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

Susan Neese, M.D and **James Hurly, M.D.**, on behalf of themselves and others similarly situated, Plaintiffs, v. **Xavier Becerra**, in his official capacity as Secretary of Health and Human Services; **United States of America**, Defendants.	Case No. 2:21-cv-00163-Z

REPLY BRIEF IN SUPPORT OF MOTION FOR CLASS CERTIFICATION

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I. The Representative Plaintiffs Have Established Article III Standing

The plaintiffs are asking this Court to: (1) "hold unlawful and set aside" the Secretary's notification of May 10, 2021, under section 706 of the APA; (2) declare that section 1557's prohibition on "sex" discrimination does not prohibit *all* discrimination on account of "sexual orientation" and "gender identity," but only conduct in which the provider would have acted differently toward an identically situated member of the opposite biological sex; and (3) enjoin the Secretary from using or enforcing the interpretation of section 1557 that appears in the notification of May 10, 2021. *See* First Amended Complaint, ECF No. 11, at ¶¶ 44–50.

The defendants try to defeat standing by observing that the plaintiffs are uninjured by the portion of the notification that prohibits discrimination on account of "sexual orientation." *See* Defs.' Br., ECF No. 57, at 4–5. But judicial review under the APA requires courts to review the challenged agency *action*—and to "hold unlawful and set aside" the challenged action if it is "not in accordance with law." 5 U.S.C. § 706 ("The reviewing court shall—. . . (2) hold unlawful and set aside agency *action*, findings, and conclusions found to be—(A) . . . not in accordance with law" (emphasis added)); 5 U.S.C. § 704 ("[F]inal agency *action* for which there is no other adequate remedy in a court are subject to judicial review." (emphasis added)). The plaintiffs are challenging the Secretary's "action" in issuing the notification of May 10, 2021. The plaintiffs' injuries are "fairly traceable" to this action—even if they are not injured by every single word that appears in the notification. And the proper remedy under the APA, upon finding an agency action "not in accordance with law," is to formally revoke the "action," (*i.e.* the notification), rather than merely enjoin the enforcement of the disputed provisions. *See Data Marketing Partnership, LP v. United States Dep't of Labor*, 45 F.4th 846, 2022 WL 3440652, *8 (5th Cir. 2022) ("The APA gives courts the power to 'hold unlawful and set aside agency action[s].' 5 U.S.C.

§ 706(2). . . . [Section] 706 'extends beyond the mere non-enforcement remedies available to courts that review the constitutionality of legislation, as it empowers courts to "set aside"—*i.e.*, formally nullify and revoke—an unlawful agency action.'" (citation omitted)); *Driftless Area Land Conservancy v. Valcq*, 16 F.4th 508, 522 (7th Cir. 2021) ("Vacatur [of an agency action] retroactively undoes or expunges a past [agency] action. . . . Unlike an injunction, which merely blocks enforcement, vacatur unwinds the challenged agency action."). The plaintiffs have standing to seek this remedy, even if their injuries arise only from the gender-identity edict.

The defendants also claim that the plaintiffs' injuries have been obviated by the Notice of Proposed Rulemaking, which (according to the defendants) disclaims any interpretation of section 1557 that would prohibit the conduct that the plaintiffs wish to engage in. *See* Defs.' Br., ECF No. 57, at 5. There are many problems with this argument. First, a plaintiff's standing is assessed at the moment the lawsuit is filed and is unaffected by post-filing developments. *See Carney v. Adams*, 141 S. Ct. 493, 499 (2020) ("[S]tanding is assessed 'at the time the action commences'" (citation omitted)). The Notice of Proposed Rulemaking concerns only whether the plaintiffs' claims have become moot. *See Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189–90 (2000) (explaining distinction between standing and mootness). But the defendants are not making a mootness argument, and they cannot show that the Notice of Proposed Rulemaking moots the plaintiffs' claims when the rulemaking process is not complete and the contents of the proposed rule could change between now and when the rule becomes final. *See El Paso Electric Co. v. FERC*, 667 F.2d 462, 467 (5th Cir. 1982) ("A case is not rendered moot simply because there is a possibility, or even a probability, that the outcome of a separate administrative proceeding may provide the litigant with similar relief.").

The second problem is that a notice of proposed rulemaking has no legal force, and it does not withdraw or nullify the earlier agency "action" that the plaintiffs are

challenging. The notice of proposed rulemaking will culminate in a separate and distinct final agency action that can be challenged, but the mere issuance of a notice does nothing to affect the notification of May 10, 2021, or its contents. *See Biden v. Texas*, 142 S. Ct. 2528, 2544–45 (2022) (explaining how separate DHS memoranda that sought to terminate the Migrant Protection Protocol were distinct agency "actions").

The final problem is that the Notice of Proposed Rulemaking does nothing to alleviate the plaintiffs' objections to the Secretary notification of May 10, 2021. The proposed rule goes well beyond *Bostock* by interpreting section 1557's prohibition on "sex" discrimination to encompass "discrimination on the basis of sex stereotypes; sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; and gender identity." Dep't of Health & Human Services, *Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking*, 87 Fed. Reg. 47,824, 47,916 (Aug. 4, 2022) (text of proposed 45 C.F.R. § 92.101). It also forbids covered entities to "[d]eny or limit health services, including those that are offered exclusively to individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded," a prohibition that would appear to compel providers to offer and provide prostate-cancer screenings to biological women who identify as men on the same terms that they would give them to biological men. *See id.* at 47,918 (text of proposed 45 C.F.R. § 92.206(b)(1)). And the supposed "safe harbors" in the proposed rule only reaffirm the legal jeopardy that the plaintiffs will face if they refuse to refer minors for puberty blockers or sex-change operations, or if they refuse to provide "gender-affirming care" to any patient with gender dysphoria. Consider the text of proposed 45 C.F.R. § 92.206(c):

> Nothing in this section requires the provision of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not

> clinically appropriate for a particular individual. However, a provider's belief that gender transition or other gender-affirming care can never be beneficial for such individuals (or its compliance with a state or local law that reflects a similar judgment) is not a sufficient basis for a judgment that a health service is not clinically appropriate.

Dep't of Health & Human Services, *Nondiscrimination in Health Programs and Activities, Notice of Proposed Rulemaking*, 87 Fed. Reg. 47,824, 47,916 (Aug. 4, 2022). Terms like "legitimate" or "nondiscriminatory" are in the eye of the beholder—and a provider can only guess as to whether the powers that be at HHS will regard its refusal to provide puberty blockers to a minor as "legitimate" or "nondiscriminatory."

II. The Defendants' Commonality, Typicality, And Adequacy-Of-Representation Objections Do Not Defeat Class Certification

The defendants try to defeat class certification by pointing out that many absent class members support Secretary Becerra's interpretation of section 1557 and oppose the named plaintiffs' efforts to have it set aside—and they argue that this precludes the plaintiffs from establishing commonality, typicality, or adequacy of representation. Defs.' Br., ECF No. 57, at 5–13. But this does not warrant denial of class certification. *See* Br. in Support of Mot. for Class Cert., ECF No. 45, at 4–5 (citing *J.D. v. Azar*, 925 F.3d 1291, 1313 (D.C. Cir. 2019)). At most, these objections should lead the court to certify a sub-class limited to providers who oppose Secretary Becerra's edict.

A. The Proposed Class Satisfies The Commonality Requirement

Commonality requires only a single common question of law or fact, and the proposed class satisfies that requirement. *See* Br. in Support of Mot. for Class Cert., ECF No. 45, at 2–3. That some class members may not share the plaintiffs' opposition to Secretary Becerra's interpretation of the statute does not defeat commonality. The common issues in this case are pure questions of law, and the answers to those questions do not turn on whether a particular class member supports or opposes Secretary Becerra's interpretation of section 1557. The plaintiffs are seeking a ruling on the

legality of the notification of May 10, 2021, and it does not matter in answering those questions whether some of the class members approve of the Secretary's action.

B. The Proposed Class Satisfies The Typicality Requirement

The defendants also try to defeat typicality by asserting that individual class members have differing views about Secretary Becerra's interpretation of section 1557, and that not every class member will share the plaintiffs' unwillingness to provide puberty blockers and referrals for sex-change operations to minors, or their unwillingness to provide "gender-affirming care" that is inappropriate in light of a patient's biologically assigned sex. *See* Defs. Br., ECF No. 57, at 9–10. But that does not defeat typicality (or commonality) because the plaintiffs are seeking a declaration of the class members' *right to choose* whether to provide gender-affirming care as envisioned by Secretary Becerra. This presents a legal question common to every class member, and the plaintiffs are not required to show or allege that every single class member will exercise that right in the same manner that they would. *See Prantil v. Arkema Inc.*, 986 F.3d 570, 581–82 (5th Cir. 2021) ("Rule 23(b)(2) does not require 'a specific policy uniformly affecting—and injuring—each [plaintiff] . . . so long as declaratory or injunctive relief "settling the legality of the [defendant's] behavior with respect to the class as a whole is appropriate." ' " (quoting *M.D. ex rel. Stukenberg v. Perry*, 675 F.3d 832, 847–48 (5th Cir. 2012)); *J.D. v Azar*, 925 F.3d 1291, 1313 (D.C. Cir. 2019) (certifying Rule 23(b)(2) class of pro-abortion and anti-abortion women because "[t]he class members all assert a common entitlement to make that choice on their own, free from any veto power retained" by the government).

The defendants also express concern that some class members will have additional objections to the notification that go beyond the plaintiffs' arguments. *See* Defs. Br., ECF No. 57, at 10 (arguing that the plaintiffs' claims are "atypical of claims of any proposed class members who wish to discriminate on the basis of sexual orientation.").

But the plaintiffs are seeking a remedy that will "hold unlawful and set aside" the notification under the APA, and that remedy will satisfy anyone in the class who objects to any requirement set forth in the notification. And in all events, if the Court is persuaded that these differences in opinion among the class members defeat typicality, the proper response is not to deny certification but certify a smaller class of those who share the plaintiffs' views. *See infra* at 7.

C. The Plaintiffs Are Adequate Class Representatives

The defendants try to drive a wedge between the plaintiffs and the absent class members who are supportive or indifferent toward the Secretary's interpretation of section 1557. *See* Defs. Br., ECF No. 57, at 11–13. But the plaintiffs are not pursuing any relief that would make those absent class members worse off. Providers who wish to continue providing minors with puberty blockers and referrals for sex-change operations will remain free to do so, even if the plaintiffs prevail in this litigation. And any provider may continue providing gender-affirming care that they think appropriate regardless of how this Court ultimately rules on the plaintiffs' claims. A litigant who seeks to vindicate individual rights on behalf of a class should not be denied certification merely because some class members have no interest in exercising those rights. *See J.D. v. Azar*, 925 F.3d 1291, 1313 (D.C. Cir. 2019).

The defendants attempt to distinguish *J.D.* by claiming that some class members will be affirmatively harmed by the relief that the plaintiffs seek. *See* Defs. Br., ECF No. 57, at 12–13. But their theories of harm are dubious and implausible. They point to the Whitman–Walker Clinic and the Los Angeles LGBT Center, which had alleged that the Trump Administration's refusal to extend section 1557's anti-discrimination protections to LGBTQ individuals would "harm" them by increasing their LGBTQ clientele, as those patients would be scared away from seeking services from other health-care providers. *See id.* (citing *Whitman–Walker Clinic, Inc. v. U.S. Dept. of*

Health and Human Services, 485 F. Supp. 3d 1, 20–21 (D.D.C. 2020)). But *Bostock* now provides a firm baseline of anti-discrimination protections for LGBTQ individuals, and those protections will remain in place even if the Secretary's notification is held unlawful and set aside. It is also entirely speculative to claim that LGBTQ patients would change health-care providers in response to a decision that holds unlawful or sets aside the Secretary's notification. Finally, it is far from clear that a health-care provider will be "harmed" by an increased demand for its services; that is typically regarded as a positive development by any entity that provides services to the general public.

D. The Court May Certify A Smaller Class Of Health-Care Providers

If the Court is unwilling to certify the class as initially proposed, then it can (and should) certify a smaller class consisting of "all health-care providers subject to section 1557 of the Affordable Care Act who: (1) object to providing puberty blockers, hormone therapy, or referrals for sex-change operations to minors; or (2) object to providing health care or services to a patient that they regard as inappropriate given the patient's biologically assigned sex." A class of this sort would obviate the defendants' commonality, typicality, and adequacy-of-representation objections (as well as their Rule 23(b)(2) objections, *see* Defs. Br., ECF No. 57, at 15–16). And it would easily clear the numerosity threshold of Rule 23(a)(1). *See In re Nat'l Football League Players Concussion Injury Litig.*, 821 F.3d 410, 426 (3d Cir. 2016) ("[N]umerosity is generally satisfied if there are more than 40 class members."). The Catholic Medical Association and its members, for example, believe that "healthcare that provides gender-transition procedures and interventions is neither healthful nor caring; it is dangerous," and the CMA has adopted an official resolution stating that "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." *See*

Ex. 2 at ¶¶ 210, 214. And the CMA has 2,500 members—well in excess of the numerosity threshold. *See* Ex. 3 at ¶ 3.

III. The Proposed Classes Are Ascertainable

Nothing in the text of Rule 23 requires a class to be "ascertainable" or "identifiable."[1] But numerous courts—including the Fifth Circuit—have imposed an "ascertainability" requirement on top of the criteria for class certification spelled out in Rule 23. *See DeBremaecker v. Short*, 433 F.2d 733, 734 (5th Cir. 1970) (per curiam) ("[T]o maintain a class action, the class sought to be represented must be adequately defined and clearly ascertainable."). This "ascertainability" doctrine allows courts to deny certification to vague or poorly defined classes. *See John v. National Security Fire & Casualty Co.*, 501 F.3d 443, 445 (5th Cir. 2007) ("There can be no class action if the proposed class is 'amorphous' or 'imprecise.'" (citation omitted)). *DeBremaecker*, for example, rejected a proposed class of "residents of this State active in the 'peace movement,'" because of the "patent uncertainty of the meaning of 'peace movement' in view of the broad spectrum of positions and activities which could conceivably be lumped under that term." *Id.*

There is nothing vague or imprecise about the proposed class definitions. A health-care provider is either subject to section 1557 or it isn't. And it either objects to providing puberty blockers to minors or it doesn't. More importantly, the requirement of "ascertainability" is applied with far less rigor when certification is sought under Rule 23(b)(2). At least three circuits hold that "ascertainability" is categorically inapplicable to (b)(2) classes.[2] And the Fifth Circuit (along with other courts) has

1. *See* Robert G. Bone, *Justifying Class Action Limits: Parsing the Debates over Ascertainability and Cy Pres*, 65 U. Kan. L. Rev. 913, 913 (2017) ("[C]lass ascertainability . . . [is] neither mandated by the text of Rule 23 nor supported by a reasonable interpretation of the Rule's language and purpose.").
2. *See Shelton v. Bledsoe*, 775 F.3d 554, 563 (3rd Cir. 2015) ("[A]scertainability is not a requirement for certification of a (b)(2) class seeking only injunctive and declaratory relief"); *Cole v. City of Memphis*, 839 F.3d 530, 542 (6th Cir. 2016) ("The

recognized that the ascertainability requirement is greatly relaxed in the (b)(2) context:

> [T]he precise definition of the [(b)(2)] class is relatively unimportant. If relief is granted to the plaintiff class, the defendants are legally obligated to comply, and it is usually unnecessary to define with precision the persons entitled to enforce compliance.

In re Monumental Life Ins. Co., 365 F.3d 408, 413 n.6 (5th Cir. 2004) (quoting *Rice v. City of Philadelphia*, 66 F.R.D. 17, 19 (E.D. Pa. 1974)).[3] *In re Rodriguez*, 695 F.3d 360 (5th Cir. 2012), and *Mullen v. Treasure Chest Casino, LLC*, 186 F.3d 620, 623 (5th Cir. 1999), approved (b)(3) classes despite the extensive individualized inquiries that were required; that creates an even steeper hill for the defendants, who must explain why this Court should reject ascertainability in the more forgiving (b)(2) context.

IV. The Proposed Classes Satisfy Article III

The Supreme Court has never resolved whether the Constitution requires every absent class member to possess Article III standing. *See TransUnion LLC v. Ramirez*,

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advisory committee's notes for Rule 23(b)(2) assure us that ascertainability is inappropriate in the (b)(2) context."); *Shook v. El Paso County*, 386 F.3d 963, 972 (10th Cir. 2004) ("[W]hile the lack of identifiability [of class members] is a factor that may defeat Rule 23(b)(3) class certification, such is not the case with respect to class certification under Rule 23(b)(2).").

3. *See also Finch v. New York State Office of Children and Family Services*, 252 F.R.D. 192, 198 (S.D.N.Y. 2008) ("A Rule 23(b)(2) class need not be defined as precisely as a Rule 23(b)(3) class"); *Multi-Ethnic Immigrant Workers Organizing Network v. City of Los Angeles*, 246 F.R.D. 621, 630 (C.D. Cal. 2007) ("[L]ess precision is required of class definitions under Rule 23(b)(2) than under Rule 23(b)(2), where mandatory notice is required by due process . . . . Manageability is not as important a concern for injunctive classes as for damages classes." (citations omitted)); Suzette M. Malveaux, *The Modern Class Action Rule: Its Civil Rights Roots and Relevance Today*, 66 U. Kan. L. Rev. 325, 390 (2017) ("Conditioning certification on the ascertainability of class members should not apply to Rule 23(b)(2) classes because it is immaterial whether individual class members can be identified."); Michael T. Morley, *Nationwide Injunctions, Rule 23(b)(2), and the Remedial Powers of the Lower Courts*, 97 B.U. L. Rev. 615, 638–39 (2017) ("The definiteness and ascertainability requirements either do not apply in Rule 23(b)(2) cases, or apply in a far less demanding and precise manner.").

141 S. Ct. 2190, 2208 n.4 (2021) ("We do not here address the distinct question whether every class member must demonstrate standing before a court certifies a class."). Neither has the Fifth Circuit. *See Flecha v. Medicredit, Inc.*, 946 F.3d 762, 768 (5th Cir. 2020) ("Our court has not yet decided whether standing must be proven for unnamed class members, in addition to the class representative."). But the idea that *every* absent class member must have standing is very hard to square with the Supreme Court's repeated pronouncements that only one plaintiff needs to establish standing to seek declaratory or injunctive relief. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379 n.6 (2020) ("Under our precedents, at least one party must demonstrate Article III standing for each claim for relief. . . . The Third Circuit accordingly erred by inquiring into the Little Sisters' independent Article III standing."); *Department of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019) ("For a legal dispute to qualify as a genuine case or controversy, at least one plaintiff must have standing to sue."); *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 53 n.2 (2006) ("[T]he presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement."). The defendants correctly observe that the Second Circuit requires every absent class member to have Article III standing,[4] but that is not a binding pronouncement and should not (in our view) be followed.

CONCLUSION

The motion for class certification should be granted.

4. *See Denney v. Deutsche Bank AG*, 443 F.3d 253, 263–64 (2d Cir. 2006) ("[N]o class may be certified that contains members lacking Article III standing.").

Respectfully submitted.

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EXHIBIT 1

ISSUE_JOINED,JURY_TRIAL

Live Database
U.S. District Court - Eastern District of Tennessee (Chattanooga)
CIVIL DOCKET FOR CASE #: 1:21-cv-00195-TRM-SKL

American College of Pediatricians et al v. Becerra et al
Assigned to: District Judge Travis R McDonough
Referred to: Magistrate Judge Susan K Lee
Cause: 05:702 Administrative Procedure Act

Date Filed: 08/26/2021
Jury Demand: Plaintiff
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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Date Filed	#	Docket Text
08/26/2021	1	COMPLAINT against All Defendants (Filing fee $ 402 receipt number ATNEDC-4826494.), filed by American College of Pediatricians, Jeanie Dassow, Catholic Medical Association. (Attachments: # 1 Other Civil Cover Sheet, # 2 Summons for Xavier Becerra, # 3 Summons for United States Department of Health and Human Services, # 4 Summons for Robinsue Frohboese, # 5 Summons for Office for Civil Rights of the U.S. Department of Health and Human Services, # 6 Other Corporate Disclosure Statement of American College of Pediatricians, # 7 Other Corporate Disclosure Statement of Catholic Medical Association)(Scruggs, Jonathan) (Entered: 08/26/2021)
08/26/2021	2	Certificate of Corporate Interest by Catholic Medical Association. (BJL) (Entered: 08/31/2021)
08/26/2021	3	Certificate of Corporate Interest by American College of Pediatricians. (BJL) Modified on 9/1/2021 (BJL). (Entered: 08/31/2021)
08/26/2021		District Judge Katherine A Crytzer and Magistrate Judge Susan K Lee added. (BJL) (Entered: 08/31/2021)
08/31/2021	4	NOTICE of Deficiency (Pro Hac) (BJL)*Mailed to Attorneys Julie Blake, Anthony Biller and Ryan Bangert (Entered: 08/31/2021)
08/31/2021	5	Summons Issued as to All Defendants (BJL) (Entered: 08/31/2021)
08/31/2021	6	Order Governing Depositions, Signed by District Judge Katherine A Crytzer on 8/31/2021. (BJL) (Entered: 08/31/2021)
08/31/2021	7	Order Governing Motions To Dismiss, Signed by District Judge Katherine A Crytzer on 8/31/2021. (BJL) (Entered: 08/31/2021)
08/31/2021	8	Order Governing Sealing Confidential Information, Signed by District Judge Katherine A Crytzer on 8/31/2021. (BJL) (Entered: 08/31/2021)
09/08/2021	9	MOTION for Leave to Appear Pro Hac Vice for Attorney Ryan L. Bangert (Filing fee $ 90.00, Receipt No. C1818571) by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (BJL) (Additional attachment(s) added on 9/8/2021: # 1 Other Receipt) (BJL). (Entered: 09/08/2021)
09/08/2021	10	MOTION for Leave to Appear Pro Hac Vice for Attorney Julie M Blake (Filing fee $ 90.00, Receipt NO C1818571) by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Attachments: # 1 Receipt)(BJL) Modified on 9/8/2021 (BJL). (Entered: 09/08/2021)
09/08/2021		Clerk's Verification of PHV Requirements is complete *regarding document: 9 MOTION for Leave to Appear Pro Hac Vice (Filing fee $ 90.) filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, M.D., 10 MOTION for Leave to Appear Pro Hac Vice (Filing fee $ 90.) filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, M.D.* (BJL) (Entered: 09/08/2021)
09/13/2021	11	ORDER OF RECUSAL.Signed by District Judge Katherine A Crytzer on 9/13/21. (ABF) Modified on 9/14/2021 (BJL). Copy sent via email to Chief Judge McDonough's Chambers. (Entered: 09/13/2021)
09/14/2021	12	ORDER REASSIGNING CASE. District Judge Katherine A Crytzer no longer assigned to case. Case reassigned to District Judge Thomas A Varlan for all further proceedings. Signed by District Judge Travis R McDonough on 9/14/2021. (BJL) Modified on 9/14/2021 (BJL).*Mailed to Attorneys Julie M. Blake and Ryan L Bangert. (Entered: 09/14/2021)
09/14/2021	13	ORDER granting 9 Motion for Leave to Appear Pro Hac Vice by Attorney Ryan L. Bangert on behalf of Plaintiffs American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. This entry constitutes the complete Order of the Court. There is no document attached to this entry. You MUST register as an E-Filer here: https://pacer.psc.uscourts.gov/pscof/regWizard.jsf. Signed by Magistrate Judge Susan K Lee on 09/14/2021. (KRS) Modified on 9/15/2021 (BJL). Mailed to Attorney Ryan L. Bangert. (Entered: 09/14/2021)
09/14/2021	14	ORDER granting 10 Motion for Leave to Appear Pro Hac Vice by Attorney Julie Marie Blake on behalf of Plaintiffs American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. This entry constitutes the complete Order of the Court. There is no document attached to this entry. You MUST register as an E-Filer here: https://pacer.psc.uscourts.gov/pscof/regWizard.jsf. Signed by Magistrate Judge Susan K Lee on 09/14/2021. (KRS) Modified on 9/15/2021 (BJL).*Mailed to Attorney Julie Marie Blake (Entered: 09/14/2021)
11/10/2021	15	AMENDED COMPLAINT by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. . (Attachments: # 1 Exhibit 1 - Declaration of Dr. Van Meter, # 2 Exhibit 2 - Declaration of Mr. Dickerson, # 3 Exhibit 3 - Declaration of Dr. Dassow, # 4 Summons for Xavier Becerra, # 5 Summons for Merrick Garland, # 6 Summons for Francis Hamilton, # 7 Summons for Office for Civil Rights, # 8 Summons for Lisa Pino, # 9 Summons for Department of HHS)(Scruggs, Jonathan) Modified Docket Text on 11/12/2021 (BJL). (Entered: 11/10/2021)
11/12/2021	16	Summons Issued as to All Defendants (including the US Attorney's Office and the Office of the US Attorney General) (Attachments: # 1 Becerra, # 2 Garland, # 3 Pino, # 4 Office of Civil Rights)(BJL) Modified on 11/12/2021 (BJL). Modified text on 11/12/2021 (BJL). (Entered: 11/12/2021)
11/12/2021	17	Summons Issued as to United States Department of Health and Human Services (BJL) (Entered: 11/12/2021)
11/19/2021	18	SUMMONS Returned Executed by Jeanie Dassow, MD, Catholic Medical Association, American College of Pediatricians. Xavier Becerra served on 11/15/2021. (Scruggs, Jonathan) (Entered: 11/19/2021)
11/19/2021	19	SUMMONS Returned Executed by Jeanie Dassow, MD, Catholic Medical Association, American College of Pediatricians. Lisa J. Pino served on 11/15/2021. (Scruggs, Jonathan) (Entered: 11/19/2021)
11/19/2021	20	SUMMONS Returned Executed by Jeanie Dassow, MD, Catholic Medical Association, American College of Pediatricians. United States Department of Health and Human Services served on 11/15/2021. (Scruggs, Jonathan) (Entered: 11/19/2021)
11/19/2021	21	SUMMONS Returned Executed by Jeanie Dassow, MD, Catholic Medical Association, American College of Pediatricians. Office for Civil Rights of the U.S. Department of Health and Human Services served on 11/15/2021. (Scruggs, Jonathan) (Entered: 11/19/2021)
11/19/2021	22	AFFIDAVIT of Service for Summons served on USA via US Attorney General Merrick Garland on 11/15/2021, filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Scruggs, Jonathan) (Entered: 11/19/2021)
11/19/2021	23	AFFIDAVIT of Service for Summons served on USA via Acting U.S. Attorney Eastern District of Tenn. F. (Trey) Hamilton on 11/15/2021, filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Scruggs, Jonathan) (Entered: 11/19/2021)
12/06/2021	24	NOTICE of Appearance by Matthew S. Bowman on behalf of All Plaintiffs (Bowman, Matthew) (Entered: 12/06/2021)
01/07/2022	25	NOTICE of Appearance by Jordan Von Bokern on behalf of All Defendants (Von Bokern, Jordan) (Entered: 01/07/2022)
01/07/2022	26	Consent MOTION for Leave to File Excess Pages *and Set Deadlines* by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Bowman, Matthew) (Entered: 01/07/2022)
01/07/2022	27	MOTION for Summary Judgment *(Partial Summary Judgment)* by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Attachments: # 1 Brief in Support of Motion for Partial Summary Judgment)(Bowman, Matthew) (Entered: 01/07/2022)
01/14/2022	28	MOTION to Stay *or Deny as Premature Plaintiffs' Early Motion for Summary Judgment* by Xavier Becerra, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino, United States Department of Health and Human Services. (Attachments: # 1 Other Memorandum in Support, # 2 Exhibit 1 - Motion to Dismiss, Neese v. Becerra, # 3 Exhibit 2 - Opposition to Preliminary Injunction, Christian Employers Alliance v. EEOC et al.)(Von Bokern, Jordan) (Entered: 01/14/2022)
01/18/2022	29	Administrative Notice to Counsel RE 28 MOTION to Stay *or Deny as Premature Plaintiffs' Early Motion for Summary Judgment*: requirements due by **1/20/2022**. (BJL) (Entered: 01/18/2022)
01/18/2022	30	DISREGARD - FILED IN ERROR (Attorney will refile under corrected event code) MOTION for Admission to Practice by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Attachments: # 1 Other Certificate of Good Standing)(Biller, Anthony) Modified on 1/18/2022 (AML). (Entered: 01/18/2022)
01/18/2022	31	MOTION for Leave to Appear Pro Hac Vice (Filing fee $ 90 receipt number ATNEDC-4948139.) by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Attachments: # 1 Other Certificate of Good Standing)(Biller, Anthony) (Entered: 01/18/2022)
01/18/2022	32	MEMORANDUM in Support of Motion re 28 MOTION to Stay *or Deny as Premature Plaintiffs' Early Motion for Summary Judgment* filed by Xavier Becerra, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino,

		United States Department of Health and Human Services (Attachments: # 1 Exhibit 1 - Motion to Intervene, Neese v. Becerra, # 2 Exhibit 2 - Opposition to Preliminary Injunction)(Von Bokern, Jordan) (Entered: 01/18/2022)
01/19/2022	33	NOTICE of Deficiency (Pro Hac) 31 MOTION for Leave to Appear Pro Hac Vice for Attorney Anthony Biller. * Please file, as a supplement, a certificate of good standing from another district court. (BJL) (Entered: 01/19/2022)
01/19/2022	34	SUPPLEMENT to 31 MOTION for Leave to Appear Pro Hac Vice (Filing fee $ 90 receipt number ATNEDC-4948139.) by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Biller, Anthony) (Entered: 01/19/2022)
01/20/2022		Clerk's Verification of PHV Requirements is complete *regarding document: 31 MOTION for Leave to Appear Pro Hac Vice (Filing fee $ 90 receipt number ATNEDC-4948139.) filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, M.D.* (BJL) (Entered: 01/20/2022)
01/21/2022	35	RESPONSE in Opposition re 28 MOTION to Stay *or Deny as Premature Plaintiffs' Early Motion for Summary Judgment* filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Bowman, Matthew) (Entered: 01/21/2022)
01/24/2022	36	ORDER granting 31 Motion for Leave to Appear Pro Hac Vice by Attorney Anthony J. Biller on behalf of Plaintiffs American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. This entry constitutes the complete Order of the Court. There is no document attached to this entry. You MUST register as an E-Filer here: https://pacer.psc.uscourts.gov/pscof/regWizard.jsf. Signed by Magistrate Judge Susan K Lee on 1/24/2022. (KRS) (Entered: 01/24/2022)
04/20/2022	37	VACATED pursuant to 46 ORDER SCHEDULING ORDER: Jury Trial set for **6/27/2023** 09:00 AM in Courtroom 4 - Knoxville before District Judge Thomas A Varlan. Final Pretrial Conference set for **6/20/2023** 02:00 PM in Courtroom 4 - Knoxville before District Judge Thomas A Varlan. Signed by District Judge Thomas A Varlan on 4/20/22. (JBR) Modified on 7/6/2022 (BJL). (Entered: 04/20/2022)
04/22/2022	38	NOTICE of Appearance by Jeremy S.B. Newman on behalf of All Defendants (Newman, Jeremy) (Entered: 04/22/2022)
05/05/2022	39	Notice of Attorney Withdrawal Attorney Jordan Von Bokern terminated. (Von Bokern, Jordan) (Entered: 05/05/2022)
05/16/2022	40	See 42 for correct filing-STATUS REPORT *Joint Discovery Plan Report* by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Bowman, Matthew) Modified on 5/19/2022 (BJL). (Entered: 05/16/2022)
05/17/2022	41	Administrative Notice to Counsel re 40 Status Report: requirement due by **5/23/2022**. (BJL) (Entered: 05/17/2022)
05/17/2022	42	REPORT of Rule 26(f) Planning Meeting. (Bowman, Matthew) (Entered: 05/17/2022)
06/24/2022	43	ORDER OF RECUSAL.Signed by District Judge Thomas A. Varlan on 6/24/22. (ADA) (Entered: 06/24/2022)
06/28/2022	44	ORDER REASSIGNING CASE. District Judge Thomas A Varlan no longer assigned to case Case reassigned to Chief District Judge Travis R McDonough for all further proceedings. Signed by Chief District Judge Travis R McDonough on 6/28/2022. (BJL) (Entered: 06/28/2022)
06/30/2022	45	TEXT ORDER A Telephonic Status Conference is set for **7/12/2022** at 01:30 PM before District Judge Travis R. McDonough. Dial-in instructions will be circulated via email. Signed by District Judge Travis R. McDonough on 06/30/2022. (ACC) (Entered: 06/30/2022)
07/05/2022	46	ORDER: This case was reassigned to the undersigned on June 28, 2022, following prior recusals. (Doc. 44 .) In light the reassignment, the Court hereby VACATES the scheduling order (Doc. 37). Accordingly, the Court will DENY WITH LEAVE TO REFILE the Plaintiffs' motion for leave to file excess pages (Doc. 26), as well as their motion for partial summary judgment (Doc. 27). Plaintiffs motion for partial summary judgment with leave to refile, it will DENY AS MOOT Defendants motion to stay or deny as premature Plaintiffs' early motion for summary judgment (Doc. 28). Therefore, the Court also DENIES the motion (Doc. 26)with respect to the requested deadlines, and Defendants are hereby ORDERED to serve a responsive pleading no later than fourteen days from the entry of this order, in accordance with Federal Rule of Civil Procedure 12(a)(4)(A). Signed by District Judge Travis R McDonough on 7/1/2022. (BJL) (Entered: 07/05/2022)
07/07/2022	47	Joint MOTION for Leave to File Excess Pages *for Briefing on Defendants' Motion to Dismiss First Amended Complaint* by Xavier Becerra, Robinsue Frohboese, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino, United States Department of Health and Human Services. (Newman, Jeremy) (Entered: 07/07/2022)
07/12/2022		Minute Entry for proceedings held before District Judge Travis R McDonough: Scheduling Conference held on 7/12/2022. (No Court Reporter/No Courtroom Deputy) (BJL) (Entered: 07/13/2022)
07/13/2022	48	[Please disregard] see 50 SCHEDULING ORDER: Oral Argument set for **10/7/2022** 09:00 AM in Courtroom 3 - Chattanooga before District Judge Travis R McDonough. Signed by District Judge Travis R McDonough on 7/13/2022. (BJL) Modified on 7/19/2022 (BJL). (Entered: 07/13/2022)
07/15/2022	49	ORDER granting 47 Motion for Leave to File Excess Pages. Signed by District Judge Travis R McDonough on 7/15/2022. (AWS) (Entered: 07/15/2022)
07/19/2022	50	SCHEDULING ORDER: Oral Argument set for **10/27/2022** 09:00 AM in Courtroom 3 - Chattanooga before District Judge Travis R McDonough. Dispositive Motion Hearing (if the Court deems necessary) set for **4/24/2023** 09:00 AM in Courtroom 3 - Chattanooga before District Judge Travis R McDonough.Signed by District Judge Travis R McDonough on 7/19/2022. (BJL) (Entered: 07/19/2022)
07/19/2022	51	MOTION to Dismiss for Lack of Jurisdiction *First Amended Complaint* by Xavier Becerra, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino, United States Department of Health and Human Services. (Newman, Jeremy) (Entered: 07/19/2022)
07/19/2022	52	MEMORANDUM in Support of Motion re 51 MOTION to Dismiss for Lack of Jurisdiction *First Amended Complaint* filed by Xavier Becerra, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino, United States Department of Health and Human Services. (Newman, Jeremy) (Entered: 07/19/2022)
07/20/2022	53	ORDER: The parties are ordered to confer and return the attached form within the time provided.Signed by District Judge Travis R McDonough on 7/20/2022. (Attachments: # 1 Notice of Consent/Non Consent) (BJL) (Entered: 07/20/2022)
08/08/2022	54	NOTICE OF NONCONSENT *to Magistrate* by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD (Bowman, Matthew) (Entered: 08/08/2022)
08/18/2022	55	RESPONSE in Opposition re 51 MOTION to Dismiss for Lack of Jurisdiction *First Amended Complaint* filed by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD. (Bowman, Matthew) (Entered: 08/18/2022)
08/27/2022	56	NOTICE by American College of Pediatricians, Catholic Medical Association, Jeanie Dassow, MD re 51 MOTION to Dismiss for Lack of Jurisdiction *First Amended Complaint , notice of supplemental authority* (Bowman, Matthew) (Entered: 08/27/2022)
08/31/2022	57	REPLY to Response to Motion re 51 MOTION to Dismiss for Lack of Jurisdiction *First Amended Complaint* filed by Xavier Becerra, Office for Civil Rights of the U.S. Department of Health and Human Services, Lisa J. Pino, United States Department of Health and Human Services. (Newman, Jeremy) (Entered: 08/31/2022)

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09/09/2022 17:31:46

PACER Login:	genephamilton	**Client Code:**	afl
Description:	Docket Report	**Search Criteria:**	1:21-cv-00195-TRM-SKL
Billable Pages:	9	**Cost:**	0.90

EXHIBIT 2

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

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

PLAINTIFFS' FIRST AMENDED COMPLAINT

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

INTRODUCTION

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

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

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

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

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

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

JURISDICTION & VENUE

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

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

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

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

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

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

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

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

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

PARTIES

I. American College of Pediatricians (ACPeds)

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

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

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

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

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

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

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

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

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

II. Catholic Medical Association

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

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

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

26. CMA has individual members in Tennessee.

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

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

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

30. The Executive Director of CMA is Mario Dickerson.

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

III. Jeanie Dassow, M.D.

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

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

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

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

IV. Defendants

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

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

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

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

FACTUAL ALLEGATIONS

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

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

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

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

I. Section 1557 of the Affordable Care Act

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

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

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

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

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

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

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

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

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

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

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

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

II. Effects of the 2016 ACA Rule

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

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

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

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

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

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

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

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

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

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

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

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

A. Requirements to offer and recommend gender interventions

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

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

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

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

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

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

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

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

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

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

B. Compelled speech affirming gender identity as sex

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

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

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

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

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

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

C. Prohibition on single-sex programs and facilities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. HHS's Separate Gender Identity Mandate for Grants

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

127. For Plaintiffs, demand nothing less.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

188. Morehouse School of Medicine receives grants from HHS.

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

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

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

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

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

B. Effect on Catholic Medical Association and its members.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Effect on Dr. Dassow

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. Effect of Threatened Enforcement

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VIII. HHS's SUNSET Rule and Delay Rule

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

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

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

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

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

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

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

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

B. HHS's Unilateral Delay Rule

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IX. The Propriety of Prompt Judicial Relief

A. HHS's actions are subject to judicial review

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

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

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

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

330. Plaintiffs have no adequate remedy at law.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Plaintiffs face imminent irreparable harm

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

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

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

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

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

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

CLAIMS FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. Without Procedure Required by Law

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

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

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

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

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

C. Arbitrary, Capricious, and an Abuse of Discretion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CLAIM SIX
GRANTS GENDER IDENTITY MANDATE
(ALL PLAINTIFFS)

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

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

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

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

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

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

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

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

B. RFRA and the Free Exercise Clause

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Free Speech Clause

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

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

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

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

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

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

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

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

D. Federalism, Tenth Amendment, and Clear Notice

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

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

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

C. Arbitrary, Capricious, and an Abuse of Discretion

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

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

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

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

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

516. Defendants failed to consider alternative policies.

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

E. Relief

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

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

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

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

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

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

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

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

A. Without Procedure Required by Law

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

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

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

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

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

B. Regulatory Flexibility Act

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

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

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

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

C. In excess of statutory authority

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

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

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

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

D. Arbitrary, Capricious, and an Abuse of Discretion

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

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

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

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

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

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

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

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

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

E. Relief

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

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

PRAYER FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

F. That this Court award nominal damages under RFRA;

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

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

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

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

Respectfully submitted this 10th day of November, 2021.

s/ Jonathan A. Scruggs

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CERTIFICATE OF SERVICE

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

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s/ Jonathan A. Scruggs

Jonathan A. Scruggs

EXHIBIT 3

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

AMERICAN COLLEGE OF PEDIATRICIANS, on behalf of itself and its members;
CATHOLIC MEDICAL ASSOCIATION, on behalf of itself and its members; and
JEANIE DASSOW, M.D.,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**; **LISA J. PINO**, in her official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services; and **OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**,

Defendants.

Civil Action No. 1:21-cv-195

DECLARATION OF MARIO DICKERSON

I, Mario Dickerson, pursuant to 28 U.S.C. § 1746, hereby declare as follows:

1. I am over eighteen years of age and make this declaration on personal knowledge. If called as a witness, I could and would testify competently to the matters set for herein.

2. I serve as the Executive Director of the Catholic Medical Association ("CMA"). Given my involvement in CMA, I am familiar with the organization's history, the issues confronting it, and the views of the organization and its members concerning various emerging issues, including the gender identify mandate at issue in this litigation.

I. CMA's Membership and Mission

3. CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2500 physicians and health providers nationwide.

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

5. 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.

6. CMA also has individual members in Tennessee.

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

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

9. 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.

10. For CMA and its members, medical ethics and science, not cultural ideologies or political correctness, serve as the basis of all true healthcare.

11. 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.

12. 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.

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

14. 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.

15. 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.

16. 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.

17. 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.

18. Since its early founding, CMA has published a scholarly journal, *The Linacre Quarterly*, which was designed to educate members and subscribers on how the principles of the Catholic faith applied to pertinent medical and scientific issues of the times. The name, The Linacre Quarterly, was chosen to honor Thomas Linacre, M.D., a physician and priest in 16th century England, who served as the private physician to King Henry VIII and was a founding member of the Royal College of

Physicians. Dr. Linacre was well known for his scholarship, high standards for scientific medicine, and strong Catholic faith.

II. Core Beliefs Regarding Conscience, Sex, and Gender

A. Freedom of Conscience

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

20. Pope Francis, speaking recently in Morocco, reminds us that "freedom of conscience and religious freedom—which is not limited to freedom of worship alone, but allows all to live in accordance with their religious convictions—are inseparably linked to human dignity."

21. The importance of freedom of conscience is taught by the Second Vatican Council and emphasized by St. John Paul II, who reiterated that conscience must be allowed to seek the truth of a question, thus necessarily allowing for open public discourse.

22. As the Catechism explains, "Conscience includes the perception of the principles of morality (synderesis); their application in the given circumstances by practical discernment of reasons and goods; and finally judgment about concrete acts yet to be performed or already performed. the truth about the moral good, stated in the law of reason, is recognized practically and concretely by the prudent judgment of conscience." Catechism § 1780.[1] "A human being must always obey the certain judgment of his conscience." Catechism § 1800.

23. The Catholic Church teaches that each person must be respected in their conscience. "Man has the right to act in conscience and in freedom so as personally to make moral decisions. 'He must not be forced to act contrary to his conscience. Nor

[1] *See, e.g.*, Catechism of the Catholic Church § 1780 (2d ed.), https://www.usccb.org/beliefs-and-teachings/what-we-believe/catechism/catechism-of-the-catholic-church ("Catechism").

must he be prevented from acting according to his conscience, especially in religious matters.'" Catechism § 1782 (citation omitted).

24. In the same way, the Catholic Church teaches that freedom of religion must be respected for all. "Nobody may be forced to act against his convictions, nor is anyone to be restrained from acting in accordance with his conscience in religious matters in private or in public, alone or in association with others, within due limits." This right is based on the very nature of the human person, whose dignity enables him freely to assent to the divine truth which transcends the temporal order. For this reason it "continues to exist even in those who do not live up to their obligation of seeking the truth and adhering to it." Catechism § 2106 (citation omitted). "The right to religious liberty is neither a moral license to adhere to error, nor a supposed right to error, but rather a natural right of the human person to civil liberty, i.e., immunity, within just limits, from external constraint in religious matters by political authorities. This natural right ought to be acknowledged in the juridical order of society in such a way that it constitutes a civil right." Catechism § 2108.

25. In the medical context, CMA continues to uphold the importance for conscience protection and religious freedom for healthcare providers in accord with their personal dignity.

26. 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 so no government mandates would be appropriate while this discussion is ongoing, and no mandates would be appropriate in a way that violates conscience rights or religious freedom.

B. Core Understanding of Sex and Gender

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

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

29. They respect the dignity of the human person as an embodied true male or female.

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

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

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

33. These beliefs reflect scientific reality, as well as thousands of years of Christian anthropology, with its roots in the narrative of human origins that appears in the Book of Genesis, when "God created man in his own image . . . male and female he created them." Gen. 1:27.

34. The Catholic Church teaches that men and women are created in two sexes with corresponding identities.[2]

35. 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.

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

[2] *See, e.g.*, Catechism § 2333, 2393; Pope Francis, Encyclical letter *Laudato Si'* ¶ 155 (2015), https://www.vatican.va/content/francesco/en/encyclicals/ documents/papa-francesco_20150524_enciclica-laudato-si.html.

37. 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*.[3] The Church calls for love and respect for all people.

38. 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.

C. Concerns on Gender Interventions

39. More and more people now no longer identify with their biological sex, and teens in particular are identifying as transgender in record numbers. Studies report that in 2017, 3–4 in 100 teens in the United States reported that they are or may be transgender. Even now, a more recent 2021 study suggests that the rate of transgender identification among America's youth may be as high as 9 in 100. Studies also show that every major gender center in the world have reported a several-thousand-percent increase in youth presenting with gender distress.[4]

40. 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

[3] 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.
[4] William Malone, *Time to Hit Pause on 'Pausing' Puberty in Gender-Dysphoric Youth*, Medscape (Sept. 17, 2021), https://wb.md/3D4IVf5.

sperm in boys and eggs in girls. Further interventions include hormones and surgeries.

41. 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.[5]

42. 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 opinion. It explains the serious deficits in understanding the cause of this condition or in understanding the reasons for the marked increase in people presenting for medical care.

43. While a need for effective treatment modalities for patients in this distress is clear, the article 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.

44. The article notes that, on top of substantial moral 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. It recommends continued consideration and rigorous investigation of alternate approaches to alleviating suffering in people with gender dysphoria. It particularly encourages further investigation of the phenomenon of adolescent girls with no prior expression of gender dysphoria presenting as having a transgendered identity in social networks (aka rapid onset gender dysphoria).

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[5] 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.

45. 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.

D. Concerns on Gender Interventions

46. Science shows that arresting puberty as a gender identity intervention is scientifically dangerous to children. Arresting puberty past its natural onset is therefore ethically, scientifically, and religiously objectionable for CMA members to support.

47. 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.

48. These scientific facts are reflected in Christian anthropology, which is ground in biological and medical reality. As one bishop explained in a recent pastoral letter, "We know from biology that a person's sex is genetically determined at conception and present in every cell of the body. Because the body tells us about ourselves, our biological sex does in fact indicate our inalienable identity as male or female. Thus, so-called transitioning' might change a person's appearance and physical traits (hormones, breasts, genitalia, etc.) but does not in fact change the truth of the person's identity as male or female, a truth reflected in every cell of the body." "Indeed, no amount of masculinizing' or 'feminizing' hormones or surgery can make a man into a woman, or a woman into a man."[6] As a result, the "claim to 'be

[6] Most Rev. Michael F. Burbidge, Bishop of Arlington, A Catechesis on the Human Person and Gender Ideology,https://www.arlingtondiocese.org/bishop/public-messages/2021/a-catechesis-on-the-human-

transgender' or the desire to seek 'transition' rests on a mistaken view of the human person, rejects the body as a gift from God, and leads to grave harm. To affirm someone in an identity at odds with biological sex or to affirm a person's desired 'transition' is to mislead that person. It involves speaking and interacting with that person in an untruthful manner." *Id*.

49. CMA thus 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.

50. In accord with these scientific and religious understandings, CMA and its members believe that healthcare that provides gender-transition procedures and interventions is neither healthful nor caring; it is experimental and dangerous.

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

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

53. CMA thus opposes pubertal suppression of minors, as well as hormone administration or other surgical interventions for purposes of "choosing" a gender or sex, and it objects to engaging in speech affirming these gender interventions.

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person-and-gender-ideology/. Of course, at the same time, every "disciple of Christ desires to love all people and to seek their good actively. Denigration or bullying of any person, including those struggling with gender dysphoria, is to be rejected as completely incompatible with the Gospel." *Id*.

54. 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."

55. 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."

56. 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."

57. In short, 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.

III. HHS's Gender Identity Mandate is Inconsistent with CMA and its Members' Beliefs.

58. Our members provide high-quality medical services to all people, regardless of their "internal sense of gender."

59. For our members, the Hippocratic Oath, their faith, and commitment to the medical professional demand nothing less.

60. Our members 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.

61. But HHS' gender identity mandate conflicts with our organization's foundational principles, and the core ethical beliefs of our members.

62. This pertains to both HHS's gender identity mandate under Section 1557 of the ACA, in the 2016 ACA Rule and the May 10, 2021 notice of enforcement, and HHS's gender identity mandate under HHS's 2016 Grants rule, since CMA members are affected by both. Herein, I refer to these collectively as the gender identity mandate.

63. Most of CMA's members treat patients within federal healthcare programs such as Medicaid, Medicare, and CHIP.

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

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

66. CMA has many members who receive federal funds.

67. CMA has many members who provide medical services that are used by others as part of attempted medical gender transitions.

68. At its core, HHS's gender identity mandate requires CMA members 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.

69. The gender identity mandate requires CMA members to engage in various practices to which our members objection on medical and ethical grounds, including the following:

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

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

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

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

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

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

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

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

i. Performing or participating in any combination of the above mutilating cosmetic procedures or similar surgeries,[7] 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;

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

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; and

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

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

70. The objectionable practices violate the teachings of the Church, and our organization's members cannot carry them out in good conscience.

71. Our members do not have policies or practices in favor of 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.

72. Our members 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.

73. Our members write pronouns on charts and refer to clients with biologically correct pronouns, as well as create charts and medical records by biological sex.

IV. Effect on Patient Privacy and to Single-Sex Medical Programs

74. CMA 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.

75. 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.

V. Specific CMA Members Impacted by the Gender Identity Mandate.

76. Several specific CMA members are impacted by HHS's gender identity mandate.

77. Dr. Quentin Van Meter, President of Plaintiff American College of Pediatricians, is also a member of the Catholic Medical Association. Facts concerning his practice and the effect of the mandate on him are set forth separately in his declaration.

78. As another example, Dr. Rachel Kaiser practices medicine in Nashville, TN.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

96. Dr. Parker is not a member of the Christian Medical & Dental Associations.

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

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

VI. Injury that HHS's Gender Identity Mandate Causes to CMA Members.

99. The gender identity mandate presents our members with three choices: (1) not comply with the government's mandate, 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.

100. Our members are susceptible to risk under the gender identity mandate at any moment of practice.

101. If our members do not abide by HHS's mandate, they face losing access to federal healthcare program funds, potential civil lawsuits from plaintiffs, and being

investigated by HHS's Office for Civil Rights or the Attorney General, imposing significant costs of time, money, attorney's fees, and diversion of resources our members could use to continue providing quality medical care and receive compensation for the same.

102. HHS's announcement of enforcement of HHS's gender identity mandate under Section 1557, the 2016 ACA Rule's gender identity language, the May 10, 2021 announcement, and the 2016 Grants rule's gender identity language, create substantial confusion and uncertainty for CMA's members.

103. If our members 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 or HHS grants.

104. Failure to comply with the gender identity mandate threatens our members with loss of income and employment.

105. CMA members will incur increased costs from the investigation and enforcement of claims against them, and they will suffer damaging barriers to their ability to participate in the marketplace as healthcare providers.

106. Many of our members cannot continue their healthcare practices if they are not eligible to participate in federal healthcare programs like Medicare, Medicaid, and CHIP, or to work in programs receiving HHS grants.

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

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

109. The gender identity mandate limits and compels the speech of our members, including what they can say to patients.

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

111. If our members 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.

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

113. At the same time, all providers and members need assurance that they can provide complete, accurate information and timely and responsive medical care in an environment that protects their constitutional rights and does not expose them to stigma and harm because of their medical judgment, conscientious objections, and religious beliefs.

VII. The Impact on CMA's Members from Complying with the Gender Identity Mandate

114. If our members comply with the gender identity mandate by performing or recommending 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. CMA members are thus stuck between HHS and a risk of litigation that is significant, but difficult to quantify.

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

116. 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.

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

118. Imposing the gender identity mandate on our members will deprive our members' patients, who want to receive care from them because of their ethical and religious beliefs, of their chosen doctor.

119. Imposing the gender identity mandate's penalties on our members will harm patients in low-income and underserved communities and regions because it will deprive those patients of our members' care. These are the very communities our organization is called to serve by Catholic social teaching.

VIII. The Impact of the Gender Identity Mandate on Doctor-Patient Communications

120. 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.

121. In the past, our members have conveyed medical views and concerns, in appropriate and patient-sensitive ways, to their patients and their families in the context of their clinical practice, but under the gender identity mandate, the government would consider the expression of these views to be unlawful harassment, the creation of hostile environment, or discrimination on the basis of gender identity.

122. The gender identity mandate prevents conversations between our members and their patients, and it casts a credible threat of government prosecution over those conversations.

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

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

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

126. Our members 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.

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

128. The gender identity mandate forces our members 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.

129. The gender identity mandate chills the speech of all similarly situated healthcare providers who engage in private speech or religious expression through statements, notices, and other means in healthcare based on sex.

IX. Coercion of CMA Members' Freedom of Religion

130. Our members' sincerely held religious beliefs prohibit them providing, offering, facilitating, or referring for gender transition interventions and also from engaging in or facilitating the objectionable practices.

131. Our members exercise their religious beliefs through providing healthcare and through expressing messages during their healthcare practices.

132. Our members exercise their religious beliefs, consistent with Catholic social teaching, 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.

133. Our members' compliance with these beliefs is a religious exercise.

134. Our members' speech about these beliefs is a religious exercise.

135. 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.

136. Our members' provision of healthcare in accord with their religious beliefs prevents no one from obtaining gender transition interventions from other providers.

X. Cumulative Effect of the Gender Identity Mandate

137. Defendants' gender identity mandate, if not enjoined, would cause CMA 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.

138. 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.

139. Most of CMA's members treat patients within federal healthcare programs such as Medicare, Medicaid, and CHIP.

140. 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.

141. 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.

142. If our members 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.

143. Failure to comply with the gender identity mandate threatens our members with loss of income and employment.

144. 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.

145. 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.

146. 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.

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

148. 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.

149. There are CMA members in each of these various situations who would suffer the harm identified if the HHS gender identity mandate is fully enforced.

150. There are CMA members who are self-censoring out of fear of enforcement of the HHS gender identity mandate.

151. There are CMA members continuing to practice consistent with their views and therefore face the danger of enforcement penalties as the result of the HHS gender identity mandate.

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

153. Seeking such relief is part of the mission of CMA as approved by its board of directors.

XI. Effects on Patients, Society, and the Medical Profession

154. 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.

155. For our members, a career in health care is not just a job, but rather a sacred calling which involves putting their faith into practice. That result of the gender identity mandate is harmful in and of itself.

156. Driving our members 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. Among other things, the consequences of driving our members out of the health care profession include the following:

a. Patients will experience limited choices for future care, creating likely delays in care and reduced access to care, and all patients will no longer be able to receive care from doctors who share CMA's values;

b. Patients will be more likely to hesitate in seeking care because they feel that the doctor–will not have their best medical interests or personal religious values at heart, or because they fear putting their doctor in legal jeopardy;

c. This delay will strain the other providers and increase costs for providers, patients, and the healthcare system as a whole;

d. HHS will also cause widespread health disparities by those who share the government's position and those who have other medical opinions, conscientious objections, or religious beliefs;

e. This limited access to care will cause unavoidable human suffering, higher medical costs for everyone, and the inefficient use of medical talents and energy;

f. It will also lead to a cultural disrespect for those with differing medical and religious views, causing discriminatory effects for those doctors and patients who do not share the government's position out of their own

medical judgment, ethical positions, conscientious objections, or religious beliefs; and

157. At the same time, most healthcare providers in the profession are willing to comply with HHS's view of the law and policy, so this agency action will reduce overall access to care, unnecessarily creating many more health disparities than it will resolve.

XII. The Impact of the Delay of HHS's SUNSET Rule

158. The delay of the SUNSET Rule harms our members because it removes a procedural avenue for the repeal or modification of the gender identity mandate, and for our members' participation in that review process, including through CMA submitting comments.

159. If the Delay Rule itself were subject to notice and comment, CMA and our members would raise their concerns to the agency.

160. CMA would also submit comments on rules that HHS would review if subjected to the SUNSET Rule, such as the Section 1557 Rule, the HHS Grants rule, and rules concerning healthcare conscience rights at 45 CFR Part 88.

161. Our members include those who operate small entities, such as members who independently own medical practices organized for profit that are not dominant in their fields on a national basis.

162. CMA is itself a small entity.

163. The SUNSET Rule specifically calls for retrospective review of rules like the 2016 Rule which has a significant economic impact on a substantial number of small entities.

164. The delay of the SUNSET Rule also harms our members because it removes a procedural avenue for the repeal or modification of the gender identity mandate, and for our members' participation in that review process.

VERIFICATION

I, Mario Dickerson, a citizen of the United States, hereby declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing Declaration is true and correct based on my personal knowledge.

Executed this 4th day of November, 2021.

Mario R. Dickerson

Mario Dickerson
Executive Director, Catholic Medical Association

EXHIBIT 4

Catholic Medical Association joins lawsuit over HHS 'transgender mandate'

In this 2015 file photo, LGBTQ supporters wave a flag outside the U.S. Supreme Court in Washington. The Catholic Medical Association joined a lawsuit Aug. 26, 2021, challenging the U.S. Department of Health and Human Services' mandate that doctors and hospitals must perform gender-transition procedures over their own moral or medical objections. (CNS photo/Tyler Orsburn)

PHILADELPHIA (CNS) — The Philadelphia-based Catholic Medical Association Aug. 26 joined in a lawsuit challenging the Biden administration's mandate that doctors and hospitals perform gender-transition procedures on any patient despite any moral or medical objections of the doctor or health care facility.

"Biological identity must remain the basis for treating patients," said Dr. Michael Parker, president of the association, a national, physician-led community of more than 2,300 health care professionals in 114 local guilds.

The suit was filed Aug. 26 in U.S. District Court by Alliance Defending Freedom, a national faith-based nonprofit in Arizona that focuses on legal advocacy.

Other joining the suit are Dr. Jeanie Dassow, a Tennessee OB-GYN doctor who specializes in caring for adolescents, and the American College of Pediatricians, made up of more than 600 physicians and other health care professionals in 47 states who treat children.

A news release said the association and the college joined the suit on behalf of their members. It was filed in U.S. District Court for the Eastern District of Tennessee in Chattanooga.

The suit over what it opponents call a "transgender mandate" names as defendants Secretary Xavier Becerra, head of the Department of Health and Human Services, and Robinsue Frohboese, acting director and principal deputy of the HHS Office for Civil Rights.

Alliance Defending Freedom's attorneys argue in the filing that HHS has reinterpreted Section 1557 of the Affordable Care Act, which prohibits sex discrimination, "to include gender identity and thus require gender-transition interventions, services, surgeries, and drugs on demand, even for children, no matter a doctor's medical judgment, religious beliefs or conscientious objection." If doctors and hospitals do not comply, they will be held liable for discrimination.

“This mandate not only puts the health and safety of our patients in jeopardy, but it in effect also mandates that health care providers give up their fundamental right to conscience,” Parker added in a statement. “This sets a dangerous precedent with incalculable implications for the ethical practice of medicine.”

Ryan Bangert, the alliance’s senior counsel, said in a statement: “The laws of our land and the medical profession have long respected the biological differences between boys and girls and the unique needs they each present in health care.”

“Forcing doctors to prescribe transition hormones for 13-year-olds or perform life altering surgeries on adolescents is unlawful, unethical and dangerous,” he said.

On Aug. 9, a U.S. District Court judge ruled to block the so-called “transgender mandate” in its current form as proscribed by the Biden administration.

Judge Reed O’Connor of the District Court for the Northern District of Texas in Wichita Falls ruled in Franciscan Alliance v. Becerra.

Franciscan Alliance, based in Mishawaka, Indiana, is a Catholic health care system now known as Franciscan Health that operates hospitals serving Indiana and one hospital in Illinois and employs over 18,000 full- and part-time employees.

“The Christian plaintiffs contend that violation of their statutory rights under RFRA (Religious Freedom Restoration Act) is an irreparable harm,” O’Connor said in his ruling.

“The court agrees,” he said, “and concludes that enforcement of the 2021 interpretation (of Section 1557) forces Christian plaintiffs to face civil penalties or to perform gender-transition procedures and abortions contrary to their religious beliefs — a quintessential irreparable injury.”

“The court grants plaintiffs’ request for a permanent injunction and permanently enjoins” HHS, Becerra and all HHS-related divisions, agencies and employees “from interpreting or enforcing Section 1557 of the Affordable Care Act.”

In 2020, the Trump administration put in place a final rule that eliminated the general prohibition on discrimination based on gender identity and also adopted abortion and religious freedom exemptions for health care providers. But the courts blocked this rule change.

In 2021, shortly after he was inaugurated, President Joe Biden issued an executive order declaring his administration would apply in all areas — including the ACA — the ruling by the U.S. Supreme Court’s ruling in Bostock in 2020 that discrimination based on sex outlawed Title VII of the Civil Rights Act of 1964 covers people who are gay or transgender.

O’Connor’s ruling is “a victory for common sense, conscience and sound medicine,” said Luke Goodrich, vice president and senior counsel at the Becket Fund for Religious Liberty, based in Washington. He is the lead counsel for the plaintiffs in the Franciscan Alliance case.

On Jan. 19, the U.S. District Court for the District of North Dakota in Fargo blocked the mandate in ruling in in a lawsuit filed on behalf of Franciscan Alliance/Franciscan Health, and the Christian Medical and Dental Associations. The states of Texas, Kansas, Kentucky, Nebraska and Wisconsin also joined in the suit.

The Biden administration filed an appeal of that ruling April 20 with the U.S Court of Appeals for the 8th Circuit, based in St. Louis.

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

Susan Neese, M.D and **James Hurly, M.D.**, on behalf of themselves and others similarly situated, Plaintiffs, v. **Xavier Becerra**, in his official capacity as Secretary of Health and Human Services; **United States of America**, Defendants.	Case No. 2:21-cv-00163-Z

DECLARATION OF GENE P. HAMILTON

I, Gene P. Hamilton, being duly sworn, state as follows:

1. My name is Gene P. Hamilton. I am over 18 years old and fully competent to make this declaration.

2. I have personal knowledge of the facts stated in this declaration, and all of these facts are true and correct.

3. I represent plaintiffs Susan Neese and James Hurly in this litigation, and I submit this declaration in support of their reply brief in support of the motion for class certification.

4. The following materials attached as exhibits to the reply brief are authentic copies of pages from public websites that were downloaded as PDF files on September 9, 2022.

   a. Attached as Exhibit 1 is a copy of the civil docket sheet as of September 9, 2022, for *American College of Pediatricians, et al. v. Becerra, et al.*, No. 1:21-cv-00195 (E.D. Tenn.).

b. Attached as Exhibit 2 is a copy of the amended complaint in *American College of Pediatricians, et al. v. Becerra, et al.*, No. 1:21-cv-00195 (E.D. Tenn.), ECF No. 15.

c. Attached as Exhibit 3 is a copy of the declaration of Mario Dickerson filed in *American College of Pediatricians, et al. v. Becerra, et al.*, No. 1:21-cv-00195 (E.D. Tenn.), ECF No. 15-2.

d. Attached as Exhibit 4 is an article published by the Catholic Review on August 27, 2021, entitled "Catholic Medical Association joins lawsuit over HHS 'transgender mandate,'" and available at https://bit.ly/3L2LrI8.

This concludes my sworn statement. I declare under penalty of perjury that the facts stated in this declaration are true and correct.

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Dated: September 9, 2022 GENE P. HAMILTON