, and ACPeds and CMA, on behalf of their current and future members, ask:

1. That this Court declare unlawful, set aside, and vacate the 2016 Grants Rule's gender identity language;
2. That this Court issue a preliminary and permanent injunction against implementation, enforcement, or application of a gender identity nondiscrimination mandate under 45 C.F.R. § 75.300, by Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office; including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities because of the failure to perform, offer, endorse, proscribe, or refer for gender

interventions, or by otherwise pursuing any investigations or other enforcement actions;

3. That this Court render declaratory judgment that agency actions imposing or enforcing a gender identity mandate under 45 C.F.R. § 75.300 violate the Administrative Procedure Act and the ACA; and, with respect to Dr. Dassow and the Religious Members of Plaintiffs ACPeds and CMA (current and future), violates the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment; and, with respect to Dr. Dassow, Plaintiffs ACPeds' and CMA's current and future members, and all similarly situated individuals, institutions, or religious entities, violates the First and Fifth Amendments of the U.S. Constitution; and
4. That this Court render declaratory judgment that 45 C.F.R. § 75.300 and 5 U.S.C. § 301 do not authorize HHS to impose a prohibition on discrimination on the basis of gender identity; and
5. That this Court compel HHS, under 5 U.S.C. § 706(1), to allow the 2021 Grants Rule to go into effect;

C. With respect to the Delay Rule of the SUNSET Rule, all Plaintiffs ask:

1. That this Court enjoin, vacate, and set aside the Delay Rule;
2. That this Court issue a preliminary and permanent injunction against implementation, enforcement, or application of the Delay Rule by Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office;
3. That this Court render declaratory judgment that
   i. The Delay Rule violates the Administrative Procedure Act and agency regulations;

ii. That, on behalf of ACPeds and CMA, the Delay Rule violates the Regulatory Flexibility Act; and

iii. That the SUNSET Rule has remained in effect since its original scheduled implementation date of March 22, 2021;

4. That this Court compel HHS, under 5 U.S.C. § 706(1), to withdraw the Delay Rule;

D. That this Court expressly extend all such relief, respectively, to the current and future members of ACPeds and CMA, and those acting in concert or participation with them as necessary to provide the requested relief;

E. That this Court adjudge, decree, and declare the rights and other legal relations of the parties to the subject matter here in controversy so that such declarations will have the force and effect of final judgment;

F. That this Court award nominal damages under RFRA;

G. That this Court retain jurisdiction of this matter to enforce this Court's order;

H. That this Court grant to Plaintiffs reasonable costs and expenses of this action, including attorneys' fees in accordance with any applicable federal statute, including 28 U.S.C. § 2412 and RFRA;

I. That this Court grant the requested injunctive relief without a condition of bond or other security being required of Plaintiffs; and

J. That this Court grant such other and further relief as this Court deems just and proper.

Respectfully submitted this 10th day of November, 2021.

s/ Jonathan A. Scruggs

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CERTIFICATE OF SERVICE

I hereby certify that on November 10, 2021, I electronically filed the foregoing paper with the Clerk of Court using the ECF system and on November 12, 2021, I will mail notification via Certified Overnight U.S. mail of such filing, including all filings in the case, to the following:

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s/ Jonathan A. Scruggs

Jonathan A. Scruggs

Exhibit 4

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

AMERICAN COLLEGE OF PEDIATRICIANS, *et al.*, *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, *Defendants*.	Case No. 1:21-cv-195 Judge Travis R. McDonough Magistrate Judge Susan K. Lee

MEMORANDUM OPINION

Before the Court is Defendants' motion to dismiss Plaintiffs' complaint (Doc. 51), which challenges various actions taken by Defendant United States Department of Health and Human Services ("HHS"). For the following reasons, the Court will **GRANT** the motion (Doc. 51).

I. BACKGROUND

A. Section 1557 Implementing Regulations

Congress has largely forbidden discrimination on the basis of sex in healthcare. Section 1557 of the Affordable Care Act ("ACA") [hereinafter "Section 1557"] provides that

> an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance. . . .

42 U.S.C. § 18116(a). Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq*.,

prohibits discrimination "on the basis of sex" in "any education program or activity receiving Federal financial assistance. . . ." 20 U.S.C. § 1681(a). Title IX also contains a religious exemption, which states that "this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization[.]" *Id.*

i. 2016 Rule and Subsequent Litigation

On May 18, 2016, HHS promulgated a final rule that defined discrimination "on the basis of sex" to include discrimination on the basis of gender identity. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375-01, 31,467 (May 18, 2016) (formerly codified at 45 C.F.R. § 92.4) [hereinafter the "2016 Rule"]. According to that rule, "[o]n the basis of sex includes, but is not limited to, discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity." *Id.*

The 2016 Rule also defines "gender identity," "gender expression," and "transgender":

> Gender identity means 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. The way an individual expresses gender identity is frequently called "gender expression," and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

Id. The 2016 Rule incorporates these definitions into its provisions that prohibit discrimination on the basis of sex:

> (ii) A covered entity may not, directly or through contractual or other arrangements, utilize criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals on the basis of sex.

> (iii) In determining the site or location of a facility, a covered entity may not make selections that have the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the basis of sex; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity on the basis of sex.

Id. at 31,470 (formerly codified at 45 C.F.R. § 92.101). An additional provision specifically requires medical providers to treat patients consistent with their gender identity and to allow equal access to gendered medical services regardless of an individual's sex assigned at birth or gender identity:

> A covered entity shall provide individuals equal access to its health programs or activities without discrimination on the basis of sex; and a covered entity shall treat individuals consistent with their gender identity, except that a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.

Id. at 31,472 (formerly codified at 45 C.F.R. § 92.206).

The 2016 Rule also expressly states that HHS would not interpret Title IX's religious exemption to have been incorporated into Section 1557. *Id.* at 31,380. HHS reasoned that incorporating Title IX's "blanket" religious exemption could result in denial, delay, or discouragement of individuals seeking necessary medical care and that "Section 1557 itself contains no religious exemption. In addition, Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and healthcare contexts that warrant different approaches." *Id.* Nonetheless, the 2016 Rule stated that "[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." *Id.* at 31,466 (formerly codified at 45 C.F.R. § 92.2).

In *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660 (N.D. Tex. 2016) [hereinafter "*Franciscan Alliance I*"], the district court held that the 2016 Rule's expansion of sex discrimination to include gender-identity and termination-of-pregnancy discrimination violated the Administrative Procedures Act ("APA"), 5 U.S.C. § 533, *et seq*. The court reasoned that Title IX, which is incorporated by reference into Section 1557 of the ACA, unambiguously excluded gender-identity and termination-of-pregnancy discrimination from its definition of sex discrimination. 227 F. Supp. 3d at 689–691. In a later decision in the same case, the court concluded that the 2016 Rule also violated the Religious Freedom Restoration Act ("RFRA"), 42 U.S.C. § 2000bb, *et seq*. *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 943 (N.D. Tex. 2019) [hereinafter "*Franciscan Alliance II*"]. The court came to this conclusion after finding that: (1) the 2016 Rule placed substantial pressure on the plaintiffs to perform, refer, or cover gender-transition and abortion procedures, which imposed a substantial burden on their religious exercise; (2) the Government did not advance any compelling interest to justify such a burden, and the plaintiffs disputed that one existed; and (3) even if the Government had a compelling interest, it failed to show that the 2016 Rule employed the least restrictive means to advance such an interest. *Id.*

As a result, the court in *Franciscan Alliance II* vacated relevant portions of the 2016 Rule[1]—defining sex discrimination to include gender-identity and termination-of-pregnancy discrimination—and remanded the rule to HHS for further consideration in light of the opinion.

[1] HHS filed a motion to modify final judgment in *Franciscan Alliance* asking the court to clarify which "unlawful portions" of the 2016 Rule it intended to vacate. Motion to Modify Final Judgment, *Franciscan All*, No. 7:16-cv-00108-O, ECF No. 178. The court granted the motion in relevant part and specified that it "**VACATES** the Rule insofar as the Rule defines '[o]*n the basis of sex*' to include gender identity and termination of pregnancy, and the Court **REMANDS** for further consideration. The remainder of 45 C.F.R. § 92 remains in effect." Order Modifying Judgment, *Franciscan All.*, No. 7:16-cv-00108-O, ECF No. 182 (emphasis in original).

Id. at 945. However, the *Franciscan Alliance II* court declined to enter a nationwide permanent injunction against HHS's enforcement of the 2016 Rule, because it doubted such an injunction would have any meaningful practical effect independent of the outright vacatur of that rule. *Id.* at 945–46. Instead, the court "invit[ed] Plaintiffs to return if further relief independent of vacatur is later warranted." *Id.* at 946. The *Franciscan Alliance II* opinion was entered on October 15, 2019. The religious-medical-provider plaintiffs in *Franciscan Alliance II* appealed the decision insofar as it denied permanent injunctive relief. *Franciscan All., Inc. v. Becerra*, 843 F. App'x 662, 662 (5th Cir. 2021) [hereinafter "*Franciscan Alliance III*"].

ii. 2020 Rule and Subsequent Litigation

a. 2020 Rule

On June 19, 2020, HHS promulgated a final rule that rescinded the 2016 Rule's provisions that defined sex discrimination as including pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex-stereotyping, and gender identity. Nondiscrimination in Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160-01, 37,162 (June 19, 2020) [hereinafter the "2020 Rule"]. The 2020 Rule "decline[d] to replace [the 2016 Rule definition of sex discrimination] with a new regulatory definition. Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute." *Id.* at 37,178. The 2020 Rule's language regarding discrimination on the basis of sex mirrors Section 1557, simply incorporating Title IX by reference:

> (a) . . . [A]n individual shall not, on any of the grounds set forth in paragraph (b) of this section, 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 (including credits, subsidies, or contracts of insurance) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the Department under such Title; or under any program or activity administered by any entity established under such Title.

(b) The grounds are the grounds prohibited under the following statutes:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq*.) (race, color, national origin);

(2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq*.) (sex);

(3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq*.) (age); or

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

Id. at 37,244 (formerly codified at 45 C.F.R. § 92.2) (emphasis added). While this language is facially neutral as to whether sex discrimination, as incorporated through Title IX, includes the concept of gender-identity discrimination, the preamble to the 2020 Rule makes HHS's position abundantly clear: "the term 'on the basis of . . . sex' in Section 1557 does not encompass discrimination on the basis of gender identity." *Id.* at 37,191 (ellipsis in original).

The 2020 Rule also reversed course regarding Title IX's religious exemption and, this time, explicitly incorporated Title IX's blanket religious exemption into Section 1557's nondiscrimination scheme: "This part shall be construed consistently with, as applicable . . . Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4) . . . ." *Id.* at 37,243 (formerly codified at 45 C.F.R. 86.18).

Three days after HHS submitted the 2020 Rule for publication in the Federal Register, the Supreme Court decided *Bostock v. Clayton County*, 140 S.Ct. 1731 (2020). The *Bostock* Court held that Title VII's prohibition of discrimination "because of . . . sex" includes discrimination because of sexual orientation and transgender status. 140 S.Ct. at 1737–41.

After *Bostock* issued, additional litigation challenged the promulgation of the 2020 Rule under the APA. *See Washington v. HHS*, No. 2:20-cv-1105 (W.D. Wash. July 16, 2020); *Whitman-Walker Clinic, Inc. v. U.S. Department of Health & Human Services*, 485 F. Supp. 3d 1

(D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 430 (E.D.N.Y. 2020).

b. *Walker*

In *Walker*, the district court stayed and enjoined the 2020 Rule, insofar as it repealed the 2016 Rule's definition of sex discrimination. 480 F. Supp. 3d at 430. The court found that the 2020 Rule was contrary to law because its preamble interpreted discrimination on the basis of sex not to include gender-identity discrimination, in opposition to the Supreme Court's reasoning in *Bostock*. *Id.* at 429. The Court also found the 2020 Rule to be arbitrary and capricious because the 2020 Rule failed to consider "an important aspect of the problem," namely, the Supreme Court's decision in *Bostock*. *Id.* at 430 (citation and internal quotations omitted).

The *Walker* court, however, acknowledged its own ruling's apparent conflict with *Franciscan Alliance II*:

> HHS responds that the plaintiff's requested remedy cannot revive the "gender identity" portion of the 2016 definition vacated by the district court in *Franciscan Alliance [II]*. Although the Court predicts that either the district court or some higher authority will revisit the vacatur in light of *Bostock*, it agrees that it has no power to revive a rule vacated by another district court.

Id. at 427. HHS argued before the *Walker* court that the plaintiffs' alleged injuries—having to choose between forgoing medical treatment or facing discrimination as transgender individuals—was not redressable, because no action by the *Walker* court could revive the 2016 Rule's protections against gender-identity discrimination in light of *Franciscan Alliance II*. *Id.* at 426–27. The *Walker* court rejected this argument, finding that, because *Franciscan Alliance II* did not vacate the portion of the 2016 Rule defining sex discrimination as including "sex stereotyping," the 2016 Rule's definition still embodied protections against discrimination against transgender individuals. *Id.* at 427. The *Walker* court agreed with the Sixth Circuit's reasoning in *Equal Employment Opportunity Commission v. R.G. &. G.R. Harris Funeral*

Homes, Inc., 884 F.3d 560 (6th Cir. 2018), that because transgender people are "inherently 'gender non-conforming[,]' . . . an employer cannot discriminate on the basis of transgender status without imposing its stereotypical notions of how sexual organs and gender identity ought to align." *Harris Funeral Homes*, 884 F.3d 560 at 576 (citations omitted); *accord id.*. Accordingly, the *Walker* court found that the plaintiffs' injuries were redressable through the court's injunction on the enforcement of the 2020 Rule because the 2016 Rule's unvacated ban on sex-stereotyping also embodied a ban on gender-identity discrimination. 480 F. Supp. 3d at 427, 430. Ultimately, the *Walker* court ordered that "the definitions of 'on the basis of sex,'[2] 'gender identity,' and 'sex stereotyping' currently set forth in 45 C.F.R. § 92.4 will remain in effect." *Id.* at 430.

c. *Whitman-Walker Clinic*

In *Whitman-Walker Clinic*, the court also enjoined the 2020 Rule's repeal of the 2016 Rule's definition of discrimination on the basis of sex insofar as HHS defined it to include discrimination on the basis of sex-stereotyping. 485 F. Supp. 3d. at 64. The *Whitman-Walker Clinic* court also addressed the vacatur of the gender-identity language from the 2016 Rule in

[2] The *Walker* opinion recognized it could not restore the gender-identity-discrimination language from *Franciscan Alliance*'s vacatur of the 2016 Rule's definition of "on the basis of sex" but nonetheless concluded that the 2016 Rule's definition, including the gender-identity language, should "remain in effect." *Walker*, 480 F. Supp. 3d. at 427, 430. Defendants suggest "[t]hat statement, when read in light of *Walker*'s 'predict[ion] that either the district court [in *Franciscan Alliance*] or some higher authority will revisit the vacatur,' [ ] is best read as stating that because the *Walker* court enjoined the 2020 Rule's repeal of the 2016 Rule's gender-identity definition, that definition would be in effect if the *Franciscan Alliance* vacatur were set aside as the *Walker* court (erroneously) predicted." (Doc. 57, at 2–3.) "Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders." *Feller v. Brock*, 802 F.2d 722, 727–28 (4th Cir. 1986) (citations omitted). The Court, therefore, interprets the *Walker* opinion consistent with Defendants' understanding that it did not revive the vacated gender-identity language, but, if *Franciscan Alliance* were overturned, *Walker* would enjoin the 2020 Rule's repeal of the gender-identity definition.

light of *Franciscan Alliance II*. *Id.* at 25–26. It reached the same conclusion as the *Walker* court: that *Franciscan Alliance II* did not vacate the portion of the 2016 Rule regarding sex-stereotyping, so the 2016 Rule still protected transgender individuals from discrimination even without the portion of the rule prohibiting gender-identity discrimination. *Id.* at 26. The *Whitman-Walker Clinic* court enjoined HHS's repeal of only the sex-stereotyping discrimination from the definition of discrimination "on the basis of sex." *Id.* at 64. Unlike the *Walker* court, however, the *Whitman-Walker Clinic* court did not order that gender-identity discrimination be included in the sex-discrimination definition, due to the conflict that would arise with *Franciscan Alliance II*'s vacatur of that language. *Id.*; *see supra* n.2.

The *Whitman-Walker Clinic* court also found that the 2020 Rule's incorporation of the Title IX religious exemption Rule was arbitrary and capricious because the agency failed to adequately address the exemption's impact on a salient issue—access to care. *Id.* at 43–46. Therefore, the court also enjoined the 2020 Rule's incorporation of Title IX's religious exemption. *Id.* at 64.

d. *Religious Sisters of Mercy*

After the *Walker* and *Whitman-Walker Clinic* decisions issued, the plaintiffs in *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d. 1113 (D.N.D. 2021), moved "for injunctive relief because, in their view, HHS violated the APA 'by misinterpreting Section 1557' to prohibit gender-identity discrimination and by 'failing to incorporate a statutorily mandated religious exemption from Title IX.'" 513 F. Supp. 3d. at 1143. The court declined to adjudicate the plaintiffs' APA claims for reasons of comity because "[t]he *Walker* and *Whitman-Walker* decisions stand in diametric opposition" to the relief requested by the plaintiffs. *Id.* (citing *Feller v. Brock*, 802 F.2d 722, 727–28 (4th Cir. 1986) ("Prudence requires that whenever possible,

coordinate courts should avoid issuing conflicting orders." (citations omitted)); *Bergh v. State of Wash.*, 535 F.2d 505, 507 (9th Cir. 1976) ("When an injunction sought in one federal proceeding would interfere with another federal proceeding, considerations of comity require more than the usual measure of restraint, and such injunctions should be granted only in the most unusual cases." (citing *Kahn Co. v. Switzer Bros.*, 201 F.2d 55 (6th Cir. 1952))).

The *Religious Sisters of Mercy* plaintiffs, however, also raised RFRA and spending-clause claims, asking for "essentially exceptions to the agency's interpretation [of Section 1557] in the aftermath of those decisions" for religious-freedom and state-sovereignty reasons. *Id.* at 1144. The court found that "[o]rdering relief under either theory would run parallel, rather than perpendicular, to the other district court decisions." *Id.* at 1144–45 (citations omitted). Thus, the *Religious Sisters of Mercy* court reached the merits of the plaintiffs' RFRA and spending-clause claims. *Id.* at 1146. The court held that HHS's enforcement of its Section 1557 interpretation against plaintiff North Dakota did not violate the spending clause, but that enforcing the interpretation against the religious plaintiffs would violate RFRA. *Id.* at 1149–53. Therefore, the court enjoined HHS from "interpreting or enforcing Section 1557 . . . or any implementing regulations thereto against the Catholic Plaintiffs in a manner that would require them to perform or provide insurance coverage for gender-transition procedures[,]" effectively exempting the Catholic plaintiffs from the Section 1557 interpretation that the *Walker* and *Whitman-Walker Clinic* courts ordered through their nationwide injunctions against the repeal of sex-stereotyping from the sex-discrimination definition. *Id.* at 1153–54.

iii. May 2021 Bostock *Notification and Subsequent Litigation*

After the *Bostock*, *Walker*, *Whitman-Walker Clinic*, and *Religious Sisters of Mercy* opinions issued, HHS issued a "Notification of Interpretation and Enforcement":

> This Notification is to inform the public that, consistent with the Supreme Court's decision in *Bostock* and Title IX, beginning May 10, 2021, the Department of Health and Human Services (HHS) will interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity. This interpretation will guide the Office for Civil Rights (OCR) in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts.

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. 27,984-02, 27,984 (May 25, 2021) [hereinafter the "*Bostock* Notification"]. The *Bostock* Notification specified that "[i]n enforcing Section 1557, as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq*., and all other legal requirements." *Id.* at 27,985. The *Bostock* Notification also stated that HHS would comply with the applicable court orders regarding Section 1557 regulations, including *Franciscan Alliance II*, *Whitman-Walker Clinic*, *Walker*, and *Religious Sisters of Mercy*. *Id.* at 27,985 n.9–12.

After the *Bostock* Notification issued, the United States Court of Appeals for the Fifth Circuit entered an order on the *Franciscan Alliance* plaintiffs' appeal of the decision insofar as it only ordered vacatur of the 2016 Rule's sex-discrimination definition, rather than also ordering permanent injunctive relief. *Franciscan All. III*, 843 F. App'x at 662. In *Franciscan Alliance III*, the Fifth Circuit declined to reach the merits of the appeal because, since the time that the plaintiffs had appealed, "the legal landscape ha[d] shifted significantly." *Id.* at 662–63. Namely, the Fifth Circuit found that the issuance of the 2020 Rule, the Supreme Court's decision in *Bostock*, the *Walker* and *Whitman-Walker Clinic* injunctions, the *Bostock* Notification, and other agency actions rendered the court's jurisdiction and the *Franciscan Alliance* plaintiffs' claims unclear. *Id.* at 662–63. Accordingly, the Fifth Circuit remanded the case to the district court for further proceedings to determine whether the subsequent developments mooted the case or

whether the district court should have granted a permanent injunction. *Id.* at 663.

On remand, the district court found that the case was not moot and granted the plaintiffs permanent injunctive relief, thus enjoining HHS from interpreting or enforcing Section 1557 "in a manner that would require [Plaintiffs] to perform or provide insurance coverage for gender-transition procedures or abortions . . . ." *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 378 (N.D. Tex. 2021) (ellipsis in original) [hereinafter *Franciscan Alliance IV*], *amended*, No. 7:16-CV-00108-O, 2021 WL 6774686 (N.D. Tex. Oct. 1, 2021), *and aff'd in part, dismissed in part*, 47 F.4th 368 (5th Cir. 2022). HHS appealed that decision.

On August 26, 2022, the Fifth Circuit issued an opinion on HHS's appeal. *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 371 (5th Cir. 2022) [hereinafter "*Franciscan Alliance V*"]. The Fifth Circuit reversed in part, finding that the plaintiffs' APA claim was moot:

> Appellants are right that the APA claim is moot. When a challenged rule is replaced with a new rule, the case is moot so long as the change gives "the precise relief that petitioners requested." The change will not moot the case if the "government repeals the challenged action and replaces it with something substantially similar."
>
> The 2020 Rule gave Franciscan Alliance the remedy an APA violation called for—vacatur of the 2016 Rule's prohibition of discrimination on the basis of "termination of pregnancy" and "gender identity." Franciscan Alliance's APA claim sought nothing more. Nor could it have. Vacatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation.
>
> True, the *Whitman* and *Whitman-Walker* cases "resurrected" most of the 2016 Rule, but those courts expressly disclaimed any intention of altering the two portions of the rule Franciscan Alliance's APA claim takes issue with. It is also true that these injunctions and the agency's threat to enforce Section 1557 harm *Franciscan Alliance* the same way the 2016 Rule's termination of pregnancy and gender-identity clauses did (a topic discussed in more detail below). But those facts don't make a difference. Franciscan Alliance cannot use the APA to vacate those injunctions or Section 1557. For Franciscan Alliance's APA claim, then, the court is unable to provide relief beyond what the 2020 Rule already gave. The claim is therefore moot.

Id. at 374–75. The Fifth Circuit affirmed in part, however, with respect to the plaintiffs' RFRA

claim, finding it was not moot and affirming the permanent injunction against HHS interpreting or enforcing Section 1557 in a manner that would force the plaintiffs to perform or insure gender-transition services. *Id.* at 377–80.

B. HHS Grants Rules

i. 2016 Grants Rule

In 2014, HHS promulgated a comprehensive regulatory scheme governing the administrative requirements, cost principles, and audit requirements for the federal financial assistance they provide through grants and/or cooperative agreements. Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. 75,871-01 (Dec. 19, 2014). In 2016, HHS promulgated a rule modifying and adding regulatory language to this scheme to provide additional guidance to regulated entities. Health and Human Services Grants Regulation, 81 Fed. Reg. 89,393-01 (Dec. 12, 2016) [hereinafter the "2016 Grants Rule"]. The 2016 Grants Rule added the following nondiscrimination language to HHS's grants requirements:

> (c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as age, disability, sex, race, color, national origin, religion, gender identity, or sexual orientation. Recipients must comply with this public policy requirement in the administration of programs supported by HHS awards.
>
> (d) In accordance with the Supreme Court decisions in *United States v. Windsor* and in *Obergefell v. Hodges*, all recipients must treat as valid the marriages of same-sex couples. This does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

Id. at 89,395 (formerly codified at 45 C.F.R. § 75.300). The 2016 Grants Rule became effective on January 12, 2017, but, on January 20, 2017, the presidential administration changed, resulting

in "changes in compliance and enforcement priorities." Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257-01, 2,273 (Jan. 12, 2021) [hereinafter "2021 Grants Rule"]. Therefore, as HHS itself noted in the preamble to a later grants rule, "the Department and its grantmaking agencies did not make, and have not made, any concerted effort to obtain recipient compliance with the nonstatutory nondiscrimination provisions since the 2016 rule became effective and have not taken steps to enforce compliance with such requirements." *Id.*

ii. Notification of Nonenforcement

On November 19, 2019, HHS published a notification in the Federal Register to inform the public that it would not enforce the 2016 Grants Rule after determining that the rulemaking raised "significant concerns about compliance with the Regulatory Flexibility Act ['RFA']." Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809-01, 63,809 (Nov. 19, 2019) [hereinafter "Notification of Nonenforcement"]. HHS announced that it was "exercising its discretion to not enforce the [2016 Grants Rule] with respect to any grantees until the rules have been properly re-promulgated with an impact analysis that hews to the requirements of the RFA." *Id.* at 63,811. As a result of the change in administration almost immediately after the 2016 Grants Rule became effective and the subsequent Notification of Nonenforcement, the 2016 Grants Rule has never been enforced. *Id.*; 2021 Grants Rule, 86 Fed. Reg. at 2,273. At the time HHS published the Notification of Nonenforcement, it also "publishe[d] a notice of proposed rulemaking to begin the process of repromulgating, as appropriate, these rules." Notification of Nonenforcement, 84 Fed. Reg. at 63,811 n.7.

iii. 2021 Grants Rule and Subsequent Litigation

The repromulgation process resulted in HHS issuing a final rule on January 12, 2021.

2021 Grants Rule, 86 Fed. Reg. 2,257-01. The 2021 Grants Rule removed the 2016 Grants Rule's language regarding gender-identity discrimination. *Id.* at 2,278 (formerly codified at 45 C.F.R. § 75.300). Instead, the nondiscrimination language in the 2021 Grants Rule only incorporates protections from other sources of law:

> (c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services, to the extent doing so is prohibited by federal statute.
>
> (d) HHS will follow all applicable Supreme Court decisions in administering its award programs.

Id.

Before the 2021 Grants Rule even became effective, its repeal of the 2016 Rule's specific nondiscrimination language was challenged as violating the APA for being arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. Complaint, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. Feb. 2, 2021), ECF No. 1. The plaintiffs in *Facing Foster Care* moved for a temporary restraining order staying the effective date, enforcement, and implementation of the 2021 Grants Rule. Plaintiffs' Motion for Preliminary Injunction, Motion for a Temporary Restraining Order, and Motion to Stay, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. Feb. 4, 2021), ECF No. 8. HHS then conferred with the *Facing Foster Care* plaintiffs, and the parties stipulated to postpone the 2021 Grants Rule's effective date by 180 days to allow the agency time to review the Rule. Stipulated Motion to Postpone and Hold in Abeyance, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. Feb. 9, 2021), ECF No. 17. Through HHS's review process and the litigation, the *Facing Foster Care* court further delayed the 2021 Grants Rule's effective date. *See generally Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. 2021).

Eventually, HHS completed its review of the 2021 Grants Rule, and "concluded that the challenged portions of the rule were not promulgated in compliance with the Administrative Procedure Act." Defendants' Motion for Remand with Vacatur, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. June 17, 2022), ECF No. 41, at 3. Accordingly, HHS voluntarily moved the court to vacate and remand the challenged portions of the 2021 Grants Rule, and the *Facing Foster Care* court granted HHS's motion. *Id.*; Order Granting Motion to Remand, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. June 29, 2022), ECF No. 44. In its motion to vacate and remand the Rule, HHS represented that "vacating the 2021 Rule's formal repeal of the 2016 Rule will not cause disruption or change the status quo," because the 2016 Grants Rule had never been enforced and HHS stated publicly in the Notification of Nonenforcement that it will not enforce the 2016 Rule without promulgation of a new rule. Defendants' Motion for Remand with Vacatur, *Facing Foster Care in Alaska v. HHS*, No. 1-21-cv-308 (D.D.C. June 17, 2022), ECF No. 41, at 11. Therefore, neither the 2016 Grants Rule's nondiscrimination provision nor the 2021 Grants Rule's nondiscrimination provision is in effect, in light of the Notification of Nonenforcement and the *Facing Foster Care* court's vacatur, respectively.

C. SUNSET Rule

On January 19, 2021, HHS promulgated the Securing Updated and Necessary Statutory Evaluations Timely Rule ("SUNSET Rule"), with an effective date of March 22, 2021. SUNSET Rule, 86 Fed. Reg. 5,694 (Jan 19, 2021). The SUNSET Rule, promulgated pursuant to the Regulatory Flexibility Act ("RFA"), required HHS to conduct assessments or reviews of existing regulations to determine if such regulations should be maintained. *Id.* at 5,694. To ensure efficacy of the assessments, under the SUNSET Rule, all HHS regulations automatically

expire "at the end of (1) five calendar years after the year that [the SUNSET Rule] first becomes effective, (2) ten calendar years after the year of the Section's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed the Section, whichever is latest." *Id.*

However, before the SUNSET Rule became effective, a lawsuit was filed challenging the rule under the APA. *See Cnty. of Santa Clara v. HHS*, No. 5:21-cv-01655, 2021 WL 7210373, at *1 (N.D. Cal. 2021). This litigation resulted in HHS delaying the effective date of the rule, and, on May 27, 2022, HHS published a final rule "withdrawing the SUNSET final rule in its entirety[,]" effective July 26, 2022, due to concerns that the SUNSET Rule would result in serious negative repercussions for stakeholders. Withdrawing Rule on Securing Updated and Necessary Statutory Evaluations Timely, 87 Fed. Reg. 32,246 (May 27, 2022). Therefore, the SUNSET Rule is not in effect.

D. This Litigation

i. The Plaintiffs

On August 16, 2021, Plaintiffs American College of Pediatricians ("ACPeds"), Catholic Medical Association ("CMA"), and Dr. Jeanie Dassow initiated the present action. (*See* Doc. 1). According to the amended complaint, ACPeds "is a national [nonprofit organization] of pediatricians and other healthcare professionals." (Doc. 15, at 4.) Most members of ACPeds provide medical care in health programs and activities receiving federal financial assistance from HHS, and some provide medical care in programs or entities that receive grants from HHS. (*Id.*) President of ACPeds, Dr. Quentin Van Meter, averred that the organization has some religious members, but it is a secular organization that has "deep, substantial, science-based concerns about transgender interventions[,]" including "medical procedures such as surgery, and drug

regimens such as puberty-blockers and hormone therapy[.]" (*Id.*; Doc. 15-1, at 5–6, 10.)

CMA is the largest association of Catholic individuals in healthcare; because it is a nonprofit organization, most of its members also provide medical care in programs receiving federal financial assistance and/or grants from HHS. (Doc. 15, at 5.) Executive Director of CMA, Mario Dickerson, averred that the organization and its members "believe that the norm for human design is to be conceived either male or female[,]" and that "[t]hese beliefs reflect scientific reality, as well as thousands of years of Christian anthropology, with its roots in the narrative of human origins that appears in the Book of Genesis, when 'God created man in his own image . . . male and female he created them.' Gen. 1:27." (Doc. 15-2, at 7 (ellipsis in original).) CMA has adopted an official resolution stating it "does not support the use of any hormones, hormone blocking agents or surgery in all human persons for the treatment of Gender Dysphoria." (Doc. 15, at 34.)

Dr. Jeanie Dassow is a board-certified obstetrician and gynecologist in Chattanooga, Tennessee. (*Id.* at 5.) Dr. Dassow works for Erlanger Health System, which receives multi-million-dollar grants from HHS and federal financial assistance through Medicaid, Medicare, and Tennessee CoverKids (CHIP). (Doc. 15-3, at 3–4.) She is a Christian and a member of the Christian Medical and Dental Associations ("CMDA"). (Doc. 15-3, at 3, 9.) CMDA was a plaintiff in *Franciscan Alliance*, and, therefore, HHS has already been enjoined from interpreting or enforcing Section 1557 against Dr. Dassow in a way that would compel her to perform gender-transition services. *See Franciscan All. V*, 47 F.4th at 379–80; *see also Bostock* Notification, 86 Fed. Reg. at 27,985 n.9–12 (assuring regulated entities that HHS would comply with applicable court orders, including *Franciscan Alliance*, which enjoined enforcement of Section 1557 in a way that would require CMDA members to perform gender-transition

services). Dr. Dassow has medical, ethical, and religious objections to performing or referring patients for gender-intervention services. (Doc. 15-3, at 9.) However, she provides equivalent medical services, such as prescription of hormones and puberty blockers, to manage patients' menopause or to treat a condition called "precocious puberty," which causes girls as young as five-years old to begin menstruating. (*Id.* at 5.)

ii. The Allegations

For "medical, ethical, or religious reasons," Plaintiffs object to twenty-two medical services related to gender interventions:

a. Prescribing puberty blockers off-label from the FDA-approved indication to treat gender dysphoria and initiate or further transition in adults and children;

b. Prescribing hormone therapies off-label from the FDA-approved indication to treat gender dysphoria in all adults and children;

c. Providing other continuing interventions to further gender transitions ongoing in both adults and minors;

d. Performing hysterectomies or mastectomies on healthy women who believe themselves to be men;

e. Removing the non-diseased ovaries of healthy women who believe themselves to be men;

f. Removing the testicles of healthy men who believe themselves to be women;

g. Performing a process called "de-gloving" to remove the skin of a man's penis and use it to create a faux vaginal opening;

h. Remove vaginal tissue from women to facilitate the creation of a faux or cosmetic penis;

i. Performing or participating in any combination of the above mutilating cosmetic procedures, or similar surgeries, to place a patient somewhere along the socially constructed gender identity spectrum;

j. Offering to perform, provide, or prescribe any and all such interventions, procedures, services, or drugs;

k. Referring patients for any and all such interventions, procedures, services, or

drugs;

l. Ending or modifying their policies, procedures, and practices of not offering to perform or prescribe these procedures, drugs, and interventions;

m. Saying in their professional opinions that these gender intervention procedures are the standard of care, are safe, are beneficial, are not experimental, or should otherwise be recommended;

n. Treating patients according to gender identity and not sex;

o. Expressing views on gender interventions that they do not share;

p. Saying that sex or gender is nonbinary or on a spectrum;

q. Using language affirming any self-professed gender identity;

r. Using patients' preferred pronouns according to gender identity, rather than using no pronouns or using pronouns based on biological sex;

s. Creating medical records and coding patients and services according to gender identity not biological sex;

t. Providing the government assurances of compliance, providing compliance reports, and posting notices of compliance in prominent physical locations, if the 2016 ACA Rule's interpretation of the term sex governs these documents;

u. Refraining from expressing their medical, ethical, or religious views, options, and opinions to patients when those views disagree with gender identity theory or transitions; and

v. Allowing patients to access single-sex programs and facilities, such as mental health therapy groups, breastfeeding support groups, postpartum support groups, educational sessions, changing areas, restrooms, communal showers, and other single-sex programs and spaces, by gender identity and not by biological sex.

(Doc. 15, at 22–24.) Plaintiffs refer to these twenty-two services as the "objectionable practices." (*Id.* at 24.)

Plaintiffs allege that, in light of the *Walker* and *Whitman-Walker Clinic* injunctions, the 2016 Rule is still in effect and requires them to either engage in the "objectionable practices" or lose federal financial assistance. (*Id.* at 14–16.) Plaintiffs also allege that the 2016 Rule is still

in effect insofar as it does not incorporate Title IX's religious exemption. (*Id.* at 14.) They also allege that, even if *Walker* and *Whitman-Walker Clinic* did not restore gender-identity discrimination to the 2016 Rule's definition of sex discrimination, HHS has nevertheless concluded that those courts did so, and is enforcing Section 1557 accordingly, as evidenced by the May 2021 *Bostock* Notification. (*Id.* at 15.) Plaintiffs refer to the collective effect of the rules, the subsequent litigation, and the *Bostock* Notification as "the Section 1557 Gender-Identity Mandate." (*Id*. at 16.)

Plaintiffs also allege the 2016 Grants Rule imposes an independent, "second gender identity mandate on doctors who work in programs that receive grants from HHS." (*Id.* at 7.) Therefore, even though Dr. Dassow is protected under *Franciscan Alliance*'s injunction from HHS enforcing Section 1557, which might otherwise require her to engage in the "objectionable practices," Plaintiffs allege Dr. Dassow is not protected from enforcement of the 2016 Grants Rule. (*Id.* at 40.) For this reason, Plaintiffs claim, Dr. Dassow is still effectively barred from discriminating on the basis of gender identity. (*Id*.)

Finally, Plaintiffs allege in their amended complaint, which was filed before HHS withdrew the SUNSET Rule, that the delay of the SUNSET Rule's effective date harmed them because it delayed the time in which Plaintiffs could have participated in HHS's reassessment process under the rule for the 2016 Rule and 2016 Grants Rule. (*Id.* at 47–50.)

iii. The Claims

Plaintiffs assert seven claims for relief: (1) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates the APA; (2) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates their freedom of speech and association pursuant to the First and Fifth Amendments to the U.S.

Constitution; (3) CMA on behalf of its members and ACPeds on behalf of its religious members allege that the Section 1557 Gender-Identity Mandate violates the Religious Freedom Restoration Act; (4) CMA on behalf of its members and ACPeds on behalf of its religious members allege that the Section 1557 Gender-Identity Mandate violates their free exercise of religion pursuant to the First and Fifth Amendments to the U.S. Constitution; (5) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates the "structural principles of federalism" and exceeds Congress's Article I enumerated powers; (6) all Plaintiffs allege that the Grants Gender-Identity Mandate violates the APA, RFRA, Free Exercise Clause, Free Speech Clause, the "structural principles of federalism" and exceeds Congress's Article I enumerated powers; and (7) all Plaintiffs allege that the delay of the SUNSET Rule's effective date violates the APA and RFA. (Doc. 15, at 53–79.) Defendants moved to dismiss this case, contending that "[n]one of these challenges presents a case or controversy under Article III" because Plaintiffs either lack standing or do not present a ripe controversy. (Doc. 52, at 9.)

II. STANDARD OF REVIEW

The case-or-controversy requirement of Article III, Section 2 mandates that a plaintiff have standing in order to sue. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To have standing, a plaintiff must have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Daunt v. Benson*, 956 F.3d 396, 417 (6th Cir. 2020) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338, (2016)). An injury, for standing purposes, means the "invasion of a legally protected interest which is (a) concrete and particularized, and (b) 'actual or imminent.'" *Id.* (quoting *Lujan*, 504 U.S. at 560). "For an injury to be 'particularized,' it 'must

affect the plaintiff in a personal and individual way.'" *Spokeo*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). A "concrete" injury in fact does not have to be tangible, but it must be "'real,' and not 'abstract.'" *Id.* at 340. Further, "[w]here plaintiffs seek to establish standing based on an imminent injury, the Supreme Court has explained 'that "threatened injury must be *certainly impending* to constitute injury in fact," and that "[a]llegations of *possible* future injury" are not sufficient.'" *Galaria v. Nationwide Mut. Ins. Co.*, 663 F. App'x 384, 388 (6th Cir. 2016) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (emphasis in original)).

The plaintiff bears the burden of showing that standing exists. *Id*. at 387 (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)). When a case is at the pleading stage, the plaintiff must clearly allege facts demonstrating each element of standing. *See Spokeo*, 578 U.S. at 338 (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). In a pre-enforcement suit, "a plaintiff satisfies the injury-in-fact requirement [of the standing inquiry] where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but [arguably] proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers,* 442 U.S. 289, 298 (1979)).

III. ANALYSIS

Here, Plaintiffs have declared, on behalf of themselves or their members, an intention to refrain from engaging in the twenty-two "objectionable practices" related to medical gender-transition services and allege that doing so is arguably affected with a constitutional interest, namely, freedom of speech and association, free exercise of religion, and the structural principles of federalism. (Doc. 15, at 53–70.) Although Plaintiffs bring additional claims, such as their claim that the 2016 Rule and Notification violate the APA, "their other claims are affected with a

constitutional interest too, regardless of the precise legal theory" because they intend to engage in arguably protected *conduct*. *Religious Sisters of Mercy*, 513 F. Supp. 3d at 1138 (quoting *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 750 (8th Cir. 2019)); *see also Susan B. Anthony List*, 573 U.S. at 161. Thus, standing turns on whether Plaintiffs' anticipated course of conduct is proscribed by statute and, if so, whether there is a credible threat of prosecution. *See Susan B. Anthony List*, 573 U.S. at 159.

A. Section 1557 Gender-Identity-Mandate Claims

i. Whether the Intended Course of Conduct is Proscribed by Statute

In support of standing, Plaintiffs allege that their refusal to perform the objectionable practices is proscribed by Section 1557. (Doc. 55, at 17.) HHS argues that it has not taken the position that Section 1557 mandates physicians in programs receiving federal funding to perform the objectionable practices, because the gender-identity provision of the 2016 Rule was vacated in *Franciscan Alliance II* and the *Bostock* Notification is nonbinding guidance. (*Id.* at 11, 22.) HHS's arguments fall short of demonstrating that Plaintiffs' proposed course of conduct is not proscribed by statute.

First, although the provision defining sex discrimination as including gender-identity discrimination was vacated in *Franciscan Alliance II*, the *Walker* and *Whitman-Walker Clinic* courts found that, regardless of *Franciscan Alliance II*, entities receiving federal funding would still be barred from discrimination against transgender individuals under the 2016 Rule's ban on sex-stereotyping, and these courts enjoined the repeal of that provision. *See Whitman-Walker Clinic*, 485 F. Supp. 3d. at 64; *Walker*, 480 F. Supp. 3d at 430. Therefore, HHS's operative Section 1557 regulations at least arguably bar discrimination against transgender patients as a form of sex discrimination under the statute. Additionally, Plaintiffs' refusal to engage in the

"objectionable practices" would arguably amount to such sex discrimination. As the *Religious Sisters of Mercy* court found, "[c]onstruing the same definitions [in the 2016 Rule] that now control once again, HHS previously classified the categorical refusal to perform or cover gender-transition procedures as unlawfully discriminatory." 513 F. Supp. 3d at 1138 (citing the 2016 Rule, 81 Fed. Reg. at 31,471–72 (formerly codified at 45 C.F.R. §§ 92.206, 92.207(b)(4)-(5))).

Second, regardless of the operative regulations or whether the *Bostock* Notification is binding, if Title IX, as incorporated by Section 1557, is interpreted such that its definition of sex discrimination includes gender-identity discrimination, Plaintiffs' proposed course of conduct is "arguably proscribed by statute." *See Susan B. Anthony List*, 573 U.S. at 159. Following the Supreme Court's decision in *Bostock*, the reasoning of which some courts have since held applies equally to Title IX, Plaintiffs' proposed discrimination against transgender patients is at least arguably proscribed. *See, e.g.*, *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 593 (4th Cir. 2020)*, as amended* (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021). The Sixth Circuit held, before *Bostock* was even decided, that a school seeking to discriminate against a transgender student was not likely to succeed on the merits of its claims,[3] because Title IX prohibits discrimination based on sex-stereotyping and gender nonconformity. *Dodds v. United*

[3] This case came before the Sixth Circuit on appeal of a district court's preliminary injunction ordering a school district to permit an eleven-year-old transgender girl to use the girls' restroom. *Dodds v. United States Dep't of Educ.*, 845 F.3d 217, 220 (6th Cir. 2016). The Sixth Circuit denied the school district's motion to stay the injunction pending appeal. *Id.* at 222. Therefore, the Sixth Circuit did not conclusively hold that discrimination against transgender individuals would constitute sex discrimination under Title IX; rather, it held the school district did not show a likelihood of success on appeal because "settled law in this Circuit" reflected that "[s]ex stereotyping based on a person's gender non-conforming behavior is impermissible discrimination." *Id.* at 221 (quoting *Smith v. City of Salem*, 378 F.3d 566, 575 (6th Cir. 2004)). Therefore, while the precedent is not affirmatively dispositive of whether Title IX prohibits discrimination against transgender individuals, this Court is bound by its reasoning, and it supports the notion that Section 1557, by incorporating Title IX, at least arguably proscribes Plaintiffs' proposed conduct. *See id.*

States Dep't of Educ., 845 F.3d 217, 221 (6th Cir. 2016). Therefore, Plaintiffs' proposed conduct of refusing to engage in the objectionable practices is at least arguably proscribed by Section 1557.

ii. Whether There Exists a Credible Threat of Prosecution

a. Other Circuits' Jurisprudence

Whether Plaintiffs face a "credible threat of prosecution" under Section 1557, however, is a distinct inquiry. Plaintiffs argue that it is "not plausible that these doctors lack standing to bring a challenge that was successful in three other courts." (Doc. 55, at 17.) However, the two district courts that have heard similar challenges and found standing for physicians and healthcare-provider entities were the Northern District of Texas and the District of North Dakota—courts outside the Sixth Circuit whose opinions were instead predicated on precedents of the Fifth and Eighth Circuit, respectively. *Franciscan All. I*, 227 F. Supp. 3d at 678–80; *Religious Sisters*, 513 F. Supp. 3d at 1133; *Christian Emp. Alliance*, No. 1:21-cv-195, 2022 WL 1573689, at *1 (D.N.D. May 16, 2022). The Sixth Circuit's jurisprudence on standing, in particular, the issue of whether there exists a credible threat of prosecution, bears considerable differences from the Fifth and Eighth Circuit's.

The Fifth Circuit upheld the district court's finding that the plaintiffs had standing in *Franciscan Alliance V*, relying in part on its decision in *Speech First, Inc. v. Fenves*, 979 F.3d 319, 336 (5th Cir. 2020), *as revised* (Oct. 30, 2020). *Franciscan All. V*, 47 F.4th at 377. In *Speech First*, the Fifth Circuit held that the plaintiffs had standing despite the defendant's "disavowals of any future intention to enforce the policies contrary to the First Amendment," because the mere "existence of the [defendant's] policies" and the fact that the plaintiffs fell within a class whose speech was "arguably restricted" rendered the threat of future enforcement

substantial. 979 F.3d at 336–38. The Fifth Circuit held, "[w]here the policy remains non-moribund, the claim is that the policy causes self-censorship among those who are subject to it, and the students' speech is arguably regulated by the policy, there is standing." *Id.* at 336–37 (citation omitted).

Similarly, the Eighth Circuit has held that "when a course of action is within the plain text of a statute, a 'credible threat of prosecution' exists." *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019) (citing *North Dakota v. Heydinger*, 825 F.3d 912, 917 (8th Cir. 2016)). The *Religious Sisters of Mercy* court relied on this Eighth Circuit holding to find the plaintiffs had standing to challenge the Section 1557 Gender Identity Mandate. *Religious Sisters of Mercy*, 513 F. Supp. 3d at 1139 (citing *id.*). But the Sixth Circuit requires more. *See infra* Section III.A.ii.b–c.

b. Sixth Circuit Jurisprudence: *McKay* Factors

In the Sixth Circuit, "[t]he mere *possibility* of prosecution," such as the plaintiff's intended course of action falling within the plain text of a non-moribund statute, "does not amount to a 'credible threat' of prosecution. Instead, the threat of prosecution must be *certainly impending* to constitute injury in fact." *Daly v. McGuffey*, No. 21-3266, 2021 WL 7543815, at *2–3 (6th Cir. Nov. 15, 2021) (internal quotation marks omitted) (emphasis in original) (quoting *Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 454 (6th Cir. 2017)) (citing *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272, 293 (6th Cir. 1997); *Fieger v. Mich. Sup. Ct.*, 553 F.3d 955, 967 (6th Cir. 2009)). In fact, the Sixth Circuit applies a factor test, first articulated in *McKay v. Federspiel*, 823 F.3d 862 (6th Cir. 2016) and known as the "*McKay* factors," to determine whether an alleged threat of prosecution is credible:

> Various factors inform our analysis of whether there is a credible threat of prosecution sufficient to confer standing: (1) "a history of past enforcement

> against the plaintiffs or others"; (2) "enforcement warning letters sent to the plaintiffs regarding their specific conduct"; (3) "an attribute of the challenged statute that makes enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action"; and (4) the "defendant's refusal to disavow enforcement of the challenged statute against a particular plaintiff."

Online Merchs. Guild v. Cameron, 995 F.3d 540, 550 (6th Cir. 2021) (quoting *McKay*, 823 F.3d at 869). "These *McKay* factors are not exhaustive, nor must each be established," but plaintiffs must "point to some combination" of the factors to demonstrate a credible threat of enforcement. *Id.*; *McKay*, 823 F.3d at 869; *Plunderbund Media, L.L.C. v. DeWine*, 753 F. App'x 362, 366, 372 (6th Cir. 2018) (holding that plaintiffs failed to allege a "factual, non-conjectural basis for their fear of prosecution" where plaintiffs did not show a history of enforcement against them, there was no feature of the statute making enforcement easier, and the statute did not clearly apply to plaintiffs); *W.O. v. Beshear*, 459 F. Supp. 3d 833, 841 (E.D. Ky. 2020) (citing *Plunderbund*, 753 F. App'x at 367) (finding plaintiffs lacked standing where, on a motion for preliminary injunction, "even construed in the light most favorable to Plaintiffs, they fail to provide any allegation or point to any evidence which would establish any of these '*McKay* factors.'"); *Block v. Canepa*, No. 20-cv-3686, 2021 WL 1909650, at *3 (S.D. Ohio May 12, 2021) ("Courts find a credible threat exists when some combination of these factors are present.").

Plaintiffs can point to no facts relating to any of these factors to support their contention that they face a credible threat of prosecution under Section 1557. (*See generally* Doc. 15.) First, there is no history of enforcement against the plaintiffs or others. Plaintiffs allege, "[u]pon information and belief, OCR is now actively investigating, enforcing, and implementing an interpretation of Section 1557 and HHS regulations under which sex discrimination includes gender identity and sex stereotyping." (*Id.* at 16.) But Plaintiffs do not set forth any facts to support such an inference beyond the mere existence of the *Walker* and *Whitman Walker Clinic*

injunctions and the *Bostock* Notification.[4] *See Bickerstaff v. Lucarelli*, 830 F.3d 388, 396 (6th Cir. 2016) ("[W]e need not accept as true any conclusory legal allegations that do not include specific facts necessary to establish the cause of action. The plaintiff's complaint instead must contain either direct or inferential allegations with respect to all material elements necessary to sustain a recovery under some viable legal theory.") (internal quotation marks and citations omitted). Plaintiffs certainly have not alleged HHS has any history of enforcing Section 1557 against them. (*See generally* Doc. 15.) Even if HHS were enforcing Section 1557 against other entities, Plaintiffs still would not meet their burden to establish a credible threat of prosecution, because they must allege that the "*same* conduct" in which Plaintiffs intend to engage "has drawn enforcement actions or threats of enforcement in the past." *Kiser v. Reitz*, 765 F.3d 601, 609 (6th Cir. 2014) (citing *Steffel*, 415 U.S. at 459); *see also Doe v. Yost*, No. 3:20-cv-10, 2021 WL 1185807, at *3 (S.D. Ohio Mar. 30, 2021) (finding the plaintiff failed to establish a credible threat of prosecution where her conduct was not sufficiently similar to the previous conduct that had triggered prosecutions under the same statute). Plaintiffs make no allegations regarding what type of conduct has drawn or is drawing enforcement actions under Section 1557, much less that the refusal to perform gender-transition services for medical, ethical, and religious reasons has precipitated enforcement actions. (*See* Doc. 15.)

Second, Plaintiffs also did not allege that they have received any enforcement warning letters from HHS regarding their refusal to perform gender-transition services. (*See generally* Doc. 15.) Plaintiffs nonetheless contend that the *Bostock* Notification is evidence that HHS has

[4] Consistent Plaintiffs' failure to assert these facts, HHS represented in its memorandum in support of its motion to dismiss that "HHS has never enforced Section 1557 to revoke the funding of a provider for failure to provide gender-transition services . . . ," and Plaintiffs did not dispute this in their response. (Doc. 52, at 24–25, 32; *see generally* Doc. 55; Doc. 57, at 5.)

"expressed a credible threat of enforcing the § 1557 mandate" because it states that it was issued "to inform the public that, consistent with [*Bostock*], beginning May 10, 2021, [HHS] will interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Bostock* Notification, 86 Fed. Reg. at 27,984; (Doc. 55, at 28). But the *Bostock* Notification says nothing about whether this interpretation would require anyone, much less Plaintiffs, to engage in the objectionable practices, and it explicitly states both that the *Bostock* Notification "does not itself determine the outcome in any particular case or set of facts," and that "OCR will comply with [RFRA] and all other legal requirements." *Bostock* Notification, 86 Fed. Reg. at 27,984, 27,985. In *McKay*, the plaintiff argued that signs posted, which stated that violation of the challenged provisions "may result in contempt sanctions[,]" gave rise to a threat of enforcement. 823 F.3d at 869. The Sixth Circuit held that the signs did not weigh in favor of finding a credible threat of enforcement against the plaintiff, because "the signs in the present case address the general public, not McKay specifically or any of his past conduct, and the signs also reference the possibility of an exemption by judicial permission." *Id.* at 869–870. Similarly, here, the *Bostock* Notification does not support either of the *McKay* factors (history of past enforcement or enforcement warning letters sent to the plaintiffs regarding their specific conduct), because the *Bostock* Notification is explicitly addressed to the public, not to Plaintiffs, and it references the possibility for RFRA exemptions. *See id.*

Third, there is no feature of Section 1557 that makes it easier to enforce against Plaintiffs, such as a citizen-enforcement provision. To the contrary, HHS's enforcement process under Section 1557 is lengthier than those of commonly challenged state civil and criminal statutes that are often examined for standing. *See, e.g.*, *Plunderbund*, 753 F. App'x at 371 (holding plaintiffs

did not have standing to challenge a state criminal law prohibiting "telecommunication . . . with purpose to abuse, threaten, or harass another person" and no feature of the law made it easier to enforce, because "[o]nly law enforcement officials can investigate a claim of telecommunications or cyber-harassment, and only prosecutors can bring charges."). HHS's enforcement process offers regulated entities many procedural protections prior to any funding loss. *See Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1128–29 (9th Cir. 2009) (finding plaintiffs' claims unripe) ("If HHS initiates compliance proceedings against Plaintiffs based on the 2003 Policy Guidance, Plaintiffs will have an opportunity to challenge the Policy Guidance on the same legal bases on which they rely in the suit now before us."). HHS would first be required to attempt to achieve voluntary or informal compliance with the regulated entity. 45 C.F.R. § 80.8(c). Then, there must be a formal adjudication and an administrative hearing finding noncompliance with a regulation. *Id.* After that, HHS must submit to the House and Senate committees having legislative jurisdiction over the programs at issue a full written report of the circumstances and grounds for such an action and wait an additional thirty days before terminating funding. *Id.* Finally, any enforcement under Section 1557 is subject to judicial review in an Article III court. 42 U.S.C. § 18116 ("The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of [Section 1557]."); 20 U.S.C. § 1683 ("Any department or agency action taken pursuant to [Title IX] shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds."); *Tennessee v. United States Dep't of Educ.*, No. 3:21-cv-308, 2022 WL 2791450, at *18 (E.D. Tenn. July 15, 2022) ("The right to judicial review under the APA extends to agency actions 'except to the extent that—(1) statutes preclude judicial review; or (2) agency action is

committed to agency discretion by law.'").

At each point in any putative enforcement process, Plaintiffs would be able to raise the same claims they now raise (well before any enforcement action has been taken), and HHS or the reviewing court would be able to determine the merits of their claims with the benefit of further factual development, such as the nondiscriminatory reasons offered by the provider for the refusal to perform a specific medical procedure, evidence supporting those reasons, any evidence suggesting that such reasons were pretextual, and the provider's entitlement to a religious exemption. *See Ky. Press Ass'n, Inc. v. Kentucky*, 454 F.3d 505, 509 (6th Cir. 2006) ("Ripeness is a justiciability doctrine designed 'to prevent the courts, through premature adjudication, from entangling themselves in abstract disagreements.'") (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580 (1985)); *Hallandale Pro. Fire Fighters Loc. 2238 v. City of Hallandale*, 922 F.2d 756, 760 (11th Cir. 1991) ("Because both standing and ripeness analyses look to the existence of actual injury to the plaintiff caused by the alleged wrong, they overlap to some degree and often collapse into each other.").

Finally, Plaintiff has not alleged HHS's "refusal to disavow enforcement" against them. *See McKay*, 823 F.3d at 869. HHS has not taken *any* position, whatsoever, on enforcement against these Plaintiffs, besides its assurance in the *Bostock* Notification that it will comply with the *Franciscan Alliance* injunction, which precludes enforcement of Section 1557 against Dr. Jeannie Dassow, and potentially other Plaintiffs who are members of both ACPeds or CMA and CMDA, the organization protected from enforcement in *Franciscan Alliance*. *See Franciscan All. V*, 47 F.4th at 379–80 (affirming injunction against enforcement of Section 1557 in a way that would require CMDA members to perform gender-transition services); *Bostock* Notification, 86 Fed. Reg. at 27,985 n.9–12 (assuring regulated entities that HHS would comply applicable

court orders, including *Franciscan Alliance*); (Doc. 15-3, at 3, 9; Doc. 52, at 26, 28, 32; Doc. 57, at 8). This does not amount to a "*refusal* to disavow enforcement." *McKay*, 823 F.3d at 869 (emphasis added); *Thiede v. Burcroff*, No. 16-13650, 2018 WL 465968, at *14 (E.D. Mich. Jan. 18, 2018) ("And he does not credibly allege that Defendants have refused to disavow enforcement of Policy #34. (Contrary to Plaintiff's assertion [], silence as to enforcement of Policy #34 does not amount to a refusal to disavow enforcement.)") (parenthetical in original). Indeed, HHS's consistent position has been that any enforcement would depend on the particular facts of the action, including the nondiscriminatory reasons for refusing to offer a specific service and the applicability of RFRA and other legal requirements. (Doc. 52, at 26, 28, 32; Doc. 57, at 8); *Bostock* Notification 86 Fed. Reg. at 27,985 (The *Bostock* Notification "does not itself determine the outcome in any particular case or set of facts."). Accepting as true Plaintiffs' allegations that they have nondiscriminatory scientific and medical concerns regarding the objectionable practices and that RFRA protects them from engaging in the objectionable practices, HHS's position can hardly be construed as a "refusal to disavow enforcement" against Plaintiffs. (*See* Doc. 15, at 2, 26, 33–34, 63–66.)

Therefore, Plaintiffs have not alleged that they face "some combination" of *McKay* factors so as to establish that they face a credible threat of prosecution or that their alleged injury is "certainly impending." *See Daly*, 2021 WL 7543815, at *2–3. To the contrary, the *McKay* factors weigh against Plaintiffs' standing given that Plaintiffs have received no enforcement warning letters, the features of the statute make it considerably arduous for HHS to enforce, and HHS has not refused to disavow enforcement of the statute against Plaintiffs. The Sixth Circuit has "declined to find a credible threat of prosecution—and, thus, declined to find pre-enforcement standing—where," as here, "plaintiffs have failed to show such a combination and

where 'the record is silent as to whether the [defendants] threatened to punish or would have punished' a plaintiff for proposed conduct that might violate the challenged policy or statute." *McKay*, 823 F.3d at 869 (quoting *Morrison v. Bd. of Educ. of Boyd Cnty.*, 521 F.3d 602, 611 (6th Cir. 2008)) (alteration in original).

c. Availability of Exemptions

The *McKay* factors, however, are "not exhaustive." *Online Merch. Guild*, 995 F.3d at 550. From the Court's review of the amended complaint, Plaintiffs do not allege any other feature of Section 1557 that would render their injuries "certainly impending." (*See generally* Doc. 15.) Further, in addition to the *McKay* factors, the availability of a religious exemption to protect Plaintiffs from enforcement cuts against any argument that they face a credible threat of prosecution. *See Ky. Press Ass'n*, 454 F.3d at 509. *Kentucky Press Association* stands for the proposition that, where plaintiffs' intended conduct is arguably restricted by a policy, but it contains a vague exemption, by which the plaintiffs are arguably protected from enforcement of the policy, the plaintiffs do not have standing until the exemption has been interpreted so as not to protect them:

> [T]hat the Kentucky courts would deny [the Kentucky Press Association] the access it seeks is far from certain. K.R.S. § 610.070(3) allows a judge to grant access to juvenile proceedings to "such persons admitted as the judge shall find have a direct interest in the case or in the work of the court," and under K.R.S. § 610.340(1)(a) juvenile records may be disclosed to "persons authorized to attend a juvenile court hearing pursuant to KRS 610.070" and when "ordered by the court for good cause." The Kentucky courts could reasonably interpret these provisions to allow for limited access to juvenile proceedings by the media, which arguably has a "direct interest in the . . . work of the court."[5]

[5] The Court notes that this holding goes to ripeness, a justiciability doctrine that is distinct from standing. *Ky. Press Ass'n*, 454 F.3d at 509. However, "[t]here is unquestionably some overlap between ripeness and standing. When the injury alleged is not actual but merely threatened, standing and ripeness become more difficult to distinguish." *Airline Professionals Association of the International Brotherhood of Teamsters, Local 1224CIO v. Airborne, Inc.*, 332 F.3d 983,

Ky. Press Ass'n, 454 F.3d at 509.

This Sixth Circuit precedent stands in opposition to the Fifth Circuit precedent in *Speech First*, which held that a vague exemption that could arguably protect the plaintiffs from enforcement is not sufficient to defeat standing when the plaintiffs' intended conduct was still "arguably restricted." In *Franciscan Alliance V*, the Fifth Circuit relied on *Speech First* to determine that HHS's promise to comply with RFRA and all other legal requirements was insufficient to defeat standing, because the plaintiffs' conduct was still "arguably" restricted, and the exemption had not been interpreted such that the scope of liability was knowable. 47 F.4th. at 377 (quoting *Speech First*, 979 F.3d. at 338). In the Sixth Circuit, the fact that there exists an exemption to enforcement, under which Plaintiffs are arguably protected from enforcement of

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988 (6th Cir. 2003) (internal citation omitted) (citing *Warth v. Seldin,* 422 U.S. 490, 499 n.10 (1975) ("The standing question thus bears close affinity to questions of ripeness—whether the harm asserted has matured sufficiently to warrant judicial intervention.")). The first factor in the ripeness inquiry is "the likelihood that the harm alleged by the plaintiffs will ever come to pass," which overlaps with whether there is a credible threat of prosecution so as to render ripeness precedents useful analysis under this prong of the standing inquiry. *See, e.g.*, *id.*; *Ky. Press Ass'n*, 454 F.3d at 509. Nonetheless, to the extent Plaintiffs would contend this exemption analysis would only apply to ripeness, not standing, the Court would find that their claims are unripe as much as they lack standing. In addition to the unlikelihood that the injury would ever come to pass in light of the RFRA exemption and the lack of threatened or actual enforcement, the other two factors of the ripeness inquiry weigh against finding Plaintiffs' claims to be ripe. *See Ky. Press Ass'n*, 454 F.3d at 509. The second prong is "whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties' respective claims," which, as discussed, it is not here because there are no facts alleged regarding a particular patient, seeking a particular medical procedure, with their medical provider giving particular reasons, whether discriminatory or nondiscriminatory, for their refusal to perform the procedure. *See id.*; *supra* Section III.A.ii.b. The third ripeness factor is "the hardship to the parties if judicial relief is denied at this stage in the proceedings." *Ky. Press Ass'n*, 454 F.3d at 509. In this case, there is little to no hardship to the parties because Plaintiffs could raise these exact same claims, albeit in a more developed factual context, at any point after HHS initiated some kind of enforcement proceeding against them—even if HHS merely sends an enforcement-warning letter to them. *See supra* Section III.A.ii.b.; 45 C.F.R. § 80.8(c). Therefore the Court also finds Plaintiffs' claims unripe.

Section 1557, and the fact that the exemption has not yet been interpreted so as not to provide such protection, cuts against standing under *Kentucky Press Association*.

> In this case, HHS represents that it
>
> has consistently stated that it will abide by RFRA in any enforcement of Section 1557, has never enforced Section 1557 to require a provider with a religious objection to perform gender transition services, and has recently proposed a robust procedural mechanism to protect providers' rights under RFRA and other religious freedom laws.

(Doc. 57, at 7.) The regulatory record supports this contention. The 2016 Rule stated that "[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." 2016 Rule, 81 Fed. Reg. at 31,466. The *Bostock* Notification further assured that in applying Section 1557, HHS "will comply with the [RFRA] and all other legal requirements." *Bostock* Notification, 86 Fed. Reg. at 27,985. Most recently, HHS issued a notice of proposed rulemaking that would interpret Section 1557 to prohibit gender-identity discrimination, but it would not require regulated entities to provide any specific services if the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service and proposes a process for covered entities to assert claims for religious exemptions. Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824-01, 47,828 (Aug. 4, 2022) ("[T]he Department proposes to adopt a process by which recipients may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws, so that the Department may, as appropriate, make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this part."). Under *Kentucky Press Association*, the availability of a religious-freedom exemption to HHS's enforcement of Section 1557 cuts against the credibility

of any threat of enforcement in this case.[6] 454 F.3d at 509; *cf. Miller v. City of Wickliffe*, 852 F.3d 497, 506 (6th Cir. 2017) (holding plaintiffs did not have standing where they "were not required to censor themselves, at this point, to avoid violating the Ordinance. Instead, plaintiffs needed only to apply for a license to discover whether they could open their businesses.").

Additionally, in *R.K. v. Lee*, No. 22-5004, slip op. at 4 (6th Cir. Nov. 18, 2022), the Sixth Circuit held that the plaintiffs, students with disabilities that make them particularly susceptible to COVID-19, failed to show that a Tennessee statute prohibiting schools from mandating face

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[6] However, there are some Plaintiffs, the non-religious members of ACPeds, who have only ethical, scientific, or medical objections to the objectionable practices, rather than religious objections. (*See* Doc. 15-1, at 5, 10.) As such, the non-religious members of ACPeds may not be entitled to a religious exemption under RFRA from enforcement of Section 1557 against them. But even without the availability of a religious exemption, the non-religious Plaintiffs still have not met their burden to show standing, because they did not allege a credible threat of enforcement under the *McKay* factors. *See supra* Section III.A.ii.b. Additionally, not only has HHS consistently stated that its enforcement decisions would depend on the fact-specific RFRA analysis for religious providers, but also that its enforcement decisions would depend on nondiscriminatory reasons given for a refusal to perform a service, such as a bona fide treatment decision based on scientific and medical concerns. (Doc. 52, at 28–29; Doc. 57, at 4.) This position is also supported by the regulatory record. In HHS's recent notice of proposed rulemaking to replace the 2016 Rule, the proposed replacement rule would "not require health care professionals to perform services outside of their normal specialty area," and further would "not compel a provider to prescribe a specific treatment that the provider decides not to offer after making a nondiscriminatory bona fide treatment decision." Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. at 47,867.

> For example, a family practice covered by the rule would not be required to provide transition-related surgery where surgical care is not within its normal area of practice. Nor would the proposed rule require a pediatrician to prescribe hormone blockers for a prepubescent gender-nonconforming minor if that health care provider concluded, pursuant to a nondiscriminatory bona fide treatment decision, that social transition was the clinically indicated next step for that child.

Id. HHS's position that its enforcement decisions will account for the bona fide, nondiscriminatory reasons for refusing specific treatments, therefore, weighs against finding a credible threat of prosecution for the non-religious Plaintiffs who allege that they have scientific and medical objections to engaging in the objectionable practices. Considering this and considering that the non-religious Plaintiffs also failed to demonstrate the presence of any of the *McKay* factors, they have not shown a credible threat of prosecution under Section 1557.

masks concretely injured them. Central to the Sixth Circuit's reasoning was the fact that the statute contains an exception that allows students to request a reasonable accommodation, such as requiring any students within a six-foot bubble of the accommodated student to wear a face covering provided by the school. *Id.* "Equally significant is plaintiffs' failure to test the practical effect of the Act by seeking an accommodation; instead, they filed this suit on the heels of the Act's passage." *Id.* Similarly, in this case, Plaintiffs did not test the practical effect of the 2016 Rule by seeking a fact-specific religious exemption from HHS; instead, they filed this suit. (*See generally* Doc. 15.) Therefore, not only does the availability of an exemption that arguably protects Plaintiffs from enforcement cut against standing under *Kentucky Press Association*, but the fact that Plaintiffs did not test the practical effect of such an exemption by requesting coverage before filing this suit also undermines any argument that they have suffered a concrete injury under the Section 1557 Gender Identity Mandate. *See R.K. v. Lee*, No. 22-5004, slip op. at 4.

Given Plaintiffs' failure to allege any of the *McKay* factors, the availability of a religious exemption by which they are arguably protected from enforcement, which has not yet been interpreted otherwise, the fact that Plaintiffs filed this lawsuit before seeking an exemption, and the Supreme Court's mandate that the standing inquiry is "especially rigorous when reaching the merits of the dispute would force [a court] to decide the constitutionality of an action taken by one of the other two branches of the Federal Government," the Court finds Plaintiffs have not established standing as to their claims. *See Raines v. Byrd*, 521 U.S. 811, 811 (1997). Accordingly, the Court lacks jurisdiction to hear their claims and will **GRANT** Defendants' motion to dismiss (Doc. 52) as to Plaintiffs' Section 1557 claims.

B. 2016 Grants Rule Claims

Plaintiffs also lack standing to bring their claims against the 2016 Grants Rule. Plaintiffs do not allege that HHS has any history of enforcing the 2016 Grants Rule against them or others, or that Plaintiffs have received any sort of enforcement warning regarding the 2016 Grants Rule. Indeed, the history of enforcement under the 2016 Grants Rule is even more barren than that of Section 1557 because the presidential administration changed eight days after the rule first became effective, resulting in HHS never having enforced the 2016 Grants Rule against *anyone* for *any* form of discrimination. *See* 2021 Grants Rule, 86 Fed. Reg. at 2,273. Plaintiffs also fail to allege that the 2016 Grants Rule has any feature making enforcement easier or more likely, such as a citizen enforcement provision. (*See generally* Doc. 15.) Indeed, like Section 1557, the administrative enforcement process is lengthier than a typical state statute, even one without a citizen-enforcement provision, and subject to judicial review. *See* Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. at 75,919.

Further, while HHS was "silent" on whether it would enforce Section 1557 against Plaintiffs, which did not amount to a refusal to disavow enforcement against them, HHS went a step further for the 2016 Grants Rule by *expressly disavowing* any enforcement against Plaintiffs, or any other regulated entity, in the Notification of Nonenforcement. Notification of Nonenforcement, 84 Fed. Reg. at 63,809-01. Two other district courts, which follow the Fifth Circuit's more permissive standing doctrines, *see supra* Section III.A.ii.a., c., have found that plaintiffs had no standing to challenge the 2016 Grants Rule in light of this express disavowal of enforcement. *Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546, 558 (N.D. Tex. 2020) ("Defendants

have expressly disavowed enforcement of § 75.300(d). With the limited authority to file suit, this means Vita Nuova stands a negligible chance of being prosecuted under § 75.300(d). Because there exists little to no credible threat of enforcement related to 45 C.F.R. § 75.300(d), Vita Nuova's second claim cannot survive Defendants' Motion to Dismiss."); *Tex. Dep't of Fam. & Protective Servs. v. Azar*, 476 F. Supp. 3d 570, 578 (S.D. Tex. 2020) (finding the plaintiffs lacked standing because "HHS unequivocally states that it will not enforce the challenged provisions pending repromulgation"). Plaintiffs argue that they are no longer protected by the Notification of Nonenforcement since the 2016 Grants Rule is no longer pending repromulgation, because HHS repromulgated the rule already with the 2021 Grants Rule but then voluntarily vacated it. (Doc. 55, at 26–27.) Not only is this argument a reach because HHS still has not effectively promulgated a replacement rule and so is still "pending repromulgation," but also, even if the Court accepted such an argument, it still would not render HHS's actions a "*refusal* to disavow enforcement" against Plaintiffs under the *McKay* factors. Therefore, Plaintiffs also lack standing as to their 2016 Grants Rule claims, so Defendants' motion to dismiss will be **GRANTED**.

C. SUNSET Rule Claims

In their response to Defendants' motion to dismiss, Plaintiffs represent that "[b]ecause HHS repealed the SUNSET Rule through rulemaking earlier this year, Plaintiffs do not oppose dismissal of Claim Seven of their Amended Complaint. Plaintiffs reserve the possibility of bringing claims related to that rule in the future, and so ask that the dismissal be without prejudice." (Doc. 55, at 13.) In their reply brief, Defendants do not oppose Plaintiffs' request that their SUNSET Rule claims be dismissed without prejudice. (*See generally* Doc. 57.) Therefore, the motion to dismiss is **GRANTED** with respect to Plaintiffs' SUNSET Rule claims,

which will be **DISMISSED WITHOUT PREJUDICE**. *See Walther v. Fla. Tile, Inc.*, 776 F. App'x 310, 315 (6th Cir. 2019) ("Whether voluntary dismissal should be granted under Rule 41(a)(2) is within the sound discretion of the district court. The primary purpose of Rule 41(a)(2)'s requirement of a court order is to protect the nonmovant from unfair treatment. '[A]n abuse of discretion is found only where the defendant would suffer plain legal prejudice as a result of a dismissal without prejudice, as opposed to facing the mere prospect of a second lawsuit.'" (citing *Grover by Grover v. Eli Lilly & Co.*, 33 F.3d 716, 718 (6th Cir. 1994)) (internal citations omitted))).

IV. CONCLUSION

For these reasons, the Court **GRANTS** Defendants' motion to dismiss (Doc. 52). Plaintiffs' claims are **DISMISSED WITHOUT PREJUDICE**.[7]

AN APPROPRIATE JUDGMENT SHALL ENTER.

/s/ Travis R. McDonough
TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE

[7] "Traditionally, when courts find that they lack standing and therefore must dismiss a case due to lack of subject matter jurisdiction, they dismiss the case without prejudice because they did not reach the merits of the Plaintiff's claim." *Thompson v. Equifax Info. Servs., L.L.C.*, 441 F. Supp. 3d 533, 547 n.7 (E.D. Mich. 2020) (citing *Thompson v. Love's Travel Stops & Country Stores, Inc.*, 748 F. App'x. 6, 11 (6th Cir. 2018)).

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

AMERICAN COLLEGE OF PEDIATRICIANS, *et al.*, *Plaintiffs*, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, *Defendants*.	Case No. 1:21-cv-195 Judge Travis R. McDonough Magistrate Judge Susan K. Lee

ORDER

Consistent with the contemporaneously filed memorandum opinion, Defendants' motion to dismiss (Doc. 51) is **GRANTED**, and this action is **DISMISSED**. The Clerk is **DIRECTED** to **CLOSE** the case.

/s/ Travis R. McDonough
TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE

ENTERED AS A JUDGMENT
s/ LeAnna R. Wilson
CLERK OF COURT

Exhibit 5

No. 23-5053

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of its members; CATHOLIC MEDICAL ASSOCIATION, on behalf of its members,

Plaintiffs-Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; LISA J. PINO, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Tennessee (Chattanooga)
Case No. 1:21-cv-00195

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Regulations

SUMMARY OF THE ARGUMENT

The new final rule promulgated by the Department of Health and Human Services on May 6, 2024 (89 Fed. Reg. 37,522), has made this case moot. Accordingly, the Court should dismiss this appeal, vacate the decision below, and remand for dismissal without prejudice.

When Appellants American College of Pediatricians (ACPeds) and Catholic Medical Association (CMA) filed their first amended complaint on behalf of their members two-and-a-half years ago, they alleged that a complicated series of two final rules issued under prior administrations interpreting Section 1557 of the Affordable Care Act, court decisions at least partially enjoining those final rules, an executive order signed by President Biden, a public Notice of Enforcement issued by HHS, and a Statement of Interest filed by HHS, all combined to threaten their members with steep financial penalties if they declined to perform gender-transition surgeries, prescribe gender-transition drugs, and speak and write about patients according to gender identity rather than biological sex—even when doing so would violate their medical judgment or religious beliefs. Compl., R.15, PageID 126–27, 134–42.

The new 2024 Rule, which takes effect July 5, 2024, replaces all of that, making it impossible to grant Appellants effectual relief in this case. When a civil case becomes moot pending appellate review, the established practice is to vacate the judgment below and remand with instructions to dismiss. The Court should follow that practice here.

ARGUMENT

I. The 2024 Rule moots all of Appellants' claims by replacing the complicated legal regime Appellants challenged in their complaint with a comprehensive new rule.

"Article III of the United States Constitution empowers the federal courts to hear only 'cases or controversies,' U.S. Const. art. III, § 2, cl. 1, a cradle-to-grave requirement that must be met in order to file a claim in federal court and that must be met in order to keep it there." *Fialka-Feldman v. Oakland Univ. Bd. of Trs.*, 639 F.3d 711, 713 (6th Cir. 2011). "If events occur during the case, including during the appeal, that make it impossible for the court to grant any effectual relief whatever to a prevailing party, the appeal must be dismissed as moot." *Id.* (cleaned up).

One such event that can moot a case pending on appeal is a substantial change to the legal regime under review. That's "because courts apply the law as it exists at the time of the decision." *Kenjoh Outdoor, LLC v. Marchbanks*, 23 F.4th 686, 692 (6th Cir. 2022). "And a change in the law tends to eliminate the requisite case-or-controversy." *Id.* (cleaned up). To decide whether a change in the law is substantial enough to moot the case, this Court asks whether the new regime "operates in the same fundamental way" as the old one. *Green Party of Tenn. v. Hargett*, 700 F.3d 816, 823 (6th Cir. 2012) (cleaned up). If the change in the law "substantially changed [the old] scheme," then the affected claims are moot. *Id.*

And that is what has happened here. Though merely replacing one regulatory regime with a new, nearly identical regime that operates in fundamentally the same way is typically not enough to moot a challenge to the old regime, the 2024 Rule does more than that. And that's mainly because, as Appellants explained in their complaint, the old regime and the resulting threat of enforcement Appellants' members faced under that regime resulted from a complicated series of events dating back to a rule issued eight years and two presidential administrations ago. Compl., R.15, PageID 134–38.

That 2016 Rule was subsequently permanently enjoined, at least in part. *Id.*, PageID 139 (citing *Franciscan Alliance, Inc. v. Burwell*, 414 F. Supp. 3d 928, 945 (N.D. Tex. 2019)). And then the next administration issued a new rule in 2020 that revised the partially vacated 2016 Rule to remove the gender-identity mandate entirely. *Id.*, PageID 139 (citing Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) (to amend and be codified at 45 C.F.R. pt. 92)). But before the 2020 Rule's changes to the 2016 Rule could go into effect, two district courts enjoined parts of the 2020 Rule while declaring that some of the 2016 Rule's mandate remained in effect. *Id.*, PageID 139 (citing *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020), *modified by* 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020); *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020)).

Finally, upon taking office, President Biden signed an executive order purportedly applying *Bostock* and requiring that Section 1557 and Title IX be interpreted to include gender identity as a protected trait, while also requiring similar interpretations of all other federal civil rights laws and promoting related policies. Compl., R.15, PageID 140. In response, HHS announced that its Office for Civil Rights would "interpret and enforce Section 1557's prohibition on discrimination on the basis of sex to include: (1) Discrimination on the basis of sexual orientation; and (2) discrimination on the basis [of] gender identity." *Id.*, PageID 140–41 (quoting 86 Fed. Reg. 27,984, 27,985 (May 25, 2021)). And when Appellants finally sought preenforcement relief from the credible threat of enforcement that series of events posed to their members, the Government spent the next two years carefully refusing to disavow that it would enforce the resulting mandate against Appellants' members, even conceding in this appeal that "it is *possible*" that it might. Br. for Appellees at 42.

With the issuance of the 2024 Rule, that complicated amalgamation of agency actions, court decisions, and official statements that had combined to create the threat of enforcement Appellants sued to enjoin has been rendered inoperative by a single, comprehensive new rule. And while theoretically the old regime *could* one day spring back into effect if a court were to enjoin the new rule, that speculative possibility is not enough to prevent this case from becoming moot right now. *See*

Ass'n of Am. Physicians & Surgeons v. Sebelius, 746 F.3d 468, 472–73 (D.C. Cir. 2014) (rejecting the "startling argument" that a claim was not moot because a new rule that seemingly mooted the case might someday be invalidated, forcing the administration to "retreat" back to the agency actions the plaintiffs had originally challenged).

The full impact of the resulting changes remains to be seen—and litigated. But taken together, they are substantial enough to moot all of Appellants' claims challenging the old regime. *See id.* at 472 (holding that a claim attacking an interim rule became moot once it had been "superseded by a rule promulgated after notice and comment" that included "substantive changes").

While Appellants maintain the right to challenge the many deficiencies that remain in the 2024 Rule in a separate lawsuit, "it is clearly preferable as a general matter to review a set of claims in the context of an extant rather than a defunct rule." *Id.* at 473. And Appellants concede that nothing about this case warrants a departure from that general principle.

Moreover, the 2024 Rule moots Appellants' APA claim (Claim 1) for the added reason that "the new rule is *procedurally* distinct" from the 2016 Rule and the 2021 Notice of Enforcement. *Wyoming v. U.S. Dep't of Interior*, 674 F.3d 1220, 1230 (10th Cir. 2012) ("Because the procedural challenge in this case is to the analysis underlying the 2009 temporary rule and that analysis has been redone, we hold that the

procedural challenge to the 2009 temporary rule is moot."). Again, the old regime was a patchwork system created across three presidential administrations. The core rule is now eight years old, it was partially repealed and partially left in place by court order in 2020, and then its enforcement was modified by gap-filling guidance issued three years ago. This presents a stark procedural difference from the 2024 Rule, which, in effect, resets the mishmash regulatory regime Appellants challenged, thus presenting a very distinct procedural circumstance.

Finally, while Appellants included a request for nominal damages under the Religious Freedom Restoration Act in their first amended complaint, Compl., R.15, PageID 208, they have withdrawn that request for compensatory relief by not pursuing it in this appeal.

For these reasons, Appellants concede that their case challenging the previous regime is moot, and if they were to receive relief against the old regime that they challenged in their complaint, that relief would not be sufficient to shield them from injuries now caused by the new 2024 Rule. Appellants are not seeking retrospective relief for any of the harms they suffered under the old regime, and the old regime will no longer pose a credible threat entitling Appellants to prospective relief once the 2024 Rule takes effect. Thus, events have occurred during this appeal "that make it impossible for the court to grant any effectual relief whatever" to Appellants, and the "appeal must be dismissed as moot." *Fialka-Feldman*, 639 F.3d at 713 (cleaned up).

II. Because Appellants have been prevented from obtaining review of the district court's decision through no fault of their own, this Court should vacate that decision.

"When a case becomes moot on appeal, as this one did, the established practice is to reverse or vacate the judgment below and remand with a direction to dismiss." *Id.* at 716 (cleaned up) (citing *United States v. Munsingwear, Inc.*, 340 U.S. 36, 39–40 (1950)).

"The idea is that when a party seeks relief from 'the merits of an adverse ruling, but is frustrated by the vagaries of circumstance' from obtaining an appellate ruling, it makes little sense to compel the losing party to live with the precedential and preclusive effects of the adverse ruling without having had a chance to appeal it." *Id.* (quoting *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 25 (1994)). "Vacatur 'clears the path for future relitigation' by eliminating a judgment the appellant could not oppose on direct review." *Coal. for Gov't Procurement v. Fed. Prison Indus., Inc.*, 365 F.3d 435, 485 (6th Cir. 2004) (quoting *Munsingwear*, 340 U.S. at 40). "In other words, vacatur is generally appropriate to avoid entrenching a decision rendered unreviewable through no fault of the losing party." *Stewart v. Blackwell*, 473 F.3d 692, 693 (6th Cir. 2007).

All of that applies here.

First, the "principal condition to which" the Supreme Court has looked to decide whether to order *Munsingwear* vacatur "is whether the party seeking relief from the judgment below caused the mootness by

voluntary action." *Bancorp*, 513 U.S. at 24. Appellants did not cause the Government to issue the new 2024 Rule that has mooted this case.

Second, "while a dismissal for lack of jurisdiction does not constitute an adjudication upon the merits, it does constitute a binding determination on the jurisdictional question, which is not subject to collateral attack." *Shaw v. Merritt-Chapman & Scott Corp.*, 554 F.2d 786, 789 (6th Cir. 1977). As a result, "under principles of issue preclusion, even a case dismissed *without* prejudice has preclusive effect on the jurisdictional issue litigated." *Kasap v. Folger Nolan Fleming & Douglas, Inc.*, 166 F.3d 1243, 1248 (D.C. Cir. 1999) (citing *Shaw*). And that has led courts to hold that "even a dismissal without prejudice will have a preclusive effect on the standing issue in a future action." *Brereton v. Bountiful City Corp.*, 434 F.3d 1213, 1218–19 (10th Cir. 2006). *Munsingwear* vacatur is thus appropriate here to "clear[] the path" for any future litigation if the old regime should someday spring back into effect. *Munsingwear*, 340 U.S. at 40.

Third and finally, "[a]s to the public interest, the district court's judgment, in an unpublished order, has no precedential effect." *Doe v. Univ. of Mich.*, No. 20-1293, 2020 WL 9171175, at *2 (6th Cir. Dec. 23, 2020). So the public interest in precedential decisions remaining in effect does not weigh against vacating the decision below. And "[v]acatur is therefore warranted." *Id.*

CONCLUSION

The Government's issuance of the new 2024 Rule has rendered this case moot through no fault of Appellants. The Court should follow the established practice when civil cases become moot on appeal and vacate the decision below, remanding the case to the district court for dismissal without prejudice.

Dated: May 29, 2024

Respectfully submitted,

s/Christopher P. Schandevel

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CERTIFICATE OF COMPLIANCE

This brief complies with the Court's May 8, 2024 letter request for supplemental briefing because it does not exceed twenty-five pages.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Word 365 using a proportionally spaced typeface, 14-point Century Schoolbook.

Dated: May 29, 2024

s/Christopher P. Schandevel
Christopher P. Schandevel
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CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/Christopher P. Schandevel
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No. 23-5053

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

AMERICAN COLLEGE OF PEDIATRICIANS, *on behalf of its members*; and CATHOLIC MEDICAL ASSOCIATION, *on behalf of its members*,

Plaintiffs-Appellants,

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; OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and LISA J. PINO, *in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of Tennessee

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Regulations:

Other Authorities:

INTRODUCTION AND SUMMARY

Defendants-appellees respectfully submit this supplemental brief in response to this Court's order of May 8, 2024, instructing the parties to address three questions arising from the promulgation by the Department of Health and Human Services (HHS) of a final rule regarding Section 1557 of the Affordable Care Act. *See Nondiscrimination in Health Programs and Activities*, 89 Fed. Reg. 37,522 (May 6, 2024) (Final Rule).

In dismissing this case for lack of subject-matter jurisdiction, the district court properly concluded that plaintiffs failed to establish standing or ripeness. This Court can affirm that dismissal on standing grounds without addressing the effect of HHS's new Final Rule. Alternatively, this Court can affirm the dismissal on mootness or ripeness grounds because the Final Rule makes even clearer that plaintiffs' identified individual members face no credible threat of enforcement given the new provisions the Final Rule has established for providers to rely upon religious exemptions for specific conduct and prospectively seek assurances of those exemptions.

STATEMENT

In its opinion granting the government's motion to dismiss, the district court referenced HHS's then-recent Notice of Proposed Rulemaking regarding Section 1557. *See* Op., R. 61, PageID 1224-1225; *Nondiscrimination in Health Programs and*

Activities, 87 Fed. Reg. 47,824 (Aug. 4, 2022). On May 6, 2024, HHS issued the corresponding Final Rule.[1]

As relevant here, the Final Rule expressly recognizes the ability of healthcare providers to rely on federal religious freedom and conscience protections, including the Religious Freedom Restoration Act (RFRA). Section 92.3(c) provides that "[i]nsofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required." 45 C.F.R. § 92.3(c) (89 Fed. Reg. at 37,693). The Final Rule further clarifies that "a recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this part to specific contexts, procedures, or health care services, shall not be required, and does not violate section 1557 if it so relies." 89 Fed. Reg. at 37,659; *see* 45 C.F.R. § 92.302(a) (89 Fed. Reg. at 37,701-02) ("A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply."). Indeed, the Final Rule states: "When a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant

[1] On the same day that the Final Rule was published in the Federal Register, Plaintiff Catholic Medical Association brought a new lawsuit on behalf of its members in the Middle District of Florida seeking some of the same relief they seek in this case. *See* Complaint, *Florida v. HHS*, No. 8:24-cv-1080 (M.D. Fla. May 6, 2024), Dkt. No. 1.

religious freedom and conscience protections (e.g., RFRA), [HHS's Office for Civil Rights (OCR)] will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b)," and OCR will only "seek forward-looking relief as appropriate under the facts" if it determines after an investigation "that the recipient does not satisfy the legal requirements for an exception." 89 Fed. Reg. at 37,657.

Further, if a healthcare provider seeks further assurance that they are exempt, the Final Rule sets forth a process by which providers can request a written assurance from OCR of their religious- or conscience-based exemptions with respect to specific conduct. *See* 45 C.F.R. § 92.302 (89 Fed. Reg. at 37,701-02). Providers can submit a written notification to the Director of OCR, identifying "[t]he particular provision(s) of this part from which the recipient asserts they are exempt," and the legal and factual basis supporting the exemption. *Id.* § 92.302(b)(1)-(3) (89 Fed. Reg. at 37,702). Upon submitting this notification, the provider automatically receives a "temporary exemption from administrative investigation and enforcement." *Id.* § 92.302(c) (89 Fed. Reg. at 37,702). "If OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of this part or that modified application of certain provision(s) is required," OCR provides a determination in writing, and then "the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or health care

services provided." *Id.* § 92.302(d) (89 Fed. Reg. at 37,702). If OCR determines against providing the requested assurance of exemption, the provider can appeal this determination within HHS and can seek judicial review in the event of a final adverse decision from the agency. *Id.* § 92.302(e)-(f) (89 Fed. Reg. at 37,702); *see* 45 C.F.R. pt. 81.

Separately, HHS declined to import the Title IX religious exception into the Final Rule, providing a thorough explanation for this decision. 89 Fed. Reg. at 37,530-34. In doing so, HHS clarified that "the decision not to import the title IX religious exception does not compel any individual provider or covered entity with religious or conscience-based objections to provide abortion or any other care to the extent doing so would conflict with a sincerely-held belief." *Id.* at 37,533. And HHS noted that it "has taken important steps to address religious freedom and conscience protections beyond those in the 2016 Rule," including by adopting § 92.3(c) and § 92.302, and the issuance of a final rule entitled *Safeguarding the Rights of Conscience as Protected by Federal Statutes*, 89 Fed. Reg. 2078 (Jan. 11, 2024). 89 Fed. Reg. at 37,532; *see id.* at 37,533 ("Rather than importing the title IX religious exception into section 1557, … the process set forth in § 92.302 respects religious freedom and conscience protections.").

In explaining its decisions in the preamble to the Final Rule, HHS repeatedly reiterated its respect for religiously affiliated providers and its goal of protecting their religious freedom: "Religiously affiliated hospitals and health care facilities play a large

role in the health care system, and OCR recognizes the critical patient care needs they provide, particularly in reaching underserved communities." 89 Fed. Reg. at 37,658; *see id.* at 37,533 ("OCR appreciates that many religiously affiliated hospitals and providers are providing vital services in areas where people are in the most need and are often motivated by their faith to provide this important care."). HHS explained that "OCR seeks to ensure Federal civil rights protections are fulfilled and has consulted with the appropriate staff regarding the application of religious freedom and conscience protections during this rulemaking and will continue to engage such staff during OCR's enforcement of the final rule." *Id.* at 37,658; *see id.* at 37,533 ("We are committed to affording full effect to Congress's protections of conscience and religion, as detailed in § 92.302 and the Department's issuance of its final rule, Safeguarding the Rights of Conscience as Protected by Federal Statutes. 89 [Fed. Reg.] 2078.").

ARGUMENT

Question 1. Whether the final rule promulgated by the Department of Health and Human Services on May 6, 2024 (89 Fed. Reg. 37,522) has rendered or will render any of appellants' claims moot.

As the district court correctly determined, plaintiffs had not established standing as of the time the relevant complaint was filed. *See* Op., R. 61, PageID 1214-1226; *see also Barber v. Charter Twp. of Springfield*, 31 F.4th 382, 390, 392 n.7 (6th Cir. 2022) (observing that standing is assessed as of the time the relevant plaintiff was

added to the action). But even if plaintiffs could be thought to have established a credible threat of enforcement as of that time, their identified members will no longer face any such threat when the Final Rule takes effect and all of plaintiffs' claims will thus soon be moot.[2] *See* 89 Fed. Reg. at 37,693 (effective date of July 5, 2024). Accordingly, this Court need not address standing and can instead affirm the district court's dismissal on mootness grounds. *See Arizonans for Official English v. Arizona*, 520 U.S. 43, 66-67 (1997) (resolving whether there remained a live case or controversy without first addressing appellate standing); *In re: 2016 Primary Election*, 836 F.3d 584, 587 (6th Cir. 2016) (observing that this Court has "discretion to address jurisdictional issues in any sequence we wish" (quotation marks omitted)).

Under Article III's case-or-controversy requirement, "an actual controversy [must] be extant at all stages of review, not merely at the time the complaint is filed." *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 160 (2016) (quotation marks omitted). Although "ultimately separate from standing," "[m]ootness can be described as 'the doctrine of standing set in a time frame.'" *Rice v. Village of Johnstown*, 30 F.4th 584, 594

[2] As explained in the government's principal brief, plaintiffs have not identified a specific, non-religious member of the American College of Pediatricians (ACP) whose objections to the asserted practices are alleged to not be based on religious grounds. Gov't Br. 29-30. Accordingly, plaintiffs have not established that the credible threat of enforcement on which to premise jurisdiction can be assessed as to *any* identified member without properly taking account of RFRA. In their reply brief, plaintiffs did not refute this assertion or otherwise continue to insist that they could establish standing premised on a non-religious member and without regard to RFRA. *See Resurrection Sch. v. Hertel*, 35 F.4th 524, 530 (6th Cir.) (en banc) ("[A]rguments in support of justiciability can be forfeited."), *cert. denied*, 143 S. Ct. 372 (2022).

(6th Cir. 2022) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)). Accordingly, "[w]hether an 'intervening circumstance' arising after a suit has been filed causes a plaintiff's asserted injury to dissipate is really a question of mootness." *Kentucky v. Yellen*, 54 F.4th 325, 340 (6th Cir. 2022) (emphasis omitted).

As applied to cases seeking pre-enforcement review, courts inquire whether the intervening event has caused any imminent threat of enforcement that might have existed to dissipate. *See Kentucky*, 54 F.4th at 340 ("Treasury's disavowal of the money-is-fungible interpretation dispelled the States' claim that they run the risk of an imminent enforcement action[] …."); *New Hampshire Lottery Comm'n v. Rosen*, 986 F.3d 38, 53 (1st Cir. 2021) (concluding that case was not moot where intervening event "does [not] offer the plaintiffs solace that the credible threat of prosecution has subsided"). Where the intervening event "render[s] the threat of prosecution so speculative that a live controversy no longer exist[s] for Article III jurisdiction," a pre-enforcement challenge becomes moot. *Brown v. Buhman*, 822 F.3d 1151, 1163 (10th Cir. 2016); *id.* at 1170-73 (finding case moot where the defendants adopted enforcement policy under which the plaintiffs would not be prosecuted and the plaintiffs moved out of state).

Here, the Final Rule confirms that plaintiffs' identified individual members do not face a credible threat of enforcement. The Final Rule adds even more speculative contingencies that must come to pass before any of plaintiffs' members might be

subject to an enforcement action, and thus makes clear that there is no longer a live dispute for purposes of Article III.

The Final Rule establishes a process whereby plaintiffs' members can seek assurances from OCR of their RFRA exemptions from "the application of particular provision(s) of this part to specific contexts, procedures, or health care services." 45 C.F.R. § 92.302(b) (89 Fed. Reg. at 37,702). They can seek such assurances even before any administrative complaint is filed and "before an[y] investigation is initiated." *Id.* (89 Fed. Reg. at 37,702). Where members avail themselves of this option in advance and obtain an assurance, they will face no threat of investigation or enforcement. *Id.* § 92.302(d) (89 Fed. Reg. at 37,702) ("[I]f granted, the recipient will be considered exempt from OCR's administrative investigation and enforcement ….."). If the members do not seek an assurance in advance, they may still rely on RFRA and, under § 92.3(c) and § 92.302(a), application of the Final Rule's provisions "to specific contexts, procedures, or health care services" to the members shall not be required where RFRA protections apply. *Id.* § 92.302(a) (89 Fed. Reg. at 37,701-02). If any administrative complaint is filed regarding their conduct or any investigation is otherwise initiated, the members "may, during the pendency of that investigation, similarly notify OCR of their belief they are entitled to an exemption under the process provided at § 92.302(b)." 89 Fed. Reg. at 37,658.

Accordingly, in order for any of plaintiffs' members to potentially be subject to an enforcement action—once they have undergone the already attenuated chain of

events preceding the initiation of an investigation into their conduct, *see* Gov't Br. 19, 41-42—the following must still occur: (1) OCR must deny the assurance request; and (2) assuming the member does not voluntarily forgo its appeal rights, an HHS administrative hearing examiner must affirm the denial in a final agency action that would still be subject to judicial review, 45 C.F.R. § 92.302(e)-(f) (89 Fed Reg. at 37,702).[3] If the member availed itself of the assurance process in advance as well as its administrative and judicial review rights, it could be subject to potential enforcement only after a federal court has already determined that it does not merit an assurance that the conduct at issue is exempt from Section 1557 under RFRA. If the member did not seek an assurance in advance and instead waited to invoke the § 92.302(b) process until after OCR initiated an investigation, OCR will grant a temporary exemption from administrative investigation and enforcement until a final agency determination is issued. *Id.* § 92.302(c), (e) (89 Fed. Reg. at 37,702). And if a court ultimately finds that the member is entitled to the requested assurance, OCR would of course be bound by that ruling and the member would be exempt from

[3] These events must come to pass notwithstanding plaintiffs' allegations that the sincerely held religious beliefs of their members "prohibit them from engaging in or facilitating in the 'objectionable practices,'" that their "exercise of religion" would be "substantially burden[ed]" by requiring them to do so, and that their members' "provision of healthcare in accord with their religious beliefs prevents no one from obtaining gender transition interventions from other providers." Am. Compl. ¶¶ 428, 433, 438, R. 15, PageID 189-190.

"OCR's administrative investigation and enforcement." *Id.* § 92.302(d) (89 Fed. Reg. at 37,702).

Moreover, even if the assurance were denied and the denial were appealed and affirmed, before a member could be subject to an enforcement action, OCR would still need to proceed with an investigation, evaluate the reasons for the member's conduct, and determine that it does not amount to a legitimate, non-discriminatory reason, that discrimination has occurred, and that Section 1557 was violated; and any efforts at informal, voluntary compliance must fail. There is no indication that this long, speculative series of contingencies—made even longer and less certain by the Final Rule—is likely to transpire for any identified member.

The addition of a new exemption process, like the one established in § 92.302, to an already attenuated chain of events that must occur before any of the identified individual members might be injured weighs heavily against finding that a future injury is sufficiently imminent to give rise to Article III jurisdiction. *See R.K. ex rel. J.K. v. Lee*, 53 F.4th 995, 999 (6th Cir. 2022) (relying on the existence of an accommodation process and "plaintiffs' failure to test the practical effect of the Act by seeking an accommodation" in concluding that plaintiffs lacked standing), *reh'g denied*, No. 22-5004, 2022 WL 18434486 (6th Cir. Dec. 28, 2022); *Kentucky Press Ass'n v. Kentucky*, 454 F.3d 505, 509-10 (6th Cir. 2006) (concluding that challenge was unripe where, by failing to petition state courts for access to proceedings, plaintiff had not demonstrated it was likely that challenged law entirely foreclosed such access); *cf.*

Miller v. City of Wickliffe, 852 F.3d 497, 506-07 (6th Cir. 2017) (finding no credible threat of enforcement for standing purposes where plaintiffs did not apply for license).

Moreover, the Final Rule reiterates HHS's strong commitment to comply with RFRA—and all other federal religious freedom and conscience protections—in its enforcement of Section 1557. Plaintiffs invoked HHS's treatment of religious accommodations in an earlier rulemaking in attempting to argue that there was a sufficiently imminent threat of enforcement at the time this action was brought. *See* Opening Br. 27 ("HHS's decision not to import Title IX's religious exemption into Section 1557 through the 2016 Rule … bolsters the credible threat of enforcement."); *see also* Reply Br. 4, 5. The Final Rule includes a thorough discussion of HHS's decision not to import the Title IX religious exception and the role of § 93.2(c) and § 92.302 in fully protecting religious freedom rights in place of the Title IX exception. *See* 89 Fed. Reg. at 37,530-34. Thus, to the extent plaintiffs sought to rely on doubt about HHS's commitment to accommodating providers' sincerely held religious beliefs, the Final Rule dispels any plausible basis for such doubt.

Additionally, the Final Rule "resulted from the notice-and-comment process, and thus it may be rescinded only pursuant to that process as well," and there is "no evidence that [HHS] plans to pursue such rescission." *Kentucky*, 54 F.4th at 341; *Speech First, Inc. v. Schlissel*, 939 F.3d 756, 768 (6th Cir. 2019) ("Where regulatory changes are effected through formal, legislative-like procedures, we have found that to moot the

case the government need not do much more than simply represent that it would not return to the challenged policies."); *Davis v. Colerain Township*, 51 F.4th 164, 174-75 (6th Cir. 2022) ("This presumption"—that government defendants "will not resume their challenged conduct unless objective evidence suggests that they have made a bad-faith change to avoid judicial review"—"gains even more strength if the government has changed course through a formal process because the formalities involved make it more difficult to reinstitute the old policy later."). Because there is thus "no reasonable possibility" of HHS adopting a position under which plaintiffs' members cannot rely on RFRA or seek prospective assurances of RFRA exemptions as to specific conduct, plaintiffs' claims will soon be moot. *See Resurrection Sch. v. Hertel*, 35 F.4th 524, 530 (6th Cir. 2022) (en banc). When the Final Rule becomes effective, this Court can thus affirm the district court's dismissal on mootness grounds.

Question 2. **If the rule moots some but not all of appellants' claims, whether a specific member of each organization identified in the complaint still retains a live claim upon which appellants can assert associational standing.**

As explained, *see supra* pp. 5-12, the Final Rule will moot all of appellants' claims. Plaintiffs have not established that any identified individual member had standing at the time this action was filed (*see* Gov't Br. 14-39), but regardless the dispute will no longer be live once the Final Rule takes effect in light of the Final Rule's treatment of RFRA protections and the assurance process in § 92.302.

Plaintiffs did not clearly identify a non-religious individual ACP member—who cannot rely on RFRA and the assurance process—upon whom this Court could base Article III jurisdiction.

Question 3. Whether the court may consider the new rule in assessing the likelihood that any of appellants' members face a credible threat of an enforcement action, and if so, whether the new rule reduces such risk.

The Court cannot consider the new rule as relevant to standing, because "Supreme Court and Sixth Circuit caselaw have consistently held that the court must determine whether standing exists at the time of the filing of the complaint only." *Graveline v. Benson*, 992 F.3d 524, 532 (6th Cir. 2021) (quotation marks omitted); *Barber*, 31 F.4th at 390 ("When assessing standing, courts look only to the facts existing when the complaint is filed." (quotation marks omitted)). But the Court can consider the new Final Rule for purposes of assessing both mootness and ripeness. The likelihood that any of plaintiffs' identified members face a credible threat of being subject to an enforcement action is relevant to both inquiries. As explained above, *supra* pp. 5-12, the case will soon become moot in light of the Final Rule's treatment of RFRA protections and the assurance process in § 92.302. The Final Rule also confirms that plaintiffs' claims are unripe.

As the Supreme Court has recognized, "ripeness is peculiarly a question of timing, and it is the situation now rather than the situation at the time of the decision under review that must govern." *Anderson v. Green*, 513 U.S. 557, 559 (1995) (per

curiam) (alteration and quotation marks omitted); *see also, e.g.*, *Church of Our Lord & Savior Jesus Christ v. City of Markham*, 913 F.3d 670, 677 (7th Cir. 2019). Accordingly, "[r]ipeness should be decided on the basis of all the information available to the court. Intervening events that occur after decision in lower courts should be included, just as must be done with questions of mootness." 13B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure Jurisdiction* § 3532.7, Westlaw (3d ed. database updated Apr. 2023) (footnote omitted).

Cases that were ripe at the time the complaint was filed or the district court decision issued can thus become unripe on appeal due to intervening developments. *See Trump v. New York*, 592 U.S. 125, 131 (2020) (per curiam) (holding that case was unripe after "any chilling effect" had "dissipated" on appeal); *Walmart Inc. v. U.S. Dep't of Justice*, 21 F.4th 300, 313 (5th Cir. 2021) ("The bringing of the Delaware suit proves that, when this case was filed, enforcement was indeed impending. When considered from the standpoint of the present, however, the suit's existence also suggests that future enforcement is unlikely." (emphasis omitted)).

In order to satisfy ripeness, a case must "concern a dispute that is likely to come to pass" and not "turn[] on contingent future events that may not occur as anticipated, or indeed may not occur at all." *OverDrive Inc. v. Open E-Book Forum*, 986 F.3d 954, 957-58 (6th Cir. 2021) (alteration and quotation marks omitted). For pre-enforcement actions, this inquiry involves determining whether a plaintiff faces a

credible threat of enforcement and thus a sufficiently imminent future injury. *See, e.g.*, *Kiser v. Reitz*, 765 F.3d 601, 607, 609 (6th Cir. 2014).

As discussed, *supra* pp. 7-11, the Final Rule's process for seeking an assurance of religious exemption under § 92.302 underscores the lack of likelihood that there will ever be an enforcement against plaintiffs' identified individual members. The members would only be subject to an enforcement action if an unlikely chain of events were to transpire: if they face an OCR investigation, and when they raise a RFRA exemption under the § 92.302 assurance process (either before any investigation or after it begins), if OCR denies the assurance request, and—assuming the member does not voluntarily forgo its appeal rights—if an HHS hearing adjudicator then upholds the denial. "*If* and *when* do not a ripe controversy make." *OverDrive*, 986 F.3d at 958. Where, as here, intervening events make clear that the threat of enforcement is remote, a pre-enforcement challenge must be dismissed for lack of ripeness. *See Salvation Army v. Department of Cmty. Affairs of N.J.*, 919 F.2d 183, 192 (3d Cir. 1990) (finding suit nonjusticiable because "intervening event[s]" had "remove[d] [the] conditions" for an Article III controversy because any "real and immediate" enforcement threat had dissipated).

In addition to making abundantly clear that plaintiffs' members do not face a credible threat of enforcement, the Final Rule clarifies that the members will not suffer any hardship by waiting to raise their legal claims until the unlikely event that they ever do face an enforcement action. *See Ammex, Inc. v. Cox*, 351 F.3d 697, 706,

709-10 (6th Cir. 2003) (considering intervening event in assessing the hardship prong of ripeness, *i.e.*, the "hardship [plaintiff] incurs by waiting for enforcement" to raise its claims).

The Final Rule provides multiple layers of protection for plaintiffs' members that ensure they will not suffer from uncertainty or discomfort arising from the possibility of some future enforcement action. The Final Rule expressly states that providers "may rely on applicable Federal protections for religious freedom" like RFRA, and instructs that providers "shall not be required" to follow "particular provision(s) of this part" with respect to "specific contexts, procedures, or health care services … where such protections apply." 45 C.F.R. § 92.302(a) (89 Fed. Reg. at 37,701-02). In the preamble discussion, HHS clarified that a provider "does not violate section 1557 if it so relies" on applicable RFRA protections under § 92.302(a). 89 Fed. Reg. at 37,659. HHS further explained that "[w]hen a recipient acts based upon its good faith reliance that it is exempt from providing a particular medical service due to the application of relevant religious freedom and conscience protections (e.g., RFRA), OCR will not seek backward-looking relief against that recipient even if the recipient had not affirmatively sought assurance of an exemption under § 92.302(b)." *Id.* at 37,657. Nor do members need to experience uncertainty regarding whether they could validly invoke religious protections in the event of any potential future agency investigation: the Final Rule enables them to eliminate the uncertainty by seeking an assurance from OCR of their RFRA exemptions and a

permanent exemption from administrative investigation and enforcement, even before any investigation is initiated. 45 C.F.R. § 92.302(b), (d) (89 Fed. Reg. at 37,702).

Plaintiffs have consistently represented that their members "will follow their convictions and decline to participate in the objectionable practices." Reply Br. 16. Consistent with this concession that they have never been chilled from adhering to their religious beliefs, the Final Rule makes clear that providers with valid RFRA protections may rely on RFRA as a safe harbor for their religiously motivated conduct, and will face no repercussions for doing so in good faith.

After the Final Rule becomes effective, the Court can thus affirm the district court's dismissal of plaintiffs' action for lack of ripeness.

CONCLUSION

For the foregoing reasons, and the reasons set out in our principal brief, the judgment of the district court should be affirmed.

Respectfully submitted,

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May 2024

CERTIFICATE OF COMPLIANCE

This brief complies with this Court's May 8, 2024 order because it is no more than 25 pages in length. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ McKaye L. Neumeister
McKaye L. Neumeister

CERTIFICATE OF SERVICE

I hereby certify that on May 29, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Sixth Circuit by using the appellate CM/ECF system.

s/ McKaye L. Neumeister
McKaye L. Neumeister

Exhibit 6

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA TALLAHASSEE DIVISION

AUGUST DEKKER, legally known as KORI DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor by and through her parents and next friends, JANE DOE and JOHN DOE, and K.F., a minor, by and through his parent and next friend, JADE LADUE,

Plaintiffs,

v. Case No.: 4:22-cv-00325-RH-MAF

JASON WEIDA, in his official capacity as Secretary of the Florida Agency for Health Care Administration, and FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION,

Defendants.

_____/

JUDGMENT

This matter was tried to the court. It is adjudged:

1. It is declared that Florida Statutes § 286.31(2) and Florida Administrative Code rule 59G-1.050(7) are invalid to the extent they categorically ban Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria.

2. The defendants Jason Weida, in his official capacity, and the Florida Agency for Health Care Administration (a) must approve Medicaid payment for services rendered from this date forward for the evaluation, diagnosis, and treatment of the plaintiffs August Dekker, Brit Rothstein, Susan Doe, and K.F. for gender dysphoria, including with puberty blockers and cross-sex hormones, as recommended by their multidisciplinary teams, and (b) must not take any steps to prevent the administration of cross-sex hormones to August Dekker or Brit Rothstein or to prevent the administration of puberty blockers or cross-sex hormones to Susan Doe or K.F. But this injunction does not preclude the defendants from applying the professional standards that would apply to use of the same substances to treat patients with other medical conditions.

3. This injunction binds the defendants and their officers, agents, servants, employees, and attorneys—and others in active concert or participation with any of them—who receive actual notice of this injunction by personal service or otherwise.

4. Jurisdiction is reserved to award costs and attorney's fees.

JESSICA J LYUBLANOVITS,
CLERK OF COURT

June 22, 2023
DATE

s/ *Ronnie Barker*
DEPUTY CLERK

Exhibit 7

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO ENFORCE OR, ALTERNATIVELY, TO CLARIFY THE COURT'S JUDGMENT

In its Final Judgment, this Court "declared that Florida Statutes § 286.31(2) and Florida Administrative Code rule 59G-1.050(7) are invalid *to the extent they categorically ban* Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria." Doc.247 at 1 (emphasis added). This Court further required the Defendants to approve Medicaid coverage for the Plaintiffs' gender dysphoria treatments, "as recommended by their multidisciplinary teams." *Id.* at 2. Though Defendants have appealed this Court's Final Judgment, they have not sought a stay, and have otherwise complied with the Final Judgment. As such, there is no need for an order to enforce. Nor is there any basis for the Plaintiffs to seek clarification or expansion of the Final Judgment.

BACKGROUND

The Plaintiffs filed this case on September 7, 2022, alleging that Florida Administrative Code Rule 59G-1.050(7) unlawfully discriminated against them in violation of the Equal Protection Clause of the Fourteenth Amendment, Section 1557 of the Patient Protection and Affordable Care Act ("ACA"), and the Medicaid Act's EPSDT and Comparability Requirements. *See generally* Doc.1. After the Florida Legislature adopted § 286.31(2) of the Florida Statutes, the Plaintiffs amended their complaint to challenge the statute as well as the rule. *See* Doc.246 at 10. They never sought or obtained class certification.

On September 12, 2022, the Plaintiffs moved for a preliminary injunction. During the hearing on the motion, the Defendants advised this Court that, on a showing of exceptional circumstances under § 120.542 of the Florida Statutes, individual patients could obtain a variance or waiver from Rule 59G-1.050(7) to allow them to secure Medicaid coverage for the gender dysphoria treatments at issue. *See* Doc.62 at 92:24–94:7 (Transcript of Proceedings). In its order denying Plaintiffs' motion, this Court referred to this representation as a "basis for this order denying a preliminary injunction and will bind the defendants as the case goes forward." Doc.64 at 7.

Following a seven-day bench trial, this Court ultimately "declared that Florida Statutes § 286.31(2) and Florida Administrative Code rule 59G-1.050(7) are invalid *to the extent they categorically ban* Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria." Doc.246 at 53 (emphasis added);

Doc.247 at 1 (emphasis added). This Court further required the Defendants to "approve Medicaid payment for services rendered" "for the evaluation, diagnosis, and treatment of the plaintiffs August Dekker, Brit Rothstein, Susan Doe, and K.F. for gender dysphoria, including with puberty blockers and cross-sex hormones, as recommended by their multidisciplinary teams." Doc.246 at 53-54; Doc.247 at 2. It explained that "[t]hese plaintiffs are Medicaid beneficiaries who are entitled to payment, as a matter of medical necessity, for puberty blockers or cross-sex hormones as appropriately determined by their multidisciplinary teams of providers." Doc.246 at 53.

On June 27, 2023—within one week of the entry of the Court's Final Judgment—the Defendants sent the Plaintiffs' counsel an email explaining "how the Defendants read the injunction so that [they] may seek clarification from the District Court, if needed." **Exhibit A** (Email from M. Jazil to O. Gonzalez-Pagan). The email advised that the "Defendants will not enforce § 286.31(2)'s prohibition on 'managed care plan[s] providing services under part IV of chapter 409'" because "[t]he best and most obvious reading of this statutory provision is that it serves as a categorical ban on the use of puberty blockers and cross-sex hormones." *Id.* The email further advised that the "Defendants will enforce rule 59G-1.050(7) to bar the use of puberty blockers and cross-sex hormones unless someone submits [a petition for] and obtains a [] variance or waiver under § 120.542 of the Florida Statute[s]." *Id.* The email explained that "[b]ased on the District Court's reasoning, someone could submit a petition noting a gender dysphoria diagnosis from the type of multidisciplinary team the District Court

referenced and relied upon, and a treatment recommendation that includes puberty blockers or cross-sex hormones." *Id.* Finally, the email advised that "[t]he named Plaintiffs need not apply for a variance or waiver because the District Court conducted the necessary assessment and determined Medicaid payments for the named Plaintiffs must be approved." *Id.*[1]

Also on June 27, 2023, Secretary Weida and AHCA staff held a telephonic conference call with all ten of Statewide Medicaid Managed Care ("SMMC") health plans operating under contract with AHCA. **Exhibit B** (Declaration of Pamela Hull). During that call, Secretary Weida advised the SMMC plans that Medicaid coverage must be provided for the gender dysphoria treatments provided to each of the named Plaintiffs in this case. *Id.* And the Secretary advised the SMMC plans that other Medicaid-eligible patients could petition for a variance or waiver from Rule 59G-1.050(7) to obtain Medicaid coverage for gender dysphoria treatments. *Id.*

On October 4, 2023, the Plaintiffs filed their "Motion to Enforce the Court's Judgment or, Alternatively, to Clarify the Court's Judgment." Doc.258. The motion asks this Court to "enforce its Judgment, as well as its Findings of Fact and Conclusions of Law, by instructing Defendants that the Court's declaratory relief prevents them from

[1] As noted above, the Defendants have appealed this Court's Findings of Fact and Conclusions of Law, as well as the Final Judgment. Doc.248. The Defendants dispute the Court's rulings on Plaintiffs' substantive claims, as well as the conclusion that hormonal treatment is medically necessary to treat gender dysphoria. Nevertheless, the Defendants are acting in accordance with the Court's Final Judgment pending resolution of the appeal.

enforcing Rule 59G-1.050(7) of the Florida Administrative Code and issuing any other remedial relief it believes appropriate." *Id.* at 17. Alternatively, the "Plaintiffs request that the Court clarify its decision and order to make clear that the Rule, as adopted, is unlawful, *or grant broader injunctive relief* preventing Defendants from enforcing the Challenged Exclusion." *Id.* (emphasis added).

ARGUMENT

I. Plaintiffs' motion to enforce must be denied because Defendants are complying with the Court's Final Judgment.

The Court's Final Judgment is clear: Rule 59G-1.050(7) is invalid only "to the extent [it] categorically ban[s] Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria." Doc.247 at 1. As explained above, the Defendants are not enforcing Rule 59G-1.050(7) as a categorical ban on Medicaid coverage of hormonal treatment for gender dysphoria. Rather, the Defendants continue to respect the ability of gender dysphoria patients to seek a variance or waiver of the rule pursuant to § 120.542.

Section 120.542 is a generally applicable statute that provides for issuance of a variance or waiver of any agency rule "when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness." Fla. Stat. § 120.542(2). As this Court recognized in its Findings of Fact and Conclusions of Law, in the case of Rule 59G-1.050(7),

§ 409.905(9) of the Florida Statutes is the relevant provision being implemented; that statute requires AHCA to pay for services and procedures that are "medically necessary." *Id.*; *see also* Doc.246 at 7. Based on the logic of this Court's Final Judgment, a gender dysphoria patient may be able to obtain a variance or waiver of Rule 59G-1.050(7) if he or she demonstrates that a multidisciplinary team of providers of the type referenced by this Court has determined that hormonal treatment is medically necessary and that refusal of Medicaid coverage for such treatment would create substantial hardship under the particular circumstances at hand.

Contrary to the Plaintiffs' assertion, the variance and waiver process is not a "red herring." Doc.258 at 15. It is a statutorily prescribed right for any substantially affected person to seek relief from an agency rule. Any agency decision made in response to a petition for variance or waiver is subject to administrative and judicial review under Florida's Administrative Procedure Act. *See* Fla. Stat. §§ 120.569 and 120.57 (administrative review); and § 120.68 (judicial review). True, no variance or waiver of Rule 59G-1.050(7) has been granted to date. Crucially, however, no petition for variance or waiver from Rule 59G-1.050(7) has been submitted; AHCA cannot consider, review, or act on a petition unless or until it is actually submitted. **Exhibit B** (Declaration of Pamela Hull).

Given the continued ability of Medicaid-eligible gender dysphoria patients to petition for a variance or waiver on a case-by-case basis, the Defendants are not enforcing Rule 59G-1.050(7) as a categorical ban on Medicaid coverage for hormonal

treatments for gender dysphoria. It follows that there is no need for an order to enforce the Court's Final Judgment.

II. Plaintiffs' alternative motion must be denied because the alternative relief sought by Plaintiffs is improper, untimely, and jurisdictionally unavailable.

In accordance with the Court's Final Judgment, the Plaintiffs have obtained the relief they sought—Medicaid coverage for the costs of their hormonal treatments for gender dysphoria. Doc.246 at 53-54; Doc.247 at 2. That cannot be disputed. Yet the Plaintiffs now improperly seek to have the Court "clarify[] the scope of its declaratory relief" "to make clear that Defendants cannot enforce the Challenged Exclusion against anyone." Doc.258 at 17.

The Plaintiffs have not cited and cannot cite any authority entitling them to such relief on behalf of nonparties. To the contrary, the Eleventh Circuit has long held that, "in a suit brought in the plaintiff's individual capacity, injunctive relief benefiting nonparties is not required if it in no way relates to the vindication of the plaintiff's rights." *Dybczak v. Tuskegee Institute*, 737 F.2d 1524, 1527 (11th Cir. 1984). Here, the requested relief does not in any way relate to the vindication of the Plaintiffs' rights. Those rights have already been vindicated. The alternative motion to clarify should be denied for this reason alone.

Additionally, Plaintiffs' alternative motion for the Court to "expand[] the scope of its injunctive relief" or "grant broader injunctive relief" should be denied as time-barred by Federal Rule of Civil Procedure 59(e). Doc.258 at 1-2, 17-19. Rule 59(e)

expressly provides that "[a] motion to alter or amend a judgment must be filed no later than 28 days after the entry of the judgment." Federal courts "may not extend the time to file a Rule 59(e) motion." *Green v. DEA*, 606 F.3d 1296, 1300 (11th Cir. 2010); *see also* Fed. R. Civ. P. 6(b)(2). But that is precisely what Plaintiffs' alternative motion requests the Court to do—to reopen its June 22, 2023 Final Judgment and alter or amend it long after the deadline to file a Rule 59(e) motion expired on July 20, 2023.

Plaintiffs' alternative motion to expand the scope of injunctive relief or grant broader injunctive relief should be denied for an additional reason: the Court lacks jurisdiction to alter or amend its Final Judgment during the pendency of the appeal therefrom. "In general, [the] filing of a notice of appeal confers jurisdiction on the court of appeals and divests the district court of control over those aspects of the case involved in the appeal." *Marrese v. Am. Acad. of Orthopaedic Surgeons*, 470 U.S. 373, 379 (1985) (citing *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982)); *accord Coinbase, Inc. v. Bielski*, 143 S. Ct. 1915, 1919 (2023). An exception exists where a timely Rule 59(e) motion is filed (either before or after the filing of a notice of appeal). *See* Fed. R. App. P. 4(a). That is because Appellate "Rule 4(a) was specifically amended in response to *Griggs* and now provides that a notice of appeal filed during the pendency of a [timely] Rule 59 motion is simply suspended," thus allowing a "district court [to] retain[] jurisdiction to consider the [timely] Rule 59 Motion." *Stansell v. Revolutionary Armed Forces of Columbia*, 771 F.3d 713, 745-46 (11th Cir. 2014).

Here, the State's notice of appeal "is an event of jurisdictional significance." *Griggs*, 459 U.S. at 58. Because the time to file a Rule 59(e) motion has expired, the notice of appeal has "divest[ed]" the Court of jurisdiction to alter or amend its Final Judgment. *See, e.g.*, *Griggs*, 459 U.S. at 58; *cf. Cornea v. United States AG*, No. 18-13694-DD, 2018 U.S. App. LEXIS 34707, at *2 (11th Cir. Dec. 10, 2018) (district court retained jurisdiction to consider a Rule 59(e) motion that was filed within 28 days of a judgment under Appellate Rule 4(a)).

CONCLUSION

Because the Defendants are not enforcing Rule 59G-1.050(7) as a categorical ban on Medicaid coverage for hormonal treatments for gender dysphoria, there is no need for an order to enforce this Court's Final Judgment. Nor is there a basis for the Plaintiffs to seek clarification of the Court's Final Judgment or expansion of its injunctive relief. The Plaintiffs' motion should be denied.

Respectfully submitted,

/s/ Mohammad O. Jazil
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LOCAL RULE CERTIFICATIONS

The undersigned certifies that this memorandum contains 2,125 words, excluding the case style and certifications.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

CERTIFICATE OF SERVICE

I certify that on October 18, 2023, I electronically filed the foregoing with the Clerk of Court by using CM/ECF, which automatically serves all counsel of record for the parties who have appeared.

/s/ Mohammad O. Jazil
Mohammad O. Jazil

From: Mohammad O. Jazil
To: Omar Gonzalez-Pagan; Gary V. Perko; Michael Beato; Sheeran, Andrew
Cc: Katy DeBriere; Abigail Coursolle; Simone Chriss; Chelsea Dunn; Altman, Jennifer; Rivaux, Shani; Miller, William C.; Shaw, Gary J.; Little, Joe
Subject: Dekker v. Weida - Communication Post Ruling
Date: Tuesday, June 27, 2023 4:03:32 PM
Attachments: image905542.png
image947291.png
image047364.png
image782702.png

Good afternoon, counsel,

As you know, yesterday, the Defendants appealed the District Court's Findings of Fact and Conclusions of Law, as well as the Judgment.

The District Court "declared that Florida Statutes § 286.31(2) and Florida Administrative Code rule 59G-1.050(7) are invalid to the extent they categorically ban Medicaid payment for puberty blockers and cross-sex hormones for the treatment of gender dysphoria." Doc.246 at 53. The District Court then required the Defendants to "approve Medicaid payment for services rendered" "for the evaluation, diagnosis, and treatment of the plaintiffs August Dekker, Brit Rothstein, Susan Doe, and K.F. for gender dysphoria, including with puberty blockers and cross-sex hormones, as recommended by their multidisciplinary teams." *Id.*

Defendants will, of course, comply with the District Court's injunction. I write to you now to better explain how the Defendants read the injunction so that you may seek clarification from the District Court, if needed.

First, Defendants will not enforce § 286.31(2)'s prohibition on "managed care plan[s] providing services under part IV of chapter 409." The best and most obvious reading of this statutory provision is that it serves as a categorical ban on the use of puberty blockers and cross-sex hormones. Consistent with the District Court's direction, Defendants will not enforce it until or unless a higher court says otherwise.

Second, however, Defendants will enforce rule 59G-1.050(7) to bar the use of puberty blockers and cross-sex hormones unless someone submits and obtains a petition for variance or waiver under § 120.542 of the Florida Statute. As you know, the Defendants have consistently maintained that the rule is *not* a categorical ban. *See* Doc.64 at 6-7 (recognizing same). Based on the District Court's reasoning, someone could submit a petition noting a gender dysphoria diagnosis from the type of multidisciplinary team the District Court referenced and relied upon, and a treatment recommendation that includes puberty blockers or cross-sex hormones. The named Plaintiffs need not apply for a variance or waiver because the District Court conducted the necessary assessment and determined Medicaid payments for the named Plaintiffs must be approved.

Many thanks,
Mo

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email **bio** **in**

Holtzman Vogel
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Exhibit A

PRIVILEGED AND CONFIDENTIAL

This communication and any accompanying documents are confidential and privileged. They are intended for the sole use of the addressee. If you receive this transmission in error, you are advised that any disclosure, copying, distribution, or the taking of any action in reliance upon this communication is strictly prohibited. Moreover, any such disclosure shall not compromise or waive the attorney-client, accountant-client, or other privileges as to this communication or otherwise. If you have received this communication in error, please contact me at the above email address. Thank you.

DISCLAIMER

Any accounting, business or tax advice contained in this communication, including attachments and enclosures, is not intended as a thorough, in-depth analysis of specific issues, nor a substitute for a formal opinion, nor is it sufficient to avoid tax-related penalties. If desired, Holtzman Vogel Baran Torchinsky & Josefiak PLLC would be pleased to perform the requisite research and provide you with a detailed written analysis. Such an engagement may be the subject of a separate engagement letter that would define the scope and limits of the desired consultation services.

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

DECLARATION OF PAMELA HULL

I, Pamela Hull, hereby declare and state as follows:

1. I am over the age of 18, of sound mind, and in all respects competent to testify. I have personal knowledge of the information contained in this Declaration and would testify completely to those facts if called to do so.

2. I am employed by the Florida Agency for Healthcare Administration as the Agency's Assistant Deputy Secretary for Medicaid Operations. In this capacity, I oversee the operational aspects of Florida's Medicaid Program which includes the Bureaus of Plan Management Operations and Recipient and Provider Assistance.

3. On June 27, 2023, I participated in the telephonic conference with Secretary Jason Weida and representatives of all of the ten Statewide Medicaid Managed Care ("SMMC") health plans operating under contract with the Agency, including:

- Aetna

- AmeriHealth
- Children's Medical Services Plan
- Community Care Plan
- Florida Community Care
- Humana
- Molina
- Simply
- Sunshine
- United

The CEO or Plan President and one other staff member for each Plan participated in the call.

4. One of the purposes of the call on June 27, 2023, was to inform the Plans of the implications of the Court's Final Judgment in this case. During the call, Secretary Weida advised the Plans that Medicaid coverage must be provided for the gender dysphoria treatments provided to each of the named Plaintiffs in this case. The Secretary also advised the Plans that other Medicaid-eligible patients could petition for a variance or waiver from Florida Administrative Code Rule 59G-1.050(7) to obtain Medicaid coverage for gender dysphoria treatments.

5. To date, no petition for variance or waiver from Rule 59G-1.050(7) has been submitted. AHCA cannot consider, review, or act on a petition unless or until it is actually submitted.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 18th day of October 2023.

/s/ Pamela Hull
Pamela Hull

Exhibit 8

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

McComb Children's Clinic, LTD., a Mississippi Corporation, *Plaintiff*, 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 Director of the Office for Civil Rights of the United States Department of Health and Human Services; and **Office for Civil Rights of the United States Department of Health and Human Services**, *Defendants*.	)	**Case No.** 5:24-cv-48-KS-LGI

COMPLAINT
JURY TRIAL DEMANDED

INTRODUCTION

1. A new final regulation from the U.S. Department of Health and Human Services (HHS) under Section 1557 of the Affordable Care Act forces medical clinics to perform or facilitate body-altering "gender-transition" procedures. The rule also forces clinics to speak in support of gender-transition efforts and to assure the government of their compliance with this mandate. These radical changes will completely upend the practice of medicine. The Biden administration is

working to force doctors to do harm by performing harmful, sterilizing procedures to make people appear as the opposite sex.

2. The rule violates the Administrative Procedure Act, the freedom of speech, and other constitutional doctrines.

3. Congress did not authorize the rule. The rule purports to implement the sex-discrimination prohibition in Section 1557 of the Affordable Care Act, but there is no gender-transition mandate in that statute, nor in Title IX of the Education Amendments of 1972 from which it is derived.

4. If medical clinics such as Plaintiff McComb Children's Clinic, LTD. (MCC) do not change their policies and comply with the rule, HHS can punish them with huge financial penalties and exclude them from treating patients paid through federally funded programs like Medicaid or the Children's Health Insurance Program (CHIP). This would effectively prevent them from treating the most vulnerable children in Mississippi unless they ascribe to the radical gender ideology imposed by the president and his bureaucrats in Washington, D.C.

5. Thus MCC seeks judicial relief to shield its medical practice—and its patients—from HHS's illegal and harmful rule.

6. The Court should enjoin Defendants' enforcement of the rule preliminarily and permanently, declare and hold it to be unlawful, and set it aside, under the Administrative Procedure Act (APA), the Declaratory Judgment Act, and the First Amendment.

JURISDICTION AND VENUE

7. This case seeks declaratory, injunctive, and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02; the APA, 5 U.S.C. § 701–06; and Federal Rule of Civil Procedure 57.

8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.

9. This Court has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

10. This Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

11. This Court has inherent jurisdiction to review and enjoin ultra vires or unconstitutional agency action under an equitable cause of action. *See Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

12. The APA provides jurisdiction and a cause of action to review Defendants' actions and enter appropriate relief. 5 U.S.C. §§ 553, 701–06.

13. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

14. Venue is proper in this Court and this division under 28 U.S.C. § 1391, including paragraph (e).

15. Defendants are agencies of the United States, and officers and employees of the United States or of any agency thereof acting in their official capacity or under color of legal authority.

16. The Plaintiff McComb Children's Clinic, LTD. (MCC) resides at 309 Llewellyn Avenue, McComb, Mississippi, in the Western Division of the Southern District of Mississippi, and no real property interest is involved in the action.

17. A substantial part of the events or omissions giving rise to the claims occurred in this district, because the case concerns the impact of Defendants' regulation on MCC and its operations in this division of this district.

PARTIES

Plaintiff

18. Plaintiff McComb Children's Clinic, LTD. (MCC) is a Mississippi corporation located at 309 Llewellyn Avenue, McComb, Mississippi 39649.

19. MCC is a for-profit corporation founded in 1973 and incorporated in the State of Mississippi. Its registered agent is in McComb, Mississippi.

20. MCC's primary purpose is to provide healthcare.

21. MCC provides medical care in health programs and activities receiving federal financial assistance from HHS under Section 1557 of the Affordable Care Act (ACA), 42 U.S.C. § 18116.

22. Additional facts about MCC are set forth in the declaration of its president attached as Exhibit 1.

Defendants

23. Defendant Xavier Becerra is sued in his official capacity as Secretary of the United States Department of Health and Human Services. His address is 200 Independence Avenue SW, Washington, DC 20201.

24. Secretary Becerra is responsible for the overall operations of HHS, including the Department's administration of Section 1557 and the rule.

25. Defendant United States Department of Health and Human Services (HHS) is a federal cabinet agency within the executive branch of the United States government and is an agency under 5 U.S.C. §§ 551 and 701(b)(1). HHS's address is 200 Independence Avenue SW, Washington, DC 20201.

26. HHS is responsible for implementing and enforcing Section 1557 and the rule.

27. Defendant Melanie Fontes Rainer is sued in her official capacity as the Director of the Office for Civil Rights (OCR) at HHS. Her address is 200 Independence Avenue SW, Washington, DC 20201.

28. Defendant Rainer is responsible for enforcing Section 1557 and the rule.

29. Defendant the Office for Civil Rights is a division of the United States Department of Health and Human Services and is an agency under 5 U.S.C. § 551 and 701(b)(1). OCR's address is 200 Independence Avenue SW, Washington, DC 20201.

30. OCR is responsible for implementing and enforcing Section 1557 and the rule.

BACKGROUND

I. Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972

31. On May 6, 2024, HHS issued a new regulation implementing Section 1557 of the Affordable Care Act. "Nondiscrimination in Health Programs and Activities," 89 Fed. Reg. 37,522 ("the 1557 rule" or "the rule").

32. Section 1557 of the ACA states:

> Except as otherwise provided for in this title (or an amendment made by this title), *an individual shall not, on the ground prohibited under* title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), *title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.),* the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), or section 794 of title 29 [commonly known as Section 504 of the Rehabilitation Act], *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, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments). The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of this subsection.

42 U.S.C. § 18116(a) (emphasis added).

33. Section 1557 prohibits discrimination on the basis of sex to the extent such discrimination is prohibited by Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 et seq. (Title IX).

34. Under Title IX's sex discrimination provision, "no person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681.

35. Sex is a term that refers to whether a person is male or female according to biology.

36. Sex discrimination is forbidden under Title IX, its regulations, and longstanding guidance.

37. Title IX, its regulations, and longstanding guidance require education programs to provide females, as such, with equal opportunities.

38. In many cases, such as in sports with physical contact, these opportunities must be specific to sex.

39. Title IX, its regulations, and longstanding guidance do not mention or forbid discrimination based on "gender identity."

40. The ACA does not mention gender identity.

41. The ACA refers to sex and the sexes with biologically binary language.

42. The ACA acknowledges that medical practice is biological and is tailored to advance health according to biological distinctions between the male and female sexes.

43. The ACA cannot be construed legitimately to require clinics to practice medicine as if males are females or vice versa.

44. The ACA cannot be construed legitimately to require entities covered by Section 1557 to provide, facilitate, or speak in favor of "gender transitions."

45. 42 U.S.C. § 18116 does not authorize HHS to issue a rule implementing Section 1557 to require performing or promoting "gender transitions."

II. Section 1557's breadth and scope

46. Section 1557 applies to what HHS calls "covered entities," which are recipients of federal financial assistance from HHS or through the ACA.

47. These recipients of federal financial assistance include clinics, hospitals, and doctors that accept patients paying through Medicare, Medicaid, and CHIP.

48. Section 1557 applies to virtually every healthcare entity in America.

49. Through Medicare, Medicaid, and CHIP, the federal government is the single largest source of spending on healthcare—providing 33% of all U.S. health spending in 2022.[1]

50. Medicare is a federal health insurance program for people over 65 or who have certain disabilities or conditions. Medicare accounts for 21% of total health spending in the United States—over $1 out of every $5 spent.[2]

51. This year, in 2024, 98% of providers participate in Medicare.[3]

52. Medicaid is a joint federal and state health insurance program for people with limited incomes. Medicaid provides $1 out of every $6 spent nationally

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[1] Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *National Health Expenditures 2022 Highlights* 3, https://www.cms.gov/files/document/highlights.pdf (last modified Dec. 13, 2023).

[2] CMS, HHS, *National Health Expenditures*, *supra* note 1.

[3] Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *Annual Medicare Participation Announcement* 1–2, https://www.cms.gov/files/document/medicare-participation-announcement.pdf (last modified Nov. 17, 2023).

on healthcare. Seventy-four percent of all healthcare providers accept new Medicaid patients, including 81.7 percent of OB/GYNS and 84.7 percent of pediatricians.[4]

53. Medicaid is the largest source of federal revenues for state budgets, accounting for about 45% of all state expenditures from federal funds in SFY 2021 and accounting for about 27% of total state spending for all items in state budgets.[5]

54. CHIP is a joint federal and state health insurance program for certain children who do not qualify for Medicaid. In some states, CHIP covers pregnant women. More than 88 million people, including nearly 40 million children, are enrolled in Medicaid and CHIP coverage.[6]

55. In 2023, federal spending on Medicare made up 13% of net federal outlays, and federal spending on Medicaid and CHIP made up 10% of net federal outlays.[7]

56. An entity that "any part of which" participates in HHS financial assistance programs is subject *in all aspects* to Section 1557. All of the operations of the covered entity are covered—not merely that part of the covered entity that receives the funding. That means that any hospital or doctors' office that accepts a single Medicare, Medicaid, or CHIP patient must follow Section 1557's policies for *all* its patients, no matter how other patients pay for care.

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[4] Medicaid & CHIP Payment & Access Comm'n, *Physician Acceptance of New Medicaid Patients* 3–4 (June 2021), https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf.

[5] Elizabeth Williams et al., *Medicaid Financing: The Basics*, KFF, (Apr. 13, 2023), https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics/.

[6] Press Release, HHS, New State by State Analysis on Impact of CMS Strategies for States to Protect Children and Youth Medicaid and CHIP Enrollment (Dec. 18, 2023), https://www.hhs.gov/about/news/2023/12/18/new-state-by-state-analysis-on-impact-cms-strategies-for-states-protect-children-youth-medicaid-chip-enrollment.html (providing state-by-state figures).

[7] Williams et al., *Medicaid Financing: The Basics*, *supra* note 5.

III. Section 1557's enforcement mechanisms

57. 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).

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

59. Under this authority, OCR or the Attorney General may investigate the entity and demand the production of the entity's internal information. 18 U.S.C. § 3486; 45 C.F.R. §§ 80.6–80.11; 45 C.F.R. Pt. 81; 45 C.F.R. § 92.5.

60. Entities must provide this information or they arguably face criminal liability. 18 U.S.C. §§ 1516, 1518.

61. Criminal penalties also arguably apply to covered entities that receive federal funding but do not comply with Section 1557 or HHS's implementing regulations, including under federal criminal healthcare-fraud or false-claim statutes. 18 U.S.C. §§ 287, 1001, 1035, 1347; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c).

62. Violators arguably may, and after certain criminal convictions must, be excluded by HHS from future eligibility for federal healthcare funding. 42 U.S.C. §§ 1320a-7, 1320c-5.

63. Violators of Section 1557 or HHS's implementing regulations may arguably be subject to federal civil false-claims liability, including civil penalties, treble damages, and the possibility of "up to five years' imprisonment," 18 U.S.C. § 1001, and civil penalties up to $10,000 per false claim, adjusted for inflation, plus treble damages, 31 U.S.C. § 3729(a)(1).

64. The public may file with OCR complaints about healthcare entities that they believe are not complying with Section 1557, Title IX, or HHS's implementing regulations.[8]

65. OCR will accept and investigate complaints filed under the 1557 rule.

66. Multiple courts have interpreted Section 1557 to allow members of the public to sue covered entities to require compliance.

IV. President Biden's direction to add gender identity to Section 1557 and Title IX

67. The 1557 rule was issued at the President's direction.

68. Upon taking office, President Biden signed an executive order directing federal agencies to interpret Section 1557 and Title IX to prohibit gender-identity discrimination.[9]

69. Since then, federal agencies have been implementing a whole-of-government agenda to redefine "sex" discrimination to prohibit gender-identity discrimination.

70. Secretary Becerra described disagreements with his gender-identity position as "the hateful and harmful beliefs of a narrow-minded few."[10]

71. The 1557 rule, in prohibiting discrimination on the basis of "gender identity" is part of government-wide efforts by the White House.

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[8] *See, e.g.*, *How to File a Civil Rights Complaint*, U.S. Dep't of Health & Human Servs., Office for Civil Rights, https://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html (last visited May 6, 2024).

[9] Exec. Order No. 13,988, Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation, 86 Fed. Reg. 7023 (Jan. 20, 2021); Exec. Order No. 14021, Guaranteeing an Educational Environment Free From Discrimination on the Basis of Sex, Including Sexual Orientation or Gender Identity, 86 Fed. Reg. 13,803 (Mar. 8, 2021).

[10] Press Release, HHS, Statements by HHS Secretary Xavier Becerra and HHS Principals on Pride Month (June 1, 2023), https://www.hhs.gov/about/news/2023/06/01/statements-by-hhs-secretary-xavier-becerra-hhs-principals-pride-month.html.

V. The rule's gender-identity mandate

72. Under the rule, "[d]iscrimination on the basis of sex includes, but is not limited to, discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity," as well as "marital, parental, or family status," and it also includes discrimination against an individual on the basis of the sex "of the individual and another person with whom the individual has a relationship or association." 89 Fed. Reg. at 37,698–99, 37,701 (codified at 45 C.F.R. §§ 92.101(a)(2), 92.208, 92.209)).

73. The rule treats these bases of liability as overlapping ways in which Section 1557 and Title IX address gender identity.

74. For example, the rule directly defines "gender-identity" discrimination to be sex discrimination, but the rule separately defines "sex stereotypes" discrimination to be sex discrimination, and the rule considers "sex stereotypes" discrimination to encompass gender-identity discrimination.

75. The rule provides for discriminatory-intent liability, disparate-impact liability, hostile-environment liability, harassment liability, and other theories of liability on all of these bases.

76. Likewise, Section 1557 addresses disability discrimination under Section 504 of the Rehabilitation Act, but the rule references regulations that deem gender dysphoria a "disability" that can trigger the same gender-identity mandate.

77. One way or another, OCR insists using the rule to consider covered healthcare entities not to have complied with Section 1557 and not to have provided "equal access" to health programs "without discriminating on the basis of sex" or disability unless the providers do not exclude, deny benefits, or "discriminate" against individuals on the basis of gender identity. 89 Fed. Reg. at 37,698–701 (codified at 45 C.F.R. §§ 92.101(a), 92.206(a), 92.208–98.211).

78. Consequently, to the extent this Complaint refers to, or asks the Court to issue relief concerning, the rule and Defendants' actions thereunder prohibiting discrimination on the basis of gender identity, MCC intends to encompass any language or alternative theory in the rule that Defendants may use to achieve those same ends.

79. The rule considers it discriminatory to deny or limit health services, including those that are offered exclusively to individuals of one sex, to an individual based on the individual's sex assigned at birth, gender identity, or gender otherwise recorded.

80. The rule considers it discriminatory to deny or limit a healthcare entity's ability to provide health services on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity.

81. The rule considers it discriminatory to adopt a policy or engage in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity.

82. The rule considers it discriminatory to deny or limit health services sought for the purpose of "gender transition" or other "gender-affirming care" that the covered entity would provide to an individual for other purposes if the denial or limitation is based on a patient's sex assigned at birth, gender identity, or gender otherwise recorded.

A. Forcing healthcare entities to perform "gender-transition" procedures

83. The rule forces healthcare entities to perform "gender-transition" procedures.

84. "Gender-transition" procedures are drugs or interventions that block a person's natural development as a person of one sex, such as puberty-blocking drugs, cross-sex hormones, and body-altering surgeries.

85. The rule considers it discrimination if a covered entity provides a particular health service but will not provide that health service for gender transitions or to affirm gender transitions.

86. If a healthcare entity is willing to prescribe puberty blockers for therapeutic reasons related to early onset of puberty, the rule requires such an entity to also prescribe those hormones when requested by a patient to help achieve or continue a "gender transition."

87. If a healthcare entity is willing to perform a mastectomy for therapeutic reasons, such as those related to cancer, the rule requires such an entity to also perform mastectomies on women and girls to help achieve or continue a "gender transition."

88. If a healthcare entity is willing to perform a hysterectomy on a woman with a cancerous uterus, the rule requires it to perform a hysterectomy on a woman with a healthy uterus if she identifies as a man and seeks the procedure for "gender-transition" purposes.

89. By requiring healthcare entities to provide health services that have the purpose or effect of causing, assisting, or affirming "gender transition," the rule creates a new government-mandated standard of care.

90. Where the rule requires healthcare entities to provide health services with the purpose or effect of causing, assisting, or affirming "gender transition," those entities must comply with the rule even if doing so violates state law, medical ethics, or the entity's own policies.

91. By "gender-affirming care" HHS means care for "transgender" individuals (including those who identify using other terms, for example,

"nonbinary" or "gender nonconforming") that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to support gender-transition efforts.

92. Under the rule, healthcare providers must provide or refer for "gender-affirming care" unless they have a reason that the rule considers legitimate and nondiscriminatory for denying or limiting the requested service, including where the covered entity typically declines to provide the health service to any individual, or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual.

93. Under the rule, a healthcare entity's position that procedures for "gender transition" are categorically never beneficial for individuals is *not* a sufficient basis for declining to provide that service, if it is a service they will provide when it does not have the purpose or effect of causing, assisting, or affirming "gender transition."

94. Under the rule, if MCC declines to provide a procedure for "gender transition" to a minor because doing so is prohibited by Mississippi's "Regulate Experimental Adolescent Procedures (REAP) Act," House Bill 1125 (2023), that reason will not protect MCC from liability for violating the rule.

95. It is no defense to liability under the rule that in a healthcare entity's medical judgment, removing a healthy organ for "gender-transition" purposes is never clinically indicated or beneficial.

96. It is no defense to liability under the rule that a healthcare entity considers "gender-transition" efforts categorically experimental or cosmetic.

B. Forcing healthcare entities to change their speech to conform to HHS's gender ideology

97. The rules forces healthcare entities to lie to their patients.

98. The rule considers it discrimination for a covered entity to speak to patients in a way that categorically excludes the legitimacy of "gender transition."

99. The rule considers it discrimination for a covered entity to speak using a patient's pronouns that align with his or her sex according to the patient's biology if the patient prefers different pronouns that correspond to his or her gender identity.

100. The rule considers it to create a hostile environment for patients in violation of the rule if a healthcare entity and its staff speak in ways that categorically deny the medical legitimacy of gender transitions.

101. Under the rule, covered entities cannot tell their patients that in their best medical opinions, transition efforts or procedures are categorically experimental and dangerous.

102. Under the rule, covered entities cannot speak or act toward their patients on the view that transition efforts or procedures are categorically harmful.

103. Under the rule, covered entities may not raise categorical objections about transition efforts or procedures based on detransitioners' regret over these efforts.

104. Under the rule, covered entities may not raise categorical objections about "gender-transition" efforts based on their view of the harms of puberty-blocking drugs, cross-sex hormones, surgeries, and other procedures.

105. The rule forces covered entities to give patients the impression that "gender-transition" efforts can in some cases be clinically indicated or beneficial.

106. Under the rule, if a patient identifies with a gender different from his or her sex, covered entities must refer to that patient by pronouns the patient prefers corresponding to that patient's perceived gender and not by pronouns corresponding to that patient's sex.

107. Under the rule, if a patient identifies with a gender different from his or her sex, covered entities may not use biologically correct pronouns to refer to the patient.

108. Under the rule, if a patient identifies with a gender different from his or her sex, covered entities may not omit the use of pronouns concerning that patient based on the doctor's disagreement with using biologically inaccurate pronouns.

109. Under the rule, covered entities must tell patients that males can get pregnant, give birth, and breastfeed.

110. Under the rule, covered entities must not tell patients that males categorically cannot get pregnant, give birth, and breastfeed.

111. Under the rule, if covered entities provide patients with written materials stating any of the things the rule considers discriminatory, that would violate the rule and could also constitute discrimination.

C. Putting males into female private spaces

112. The rule forces females to share private spaces with males when the male identifies as female or non-binary.

113. When a male identifies as female or non-binary, covered entities must designate males to female private spaces or programs, such as sex-specific hospital rooms, lactation rooms, lactation training, exam rooms, restrooms, shared showers, and pregnancy-related educational sessions.

114. Under the rule, a hospital that assigns patients to dual-occupancy rooms based on sex would be forced to allow a man who identifies as a woman to share a room with a woman who identifies as a woman.

115. The hospital would not be allowed to assign rooms on the basis of sex according to biology.

116. Under the rule, healthcare providers will not be able to honor patient requests for a healthcare provider or chaperone of a particular sex in cases where a provider, chaperone, or patient identifies contrary to his or her sex.

117. Because the rule requires covered entities to allow access to sex-specific programs or facilities according to a person's asserted gender identity, the rule forbids sex-specific programs or facilities based on biology.

D. Requiring policies, certifications, and assurances

118. The rule requires healthcare entities to agree to comply with the rule, submit assurances or certifications of compliance, adopt policies ensuring compliance by and within the entity, notify patients of compliance, and train staff to comply.

119. Under the rule, as a condition of MCC continuing to treat patients covered by programs such as CHIP and Medicaid, MCC must begin now to repeal existing policy, adopt new policy, make assurances to the government, give notices to patients, and train staff in order to comply with the rule's requirements to provide "gender-transition" procedures and to not speak in categorical criticism or exclusion of such procedures.

VI. The rule's immediate compliance requirements

120. The rule's prohibition on discrimination on the basis of gender identity goes into effect on July 5, 2024.

A. New policies, notices, assurances of compliance, and certifications

121. The rule prohibits covered entities from having or applying policies contrary to the rule.

122. The rule requires covered entities to adopt and publish policies that comply with the rule.

123. The rule requires covered entities to have policies consistent with the rule and to state in their policies that they will not discriminate on the basis of sex or disability, which the rule defines to mean gender identity.

124. The rule requires covered entities to provide an updated notice of nondiscrimination to patients consistent with stating that they will not discriminate on the basis of gender identity.

125. The notice to patients must be provided annually and on request.

126. The notice must be posted at a conspicuous location on the covered entity's health program or activity website and in clear and prominent physical locations where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

127. The rule prohibits covered entities from stating to patients that they will engage in actions or omissions inconsistent with the rule's prohibitions on discrimination on the basis of gender identity.

128. The rule requires covered entities to train or reeducate themselves and their employees to comply.

129. Under the rule, covered entities must contemporaneously document their employees' completion of the training and maintain that documentation for at least three calendar years.

130. Under the rule, covered entities must submit an assurance of compliance to HHS that they have adopted the rule's new policies as a contractual condition of receipt of federal funding, or else they will be unable to apply or maintain eligibility for federal funding.

131. Under the assurance, covered entities must agree to comply with the rule, including the prohibition on discrimination on the basis of gender identity.

132. This assurance must be submitted by clinics seeking to receive any federal health funding from HHS, including to receive Medicaid or CHIP certification.

133. Assurance of compliance submitted by clinics prior to issuance of the rule, including assurances made by clinics for Medicaid or CHIP certification, will now be read by HHS to encompass a contractual assurance that MCC will comply with the rule.

134. Every time a covered entity requests a federal health funding payment from HHS it impliedly certifies to the federal government that it follows governing regulations, and the rule imports the prohibition on gender-identity discrimination into those implied certifications.

135. Covered entities unwilling to agree to make such an assurance or certification of compliance cannot apply for or maintain eligibility for federal health funding from HHS.

136. Each required assurance or certification that an entity makes to receive federal health funding from HHS will create or extend contractual obligations requiring the covered entity to comply with the rule.

137. Under the rule, a covered entity that employs 15 or more people must appoint a "Section 1557 Coordinator" in charge of compliance with the rule, must implement written grievance procedures for receiving and resolving allegations of any action that the rule would prohibit, must keep all grievances for three years, and must not disclose the identity of any person who files a grievance against the entity.

B. The rule's creation of new liability risks

138. The rule creates new risks that covered entities could lose federal funding or face criminal and civil liability.

139. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations risks the burdens and costs of federal investigations and enforcement proceedings.

140. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations risks disallowance, exclusion, suspension, and debarment from receipt of federal funding.

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

142. Litigants may arguably cite the rule as a binding interpretation of Section 1557 under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

143. Failure to follow the rule and its interpretation of Section 1557, Title IX, and HHS regulations arguably risks civil and criminal liability under federal healthcare-fraud and false-claims statutes and regulations.

144. The rule creates these arguable healthcare-fraud and false-claims liability risks because the rule requires covered entities to operate their practices in accord with the rule and to sign assurances of compliance as a contractual condition of receiving funds.

145. The False Claims Act, for example, makes a person liable for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

146. A "claim" means "any request or demand, whether under a contract or otherwise, for money or property" presented to an officer of the United States or a recipient of federal funding (like a state administering its state Medicaid program). 31 U.S.C. § 3729(b)(2)(A).

147. Under these laws, covered entities must ensure that they are presenting accurate and appropriate claims, such as when covered entities seek payment for providing healthcare to Medicaid patients.

148. As HHS warns physicians, "When you submit a claim for services performed for a Medicare or Medicaid beneficiary, you are filing a bill with the Federal Government and certifying that you have earned the payment requested and complied with the billing requirements."[11]

149. A covered entity is arguably liable for express or implied false certifications when a provider submits a claim for payment but does not or intends not to comply with the rule's gender-identity nondiscrimination requirement, or fails to disclose such noncompliance.

150. Such a covered entity arguably incurs this liability each time it submits a claim for federal payment or accepts federal financial assistance.

151. HHS considers compliance with the rule and its interpretation of Section 1557, Title IX, and HHS regulations material in its payment decisions.

152. HHS is substantially likely to deem a provider's request for payment misleading if the provider is not in compliance with the rule and its interpretation of Section 1557 and its implementing regulations.

VII. McComb Children's Clinic's injuries from the rule

153. MCC has an urgent need for judicial relief to shield its medical practice and its patients from HHS's harmful rule.

154. MCC is a pediatrics practice, and provides high-quality medical services to children without discrimination on the basis of sex or any other characteristic prohibited by statute.

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[11] *Physician Relationships With Payers*, Office of Inspector General, HHS, https://oig.hhs.gov/compliance/physician-education/i-physician-relationships-with-payers/ (last visited May 6, 2024) (emphasis omitted).

155. MCC's position is that a child with medical needs, such as a broken bone, an infection, or cancer, should be given the best medical care possible, regardless of his or her identity. But medical professionals cannot harm patients, nor can they lie to them.

156. Based on MCC's view of medical science and ethical medical practice, it categorically does not provide medical interventions or referrals for, and does not facilitate or speak in ways that affirm the legitimacy of, the practice of "gender transition."

157. MCC is committed to following state law, which restricts gender-transition interventions for minors.

158. MCC also cares for and welcomes each patient in its health programs and facilities based on the patient's sex as a biological male or female.

159. MCC communicates these policies and positions to its patients, including on its website.

160. The scope of MCC's pediatrics practice triggers the rule's gender-identity mandate.

161. MCC offers a full array of services to help children maintain good health.

162. These services include, but are not limited to, well-child care exams, sports physicals, newborn care, vision and hearing screenings, immunizations, sick child diagnosis and treatment, dietary and nutrition guidance, lab testing, and prescription of medication.

163. MCC treats or refers some patients for puberty blockers or sex hormones for sound medical and therapeutic reasons, such as labial adhesions, cases of precocious puberty, or pituitary failure that prevented naturally occurring puberty.

164. MCC opposes providing, referring for, facilitating, or speaking in favor of similar services for "gender-transition" interventions.

165. A doctor at MCC has encountered a patient identifying as transgender and engaging in "social transition" and has had to interact with the patient in ways that the rule would regulate.

166. MCC uses pronouns for patients that accord with the patients' sex according to biology (male or female). MCC codes and charts patients by sex.

167. MCC categorically opposes asking for its patients' gender identity, or charting or coding them according to their gender identity instead of their sex according to biology.

168. MCC categorically opposes providing advice, referrals, or care that "affirms" gender transition, or participates in "social transition" by, for example, the use of "preferred pronouns."

169. MCC has designated lactation rooms, and specifies by signage that those rooms are for use by "Breastfeeding Moms Only." MCC also provides referrals to moms of its infant patients to receive lactation consultations and treatment.

170. MCC categorically opposes allowing males in female private spaces as if the males are females, and vice versa, opposes allowing males to use its lactation rooms for so-called "chestfeeding" or for any purpose inconsistent with the rooms' proper use, opposes changing its signage to refer not to "Moms" but to "Pregnant Persons" or any other such euphemism derived from gender ideology, and opposes providing referrals for males to "chestfeed" a child.

171. Through its health professionals, MCC has freely shared its medical judgment on "gender transition" with patients.

172. MCC sees patients who may unknowingly be pregnant. MCC will administer appropriate pregnancy testing. Where a patient is pregnant, MCC refers the patient for prenatal care from an Obstetrician/Gynecologist.

173. MCC's scope of practice would include referring patients for methotrexate for an immunosuppressive condition like juvenile rheumatoid arthritis.

174. Doctors and staff also engage in discussions and counseling with a patient and/or their parent or guardian concerning pregnancy and sexual activity. For example, clinic doctors or staff will counsel that patients will maximize their sexual health by not having sex outside of marriage, and by having babies after being in marriage.

175. MCC wants to remain free to follow and share its medical views on these issues.

176. A doctor at MCC has encountered a female pediatric patient that identified as transgender and was engaged in "social transition" activities. The doctor declined to address or treat the female patient as male, including by using a male name, and the doctor shared the general position, held by the clinic, that sex is biological and "gender transition" is not a sound practice.

177. In such cases, the clinic provides the same high-quality medical care to those patients as it does to all patients, whether it is for a wellness exam, acute illness, or any other medical condition. The clinic also supports its doctors and staff in sharing the clinic's views with those patients, appropriate to the situation, about the inherent biological error of gender ideology and the dangers of gender transition.

178. MCC's views and practices are described in more detail in the attached signed declaration of MCC's president Dr. Michael Artigues. Ex. 1.

179. MCC's categorical exclusion of providing, facilitating, or affirming "gender-transition" interventions, and its commitment to complying with state law, precludes it from:

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

B. Performing surgeries to treat gender dysphoria or for transition efforts, including:

i. Removing healthy breasts, uteruses, or ovaries from females who purport to identify as males, as nonbinary, or who otherwise do not identify as females (hysterectomies, mastectomies, and oophorectomies);

ii. Removing healthy vaginal tissue from females who purport to believe themselves to be male, to be nonbinary, or otherwise not to be female, and creating for them a faux or cosmetic penis (phalloplasties and metoidioplasties);

iii. Removing healthy testicles or scrotums from males who purport to believe themselves to be female (orchiectomies or scrotectomies);

iv. Performing a process called "de-gloving" to remove the healthy skin of a male's penis and using it to create a faux vaginal opening or vulva (vaginoplasties and vulvoplasties);

v. Removing healthy internal or external genitals from any person to create a "smooth gender-neutral look" (nulloplasties or nullification surgeries); and

vi. Performing other procedures sought to make a person resemble the opposite sex or no sex, such as facial, chest, neck, skin, hair, or vocal modification;

C. Saying through its staff that these transition efforts are the standard of care, are safe, are beneficial, are not experimental, are not cosmetic, or should otherwise be recommended;

D. Offering to perform, provide, or prescribe the above such transition interventions, procedures, services, or drugs, including in published statements;

E. Referring patients for any and all such interventions, procedures, services, or drugs;

F. Refraining from expressing its views, options, and opinions to patients when those views are critical of transition efforts;

G. Refraining from informing patients or the public that they do not provide transition procedures, including by refraining from sharing this information in patient conversations or on websites;

H. Treating and referring to patients according to gender identity and not sex;

I. Saying that sex or gender is nonbinary or on a spectrum;

J. Using language affirming any self-selected gender identity inconsistent with sex or the biological binary;

K. Asking patients to share their gender identity or pronouns beyond basic inquiries into the patient's sex;

L. Using patients' self-selected pronouns according to gender identity, rather than using no pronouns or using pronouns based on sex;

M. Creating medical records and coding patients and services according to gender identity not to sex;

N. Saying that a boy is a girl, or vice versa, or say that males can be pregnant, give birth, or breastfeed;

O. Affirming or endorsing transition efforts;

P. Allowing patients to access single-sex programs and facilities, such as lactation rooms, lactation training, hospital rooms, restrooms, or other single-sex programs and spaces, by gender identity and not by sex;

Q. Repealing or modifying its policies, procedures, and practices of not offering to perform or prescribe the above procedures, drugs, and interventions for transition efforts; and

R. Providing assurances of compliance, compliance reports, express or implied certifications of compliance, and notices of compliant policies, or posting notices of compliant policies in prominent physical locations as to the rule's gender-identity requirements.

180. The rule, however, requires MCC to do or say all these things.

VIII. The rule's substantive injuries to McComb Children's Clinic

181. MCC is a covered entity under the 1557 rule.

182. MCC participates in health programs and activities receiving federal financial assistance.

183. MCC treats patients who provide payment through federally subsidized healthcare programs such as Medicaid, Medicare, and CHIP.

184. MCC bills Medicaid and CHIP for patient care, and complies with paperwork, certification, and assurances to do so.

185. The rule forces MCC to abandon its policies categorically excluding the provision of "gender transitions."

186. The rule forces MCC to violate state laws prohibiting gender transitions for minors.

187. The rule seeks to preempt state law that protects MCC from facilitating gender-transition procedures—both state laws that restrict these procedures themselves and state laws that protect healthcare institutions' rights to decline to participate in these procedures..

188. The rule threatens MCC with expulsion from participation in Medicaid, Medicare, and CHIP, and other federal financial assistance programs.

189. It would cause MCC significant financial harm to lose eligibility to participate in federal healthcare programs such as Medicare, Medicaid, and CHIP.

190. The rule threatens MCC's income and ability to pay its employees.

191. The rule arguably exposes MCC to civil penalties, criminal penalties, damages, investigative burdens, and document demands.

192. The burdens of being investigated for alleged or suspected violations—or reviews over such non-compliance—are severe, imposing significant costs of time, money, attorney's fees, and diversion of resources that these healthcare providers could use to continue providing quality medical care and to continue receiving compensation for the same.

193. The rule imposes the following no-win choice on MCC: (1) abandon or violate its policies and incur the costs of compliance with the rule; (2) maintain its positions and practices but falsify its policies, notices, and assurances of compliance to HHS and then risk continuing liability and investigative demands from OCR with no promise it will be deemed exempt from the loss of eligibility for participation in federal financial assistance programs; or (3) exit the medical field and abandon its patients.

194. Put to the same choice, the rule will drive thousands of doctors and clinics out of the medical profession, and it will dissuade students from choosing to practice medicine.

195. These effects will exacerbate shortages of medical professionals nationwide and in Mississippi specifically, reducing the availability of healthcare providers to care for underserved, low-income, and rural patients.

196. The rule will place intense strain on the healthcare system and cause immense human suffering and higher medical costs.

197. Imposing the rule will deprive patients who want to receive care from MCC.

198. If the number of physicians who take federal funding is reduced, they cannot easily be replaced, and it will reduce access to care for federally funded patients. Medicaid patients already have less access to primary and specialty care than privately insured patients.[12] Physicians historically have been significantly less likely to accept new patients covered by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent).[13]

199. If MCC were to comply with the rule, it would lose its integrity and reputation of practicing consistent with the health of children and medical ethics, and this would make patients less likely to trust MCC, driving patients away from its practice.

200. If MCC complies with the rule by performing, referring for, or legitimizing "gender-transition" procedures, it takes on increased malpractice liability because of the risks and harms of those efforts and of patients later

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[12] Walter R. Hsiang et al., *Medicaid Patients Have Greater Difficulty Scheduling Health Care Appointments Compared With Private Insurance Patients: A Meta-Analysis*, 56 Inquiry 1 (2019), https://journals.sagepub.com/doi/pdf/10.1177/0046958019838118.

[13] MACPAC, *Physician Acceptance of New Medicaid Patients*, *supra* note 4, at 2 (collecting data on the percentage of doctors accepting new patients in each category).

regretting the decision to undergo those efforts, and it takes on increased legal liability based on state laws restricting these procedures.

201. At the same time, the rule constricts MCC's ability to warn patients about the risks and harms of transition procedures.

202. Compliance with the rule also presents risks to MCC's patients—including life-threatening risks—by creating a risk of confusion as to a patient's sex that can lead to medical errors.

203. Compliance with the rule would present risks to MCC's patients—including life-threatening risks—by requiring that necessary procedures and inquiries be omitted by MCC because those are associated with the patient's sex and not the patient's gender identity.

204. Compliance with the rule would lead to medically unnecessary procedures, harming patients, wasting the time and money of providers, patients, and insurers, and draining resources that could be better spent elsewhere.

205. Compliance with the rule would cause MCC to incur increased costs from defending against Defendants' investigation and enforcement actions.

206. Compliance with the rule would force MCC to force its employees against their will to perform, refer for, facilitate, speak in favor of, or not speak against, "gender transitions."

207. Compliance with the rule would drive employees away from MCC and make it difficult for MCC to hire employees.

208. The rule requires MCC to adopt, give notice of, and post a policy that it does not discriminate on the basis of gender identity or termination of pregnancy as understood by the rule.

209. MCC opposes complying with the rule's requirement that it adopt a "nondiscrimination" policy on "gender identity," or that it provide notice that it does not discriminate on the basis of "gender identity" or "termination of pregnancy."

210. The rule will also require MCC to reverse and pull down its existing policy communication on "gender transitions."

211. MCC wants to keep its existing policy of categorically rejecting providing, referring for, or affirming "gender transitions."

212. Out of fear of punishment under the rule, MCC will remove its notice of this policy from its website on the effective date of the rule, unless it first receives a court order protecting its ability to maintain its current policy despite this rule.

213. The rule will require MCC to remove or revise its signage on its lactation rooms to eliminate reference to "Breastfeeding Moms Only," and to allow men to use the rooms for "chestfeeding."

214. MCC has provided past assurances of compliance or certifications as required by HHS to be eligible to receive federal financial assistance.

215. The rule will deem MCC's past assurances of compliance or certifications as if they encompass compliance with the rule's new gender-identity mandate.

216. The rule will likely require MCC to submit new assurances of compliance or certifications that it complies with the rule.

217. The rule will force MCC and its directors and staff to make false statements if it maintains its current policies and also continue seeing patients that pay through Medicaid or CHIP.

218. The rule will subject MCC to significant financial and legal liability if it continues its current practices instead of engaging in compliance measures under the rule.

219. The rule will require MCC to provide training to its employees to ensure their compliance with the rule.

IX. The rule inflicts compliance costs on McComb Children's Clinic

220. The rule estimates that covered entities such as MCC will incur financial costs for compliance.

221. The rule estimates that each covered entity will incur up-front costs from revising policies, training staff, and keeping records of employee training.

222. The rule estimates that each covered entity will incur annual or ongoing costs to train or refresh the training of new or returning employees, to maintain records of training and grievances, and to provide notices.

223. Defendants admit in the rule that covered entities will incur financial compliance costs, some of which are likely to occur even before the rule's effective date.

224. Defendants admit in the rule that entities with more than 15 employees will incur compliance costs even higher than smaller employers.

225. MCC is a covered entity with more than 15 employees that falls within those entities that Defendants estimate are subject to compliance costs caused by the rule.

226. The rule imposes compliance costs that MCC must start incurring now unless the rule is enjoined.

227. MCC has already incurred some compliance costs from the rule.

228. These include reviewing the rule and obtaining legal advice about compliance and legal options.

229. The rule requires MCC to spend time and money to comply with the rule that it would not expend but for the rule.

230. The rule will, at minimum, impose these costs on MCC through requiring it to: familiarize itself with the rule, draft, adopt, and publish a "nondiscrimination" policy on "gender identity"; designate a 1557 coordinator and draft grievance policies; revise clinic policies to comply with the rule; plan and

create training documents and train employees to comply with the rule; keep records of training; and keep records of patient grievances.

231. The rule states that to comply with its training requirements, covered entities will train each employee that has interactions with the public or with patients, and that the training would last an hour.

232. Including its doctors and nurse practitioners, MCC currently has 30 staff members, 29 of whom interact with patients.

233. For MCC, its cost to review and comply with the rule will amount to at least $2,715 in the first year and $376 each subsequent year.

234. The rule has caused and continues to cause MCC to divert its organizational resources and staff time from its medical practice to review the rule, consult legal counsel, and engage in statements and educational efforts towards staff and patients to mitigate confusion that the rule has caused about its application to MCC and its inconsistency with other federal and state laws.

235. MCC must continue incurring further compliance costs under the rule, both prior to and after its effective date, unless this Court issues it an injunction.

236. MCC will avoid most compliance costs from the rule if this Court preliminarily enjoins it and ultimately issues permanent relief to MCC.

X. Urgent need for judicial relief

237. Defendants HHS and OCR are federal agencies subject to the APA.

238. The APA allows a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" to seek judicial review of that action. 5 U.S.C. § 702.

239. MCC suffers legal wrong and adverse effects from the rule.

240. MCC is a regulated party under the rule.

241. The day a rule is adopted and you're a regulated party, even if nothing has happened to you by the agency, you have standing to go in to sue. That happens all the time.

242. The rule is final agency action.

243. The rule is a legislative or substantive rule.

244. The rule is "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704.

245. No statute precludes judicial review of the rule, and the rule is not committed to agency discretion by law, under 5 U.S.C. § 701(a).

246. MCC has no adequate or available administrative remedy.

247. In the alternative, any effort to obtain an administrative remedy would be futile.

248. The rule is definitive and determines the rights and obligations of persons, including MCC.

249. HHS declares the rule to be treated as if it has the full force of law.

250. MCC faces imminent irreparable harm and is susceptible to risk of enforcement under the rule beginning on its effective date.

251. MCC's compliance costs constitute irreparable harm.

252. Absent injunctive and declaratory relief granted before the rule's effective date, MCC has been and will continue to be harmed by continued exposure to legal penalties for practicing medicine in line with its best judgment and for speaking those views to its patients.

253. Unless the Court provides protection from Defendants' enforcement of the rule, MCC will continue to suffer from this ongoing violation of law.

254. MCC has no adequate remedy at law.

255. All the acts of the Defendants described above, and their officers, agents, employees, and servants, were executed and are continuing to be executed by Defendants under the color and pretense of the policies, statutes, ordinances, regulations, customs, and usages of the United States.

FIRST CLAIM
ADMINISTRATIVE PROCEDURE ACT
(5 U.S.C. § 706)

256. Plaintiff McComb Children's Clinic realleges and incorporates herein, as though fully set forth, paragraphs 1–255 of this Complaint.

257. MCC brings this claim as to the rule's gender-identity nondiscrimination requirement and the implications thereof under the rule.

A. Not in Accordance with Law, In Excess of Statutory Jurisdiction, Authority, and Limitations, and Contrary to Right, Power, Privilege, and Immunity

258. Under the APA, a court must "hold unlawful and set aside agency action" if the agency action is "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "contrary to constitutional right, power, privilege, or immunity" under 5 U.S.C. § 706.

259. The rule is not in accordance with law, is in excess of statutory jurisdiction, authority, and limitations, and is contrary to constitutional rights and power.

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

261. The rule exceeds the authority of Section 1557, the Affordable Care Act, and Title IX of the Education Amendments of 1972, as amended, as it constrains the sex-discrimination prohibition in the ACA.

262. The text of Section 1557, the ACA, and Title IX as applicable to Section 1557, speak of sex as a biological binary that preclude imposing Section 1557 as if it prohibits gender-identity discrimination.

263. Prohibiting discrimination on the basis of gender identity throughout the nation's health system, as a condition on receipt of federal health funding from HHS, is an issue of vast economic and political significance for which Congress did not give HHS clear authority.

264. The rule violates the major questions doctrine and the clear-statement federalism and spending clause canons.

265. The rule is contrary to Section 1554 of the ACA, 42 U.S.C. § 18114; specifically: parts (1)–(2) and (6) because it pressures healthcare providers like MCC out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires healthcare providers like Plaintiff to speak in affirmance of gender transition and refrain from speaking in accordance with a patient's sex and related medical needs; and part (5) because it requires healthcare providers like MCC to deprive patients of informed consent by preventing them from warning patients of the dangers of transition procedures.

266. HHS has no authority to create and impose requirements that involve compliance costs for covered entities beyond the requirement not to discriminate on grounds prohibited by Section 1557, such as by requiring policy changes, training, duties for compliance coordinators, grievance procedures, notices of nondiscrimination, and record-keeping.

267. For the reasons discussed below in Claims Two and Three, the rule violates constitutional protections for free speech, association, and assembly, as well as structural constitutional principles related to federalism and Congress' enumerated powers.

B. Arbitrary, Capricious, and an Abuse of Discretion

268. Under the APA, a reviewing Court must "hold unlawful and set aside agency action" if the agency action is "arbitrary," "capricious," or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

269. In drafting and promulgating the rule, HHS failed to undergo reasoned decision-making.

270. HHS failed to adequately consider important aspects of these issues.

271. HHS failed to adequately consider and find that, in medical practice as in education, sex is a biological reality.

272. HHS failed to adequately consider the harm that comes to patients when covered entities ignore or misconstrue the biological differences between the sexes as demanded by the rule.

273. HHS failed to adequately consider that there is an evolving state of medical knowledge about "gender-transition" efforts and that the rule short-circuits this debate.

274. HHS improperly relied on unreliable facts and studies only from one side of the issue and improperly ignored or disregarded experts who point out that there is not enough evidence to require the provision of "gender transitions."

275. HHS failed to adequately consider the disproportionately negative impact of the "gender-transition" mandate on women and girls.

276. HHS improperly ignored the effect of the rule on clinics that have medical and ethical objections to "gender-transition" procedures.

277. HHS improperly ignored the reliance interests of doctors on the absence of a "gender-transition" mandate under Section 1557.

278. HHS improperly ignored the reliance interests of patients who want to keep receiving care from clinics object to "gender transitions."

279. HHS failed to adequately consider how the rule will drive thousands of healthcare providers out of medicine and harm underserved populations treated by those doctors.

280. HHS failed to adequately consider alternative policies.

SECOND CLAIM
FREEDOM OF SPEECH AND ASSOCIATION
(FIRST AND FIFTH AMENDMENTS)

281. Plaintiff McComb Children's Clinic realleges and incorporates herein, as though fully set forth, paragraphs 1–255 of this Complaint.

282. MCC brings this claim as to the rule's gender-identity nondiscrimination requirements and the implications thereof on the First Amendment's protections of the freedoms of speech and association.

283. MCC also brings this claim as to the rule's notice of nondiscrimination requirements with respect to the rule's category of "termination of pregnancy" discrimination.

284. The Constitution and federal rules authorize claims seeking to enjoin and declare unlawful federal agency actions that are *ultra vires* for violating constitutional authority, and the APA authorizes the Court to enjoin, hold unlawful, and set aside agency actions that are contrary to constitutional power or privilege or otherwise not in accordance with constitutional law.

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

286. Under the Fifth Amendment to the U.S. Constitution, "No person shall be … deprived of life, liberty, or property, without due process of law." U.S. Const. amend. V.

287. MCC's speech and practice in the context of healthcare is protected under the First Amendment.

288. The rule restricts and compels MCC's speech in violation of the First Amendment.

289. The rule regulates speech based on content and viewpoint by requiring messages, information, referrals, and pronouns affirming transition efforts, and by prohibiting and restricting speech taking a contrary view.

290. MCC seeks to keep following its best medical and ethical judgments in communicating to patients, but the rule does not allow this.

291. But for the rule, MCC would continue to speak freely on these matters in each clinical situation as its doctors and family nurse practitioners deem appropriate, as it has done until this mandate.

292. The rule violates MCC's right of expressive association (or freedom of assembly) by coercing MCC to participate in facilities, programs, groups, and other healthcare-related endeavors that are contrary to its views and that express messages with which MCC disagrees.

293. The rule's regulations impacting speech and association are not justified by a compelling interest and are not narrowly tailored to achieve the government's purported interests.

294. No relevant statute provides any governmental interest to sustain the speech regulations of the gender-identity mandate.

295. The rule is an overbroad restriction on speech, and it sweeps within its ambit a substantial amount of First Amendment-protected speech and expression.

296. This overbreadth chills the speech of healthcare entities that engage in private speech through statements, notices, and other means in healthcare on the basis of sex.

297. The rule imposes an unconstitutional condition on MCC's receipt of federal funding.

298. Defendants' implementation of the rule through instruments such as HHS's Form 690 requirement to assure compliance with Section 1557, or statements required to be made in award applications, notices of awards, or applications to qualify as providers in Medicaid, Medicare, or CHIP, function in a way that compels speech and requires self-censorship on condition of losing federal funds in violation of the First Amendment.

299. The nondiscrimination mandate is void for vagueness and give officials' unbridled discretion in violation of due process rights.

300. The rule coerces MCC's speech by forcing it to provide notices to patients that it does not discriminate on the basis of "gender identity" or "termination of pregnancy."

301. MCC holds views against providing, referring for, or affirming the legitimacy of "gender transition" or abortion, and communicates those views to patients and the public.

302. By forcing MCC to tell its patients directly, on its walls, and on its website that it does not discriminate on the basis of gender identity or termination of pregnancy, the rule forces MCC to speak falsely, and it forces MCC to fatally undermine its communication of its own medical ethical standards. This undermines MCC's reputation and brand as a trustworthy pediatrics clinic that follows Mississippi laws on "gender transitions" and abortion.

303. The rule's coerced notices of nondiscrimination on gender identity and abortion fail any applicable level of scrutiny under the Free Speech Clause.

304. In the alternative, if Section 1557 or Title IX is found to prohibit discrimination on the basis of gender identity, and to the extent Defendants enforce

it as doing so, these statutes violate the First and Fifth Amendments of the U.S. Constitution as applied to MCC and all similarly situated healthcare professionals.

THIRD CLAIM
STRUCTURAL PRINCIPLES OF FEDERALISM AND LACK OF ENUMERATED POWERS

305. Plaintiff McComb Children's Clinic realleges and incorporates herein, as though fully set forth, paragraphs 1–255 of this Complaint.

306. MCC brings this claim as to the rule's gender-identity nondiscrimination requirements and the implications thereof under the rule.

307. The Constitution and federal rules authorize claims seeking to enjoin and declare unlawful federal agency actions that are *ultra vires* for violating constitutional authority, and the APA authorizes the Court to enjoin, hold unlawful, and set aside agency actions that are contrary to constitutional power or privilege or otherwise not in accordance with constitutional law.

308. Even if the rule's reinterpretation of Section 1557 and Title IX were a permissible interpretation of the statutes, it would be constitutionally impermissible.

309. The rule exceeds Congress's Article I enumerated powers and transgresses on the reserved powers of the States under the federal constitution's structural principles of federalism and the Tenth Amendment. U.S. Const. art. I, § 8, cl. 1; *id.* amend. X.

A. Lack of constitutionally required notice.

310. For a statute to preempt the historic police powers of the States, to abrogate state sovereign immunity, or to regulate a matter in areas of traditional state responsibility, the Constitution limits the States and the public's obligations

to those requirements unambiguously set out on the face of the statute. *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

311. No funding recipient could unmistakably know or clearly understand that Section 1557, Title IX, or Section 504 would impose the mandate created by the rule as a condition of accepting federal funds from HHS.

312. The public lacked the constitutionally required clear notice that the statutes would apply in this way when Section 1557 or Title IX was passed or when funding grants were made. *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

B. Exceeding the authority of spending power

313. The rule improperly goes beyond the authority Congress gave to HHS, or that Congress possesses and exercised in Section 1557.

314. Defendants expressly and impliedly, but improperly, seek to use a Spending Clause statute to preempt traditional state authority over healthcare, the healing professions, and standards of care.

315. The rule purports to override state conscience-protection laws as well as state laws restricting "gender-transition" procedures.

316. The rule requires the States and MCC to violate state laws and their core convictions as a condition of federal funding.

317. These state laws protect MCC's ability to operate without needing to provide, promote, facilitate, or speak in favor of such procedures.

318. Congress does not have the authority under the Spending Clause to preempt state law. An agency may not pay anyone to violate state law. Instead, if state law prevents the spending of federal funds in a certain way, the only thing an agency may do is disallow funds.

C. Unconstitutional coercion and lack of enumerated power

319. The rule requires the States and covered entities to follow the rule's gender-identity mandate as a condition of receiving federal healthcare funding. Federal Medicaid funding alone is about 27% of the average state budget, and any ineligibility for Medicare, Medicaid, or CHIP funding threatens to drive healthcare providers out of the practice of medicine entirely.

320. Such a requirement is unconstitutionally coercive. The rule requires the States and covered entities to adopt a controversial gender-identity mandate or give up more than 27% of state budgets and disregard the healthcare systems put in place over several decades. That leaves the States and covered entities with no meaningful choice. It is an improper use of the Spending Clause.

321. The States and Plaintiffs cannot accept the rule's gender-identity mandate because that would conflict with state restrictions on gender-transition procedures and state conscience-protection law. The federal government cannot commandeer state governments in that way or require the States to repeal their laws. *Murphy v. Nat'l Collegiate Athletic Ass'n*, 584 U.S. 453, 470–75 (2018).

322. Coercing the States and healthcare providers to abandon their laws or to give up federal healthcare funding that their federal tax dollars underwrite — which is what they must do to comply with the rule—is beyond the federal government's spending clause power. It amounts to a "gun to the head" for the States and covered entities. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 581 (2012) (plurality). It is "economic dragooning that leaves the States with no real option but to acquiesce." *Id.* at 582 (plurality).

323. Defendants lack any authority to preempt state laws in these fields or to impose these conditions through any federal spending power.

PRAYER FOR RELIEF

Plaintiff McComb Children's Clinic respectfully prays for judgment as follows and requests the following relief:

A. That this Court declare unlawful, set aside, and vacate the rule to the extent it prohibits discrimination on the basis of gender identity;

B. That this Court issue a preliminary and permanent injunction against Defendants implementing, enforcing, or applying a gender-identity nondiscrimination mandate under any aspect of the rule, including that Defendants may not require covered entities to:

1. Perform, provide, offer, refer for, facilitate, make arrangements for, endorse, or refrain from criticizing or from categorically rejecting "gender transition";

2. Allow members of one sex into the private spaces or sex-specific programs of the other sex in their facilities, such as by allowing males into female restrooms, lactation rooms, or lactation training program referrals;

3. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, coding, charting, or conversation, or be forced to say that a boy is a girl or vice versa, or say that men can get pregnant, give birth, or breastfeed;

4. Stay silent on the negative impacts of "gender-transition" efforts, including by being unable to say that they do not provide, offer, refer for, or endorse those procedures, or by being pressured to withhold criticism or their complete opinions on these subjects, or by being unable to use accurate sex-specific language in speech or writing;

5. Affirm "gender-transition" efforts, or refrain from providing criticism or their full opinions to patients on these subjects; or

6. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity, or of any nondiscrimination category in the rule or Section 1557 to the extent that Defendants contend it encompasses gender-identity nondiscrimination.

C. That under the First and Fifth Amendments, this Court preliminarily and permanently enjoin Defendants from implementing, enforcing, or applying the rule, or Section 1557 of the ACA, in any aspect of a covered entity's expression, including as described in *supra* Prayer for Relief B.3–6, including but not limited to the requirement that MCC provide notices to its patients that it does not discriminate on the basis of gender identity or termination of pregnancy.

D. That under 5 U.S.C. § 705 this Court enjoin and declare the rule unenforceable on a preliminary basis and delay its effective date to preserve status and rights pending review of this Court;

E. That this Court render declaratory judgment that Section 1557 of the ACA, Title IX of the Education Amendments of 1972, and Section 504 of the Rehabilitation Act as incorporated therein do not prohibit discrimination on the basis of gender identity under the ACA;

F. That this Court render declaratory judgment that the rule and Defendants' enforcement or defenses thereof violates the Administrative Procedure Act; 42 U.S.C. § 238n; 42 U.S.C. § 18023; 42 U.S.C. § 18114; the Free Speech and Assembly Clauses of the First

Amendment; the Fifth Amendment; the Tenth Amendment; the constitutional principles of federalism; the Spending Clause; and Congress's enumerated powers;

G. That this Court extend such relief to run against Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office; including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities because of the failure to perform, offer, endorse, proscribe, or refer for either gender transition efforts, or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;

H. That this Court expressly extend all such relief to protect and benefit any of McComb Children's Clinic's current or future operations, employees, or persons acting in concert or participation with MCC as necessary to protect MCC's functions;

I. That this Court define such relief to encompass any language or alternative theory in the rule that Defendants may use to achieve those same ends as to gender identity;

J. That this Court adjudge, decree, and declare the rights and other legal relations of the parties to the subject matter here in controversy so that such declarations will have the force and effect of final judgment;

K. That this Court retain jurisdiction of this matter to enforce this Court's orders;

L. That this Court grant to McComb Children's Clinic reasonable costs and expenses of this action, including attorneys' fees in accordance with any applicable federal statute, including 28 U.S.C. § 2412.

M. That this Court grant the requested injunctive relief without a condition of bond or other security being required of McComb Children's Clinic; and

N. That this Court grant all other just and proper relief.

Respectfully submitted this the 13th day of May, 2024.

/s/ *D. Michael Hurst, Jr.*

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Exhibit 9

UNITED STATES DISTRICT COURT
DISTRICT OF NORTH DAKOTA
EASTERN DIVISION

THE CATHOLIC BENEFITS ASSOCIATION, on behalf of its members; SISTERS OF ST. FRANCIS OF THE IMMACULATE HEART OF MARY; ST. ANNE'S GUEST HOME; and ST. GERARD'S COMMUNITY OF CARE, *Plaintiffs,* v. XAVIER BECERRA, Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHARLOTTE BURROWS, Chair of the United States Equal Employment Opportunity Commission; and UNITED STATES EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, *Defendants.*	No. 3:23-cv-203-PDW-ARS

CBA PLAINTIFFS' VERIFIED AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Table of Contents

Plaintiffs, the Catholic Benefits Association, on behalf of its members, The Sisters of St. Francis of the Immaculate Heart of Mary, St. Anne's Guest Home, and St. Gerard's Community of Care (collectively, either "Plaintiffs" or "CBA Plaintiffs"), through their attorneys, First & Fourteenth PLLC, and pursuant to the Court's order, Doc. 43, allege:

I. INTRODUCTION AND SUMMARY OF THE ACTION

1. Since its promulgation of its May 2016 rule ("2016 Rule"), the U.S. Department of Health and Human Services ("HHS"), in coordination with the Equal Employment Opportunity Commission ("EEOC"), has interpreted the prohibitions on "sex" discrimination in Section 1557 of the Affordable Care Act ("ACA") and Title VII of the Civil Rights Act to require Catholic healthcare providers and employers, as well as their respective insurers, third-party administrators ("TPAs"), pharmacy benefit managers ("PBMs"), and other service providers to cover gender-transition services or "gender affirming care," in violation of CBA members' Catholic faith. By defining "sex" as including "termination of pregnancy," HHS also has imposed an abortion-

coverage-and-performance mandate, requiring healthcare providers to actually perform all of these services themselves in total disregard of their Catholic values. HHS recently doubled down on its mandate, issuing a 2024 Rule interpreting Section 1557 (the "2024 Rule") that restates and amplifies the 2016 Rule. Plaintiffs refer to these continuous and coordinated interpretations of Section 1557 and Title VII challenged by this suit as the "Mandate."

2. In 2019, a federal district court found that HHS's 2016 Rule violated the Religious Freedom Restoration Act and the Administrative Procedure Act, vacated portions of the rule, and ordered HHS to reconsider. In June 2020, HHS published a new final rule, the "2020 Rule," that would have repealed much of the 2016 Rule, including its (i) rejection of Title IX's abortion-neutrality provision and (ii) its categorical exemption for religious organizations. But the new rule never became operative. Two district courts enjoined it and ordered that the 2016 Rule remain in effect.

3. In 2021, this Court permanently enjoined the Government's enforcement of the Mandate as it applied to the Catholic Benefits Association ("CBA"), its unnamed members, and three of its members who were named plaintiffs, the Roman Catholic Diocese of Fargo North Dakota, Catholic Charities of North Dakota, and the Catholic Medical Association because the Mandate violated of the Religious Freedom Restoration Act. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1153 (D.N.D. 2021). This Court found that the CBA and its members faced a credible threat of enforcement of the Mandate. *Id.* at 1143, 1147-49. This Court also concluded that the CBA had associational standing to sue on behalf of its members and granted them a permanent injunction. *Id.* at 1141. The Court's injunction extended not only to the plaintiffs and CBA's members, but also to "their respective health plans and any insurers or TPAs in connection with such

health plans." *Id.* at 1153-54. The Eighth Circuit affirmed this Court's determination that the CBA and its member-plaintiffs faced a credible threat of enforcement of the Mandate. *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 607, 609 (8th Cir. 2022). The Eighth Circuit reversed on the narrow ground that the CBA lacked associational standing because it had not identified a member other than a named plaintiff who had suffered the requisite harm under Title VII and Section 1557. *Id.* at 602. On remand, this Court dismissed CBA's claims to the extent they sought associational relief and ruled that the CBA could refile suit to properly establish associational standing: "Importantly, the dismissal is without prejudice, and nothing prevents the CBA from filing a new action, where associational standing is properly established." *Religious Sisters of Mercy v. Becerra*, 16-cv-00386, slip op. at 3 (D.N.D. Sept. 15, 2023). This Court accordingly entered an amended judgment in *Religious Sisters of Mercy v. Becerra*, 16-cv-00386, on October 11, 2023.

4. Plaintiffs, the CBA, the Sisters of St. Francis, St. Anne's Guest Home, and St. Gerard's Community of Care refiled this follow-on action to *Religious Sisters of Mercy* on October 13, 2023, which "properly establishe[s]" associational standing, and seeks a declaration for the named plaintiffs and for the CBA's unnamed members that the Mandate cannot lawfully be applied to them, as well as an injunction barring enforcement of the Mandate against them, their members, and any third parties contracting or acting in concert with them for the delivery of health coverage and services, including the unnamed members' and Plaintiffs' respective insurers, TPAs, and other service providers.

5. Almost eight years to the day after HHS issued the 2016 Rule, HHS, on May 6, 2024, HHS issued the 2024 Rule. The 2024 Rule is identical to the 2016 Rule in all material respects for purposes of this challenge: it expands Section 1557's prohibition on sex discrimination

in healthcare to require Catholic healthcare organizations and employers to cover and provide "gender-affirming care," sterilization, abortion, and infertility treatments such as IVF, surrogacy, and gamete donation contrary to their faith and medical judgment; it refuses to incorporate a categorical religious exemption as required by the rulings of this Court in *Religious Sisters of Mercy* and *Christian Employer's Alliance*, the Eighth Circuit in *Religious Sisters of Mercy*, and the North District of Texas and the Fifth Circuit in *Franciscan Alliance*; it strains the definition of "covered entity" beyond any faithful reading of Section 1557; and it targets the Ethical and Religious Directives ("ERD") and Doctrinal Note on care for those with gender dysphoria guiding Catholic healthcare organizations by forbidding such organizations from adopting policies consistent with that guidance.

6. The 2024 Rule, like the 2016 Rule, applies directly to a "covered entity," *i.e.*, an entity that operates a federally funded health program or activity. This encompasses virtually all healthcare providers and health insurers in the United States. And because the Mandate affects nearly every insurer including those that contract with CBA members, it also affects Catholic employers that are not "covered entities." As a result of the Mandate, some members of the CBA have received notices from their insurers that their health plans had begun covering gender-transition services, including "[m]ale to female surgeries," "female to male surgeries," and "cross-sex hormone therapy." And at least one CBA member has been subject to an enforcement action by EEOC pursuant to the Mandate during the *Religious Sisters of Mercy* case.

7. Catholic employers cannot avoid the Mandate by adopting a self-insured health plan and contracting with a TPA to administer benefits because the 2024 Rule, like the 2016 Rule, subjects TPAs to its requirements and because many TPAs providing services are themselves

health insurers or affiliates of health insurers. And the 2024 Rule, like the 2016 Rule, says that HHS may refer any violations of the Mandate over which HHS lacks jurisdiction to EEOC. As a result of the 2016 Rule, Catholic employers that excluded gender-transition services from their self-insured health plans have been required to indemnify their TPAs, or otherwise accept their TPAs' liability, for violating the Mandate.

8. HHS could have included a *per se* religious exemption in its new 2024 Rule. There was ample reason to do so. Section 1557 prohibits sex discrimination by incorporating Title IX, and Title IX expressly provides that it "shall not apply" to religious organizations, 20 U.S.C. § 1681(a)(3). Numerous other federal laws, including the ACA itself, the Religious Freedom Restoration Act, and the First Amendment, likewise protect rights of conscience and religious exercise. And this Court, the Eighth Circuit, the Northern District of Texas, and the Fifth Circuit have all ruled that a religious exemption is required.

9. Failure to comply with the Mandate exposes Catholic entities to severe penalties. Covered entities can be fined, barred from millions of dollars of Medicaid and Medicare funding, subjected to treble damages under the False Claims Act, and incur civil and criminal liability. Responsible persons may face prison time. Because the EEOC similarly interprets Title VII to require employer health plans to cover gender-transition services, employers ("EEOC Statement")—even for employers that are not covered entities under the 2016 Rule—may face civil lawsuits and agency enforcement actions that expose them to compensatory damages, punitive damages, and attorneys' fees.

10. The Court ordered CBA to amend its Complaint to address the effect of the 2024 Rule on the CBA's claims. Doc. 43. In this amended complaint, CBA seeks declaratory relief on

behalf of the named plaintiffs and CBA's members that the Mandate, including the 2024 Rule, is contrary to law. CBA seeks injunctive relief on behalf of the named plaintiffs and CBA's members prohibiting any interpretation of Section 1557 or Title VII to require CBA members to cover or provide gender-affirming care, abortion, and immoral infertility treatments.

II. JURISDICTION AND VENUE

11. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361 because this action arises under the Constitution and laws of the United States. The Court has jurisdiction to render declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201 and 2202, and 42 U.S.C. § 2000bb-1.

12. Venue lies in this district under 28 U.S.C. § 1391(e)(1). Plaintiffs, the Sisters of St. Francis, St. Anne's, and St. Gerard's reside in this district and this division because their principal places of business are either in Hankinson or Grand Forks, North Dakota.

III. PARTIES

A. Plaintiffs

1. The Sisters of St. Francis

13. The Sisters of St. Francis of the Immaculate Heart of Mary dba Franciscan Sisters of Dillingen ("Sisters of St. Francis"), located in Hankinson, North Dakota, is a congregation of religious women of the Third Order Regular of St. Francis. Its ecclesiastical lineage begins generally with St. Francis of Assisi and institutionally with the Congregation of Franciscan Sisters in Dillingen founded in Bavaria in 1241.

14. The Sisters of St. Francis began in the United States in 1913 when twenty-four sisters relocated from the motherhouse in Germany to Collegeville, Minnesota.

15. The Sisters of St. Francis are, to this day, governed by The Rule and Constitutions of the Congregation of the Franciscan Sisters of Dillingen as supplemented by Provincial Directives specific to their Immaculate Heart of Mary Province. Under this Rule, the Sisters of St. Francis seek "to observe the Holy Gospel of Our Lord Jesus Christ in Obedience, in Poverty, and in Chastity." They also "promise obedience and reverence to the Pope and the Holy Catholic Church." They "seek[] to witness to God's love by [their] Franciscan way of life."

16. The calling of the Sisters of St. Francis is to serve where the Catholic Church needs them and to do so consistently with Catholic values. Over the years, the Sisters of St. Francis have staffed Catholic schools, and founded and/or administered five rural Catholic hospitals, and two long term care facilities: St. Anne's Guest Home, and St. Gerard's Community of Care. Their work today, in addition to their common life of prayer and study, includes spiritual direction, operating a retreat center, and supporting St. Anne's and St. Gerard's.

17. The Sisters of St. Francis relocated to Hankinson in 1928. They civilly incorporated in August 1950.

18. Under Roman Catholic canon law, the Sisters of St. Francis are a type of public juridic person called a religious institute. Under civil law, they are a North Dakota nonprofit corporation. They are listed in *The Official Catholic Directory* and, therefore, enjoy § 501(c)(3) status under the group ruling held by the United States Conference of Catholic Bishops ("USCCB").

19. Sister Donna Marie Welder OSF is the superior or provincial of the Sisters of St. Francis. She is president and chair of the board of directors for their corporation, and also for Plaintiffs St. Anne's Guest Home ("St. Anne's) and St. Gerard's Community of Care ("St.

Gerard's"). Sister Welder has verified the allegations in this complaint related to these three entities.

20. In addition to the twelve sisters who are members of the Sisters of St. Francis, the Sisters of St. Francis have around 30 lay employees. They, therefore, are an "employer" within the meaning of Title VII of the Civil Rights Act of 1964. 42 U.S.C. § 2000e(b).

21. The Sisters of St. Francis sponsor a group health insurance plan for their employees. St. Anne's and St. Gerard's are participating employers on that plan and provide health insurance for their employees through that plan. Consistent with Catholic values, the Sisters of St. Francis' health plan categorically excludes gender transition procedures and abortion services.

22. If the Sisters of St. Francis or its health plan insurer were required to provide coverage for gender transition services, abortion, or infertility treatments such as IVF, surrogacy, or gamete donation, it would violate its Catholic values, give scandal to its employees and supporters, and otherwise compromise its religious mission.

23. The Sisters of St. Francis are a member of The Catholic Benefits Association.

2. St. Anne's Guest House

24. St. Anne's Guest Home is a Catholic health care facility and senior residence located in Grand Forks, North Dakota. It began its work in the 1940s when the Most Rev. Aloisius Muench, Bishop of Fargo, asked the Sisters of St. Francis to help homeless and other indigent people living on the streets.

25. St. Anne's provides senior residences for low-income individuals and for couples. It also provides senior residences for people capable of living independently if supported with basic care. St. Anne's nurses assist residents with management of medications and other basic care.

26. St. Anne's website describes its purpose and values:

> Our mission at St. Anne's is to provide a safe, caring, and family-like home for our residents. Inspired by St. Francis, we strive to serve each person who comes to us as we would Christ. We welcome those who come to us from various backgrounds, treating them with love and dignity while providing for their physical, emotional, and spiritual needs.
>
> St. Anne's strives to embody the gospel message in accord with the "Ethical and Religious Directives for Catholic Health Care Services" given by the U.S. Co[nference] of Catholic Bishops.

Our Story, St. Anne's Living Center, https://www.stannesguesthome.org/about-us/ (last visited May 28, 2024).

27. St. Anne's bylaws describe its purpose is to serve as a "a Catholic health care facility in an environment of living and sharing the Gospel for the healing of the spiritual and physical, as well as the psychological, social, and emotional needs of the people . . . the Corporation serves, in accordance with the Ethical, Moral, and Religious Directives" of the United States Conference of Catholic Bishops and with the USCCB's 2023 Doctrinal Note.[1]

28. St. Anne's is careful to try to inculcate its Catholic and Franciscan values in its employees to ensure that St. Anne's is a loving home for seniors. Its residents include a Catholic priest who offers Mass and is available for confessions daily at St. Anne's. A weekly ecumenical Bible study is offered. Protestant services are provided on Sunday. The Sisters live in their convent next door to St. Anne's; they work with the staff and residents of St. Anne's every day and are available around the clock.

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[1] *See infra* ¶ 88.

29. St. Anne's is a Catholic ministry. It is listed in *The Official Catholic Directory* and, therefore, enjoys § 501(c)(3) status under the USCCB group ruling. It seeks to align all of its work with Catholic values including those in opposition to abortion and transgender services.

30. St. Anne's is also a North Dakota nonprofit corporation.

31. St. Anne's receives over 85% of its funding from Medicaid.

32. St. Anne's has around 30 employees and, therefore, is an "employer" within the meaning of Title VII of the Civil Rights Act of 1964. 42 U.S.C. § 2000e(b).

33. If St. Anne's or its health plan insurer were required to provide coverage for gender transition services, abortion, or infertility treatments contrary to Catholic teaching such as IVF, gamete donation, and surrogacy; if St. Anne's were required to help perform or otherwise accommodate gender transition services, abortion, or infertility treatments contrary to Catholic teaching such as IVF, gamete donation, and surrogacy; or if St. Anne's became ineligible for Medicare or Medicaid, it would violate its Catholic values, threaten its survival, give scandal to its employees and supporters, and otherwise compromise its religious mission.

34. St. Anne's is a member of the Catholic Benefits Association.

3. St. Gerard's Community of Care

35. St. Gerard's Community of Care aka St. Gerard's Community Nursing Home is a Catholic ministry in Hankinson, North Dakota that provides independent living and skilled nursing care for seniors. At the same location, it also provides childcare for infants and toddlers, a preschool, and before and after school supervision for older grade school children.

36. St. Gerard's vision, as stated on its website is "to provide those we serve with loving and caring service based on Christ's mission of love and compassion." Its mission, as stated in its bylaws, is "to provide the residents with loving and caring service based on Christ's mission

of love and compassion in accordance Gospel values and" with the Ethical and Religious Directives promulgated by the USCCB and with the USCCB's Doctrinal Note.

37. St. Gerard's also supports the spiritual needs of its residents and patients. It provides a daily communion service and a weekly Mass for Catholics. A weekend worship service for Protestants is offered on Sundays.

38. St. Gerard's has thirty-three beds for residents in need of skilled nursing. Its nursing services include rehabilitation services, IV therapy, physical therapy, speech therapy, occupational therapy, dementia and memory care, restorative care, tracheostomy care, feeding tubes, wound care, and end of life care.

39. St. Gerard's is a Catholic ministry. It is listed in *The Official Catholic Directory* and, therefore, enjoys § 501(c)(3) status under the USCCB group ruling. It seeks to align all of its work with Catholic values including those values in opposition to abortion and transgender services.

40. St. Gerard's is a North Dakota nonprofit corporation.

41. It receives 14% to 17% of its funding from Medicare and 43% to 56% of its funding from Medicaid.

42. St. Gerard's has around 60 employees and, therefore, is an "employer" within the meaning of Title VII of the Civil Rights Act of 1964. 42 U.S.C. § 2000e(b).

43. If St. Gerard's or its health plan insurer were required to provide coverage for gender transition services abortion, or infertility treatments contrary to Catholic teaching such as IVF, gamete donation, and surrogacy; if St. Gerard's were required to help perform or otherwise accommodate gender transition services abortion, or infertility treatments contrary to Catholic teaching such as IVF, gamete donation, and surrogacy; or if St. Gerard's became ineligible for

Medicare or Medicaid, it would violate its Catholic values, threaten its survival, give scandal to its employees and supporters, and otherwise compromise its religious mission.

44. St. Gerard's is a member of The Catholic Benefits Association.

4. The Catholic Benefits Association

45. The CBA is a § 501(c)(3) nonprofit, non-stock corporation and Catholic ministry. Its certificate of incorporation states that it is "organized for charitable purposes" that are "consistent with Catholic values, doctrine, and canon law." Specifically, it states that the CBA is organized "[t]o support Catholic employers . . . that, as part of their religious witness and exercise, provide health or other benefits to their respective employees in a manner that is consistent with Catholic values"; and "[t]o work and advocate for religious freedom of Catholic and other employers seeking to conduct their ministries and businesses according to their religious values". *See* Ex. A, Amended and Restated Certificate of Incorporation of the Catholic Benefits Association ("CBA Articles"), art. IV.

46. Archbishop William E. Lori of Baltimore is chairman of the CBA's board of directors.

47. Nine of the CBA's directors are Catholic archbishops or bishops. They are Archbishop Gregory M. Aymond of New Orleans, Archbishop Paul S. Coakley of Oklahoma City, Archbishop Salvatore Cordileone of San Francisco, Bishop John T. Folda of Fargo, Archbishop Bernard A. Hebda of Saint Paul and Minneapolis, Archbishop Jerome E. Listecki of Milwaukee, Archbishop William E. Lori of Baltimore, Archbishop Joseph F. Naumann of Kansas City in Kansas, and Archbishop Thomas G. Wenski of Miami. Three of its directors are religious women, Mother Agnes Mary Donovan, S.V., Superior General of the Sisters of Life; Sister Diane Marie McGrew, President of OSF Healthcare; and Sister Mary Peter Muehlenkamp, O.P., J.D., In House Counsel for

the St. Cecilia Congregation of the Dominican Sisters of Nashville. Five of its directors are Catholic lay persons, including: Professor Helen Alvaré, J.D.; Thomas M. Buckley, General Counsel for the Archdiocese of St. Louis; Beth Elfrey, Deputy General Counsel for the Knights of Columbus; Nancy Matthews, J.D., Carla K. Mills, Chief Financial Officer of the Archdiocese of Kansas City in Kansas; and Doug Wilson, Chief Executive Officer, of the CBA.

48. All of the CBA's officers are Catholic.

49. All of its employees are Catholic.

50. The CBA has a standing Ethics Committee, comprised exclusively of the archbishops and bishops on its board. The CBA's bylaws state:

> The Ethics Committee shall have exclusive authority to review all benefits, products, and services provided by the Ministry, its affiliates or subsidiaries, or their respective contractors to ensure such conform with Catholic values and doctrine. If they do not, the committee shall determine the necessary corrections to bring such benefits, products, and services into conformity with Catholic values and doctrine. The decision of the committee shall be final and binding on the Ministry, its board, and its officers . . . .

Ex. B, CBA Bylaws, art. 5.14.2.

51. To be a member of the CBA, an organization must meet these criteria, among others: (1) it shall be a Catholic employer, and (2) with regard to the benefits it provides to its employees, independent contractors, or students, or with regard to the health care services it provides to its patients, the employer shall, as part of its religious witness and exercise, be committed to providing no benefits or services inconsistent with Catholic values. Ex. B, CBA Bylaws art. 3.1.2; *see also* Ex. A, CBA Articles, art. VI, Members; Ex. C, CBA Nonprofit Employer Application for Membership; Ex. D, CBA For-Profit Employer Application for Membership.

52. The Bylaws of the CBA provide that an employer "shall satisfy the requirement of being Catholic if either the employer is listed in the current edition of *The Official Catholic Directory*

or the secretary or his or her designee makes such a determination." Ex. B, CBA Bylaws, art. § 3.1.1.1.

53. The Bylaws further provide that a for-profit employer seeking membership in the CBA "shall be deemed Catholic only if (i) Catholics (or trusts or other entities wholly controlled by such Catholic individuals) own 51% or more of employer, (ii) 51% or more of the members of the employer's governing body, if any, is comprised of Catholics, and (iii) either the employer's owners or governing body has adopted a written policy stating that the employer is committed to providing no benefits to the employer's employees or independent contractors inconsistent with Catholic values." Ex. B, CBA Bylaws, art. § 3.1.1.2.

54. All members of the CBA meet its criteria for being Catholic.

55. CBA members include 85 Catholic dioceses and archdioceses. Its members total over 1,471 Catholic employers, plus 7,100 Catholic parishes, and 1900 parochial schools. Together, they provide health care benefits to approximately 161,500 employees and their families.

56. CBA members also include schools, colleges, religious orders, and other Catholic ministries and Catholic-owned businesses.

57. CBA members include hospitals, medical clinics, physician medical practice groups, skilled nursing facilities, and other healthcare entities. Most of these receive Medicaid and Medicare payments and thus are covered entities under the 2016 and 2024 rules.

58. CBA members include Catholic Charities and other social service organizations that offer counseling and other mental health services, in individual and group settings. Many of these also receive Medicaid and Medicare payments and participate in HHS-funded programs and thus are covered entities under the 2016 and 2024 rules.

59. CBA members provide employee health benefits by contracting with health insurers and TPAs. These insurers and TPAs participate in federally funded marketplaces and thus are covered entities under the 2024 Rule.

60. A substantial portion of its members have fifteen or employees and, thus, are "employers" within the meaning of Title VII of the Civil Rights Act of 1964. 42 U.S.C. § 2000e(b).

61. The Mandate thus constrains CBA members' ability to arrange for and secure health plans that reflect their Catholic values.

5. The CBA's associational standing

62. The CBA has associational standing to represent its present and future members.

63. To have associational standing, the Eighth Circuit clarified that the CBA must, through testimony other than "the organizations' self-description of their membership," identify at least one member who would have standing to sue in its own right. *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 602 (8th Cir. 2022); *see also id.* at 601-02 ("[P]laintiff-organizations [must] make specific allegations establishing that **at least one** identified member had suffered or would suffer harm." (Emphasis added) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009)).

64. This complaint is verified not only by the CBA's Chief Executive Officer and the Chairman of its board, but by the Sisters of St. Francis, St. Anne's, and St. Gerard's. These three members are specifically named and have suffered the requisite harm from the Mandate.

65. In addition, CBA Plaintiffs attaches to this complaint, four declarations from nine non-plaintiff members of the CBA that specifically identify the following CBA members and that would have standing in their own right and have suffered the requisite harm. These include:

a. Exhibit E: Declaration of Chris Baechle for Cardinal Ritter Senior Services, Mary Queen and Mother Center, Our Lady of Life Apartments, Mother of Perpetual Help Residences, St. Elizabeth Hall, and Affordable Senior Living;

b. Exhibit F: Declaration of Dr. Michael Sherman for Holy Family Catholic Clinic;

c. Exhibit G: Declaration of Dr. Michelle Stanford for Centennial Pediatrics;. And

d. Exhibit H: Declaration of Deacon Anthony Ternes for Catholic Charities North Dakota.

66. Each of these CBA members receives HHS funding (standing for purposes of Section 1557), employs more than 15 individuals (standing for purposes of Title VII), and oppose providing or covering gender-transitions services, abortion, and certain infertility treatments because of their adherence to Catholic social teaching. Exh. E at ¶¶ 7, 9-14, 17-18, 20; Exh. F at ¶¶ 4, 6, 9, 12, 14-15; Exh. G at ¶¶ 4-5, 10, 12-14; Exh. H at ¶¶ 3-4, 9-10, 12-13.

67. Many of these members also contract with private insurers and/or TPAs who are themselves bound by the Mandate. Exh. E at ¶ 14; Exh. F at ¶ 5; Exh. H at ¶ 4.

68. Thus, between the three plaintiff verifications of this complaint, plus the four declarations of nine non-plaintiff CBA members, the CBA Plaintiffs have, through sworn testimony, identified to this Court twelve CBA members by name each of whom has over fifteen employees, each of whom receive Medicare or Medicaid, and each of whom are, because of their Catholic values morally opposed to covering transgender services in its health plan each of whom is morally opposed to performing such services. Accordingly, they have suffered suffer the requisite harm and satisfied other requirements for standing.

69. The Mandate harms the CBA's members.

70. The CBA seeks to protect its members' ability to operate in accordance with Catholic values and to access morally compliant health coverage for their respective employees or agents. It additionally seeks, for members that are covered entities, protection from being required to provide medical services and drugs, and to perform surgeries contrary to Catholic values.

71. The CBA can adequately represent its members' interests. CBA members are similarly situated in that the Defendants' Mandate coerces CBA members to cover, provide, pay for, or otherwise directly or indirectly facilitate access to gender transition services, abortions, and infertility treatments for their patients or for their employees in violation of members' sincerely held Catholic beliefs. The Mandate also deprives or will deprive certain CBA members of the option to purchase group insurance or to arrange self-funded plans without gender transition, abortion, and/or infertility coverage.

72. The CBA brings this action on behalf of its members who themselves have suffered and will suffer concrete harm as a result of Defendants' actions.

B. Defendants

73. Defendants are appointed officials of the federal government and federal government agencies responsible for promulgating, administering, and enforcing the Mandate.

74. Defendant United States Department of Health and Human Services is an executive agency of the United States government and is responsible for the promulgation, administration, and enforcement of the 2016, 2020, and 2024 Rules.

75. Defendant Xavier Becerra is the Secretary of HHS. He is sued only in his official capacity.

76. Defendant Equal Employment Opportunity Commission is a federal agency that administers, interprets, and enforces certain laws, including Title VII. The EEOC is responsible for, among other things, investigating complaints and bringing enforcement actions against employers for discrimination "because of . . . sex" in violation of Title VII.

77. Defendant Charlotte Burrows is the EEOC Chair. She is, in this capacity, responsible for the administration and implementation of policy within the EEOC, including investigation and enforcement pursuant to Title VII. She is sued only in her official capacity.

IV. PLAINTIFFS' BELIEFS AND PRACTICES RELATED TO THE MANDATE

78. All Plaintiffs and all CBA members are Catholic ministries or Catholic-owned businesses that believe and practice the teachings of the Catholic Church on the nature of the human person, the dignity of humankind, the right to life, the right of conscience and religious freedom, and related ethical issues. *See generally* Exhs. E, F, G, H; and *supra* at ¶¶ 13-44.

A. Catholic teaching on the duty to treat all persons with dignity

79. The Catholic Church teaches that all people are created in the image and likeness of God and are thus imbued with human dignity. Catechism of the Catholic Church ("CCC") 1701. All persons are therefore to be loved and respected in their human freedom, CCC 1738, even if they reject the Church's teaching on matters of sexual identity and sexual morality, CCC 2358.

80. The United States Conference of Catholic Bishops ("USCCB") has applied this teaching to transgender persons and those afflicted with gender dysphoria. In response to the U.S. Department of Education's guidance letter asserting that Title IX bars discrimination based on "gender identity," the USCCB stressed that the Catholic Church "consistently affirms the inherent dignity of each and every human person and advocates for the wellbeing of all people,

particularly the most vulnerable." The USCCB statement affirms that people who struggle with their gender identity "deserve compassion, sensitivity, and respect."[2]

81. The comments the USCCB filed along with other Christian bodies in response to HHS's 2016 rule under Section 1557 likewise affirmed that "[e]veryone should have access to health care and health coverage,"[3] as did their comments on HHS's 2024 rule.[4]

82. HHS has previously acknowledged that every religious group that submitted comments in response to 2016 proposed rule shared similar sentiments. The 2016 Rule notes, "None of the commenters supporting a religious exemption asserted that there would be a religious basis for generally refusing to treat LGBT individuals for a medical condition." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,379 (May 18, 2016).

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[2] *USCCB Chairmen Respond to Administration's New Guidance Letter on Title IX Application*, USCCB (May 16, 2016), https://www.usccb.org/news/2016/usccb-chairmen-respond-administrations-new-guidance-letter-title-ix-application (last visited Sept. 26, 2023).

[3] Comments from USCCB et al. to U.S. Dept. of Health and Human Services Re: Nondiscrimination in Health Programs and Activities RIN 0945-AA-2, at 2 (Nov. 6, 2015), http://www.usccb.org/about/general-counsel/rulemaking/upload/Comments-Proposal-HHS-Reg-Nondiscrimination-Federally-Funded-Health.pdf (last visited Sept. 26, 2023).

[4] Comments from USCCB et al. to U.S. Dept. of Health and Human Services Re: Nondiscrimination in Health Programs and Activities RIN 0945-AA17, at 2 (Sept. 7, 2022), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2022.comments.1557.regulations.final_.pdf (last visited May 21, 2024) ("Ensuring access to health coverage and health care, and removing barriers to these, is without question a laudable goal. Concern for the health of its citizens requires that society help in the attainment of living conditions that allow them to grow and reach maturity which . . . [includes] health care." (Cleaned up).).

B. Catholic teaching on gender identity

83. Catholic teaching on the nature of the human person begins with the Book of Genesis, which teaches that "God created man in his own image . . . male and female he created them." CCC 2331 (quoting Genesis 1:27).

84. The Catechism further teaches that "[e]veryone, man and woman, should acknowledge and accept his sexual identity." CCC 2333 (emphasis omitted). "By creating the human being man and woman, God gives personal dignity equally to the one and the other. Each of them, man and woman, should acknowledge and accept his sexual identity." CCC 2393.

85. Pope Francis has reiterated this Catholic teaching in recent years, affirming that "'man too has a nature that he must respect and that he cannot manipulate at will.' . . . The acceptance of our bodies as God's gift is vital for welcoming and accepting the entire world as a gift from the Father. . . . Learning to accept our body, to care for it and to respect its fullest meaning, is an essential element of any genuine human ecology." *Laudato Si*, No. 155 (2015) (quoting Pope Benedict XVI, Address from His Visit to the Bundestag (Sept. 22, 2011)).

86. This bedrock Church teaching on the dignity of all human persons is intertwined with all Catholic Social Teaching—not only on sex and sexuality, but also poverty, genocide, euthanasia, unjust war, the travail of migrants, human trafficking, the marginalization of people with disabilities, and other matters. *See* Declaration of the Dicastery for the Doctrine of the Faith, *Dignitas Infinita*, *on Human Dignity* (April 4, 2024), *available at* https://press.vatican.va/content/salastampa/en/bollettino/pubblico/2024/04/08/240408c.html (last visited May 28, 2024).

87. As for youth who are struggling with their gender identity, Pope Francis has taught that "the young need to be helped to accept their own body as it was created." *Amoris Laetitia*, No. 285 (2016).

88. On March 20, 2023, the USCCB's Committee on Doctrine issued a "Doctrinal Note on the Moral Limits to Technological Manipulation of the Human Body" (the "Doctrinal Note"). Paragraphs 14 and 15 of the Doctrinal Note explain that "the use of surgical or chemical techniques that aim to exchange the sex characteristics of a patient's body for those of the opposite sex or for simulations thereof" and, "[i]n the case of children, the exchange of sex characteristics . . . prepared by the administration of chemical puberty blockers, which arrest the natural course of puberty and prevent the development of some sex characteristics in the first place" to treat "gender dysphoria" and "gender incongruence" are not "morally justified either as attempts to repair a defect in the body or as attempts to sacrifice a part of the body for the sake of the whole." "First, they do not repair a defect in the body: there is no disorder in the body that needs to be addressed; the bodily organs are normal and healthy." "Second, the interventions do not sacrifice one part of the body for the good of the whole." The Doctrinal Note continues at Paragraph 18:

> Such interventions, thus, do not respect the fundamental order of the human person as an intrinsic unity of body and soul, with a body that is sexually differentiated. Bodliness is a fundamental aspect of human existence, and so is the sexual differentiation of the body. Catholic health care services must not perform interventions, whether surgical or chemical, that aim to transform the sexual characteristics of a human body into those of the opposite sex or take part in the development of such procedures. They must employ all appropriate resources to mitigate the suffering of those who struggle with gender incongruence, but the means used must respect the fundamental order of the human body. Only by using morally appropriate means do healthcare providers show full respect for the dignity of each human person.

89. "Sexual reassignment surgery requires the destruction of healthy sexual and reproductive organs."[5]

90. The Catholic Church teaches that intentionally removing healthy organs that identify as a person as male or female is a type of amputation or mutilation that is not morally licit.

91. Some gender transition surgeries also involve sterilization. The Catholic Church teaches that all forms of sterilization are contrary to the moral law. CCC 2370.

92. The Catholic Church teaches that "[e]xcept when performed for strictly therapeutic medical reasons, directly intended amputations, mutilations, and sterilizations performed on innocent persons are against the moral law." CCC 2297.

C. Catholic teaching on abortion

93. The Catechism of the Catholic Church teaches that life begins at conception and that "[h]uman life must be respected and protected absolutely from the moment of conception." CCC 2270. Thus, "[d]irect abortion, that is to say, abortion willed either as an end or a means, is gravely contrary to the moral law." CCC 2271.

94. While "[a]bortion . . . (that is, the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus) is never permitted" for Catholic individuals and organizations, "[o]perations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable," are, "even if they

[5] Richard P. Fitzgibbons, M.D., et al., *The Psychopathology of "Sex Reassignment" Surgery: Assessing its Medical, Psychological and Ethical Appropriateness*, 9 Nat'l Catholic Bioethics Q. 97, 100 (2009), https://repository.library.georgetown.edu/handle/10822/1029434.

will result in the death of the unborn child." *See* United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, p. 18-19, ¶¶ 45, 47 (6th ed. 2018).

D. Catholic teaching on artificial reproductive technology

95. The Catechism of the Catholic Church, which is the universal teaching of the Catholic Church, expresses that the sexual relationship between spouses is more than mere biology (*Familiaris Consortio*, Pope John Paul II, Paragraph 11 (1981)), and the conception of a child is the most serious role of spouses, involving co-creation with God, and holding that each child is to be received as a gift from the Creator (CCC 2367, 2378). The Catechism acknowledges the sorrow caused by infertility and supports the use reproductive technologies that restore normal fertility to marital intercourse (CCC 2375), preserving its unitive and procreative purposes (United States Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services, pg. 17, ¶ 38 (6th ed. 2018)). However, methods that involve third parties (medical technicians, donor gametes, or surrogate wombs) or separate fertilization from the conjugal act, are a violation of the dignity of the persons involved and are gravely immoral. Thus, Catholics commit grave sin if they participate in these technologies, either financially or through performance, (CCC 2376-77) Catholic teaching permits infertility treatment "that does not separate the unitive and procreative ends of" a "marital act of sexual intercourse." United States Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services, p. 17, ¶ 38 (6th ed. 2018). Accordingly, infertility treatments that support the procreative and unitive nature of marriage, for example hormonal support, are permissible. By contrast, Catholic healthcare providers and health plans may not provide or cover procedures such as IVF, surrogacy, or gamete donation that separate the procreative and unitive ends of the marital union, *id.* at p. 17, ¶¶ 39-43, or provide

any fertility treatments to individuals and couples in relationships not recognized as marriage by the Catholic church. *Id.* at p. 17, ¶ 38.

E. Catholic teaching on scandal

96. Catholic moral also theology prohibits acts that may give rise to "scandal." The Catechism defines scandal as "an attitude or behavior which leads another to do evil." CCC 2284. The Catechism teaches that "[a]nyone who uses the power at his disposal in such a way that it leads others to do wrong becomes guilty of scandal and responsible for the evil that he has directly or indirectly encouraged." CCC 2287. Avoiding scandal is particularly important for Catholic entities that seek to inculcate Catholic faith and values.

F. The USCCB's Ethical and Religious Directives governing Catholic healthcare

97. These teachings are reflected in the Ethical and Religious Directives for Catholic Health Care Services ("Ethical and Religious Directives" or "ERDs"), a document issued by the United States Conference of Catholic Bishops in order "to reaffirm the ethical standards of behavior in health care that flow from the Church's teaching about the dignity of the human person" and "to provide authoritative guidance on certain moral issues that face Catholic health care today." United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* 4 (6th ed. 2018), https://www.usccb.org/resources/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06_0.pdf (last visited May 28, 2024).

98. The ERDs teach that "[d]irect sterilization of either men or women, whether permanent or temporary, is not permitted in a Catholic health care institution. Procedures that induce sterility are permitted when their direct effect is the cure or alleviation of a present and serious pathology and a simpler treatment is not available." *Id.* at p. 19, ¶ 53.

99. The ERDs teach that "Catholic health care organizations are not permitted to engage in immediate material cooperation in actions that are intrinsically immoral, such as abortion, euthanasia, assisted suicide, and direct sterilization." *Id*. at p. 25, ¶ 70.

G. The Catholic Benefits Association's Ethics Committee

100. As noted above, the CBA's Ethics Committee, comprised exclusively of Catholic archbishops, has the duty and responsibility to define Catholic values and doctrine on relevant issues for CBA members.

101. In November 2016, the CBA's Ethics Committee convened to address doctrinal and ethical issues related to the Mandate. After consultation, it unanimously adopted the following resolutions:

> **RESOLVED**: that treatments and services designed to alter a person's biological sex are contrary to Catholic values. A Catholic employer, therefore, cannot, consistent with Catholic values, comply with the government's mandate to include coverage in its employee health plan for treatments services designed to alter a person's biological sex.
>
> **RESOLVED**: that treatments and services designed to alter a person's biological sex are contrary to Catholic values. A Catholic hospital, clinic, physicians practice group, or other medical provider, therefore, cannot, consistent with Catholic values, comply with the government's mandate to provide or deliver treatments or services designed to alter a person's biological sex.
>
> **RESOLVED**: that abortion is contrary to Catholic values. A Catholic employer, therefore, cannot, consistent with Catholic values, comply with any government mandate to include coverage in its employee health plan for abortion.
>
> **RESOLVED**: that abortion is contrary to Catholic values. A Catholic health care insurer or third party administrator, therefore, cannot, consistent with Catholic values, comply with any government abortion mandate by operating or administering a plan that provides coverage for abortion.
>
> **RESOLVED**: that abortion is contrary to Catholic values. A Catholic hospital, clinic, physicians practice group, or other medical provider, therefore, cannot, consistent with Catholic values, comply with any government abortion mandate that requires the provision and delivery of abortion services.

102. Consistent with the Ethics Committee's guidance, all CBA members believe they must adhere to the above teachings as matters of religious faith and doctrine. Consequently, CBA members believe that gender-transition procedures, sterilization, abortion, immoral infertility treatments, and related drugs or counseling are categorically contrary to the Catholic faith. CBA members further believe, as part of their faith, that they must not provide, pay for, or directly or indirectly facilitate access to such services and, therefore, that they must not perform gender transition services, sterilization, abortion, certain infertility treatments, and/or related counseling and must not include coverage for such procedures in their group health plans.

H. The Mandate is bad medicine[6]

103. In addition to the religious and ethical convictions described above, Plaintiffs and all CBA members also believe that the Mandate constitutes bad medicine. As the Supreme Court has observed, "sex . . . is an immutable characteristic." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973) (plurality opinion)); *see also* Expert Report of Stephen B. Levine 8 (Feb. 23, 2022), *in* Attachments to Comments of Alliance Defending Freedom, *Factual Evidence*, HHS-OS-2022-0012-68192.

104. Because Defendants' Mandate has no age limit, it requires covered entities to provide gender transition services for adolescents diagnosed with gender dysphoria.

105. Placing adolescents on puberty blockers or cross-sex hormones may cause permanent infertility and increased health risks.

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[6] With regard to the facts stated in this section, *see* Ex. F, Declaration of Dr. Michael Sherman, ¶¶ 16-17; Ex. G, Declaration of Dr. Michelle Stanford, ¶¶ 11-13.

106. For example, male adolescents on cross-sex hormones are at a higher risk for thrombosis, cardiovascular disease, weight gain, elevated blood pressure, decreased glucose tolerance, gallbladder disease, and breast cancer.

107. Similarly, female adolescents on cross-sex hormones are at a higher risk for hepatotoxicity, polycythemia, increased risk of sleep apnea, insulin resistance, and unknown effects on breast, endometrial, and ovarian tissues.

108. These consequences are even more serious given that the overwhelming majority of adolescents who are formally diagnosed with gender dysphoria naturally come to accept their sex and enjoy emotional health by late adolescence.

109. Even where gender transition surgeries are effective in helping patients' physical bodies match their gender identity, post-surgical individuals have substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts, and hospitalizations compared to a healthy control population, especially as the years progress.

110. Plaintiffs believe that Defendants' Mandate also declares as "medically necessary" a radical course of treatment that the medical profession properly rejects when it comes to other psychological conditions where people experience emotional distress because of a discrepancy between their self-image and the physical reality. According to Defendants' logic, it would be "medically necessary" to perform liposuction on someone with anorexia nervosa (belief that one is obese), cosmetic surgery on someone with body dysmorphic disorder (belief that one is disfigured), or amputations for someone with body integrity identity disorder (belief that one is meant to be disabled).

111. Plaintiffs also believe that optimal patient care—including patient education, diagnosis, and treatment—requires taking account of the biological differences between men and women. To cite but one example, optimal prevention of and treatment for heart disease in women requires monitoring for different warning signs, accounting for different risk factors, and providing different counseling than it would for men.

112. For all these reasons, the CBA and its members believe that providing gender transition services constitutes bad medicine and, therefore, is contrary to their religious and professional obligations.

V. THE MANDATE

A. Statutory and regulatory overview

1. Section 1557 of the Affordable Care Act, and its incorporation of Title IX of the Education Amendments of 1972 and section 794 of title 29

113. Together, the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (Mar. 23, 2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (Mar. 30, 2010), make up and are known as the Affordable Care Act ("ACA").

114. Section 1557(a) of the ACA prohibits discrimination in federally funded healthcare programs and activities on the basis of (1) race, color, and national origin, (2) sex, (3) age, and (4) disability. *See* 42 U.S.C. § 18116(a). The statute does not do this directly. Instead, it incorporates by reference, and bars discrimination "on the ground prohibited" by four other federal laws: (1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), (2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.); (3) the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.); and (4) section 794 of Title 29 (the Rehabilitation Act).

115. Section 1557(b) of the ACA provides that nothing in the statute "shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e et seq.), title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), section 794 of Title 29, or the Age Discrimination Act of 1975." 42 U.S.C. § 18116(b).

116. Section 1554 of the ACA provides that "notwithstanding any other provision of [the ACA, HHS] shall not promulgate any regulation that— . . . violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5).

117. Title IX was enacted in 1972. Public Law No. 92-318, 86 Stat. 235 (June 23, 1972). It states that no person "shall, on the basis of sex, be excluded from participating 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).

118. Title IX's prohibition, however, "shall not apply" to an institution "controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." 20 U.S.C. § 1681(a)(3).

119. Nor does Title IX's prohibition on sex discrimination require a "public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion." 20 U.S.C. § 1688.

120. The Rehabilitation Act prohibits certain forms of disability discrimination.

121. The Rehabilitation Act's prohibition, however, specifically excludes "transsexualism" and "gender identity disorder" "not resulting from physical impairments." 42 U.S.C.

§ 18116(a)(pointing to section 794 of title 29 as providing substantive content of protection). 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." 42 U.S.C. § 18116(a). The specific exclusion of transgender identity governs the general prohibitions of Section 1557, so the general term "based on sex" cannot be read to include discriminating based on transgender identity in Section 1557.

2. Title VII of the Civil Rights Act of 1964

122. Congress enacted Title VII in 1964. Public Law 88-352, 78 Stat. 241 (July 2, 1964).

123. Title VII makes it unlawful for an employer to discriminate against an employee or prospective employee "because of such individual's . . . sex." 42 U.S.C. § 2000e-2(a)(1).

124. Title VII defines an "employer" subject to its provisions as "a person engaged in an industry affecting commerce who has fifteen or more employees for each working day in each of twenty or more calendar weeks in the current or preceding calendar year." 42 U.S.C. § 2000e(b).

125. The U.S. Census Bureau estimates that there are over 875,000 employers in the United States with 15 or more employees.[7]

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[7] *See 2017 SUSB Annual Data Tables by Establishment Industry*, U.S. Census Bureau (Mar. 2020), https://web.archive.org/web/20200307131234/https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html (select "U.S. and states, NAICS sectors, small employment sizes less than 500" for statistics on firm size measured by number of employees).

126. Title VII has a broad religious exemption. It states that Title VII "shall not apply" to a religious organization's "employment of individuals of a particular religion." *See* 42 U.S.C. § 2000e-1(a). The statute defines "religion" broadly to include "all aspects of *religious observance and practice*, as well as belief." 42 U.S.C. § 2000e(j) (emphasis added).

127. Congress enacted the Pregnancy Discrimination Act in 1978 to further define what constitutes "sex" discrimination under Title VII. It specified that the terms "because of sex" or "on the basis of sex" include "because of or on the basis of pregnancy, childbirth, or related medical conditions." 42 U.S.C. § 2000e(k).

B. The 2016 Rule

128. The regulatory background to this dispute begins with the 2016 Rule that HHS issued interpreting Section 1557. On May 18, 2016, HHS finalized a rule pursuant to Section 1557 stating that impermissible discrimination "on the basis of sex" "includes . . . discrimination on the basis of . . . termination of pregnancy, . . . sex stereotyping, and gender identity." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376, 31,467 (May 18, 2016). Plaintiffs refer to this as the "2016 Rule."

129. The 2016 Rule defined "gender identity" to include a person's "internal sense of gender, which may be male, female, neither, or a combination of male and female." *Id.*; *see also id.* at 31,392 (stating that the "gender identity spectrum includes an array of possible gender identities beyond male and female"); *id.* at 31,384 (stating that individuals with "non-binary gender identities are protected under the rule").

130. The 2016 Rule defined "sex stereotypes" to mean "stereotypical notions of masculinity or femininity, including expectations of how individuals represent or communicate their

gender to others, such as behavior, clothing, hairstyles, activities, voice, mannerisms, or body characteristics." *Id.* at 31,468.

131. The 2016 Rule applied to a "covered entity," defined to mean "any entity that has a health program or activity, any part of which receives Federal financial assistance from [HHS]." *Id.* at 31,445. HHS estimated that the 2016 Rule covered "almost all licensed physicians because they accept Federal financial assistance," including payments from Medicare and Medicaid. *Id.* Other observers estimate that 2016 Rule applies "to over 133,000 (virtually all) hospitals, nursing homes, home health agencies, and similar provider facilities, about 445,000 clinical laboratories, 1,200 community health centers, 171 health-related schools, state Medicaid and CHIP programs, state public health agencies, federally facilitated and state-based marketplaces, at least 180 health insurers that market policies through the [federally facilitated marketplace] and state-based marketplaces, and up to 900,000 physicians." Timothy Jost, Implementing Health Reform: HHS Proposes Rule Implementing Anti-Discrimination ACA Provisions (Contraceptive Coverage Litigation Update), *Health Affairs Blog* (Sept. 4, 2015), http://healthaffairs.org/blog/2015/09/04/implementing-health-reform-hhs-proposes-rule-implementing-anti-discrimination-aca-provisions/.

132. The 2016 Rule's extension of Section 1557 to "gender identity" and "termination of pregnancy," coupled with its expansive definition of a "covered entity," meant that (1) healthcare providers were required to perform or refer for gender transition procedures and abortions, (2) healthcare providers were required to alter their speech and medical advice, (3) covered employers, insurance providers and TPAs were required to offer employee benefits covering gender transition procedures, and (4) sex-specific healthcare facilities and programs, including

shower facilities and hospital wards, must be opened to individuals based on gender identity, among other requirements.

133. As explained below, the gender-identity portions of the 2016 Rule have been in continuous effect since its issuance. The recently promulgated 2024 Rule merely restates and amplifies the 2016 Rule's provisions objected to by the CBA and its members.

C. HHS'S unsuccessful effort to repeal the mandate

1. Litigation against the 2016 Rule

134. On December 31, 2016, the U.S. District Court for the Northern District of Texas issued a nationwide preliminary injunction prohibiting HHS from "enforcing the [2016] Rule's prohibition against discrimination on the basis of gender identity or termination of pregnancy." *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016) (order granting nationwide preliminary injunction). The court concluded that the 2016 Rule's "expanded definition of sex discrimination" exceeded HHS's statutory authority under Section 1557, and that the 2016 Rule's failure to incorporate the religious and abortion exemptions in Title IX "renders the Rule contrary to law" in violation of the APA. *Id.* at 689, 691. The court also found that that the rule violated RFRA because it placed "substantial pressure on Plaintiffs to perform and cover [gender] transition and abortion procedures" in violation of their religious beliefs, and HHS could not show that the rule satisfied RFRA's requirement of strict scrutiny. *Id.* at 692-93.

135. On October 15, 2019, as clarified in the order of November 21, 2019, the same court entered summary judgment vacating the 2016 Rule "insofar as the Rule defines 'On the basis of sex' to include gender identity and termination of pregnancy," and remanded to HHS for further consideration. *See Franciscan All. v. Azar*, 414 F.3d 928, 946–47 (N.D. Tex. 2019); *Franciscan All., Inc. v. Azar*, No. 16-00108-O, slip op. at 2 (N.D. Tex. Nov. 21, 2019) (emphasis omitted).

136. On December 30, 2016, this Court in the *Religious Sisters of Mercy* case issued an order temporarily staying enforcement of the 2016 Rule against Plaintiffs. On January 23, 2017, the Court amended its December 30, 2016 order "to make clear that it temporarily stays enforcement, as to the named Plaintiffs, of Section 1557's prohibitions against discrimination on the bases of gender identity and termination of pregnancy."

2. The 2020 Rule

137. In May 2019, HHS issued a Notice of Proposed Rulemaking, and in June 2019 it published a proposed rule, to amend the 2016 Rule. *See* Nondiscrimination in Health and Health Education Programs or Activities, 84 Fed. Reg. 27,846 (June 14, 2019). Citing the *Franciscan Alliance* court's preliminary-injunction decision, the proposed rule stated that the Rule's definition of "sex" "exceeded [HHS's] authority under Section 1557." *Id.* at 27,849. The proposed rule sought to address this issue by repealing the 2016 Rule's definition of "sex" in its entirety, which, HHS said, would "allow the Federal courts, in particular, the U.S. Supreme Court . . . to resolve any dispute about the proper legal interpretation of" the term "sex" in Section 1557. *Id.* at 27,873. As the proposed rule noted, *see id.* at 27,855, the Supreme Court had recently granted certiorari to decide whether sex discrimination under Title VII included discrimination on the basis of sexual orientation and gender identity, in three cases that would later be decided together as *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020).

138. On June 12, 2020, HHS finalized its new rule, the "2020 Rule." *See* Nondiscrimination in Health and Health Education Programs or Activities, 85 Fed. Reg. 37,160 (June 19, 2020).

139. The 2020 Rule would have taken effect on August 18, 2020. *Id.* at 37,160.

140. The 2020 Rule sought to repeal certain portions of the 2016 Rule, and in particular, "omit[] the vacated language concerning gender identity and termination of pregnancy." *Id.* at

37,162; *see also id.* at 32,236 ("[T]his final rule removes . . . the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination."). But HHS declined to replace the 2016 Rule's definition of "sex" with a new definition, reasoning instead that the Supreme Court's then-forthcoming decision in *Bostock* would "likely have ramifications for the definition of 'on the basis of sex' under Title IX." *Id.* at 37,168. Thus, simply repealing the prior definition would permit "application of the [*Bostock*] Court's construction." *Id.*

141. Responding to the *Franciscan Alliance* court's vacatur order, HHS said that, under the 2020 Rule, it "will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations," *id.* at 37,192, and that it was amending its Title IX regulations "to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption," *id.* at 37,162.

Gender identity

142. The 2020 Rule sought to clarify that Section 1557 does not require healthcare professionals to perform gender transition procedures. *Id.* at 37,188. HHS "believes providers should be generally free to use their best medical judgment, consistent with their understanding of medical ethics, in providing healthcare to Americans." *Id.* at 37,187. "[T]he 2016 Rule inappropriately interfered with the ethical and medical judgment of health professionals." *Id.* The 2020 Rule "does not presume to dictate to medical providers the degree to which sex matters in medical decision making, nor does it impose the 2016 Rule's vague and overbroad mandate that they 'treat individuals consistent with their gender identity.'" *Id.* at 37,188.

143. The 2020 Rule sought to "clarif[y] that sex, according to the Title IX's plain meaning, may be taken into account in the provision of healthcare, insurance (including insurance coverage), and health research, as was the practice before the 2016 Rule." *Id.* at 37,189. At the same

time, the 2020 Rule did not "prohibi[t] a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis." *Id.* at 37,188.

144. While the 2016 Rule prohibited health insurers from "hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition," *id.* at 37,196 (quotation omitted), the 2020 Rule sought to repeal this prohibition, noting that there is a lack of "medical consensus to support one or another form of treatment for gender dysphoria," *id.* at 37,198. In HHS's view, "the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures." *Id.* Even if it were appropriate policy to mandate the provision and coverage of gender transition procedures, HHS could not do so "through application of Section 1557 and Title IX" because "[t]here is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex." *Id.*

Protections for religious freedom and conscience

145. The 2020 Rule "d[id] not craft a religious exemption to Section 1557." *Id.* at 37,207. Rather, it "simply state[d] that the Section 1557 regulation will be implemented consistent with" various religious and conscience protections already present in federal law, "including RFRA, healthcare conscience statutes, and the religious organization exception in Title IX." *Id.*

146. Accordingly, the 2020 Rule stated that "[i]nsofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by" Title IX, RFRA, and numerous other federal laws protecting conscience, "such application shall not be imposed or required." 45 C.F.R. § 92.6(b).

147. HHS stated that it "agrees with the court in *Franciscan Alliance* that particular provisions in the 2016 Rule violated RFRA as applied to private plaintiffs." 85 Fed. Reg. at 32,707. Regarding the 2016 Rule's gender identity provisions, HHS conceded that it "sees no compelling interest in forcing the provision, or coverage, of . . . medically controversial [gender transition] services by covered entities, much less in doing so without a statutory basis." *Id.* at 37,188.

148. Like the 2016 Rule, the 2020 Rule sought to make Section 1557 applicable to "any entity that has a health program or activity, any part of which receives Federal financial assistance from [HHS]." *Id.* at 37,226. If an entity receives HHS funds and is "principally engaged in the business of providing healthcare," then Section 1557 applies to the entity as a whole. *Id.* at 37,244. Otherwise, Section 1557 applies only to the "health program or activity" of the entity that receives HHS funds. *See id.*

149. But the 2020 Rule sought to narrow the application of Section 1557 to health insurance issuers. While the 2016 Rule declares that health insurance issuers are entities "principally engaged in the business of providing healthcare," the 2020 Rule seeks to repeal this aspect of the 2016 Rule and clarify that the provision of health insurance coverage is not *per se* the provision of "healthcare." Under the new rule, "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." *Id.* at 37,244-45 (45 C.F.R. § 92.3(c)). Thus, a health insurance issuer not principally engaged in the business of healthcare would be subject to Section 1557 only to the extent of any federally funded health program or activity of the issuer.

150. The 2020 Rule stated that employer-sponsored (i.e., self-insured) health plans are not covered entities "[t]o the extent that [they] do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare." *Id.* at 37,173.

Enforcement mechanisms

151. The 2020 Rule sought to repeal the "patchwork" of enforcement mechanisms contained in the 2016 Rule, and to adopt the enforcement mechanisms of the four statutes which Section 1557 incorporates along with "their implementing regulations respectively, each for its own statute." *Id.* at 37,202; *see also Doe v. BlueCross BlueShield of Tennessee, Inc.*, 926 F.3d 235, 240 (6th Cir. 2019) (stating that the 2016 Rule's blending of different enforcement mechanisms under Section 1557 "failed to respect" the plain language of Section 1557); *Briscoe v. Health Care Serv. Corp.*, 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (language of Section 1557 "unambiguously demonstrate[s] Congress's intent to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue" (quotation omitted)).

152. Because the incorporated statutes and their implementing regulations contain their own enforcement mechanisms, the enforcement mechanisms described above for the 2016 Rule continued to apply, in substantial part, under the 2020 Rule.

153. In the 2020 Rule, HHS declined to "to take a position in its regulations on the issue of whether Section 1557 provides a private right of action." *Id.* at 37,203. HHS stated that, "[t]o the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department's Section 1557 regulation." *Id.*

154. Courts have held that Section 1557 authorizes a private right of action to the extent that the incorporated statutes do. *See Doe*, 926 F.3d at 239; *Briscoe*, 281 F. Supp. 3d at 737.

D. *Bostock v. Clayton County*

155. On June 15, 2020, the Supreme Court decided *Bostock*. The Court held that when "an employer . . . fires someone simply for being homosexual or transgender," the employer has "discriminated against that individual 'because of such individual's sex'" within the meaning of Title VII. 140 S. Ct. at 1753.

156. *Bostock* did not hold that the term "sex" in Title VII equates to gender identity. Rather, the *Bostock* Court "assum[ed]" that "sex" means biological sex. *Id.* at 1739. But the Court reasoned that if an employer "fires a transgender person who was identified as a male at birth but who now identifies as a female," while "retain[ing] an otherwise identical employee who was identified as female at birth," then "the individual employee's sex plays an unmistakable and impermissible role in the discharge decision." *Id.* at 1741-42.

157. The Court cautioned, however, that its opinion did not "prejudge" the proper interpretation of "other federal . . . laws that prohibit sex discrimination," *id.* at 1753, including Section 1557 and Title IX, *see id.* at 1779-82 & n.57 (Alito, J., dissenting).

158. The Court further said it was "deeply concerned with preserving the promise of the free exercise of religion," and emphasized that the First Amendment and RFRA, among other laws, protect religious employers against being forced to "violate their religious convictions." *Id.* at 1754. Religious liberty protections, the Court explained, may "supersede Title VII's commands in appropriate cases." *Id.*

159. *Bostock* also instructs courts to read statutes "in accord with the[ir] ordinary public meaning." *Id.* at 1738.

E. Legal challenges to, and preliminary injunctions against, the 2020 Rule

160. Before the 2020 Rule could take effect, on August 17, 2020, the U.S. District Court for the Eastern District of New York entered "a stay and preliminary injunction to preclude the [2020 Rule] from becoming operative." *Walker v. Azar*, 2020 WL 4749859, at *1 (E.D.N.Y. 2020). The court concluded that the 2020 Rule is "contrary to *Bostock,*" that HHS's attempt to repeal the 2016 Rule was "contrary to law," and that the plaintiffs were likely to succeed on the merits of their APA claim. *Id.* at *1, *9. The court acknowledged that the *Franciscan Alliance* court had vacated the 2016 Rule in part and "agree[d] that it has no power to revive a rule vacated by another district court." *Id.* at *7. The court nonetheless thought that "*Franciscan Alliance* did not address the concept of 'sex stereotyping' embodied in the 2016 Rule." *Id.* The court entered the following order:

> [T]he Court stays the repeal of the 2016 definition of discrimination on the basis of sex. As a result, the definitions of "on the basis of sex," "gender identity," and "sex stereotyping" currently set forth in 45 C.F.R. § 92.4 [sic] will remain in effect. In addition, the Court preliminarily enjoins the defendants from enforcing the repeal.

161. The *Walker* court's preliminary injunction reinstated the 2016 Rule and the Mandate.

162. On September 2, 2020, the U.S. District Court for the District of Columbia entered a nationwide preliminary injunction against aspects of the 2020 Rule. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 2020 WL 5232076, at *45 (D.D.C. 2020).

163. Citing the *Franciscan Alliance* vacatur, the court acknowledged that it had "no authority . . . to disregard the final order of a district court vacating part of a regulation." *Id.* at *13. But the court distinguished between what it called the "'gender identity' portion" of the 2016 Rule and that rule's "prohibition on discrimination based on sex stereotyping." *Id.* at *14.

Believing that *Franciscan Alliance* vacated only the former "portion," the court enjoined the 2020 Rule to the extent that it "eliminated 'sex stereotyping' from the [2016] Rule's definition of 'discrimination on the basis of sex." *Id.* at *1, *45.

164. The court also held that HHS erroneously incorporated Title IX's religious exemption into its new rule without considering "the potential negative consequences that importing a blanket religious exemption into Section 1557 might have for access to health care." *Id.* at *28. The court stated, however, that "nothing in this decision renders religiously affiliated providers devoid of protection" and identified two "statutory safeguards": the ACA's explicit conscience and abortion protections, 42 U.S.C. § 18023(c)(2), and RFRA, *Id.* at *29.

165. The court refused to invalidate the provision of the 2020 Rule that repealed the 2016 Rule's prohibition on categorical coverage exclusions for gender-transition services. The court was satisfied that HHS had "thoroughly considered the evidence" on this issue and that it was "not this Court's place to resolve this scientific debate." *Id.* at *31.

166. The court concluded that HHS is "preliminarily enjoined from enforcing the repeal of the 2016 Rule's definition of discrimination '[o]n the basis of sex' insofar as it includes 'discrimination on the basis of . . . sex stereotyping'" and "from enforcing its incorporation of the religious exemption contained in Title IX." *Id.* at *45.

167. The effect of these two overlapping injunctions is that the 2016 Rule remained in place and that the 2020 rule never took effect. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1138 (D.N.D. 2021).

F. This Court's injunction of the Mandate and the Eighth Circuit's affirmance

168. On January 19, 2021, this Court granted the Religious Sisters of Mercy Plaintiffs' and the CBA's and its member plaintiffs' motions for summary judgment. *Religious Sisters of Mercy*,

513 F. Supp. 3d at 1137 (subsequent history omitted). The Court first held that the Plaintiffs had standing to challenge the Mandate to the extent it requires Plaintiffs to "perform or cover gender-transition procedures" under Section 1557. *Id.* at 1138. The Court ruled that Plaintiffs' claims implicate constitutional interests; Section 1557 arguably requires such coverage; and Plaintiffs are under a credible threat of enforcement. *Id.* The Court next held that the CBA Plaintiffs has standing to "pursue RFRA claims against the EEOC's interpretation of Title VII" that Title VII requires CBA members to "cover gender-transition procedures in their health plans." *Id.* at 1141. Finally, the Court concluded that the Mandate substantially burdens the Plaintiffs' sincerely held religious beliefs without satisfying strict scrutiny. *Id.* at 1147-49.

169. For both Section 1557 and Title VII, the Court also ruled that the CBA had associational standing to sue on behalf of its members. *Id.* at 1137. The Court explained that "[a]n organizational plaintiff 'need not establish that all of its members would have standing to sue individually so long as it can show that 'any one of them' would have standing.'" *Id.* at 1137 (quoting *Iowa League of Cities v. EPA*, 711 F.3d 844, 869 (8th Cir. 2013)). The CBA satisfied this test because its "verified second amended complaint confirms that its membership includes Catholic hospitals and other healthcare entities 'that receive Medicaid and Medicare payments and participate in HHS-funded programs'" and the named-CBA-member Plaintiffs had standing to challenge the Defendants' interpretation "in their own right." *Id.* at 1137, 1141. The Court entered a permanent injunction on February 19, 2021. *Religious Sisters of Mercy*, 2021 WL 1574628, at *1 (D.N.D. Feb. 19, 2021).

170. The Government appealed only the Court's rulings as to justiciability. The Eighth Circuit affirmed this Court's injunction in full, with one exception. *Religious Sisters of Mercy v.*

Becerra, 55 F.4th 583, 609 (8th Cir. 2022). The Eighth Circuit held that the CBA itself and the individual CBA members had standing to challenge the Defendants' interpretations of Section 1557 and Title VII. *Id.* at 602-07. Yet the Circuit reversed this Court's holding that the CBA had associational standing to sue on behalf of its unnamed members. The Eighth Circuit held that the CBA had to identify, through testimony from someone other than the "organization's self-descriptions of their membership", an additional, non-named-plaintiff member who had standing to sue in its own right in order to have associational standing. *Id.* at 601-02.

171. On remand, this Court dismissed without prejudice the CBA's claims to the extent they sought relief for the CBA's unnamed members, but invited the CBA to refile a suit in "properly establish[ed]" associational standing. *Religious Sisters of Mercy v. Becerra*, 16-cv-00386, slip op. at 3, (D.N.D. Sept. 15, 2023) ("Importantly, the dismissal is without prejudice, and nothing prevents the CBA from filing a new action, where associational standing us properly established."). This Court entered a corresponding amended judgment on October 11, 2023.

172. This suit was filed the next day, and docketed by the clerk on October 13.

G. The 2021 and 2022 Notices

173. The day he was sworn into office, President Biden issued an executive order asserting that "laws that prohibit sex discrimination . . . prohibit discrimination on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

174. On May 25, 2021, pursuant to this executive order, HHS published a document titled "Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972." 86 Fed. Reg. 27,984 (May 25, 2021). The May 2021 notice announced that "consistent with the Supreme Court's decision in *Bostock* and

Title IX," HHS would "interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Id.* at 27,984.

175. Shortly thereafter a group of physicians challenged the notification on the grounds that it would force them to treat youth suffering from gender dysphoria in a manner that violated their clinical judgment and conscience. *Neese v. Becerra*, 640 F. Supp. 3d 668, 668–70 (N.D. Tex. 2022). The U.S. District Court for the Northern District of Texas found the Notification to be "not in accordance with the law." *Id.* at 3. The Court entered a declaratory judgment declaring that "Section 1557 of the ACA does not prohibit discrimination on account of sexual orientation and gender identity, and the interpretation of 'sex' discrimination that the Supreme Court of the United States adopted in [*Bostock*] is inapplicable to the prohibitions on 'sex' discrimination in Title IX of the Education Amendments of 1972 and in Section 1557 of the ACA." Final Judgment, *Neese*, 2:21-cv-163-Z (N.D. Tex. Nov. 22, 2022), ECF No. 71.

H. The 2024 Rule

176. On May 6, 2024, HHS published a rule interpreting Section 1557, Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522 (May 6, 2024). Plaintiffs refer this rule as the "2024 Rule."

177. The 2024 Rule repeals the never-in-effect 2020 Rule and reiterates the commands of the 2016 Rule, including the Mandate.

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

179. The 2024 Rule applies to a "health program or activity operated by a covered entity." 89 Fed. Reg. at 37,699, to be codified at 45 C.F.R. § 92.101(a)(1). The 2024 Rule defines "covered entity" as, *inter alia*, a "recipient of Federal financial assistance." 89 Fed. Reg. at 37,694, to be codified at 45 C.F.R. § 92.4. The 2024 Rule defines "health program or activity" to cover virtually all healthcare providers and facilities, as well as health insurers, third-party administrators, pharmacy benefits managers, and other health service providers in the United States: Health program or activity means: "(1) Any project, enterprise, venture, or undertaking to: (i) Provide or administer health-related services, health insurance coverage, or other health-related coverage; (ii) Provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage; (iii) Provide clinical, pharmaceutical, or medical care; (iv) Engage in health or clinical research; or (v) Provide health education for health care professionals or others." 89 Fed. Reg. at 37,694, to be codified at 45 C.F.R. § 92.4; *see also* 89 Fed. Reg. at 37,538 ("OCR agrees with commenters' assessment that the Proposed Rule's approach to the inclusion of health insurance coverage and other health-related coverage in the definition of 'health program or activity' is most consistent with section 1557's statutory text and Congressional intent."); *id.* (noting that the 2024 Rule applies to all the operations of a health program or activity if any part receives federal financial assistance).

180. The 2024 Rule provides: "Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of: (i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, to be codified at 45 C.F.R. § 92.101(a)(2).The 2024 Rule does not provide definitions of these terms.

181. HHS previously defined "gender identity" in the 2022 Notice of Proposed Rulemaking to include the terms "transgender," "nonbinary," "gender nonconforming," "genderqueer," or "genderfluid." Notice of Proposed Rulemaking, Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824, 47,867 (Aug. 4, 2022) ("2022 NPRM").

182. The 2022 NPRM defines the Rule's prohibition on "gender identity" discrimination to require coverage and performance of "gender affirming care." "'[G]ender-affirming care' refers to care for transgender individuals (including those who identify using other terms, for example, nonbinary or gender nonconforming) that may include, but is not necessarily limited to, counseling, hormone therapy, surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." 87 Fed. Reg. at 47,834 n. 139. HHS has apparently adopted the standards of the World Professional Association for Transgender Health ("WPATH") as governing its interpretation of Section 1557. *See id.*; *see also id.* at 47,867 n. 416, 47,868 n. 423, 47,870 n. 448.

183. Guidance from HHS's Office of Population Affairs defines "gender affirming care" to include:

Affirming Care	**What is it?**	**When is it used?**	**Reversible or not**
Social Affirmation	Adopting gender-affirming hairstyles, clothing, name, gender pronouns, and restrooms and other facilities.	At any age or stage.	Reversible.
Puberty Blockers	Using certain types of hormones to pause pubertal development.	During puberty.	Reversible.
Hormone Therapy	Testosterone hormones for those who were assigned female at birth Estrogen hormones for those who were assigned male at birth.	Early adolescence onward.	Partially reversible.

Gender-Affirming Surgeries	"Top" surgery – to create male-typical chest shape or enhance breasts. "Bottom" surgery – surgery on genitals or reproductive organs Facial feminization or other procedures.	Typically used in adulthood or case by-case in adolescence.	Not reversible.

HHS Office of Population Affairs, Gender-Affirming Care and Young People, available at https://opa.hhs.gov/sites/default/files/2023-08/gender-affirming-care-young-people.pdf (last visited May 22, 2024).

184. The 2024 Rule defines "[p]regnancy or related conditions" to include "termination of pregnancy," *i.e.* abortion. 89 Fed. Reg. at 37,576; *see also id.* ("A covered entity that chooses to provide abortion care but refuses to provide an abortion for a particular individual on the basis of a protected ground—such as race—would violate section 1557."); *id.* at 37,556 ("We clarify that a Nondiscrimination Policy's prohibition of sex discrimination encompasses protections afforded for various types of sex discrimination such as pregnancy, including termination of pregnancy or related conditions."); *id.* at 37,556 ("OCR has concluded as a matter of statutory interpretation that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision."); *id.* at 37,557 ("We note also that, as commenters suggested, this provision protects patients from discrimination on the basis of actual or perceived prior abortions."); *id.* at 37,606 ("To the extent plans offer coverage for termination of pregnancies and related services, they must do so on a nondiscriminatory basis."). The Fifth Circuit has previously explained that defining sex discrimination to include "termination of pregnancy" "require[s] that hospitals perform . . . abortions." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 374 (5th Cir. 2022). This

interpretation of Section 1557 follows, *inter alia*, HHS's recent guidance to pharmacies, requiring pharmacies to stock abortion-inducing drugs pursuant to Section 1557.[8]

185. The 2024 Rule also defines sex discrimination and sexual-orientation discrimination to include "fertility care," including procedures like IVF, surrogacy, and gamete donation. 89 Fed. Reg. at 37,577 (defining "fertility care" to include "IVF"). The Rule also requires covered entities to provide infertility treatments to non-married couples. *Id.* (stating that "if a covered entity elects to provide or cover fertility services but categorically denies them to same-sex couples, it may violate section 1557's prohibition on sex discrimination."). In other words, a Catholic covered entity or employer must provide or cover IVF, surrogacy for all individuals, and must provide fertility treatments that are otherwise in line with Catholic belief for a non-married individual or a couple in a non-traditional relationship.

186. The 2024 Rule's extension of Section 1557 to "gender identity," abortion, and fertility, coupled with its expansive definition of a "covered entity," means that (1) healthcare providers are required to perform or refer for gender transition procedures, abortion, and infertility procedures; (2) healthcare providers are required to alter their speech and medical advice; (3) covered employers, insurance providers and TPAs are required to offer employee benefits covering

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[8] *See* Dep't of Health and Hum. Servs., Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies (Sept. 29, 2023) ("An individual experiences an early pregnancy loss (first-trimester miscarriage) and their health care provider prescribes medication to assist with the passing of the miscarriage. If a pharmacy refuses to fill the individual's prescription—which is prescribed to manage a miscarriage or complications from pregnancy loss, because this medication can also be used to terminate a pregnancy—the pharmacy may be discriminating on the basis of sex."), *available at* https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html (last visited May 22, 2024).

gender transition procedures and abortions; and (4) sex-specific healthcare facilities and programs, including shower facilities and hospital wards, must be opened to individuals based on gender identity, among other requirements.

1. Healthcare professionals are required to perform or refer for gender transition procedures, abortion, and immoral infertility treatments.

187. The 2024 Rule, like the 2016 Rule, requires healthcare providers to cover, perform, or refer for; and insurers, PBMs, and TPAs to cover, gender transition procedures if they offer analogous services in other contexts. *See* 89 Fed. Reg. at 37,700-01, to be codified at 45 C.F.R. § 92.206. Section 206 of the 2024 Rule specifically prohibits denying or limiting "health services sought for purpose of gender transition or other" so-called "gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,701, to be codified at 45 C.F.R. § 92.206(b)(4). That includes, according to HHS, "counseling, hormone therapy surgery, and other services designed to treat gender dysphoria or support gender affirmation or transition." NPRM, 87 Fed. Reg. at 47,834 n.139; *see* 89 Fed. Reg. at 37,596 ("gender-affirming care" includes "hormone therapy, surgery, and other related services").

188. For example, if a provider specializing in reconstructive surgery would perform a mastectomy for a woman suffering from breast cancer, the 2024 Rule requires that provider to perform a mastectomy for a minor who for a transgender man. *See* 87 Fed. Reg. at 47,867 ("By contrast, 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 the patient is a transgender man."). It would similarly be discriminatory under the 2024 Rule for a clinic to prescribe and administer puberty blockers to treat precocious puberty—an FDA-approved use—but not a

"gender transition"—a non- FDA-approved use. It would also be presumptively discriminatory for a hospital to provide an orchidectomy to treat testicular cancer but refuse to remove healthy testicles for a "gender transition."

189. Although HHS disclaims an attempt to mandate standards of care for gender-transition services in the final rule, the proposed rule mentioned the clinical "guidelines" it expects covered entities will follow: the guidelines of the WPATH and Endocrine Society. 2022 NPRM, 87 Fed. Reg. at 47,868 (asserting that covered entities "should follow clinical practice guidelines and professional standards of care," and citing WPATH Standards of Care ("SOC") 7 & Endocrine Society Guideline). HHS does not disavow that endorsement in the final rule or provide any examples of competing guidelines that would not require covered entities to support a "gender-transition."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

k. "Platysmaplasty" (neck lift);

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

m. "Rhinoplasty" (nose reshaping);

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

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

Case 3:23-cv-00203-PDW-ARS Document 32-9 Filed 10/30/24 Page 54 of 104

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

q. "Chin reshaping" surgery.

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

s. "Vocal cord surgery;"

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

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

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

w. "Nipple-areola tattoo;"

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

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

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

WPATH 8, supra, at S128.

192. The 2024 Rule, like the 2016 Rule, requires healthcare providers to perform (or refer for), and insurers and TPAs to cover abortions if they offer analogous services in other contexts. For example, the 2024 Rule states: "A covered provider that generally offered abortion care could violate that prohibition if, for example, it refused to provide an abortion to a particular patient because of that patient's race or disability." 89 Fed. Reg. at 37,576. Thus, if a Catholic healthcare provider would perform a surgery to save the life of the mother, the unintended effect of which is

an abortion (*e.g.*, in the case of ectopic pregnancies[9]), or would provide procedures to treat miscarriage that could also be used for abortion, *see Religious Sisters of Mercy,* 513 F. Supp. 3d at 1124 ("The same concept theoretically applied for abortions. So if an obstetrician performed dilation and curettage procedures for miscarriages, then the 2016 Rule barred a later refusal to perform those procedures for abortions."), the 2024 Rule would require that healthcare provider to offer abortion in violation of the providers' faith.

193. The 2024 Rule also requires healthcare providers to perform (or refer for), and insurers, PBMs, other service providers, and TPAs to cover artificial reproductive technologies such as IVF, surrogacy, and gamete donation for any individual, regardless of marital status. 89 Fed. Reg. at 37,577 ("OCR acknowledges the unique challenges faced by LGBTQI+ individuals seeking fertility treatment. Individuals are protected from discrimination regardless of the type of health care they seek.").

194. In crafting the 2024 Rule, HHS and EEOC disregarded the commenters that asked HHS to make clear that health services need only be covered if they are deemed to be "medically necessary" or "medically appropriate" in the professional opinion of those charged with the care of the patient. For example, the 2024 Rule prohibits any categorical exclusion of "gender affirming care." 89 Fed. Reg. at 37,701, to be codified at 45 C.F.R. § 92.207(b)(4). "When medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of

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[9] *See* United States Conference of Catholic Bishops, Ethical and Religious Directives for Catholic Health Care Services, p. 18, ¶ 47 (6th ed. 2009) ("Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child.").

gender-affirming care, but the same such treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex." 89 Fed. Reg. at 37,671.

2. Catholic healthcare organizations cannot adopt the Ethical and Religious Directives or the Doctrinal Note.

195. The 2024 Rule prohibits Catholic healthcare organizations from adopting policies, such as the Ethical and Religious Directives or Doctrinal Note, that would prohibit the organizations' constituents or agents from providing abortions, gender-affirming care, or immoral artificial reproductive procedures. The 2024 Rule "prohibits covered entities from . . . limiting a health care professional's ability to provide health services on the basis of a patient's . . . gender identity." 89 Fed. Reg. at 37,591; *see also id.* at 37,700 (same), to be codified at 45 C.F.R. § 92.206(b)(1). Indeed, this appears to be HHS's intent in adopting this provision. Although it was aware of commenters concerned that §§ 92.206(b)(1) 92.207(b)(4) would eliminate the ability of Catholic healthcare organizations to adopt the Ethical and Religious Directives, the Department declared that it harbored no anti-Catholic animus, 89 Fed. Reg. at 37,593, *and promulgated this provision regardless*, *id.*

3. Healthcare providers are required to alter their speech and medical advice.

196. The 2024 Rule, like the 2016 Rule, continues to compel the speech of healthcare institutions and professionals in several ways. For example, the Rule mandates revisions to healthcare program and activity's written policies, requiring express affirmations that gender transition-related procedures would be provided, 89 Fed. Reg. at 37,697, to be codified at 45 C.F.R. § 92.10(a)(1)(i), even if such revisions do not reflect the entity's medical judgment, values, or beliefs. The 2024 Rule also prohibits healthcare programs and activities from stating their view that "gender-affirming care" is not medically necessary. Thus, to avoid liability, healthcare providers

are compelled to speak by revising their policy to endorse gender transition-related services, to express language that is "affirming" of gender transition, and to express a non-binary view of gender. Further, by treating as discriminatory a medical view of transition-related treatment as experimental, the 2024 Rule coerces healthcare providers to speak about these procedures the way the government wants them to, even though they disagree and even though they believe they would disserve patients in so doing.

197. Like the 2016 Rule, 81 Fed. Reg. at 31,452, 31,458-59, the 2024 Rule requires covered entities to train their employees regarding the non-discrimination requirements in the Rule related to gender-affirming care, abortion, and artificial reproductive technology. 89 Fed. Reg. at 37,697, to be codified at 45 C.F.R. § 92.9.

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

199. Under the 2024 Rule, covered entities must tell patients that males can get pregnant, give birth, and breastfeed. As HHS explains in the 2022 NPRM, healthcare providers are responsible for "'discrimination, stigma, and erasure'" if they speak or act in way that treats "pregnancy and childbirth . . . as something exclusively experienced by . . . women." 87 Fed. Reg. at 47,865.

4. Covered employers and insurance providers are required to offer employee benefits covering gender transition procedures and immoral infertility treatments.

200. The 2024 Rule, like the 2016 Rule, prohibits certain employers, health programs, and insurance plans from exercising judgment as to what they cover. HHS stated, "When medically necessary treatments are categorically excluded when sought by transgender enrollees for purposes of gender-affirming care, but the same such treatments are covered for cisgender enrollees, such exclusions may deny transgender individuals access to coverage based on their sex." *Id.* at 37,671. And so Section 92.207(b)(4) and (5) of the 2024 Rule prohibits a covered entity from "[h]av[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care" or "[o]therwise deny[ing] or limit[ing] coverage, deny[ing] or limit[ing] coverage of a claim, or impos[ing] additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex." 89 Fed. at 37,701.

201. This conflict with religious employers extends beyond treatment related to gender dysphoria because some required procedures (such as elective hysterectomies) result in sterilization, and the 2024 Rule also extends to "termination of pregnancy." 89 Fed. Reg. at 37,576.

202. As a result of the 2016 Rule's materially identical requirement, some CBA members received notices from their insurance companies that their health plans were changing. These changes were not requested by these members. They were imposed involuntarily by the insurers on the ground that the changes were mandated by the 2016 Rule. Exhibits K and L hereto are, respectively, the gender dysphoria policies that United Healthcare and Blue Cross Blue Shield of

Kansas City delivered to CBA member dioceses – even those these dioceses are not themselves "covered entities" under the 2016 Rule.

203. The United Healthcare "Gender Dysphoria Rider" informed the diocese that its plan would now cover "[b]enefits for the treatment of Gender Dysphoria" and that any "exclusion for sex transformation operations and related services . . . is deleted." Ex. K at 1, 3. "Benefits for the treatment of Gender Dysphoria" include psychotherapy, "[c]ross-sex hormone therapy," and "[s]urgery for the treatment of Gender Dysphoria." *Id.* The latter category of surgery includes "Male to female surgeries" such as orchiectomy and penectomy (removal of testicles and penis) and clitoroplasty, labiaplasty, and vaginoplasty (creation of a clitoris, labia, and vagina). It also includes "Female to male surgeries" such as mastectomy, hysterectomy, vulvectomy and vaginectomy (removal of vulva and vagina), and metoidioplasty and phalloplasty (creation of penis).

204. After receiving notice of the United Healthcare rider in the mail, the CBA member diocese called the insurance company to demand the rider be removed from its plan. The insurer refused, informing the diocese that its plan must include the rider a result of the 2016 Rule.

205. The Blue Cross Blue Shield of Kansas City "Treatment of Gender Dysphoria" Policy informed the covered diocese that "[i]f coverage for gender reassignment surgery is available per the member's benefit, Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for treatment of gender dysphoria including gender reassignment surgery when it is determined to be medically necessary." Ex. L at 1. Under the policy, the diocesan plan covers "[p]sychotherapy for gender dysphoria"; "Continuous Hormone Replacement Therapy" with "[h]ormones of the desired gender," and surgeries for a "medically necessary initial gender reassignment," such as those identified above.

206. After receiving notice of the Blue Cross Blue Shield policy, the CBA member diocese called the insurer and was informed that the policy applied to the diocese's plan as a result of HHS's interpretation of Section 1557.

5. Sex-specific healthcare facilities or programs, including shower facilities or hospital wards, must be opened to individuals based on gender identity.

207. With regard to facilities, the 2024 Rule, like the 2016 Rule, prohibits sex-specific facilities. The 2024 Rule states, "A covered entity must not deny a nonbinary individual access to a health program or facility on the basis that the program or facility separates patients based on sex or offers separate male and female programs or facilities." 89 Fed. Reg. at 37,593. "For example, a hospital that assigns patients to dual-occupancy rooms based on sex would be prohibited from requiring a transgender woman to share a room with a cisgender man, regardless of how [that person's] sex is recorded in [their] insurance or medical records." 87 Fed. Reg. at 47,866-67.

208. When Title IX—the foundation for the 2016 and 2024 rules—was enacted, Congress ensured that it protected and preserved the privacy rights of individuals in intimate areas. *See* 20 U.S.C. § 1686; 117 Cong. Rec. 30407 (1971); 117 Cong. Rec. 39260 (1971); 117 Cong. Rec. 39263 (1971); 118 Cong. Rec. 5807 (1972). HHS's predecessor, the Department of Health, Education, and Welfare, promulgated regulations guaranteeing the privacy of individuals in intimate areas. *See* 34 C.F.R. § 106.32(b); 34 C.F.R. § 106.33 ("A recipient may provide separate toilet, locker room, and shower facilities on the basis of sex . . . ."). But in the 2016 and 2024 rules, HHS disregarded any right to "privacy" that could be violated "simply by permitting another person access to a sex-specific program or facility which corresponds to their gender identity." 81 Fed. Reg. at 31,389, 31,409; *see also* 89 Fed. Reg. at 37,593 (explaining that any policy protecting patient privacy must

be implement "consistent with the requirements of this rule" that non-binary individuals cannot be excluded from sex-specific facilities).

209. With regard to other health programs, HHS stated that sex-specific health programs or activities are permissible only when they do not cause more than *de minimis* harm. 89 Fed. Reg. at 37,594-95; *see also id.* at 37,701, to be codified at 45 C.F.R. 92.206(b)(3) ("In providing access to health programs and activities, a covered entity must not adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity.").

6. Other requirements of the 2024 Rule

210. Like the 2016 Rule, 81 Fed. Reg. at 31,468, the 2024 Rule requires that covered entities applying for federal financial assistance affirm up front that they will comply with the rule, 89 Fed. Reg. at 37,596, to be codified at 45 C.F.R. 92.5(a).

211. Like the 2016 rule, 81 Fed. Reg. at 31,472, the 2024 Rule requires covered entities to post notices regarding compliance with the 2024 Rule in conspicuous locations, 89 Fed. Reg. at 37,597-98, to be codified at 45 C.F.R. 92.10.

7. HHS rejects calls to accommodate religious exercise consistent with the Eighth Circuit's ruling in *Religious Sisters of Mercy*.

212. Like the 2016 Rule, 81 Fed. Reg. at 31,378, HHS was aware that the 2024 Rule would substantially burden the religious exercise of religious hospitals, churches, ministries, and other employers, 89 Fed. Reg. at 37,674.

213. During the comment period, many religious organizations voiced their alarm at the scope of the earlier proposed rule and explained why it was essential for HHS to include categorical protections for religious employers and healthcare organizations. For example, the United States Conference of Catholic Bishops joined with the National Association of Evangelicals, the Christian Medical Association, the National Catholic Bioethics Center, and other religious organizations to submit comments explaining how HHS's proposed rules would affect religious employers and urging HHS to protect religious exercise. Comments from USCCB et al. to U.S. Dept. of Health and Human Services Re: Nondiscrimination in Health Programs and Activities RIN 0945-AA17, at 2 (Sept. 7, 2022), https://www.usccb.org/sites/default/files/about/general-counsel/rulemaking/upload/2022.comments.1557.regulations.final_.pdf (last visited May 21, 2024).

214. HHS and EEOC ignored the calls to accommodate religious exercise as required by law in at least two ways.

215. *First*, like the 2016 Rule, 81 Fed. Reg. at 31,380, the 2024 Rule refuses to incorporate Title IX's categorical religious exception, 89 Fed. Reg. at 37,530-32. In doing so, HHS expressly rejected commenters' calls to follow the decision in *Franciscan Alliance v. Burwell*, 227 F. Supp. 3d 660, 691 (N.D. Tex. 2016) that failure to incorporate Title IX's religious exemption is "contrary to law." 89 Fed. Reg. at 37,532.

216. The 2024 Rule also refuses to incorporate Title IX's abortion-neutrality provision. 89 Fed. Reg. at 37,532 ("OCR has concluded as a matter of statutory interpretation that section 1557 does not require the Department to incorporate the language of title IX's abortion neutrality provision."). And although HHS gestures toward other federal laws that prohibit the Department from imposing an abortion mandate, *id.*, it refuses to provide a categorical exemption for religious

covered entity from the 2024 Rule's inclusion of "termination of pregnancy" in the definition of "sex" for purposes of Section 1557.

217. The 2024 Rule, like the 2016 Rule, is, in this regard, even more extreme and unyielding than the contraceptive/abortifacient mandate that HHS created based on another section of the Affordable Care Act. *See Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, 801 F.3d 927, 933-35 (8th Cir. 2015) (describing HHS's contraceptive and abortifacient mandate). While HHS reluctantly decided to exempt a narrowly defined group of "religious employers" from its abortifacient and contraception mandate, *id*. at 933, it refused to categorically exempt *any* religious employers from the 2024 Rule. And while many non-exempt religious employers could avoid the contraceptive/abortifacient mandate (though at substantial cost) by maintaining a grandfathered group health plan, there is no grandfather exemption from the requirements of Section 1557 or the 2024 Rule.

218. Even while refusing to exempt religious organizations from its Mandate, the government has exempted its own insurance programs. TRICARE, the military's insurance program, generally does not cover "surgery for the treatment of gender dysphoria." Covered Services, Gender Dysphoria Services, TRICARE. A TRICARE guidance memo states that in the context of gender dysphoria treatment, "[i]n no circumstance will a provider be required to deliver care that he or she feels unprepared to provide either by lack of clinical skill or due to ethical, moral, or religious beliefs." Yet no similar protections for providers' medical judgment or religious beliefs are offered under the 2024 Rule.

219. Further, Medicare and Medicaid do not require coverage for gender-reassignment surgery but allow states and local administrators to make coverage determinations on a case-by-

case basis. Ctrs. for Medicare & Medicaid Servs., Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (Aug. 30, 2016).[10] The Centers for Medicare & Medicaid Services, which is part of HHS, concluded that "there is not enough evidence to determine whether gender reassignment surgery improves health outcomes" because while some studies "reported benefits," "others reported harms." Ctrs. for Medicare & Medicaid Servs., Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (June 2, 2016).[11]

220. *Second*, the 2024 Rule fails to follow this Court's and the Eighth Circuit's decisions in *Religious Sisters of Mercy*, holding that the Religious Freedom Restoration Act requires an exemption for Catholic employers and healthcare providers who object to performing and providing the immoral procedures mandated by the 2024 Rule. *See Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1149 (D.N.D. 2021) ("As applied, the challenged interpretations of Section 1557 and Title VII violate the RFRA."); *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583 (8th Cir. 2022) (affirming judgment that requiring Catholic employers and healthcare providers to cover and provide gender-affirming care violates RFRA). Notably, HHS refused to even acknowledge the existence of these rulings in the 2024 Rule or its preamble.

I. EEOC, invoking Title VII, has imposed on non-covered entities the Mandate's requirement of gender-transition coverage.

221. Although the 2024 Rule directly applies only to "covered entities," it announces, like the 2016 Rule did, 81 Fed. Reg. at 31,432, that the EEOC will enforce a similar rule against

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[10] Available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282.

[11] Available at https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=282.

employers under Title VII. The 2024 Rule declares that although HHS lacks jurisdiction over "employment practices," 89 Fed. Reg. at 37,552, it will "transfer matters to the EEOC or DOJ where OCR lacks jurisdiction over an employer," *id.* at 37,624, 37,627; *see also* 87 Fed. Reg. at 47,877 ("For example, OCR will transfer matters to the EEOC where OCR lacks jurisdiction over an employer responsible for the benefit design of an employer-sponsored group health plan."). HHS has decided that, for non-healthcare entities, Title VII is better suited to "address claims that an employer has discriminated in the provision of benefits, including health benefits, to its employees." *Id.* at 31,437.

222. In the context of Title VII, the EEOC has adopted similar substantive standards as HHS. For eight years, the EEOC has interpreted Title VII as prohibiting discrimination against employees on the basis of "transgender status." EEOC, What You Should Know About EEOC and the Enforcement Protections for LGBT Workers.[12] The EEOC maintains this interpretation today. *See* EEOC, What You Should Know: The EEOC and Protections for LGBT Workers ("EEOC Statement").[13]

223. The EEOC has specifically enforced this interpretation by requiring employer health plans to cover "medically necessary care based on transgender status." EEOC, Deluxe Financial to Settle Sex Discrimination Suit on Behalf of Transgender Employee, 2016 WL 246967 (Jan. 21, 2016) (noting that three-year consent decree with employer "provides that, as of January

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[12] This EEOC Statement was previously available at https://www.eeoc.gov/eeoc/newsroom/wysk/enforcement_protections_lgbt_workers.cfm. The version of this page, as accessed and preserved on December 15, 2016 by the Internet Archive, is attached hereto as Exhibit J.

[13] Available at https://www.eeoc.gov/laws/guidance/what-you-should-know-eeoc-and-protections-lgbt-workers.

1, 2016, [employer's] national health benefits plan will not include any partial or categorical exclusion for otherwise medically necessary care based on transgender status"); *see also Darin B. v. U.S. Office of Personnel Mgmt.*, EEOC Appeal No. 0120161068, 2017 WL 1103712 (Mar. 6, 2017) (a transgender male complainant stated a cognizable claim of sex discrimination when he alleged that his Federal Employee Health Benefits insurance plan denied pre-authorization for nipple-areola reconstruction; the failure to use or exhaust the process for Agency review of an insurance carrier's decision does not preclude an employee from asserting a viable claim in the EEO process).

224. Dignity Health is one of the largest healthcare systems in the United States and includes many Catholic hospitals. It has now merged with Catholic Health Initiatives to form Common Spirit Health, the largest Catholic Hospital network in the world. In June 2016, Josef Robinson, a transgender male, sued Dignity Health for maintaining an employee health plan that categorically excluded coverage for gender transition services. Robinson's complaint asserted a violation of Title VII, claiming that "[d]iscrimination on the basis of transgender status or gender nonconformity is discrimination on the basis of 'sex' under Title VII," and that the hospital's exclusion of transgender surgery constituted a violation of Section 1557 of the Affordable Care Act. EEOC filed an amicus brief in the case in support of Robinson, arguing that the employer's transgender exclusion violated Title VII by denying Robinson "access to medically necessary treatment for his gender dysphoria, a serious health condition directly related to the fact that he is transgender." Amicus Brief of EEOC in Support of Plaintiff, *Robinson v. Dignity Health*, 16-cv-03035 YGR (N.D. Cal.) (filed Aug. 22, 2016).[14]

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[14] Available at https://www.eeoc.gov/sites/default/files/migrated_files/eeoc/litigation/briefs/robinson.html.

225. The EEOC has taken enforcement action against other employers for the "categorical exclusion" from their health plans of "services related to transgender treatment/sex therapy." Soc'y for Human Res. Mgmt., Wal-Mart Loses Perfect LGBTQ Rating Because of Transgender Harassment, Nov. 30, 2017.[15]

226. The EEOC has attempted to enforce the Mandate against at least one CBA member. While the appeal in *Religious Sisters of Mercy* was pending before the Eighth Circuit, in October 2022, the CBA was notified by one of its members, a Catholic ministry with "Catholic" in its name, that the EEOC had begun an enforcement action for its refusal to provide gender-transition coverage. The EEOC demanded reams of information from this CBA member (hereafter "Catholic Ministry"), including "all contracts" with insurers and third party administrators, "all benefits and/or health plans," "all hard copy and/or electronic communications and/or notes" regarding health plans, "all medically necessary reason(s) for which [Catholic Ministry] has covered hysterectomy procedures," and "the software and/or additional data systems" used by Catholic Ministry to manage health benefits. The injunction previously entered by this Court was the only thing protecting this CBA member. However, when the Court vacated its injunction to the extent it protected CBA on an associational basis, the CBA's members are currently under threat of similar enforcement actions. *See* Ex. I, incorporated by reference herein.

227. Since promulgating the guidance and taking the positions and enforcement actions described above, the EEOC has never changed its interpretation or application of Title VII.

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[15] Available at https://www.shrm.org/resourcesandtools/legal-and-compliance/employment-law/pages/wal-mart-lgbtq-rating.aspx.

228. Courts have recently interpreted Title VII consistent with the EEOC position that health insurance coverage cannot exclude care for transgender services, such as vaginoplasty could not be excluded from coverage. See *Lange v. Houston Cnty., Georgia*, No. 22-13626, 2024 WL 2126748, at *1 (11th Cir. May 13, 2024) ("a health insurance provider can be held liable under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq.*, for denying coverage for gender-affirming care to a transgender employee *because* the employee is transgender. We hold that it can.").

229. Indeed, in *Lange*, the United States filed an *amicus* brief in support of the plaintiff in that case, who alleged discrimination under Title VII by her employer for its categorical exclusion of "gender-affirming care" from the employer's health plan. Brief for the United States as Amicus Curiae Supporting Plaintiff-Appellee and Urging Affirmance on the Issues Addressed Herein, *Lange v. Houston Cnty., Georgia*, No. 22-13626, (Mar. 17, 2023), attached here as Exhibit N. In that brief, the United States argued that an employer-sponsored health insurance plan violates Title VII if it excludes coverage for medical treatments only when they are needed to provide gender-affirming care." *Id.* at 10. The United States filed this brief because of its "substantial interest . . . [in] the proper application of the prohibition on sex discrimination in Title VII . . . to an employer's denial of health insurance benefits to a transgender worker" in light of EEOC's and DOJ's "enforcement authority under Title VII." *Id.* at 1-2.

230. Accordingly, it is the policy and official position of the EEOC, based on the EEOC's statements and the agency's actual enforcement actions, that exclusion of gender-transition coverage in employer health plans constitutes a violation of Title VII's ban on "sex" discrimination.

J. Enforcement Mechanisms

231. CBA members that do not comply with the Mandate may face enforcement actions initiated by federal agencies or by individuals who allege they have been discriminated against.

232. The 2024 Rule, like the 2016 Rule, Fed. Reg. at 31,467-68, 31,472, 31,439, subjects "covered entities" to enforcement actions brought by HHS's Office of Civil Rights ("OCR"). If the Director of OCR concludes that a covered entity had discriminated on the basis of "gender identity," "sexual orientation," or "termination of pregnancy," the entity would have to take "remedial action . . . to overcome the effects of the discrimination." 89 Fed. Reg. at 37,696, to be codified at 45 C.F.R. § 92.6(a)(1). If it refuses, OCR could initiate an administrative procedure to terminate the entity's HHS funding. 89 Fed. Reg. at 37,664.

233. The 2024 Rule, like the 2016 Rule, *see* 81 Fed. Reg. at 31,439, 31,472, also empowers OCR to compel covered entities to record and submit compliance reports under Section 1557, 89 Fed. Reg. at 37,664.

234. Under the 2024 Rule, like the 2016 Rule, where HHS does not have jurisdiction over an alleged discriminatory act, it said it would refer the matter to the EEOC for enforcement under Title VII. 89 Fed. Reg. at 37,626. Similar to HHS's authority under Section 1557, the EEOC has authority to investigate alleged Title VII violations and will ask violators to voluntarily take corrective action for the discriminatory behavior. 42 U.S.C. § 2000e-5(a).

235. If HHS or the EEOC are dissatisfied with an entity's corrective remedial actions, the 2024 Rule permits referral of the matter to the Department of Justice to bring a federal lawsuit to enforce federal civil rights laws. *See, e.g.*, 89 Fed. Reg. at 37,664.

236. Title VII creates a private right of action. In the 2016 and 2024 rules, HHS interpreted Section 1557 as authorizing a private right of action. *See* 81 Fed. Reg. at 31,440; 89 Fed. Reg. at 37,654. This means that individuals who believe they have been discriminated against on the basis of gender identity may bring their own federal lawsuits. These laws can also be enforced by class action suits.

237. Sanctions for failing to comply with the 2024 Rule are severe. They include compensatory damages, punitive damages, treble damages, civil penalties, attorney fees, injunctive relief, and even loss of federal funding.

238. *Loss of federal funding*: Catholic healthcare entities subject to the 2024 Rule risk the denial or discontinuance of federal funding if they do not comply. 89 Fed. Reg. at 37,664. HHS Form 690 makes compliance "a condition of continued receipt of Federal financial assistance" and authorizes the government "to seek judicial enforcement of this assurance." *Assurance of Compliance*, U.S. Dep't of Health and Hum. Servs., https://www.hhs.gov/sites/default/files/form-hhs690.pdf. (last visited May 22, 2024).

239. *Civil and criminal penalties and treble damages*: Covered entities that submit HHS Form 690 but do not comply with the 2024 Rule could be liable under the False Claims Act, which authorizes a civil penalty of up to $11,000 for each false claim, "plus 3 times the amount of damages which the Government sustains because of" the false claim. 31 U.S.C. § 3729(a)(1). False claims related to a health program may also subject responsible persons to fines and up to five years imprisonment under 18 U.S.C. § 1035(a).

240. *Compensatory damages*: Catholic employers that violate the 2024 Rule may be subject to compensatory damages under Section 1557 or under Title VII. 89 Fed. Reg. at 37,654 ("The

enforcement mechanisms available for and provided under . . . Title IX . . . shall apply for purposes of Section 1557."); *Franklin v. Gwinnett Cnty. Pub. Schs.*, 503 U.S. 60, 76 (1992) (compensatory damages available under Title IX); 42 U.S.C. § 1981a(b)(3) (compensatory damages available under Title VII). Compensatory damages may include pecuniary losses and even nonpecuniary losses such as "emotional pain" and "mental anguish." 42 U.S.C. § 1981a(b)(3); *Williams v. Pharmacia, Inc.*, 137 F.3d 944, 954 (7th Cir. 1998).

241. *Punitive damages*: Punitive damages are available under Title VII if the employer acted "with malice or with reckless indifference to the federally protected rights" of an employee. 42 U.S.C. § 1981a(b)(1). Punitive damages are subject to the same statutory caps that are imposed for nonpecuniary losses. *See id.* § 1981a(b)(3).

242. *Injunctive relief*: Courts may order broad forms of injunctive relief under Title VII, *see* 42 U.S.C. §2000e-5(g)(1); *United States v. Criminal Sheriff, Parish of Orleans*, 19 F.3d 238, 239 (5th Cir. 1994), and may even mandate that employers adopt certain policies, *see, e.g.*, *Morris v. Am. Nat'l Can Corp.*, 730 F. Supp. 1489, 1498 (E.D. Mo. 1989), *aff'd in part, rev'd in part on other grounds*, 952 F.2d 710 (8th Cir. 1991); *Robinson v. Jacksonville Shipyards, Inc.*, 760 F. Supp. 1486, 1541 (M.D. Fla. 1991). Title IX, and hence Section 1557, also permit broad injunctive relief. *See Roberts v. Colo. State Bd. of Agriculture*, 998 F.2d 824, 833 (10th Cir. 1993).

243. *Attorney's fees*: Under Title VII and Section 1557, a prevailing party is entitled to costs and attorney's fees. *See* 42 U.S.C. § 2000e-5(k); *id.* § 1988(b).

VI. THE MANDATE AND THE EEOC'S INTERPRETATION CONTINUE TO BURDEN THE RELIGIOUS EXERCISE OF CBA'S MEMBERS

244. The Mandate continues to burden the religious exercise of the CBA's members.

245. The EEOC's interpretation of Title VII applies to all employers with 15 or more employees.

246. The decisions of CBA members to refuse to cooperate in their patients', employees', or plan beneficiaries' efforts to undergo gender transition procedures qualify as the exercise of religion.

A. The Mandate's effects on CBA members that are covered entities – medical services

247. The Mandate's regulatory scheme makes it virtually impossible for CBA members that qualify as a "covered entity" to continue their healthcare and ministries. Their options are: (1) provide gender transition services, abortion, and/or immoral infertility treatments; (2) cease providing any services that HHS may correlate with gender transition, abortion, and/or immoral infertility treatments; (3) continue to meet patients' needs but refuse to provide gender transition, abortion, and/or immoral infertility treatments; (4) stop participating in all HHS-related programs, including Medicaid and Medicare; and (5) cease providing health services and activities.

248. Option 1, directly providing gender transition, abortion, and/or immoral infertility treatments, is contrary to Catholic values and would give rise to scandal. Directly providing gender transition, abortion, and/or immoral infertility treatments is contrary to Catholic teaching and belief. This situation gives rise to scandal and the loss of members' reputation because patients, employees, and the larger community would perceive that CBA-member healthcare providers profess one thing but do another. Such scandal devastates ministry.

249. Option 2, ceasing providing any services that HHS may correlate with gender transition, abortion, and/or immoral infertility treatments, would be ruinous for covered-entity CBA members and their patients. To avoid the Mandate, CBA members could refuse to perform any

procedure that might be used as part of a gender transition, such as hysterectomies, mastectomies, hormone treatments, and plastic surgery; abortion, such as treatment for miscarriage or surgeries to save a mother's life; or fertility treatments such as hormonal therapy or surgeries. Doing so would prevent these CBA members from being able to use such procedures to address medical illnesses or conditions—such as uterine cancer, breast cancer, menopause, miscarriage, and polycystic ovarian syndrome—thus injuring their healing ministries. Artificially restricting their medical services in this manner would cause these CBA members to incur financial losses, lose valuable employees, and suffer other injuries.

250. Absent injunctive relief from this Court, option 2 is ruinous because it would expose covered entity CBA members to HHS and EEOC enforcement actions and other penalties as described above.

251. Option 3, stopping participation in HHS-related programs, including Medicaid and Medicare, would severely penalize CBA members for maintaining their religious convictions. This would also require them to severely curtail their services to the poor, disabled, and the elderly, thus injuring their healing ministries.

252. Option 4, ceasing their health services and activities, would burden CBA members' religious exercise, because they are called by their Catholic values to engage in the healing ministry of Christ.

B. The Mandate's effects on CBA members that are covered entities – insurance coverage

253. The Mandate also affects CBA members' ability to offer their employees health benefits that reflect their Catholic values. Their options are: (1) provide a group health plan that includes coverage for gender transition, abortion, and/or immoral infertility treatments; (2)

provide a group health plan that excludes coverage for gender transition, abortion, and/or immoral infertility treatments; or (3) cease providing health coverage.

254. Option 1, providing a group health plan that covers gender transition, abortion, and/or immoral infertility treatments, is contrary to Catholic values and would give rise to scandal.

255. Absent injunctive relief from this Court, option 2 is ruinous because it would expose covered entity CBA members to HHS and EEOC enforcement actions and other penalties as described above.

256. Option 3, dropping health benefits, would burden CBA members' exercise of religion because: (a) Catholic values commend providing just compensation and benefits supportive of family values, including, whenever possible, health care; (b) eliminating health insurance for employees subjects CBA members to annual excise taxes of $2,000 per employee after the first 30 employees, 26 U.S.C. § 4980H(a), (c)(1); and (c) eliminating health insurance would put CBA members at a significant disadvantage in the market for recruiting the best workers and thereby harm the operation of their ministries.

C. The Mandate's effects on insured CBA members

257. The Mandate also injures CBA members who are not covered entities, and are thus not directly regulated by the 2024 Rule. Regardless of whether a CBA member is a covered entity, the Mandate restricts its ability to acquire a group health plan that reflects Catholic values. This is because group insurers are covered entities that are required, under the 2024 Rule, to cover gender transition, abortion, and/or immoral infertility treatments.

258. For CBA members that sponsor an insured group plan, their options are: (1) provide a group health plan that includes coverage for gender transition, abortion, and/or immoral

infertility treatments; (2) provide a group health plan that excludes coverage for gender transition, abortion, and/or immoral infertility treatments; or (3) cease providing health coverage.

259. Option 1, providing a group health plan that covers gender transition, abortion, and/or immoral infertility treatments is contrary to Catholic values and would give rise to scandal.

260. The Mandate has made option 2, providing a group health plan that excludes gender transition, abortion, and/or immoral infertility treatments, either impossible or unduly burdensome. Insured CBA members have been told by their insurers that, as a direct result of the Mandate, their plans must include gender-transition coverage. Absent injunctive relief from this Court, even if a non-covered entity CBA member were able to secure a morally compliant insured plan, option 2 is ruinous because it would expose CBA members to EEOC enforcement actions and other penalties as described above.

261. Option 3, dropping health benefits, would burden CBA members' exercise of religion as described above.

D. The Mandate's effects on self-insured CBA members

262. The Mandate also injures CBA members who have a self-insured group health plan. For CBA members that sponsor a self-insured group health plan, their options are: (1) provide a group health plan that includes coverage for gender transition, abortion, and/or immoral infertility treatments; (2) provide a group health plan that excludes coverage for gender transition, abortion, and/or immoral infertility treatments; or (3) cease providing health coverage.

263. Option 1, providing a group health plan that covers gender transition, abortion, and/or immoral infertility treatments is contrary to Catholic values and would give rise to scandal.

264. The Mandate has made option 2, providing a group health plan that excludes gender transition, abortion, and/or immoral infertility treatment coverage, either impossible or unduly burdensome. Absent injunctive relief from this Court, even if a non-covered entity CBA member were able to secure a morally compliant self-insured plan, option 2 is ruinous because it would expose members to EEOC enforcement actions and other penalties as described above.

265. Option 3, dropping healthcare benefits, would burden CBA members' exercise of religion as described above.

VII. NEED FOR RELIEF

266. The 2024 Rule continues and amplifies the Mandate. As a result, absent relief from this Court, CBA members are presently subject to the Mandate and are required to perform, or include in their health plans, gender-transition services or else risk enforcement actions, civil lawsuits, and other penalties.

267. As a direct result of the Mandate, self-insured CBA members have been notified by their TPAs that they must indemnify their TPA or accept their TPA's liability in order to maintain their exclusion of all gender transition coverage.

268. Absent relief from this Court, CBA members that are covered entities are currently threatened by the Mandate with administrative investigations, civil lawsuits, and various penalties if they continue to offer health services in a manner that reflect their Catholic convictions.

269. Absent relief from this Court, all CBA members are currently threatened by the Mandate with administrative investigations, civil lawsuits, and various penalties if they continue to offer employee health benefits in a manner that reflects their Catholic convictions.

VIII. CAUSES OF ACTION

COUNT I

Violation of the Administrative Procedure Act
Agency Action Not in Accordance with Law

270. Plaintiffs incorporate by reference all preceding paragraphs.

271. Defendants are "agencies" under the APA, 5 U.S.C. § 551(1), and the 2016 Rule, along with the EEOC Statement complained of herein, constitute "rules" under the APA, *id.* § 551(4), and constitute "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court," *id.* § 704.

272. The 2024 Rules are a "rule" under the APA. 5 U.S.C. § 551.

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

274. The APA prohibits agency actions that are "not in accordance with law, in excess of statutory authority, or limitation, or short of statutory right." *Id.* § 706(2)(A), (C). The 2024 Rule and the EEOC Statement are not in accordance with law for a number of independent reasons.

275. The 2024 Rule will require physicians to perform gender transition procedures, abortion, and/or fertility treatments regardless of whether those procedures are "medically necessary" or "medically appropriate." It is not in accordance with law for HHS to require medical professionals to perform procedures that may not be necessary or appropriate and may in fact be harmful to the patients.

276. The 2024 Rule is not in accordance with Section 1557 of the Affordable Care Act (42 U.S.C. § 18116), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 et seq., or the Rehabilitation Act, 29 U.S.C. § 705(20)(F)(i). The 2024 Rule define discriminating "on the

basis sex" in a manner that is contrary to Section 1557, Title IX, and the Rehabilitation Act. *See* 89 Fed. Reg. at 37,699. Neither Section 1557, the Rehabilitation Act, nor Title IX requires performance of abortion or fertility treatments, nor prohibit consideration of the real biological differences between the sexes in the context of healthcare and health coverage. HHS's attempt to expand the definition is not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A).

277. The Mandate is not in accordance with Title VII. Title VII does not require coverage of fertility treatments or sterilization, or prohibit consideration of the real biological differences between the sexes in the context of healthcare and health coverage. EEOC's attempt to expand the definition is not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A).

278. HHS's failure to include in the 2024 Rule a religious exemption and abortion neutrality provisions that parallels the religious exemption and abortion neutrality provisions in Title IX is also not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A).

279. HHS's failure to include an exclusion for gender identity and/or transgender status from the 2024 Rule as required by 42 U.S.C. § 18116(a) and 29 U.S.C. § 705(20)(F)(i) is not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A).

280. HHS's failure to include an exclusion for sterilization and sterilization-related services is not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A) because it is inconsistent with the Church Amendments, 42 U.S.C. § 300a-7(b), which protect the right of healthcare entities who receive federal funding to refuse to participate in or assist with sterilizations.

281. The 2024 Rule violates the Church Amendments, 42 U.S.C. § 300a-7, which protect the right of healthcare entities that receive federal funding to refuse to participate, perform, or

assist with gender-transition procedures, including when it would be contrary to his religious beliefs or moral convictions.

282. The 2024 Rule also forces physicians to provide medical services related to gender transition, abortion, and infertility treatments. This is not in accordance with substantive due process rights protecting a medical professional's right to not perform a procedure he or she believes to be experimental, ethically questionable, and potentially harmful.

283. The 2024 Rule is not in accordance with law because it violates the First Amendment, Fifth Amendment, and the Religious Freedom Restoration Act, as hereafter described.

284. Further, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors v. HHS*, 594 U.S. 758, 764 (2022) (cleaned up). Section 1557 doesn't clearly authorize the 2024 Rule.

285. Plaintiffs have no adequate or available administrative remedy, or, in the alternative, any effort to obtain an administrative remedy would be futile.

286. Plaintiffs have no adequate remedy at law.

287. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT II

Violation of the Administrative Procedure Act
Agency Action In Excess of Statutory Authority and Limitations

288. Plaintiffs incorporate by reference all preceding paragraphs.

289. The APA prohibits agency actions that are "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C). The 2024 Rule and the EEOC Statement are in excess of statutory jurisdiction, authority, and limitations for a number of reasons.

290. For the reasons described above, there is no statutory authority or jurisdiction for HHS to require medical professionals and facilities to perform procedures (or refer for the same) that may not be necessary or appropriate, and may in fact be harmful to the patients.

291. For the reasons described above, HHS's decision to interpret Section 1557 to ban "gender identity" and "termination of pregnancy" discrimination in the context of healthcare and health coverage is in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C).

292. For the reasons described above, EEOC's decision to interpret Title VII to ban "gender identity" discrimination in the context of healthcare and health coverage is in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C).

293. For the reasons described above, HHS's failure to include a religious exemption or an abortion-neutrality provision in the 2024 Rule that parallels the religious exemption in Title IX is in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C).

294. For the reasons discussed above, HHS's failure to include an exclusion for sterilization and sterilization-related services is in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C) because it is inconsistent with the Church Amendments, 42 U.S.C. § 300a-7(b).

295. For the reasons described above, EEOC's decision to require CBA members to act in violation of Title VII by not accommodating their employees' religious and conscientious objections to participating in (or referring for) gender transition services and/or infertility treatments is

in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C).

296. For the reasons discussed above, the 2024 Rule is in excess of statutory jurisdiction, authority, and limitations within the meaning of 5 U.S.C. § 706(2)(C) as it violates the First Amendment, Fifth Amendment, and the Religious Freedom Restoration Act, as hereafter described.

297. Plaintiffs have no adequate or available administrative remedy, or, in the alternative, any effort to obtain an administrative remedy would be futile.

298. Plaintiffs have no adequate remedy at law.

299. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT III

Violation of the Administrative Procedure Act
Agency Action that is Arbitrary, Capricious and an Abuse of Discretion

300. Plaintiffs incorporate by reference all preceding paragraphs.

301. The APA prohibits agency actions that are "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). The 2016 Rule is arbitrary and capricious agency action for a number of reasons.

302. For the reasons discussed above, HHS's prohibition on "gender identity" discrimination in the context of healthcare and health coverage is an arbitrary and capricious interpretation of Section 1557 of the Affordable Care Act (42 U.S.C. § 18116) and Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 *et seq.*

303. For the reasons discussed above, HHS's prohibition on "termination of pregnancy" discrimination in the context of healthcare and health coverage is an arbitrary and capricious interpretation of Section 1557 of the Affordable Care Act (42 U.S.C. § 18116) and Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 *et seq.*

304. For the reasons discussed above, EEOC's prohibition on "gender identity" discrimination in the context of healthcare and health coverage is an arbitrary and capricious interpretation of Title VII.

305. For the reasons discussed above, HHS's failure to include a religious exemption in the 2024 Rule that parallels the religious exemption and abortion neutrality provision in Title IX is arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A).

306. For the reasons discussed above, HHS's failure to include an exclusion for sterilization and sterilization-related services is arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A) because it is inconsistent with the Church Amendments, 42 U.S.C. § 300a-7(b), the Religious Freedom Restoration Act, the prior decisions of this Court, and the Weldon Amendment.

307. For the reasons described above, HHS's decision to require Plaintiffs to act in violation of Title VII by not accommodating their employees' religious objections to participating in gender transition procedures, abortion, and/or infertility treatments is arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A).

308. For the reasons discussed above, the 2024 Rule is arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A) as it violates the First Amendment, Fifth Amendment, and Religious Freedom Restoration Act as hereafter described.

309. Plaintiffs have no adequate or available administrative remedy, or, in the alternative, any effort to obtain an administrative remedy would be futile.

310. Plaintiffs have no adequate remedy at law.

311. Absent injunctive and declaratory relief against the 2024 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT IV

Violation of the First Amendment of the United States Constitution
Freedom of Speech
Compelled Speech and Compelled Silence

312. Plaintiffs incorporate by reference all preceding paragraphs.

313. CBA members plan to continue using their best medical and ethical judgment in treating and advising patients. Performing (or referring for) gender transition procedures is contrary to their best medical and/or ethical judgment.

314. The 2024 Rule prohibits CBA members from expressing their professional opinions that gender transition procedures, abortion, and certain infertility treatments are not the best standard of care, immoral, and/or are experimental.

315. The 2024 Rule also requires CBA members to amend their written policies to expressly endorse gender transition procedures, abortion, and certain infertility treatments, even if such revisions do not reflect the medical judgment, values, or beliefs of CBA members. The 2024 Rule also requires CBA members to use gender-transition affirming language in all situations, regardless of circumstance.

316. Performing (or referring for) gender transition procedures, abortion, and certain infertility treatments is also contrary to the religious and conscientious beliefs of CBA members, and their beliefs prohibit them from conducting, participating in, or referring for such procedures.

317. The 2024 Rule compels CBA members to conduct, participate in, refer for, or otherwise facilitate gender transition procedures abortion, and certain infertility treatments.

318. The 2024 Rule prohibits CBA members from expressing their religious views that gender transition procedures, abortion, and certain infertility treatments are not the best standard of care or are experimental.

319. The 2024 Rule compels CBA members to speak in ways that they would not otherwise speak.

320. The 2024 Rule thus violates CBA members' right to be free from compelled speech as secured to them by the First Amendment of the United States Constitution.

321. The 2024 Rule's compelled speech requirement is not justified by a compelling governmental interest.

322. Even if HHS has a compelling government interest, the 2024 Rule is not narrowly tailored to achieve that interest.

323. Absent injunctive and declaratory relief against the 2024 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT V

Violation of the First Amendment of the United States Constitution
Freedom of Speech and Free Exercise Clause
Viewpoint Discrimination

324. Plaintiffs incorporate by reference all preceding paragraphs.

325. CBA members' sincere religious and conscientious beliefs prohibit them from covering, facilitating, or participating in gender transition procedures, abortion, and/or certain infertility treatments.

326. CBA members' medical judgment is that it is harmful and unethical to encourage a patient to undergo gender transition procedures, gender transition procedures, abortion, and/or certain infertility treatment.

327. The 2024 Rule would prohibit CBA members from expressing their religious or conscientious viewpoint that gender transition procedures, abortion, and/or certain infertility treatments are not the best standard of care. The 2024 Rule also requires CBA members to affirm their provision of such services and to train their staff members regarding their willingness to cover and provide such services.

328. The 2024 Rule withholds funding based on an intent to restrict CBA members' speech.

329. The 2024 Rule's viewpoint discrimination is not justified by a compelling governmental interest.

330. Even if HHS has a compelling government interest, the 2024 Rule is not narrowly tailored to achieve that interest.

331. Defendants' actions thus violate CBA members' rights as secured to them by the First Amendment of the United States Constitution.

332. Absent injunctive and declaratory relief against the 2024 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT VI

Violation of the First and Fifth Amendments of the United States Constitution
Freedom of Speech and Due Process
Overbreadth

333. Plaintiffs incorporate by reference all preceding paragraphs.

334. The 2024 Rule regulates protected speech. The 2024 Rule states, in the context of covered entities offering health services, that a "categorical" belief that gender-affirming care is never warranted "impermissibly single[s] out an entire category of services based on an individual's transgender status and [is] presumptively discriminatory." 89 Fed. Reg. at 37,602.

335. This exposes CBA members to penalties for expressing their medical and moral views of gender transition procedures. It also prohibits CBA members from using their medical judgment to determine the appropriate standard of care for interactions with their patients.

336. CBA members believe that the 2024 Rule restricts their speech regarding the best standard of care for patients.

337. The 2024 Rule states, the "determination of whether a challenged action is discriminatory is necessarily a fact-specific, case-by-case analysis dependent on the facts of the particular situation." *Id.* at 37,616.

338. The 2024 Rule chills CBA members' speech.

339. The 2024 Rule's overbreadth is not justified by a compelling governmental interest.

340. Even if HHS has a compelling government interest, the 2024 Rule is not narrowly tailored to achieve that interest.

341. Defendants have therefore violated CBA members' rights secured to them by the Free Speech Clause of the First Amendment and the Due Process Clause of the Fifth Amendment by prohibiting speech that would otherwise be protected.

342. Absent injunctive and declaratory relief against the 2024 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT VII

Violation of the First Amendment of the United States Constitution Free Exercise Clause and Freedom of Speech Unbridled Discretion

343. Plaintiffs incorporate by reference all preceding paragraphs.

344. The 2024 Rule "appl[ies] to every health program or activity, any part of which receives Federal financial assistance, directly or indirectly from the Department; every health program or activity administered by the Department; and every health program or activity administered by a Title I entity." 89 Fed. Reg. at 37,693, to be codified at 45 C.F.R. § 92.2(a).

345. The 2024 Rule also states, "A fact-specific analysis is necessary to determine whether prohibited discrimination has occurred." 89 Fed. Reg. at 37,597.

346. The 2024 Rule also says: "Insofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required." 89 Fed. Reg. at 37,893, to be codified at 45 C.F.R. 92.3(c).

347. Because the Defendants have sole discretion over financial assistance provided or made available, and because Defendants have sole discretion over the application of the 2024 Rule and any religious freedom protection that applies, the 2024 Rule vests unbridled discretion over which organizations will have their First Amendment interests accommodated.

348. In Title IX of the Education Amendments of 1972, Congress precluded discrimination on the basis of "sex" in federally funded education programs, "except that . . . this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization." 20 U.S.C. § 1681(a)-(a)(3). Defendants have exercised unbridled discretion by declining to apply the clear religious freedom protections of Title IX.

349. Defendants' actions therefore violate CBA members' rights not to be subjected to a system of unbridled discretion when engaging in speech or when engaging in religious exercise, as secured to them by the First Amendment of the United States Constitution.

350. Absent injunctive and declaratory relief against the 2016 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT VIII

Violation of the First Amendment to the United States Constitution
Free Speech Clause
Unconstitutional Conditions

351. Plaintiffs incorporate by reference all preceding paragraphs.

352. The 2024 Rule imposes an unconstitutional condition on Plaintiffs' receipt of federal funding.

353. The 2024 Rule applies to any healthcare provider who accepts federal funding from any source for any program.

354. The 2024 Rule requires CBA members to adopt policies regarding standards of care for patients that violate Plaintiffs' religious and conscientious beliefs, as well as their medical judgment, and also interfere with CBA members' practice of medicine.

355. Defendants' actions therefore impose an unconstitutional condition on CBA members' receipt of federal funding and violate Plaintiffs' rights as secured to them by the First and Fourteenth Amendments of the United States Constitution.

356. Absent injunctive and declaratory relief against the 2024 Rule, the CBA Plaintiffs have been and will continue to be harmed.

COUNT IX

Violation of the First Amendment
Freedom of Speech
Expressive Association

357. Plaintiffs incorporate by reference all preceding paragraphs.

358. CBA members believe and teach that participating in actions, procedures, and services with the goal of transitioning from one sex to another violate their religious beliefs.

359. CBA members believe and teach that participating in actions, procedures, and services with the goal of procuring an abortion violate their religious beliefs.

360. CBA members believe and teach that participating in actions, procedures, and services that separate the unitive and procreative nature of a marital union violate their religious beliefs.

361. CBA members believe and teach that participating in actions, procedures, and services that result in elective sterilizations violate their religious beliefs.

362. The Mandate compels CBA members to participate in procedures, services, and activities that contradict their religious beliefs and message.

363. The Mandate compels CBA members to offer health coverage for procedures, services, and activities that violate their religious beliefs and message.

364. The Mandate refuses to allow CBA to assert the rights of its members on an associational basis.

365. Defendants' actions thus violate CBA members' rights of expressive association as secured to them by the First Amendment of the United States Constitution.

366. Absent injunctive and declaratory relief against the Mandate, the CBA and its members have been and will continue to be harmed.

367. The Mandate exposes CBA members to civil suits that would hold them liable for practicing and expressing their sincerely held religious beliefs.

368. The Mandate furthers no compelling governmental interest.

369. The Mandate is not the least restrictive means of furthering Defendants' stated interests.

370. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT X

Violation of the Religious Freedom Restoration Act
Compelled Medical Services

371. Plaintiffs incorporate by reference all preceding paragraphs.

372. CBA members' sincerely held religious beliefs prohibit them from deliberately offering services and performing (or referring for) operations or other procedures required by the the Mandate. CBA members' compliance with these beliefs is a religious exercise.

373. CBA members sincerely held religious beliefs prohibit them facilitating gender transition procedures. CBA members' compliance with these beliefs is a religious exercise.

374. CBA members' sincerely held religious beliefs prohibit them facilitating sterilization procedures. CBA members' compliance with these beliefs is a religious exercise.

375. CBA members' sincerely held religious beliefs prohibit them facilitating procedures intended to procure an abortion. CBA members' compliance with these beliefs is a religious exercise.

376. CBA members' sincerely held religious beliefs prohibit them facilitating procedures that separate that separate the unitive and procreative nature of a marital union. CBA members' compliance with these beliefs is a religious exercise.

377. The Mandate creates government-imposed coercive pressure on CBA members to change or violate their religious beliefs.

378. The Mandate chills CBA members' religious exercise.

379. The Mandate exposes CBA members to the loss of substantial government funding as a result of their religious exercise.

380. The Mandate exposes CBA members to substantial penalties under the False Claims Act, 31 U.S.C. § 3729 et seq.

381. The Mandate exposes CBA members to criminal penalties under 18 U.S.C. § 1035.

382. The Mandate exposes CBA members to civil suits that would hold them liable for practicing their sincerely held religious beliefs.

383. The Mandate thus imposes a substantial burden on the CBA's and its members' religious exercise.

384. The Mandate furthers no compelling governmental interest.

385. The Mandate is not the least restrictive means of furthering Defendants' stated interests.

386. The Mandate violates the CBA's and its members' rights secured to them by the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb et seq.

387. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT XI

Violation of the Religious Freedom Restoration Act
Compelled Coverage

388. Plaintiffs incorporate by reference all preceding paragraphs.

389. For the same reasons discussed above, CBA members' sincerely held religious beliefs prohibit them from deliberately covering or offering health insurance or other benefits that would cover or facilitate services related to gender transition, sterilization, abortion, and certain infertility treatments.

390. CBA members specifically exclude coverage of any services related to gender transition, abortion, sterilization, and certain infertility treatments in their group health plans.

391. CBA members' compliance with these beliefs by maintaining these exclusions is a religious exercise.

392. Under the Mandate, such health-plan exclusions are facially invalid.

393. The Mandate exposes CBA members to the loss of substantial government funding as a result of their religious exercise.

394. The Mandate also makes it more expensive for CBA members to do business with a third-party administrator for a health benefits plan. The Mandate subjects third party

administrators to potential liability for administering plans that reflect Catholic teachings, and thus CBA members will be forced to indemnify, or accept liability for, any TPA. This constitutes an additional substantial burden on the CBA's and its members' religious exercise.

395. The Mandate exposes CBA members to substantial penalties under the False Claims Act, 31 U.S.C. § 3729 et seq.

396. The Mandate exposes CBA members to criminal penalties under 18 U.S.C. § 1035.

397. The Mandate exposes CBA members to civil suits that would hold them liable for practicing their sincerely held religious beliefs.

398. The Mandate thus imposes a substantial burden on the CBA's and its members' religious exercise.

399. The Mandate furthers no compelling governmental interest.

400. The Mandate is not the least restrictive means of furthering Defendants' stated interests.

401. The Mandate violates the CBA's and its members' rights secured to them by the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb et seq.

402. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT XII

Violation of the First Amendment to the United States Constitution Free Exercise Clause

403. Plaintiffs incorporate by reference all preceding paragraphs.

404. Plaintiffs and CBA members object to providing, facilitating, covering, or otherwise participating in gender transition procedures, abortions, and certain infertility treatments.

405. The Mandate imposes substantial burdens on CBA members by forcing them to choose between their exercise of religion and the avoidance of fines, penalties, liability, and other adverse consequences.

406. The Mandate seeks to suppress the religious practice of individuals and organizations such as CBA members, while allowing exemptions for similar conduct based on secular and non-religious reasons. Thus, the Mandate is neither neutral nor generally applicable.

407. The 2024 Rule repeatedly states that any request for a religious or conscience exemption must be evaluated on an individualized, case-by-case basis. *E.g.*, 89 Fed Reg. at 37,656. Thus, the mandate imposes a system of individualized assessments in violation of the First Amendment.

408. None of the statutes pursuant to which the Mandate is promulgated is generally applicable. Section 1557, Title IX, and Title VII are not generally applicable. For example, Title VII is not generally applicable because it exempts or does not cover employers that employ fewer than 15 employees and, as a result, does not apply to millions of employers that together employ hundreds of millions of people.

409. The Mandate is not justified by a compelling governmental interest.

410. Even if the Mandate is justified by a compelling government interest, it is not the least restrictive means of achieving that interest.

411. Defendants' actions thus violate the CBA's and its members' rights secured to them by the Free Exercise Clause of the First Amendment of the United States Constitution.

412. Absent injunctive and declaratory relief against the Mandate, the CBA Plaintiffs have been and will continue to be harmed.

COUNT XIII

Violation of the Fifth Amendment to the United States Constitution
Due Process Clause
Substantive Due Process

413. Plaintiffs incorporate by reference all preceding paragraphs.

414. The United States has a deeply rooted tradition of honoring physicians' and healthcare institutions' rights to provide medical treatment in accordance with their moral and religious beliefs.

415. CBA members possess a fundamental right of liberty of conscience.

416. CBA members possess a fundamental right not to be coerced to provide medical procedures and services in violation of their conscience.

417. The Mandate coerces CBA members to provide medical services and coverage in violation of their conscience.

418. Defendants' conduct cannot be justified by a compelling governmental interest.

419. The Mandate is not justified by a compelling governmental interest.

420. Even if Defendants have a compelling government interest, the Mandate is not narrowly tailored to achieve that interest.

421. Defendants' actions therefore violate CBA members' rights to substantive due process.

422. Absent injunctive and declaratory relief against the Mandate, the CBA and its members have been and will continue to be harmed.

COUNT XIV

Violation of the Fifth Amendment to the United States Constitution Due Process and Equal Protection

423. Plaintiffs incorporate by reference all preceding paragraphs.

424. The Due Process Clause of the Fifth Amendment mandates the equal treatment of all religious faiths and institutions without discrimination or preference.

425. The Mandate discriminates on the basis of religious views or religious status by refusing to recognize religious exemptions that exist in the law.

426. The Mandate discriminates on the basis of religious views or religious status by refusing to recognize valid medical views of religious healthcare professionals on gender transition procedures.

427. The Defendants' actions thus violate Plaintiffs' rights secured to them by the Fifth Amendment of the United States Constitution.

428. Absent injunctive and declaratory relief against the Mandate, CBA and its members have been and will continue to be harmed.

COUNT XV

Violation of Title VII, 42 U.S.C. §§ 2000e-1(a) and 2000e(j)

429. Plaintiffs incorporate by reference all preceding paragraphs.

430. Title VII does not apply to religious entities or societies "with respect to the employment of individuals of a particular religion." 42 U.S.C. § 2000e-1(a).

431. The term "religion" includes all aspects of religious observance and practice. 42 U.S.C. § 2000e(j).

432. The health plan coverage portion of the EEOC Statement is contrary to the Catholic values and to the observance and practice of the CBA Plaintiffs.

433. Applying the health plan coverage portion of the EEOC Statement to the CBA Plaintiffs violates the religious exemption within Title VII.

434. Absent injunctive and declaratory relief against the EEOC Statement, the CBA Plaintiffs have been and will continue to be harmed.

IX. PRAYER FOR RELIEF

Wherefore Plaintiffs request that the Court:

A. Declare Section 1557 does not require Plaintiffs to perform, facilitate, refer for, provide insurance coverage for, or a self-funded plan for: gender-transition procedures, including surgery, counseling, provision of pharmaceuticals, or other treatments sought in furtherance of a gender transition; abortion; and artificial reproductive technologies that violate Catholic beliefs, including without limitation IVF, surrogacy, and gamete donation; violates their sincerely held religious beliefs without satisfying strict scrutiny under the RFRA;

B. Declare that Title VII does not require the CBA and its members to provide insurance coverage for: gender-transition procedures, including surgery, counseling, provision of pharmaceuticals, or other treatments sought in furtherance of a gender transition; abortion; and artificial reproductive technologies that violate Catholic beliefs, including without limitation IVF, surrogacy, and gamete donation; violates Plaintiffs' sincerely held religious beliefs without satisfying strict scrutiny under the RFRA and without complying with Title VII's religious exemption that protects employers' religious practices, 42 U.S.C. § 2000e-1(a) and 42 U.S.C. § 2000e(j);

C. Issue a temporary restraining order, preliminary injunction, and permanent injunction prohibiting:

a. The Department of Health and Human Services, Secretary Becerra, their divisions, bureaus, agents, officers, commissioners, employees, and anyone acting in concert or participation with them, including their successors in office, from interpreting or enforcing Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116(a), or any implementing regulations thereto against the CBA Plaintiffs and the CBA members in a manner that would require them to perform gender-transition procedures, abortion, or infertility treatments contrary to Catholic beliefs; or provide insurance coverage or a self-funded plan for the same, including by denying federal financial assistance because of their failure to perform such procedures or provide insurance coverage for such procedures or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement action; and

b. The Equal Employment Opportunity Commission, Chair Burrows, their divisions, bureaus, agents, officers, commissioners, employees, and anyone acting in concert or participation with them, including their successors in office, from interpreting or enforcing Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., or any implementing regulations thereto against the CBA Plaintiffs and the CBA members in a manner that would require them to accommodate gender-transition procedures or infertility treatments contrary to Catholic beliefs; or to provide insurance coverage for gender-transition procedures, including by denying federal financial assistance because of their failure to provide insurance coverage for such

procedures or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;

D. Extend the relief above to: CBA Plaintiffs and the CBA present and future members, anyone acting in concert or participation with them, and their respective health plans any insurers, pharmacy benefit managers ("PBM"), service provider, or third-party administrators ("TPA") in connection with such health plans.

E. Declare that to come within the scope of this order, a CBA member must meet the following criteria: (a) The employer is not yet protected from interpretations of Section 1557 and Title VII that require the provision or coverage of gender transitions by any other judicial order; (b) The CBA has determined that the employer meets the CBA's membership criteria; (c) The CBA's membership criteria have not changed since the CBA filed its this complaint on May 30, 2024; and (d) The employer is not subject to an adverse ruling on the merits in another case involving interpretations of Section 1557 and Title VII that require the provision or coverage of gender transitions.

F. Declare that the Mandate and Defendants' enforcement of the Mandate against the CBA and its members violate the Administrative Procedure Act, and that no taxes, penalties, or other burdens can be charged or assessed against these members for failure to pay for, provide, or directly or indirectly facilitate access to abortion, infertility treatments contrary to Catholic beliefs, or gender transition services;

G. Declare that the Mandate and Defendants' enforcement of the Mandate against the CBA and its members violate the laws and constitutional provisions described in their causes of action and that no taxes, penalties, or other burdens can be charged or assessed against the

CBA and its members for failure to pay for, provide, or directly or indirectly facilitate access to abortion, infertility treatments contrary to Catholic beliefs, or gender transition services;

H. Declare that any interpretation of Title VII and Section 1557 to require coverage or provision of gender-transition procedures, including surgery, counseling, provision of pharmaceuticals, or other treatments sought in furtherance of a gender transition; abortion; and artificial reproductive technologies that violate Catholic beliefs, including IVF, surrogacy, and gamete donation may not be applied against the CBA and its members' insurers, PBM's, service providers, and TPAs of the CBA and its members; may not interfere with members' attempts to arrange or contract for morally compliant health coverage or related services for their employees; and that no taxes, penalties, or other burdens can be charged or assessed against such insurers or TPAs in relation to their work for the CBA and its members;

I. Declare that CBA members have the right to contract with service providers, including insurers and third-party administrators, to secure morally compliant health plans;

J. Award Plaintiffs the costs of this action and reasonable attorney's fees as provided by law, including 28 U.S.C. § 2412(d) and 42 U.S.C. § 1988(b); and

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

DATED: May 30, 2024.

Respectfully submitted,

/s/ L. Martin Nussbaum

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VERIFICATION PURSUANT TO 28 U.S.C. § 1746

I declare under penalty of perjury that the foregoing allegations pertaining to The Catholic Benefits Association and its members are true and correct to the best of my knowledge. I further declare under penalty of perjury that Exhibit A attached hereto is a true and ac- curate copy of the Amended and Restated Certificate of Incorporation of The Catholic Benefits Association, that Exhibit B is a true and accurate copy of the Third Amended and Restated Bylaws of The Catholic Benefits Association, that Exhibit C is a true and accurate copy of the CBA Nonprofit Employer Application for Membership, that Exhibit D is a true and accurate copy of the CBA For Profit Employer Application for Membership; Exhibit I are documents related to an EEOC enforcement action brought against a CBA member; and Exhibits K and L are true and accurate copies of insurance riders sent to CBA members.

Executed on May 29, 2024

Douglas Wilson, Jr.
CEO, the Catholic Benefits Association

VERIFICATION PURSUANT TO 28 U.S.C. § 1746

I declare under penalty of perjury that the foregoing allegations pertaining to the teachings of the Catholic Church, Catholic values, and the beliefs and values of The Catholic Benefits Association are true and correct to the best of my knowledge.

Executed on May 29, 2024

+William E. Lori

Most Rev. William E. Lori
Archbishop of Baltimore
Chairman of the Board, The Catholic Benefits Association

VERIFICATION PURSUANT TO 28 U.S.C. § 1746

I declare under penalty of perjury that the foregoing allegations: pertaining to the Sisters of St. Francis of the Immaculate Heart of Mary (described herein as the Sisters of St. Francis), St. Anne's Guest Home, and St. Gerard's Community of Care, including their membership in the CBA and adherence to Catholic teaching regarding human dignity, gender dysphoria, abortion, and infertility are true and correct to the best of my knowledge.

Executed on May 29, 2024

Sister Donna Marie Welder, OSF

Sister Donna Marie Welder, OSF
Provincial, President, and Chair of the Sisters of St. Francis of the Immaculate Heart of Mary
President and Chair of St. Anne's Guest Home
President and Chair of St. Gerard's Community of Care

Exhibit 10

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,

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Exhibit 11

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TYLER DIVISION

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

COMPLAINT

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

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

3. Section 1557 of the ACA prohibits any federally funded health program from discriminating "on the grounds prohibited under . . . title IX of the Education Amendments of 1972." 42 U.S.C. § 18116(a). Title IX, in turn, prohibits discriminating "on the basis of sex." 20 U.S.C. § 1681(a). In other words, federally funded health programs are prohibited from engaging in any practices that would treat men better than women, or vice versa.

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

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

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

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

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

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

Parties

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

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

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

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

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

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

Jurisdiction and Venue

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

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

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

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

Legal Background

I. The Affordable Care Act and Title IX.

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

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

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

22. The ACA sets further limits on HHS's ability to promulgate regulations interfering with healthcare entities' and professionals' provision of medical services. Section 1554 of the ACA provides that "notwithstanding any other provision of [the ACA, HHS] shall not promulgate any regulation that— . . . violates the principles of informed consent and the ethical standards of health care professionals." 42 U.S.C. § 18114(5).

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

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

24. Covered entities include hospitals, clinics, and doctors that accept patients paying for services through these financial assistance programs, as well as pharmacies and insurance issuers.

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

26. Any entity "any part of which" participates in HHS financial assistance programs is subject in all aspects of its health programs and activities to Section 1557. 42 U.S.C. § 18116(a). That means that any hospital or doctors' office that accepts a single Medicaid of CHIP patient must follow Section 1557 for *all* its patients, no matter how other patients pay for care.

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

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

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

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

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

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

31. Title IX states: "No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance. . . ." 20 U.S.C. § 1681(a).

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

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

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

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

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

37. In fact, Section 1557 specifically excludes from the scope of its nondiscrimination rule "transsexualism" and any "gender identity disorder" "not resulting from physical impairments." 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under . . . section 794 of title 29"); 29 U.S.C. § 705(20)(F)(i) (providing that "transsexualism" and "gender identity disorders not resulting from

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

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

II. Prior 1557 Rules, Guidance, and Related Litigation

A. The 2016 Rule

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

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

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

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

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

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

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

B. The 2020 Rule and *Bostock*

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

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

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

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

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

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

50. Following *Bostock*, plaintiffs in multiple jurisdictions sued HHS, challenging the 2020 Rule in light of *Bostock* and seeking restoration of the 2016 Rule, in whole or in part. In that litigation, "[t]wo courts entered nationwide injunctions preventing much of the 2020 Rule from going into effect," purporting to "reinstat[e] portions of the 2016 Rule" that had been vacated in *Franciscan*. *Franciscan*, 47 F.4th at 372 (citing *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60 (D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020)).

C. The 2021 Notification and 2022 Guidance

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

52. First, on January 20, 2021, President Biden issued an executive order asserting that "laws that prohibit sex discrimination . . . prohibit discrimination on the basis of gender identity or sexual orientation." Exec. Order No. 13,988, 86 Fed. Reg. 7023, 7023 (Jan. 20, 2021).

53. Pursuant to the President's executive order, HHS then issued a "Notification of Interpretation and Enforcement" addressing Section 1557 (2021 Notification). 86 Fed. Reg. 27,984 (May 25, 2021). The 2021 Notification stated that, "consistent with the Supreme Court's decision in *Bostock* and Title IX," HHS would "interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity." *Id.* at 27,984.

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

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

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

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

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

D. The 2024 Final Rule

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

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

60. Broadly speaking, the Final Rule expands "[d]iscrimination on the basis of sex" to include discriminating based on "(i) Sex characteristics, including intersex traits; (ii) Pregnancy or related conditions; (iii) Sexual orientation; (iv) Gender identity; and (v) Sex stereotypes." 89 Fed. Reg. at 37,699, *to be codified at* 45 C.F.R. § 92.101(a)(2). And it expands this definition all while claiming that "it is not necessary to define 'sex' in this rule." 89 Fed. Reg. at 37,575.

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

1. Section 1557 Regulations

a. Gender-transition and abortion

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

63. First, under Section 92.206(b)(1), "a covered entity must not . . . [d]eny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded." 89 Fed. Reg. at 37,700.

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

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

66. HHS explains that, under this provision, it is a "violation" for a hospital with dual-occupancy rooms to prevent a man who identifies as a woman to share a room with a woman. *Id.* at 37,593 ("A covered entity will be in violation of this rule if they refuse to admit a transgender person for care or refuse to place them in facilities consistent with their gender identity, because doing so would result in more than *de minimis* harm."); *see also* NPRM, 87 Fed. Reg. at 47,866–67.

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

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

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

69. The Final Rule further makes it presumptively discriminatory for covered hospitals, clinics, residential treatment centers, medical practices, and pharmacies to "[d]eny or limit" puberty blockers, cross-sex hormones, or surgeries "sought for purpose of gender-transition," if covered entities provide those services for "other purposes." 89 Fed. Reg. at 37,701, *to be codified at* 45 C.F.R. § 92.206(b)(4). Again, for example, the Final Rule presumptively requires that a gynecological surgeon who performs a hysterectomy to treat endometrial cancer must remove a healthy uterus for a "gender-transition." *Id.*; *see also* NPRM, 87 Fed. Reg. 47,824, 47, 867.

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

71. Repeatedly, however, HHS emphasizes that covered entities must make an "*individualized* clinical judgment" for gender-change interventions, *id.* at 37,575, 37,595–

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

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

73. The Final Rule forces States to subsidize gender-transitions. Indeed, the Final Rule makes it presumptively illegal for covered insurance providers and other entities—including States administering HHS programs such as ACA health-insurance exchanges, and joint federal/state programs such as Medicaid and CHIP—to set "limitations or restrictions" on claims "for specific health services related to gender-transition" if doing so "results in discrimination on the basis of sex." 89 Fed. Reg. 37,701, *to be codified* at 45 C.F.R. § 92.207(b)(5). Again, under the Final Rule, sex discrimination includes discriminating based on "gender identity" and does not distinguish between providing a service for one purpose as opposed to another. *Id.* at 37,699, 37,701.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Insurance coverage for transition procedures

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

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

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

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

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

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

2. CMS Regulations

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

94. Under CMS's revised Medicaid and CHIP regulations, contracts with entities that deliver services must now include a promise that the entities "will not discriminate against individuals eligible to enroll on the basis of . . . sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that *has the effect* of discriminating on the basis of . . . sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." 89 Fed. Reg. at 37,691 (emphasis added). Thus, a managed care organization's facially neutral policies or practices that lack any discriminatory purpose that nonetheless have a discriminatory *effect* on transgender individuals may now violate its contract.

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

96. And under the Final Rule, States' Medicaid and CHIP programs "must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, . . . and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes." *Id.* at 37,692.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[7] *Id.* ¶¶ 145–54.

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

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

112. Even HHS has previously recognized as much. In 2016, HHS, under the Obama Administration, refused to require national coverage of "gender reassignment surgery" under Medicare, concluding that "[b]ased on an extensive assessment of the clinical evidence . . ., there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria." CMS, Final Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (Aug. 30, 2016), https://perma.cc/R2ME-YQRA. "There were conflicting (inconsistent) study results—of the best designed studies, some reported benefits while others reported harms." *Id.*

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

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

healthcare entities of Sweden, Finland, France, Australia, New Zealand, and the United Kingdom have raised concerns about the risks associated with puberty blockers and cross-sex hormone treatment and supported greater caution and/or more restrictive criteria in connection with such interventions." *Eknes-Tucker v. Gov. of Ala.*, 80 F.4th 1205, 1218 (11th Cir. 2023). NHS England has halted the use of puberty blockers "as a routine commissioning treatment option for treatment of children and young people who have gender incongruence/gender dysphoria." NHS England, *Clinical policy: puberty suppressing hormones* (Mar. 12, 2024), https://tinyurl.com/NHSclinicalpolicy.

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

IV. Impact on Plaintiffs

A. Impact on Texas

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Impact on Montana

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

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

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

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

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

Claims

Count I

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

139. Plaintiffs incorporate by reference all preceding paragraphs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COUNT II

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

160. Plaintiffs incorporate by reference all preceding paragraphs.

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

162. "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

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

164. An agency action is arbitrary or capricious if it fails to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43. Under

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

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

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

167. *Second*, the Final Rule never defines "sex." But without defining sex, HHS cannot reasonably explain what it means to discriminate "based on" sex. HHS failed to adequately consider and find that in medical practice, as in education, differences between the sexes are a biological reality. HHS's 2020 Rule previously conceded as much: It explained that preferencing ideology over science "risk[s] masking clinically relevant, and sometimes vitally important, information"—like potential pregnancy in a transgender male. 85 Fed. Reg. 37,189–90. But the Final Rule does not engage with the biological and medical realities that sex has in medical care, or the "life-and-death" risks associated with ignoring them. *Id.*

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

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

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

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

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

Count III

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

172. Plaintiffs incorporate by reference all preceding paragraphs.

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

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

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

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

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

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

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

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

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

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

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

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

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

Declaratory Judgment

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

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

Prayer for Relief

Plaintiffs pray the Court:

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

b. Declare that the Final Rule is unlawful;

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

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

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

Dated: June 10, 2024.

Respectfully submitted.

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JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
State of Texas,
State of Montana

(b) County of Residence of First Listed Plaintiff Smith County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
See attached document

DEFENDANTS
Xavier Becerra, Melanie Fontes Rainer, Centers for Medicare & Medicaid Services, and US Dept of Health and

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Administrative Procedure Act

Brief description of cause:
Challenge to agency action outside authority in violation of APA and U.S. Constitution.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
6/10/2024

SIGNATURE OF ATTORNEY OF RECORD
/s/ Amy S. Hilton

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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MELANIE FONTES RAINER, IN HER OFFICIAL CAPACITY AS DIRECTOR OF THE OFFICE FOR CIVIL RIGHTS;

CENTERS FOR MEDICARE & MEDICAID SERVICES;

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES