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

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of its members; **CATHOLIC MEDICAL ASSOCIATION**, on behalf of 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**; **ROBINSUE FROHBOESE**, in her official capacity as Acting Director and Principal Deputy 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.*	Civil Action No. 1:21-cv-195 **COMPLAINT** **Jury Trial Demanded**

PLAINTIFFS' COMPLAINT

Plaintiff American College of Pediatricians, on behalf of its members; Plaintiff Catholic Medical Association, on behalf of its members; and Plaintiff Jeanie Dassow, M.D. (collectively, Plaintiffs), for the 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-transition 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.

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.

4. Plaintiffs are two medical associations, which together represent 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. Two courts have already recognized that this 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); *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 plaintiffs or their members here. 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 crippling penalties that threaten to drive thousands of doctors out of practice.

JURISDICTION & VENUE

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

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

7. 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.

8. 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.

9. 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).

10. 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.

11. 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.

12. 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)

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

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

15. ACPeds has members in Tennessee.

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

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

II. Catholic Medical Association

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

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

20. 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.

21. CMA has individual members in Tennessee.

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

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

III. Jeanie Dassow, M.D.

24. Plaintiff Jeanie Dassow, M.D., is a board-certified obstetrician and gynecologist in Chattanooga, Tennessee.

25. Dr. Dassow serves as the Clerkship Director and Assistant Professor of Obstetrics and Gynecology at the University of Tennessee Chattanooga – College of Medicine.

26. Dr. Dassow practices medicine in Chattanooga at UT Erlanger Women's Health, a medical clinic, and also travels to rural clinics to treat patients.

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

IV. Defendants

28. 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.

29. 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.

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

31. 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

I. Section 1557 of the Affordable Care Act

32. 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."

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

34. 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).

35. 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.

36. 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).

37. 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.

38. 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.

39. 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.

40. 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.

II. Effects of the 2016 Rule

41. 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 Rule).

42. The 2016 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 transitions. 81 Fed. Reg. at 31,467, 31,468 (45 C.F.R. § 92.4).

43. The 2016 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 that, "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 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).

Mandatory Gender Interventions

44. The 2016 Rule states, in the context of physicians offering "health services" or medical advice, that a "categorization of all transition-related treatment, for example as experimental, is outdated and not based on current standards of care." 81 Fed. Reg. at 31,435; *see also id.* at 31,429. The 2016 Rule also relies for the applicable standard of care upon a transgender advocacy group's document, which states that "Mental health professionals should not impose a binary view of gender." *Id.* at 31,406 n.263 (citing World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People at 16 (7th ed. 2012)).

45. The 2016 Rule required 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. *Id.* at 31,455.

46. The 2016 Rule provides, "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." 81 Fed. Reg. at 31,445. HHS also explained such procedures would be "medically necessary to treat gender dysphoria" and would be required even if they were not "strictly identified as medically necessary or appropriate." *Id*. at 31,429.

47. Under the 2016 Rule, many providers thus would have to perform hysterectomies, even if the provider sincerely believed such a procedure would not be in the patients' best interest or if doing so conflicted with the providers' religious beliefs.

Requirements to Offer and Recommend Gender Interventions

48. Under the 2016 Rule, a doctor must advise patients about these procedures in ways that suggest they are appropriate for gender dysphoria and may not deter patients away from them.

49. The 2016 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.

50. The 2016 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-transition interventions on demand.

51. The 2016 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 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.

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

53. The 2016 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. 81 Fed. Reg. at 31,455.

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

55. And the 2016 Rule requires providers to amend their written policies to expressly endorse gender-transition procedures, even if these policies would not reflect their medical judgment or ethical, conscientious, and religious positions. *Id.* at 31,455.

56. The 2016 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 Rule. 45 C.F.R. § 92.4(a); 81 Fed. Reg. at 31,392, 31,442.

57. Covered entities must post notices about compliance with the 2016 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.[1]

58. The 2016 Rule incorporates these requirements into the HHS-690 Form, which references Section 1557, through which a covered entity must certify that "no person in the United States shall, on the ground of race, color, national origin, sex, age, or disability be excluded from participation in, be denied the benefits of, or be

[1] https://www.federalregister.gov/articles/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities#h-139.

subjected to discrimination under any health program or activity for which the Applicant receives Federal financial assistance from the Department."[2]

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

Compelled Speech Affirming Gender Identity as Sex

60. The 2016 Rule requires providers to use gender-transition affirming language in all situations, regardless of circumstance. *Id.* at 31,406.

61. HHS also requires a patient to be treated and spoken about according to the person's stated gender identity, including use of the person's preferred pronouns, and it prohibits using pronouns and other sex-specific language reflecting biological and medical reality. The 2016 Rule said, "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.*

62. The 2016 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.

63. The 2016 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.

[2] HHS, OCR, Assurance of Compliance, https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf (last visited Aug. 23, 2021).

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

Prohibition on Single-Sex Programs and Facilities

65. The 2016 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.

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

67. 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*.

68. The 2016 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*.

Mandatory Insurance Coverage for Gender Interventions

69. The 2016 Rule also requires health insurance plans provided by covered entities to pay for and cover gender-transition interventions.

70. The 2016 Rule applies to health insurance plans for employees of HHS-funded entities providing health services, such as hospitals and doctors' offices, as well as other health programs or activities funded by HHS. 81 Fed. Reg. at 31,437, 31,472 (45 C.F.R. § 92.208).

71. The 2016 Rule prohibits insurers, on the basis of gender identity, from denying, limiting, or refusing to issue insurance plans or policies; denying or limiting coverage, or imposing additional cost sharing or other limitations on coverage; maintaining "discriminatory" marketing practices or benefit designs; and denying or limiting coverage to transgender people both for routine and transition-related healthcare. 81 Fed. Reg. at 31,471–72 (45 C.F.R. § 92.207).

72. The 2016 Rule required that a covered entity apply "neutral, nondiscriminatory criteria that it uses for other conditions when the coverage determination is related to gender transition" and "decline[s] to limit application of the rule by specifying that coverage for the health services addressed in § 92.207(b)(3)–(5) must be provided only when the services are medically necessary or medically appropriate." 81 Fed. Reg. at 31,435. It refused to allow a healthcare provider to decide whether such services are "medically necessary" or "medically appropriate" in their professional opinion. *Id.* at 31,429, 31,435.

73. The 2016 Rule stated that the "explicit, categorical (or automatic) exclusion or limitation of coverage for all health services related to gender transition is unlawful on its face." 81 Fed. Reg. at 31,429, 31,472 (45 C.F.R. § 92.207(b)(4)). Such an exclusion is deemed "discriminatory on its face." 81 Fed. Reg. at 31,456. It also prohibited denying or limiting care or coverage for a transgender person for "health services that are ordinarily or exclusively available to individuals of one sex." 81 Fed. Reg. at 31,471 (45 C.F.R. § 92.206). Such "exclusions of coverage for all care related to gender dysphoria or associated with gender transition" were "outdated and not based on current standards of care." 81 Fed. Reg. at 31,429.

74. The "range of transition-related services, which 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.

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

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

76. In December 2016, a district court held under the Administrative Procedure Act that HHS lacked statutory authority under Section 1557 and Title IX to prohibit discrimination on the basis of gender identity in its 2016 Rule, and that religious healthcare providers had a substantial likelihood of success against that mandate under the Religious Freedom Restoration Act. *Franciscan Alliance, Inc. v. Burwell*, 227 F. Supp. 3d 660, 695–96 (N.D. Tex. 2016).

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

78. In 2020, HHS issued a final rule substantially revising the 2016 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 Rule").

79. The 2020 Rule stated that the 2016 Final 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).

80. Two courts, however, issued injunctions declaring that the gender identity language from the 2016 rule would remain 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).

81. As the result of *Walker* and *Whitman-Walker Clinic*, the 2016 Rule's gender identity language, and the implications of that language described in the 2016 Rule's preamble, remain in effect.

82. Specifically, the following requirements of the 2016 Rule are in effect:

a. The 2016 Rule's definition of the term sex to include "gender identity" which in turn includes an individual's "internal sense of gender" among other things;

b. The 2016 Rule's expansive definition of sex stereotyping to include gender identity discrimination;

c. The 2016 Rule's application of harassment, hostile environment, and disparate impact liability to gender identity discrimination;

d. The 2016 Rule's recognition of a gender identity spectrum in enforcing discrimination prohibitions;

e. The 2016 Rule's requirement to treat individuals consistent with their gender identity,

f. The 2016 Rule's prohibition on denying or limiting health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual because the individual's "sex assigned at birth,"

gender identity, or gender otherwise recorded differs from the one to which the health services are ordinarily or exclusively available;

g. The 2016 Rule's forced provision of sex transition surgery, sex transition hormones, puberty blockers, and other gender interventions;

h. The 2016 Rule's censorship of healthcare concerns involving gender-transition regret;

i. The 2016 Rule's ban on a policy, procedure, and practice of not offering to perform these procedures, prescribe these drugs, and conduct these interventions;

j. The 2016 Rule's requirements that covered entities modify their policies, create compliance reports, provide the government assurances of compliance and post notices of compliance in prominent physical locations, 81 Fed. Reg. at 31,439, 31,472, 45 C.F.R. § 92.301;

k. The 2016 Rule's speech mandates that providers treat patients by gender identity, express views on gender procedures or interventions that they do not share, refer to gender as non-binary and on a spectrum, and use gender-affirming language, including the use of preferred pronouns (as well as the 2016 Rule's censorship of any contrary forms of speech or beliefs);

l. The 2016 Rule's mandate that providers create inaccurate and dangerous documentary codes and medical records;

m. The 2016 Rule's referral mandate;

n. The 2016 Rule's bar on sex-separate facilities and programs, such as showers, support groups, and other intimate areas;

o. The 2016 Rule's requirements for health insurance coverage by healthcare employers to pay for gender interventions; and

p. The 2016 Rule's lack of incorporation of the religious exemption from Title IX (formerly codified at 45 C.F.R. § 92.6(b)).

83. In the gender identity mandate, Defendants are imposing not merely a rule, under which male treatments, if provided, must be given on demand to females, and vice versa, but also a freestanding principle under which any objection to providing, offering, referring for, or affirming gender-transition interventions would be deemed gender identity "discrimination" in itself or by its effects.

84. 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.[3]

85. On May 10, 2021, HHS announced that its Office for Civil Rights (OCR) "will 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 gender identity." 86 Fed. Reg. 27,984, 27,985 (May 25, 2021) (May 10, 2021 Notice of Enforcement).

86. OCR also announced on the same day 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.[4]

87. 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 this compliance would occur. 86 Fed. Reg. at 27,985.

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

[4] 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.

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

89. To the extent either the substantive requirements of the 2020 Rule, or Section 1557 itself, are interpreted (incorrectly) to impose the same gender identity mandate contained in the gender identity language of the 2016 Rule and the May 10, 2021 Notice of Enforcement, Plaintiffs challenge those as well in their respective claims. Thus, to that extent, Plaintiffs' allegations concerning the gender identity mandate stemming from the 2016 Rule and the May 10, 2021 Notice of Enforcement apply, in the alternative, to the 2020 Rule or Section 1557 itself.

90. 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.

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

92. HHS currently recognizes no RFRA exemptions under its interpretation of Section 1557 except those ordered by a court

93. 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 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 the gender identity mandate

94. 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).

95. In another case, on August 9, 2021, a district court issued a permanent injunction against HHS under RFRA to stop the gender identity mandate against the plaintiffs in that case, including named health care providers and a nonprofit association, some of whose members are health care providers. *Franciscan Alliance, Inc. v. Becerra*, No. 7:16-cv-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021).

96. The court held that, because of *Walker* and *Whitman-Walker Clinic* and subsequent HHS actions, "the current regulatory scheme for Section 1557 'clearly prohibits" Plaintiffs' conduct, thus, putting them to the 'impossible choice' of either 'defying federal law' and risking 'serious financial and civil penalties,' or else violating their religious beliefs." *Id.* at *9.

V. The Effect of the Gender Identity Mandate on Plaintiffs

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

98. For Plaintiffs, the Hippocratic Oath, their faith, and commitment to the medical professional demand nothing less.

99. 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.

100. But the gender identity mandate forces doctors to provide gender-transition 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.

101. The gender identity mandate imposes tangible, concrete harm for the Plaintiffs.

102. Plaintiffs have medical, ethical, or religious objections to the following activities and speech that the gender identity mandate 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 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 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;

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; and

w. paying for or providing insurance coverage for any or all objectionable procedures, drugs, interventions, or speech.[5]

103. Plaintiffs do not have policies or practices for engaging in these objectionable practices, and they object to changing their current policies or to implementing different policies, as the gender identity mandate would require of them for these objectionable practices.

104. Plaintiffs will never abandon a patient and they will discuss procedures and interventions used for altering biological sex characteristics under informed consent. If a patient still requests such procedures, the patient's care can be safely transferred to a provider selected by the patient. All medical care available through a medical practice will be provided to all persons except those objectionable procedures and interventions that alter biologically determined sex characteristics.

105. Plaintiffs write pronouns on charts and refer to clients with biologically correct pronouns, as well as create charts and medical records by biological sex, but HHS now would require them to do otherwise.

106. Some members of ACPeds and CMA operate their own healthcare practices and provide health insurance to employees. They seek to not cover and pay for gender-transition interventions in those insurance plans. Many of them reside in states that do not mandate coverage of such practices, and obtain insurance from companies that have provided coverage without including such practices. But the gender identity mandate will require such practices to be covered in their employee health plans.

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

107. Defendants now require Plaintiffs to provide at least some of the objectionable practices, as well as other gender identity related interventions to be articulated by HHS in the future.

108. For example, the 2016 Rule would require Dr. Dassow to offer and perform procedures and services that are within the scope of her regular practice to patients who seek those interventions to accomplish or support gender transition.

109. Defendants would require her to refer patients for other such procedures, and to engage in or refrain from speech as described in the objectionable practices.

110. HHS's announcement of enforcement of HHS's gender identity mandates, and the 2016 Rule's gender identity language thus creates substantial confusion and uncertainty for ACPeds and CMA's members, and Dr. Dassow.

111. In addition, the Plaintiffs are affected in the following particular ways.

A. Effect on American College of Pediatricians

a. Views of ACPeds and its members

112. 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.

113. 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, to include children who identify as a gender other than their biological sex, often referred to as transgender youth.

114. ACPeds members care for transgender youth 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 transgender youth. 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.

115. ACPeds and its members understand how individual teachers, educators, physicians, and therapists may be well-meaning when they encounter children with symptoms of depression or anxiety, but it opposes efforts to sterilize children as a way to escape their anxiety.

116. Human sexuality is an objective biological binary trait: "XY" and "XX" are genetic markers of sex—not genetic markers of a disordered body. The norm for human design is to be conceived either male or female with the obvious purpose being the reproduction and flourishing of our species. This principle is self-evident. Children who identify as 'feeling like the opposite sex' or 'somewhere in between' do not comprise a third sex. They remain biological boys or biological girls.[6]

117. The idea that a child with gender dysphoria is born with a brain of the sex opposite that of the body is incorrect and biologically impossible, although this idea persists in the culture despite scientific objections by medical experts and researchers. Every cell of the human body contains identical copies of a person's sex chromosomes, and the brains of biologically normal infants are imprinted prenatally by their own endogenous sex hormones at eight weeks of age.

118. Every infant boy is born with a brain imprinted by testosterone; every infant girl is born with a brain imprinted by estrogen. Brain studies of transgender adults that purport to show differences in brain microstructures are of notoriously poor quality and more than likely reflect the fact that long-term transgender behavior alters brain microstructures. The latter is known as the well-established

[6] For more details, see the ACPeds position statements, ACPeds, Sex is a Biological Trait of Medical Significance (March 2021), https://acpeds.org/position-statements/sex-is-a-biological-trait-of-medical-significancehttps://acpeds.org/position-statements/sex-is-a-biological-trait-of-medical-significance, & ACPeds, Gender Dysphoria in Children (November 2018), https://acpeds.org/position-statements/gender-dysphoria-in-childrenhttps://acpeds.org/position-statements/gender-dysphoria-in-children.

phenomenon of neuroplasticity, whereby behavior alters the chemical and physical structure of the brain. However, these brain cells remain biologically male or female. Normalizing the myth of innate gender fluidity will cause psychological trauma to youth who are not confused about their gender identity.

119. Disorders of sex development (DSD), commonly referred to as intersex conditions, are not to the contrary. Disorders of sex development are maladies in which normal sexual differentiation and function are disrupted. Some argue that disorders of sex development demonstrate the existence of more than two sexes. But disorders of sex development do not represent additional reproductive organs, gonads, or gametes. Thus, by definition, disorders of sex development do not constitute additional sexes. Human sex is a binary, not a spectrum, and disorders of sex development are rare congenital disorders affecting 0.02% of the population in which either genitalia are ambiguous in appearance, or an individual's sexual appearance fails to match what would be expected given the person's sex chromosomes. Reflecting the unfortunate nature of these conditions, all disorders of sex development are linked to impaired fertility. (This lawsuit does not address the cases of ambiguous genitalia or chromosomal aberrations.)

120. Puberty is not a disease. It is a critical window of normal development that is irreparably disrupted by puberty blockers. There are no long-term studies of Lupron or other puberty blockers for gender incongruence. There is thus no evidence that puberty blockers are reversible and harmless in gender incongruent youth as is claimed. To the contrary, when normal puberty is artificially arrested, valuable time is forever stolen from these children, time that should be spent in normal development. This time period, during which highly significant and irreplaceable advances in bone, brain, and sexual development occur, is time – and development – that can never be recovered.

121. In the United States, there are no drugs such as hormones or puberty blockers approved by the Food and Drug Administration (FDA) to treat gender dysphoria, much less to treat the condition through transgender interventions.

122. There is no long-term study to prove the safety or efficacy of interventions such as puberty blockers, cross-sex hormones, and surgeries for youth who suffer from gender dysphoria or identify as transgender.

123. By contrast, there is research showing these interventions are harmful.

124. Puberty blockers also have very harmful side effects listed in Lupron's package insert. All puberty blockers, including Lupron, arrest sexual development by acting on the brain. Boys are chemically castrated and girls chemically driven into premature menopause for as long as the puberty blockers are used. This developmental arrest may cause permanent sexual dysfunction, infertility, bone loss, and altered brain development. In one report, gender-distressed girls exhibited greater self-harm, emotional problems, and body dissatisfaction while taking puberty blockers.[7]

125. Before these new procedures and interventions, the majority of gender-distressed children would embrace their bodies when supported through natural puberty. In contrast, all studies of gender dysphoric youth given puberty blockers reveal nearly 100% of them go on to identify as 'transgender' and request cross-sex hormones. This suggests that puberty blockers "lock" kids into their gender confusion. As a result, these children who have their development blocked in early puberty, and are later given cross-sex hormones, may be permanently sterilized, when they would otherwise naturally resolve their confusion.

[7] Michael Biggs, Tavistock's Experimentation with Puberty Blockers: Scrutinizing the Evidence, Transgender Trend (March 2, 2019), https://www.transgendertrend.com/tavistock-experiment-puberty-blockers/.

126. Cross-sex hormones also put youth at an increased risk of heart attacks, stroke, diabetes, blood clots, cancer and other serious diseases across their lifespan. The best long-term evidence we have among adults shows medical intervention fails to reduce suicide.

127. ACPeds and its members thus have deep, substantial, science-based concerns about transgender 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.[8]

128. ACPeds and its members view such interventions to be experimental, and so parents cannot provide informed consent, nor can minors provide assent for these interventions. In December 2020, the High Court of the United Kingdom in the case of Keira Bell barred hormonal interventions in youth under the age of 16, and decreed physicians seek court approval for hormonal interventions in youth between 16 and 18 years old.

129. These interventions are thus not the international standard of care for youth. Many medical organizations around the world, including the Australian College of Physicians, the Royal College of General Practitioners in the United Kingdom, and the Swedish National Council for Medical Ethics have characterized prescribing puberty blockers and cross-sex hormones in youth as experimental and dangerous. Sweden and Finland have taken steps to limit these interventions in youth.

[8] 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 Aug. 23, 2021), & Family Watch International, Transgender Issues Videos, https://familywatch.org/transgenderissues/#.YRl6kohKg2x (last visited Aug. 23, 2021).

130. Further, alternatives to transgender interventions as a treatment for gender dysphoria exist, including counseling, which have proven successful for nearly all children.

131. ACPeds and its members are aware of cases in which pediatric patients are being treated with surgical interventions for gender dysphoria. Girls as young as 13 years-old are now receiving double mastectomies to facilitate their belief that they are a boy. Healthcare providers have removed the penises and testicles of boys as young as 16 years old. Given the nature of these procedures, the consequences are traumatic, permanent, lifelong, and irreversible.

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

b. Impact of the gender identity mandate on ACPeds members

133. 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. Some ACPeds members also have religious objections to such participation.

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

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

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

137. Most ACPeds members treat patients who are members of federal healthcare programs such as Medicaid and the State Children's Health Insurance Program (CHIP).

138. ACPeds is a scientific medical association in which members share and discuss medical research, emerging treatments, and trends related to caring for children. ACPeds and its members also conduct their own research.

139. 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.

140. Thus, ACPeds and its members believe providing or referring patients for the provision of such services violates their core beliefs and their oath to "do no harm."

141. The 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.

142. ACPeds and its members believe that the gender identity interventions described herein can be harmful to patients, particularly children, and that medical science does not support the provision of such procedures and interventions.

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

144. ACPeds has members who have treated or currently treat transgender individuals, and who would be liable for failure to engage in the objectionable practices under the gender identity mandate.

145. ACPeds has members who currently provide healthcare coverage for employees, coverage which excludes medical transition procedures consistent with

state laws. The gender identity mandate would force those members to provide insurance coverage for these procedures.

146. ACPeds members thus include healthcare providers with medical, ethical, and conscientious objections to providing gender-transition interventions as being not in the best interests of patients, as well as members with religious objections.

147. ACPeds also believes that to eliminate sex-specific private spaces violates fundamental rights of all persons to privacy, safety, and a secure environment. In healthcare programs, as in schools, locker rooms, and restrooms, the facilities exist for the utilitarian purpose of hygiene, not to affirm the self-identified gender of certain individuals. These facilities are traditionally restricted to persons of the same sex for the sound and self-evident reason that such separation protects the bodily privacy of all. It also shields girls and women from offensive, criminal, or dangerous behaviors of voyeurs, exhibitionists, and rapists, whose claim to= transgender status may exist to take advantage of access given to transgender persons.

148. Rather than end single-sex spaces by allowing persons of either sex to access them, there is a commonsense solution to respect the many individuals who are uncomfortable in public facilities for various reasons, including religious beliefs, disability, deformity, or discomfort with their body, as well as gender dysphoria. A reasonable accommodation is a single-occupancy restroom available for all people who are uncomfortable with the standard arrangement of sex-specific bathrooms or locker rooms.

149. Defendants' gender identity mandate, 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.

B. Effect on Catholic Medical Association

a. Views of CMA and its members

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

151. 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.

152. 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.

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

154. 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.

155. CMA is dedicated to educating and supporting the next generation. Through the Catholic Medical Association Student Section (CMA-SS) and its student chapters, as well as the Catholic Medical Association Resident Section, CMA provides meaningful support and instruction to medical students as they grow in the Catholic faith and as medical professionals.

156. 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.

157. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. CMA creates and organizes educational resources and events; advocates for members, the Church, and the medical profession in public forums; and provides guidance for bishops and other national leaders on healthcare ethics and policy.

158. 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.

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

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

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

162. Every cell in the human body holds either an "XY" or "XX" pair of sex chromosomes, the genetic markers for males and females, respectively.

163. Human sexuality is binary by design to ensure the reproduction and flourishing of our species.

164. The very rare disorders of sex development ("intersex" individuals) are medical deviations from the sexual binary norm, and do not constitute additional sexes.

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

166. Their beliefs reflect 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.

167. The Catholic Church teaches that men and women are created in two sexes with corresponding identities.[9]

168. The Catholic Church thus opposes invasive and drastic medical interventions promoted by modern gender ideology. "Except when performed for strictly therapeutic medical reasons, directly intended amputations, mutilations, and sterilizations performed on innocent persons are against the moral law." Catechism § 2297.

169. The Catholic Church also teaches this lived biological reality of two sexes creates various obligations for public authorities. Catechism § 1907.

170. The Catholic Church's most extensive statement today exclusively on gender identity is *Male and Female He Created Them: Towards a Path of Dialogue on the Question of Gender Theory in Education*.[10] The Church calls for love and respect for all people and in this guide it outlines both theological and scientific truths about the human person, including that there are two sexes created by God and found in nature, that one cannot separate one's sex from one's gender, and that there are biological and unchangeable differences between men and women. Ignoring these truths does not address or help persons who are suffering.

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[9] See, e.g., Catechism of the Catholic Church § 2333, 2393 (2d ed.), https://www.usccb.org/beliefs-and-teachings/what-we-believe/catechism/catechism-of-the-catholic-church ("Catechism"); Pope Francis, Encyclical letter *Laudato Si'* ¶ 155 (2015), , https://www.vatican.va/content/francesco/en/encyclicals/documents/papa-francesco_20150524_enciclica-laudato-si.html.

[10] Congregation for Catholic Education, *Male and Female He Created Them: Towards a Path of Dialogue on the Question of Gender Theory in Education* (2019), http://www.educatio.va/content/dam/cec/Documenti/19_0997_INGLESE.pdf.

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

172. CMA and its members believe that gender-transition procedures and interventions can be harmful, particularly to children, and that medical science does not support the provision of such procedures or interventions.

173. 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."

174. CMA and its members believe that the controversial and complex issues addressed in the gender identity mandate 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.

175. One representative article outlining and illustrating CMA members' concerns with invasive gender interventions was published in a scholarly format in CMA's quarterly journal by Paul W. Hruz, M.D., PhD at the Washington University School of Medicine.[11]

176. The article identifies a lack of high-quality scientific data for common gender identity interventions, such as the general lack of randomized prospective trial design, a small sample size, recruitment bias, short study duration, high subject dropout rates, and reliance on "expert" opinion.

177. The article also shows the immediate and long-term risks relative to benefit of these new forms of medical intervention, including significant intervention-associated morbidity, raising concerns that the primary goal of suicide prevention is not achieved. The article notes that, on top of substantial moral

[11] Paul W. Hruz, *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria*, 87 Linacre Quarterly 34, 34-42 (Sept. 20, 2019), https://doi.org/10.1177/0024363919873762.

questions, under the established principles of evidence-based medicine, providers should have a high degree of caution in accepting gender-transition medical interventions as a preferred treatment approach.

178. Increasing numbers of children with gender dysphoria are being placed on puberty-arresting medications, to allow them more time to "decide" on their gender. Along with preventing the development of secondary sex characteristics, these medications arrest bone growth, decrease bone density, prevent the normal pubertal organization and maturation of the adolescent brain, and prevent the development of sperm in boys and eggs in girls.

179. CMA is especially concerned about the lack of studies revealing the long-term effects of these procedures and interventions. In no other area of science would these types of surgeries, procedures, and interventions move forward without the research to back it up. CMA has always favored sound medical science and ignoring biology would do a great disservice to the medical profession.

180. CMA believes science shows that arresting puberty as a gender identity intervention is scientifically dangerous to children, and therefore religiously objectionable for CMA members to support.

181. CMA and its members also take the position that healthcare professionals need to use biological identity to treat the hundreds of sex-linked disorders that patients may present. Otherwise, poor care would result. Doctors must treat patients based on their genetic make-up, the presence of reproductive organs and diseases unique to biological gender. Changing pronouns will not and cannot change this obligation.

182. CMA urges healthcare professionals to adhere to genetic science and sexual complementarity over ideology in the treatment of gender dysphoria in children. This includes especially avoiding puberty suppression and the use of cross-

sex hormones in children with gender dysphoria. One's sex is not a social construct, but an unchangeable biological reality.

183. CMA thus opposes pubertal suppression of minors, as well as hormone administration or other surgical interventions for purposes of "choosing" a gender or sex.

184. 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."

185. 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."

186. 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."

187. CMA holds that the longstanding principle of "First do no harm" must be upheld in all medical treatment, including for children and adolescents with gender dysphoria. Medical ethics, beginning with a respect for the dignity of the human person as an embodied true male or female, and science, not cultural ideologies or political correctness, serve as the basis of all true healthcare.

b. Impact of the gender identity mandate on CMA members

188. 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.

189. Most of CMA's members treat patients within federal healthcare programs such as Medicare, Medicaid, and the State Children's Health Insurance Program (CHIP).

190. CMA has many members who will be subject to the gender identity mandate because they receive federal funds, provide medical services that may be used as part of a medical transition, and provide health coverage for employees.

191. CMA's members will be impacted by the gender identity mandate because it limits or prohibits their ability to engage in speech advising patients of their medical judgment about gender-transition procedures and it forces them to offer services or facilities to further gender transitions.

192. CMA's members will be impacted by this agency action because it limits or prohibits their ability to continue to accurately refer to patient sex by speech or in writing, including accurately referring to a patient with biologically correct pronouns and accurately coding patient sex in medical records or charts. The government forces providers to inaccurately refer to sex, including with inaccurate pronouns and inaccurate medical records.

193. CMA has members who have treated or currently treat transgender individuals, and who would be liable for failure to provide, offer, or refer for medical transition procedures. Their ability to discuss their medical opinions with their patients and offer medical advice freely has been chilled by this agency action.

194. CMA has members who object to providing, offering, or participating in medical transitions and who provide services such as hysterectomies, breast reconstruction, and hormone administration for patients who need these services for medical reasons. But these members would be required by HHS to provide, offer, and refer for those services as part of a medical transition procedure, despite their objections.

195. CMA has members who currently provide healthcare coverage for employees, coverage which excludes medical transition procedures consistent with state laws. These members will be impacted by the gender identity mandate as long as it requires them to provide insurance coverage for these procedures.

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

197. CMA and its members believe that the gender identity mandate will harm those they are devoted to serving, as well as their ability as medical professionals to practice in conformity with their sound medical judgment and moral conscience. This agency action will violate the quality of healthcare provided to patients, as well as the conscience rights of healthcare professionals everywhere.

C. Effect on Dr. Dassow

198. 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.

199. Dr. Dassow is a specialist in pediatric and adolescent gynecology, including complex medical problems, along with premenstrual syndrome and menopause.

200. Along with a general ambulatory OBGYN care, Dr. Dassow has a special practice focus on pediatric and adolescent gynecology. As a result, she 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.

201. Dr. Dassow through her practice participates in health programs and activities that receive federal financial assistance.

202. 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.

203. 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, which are required by the government's interpretation of the ACA and related regulations.

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

205. Dr. Dassow's more than 30 years of experience reflects a compassionate and inclusive practice of healthcare. Dr. Dassow treats each patient as an individual, seeking to understand the person's holistic needs and personal medical and psychological history. She understands that people have many different views and experiences in life, and so she seeks to help them in a non-judgmental way explore what medical care may be best for them. She strives to have a patient-centric practice under which patients can obtain the care and treatment that they seek and prefer.

206. 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. For instance, in her non-directive counseling attendant on her medical examinations, Dr. Dassow respects her patients who have had elective abortions without regrets, and she also respects her patients who have had abortions but who do experience regret, referring these patients to a compassionate therapist if counseling is indicated and desired.

207. 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.

208. 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.

209. 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.

210. 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.

211. Dr. Dassow also understands that times occur when the use of puberty blockers is appropriate for minors with parental consent. As already noted, she has prescribed puberty blockers for minors with precocious puberty, such as a five-year-old who begins menstruation prematurely, given the proven safety of these interventions at younger ages to delay puberty until the time of its natural onset. But 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. Multiple studies suggest that puberty blockers prescribed for gender dysphoria almost invariably lead to minors proceeding with dangerous cross-sex hormones and surgery.

212. Dr. Dassow wishes to retain and not modify her current policies and practices of not offering, prescribing, or performing these interventions. She wishes to reserve her medical judgment for individual cases, as well as abide by her religious, conscientious, and ethical judgments about prescribing hormones or puberty blockers for new or ongoing gender transitions or other patients experiencing gender dysphoria. Dr. Dassow thus objects to HHS's 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.

213. 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.

214. Dr. Dassow's medical care is provided in health programs and activities subject to Section 1557.

215. The 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.

216. Dr. Dassow will be impacted by the gender identity mandate because it limits or prohibits her ability to continue to accurately refer to patient sex by speech or in writing, including accurately referring to a patient with biologically correct pronouns and accurately coding patient sex in medical records or charts. The government forces providers to inaccurately refer to sex, including with inaccurate pronouns and inaccurate medical records.

217. Dr. Dassow has treated or currently treats transgender individuals, and she would be liable for failure to provide, participate in, offer, or refer for medical transition procedures. Her ability to discuss her medical opinions with her patients and offer medical advice freely has been chilled by this agency action.

VI. Effect of Threatened Enforcement

218. The gender identity mandate imposes 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.

219. If Plaintiffs do not abide by HHS's mandates, 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.

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

221. Violators can be subjected to private lawsuits for damages under Section 1557's enforcement mechanisms, in which they may have to pay attorney's fees, 42 U.S.C. § 1988, and they risk federal False Claims Act liability if they participate in covered federal programs while not in compliance. 31 U.S.C. § 3729, et seq. False certification claims trigger 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. Civil penalties are up to $11,000 per false claim "plus 3 times the amount of damages which the Government sustains because of" any false claim. 31 U.S.C. § 3729(a)(1).

222. The gender identity mandate exposes Plaintiffs to criminal penalties for their current speech and conduct if they do not comply but have participated or continue to participate in federal programs. An individual who makes a materially false statement to the government in connection with or with the delivery of or payment for healthcare benefits or services is subject to criminal monetary penalties, up to five years' imprisonment, or both. 18 U.S.C. §§ 287, 1001, 1035, 1347. An individual who makes any false statement or representation, or who fails to disclose a material fact of any kind to Medicare or Medicaid, including about eligibility for payment for services or eligibility for certification is guilty of a felony, imprisoned for up to ten years, and can be fined up to $100,000 per violation. 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c).

223. Plaintiffs also face potential criminal liability if they fail to provide affirmative evidence of compliance, as required by the government in an

investigation, because it is a criminal offence punishable by fines and up to five years in prison to obstruct the criminal investigation of health care fraud offenses, including by frustrating certain audits or by delaying the flow of information or records to investigators. 18 U.S.C. §§ 1516, 1518.

224. Many Plaintiffs, and Dr. Dassow specifically, are providers in the federal Medicaid, Medicare, or CHIP programs.

225. Many Plaintiffs, and Dr. Dassow specifically, are employed by facilities that receive federal financial assistance, or offer medical care in health programs and activities that receive such assistance.

226. If Plaintiffs do not comply with the gender identity mandate, they risk expulsion from participation in Medicaid, Medicare, and CHIP, and from receiving, or participating in other programs receiving, federal financial assistance.

227. Failure to comply with the gender identity mandate threatens Plaintiffs with loss of income and employment.

228. ACPeds members, CMA's members, and Dr. Dassow will incur increased costs from the investigation and enforcement of claims under Section 1557 or its regulations against them, and they will suffer damaging barriers to their ability to participate in the marketplace as healthcare providers.

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

230. The government has already caused ACPeds members, CMA's members, and Dr. Dassow to lose their medical, conscientious, and religious protections from government enforcement, and that they may lose their ability to practice medicine, even though federal legal protections exist and should be respected by the government.

231. The gender identity mandate requires Plaintiffs to incur significant burdens of time and resources to plan for how they must either comply or risk loss of participation in federal programs.

232. The gender identity mandate has necessitated that Plaintiffs spend time and money training staff, issuing guidance, and engaging in public education campaigns to mitigate the confusion caused by the mandate.

233. The gender identity mandate limits and compels the speech of Plaintiffs, including what they can say to patients.

234. As the result of the gender identity mandate, many Plaintiffs are unlikely to express their full and frank views to patients for fear of liability.

235. If Plaintiffs were to comply with the gender identity mandate, they would suffer the loss of their integrity and reputation because it will be perceived that they profess one thing but do another.

236. Such loss of integrity and reputation devastates conscientious medical professionals and their practices, and makes patients less likely to trust them, which in turn drives patients away from their practices.

237. If Plaintiffs comply with the 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.

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

239. Compliance with the gender identity mandate leads to medically unnecessary procedures, wasting the time and money of providers, patients, and

insurers, and draining resources that could be better spent elsewhere, especially during a pandemic.

240. Compliance with the 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.

241. ACPeds and CMA members who provide employee health insurance plans will face increased costs in covering gender transition interventions, and in paying for the increased costs of unnecessarily delayed medical procedures.

242. ACPeds and CMA members who provide employee health insurance plans face significant penalties under federal law for failing to include coverage of gender transition interventions.

243. Imposing the 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.

244. Imposing the gender identity mandate's penalties on Plaintiffs will harm patients in low-income and underserved communities and regions because it will deprive those patients of Plaintiffs' care.

245. The gender identity mandate will drive thousands of doctors out of the medical profession and out of the care of low-income and underserved patients, and it will dissuade students from choosing to practice medicine.

246. Driving Plaintiffs out of the health care field by means of the gender identity mandate will place intense strain on the healthcare system in America, will exacerbate disparities of care among low-income and underserved populations, and will cause immense human suffering and higher medical costs for all.

D. The Propriety of Urgent Judicial Relief

247. The gender identity mandate is irreparably harming Plaintiffs 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.

248. Plaintiffs are susceptible to risk under the gender identity mandate at any moment of practice.

249. Unless the Court provides protection from the gender identity mandate, including the 2016 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 Rule and Section 1557 itself, the Plaintiffs will continue to suffer from this ongoing violation of law.

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

251. Plaintiffs have no adequate remedy at law.

252. Absent injunctive and declaratory relief against the gender identity mandate, Plaintiffs have been and will continue to be harmed.

253. 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.

CLAIMS FOR RELIEF

CLAIM ONE
ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706) AND REGULATORY FLEXIBILITY ACT (5 U.S.C. § 611)

254. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–253 of this complaint.

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

256. The gender identity language from the 2016 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.

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

258. In this claim, these two sources are referred to as "the gender identity mandate." Plaintiffs challenge them together, and each of them separately.

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

260. Plaintiffs' APA challenge includes any action or publication by HHS to enforce the gender identity mandate against them.

261. The 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.

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

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

263. 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(A)–(C).

264. The gender identity mandate is not in accordance with law, and is in excess of statutory jurisdiction, authority, and limitations.

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

266. The 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 to not encompass discrimination on the basis of gender identity.

267. The 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.

268. The 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).

269. The gender identity mandate is contrary to the Religious Freedom Restoration Act, because it substantially burdens Plaintiffs' exercise of religion, and is not the least restrictive means of advancing a compelling government interest.

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

271. The 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 Plaintiffs out of federally funded health programs and the practice of healthcare; parts (3)–(4) because it requires Plaintiffs 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 Plaintiffs 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 Plaintiffs to violate their ethical and conscientious standards as healthcare professionals.

272. The gender identity mandate violates 42 U.S.C. § 300a-7(d) because it compels Plaintiffs, 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.

273. The 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).[12]

274. For the reasons discussed below in Claims Two through Five, the 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.

275. Alternatively, if the courts in *Whitman-Walker* and *Walker* were incorrect that the 2016 Rule's gender identity language remains in effect despite the vacatur in *Franciscan Alliance*, HHS lacks authority to enforce the gender identity provisions from the 2016 Rule by means of or consistent with its May 10, 2021 Notice of Enforcement, because the 2020 Rule repealed the gender identity

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

language and cannot be used to support the interpretation that Section 1557 includes such prohibitions, and the Notice of Enforcement would, at minimum, have needed to undergo notice and comment rulemaking under the APA in order to restore such provisions and render them enforceable.

B. Arbitrary, Capricious, and an Abuse of Discretion

276. 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).

277. In promulgating the gender identity mandate, Defendants failed to adequately consider that in medical practice, sex is a biological reality, patients are harmed by imposing the provision of controversial and dangerous medical procedures, and patients are harmed by preventing doctors from providing full and timely disclosure of all relevant health information about gender identity procedures and interventions.

278. The gender identity mandate cut short the evolving state of medical knowledge by mandating provision of and referral for experimental gender transition interventions, and to prescribe puberty blockers and hormone therapies off label for such purposes.

279. The gender identity mandate unlawfully requires Plaintiffs to remove or modify healthy organs and tissues in hysterectomies, mastectomies, ovary removal, testicle removal, "de-gloving," and the creation of faux genitalia, in furtherance of gender transition purposes, or to offer or refer for any such procedures, or to provide information in affirmance of them.

280. The gender identity mandate unlawfully requires Plaintiffs to treat patients according to gender identity and not sex, express views on gender identity interventions that they do not share, say that sex or gender is nonbinary or on a

spectrum, use language and preferred pronouns affirming and reflecting self-professed gender identity, create medical records according to gender identity and not biological sex, refrain from expressing their medical, ethical, or religious views in disagreement with gender identity ideology or interventions, provide government assurances of compliance with the mandate, or post notices of such compliance.

281. The gender identity mandate unlawfully requires Plaintiffs to allow patients to access single-sex program and facilities by gender identity and not by biological sex.

282. The gender identity mandate unlawfully requires Plaintiffs who provide employee health insurance to pay for insurance coverage for gender interventions.

283. Section 92.206 of the 2016 Rule, which is in effect, claims to allow some services to "one sex" based on biology but requires access to single-sex services or facilities regardless of their sex, creating inconsistent standards and confusion.

284. The 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. HHS's own experts wrote at the time that not enough evidence existed on this subject: "Based on a thorough review of the clinical evidence available at this time, there is not enough evidence to determine whether gender-reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria. There were conflicting (inconsistent) study results—of the best designed studies, some reported benefits while others reported harms."[13]

285. Defendants failed to adequately consider the gender identity mandate's impact on doctors and medical associations with medical, ethical, conscientious, and

[13] Centers for Medicare & Medicaid Services, Proposed Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (June 2, 2016).

religious objections to it, or their reliance interests in not being subject to such a mandate.

286. Defendants failed to adequately consider the gender identity mandate's harm to low-income and underserved populations by the expulsion of Plaintiffs and similar healthcare providers from federally funded health programs and activities, the shortages of care and providers that would result, and the negative impact on the health of such patients due to that reduced access.

287. Defendants failed to adequately consider the harm to Plaintiffs' own patients who want to continue receiving care from Plaintiffs but will not be able to do so when the mandate drives Plaintiffs out of their jobs, specific health programs, and healthcare generally.

288. Defendants failed adequately to consider the interests health care professionals possess under RFRA even if they do not yet have court injunctions against the gender identity mandate.

289. The 2020 Rule's consideration of various issues underscores these failings in the gender identity mandates. The 2020 Rule not only did not impose a gender identity mandate, it took the position that Section 1557 does not authorize such a mandate, and it attempted to repeal the gender identity mandate to avoid such costs.

290. 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.

291. In issuing the 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.

292. The gender identity mandate violates the APA 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.

293. The 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).

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

295. The 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.

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

C. Invalid Delay of the Sunset Rule

297. Plaintiffs also challenge another recent rule delaying a separate rule that would have provided for agency review of the gender identity mandates.

298. Plaintiffs bring this claim both as violation of the APA, 5 U.S.C.§ 706, for being arbitrary and capricious, contrary to law and statutory authority, and without observance of required procedure, and, to the extent it violates the Regulatory Flexibility Act (RFA) itself as discussed herein, under the judicial review provision of the RFA, 5 U.S.C. § 611.

299. On January 19, 2021, HHS published in the Federal Register a final rule entitled "Securing Updated and Necessary Statutory Evaluations Timely" (SUNSET Rule). 86 Fed. Reg. 5,694 (Jan. 19, 2021). The SUNSET Rule was set to go into effect on March 22, 2021.

300. The SUNSET Rule requires HHS to engage in periodic review of its regulations, including the 2016 and 2020 Rules, or else those regulations would expire. 86 Fed. Reg. at 5,756 (amending 45 C.F.R. Pt.8 and citing 42 U.S.C. § 18116 as authority).

301. 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). If the rules have such an impact, then HHS must "review" the rulemaking in view of the five factors listed in section 3(a) of the Regulatory Flexibility Act, 5 U.S.C. § 610(b). 45 C.F.R. § 8.1(d)(1). HHS must review existing regulations 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 each regulation's promulgation, or (3) ten calendar years after the last year in which HHS assessed and, if required, reviewed the regulation, whichever is latest. If HHS does not comply, the unreviewed regulations will automatically expire. The SUNSET Rule excludes regulations "that are prescribed by Federal Law, such that the Department exercises no discretion as to what is prescribed." 45 C.F.R. § 8.1(g)(1).

302. On March 9, 2021, entities brought litigation against the SUNSET Rule. *County of Santa Clara v. HHS*, No. 5:21-cv-01655-BLF (N.D. Cal. filed Mar. 9, 2021).

303. Promptly, HHS released a final rule entitled "Securing Updated and Necessary Statutory Evaluations Timely; Administrative Delay of Effective Date;

Correction" (Delay Rule). The rule was published in the Federal Register on March 23, 2021. 86 Fed. Reg. 15,404.

304. The Delay Rule was published March 23, 2021, but HHS claims that it stayed the SUNSET Rule's effective date on March 19, 2021, three days before the Delay Rule was published in the Federal Register. *Id*.

305. The Delay Rule unilaterally delayed, without public notice and an opportunity for comment, the effective date of the SUNSET Rule for one year, citing 5 U.S.C. § 705 as its authority.

306. The Delay Rule thus removes from Plaintiffs the procedural protections of the SUNSET Rule, under which the Section 1557 rules imposing the gender identity mandate would be subject to periodic review, including amendment or recission, or would be subject to automatic rescission.

307. 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."

308. Courts have jurisdiction to review the delay of rules.

309. The Delay Rule is subject to review under the APA.

310. The Delay Rule is a "rule" under the APA, 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.

311. Section 705 stays are not "committed to agency discretion by law" and are therefore reviewable.

312. 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.

313. 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.

314. 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).

315. The Delay Rule also prescribes "law or policy," 5 U.S.C. § 551(4), and thus, in reality, is not a true delay rule under 5 U.S.C. § 705, and therefore independently required notice and comment under the APA.

316. But HHS and the HHS Secretary failed to provide the public with advance notice and comment before issuing the Delay Rule, in violation of the APA.

317. Therefore 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.

318. HHS failed to consider its statutory duties to review regulations, particularly under the Regulatory Flexibility Act, and HHS failed to explain why its new view complied with these legal obligations. These legal duties were identified in the SUNSET Rule as the legal grounds for the SUNSET Rule.

319. Section 3(a) of the Regulatory Flexibility Act (RFA) requires each agency "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. § 610(a). It must "provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective

date of this chapter within ten years of the publication of such rules as the final rule." *Id.* "If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years." *Id.*

320. HHS was and is not otherwise in compliance with the RFA: as it admits, despite sporadic reviews, "the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking" and overall HHS has had "limited success in performing retrospective regulatory review." 86 Fed. Reg. at 5,696, 5,738 (collecting examples of HHS's failure to review regulations despite statutory mandates and reporting the results of an AI-driven data analysis of past inadequate efforts).

321. The Delay Rule violates section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 610, because it repealed or delayed the SUNSET Rule without otherwise providing for HHS compliance with the RFA, and HHS admitted that it did not comply with the RFA.

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

323. Many ACPeds and CMA members are small entities under the Regulatory Flexibility Act.

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

325. HHS issued the Delay Rule without satisfying the standard that "justice so requires" it to "postpone the effective date of action taken by it, pending judicial review."

326. The reasons offered by HHS in the Delay Rule are insufficient to satisfy 5 U.S.C. § 705.

327. 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.

328. HHS failed to specifically address the inconsistency between its current view that those provisions stand on legally questionable footing, and its prior conclusion that they were legally sound.

329. HHS also acted arbitrarily and capriciously by not even considering its compliance or non-compliance with the RFA without the SUNSET Rule.

330. The Delay Rule ignored HHS's authority to conduct periodic rulemakings. *See* 86 Fed. Reg. at 5,703 (collecting statutes).

331. All policy issues raised by HHS in the Delay Rule, such as uncertainty or disruption for the public, or burdens on the agency, or the length of the SUNSET Rule's comment window, or the need for tribal consultation, or the ongoing pandemic, or the deregulatory effect of the SUNSET Rule, were already raised in comments and addressed in its response to comments, 86 Fed. Reg. at 5,704–5,750, and HHS's lack of sufficient reason to change course is an insufficient basis to issue the Delay Rule under 5 U.S.C. § 705.

332. The Delay Rule is not grounded on the existence or consequences of the pending litigation.

333. HHS's stated reasons for the Delay Rule are not tailored to the litigation but are general reasons to halt the SUNSET Rule, which does not satisfy 5 U.S.C. § 705.

334. Stating its delay of the SUNSET Rule was pending judicial review under 5 U.S.C. § 705 was a pretext that was 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 simply repeal the SUNSET Rule.

335. Nothing in the litigation challenging the SUNSET Rule required the Delay Rule—that litigation could have gone to final judgment without any need to issue the Delay Rule.

336. The case against the SUNSET Rule has had no action since its filing on March 9, 2021 and it is now stayed until November 1, 2021, and presumably will be stayed further upon the same stipulations.

337. HHS's examination of the benefits of the SUNSET Rule and the harms of a delay lacked any meaningful analysis or balance of the two sides of the issues

338. 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

339. 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 mandate.

340. The Delay Rule also does not consider the degree of regulatory uncertainty that it creates.

341. HHS improperly failed to consider any alternative to the Delay Rule that respect 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.

342. Delaying the SUNSET Rule through the Delay Rule injures Plaintiffs by depriving them of the procedural protections of the SUNSET Rule, namely that the

Section 1557 rules imposing the gender identity mandate would be subject to periodic review or would otherwise expire.

343. This delay harms Plaintiffs because it removes a procedural avenue for the repeal or modification of the gender identity mandate, and for Plaintiffs' participation in that review process, and it does so in violation of the APA.

344. If the SUNSET Rule applied to the gender identity mandate, there is a reasonable probability that in its review HHS would reconsider and rebalance the effects of the mandate to better address Plaintiffs' concerns.

345. Because the Delay Rule violates the APA and the RFA, the Court should hold it unlawful and set it aside under 5 U.S.C. §§ 706 and 611(a). 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.

CLAIM TWO
FREEDOM OF SPEECH AND ASSOCIATION
(FIRST AND FIFTH AMENDMENTS)

346. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–253 of this complaint.

347. 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.

348. 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.

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

350. Plaintiff's speech in the context of healthcare is protected under the First Amendment.

351. Plaintiffs bring this claim against the gender identity language in the 2016 Rule and the May 10, 2021 Notice of Enforcement.

352. In the alternative, to the extent the 2020 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, Plaintiffs seek relief against those requirements.

353. In this claim, the term "gender identity mandate" refers to the requirements of the 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.

354. Plaintiffs also challenge any actions of Defendants, their officers, or their agents, to enforce the gender identity mandate.

355. The gender identity mandate both restricts Plaintiffs' speech and compels their speech.

356. Plaintiffs oppose the 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.

357. 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.

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

359. In the past, Plaintiffs 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 by expressing views that under the gender identity mandate would consider harassment, hostile environment, or discrimination on the basis of gender identity.

360. The gender identity mandate prevents conversations between Plaintiffs and their patients, and casts a credible threat of government prosecution over those conversations.

361. The gender identity mandate chills the speech of a health care professional of ordinary firmness, and it chills the speech of Plaintiffs 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.

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

363. Plaintiffs' views also prohibit them from telling patients that they should have healthcare treatments based on gender identity, rather than on biological sex.

364. Plaintiffs' 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 Plaintiffs' best medical and ethical judgment.

365. The 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.

366. The 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.

367. The gender identity mandate prohibits Plaintiffs 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.

368. The gender identity mandate prohibits the religious Plaintiffs from expressing their religious or conscientious viewpoint on gender identity interventions to their patients.

369. The gender identity mandate compels Plaintiff employers to offer insurance coverage for procedures, services, drugs, and activities that violate Plaintiffs' religious beliefs and message.

370. Plaintiffs wish to keep using their best medical, ethical, and religious judgments in speaking and giving information to patients, but the gender identity mandate does not allow this.

371. But for the gender identity mandate, Plaintiffs 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.

372. The gender identity mandate compels Plaintiffs to speak in ways that they would not otherwise speak.

373. Defendants intrude upon the right to expressive association (or freedom of assembly) of Plaintiffs, and their employees, 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.

374. The gender identity mandate compels and prohibits speech and association on the basis of viewpoint, and therefore it is presumptively unconstitutional.

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

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

377. 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.

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

379. The 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.

380. 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.

381. The gender identity mandate's overbreadth is not justified by a compelling governmental interest or narrowly tailored to any interest.

382. The gender identity mandate imposes an unconstitutional condition on Plaintiffs' receipt of federal funding.

383. Defendants' administrative requirements that incorporate the 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.

384. This Court may review and enjoin *ultra vires* or unconstitutional agency action. *Larson*, 337 U.S. at 689–91.

385. The Court should therefore declare that the gender identity mandate, whether through the 2016 Rule, the May 10, 2021 Notice of Enforcement, the 2020 Rule, or Section 1557 itself, are unconstitutional regulations of speech.

386. The Court should likewise enjoin Defendants from implementing and enforcing the mandate.

CLAIM THREE
RELIGIOUS FREEDOM RESTORATION ACT
(42 U.S.C. § 2000BB, ET SEQ.)

387. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–253 of this complaint.

388. 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).

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

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

391. The gender identity mandate, whether from the 2016 Rule, the May 10, 2021 Notice of Enforcement, the 2020 Rule, Section 1557, or any other action by Defendants to enforce gender identity nondiscrimination against plaintiffs under Section 1557, are subject to RFRA.

392. All Plaintiffs bring this RFRA claim except the non-religious members of ACPeds. CMA asserts the claim on behalf of its members, and ACPeds brings it on behalf of its religious members. Dr. Dassow brings the claim on behalf of herself. Collectively, these are referred to as the Religious Plaintiffs.

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

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

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

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

397. The Religious Plaintiffs 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.

398. The Religious Plaintiffs' compliance with these beliefs is a religious exercise.

399. The Religious Plaintiffs' speech about these beliefs is a religious exercise.

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

401. The gender identity mandate exerts significant pressure on them 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.

402. The gender identity mandate exposes Religious Plaintiffs to cicil 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).

403. The gender identity mandate imposes an unconstitutional condition on Plaintiffs' receipt of federal funding.

404. The gender identity mandate substantially burdens the Religious Plaintiffs' free exercise of religion by conditioning their ability to provide healthcare or speak in healthcare settings on foregoing their free exercise rights.

405. The gender identity mandate forces the Religious Plaintiffs to choose between providing healthcare in violation of their religious beliefs and at risk of significant malpractice liability due to the harms of gender transition interventions, dropping out of federally funded health programs and activities altogether and losing their livelihoods, or facing loss of federal funding and the imposition of significant penalties and investigatory burdens for violating the gender identity mandate.

406. If the Religious Plaintiffs continue to provide healthcare, they will have to either violate the gender identity mandate or violate their sincere religious beliefs.

407. The gender identity mandate imposes special disabilities on the Religious Plaintiffs because of their religion and their intent to engage in private religious expression.

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

409. The gender identity mandate furthers no compelling governmental interest.

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

411. The exemptions and exceptions to the gender identity mandate and Section 1557 of the ACA undermine any compelling government interest and show less restrictive means of achieving any government interests.

412. The ACA does not prohibit discrimination on the basis of gender identity, and therefore does not support any governmental interest to sustain the restrictions on speech or association/assembly described herein.

413. Therefore, Defendants' actions promulgating and enforcing the gender identity mandate violate RFRA.

414. 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 RFRA for the same reasons set forth in this claim.

415. The Court should thus declare that the gender identity mandate, whether from the 2016 Rule or the May 10, 2021 Notice of Enforcement, or in the alternative the 2020 Rule or Section 1557 itself, and any enforcement thereof by Defendants, violates Plaintiffs rights secured to them by the Religious Freedom Restoration Act, 42 U.S.C. § 2000bb *et seq.*, and should enjoin their application under 42 U.S.C. § 2000bb-1(c).

CLAIM FOUR
FREE EXERCISE OF RELIGION
(FIRST AND FIFTH AMENDMENTS)

416. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–253 of this complaint.

417. 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.

418. 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.

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

420. All Plaintiffs bring this Free Exercise Clause claim except the non-religious members of ACPeds. CMA asserts the claim on behalf of its members, and ACPeds brings it on behalf of its religious members. Dr. Dassow brings the claim on behalf of herself. Collectively, these are referred to as the Religious Plaintiffs.

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

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

423. The Religious Plaintiffs' sincerely held religious beliefs prohibit them from engaging in or facilitating in the objectionable practices.

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

425. The Religious Plaintiffs 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.

426. The Religious Plaintiffs' compliance with these beliefs is a religious exercise.

427. The Religious Plaintiffs' speech about these beliefs is a religious exercise.

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

429. The gender identity mandate exerts significant pressure on them 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.

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

431. The gender identity mandate substantially burdens the Religious Plaintiffs' free exercise of religion by conditioning their ability to provide healthcare or speak in healthcare settings on foregoing their free exercise rights.

432. The gender identity mandate forces the Religious Plaintiffs to choose between providing healthcare in violation of their religious beliefs and at risk of significant malpractice liability due to the harms of gender transition interventions, dropping out of federally funded health programs and activities altogether and losing their livelihoods, or facing loss of federal funding and the imposition of significant penalties and investigatory burdens for violating the gender identity mandate.

433. If the Religious Plaintiffs continue to provide healthcare, they will have to either violate the gender identity mandate or violate their sincere religious beliefs.

434. The gender identity mandate imposes special disabilities on the Religious Plaintiffs because of their religion and their intent to engage in private religious expression.

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

436. The gender identity mandate suppresses the religious practice of individuals and organizations such as Plaintiffs, while allowing exemptions for similar conduct based on secular and non-religious reasons, making the gender identity mandate not neutral and generally applicable.

437. Upon information and belief, the gender identity mandate specifically and primarily burdens religious conduct, making it not neutral and generally applicable.

438. Upon information and belief, the gender identity mandate favors some religious beliefs over others, making it not neutral and generally applicable.

439. 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 gender identity mandate for religious reasons.

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

441. The gender identity mandate is not neutral because it can be and 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.

442. The gender identity mandate is likewise not generally applicable because it grants federal officials unbridled discretion to censor the Religious Plaintiffs' religious expression while permitting other providers to express their messages.

443. The gender identity mandate furthers no compelling or legitimate governmental interest.

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

445. The exemptions and exceptions to the gender identity mandate and Section 1557 of the ACA undermine any compelling government interest and show less restrictive means of achieving any government interests.

446. The ACA does not prohibit discrimination on the basis of gender identity, and therefore does not support any governmental interest to sustain the restrictions on speech or association/assembly described herein.

447. Defendants' inconsistent application of the ACA burdens the Religious Plaintiffs' First Amendment rights.

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

449. The gender identity mandate, and Defendants' enforcement of it, violates Plaintiffs' hybrid free speech and religious exercise rights under the First Amendment and is subject to strict scrutiny.

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

451. 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.

452. The Court should thus declare that the gender identity mandate, whether from the identified agency actions or Section 1557 itself, and Defendants' enforcement thereof, violates Plaintiffs rights secured to them by the Free Exercise Clause, and enjoin their application under the APA and *Larson*, 337 U.S. at 689-91.

CLAIM FIVE
STRUCTURAL PRINCIPLES OF FEDERALISM AND LACK OF ENUMERATED POWERS

453. Plaintiffs re-allege and incorporate herein, as though fully set forth, paragraphs 1–253 of this complaint.

454. Any application or enforcement of Section 1557 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.

455. 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).

456. 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. *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

457. Under the U.S. Constitution's structural principles of federalism and the Tenth Amendment, 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. *Gregory v. Ashcroft,* 501 U.S. 452, 460-70 (1991).

458. 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 the Plaintiffs.

459. In the 2016 Rule and the May 10, 2021 Notice of Enforcement, and actions taking to implement those measures, Defendants expressly and impliedly, but improperly, 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.

460. 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.

461. 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 gender identity mandate imposes on Plaintiffs, the public, or the States.

462. The 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 Plaintiffs chose to begin accepting Medicare, Medicaid, and CHIP as payment for medical services provided.

463. 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.

464. 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. *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985).

465. 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 and effectively coerces or commandeers the States, including in grant conditions and in the States' historical and well-established regulation of healthcare, freedom of speech, conscience protection, and religious freedom. *New York v. United States*, 505 U.S. 144, 162 (1992).

466. These structural principles protect citizens, not just states. *Bond v. United States*, 564 U.S. 211, 220, 222 (2011).

467. This Court may review and enjoin ultra vires or unconstitutional agency action. 5 U.S.C. §§ 702–705; *Larson*, 337 U.S. at 689-91.

468. The Court should therefore declare that the gender identity mandate is unconstitutional and enjoin its application.

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 agency action:

1. That this Court vacate and set aside the 2016 Rule's gender identity language, and the May 10, 2021 notice of enforcement of a gender identity discrimination prohibition;
2. That, if the 2020 Rule is interpreted to prohibit gender identity discrimination, this court set aside and vacate that rule;
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, against Plaintiffs (inclusive of Dr. Dassow and ACPeds' and CMA's current and future members), by Defendants, their officials, agents, employees, and all persons in active concert or participation with them; divisions, including their successors in office; including any actions by them to deny federal financial assistance or qualification for participation in federally funded programs or activities because of Plaintiffs' failure to perform, offer, endorse, proscribe, or refer for gender interventions, or provide insurance coverage, or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;

4. That this Court render declaratory judgment that the agency actions enforcing a gender identity mandate under the ACA violate the Administrative Procedure Act and the ACA; as applied to Religious Plaintiffs, violates the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment; and, as applied to Plaintiffs, inclusive of Dr. Dassow and 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, including by any acts that tend to prohibit

private healthcare providers from treating patients and speaking based on biological sex not gender identity, or from having and publishing such policies governing their objection to providing sex transition procedures, drugs, services, or interventions on demand or insurance coverage for these services;

B. In the alternative, if Section 1557 is deemed to prohibit discrimination on the basis of gender identity:

1. That this Court issue declaratory relief that, as applied to Religious Plaintiffs (inclusive of Dr. Dassow, CMA's members, and ACPeds' religiously objecting members), that Section 1557 violates the Religious Freedom Restoration Act and the Free Exercise Clause of the First Amendment, and that, as applied to such Plaintiffs, their members, and all similarly situated individuals, institutions, or religious entities, that Section 1557 violates the First Amendment, and the Fifth Amendment, the constitutional principles of federalism, the Spending Clause, the Tenth Amendment, and Congress's enumerated powers;
2. That this Court issue declaratory relief that Section 1557 and its implementing regulations may not be construed to prohibit discrimination on the basis of gender identity, including by any acts that tend to prohibit healthcare providers from treating patients and speaking based on biological sex not gender identity, or from having and publishing such policies governing their objection to providing sex transition procedures, drugs, services, or interventions on demand or insurance coverage for these services.

3. That this Court issue a preliminary and permanent injunction against implementation of, enforcement of, application of, or taking any action relying on any such interpretation or application of Section 1557 or any of its implementing regulations, including enforcement against doctors, by Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office, and including any enforcement in any way inconsistent with the declaratory relief described in paragraphs B.1–2 of this request for relief, including by denying federal financial assistance because of their failure to perform, offer, endorse, proscribe, or refer for gender interventions, or provide insurance coverage or by otherwise pursuing, charging, or assessing any penalties, fines, assessments, investigations, or other enforcement actions;

C. With respect to the Delay Rule of the SUNSET Rule,

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 Delay Rule violates the Administrative Procedure Act, and thus the SUNSET Rule has been in effect since its original scheduled implementation date of March 22, 2021; and

4. That this Court defers the effectiveness of the Delay Rule as to its effect on small entities, leaving in place the SUNSET Rule as to regulations that affect such entities.

D. That this Court expressly extend all such relief to Plaintiffs, their current and future members, and those acting in concert or participation with them, including their respective healthcare practices, employees, health plans, and any insurers or third-party administrators in connection with such health plans;

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 and any actual damages;

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 26th day of August, 2021.

s/ Jonathan A. Scruggs

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