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

AMERICAN COLLEGE OF PEDIATRICIANS, *et al.*, *Plaintiffs*, v. XAVIER BECERRA, *et al.*, *Defendants*.	)	Case No. 1:21-cv-195 Chief Judge Travis R. McDonough Magistrate Judge Susan K. Lee

PLAINTIFFS' MEMORANDUM IN OPPOSITION
TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

INTRODUCTION

There have been three other district court rulings on the government's mandate prohibiting gender identity discrimination under Section 1557 of the Patient Protection and Affordable Care Act (ACA). All three judges held that the mandate exists and that doctors and health care entities regulated by it have standing to bring their claims. And all three courts enjoined the United States Department of Health and Human Services (HHS) from imposing the mandate against those plaintiffs. *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113 (D.N.D. 2021); *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 371 (N.D. Tex. 2021); *Christian Emps. All. v. EEOC*, No. 1:21-CV-195, 2022 WL 1573689 (D.N.D. May 16, 2022). Moreover, Congress explicitly derived § 1557 from Title IX, and Judge Atchley recently enjoined a Title IX gender identity mandate by the Department of Education. *Tennessee v. U.S. Dep't of Educ.*, No. 3:21-CV-308, 2022 WL 2791450 at *7 (E.D. Tenn. July 15, 2022) ("Defendants' guidance appears to deem conduct required by Plaintiffs' state laws to be unlawful sex discrimination under federal law.").

Yet here, the government contends there is no standing to raise essentially the same claims. This is incorrect. The doctors here face a far more deferential standard than the successful plaintiffs faced in those four cases. Here the American College of Pediatricians (ACPeds), the Catholic Medical Association (CMA), and Dr. Jeanie Dassow of Chattanooga (collectively, the doctors), sue HHS seeking relief against the § 1557 mandate and another HHS gender identity mandate applicable to its grants. Because this Motion to Dismiss is a facial challenge to jurisdiction under Rule 12(b)(1), the Court must assume the legal merits of the doctors' claims, *FEC v. Cruz*, 142 S. Ct. 1638, 1647 (2022), and must accept the facts alleged and verified in their Amended Complaint, *Howard v. City of Detroit*, 40 F.4th 417, 422 (6th Cir. 2022).

Under that standard, the doctors have more than "plausibly alleged" injury, because these mandates exist and they regulate the doctors' conduct. *Charlton-*

Perkins v. Univ. of Cincinnati, 35 F.4th 1053, 1059 (6th Cir. 2022). HHS's two gender identity mandates govern the doctors, who practice as recipients of, and employees at recipients of, federal health funding including Medicaid, Medicare, Children's Health Insurance Program (CHIP), and HHS grants. *See* First Am. Compl. ("Am. Compl."), ECF No. 15 ¶¶ 152–192, 222–244. Recent HHS announcements show the government could not be clearer, or more insistent, on enforcing its ban on gender identity discrimination in these programs.[1]

Despite the government's protestations here, these gender identity mandates exist, they force the doctors to violate their religious beliefs and medical judgment, and in this motion the Court must assume Plaintiffs' claims will succeed. The Administrative Procedure Act (APA) allows regulated persons to challenge final regulations and binding guidances, and the Religious Freedom Restoration Act (RFRA) and constitutional provisions allow the doctors to challenge illegally enforced statutes. The doctors have standing to protect themselves from illegal mandates that would drive them out of their medical practices. The Court should deny the government's motion.

---

[1] *See, e.g.*, Press Release, HHS, HHS Announces Prohibition on Sex Discrimination Includes Discrimination on the Basis of Sexual Orientation and Gender Identity (May 10, 2021) [hereinafter HHS Announcement], https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html [https://perma.cc/2QTR-Q3DT]; HHS Office for Civil Rights, HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy (Mar. 2, 2022), [hereinafter HHS Notice & Guidance], https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf [https://perma.cc/LX26-59QR].

BACKGROUND

I. HHS issues a gender identity mandate under § 1557 of the ACA.

The ACA prohibits, among other things, discrimination on the basis of sex in federal healthcare programs like Medicaid or CHIP.[2] To accomplish this, Congress incorporated by reference the prohibitions on sex discrimination under "title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.)."[3]

In 2016, HHS issued a final rule decreeing that § 1557 prohibits gender identity discrimination.[4] According to HHS, the rule required healthcare providers to perform a variety of medical interventions to attempt to transition patients' genders, and to speak in support of those actions. It prohibited imposing a binary view of gender, *see* 81 Fed. Reg. at 31,435 n.263, 31,471, or choosing not to perform such interventions in a categorical way, including based on the healthcare provider's view of current standards of care, *id*. at 31,429, 31,435. *See also* 45 C.F.R. § 92.206. And it triggered broad enforcement mechanisms that drive physicians and entities out of government funded healthcare programs. Am. Compl. ¶¶ 272–92.

Under this mandate, for example, a doctor who provides drugs and medical procedures for reasons unrelated to gender identity transitions must also provide those same drugs and procedures when requested to change someone's biological sex. 81 Fed. Reg. at 31,429, 31,455. A gynecologist who removes cancerous uteruses by hysterectomies must, under this mandate, remove healthy uteruses for any woman who identifies as a man. *Id*.

---

[2] ACA, Pub. L. No. 111-148, § 1557, 124 Stat. 119 (2010); 42 U.S.C. § 18116.

[3] 42 U.S.C. § 18116(b).

[4] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016) (the "2016 ACA Rule"); Compl. ¶¶ 50–73.

II. Federal courts keep the 2016 gender identity mandate in effect.

A federal court preliminarily enjoined the 2016 ACA Rule's gender identity mandate and said it vacated the language. *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019). But in 2020, when the next administration in charge of HHS used the rulemaking process to repeal the gender identity mandate in conformity with the apparent vacatur,[5] two other courts enjoined the repeal. *Walker v. Azar*, 480 F. Supp. 3d 417 (E.D.N.Y. 2020); *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020). According to *Walker*, the gender identity language from the 2016 ACA Rule "will remain in effect." 480 F. Supp. 3d at 430; *see also id.* at 427 (holding that *Franciscan Alliance* did not vacate gender identity language from the sex stereotyping definition), and *Walker v. Azar*, No. 20-CV-2834, 2020 WL 6363970 at *4 (E.D.N.Y. Oct. 29, 2020) (also restoring the 2016 ACA Rule's language requiring gender transition insurance coverage).

As a result, under *Walker* and *Whitman-Walker Clinic*, the § 1557 gender identity mandate in the 2016 ACA Rule is still in effect. Other sources confirm this. First, three other district courts have held that the 2016 ACA Rule's gender identity mandate is still in effect, and that health care providers may sue.[6] Second, HHS itself insists both that § 1557 prohibits gender identity discrimination, and that it is vigorously using its regulatory authority to enforce that prohibition.[7]

---

[5] Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160, 37,161–62, 37,178 (June 19, 2020).

[6] "The end result is the 2016 Rule was put back into effect." *Christian Emps. All.*, 2022 WL 1573689 at *5; *Religious Sisters*, 513 F. Supp. 3d at 1138 ("two district courts entered partially overlapping preliminary injunctions that collectively reinstate the prior definition of 'on the basis of sex' to include 'gender identity' and 'sex stereotyping'"); *Franciscan All.*, 553 F. Supp. 3d at 372–73 (describing the requirements of *Walker* and *Whitman-Walker Clinic*).

[7] *See* HHS Announcement, *supra* note 1; HHS Notice & Guidance, *supra* note 1.

III. HHS issues a separate gender identity mandate for all its grants.

In another 2016 regulation, HHS issued a gender identity nondiscrimination mandate applicable to all participants in programs funded by HHS grants (in both health care and human services).[8] This mandate and the § 1557 mandate apply separately, but in overlapping contexts. The doctors fall in the center of that overlap, because they practice in health programs receiving federal funding from HHS subject to § 1557, and in programs receiving HHS grants subject to the 2016 Grants Mandate. The 2016 Grants Mandate therefore governs Dr. Dassow and many members of Plaintiffs ACPeds and CMA who work in programs that accept HHS grants, such as doctors who care for the poor at community health centers.

In early January 2021, the previous administration finalized a rule to repeal the 2016 Grants Mandate.[9] But during the last 18 months, and with no adversarial opposition, the government consented to a series of court orders against itself, and those orders culminated in HHS voluntarily vacating the repeal rule two months ago.[10] This left the 2016 Grants Mandate fully in place today, with no pending repeal. In the previous administration, which proposed that repeal rule and published it in final form, HHS issued a notice stating that it would not enforce the 2016 Grants Mandate "pending" its repeal.[11] Because that repeal is no longer pending, and the new leadership at HHS has done everything it could to negate the repeal, the 2019

---

[8] HHS Grants Regulation, 45 C.F.R. § 75.300, 81 Fed. Reg. 89,393, 89,395 (Dec. 12, 2016) (the "2016 Grants Mandate"). *See also* 45 C.F.R. § 75.101 (describing applicability to subawardees).

[9] HHS Grants Regulation, 86 Fed. Reg. 2,257, 2,257 (Jan. 12, 2021) (the 2021 grants rule).

[10] *Facing Foster Care in Alaska v. HHS*, No. 1:21-cv-00308, ECF No. 44 (D.D.C. June 29, 2022) (vacating final repeal rule).

[11] Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809 (Nov. 19, 2019), https://www.govinfo.gov/content/pkg/FR-2019-11-19/pdf/2019-24384.pdf.

notice is defunct. The predicate for that notice no longer exists. There is no final repeal rule, there is the opposite: the negation of the final repeal rule. Even if the notice were still in effect, it is not itself a rule and does not bind the agency in the future. Thus, at any time, HHS can engage in enforcement of the 2016 Grants Mandate that it fought so long to keep in place. To further evidence its intent to enforce the 2016 Grants Mandate, HHS also repealed all religious exemptions it had previously provided to entities objecting to the 2016 grants rule.[12]

IV. HHS issues, and delays, the "SUNSET Rule."

HHS issued a third rule that was the subject of Claim Seven of the Amended Complaint, known as the SUNSET Rule.[13] The doctors had challenged, not the SUNSET Rule, but HHS's improper delay of that rule without rulemaking.

Because HHS repealed the SUNSET Rule through rulemaking earlier this year, Plaintiffs do not oppose dismissal of Claim Seven of their Amended Complaint. Plaintiffs reserve the possibility of bringing claims related to that rule in the future, and so ask that the dismissal be without prejudice.

V. HHS's gender identity mandates injure the doctors.

The doctors filed Claims One through Six challenging both of HHS's gender identity mandates (the § 1557 and grants mandates). The gender identity mandates require them to provide gender interventions and engage in speech in support of

---

[12] Press Release, HHS, HHS Takes Action to Prevent Discrimination and Strengthen Civil Rights, (Nov. 18, 2021) [hereinafter HHS Action], https://www.hhs.gov/about/news/2021/11/18/hhs-takes-action-to-prevent-discrimination-and-strengthen-civil-rights.html.

[13] Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5,694, 5,695–97 (Jan. 19, 2021).

gender "transitions," regardless of the doctors' medical judgment, faith, or ethics. The doctors all have medical, ethical, or religious objections to HHS' requirements.[14]

Plaintiff American College of Pediatricians (ACPeds) members include more than six hundred pediatricians and other healthcare professionals. Am. Compl. Ex. 1, ECF No. 15-1, Van Meter Decl. ¶ 18. These members have deep, science-based concerns against transgender interventions; many members also have religious objections, but not all have religious objections. *Id.* ¶¶ 25–81.

Plaintiff Catholic Medical Association (CMA) is the largest association of Catholic individuals in healthcare, with approximately 2,500 members. Am. Compl. Ex. 2, ECF No. 15-2, Dickerson Decl. ¶ 3. CMA members share the scientific and clinical concerns of ACPeds members, as well as all sharing objections based on their Catholic religious beliefs. *Id.* ¶¶ 27–57, 147.

Plaintiff Jeanie Dassow, M.D., is a board-certified obstetrician and gynecologist in Chattanooga, Tennessee who specializes in treating adolescents and shares many of the above positions. Am. Compl. Ex. 3, ECF No. 15-3, Dassow Decl. ¶¶ 3, 9–10. Although she is protected from the *§ 1557* mandate by being a member of an organization protected by the *Franciscan Alliance* injunction, she is not protected from HHS's separate 2016 Grants Mandate, which prohibits gender identity discrimination where she works at facilities receiving HHS grants. *Id.* ¶¶ 12–17. Without relief from the 2016 Grants Mandate, she is in the same position as all of the other doctors subject to both mandates.

These doctors are subject to HHS's gender identity mandates. Most members of ACPeds and CMA provide medical care in health programs and activities receiving federal financial assistance, subjecting them to the § 1557 mandate. Some of their

[14] A list of the specific objectional practices required by the HHS gender identity mandates is described in the Amended Complaint, ¶ 131.

members provide medical care in programs or entities receiving grants from HHS, subjecting them to the 2016 Grants Mandate.[15] Dr. Dassow provides medical care in programs and entities covered by the 2016 Grants Mandate.[16]

Were the doctors to comply with the government's gender identity mandates, they would suffer immeasurable harm to their religious exercise and free speech rights, as well as harm to their patients' best interests.[17] The doctors would also incur compliance costs because they would have to change their policies, alter their speech, spend time and resources to plan for how they must either comply or risk loss of participation in federal programs, re-train staff, and engage in public education campaigns to mitigate the confusion caused by the mandates.[18] But if the doctors disregard the government's mandates, they risk HHS's promised enforcement.[19]

The penalties for non-compliance with these mandates are meant to ensure that doctors either comply or are exiled from virtually all healthcare settings. *See* Am. Compl. ¶¶ 50–73, 272–92 (discussing enforcement, penalties, and burdens of § 1557 and grants rules); *see also* enforcement mechanisms at 18 U.S.C. §§ 287, 1001, 1035, 1347, 1516, 1518, 3486. They include not only expulsion from all health programs funded by HHS, such as Medicaid, Medicare, and countless hospitals and clinics receiving HHS grants, but also federal false-claims liability, with civil penalties up to $10,000 per false claim plus treble damages, 31 U.S.C. § 3729(a)(1), and up to five years' imprisonment, 18 U.S.C. § 1001.

---

[15] Van Meter Decl. ¶¶ 21–24, 97, 124, 126–27; Dickerson Decl. ¶¶ 7–8, 63–66.

[16] Dassow Decl. ¶¶ 12–17.

[17] Van Meter Decl. ¶¶ 143–48, 156–71; Dickerson Decl. ¶¶ 109–12; Dassow Decl. ¶¶ 41–43, 47.

[18] Van Meter Decl. ¶¶ 141–42; Dickerson Decl. ¶¶ 107–08; Dassow Decl. ¶ 46.

[19] Van Meter Decl. ¶ 135; Dickerson Decl. ¶ 101; Dassow Decl. ¶¶ 44–45.

When the doctors are driven out of their practices, the public will suffer in accessing care—especially their underserved, rural, and low-income patients.[20] The doctors are subject to these mandates now, and face penalties at any moment.[21]

ARGUMENT

Plaintiffs have standing—and their challenges are ripe—because the government's interpretation and enforcement of federal law are forcing the doctors to either abandon their religious and ethical beliefs or risk devastating government penalties.

I. Plaintiffs here have standing similar to that of other healthcare providers, which have not only been found to have standing, but also were awarded injunctions, by three other federal courts.

The government claims that the doctors lack standing to even *request* injunctive relief against its gender identity mandates. But three other courts hearing from other associations of doctors and healthcare entities have held that they have standing and have *granted injunctions* to protect their members from the § 1557 mandate. The doctors in this case stand in the same position as the plaintiffs in the other cases for standing purposes. In *Franciscan Alliance*, the plaintiffs included the Christian Medical and Dental Associations, a "Christian healthcare professional association," that is, an association of physicians facing the same sort of threat of enforcement of HHS's gender identity mandate as faced by the members of ACPeds and CMA. 553 F. Supp. 3d at 366. In *Religious Sisters*, 513 F. Supp. 3d at 1133, and in *Christian Employers Alliance*, 2022 WL 1573689 at *1, the plaintiffs included associations that asserted the interests of their members who were healthcare provider entities, which had corporate objections to providing gender identity

[20] Van Meter Decl. ¶¶ 152–55; Dickerson Decl. ¶¶ 118–19, 154–56; Dassow Decl. ¶¶ 36, 44–45.

[21] Van Meter Decl. ¶ 134; Dickerson Decl. ¶ 100; Dassow Decl. ¶¶ 37, 48.

interventions no different than objections made by the individual physicians here and in *Franciscan Alliance*.

Despite these parallels, the government seeks to prematurely dispense with this case without even allowing the doctors here to have their day in court. It is not plausible that these doctors lack standing to bring a challenge that was successful in three other courts.

In *Religious Sisters*, 513 F. Supp. 3d 1113, the plaintiffs sought an injunction against the § 1557 mandate under the 2016 regulation. The ruling came in January 2021, after the 2020 rule attempted to repeal the 2016 ACA Rule, and after two other district courts blocked that repeal. At that time, Judge Welte in the District of North Dakota held that the association had standing because "Section 1557 'arguably proscribe[s]' the Plaintiffs' refusal to perform or cover gender-transition procedures" due to the 2016 ACA Rule, whose repeal "never took effect." *Id.* at 1138 (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 162 (2014)). The court also held that a "credible threat of enforcement" exists because the plaintiffs' "'course of action is within the plain text of the statute.'" *Id.* at 1139 (quoting *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019)). The court credited HHS's promise to "vigorously enforce" its § 1557 rule as being "more than sufficient to establish a credible threat of enforcement." *Id.* at 1139. And the court not only held the plaintiffs had standing to sue, it granted them summary judgment and declaratory and injunctive relief—which is possible only if the case is justiciable. *Id.* at 1153.

Later in 2021, Judge O'Connor in the Northern District of Texas heard claims from a hospital network and from the Christian Medical and Dental Associations. The court similarly held that the plaintiffs had standing and granted them injunctive relief. *Franciscan All.*, 553 F. Supp. 3d at 374 & n.12, 378.

Finally, just three months ago, an association of healthcare and non-healthcare entities that had challenged the § 1557 mandate before Judge Traynor in North Dakota obtained relief. The court conducted its own analysis, independent of Judge Welte's decision, held that the plaintiffs had standing, and granted them injunctive relief. *Christian Emps. All.*, 2022 WL 1573689 at *4–5, *9.

This Court should decline the government's invitation to prematurely dispose of this case rather than allowing it proceed to the merits like these other cases.

II. The doctors have standing to challenge the gender identity mandates.

Standing consists of "(1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be addressed by a favorable decision." *Susan B. Anthony List*, 573 U.S. at 157–58 (2014) (cleaned up). Plaintiffs need only "plausibly allege" these elements. *Charlton-Perkins*, 35 F.4th at 1059.

In a pre-enforcement challenge, a plaintiff "satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List*, 573 U.S. at 159 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)).

For this motion, the Court must "accept as valid the merits of [plaintiffs'] legal claims." *Cruz*, 142 S. Ct. at 1647. "[W]hether a plaintiff can get into federal court under Article III—a jurisdictional question—is not determined by whether he can also plausibly plead the elements of a cause of action—a merits question." *Charlton-Perkins*, 35 F.4th at 1058–59.

This Court must also accept Plaintiffs' complaint allegations as true. *Howard*, 40 F.4th at 422. The government's motion is a "facial" attack on jurisdiction that

merely questions the sufficiency of the pleading, with no "factual" attack trying to rebut Plaintiffs' sworn affidavits or that gives occasion to make findings of fact. *Id.*

A. The doctors have shown an injury in fact because they face a credible threat of prosecution.

The doctors have shown a credible threat of prosecution under HHS's statutory and regulatory gender identity mandates that directly govern their conduct. *Susan B. Anthony List*, 573 U.S. at 159.[22]

1. The doctors engage in a course of conduct affected by constitutional interests.

The doctors' standing is shown because they are objects of the government's regulations. There "is ordinarily little question" about standing if an entity is the "object of the [challenged] action." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). Entities are the object of a regulation (1) when "the regulation is directed at them in particular"; (2) when "it requires them to make significant changes in their everyday business practices"; and (3) when, "if they fail to observe the [new] rule they are quite clearly exposed to the imposition of strong sanctions." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 153–54 (1967). The doctors meet these criteria.

First, the facts of the doctors' practices—that they provide excellent care to patients but religiously or ethically object to provide interventions to further gender transitions, or to engage in speech "affirming" gender identity—are alleged and verified in the Amended Complaint. *See supra*, Background section V and accompanying footnotes, citing paragraphs from evidentiary exhibits to the Amended

---

[22] The government's motion does not challenge ACPeds' and CMA's ability to assert associational standing on behalf of their members. Both entities have associational standing, because they have each identified multiple members who face the credible threat of enforcement injury-in-fact identified in this brief and who meet the other standing factors since they share the organizations' views on this matter. *See* Van Meter Decl. ¶¶ 95–131; Dickerson Decl. ¶¶ 77–98; *cf. Ass'n of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 543 (6th Cir. 2021).

Complaint. Second, the doctors engage in that conduct as participants in programs receiving HHS funding, triggering both the § 1557 and the 2016 Grants Mandates. *Id.* The Court must accept these allegations as true for this motion. *Howard*, 40 F.4th at 422.

To reiterate one example of how the gender identity mandates prohibit the doctors' conduct, the doctors engage in what HHS would characterize as "categorical" exclusions—that is, an unwillingness to provide interventions or affirming speech—to support gender "transitions" of minors, whether by drugs, surgeries, counseling, or use of pronouns inconsistent with biological sex. Am. Compl. ¶ 131. HHS prohibits such categorical exclusions when it bans gender identity discrimination. Am. Compl. ¶ 53. As another example, HHS explains its mandate forces healthcare providers to perform hysterectomies in attempts to transition women to men. *See* 81 Fed. Reg. at 31,455.

Third, as described above, the mandates carry significant penalties for noncompliance. *See supra* Background section V. The § 1557 rules carry both exclusionary and punitive penalties, forcing the doctors to choose between following their religious and ethical beliefs and practicing medicine in most contexts. *Id.* The 2016 Grants Mandate would inherently exclude doctors such as Dr. Dassow from practicing in many settings, ranging from rural community health clinics to care for the underserved, to large hospitals receiving major HHS grants. *See id.; see also* 45 C.F.R. § 75.371 through 75.375 (remedies for noncompliance).

The doctors' actions are also "affected with . . . constitutional interest[s]." *Susan B. Anthony List*, 573 U.S. at 159. Many of the doctors, and CMA's members explicitly, exercise their religious beliefs through their conduct; and all the doctors

exercise their freedom of speech through their patient counseling, speech, and record keeping, including their use or non-use of pronouns towards patients.[23]

2. The gender identity mandates ban the doctors' conduct.

a) The § 1557 gender identity mandate exists.

The government suggests these mandates do not exist, or their enforcement is not sufficiently likely. These suggestions cannot be reconciled with anything HHS says outside of court briefs.

HHS is proudly imposing a gender identity mandate under § 1557. HHS repeatedly sends out notices and press releases saying so. There are too many examples to cite them all. Most notably, in May 2021 the government published in the Federal Register a notice declaring HHS would immediately begin enforcing a ban on gender identity discrimination under § 1557 and its regulations.[24] In an associated press release, HHS declared that its "Office for Civil Rights will interpret *and enforce* Section 1557 and Title IX's prohibitions on discrimination based on sex to include: (1) discrimination on the basis of sexual orientation; and (2) discrimination on the basis of gender identity."[25] HHS has since reiterated it continues to enforce this mandate, saying such things as, "OCR is investigating and, where appropriate, enforcing Section 1557 of the Affordable Care Act cases involving discrimination on the basis of sexual orientation and gender identity in accordance with all applicable law."[26] As the *Franciscan Alliance* court explained, HHS's 2021 enforcement

---

[23] *See, e.g.*, Am. Compl. ¶¶ 147, 148, 217, 219, 250, 269 (alleging religious exercise and free speech aspects of the doctors' practices and objections).

[24] Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984, 27,985 (effective May 10, 2021; published May 25, 2021).

[25] HHS Announcement, *supra* note 1 (emphasis added).

[26] HHS Notice & Guidance, *supra* note 1 (footnote omitted).

announcement promises to "enforce Section 1557 in the near identical way as, if not an enhanced version of, how the 2016 Rule dictated." 553 F. Supp. 3d at 373.

The government appears to dispute the source of the § 1557 mandate, but that dispute is irrelevant because the doctors challenge the mandate from all possible sources. The government first suggests there is no such mandate under the final 2016 ACA Rule. This is mistaken, as explained above, because two judges in 2020 issued rulings that retained the gender identity language from the 2016 ACA Rule, and three other judges have agreed the language is still in effect.[27]

Ultimately, where the mandate comes from is not relevant to this motion because the doctors' challenge is broad and the Court must construe it in their favor. The doctors challenge the mandate from the 2016 ACA Rule. They challenge the 2020 rule if it is interpreted to prohibit gender identity discrimination. They challenge HHS's repeated announcements since 2021 that they are enforcing a § 1557 gender identity mandate. And they challenge the § 1557 statute itself, if the Court interprets the statute to prohibit gender identity discrimination.[28]

The precise location of the mandate is a matter for the Court to consider at the merits stage of this case. The doctors contend that it resides in the 2016 ACA Rule, and multiple courts agree. But the fact that the mandate exists, that HHS is enforcing it, and that the doctors challenged it, cannot be seriously disputed. The government cannot show that no mandate exists in *any* of these sources when HHS is broadly

---

[27] *See supra* Background section II. In addition, some courts interpret the statutory text of § 1557 to prohibit gender identity discrimination. *See, e.g.*, *Fain v. Crouch*, No. CV 3:20-0740, 2022 WL 3051015 (S.D. W. Va. Aug. 2, 2022). Plaintiffs disagree with that view, but HHS has taken that view, and it provides yet another reason that a mandate does exist—which means that doctors regulated by that mandate have standing to challenge it.

[28] The doctors' claims explicitly encompass all these possible sources of the § 1557 mandate. *See, e.g.*, Am. Compl. ¶¶ 347, 383, 391, 420, 424, 446, and 462.

advertising that it is enforcing that mandate. Because a mandate exists, those regulated by it have standing to challenge it.

The government suggests that if it is imposing a gender identity mandate, it is only following *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). This is both incorrect and inapposite. Agencies cannot take any action without statutory authority. A key purpose of review under the APA is to consider whether an agency acted "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C). Here, if HHS claims its actions are just an enforcement of plain statutory text, the doctors can challenge those actions under § 706 as exceeding that statutory text, and in this motion the Court must assume the doctors' legal claim will succeed.

In addition, the doctors can challenge agency actions taken under a statute under RFRA and under the First Amendment, to enjoin government officials from implementing a statute in violation of RFRA or the Constitution. 42 U.S.C. § 2000bb-1 (authorizing judicial review) & § 2000bb-2 (specifying an "agency" can be sued); *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–90, 693 (1949) (courts of equity have the power to set aside ultra vires and unconstitutional federal actions); *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491, n.2 (2010) (there is "an implied private right of action directly under the Constitution to challenge governmental action . . . as a general matter"); 33 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 8304 (2d ed. 2022) (the "Supreme Court has long recognized that injunctive relief" apart from the APA can "be available to test the legality of administrative action").

The government's reliance on *Bostock* does not support their motion. HHS is wrong about *Bostock*, which limited its holding to Title VII, and the Court said it was not interpreting sensitive matters or any "other laws" including the ACA. 140 S. Ct. at 1753. But that is a merits question. In assessing the Plaintiffs' standing, this Court must assume Plaintiffs will prevail on the merits.

b) The grants gender identity mandate exists.

The government also disputes the existence of the gender identity mandate that resides in HHS's grants rule, which prohibits gender identity discrimination separately from § 1557. The 2016 Grants Mandate is in effect. As explained above, *supra* Background section III, HHS finalized the grants mandate in 2016, it finalized a repeal rule in January 2021, HHS's new leadership immediately prevented the repeal rule from going into effect in February 2021, and in June 2022 HHS vacated the repeal rule, leaving the 2016 ACA Rule in place. *Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 44. In other words, HHS had finalized an actual repeal of the 2016 Grants Mandate, but the new administration not only refused to let it go into effect, it immediately thwarted that appeal and eventually eliminated it by voluntarily agreeing to injunctions.

Despite this consistent support for the 2016 Grants Mandate, the government claims it does not present a credible threat of enforcement because of a notice issued by the previous administration's HHS.[29] The previous HHS leadership issued that notice in 2019 simultaneously with the proposed rule that would repeal the 2016 Grants Mandate. That notice said HHS would not enforce the 2016 Grants Mandate "pending" its repeal.[30] That notice is no longer relevant, however, because HHS spent the last 18 months blocking and eventually vacating the repeal rule. Since the final repeal rule has been vacated, their pending repeal on which the notice rested no longer exists. Since HHS eliminated the premise of the 2019 notice, the notice is now defunct and obsolete on its own terms.

The government claims that in a non-adversarial court filing in the *Facing Foster Care* case, HHS "reaffirmed the Notice of Nonenforcement." Def.s' Mem. in

---

[29] Notification of Nonenforcement, *supra* note 11.

[30] *Id.*

Supp. of Def.s' Mot. to Dismiss First Am. Compl. ("Gov. Br.") at 7, ECF No. 52. This is not correct. The government never said that the notice would survive vacatur of the repeal rule. The government simply stated that the notice *said* the 2016 Grants Mandate would not be enforced pending its repeal. *Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 41 at 9. With the repeal rule vacated, that past fact no longer applies. HHS cannot have its cake and eat it too: it publicly insists on the paramount need to enforce its prohibitions on gender identity discrimination, but equivocally suggests to courts that maybe it is not fully enforcing this requirement. Ambiguous court filings do not negate final rules, especially when the agency has relentlessly worked to keep those rules fully applicable in the Code of Federal Regulations. "[E]quivocal statements cannot be accepted as a disavowal; 'the government's disavowal must be more than a mere litigation position.'" *Poe v. Snyder*, 834 F. Supp. 2d 721, 730 (W.D. Mich. 2011) (quoting *Lopez v. Candaele*, 630 F.3d 775, 788 (9th Cir. 2010)).

The statement by HHS in litigation does not approach the level of a disavowal. Allowing the repeal rule to go into effect would have been a disavowal, and HHS did everything in its power to prevent the repeal. Nothing in the notice stops HHS from enforcing the 2016 Grants Mandate today. It is not a regulation. It is not binding on HHS. It does not say HHS will not enforce the 2016 Grants Mandate tomorrow or in the future.

The recency of the 2016 Grants Mandate establishes the baseline of its effectiveness. 2016 is only six years ago. And even more recent are HHS's actions from February 2021 through June 2022 to block and vacate that mandate's repeal. As a matter of printed regulatory text, therefore, HHS has twice in the last six years codified an intent to prohibit gender identity discrimination in its grants. A disavowal requires more under this circuit's precedent. Even when "defendants have not enforced or threatened to enforce this statute against plaintiffs or any other . . . party"

in the past, standing exists to challenge an applicable legal requirement *unless* the government "explicitly disavowed enforcing it in the future." *Green Party of Tenn. v. Hargett*, 791 F.3d 684, 696 (6th Cir. 2015). The notice is both defunct and says nothing about the future.

Likewise the notice does not name these doctors. The Sixth Circuit held no disavowal existed in *Platt v. Bd. of Comm'rs on Grievances & Discipline of Ohio Sup. Ct.*, 769 F.3d 447, 452 (6th Cir. 2014), where no promise existed not to enforce the law against those plaintiffs. Here the government's brief nowhere says it will not enforce the 2016 Grants Mandate against the doctors in the future. Nor is that prospect a strange one. In the previous administration, HHS issued three separate notices providing religious exemptions to specific HHS grantees and programs that objected to the 2016 Grants Mandate. Not only has HHS not given such exemptions to the doctors here, HHS has repealed all previously granted religious exemptions under the 2016 Grants Mandate.[31]

In light of HHS vacating the repeal rule, the cases HHS cites do not apply. In *Texas Department of Family and Protective Services v. Azar*, 476 F. Supp. 3d 570 (S.D. Tex. 2020), the court only ruled that there was no threat of enforcement because HHS had sent the plaintiffs in that case a "letter" specifically saying that RFRA prevents HHS from applying the 2016 Grants Mandate to them. *Id.* at 574. Here the government refuses to send such a letter to these doctors. Indeed, HHS revoked the Texas letter as well, and all similar letters, as noted above. The facts were also dissimilar in *Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546 (N.D. Tex. 2020), because the plaintiff in that case was admittedly not subject to the 2016 Grants Mandate, since it had never applied for federal funds. *Id.* at 557. The doctors here are subject to the mandate currently. And in both these cases, the previous administration had

[31] *See* HHS Action, *supra* note 12.

a pending repeal that it intended to finalize. The opposite is true now. This administration voluntarily vacated the repeal rule and withdrew all religious exemptions. HHS even said it was "reestablish[ing] its commitment to furthering nondiscrimination and upholding the law" of the 2016 grants rule's "gender identity" mandate.[32] There is a credible threat of enforcement now that was not present in either Texas case due to HHS's recent actions.

The government contends that the lack of past enforcement of the 2016 Grants Mandate undermines the doctors' standing. This is incorrect. When a law (or, here, a regulation) governs conduct on its face, standing exists to challenge it even when it has never been enforced. *Epperson v. Arkansas*, 393 U.S. 97, 98 (1968) (challenge to 40-year-old statute that had never been enforced); *Holder v. Humanitarian Law Project*, 561 U.S. 1, 16 (2010) (standing existed even though government had only prosecuted "several" others under law); *Babbitt*, 442 U.S. at 302 (standing existed to challenge provision that "has not yet been applied and may never be applied"). Here the 2016 Grants Mandate is far newer than the 40-year-old statute in *Epperson*. Indeed, HHS has spent the last 18 months successfully doing everything it could to negate this mandate's repeal and emphasize its central importance.

This up-to-the-minute "reestablish[ment]" of HHS's commitment to the 2016 grants rule provides ample "evidence to establish that [plaintiffs'] challenge is capable of repetition yet evading review" even if the notice applies today, justifying this Court's jurisdiction. *Graveline v. Benson*, 992 F.3d 524, 533–34 (6th Cir. 2021); *see also Stilwell v. Off. of Thrift Supervision*, 569 F.3d 514, 518 (D.C. Cir. 2009) (finding it "more than a little ironic that [government] would suggest Petitioners lack standing and then, later in the same brief, label [Petitioners] as a prime example of . . . the very problem the Rule was intended to address") (cleaned up). Temporary

[32] *See* HHS Action, *supra* note 12.

government nonenforcement does not negate justiciability "unless it is absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur," and unless the government "will not" undertake the challenged action subsequently. *West Virginia v. EPA*, 142 S. Ct. 2587, 2594 (2022) (cleaned up).

3. The doctors face a credible threat of prosecution under both gender identity mandates.

HHS's recent actions to enshrine and implement these mandates amply demonstrate a credible threat of enforcement.

The government argues that the doctors cannot sue until after they face actual prosecution, because only then can the specific facts of a case show a threat of enforcement. That is not correct. Plaintiffs need not wait for the government to enforce a provision before challenging it. *See e.g.*, *Susan B. Anthony List*, 573 U.S. at 158–59; *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016). The Sixth Circuit consistently recognizes standing in pre-enforcement cases. *See, e.g.*, *Gun Owners of Am., Inc. v. Garland*, 19 F.4th 890, 897 (6th Cir. 2021); *Nat'l Cotton Council of Am. v. EPA*, 553 F.3d 927, 929 (6th Cir. 2009).

The government contends that the bar to show a threat of future injury is "rigorous," and thus Plaintiffs fail to meet it. Gov. Br. at 16. But the doctors must only plausibly allege a "substantial risk" of the harm to sufficiently show a threat of future injury, and they have done so here. *Susan B. Anthony List*, 573 U.S. at 158. HHS has repeatedly expressed a credible threat of enforcing the § 1557 mandate, as noted above, including HHS's May 2021 notice of enforcing the gender identity mandate under § 1557. And in HHS's relentless and successful attempt to prevent the 2016 Grants Mandate from being repealed, and its withdrawal of previous exemptions that protected religious entities from enforcement, HHS claimed it is

"reestablish[ing]" the preeminence of ensuring that rule prevents gender identity discrimination.[33]

Religious Sisters, *Franciscan Alliance*, and *Christian Employers Alliance* all found a credible threat of enforcement of § 1557 by HHS. "HHS's interpretation of Section 1557—as influenced by *Bostock* and the two nationwide preliminary injunctions against the 2020 Rule—provokes a credible threat of enforcement for refusal to provide or insure gender-transition procedures." *Religious Sisters*, 513 F. Supp. 3d at 1135. "[T]he current regulatory scheme for Section 1557 clearly prohibits Plaintiffs' conduct, thus, putting them to the impossible choice of either defying federal law and risking serious financial and civil penalties, or else violating their religious beliefs." *Franciscan All.*, 553 F. Supp. 3d at 374 (cleaned up). HHS "admitted there have been complaints that have likely gone through the conciliation process. . . . Government harassment of religious organizations requiring them to prove they are religious or evaluating whether their religious preferences can withstand a case-by-case analysis is a sufficient injury. Accordingly, this matter is ripe. . . . " *Christian Emps. All.*, 2022 WL 1573689 at *5.

HHS also reacted to those decisions by telling the courts they are enforcing § 1557 against religious health care providers and need further instruction from the court to avoid violating the injunctions. In all three cases, after the courts issued their injunctions, the government promptly moved to modify the injunction in light of HHS's pending enforcement of its gender identity mandate. For example, in *Franciscan Alliance*, HHS claimed the injunction needed to be made more specific because HHS planned to enforce § 1557 against health providers who "fail[] to perform or provide insurance coverage for gender-transition procedures or abortion," and therefore HHS ran significant risk of targeting the religious health care providers

[33] *See* HHS Action, *supra* note 12.

granted an injunction in that case unless the injunction was modified to help HHS identify those providers.[34] HHS filed the same motion to modify in the other two cases.[35]

This administration has therefore told three other district courts its danger of enforcing its gender identity mandate against religious health care providers is so great it needs intricate injunction language just to comply with those court orders. That robust enforcement creates the same credible threat of enforcement against the doctors of ACPeds and CMA, except they have no injunction protecting them.

4. RFRA allows this suit, it does not preclude it.

The government argues that because religious freedom laws exist, they might (but might not) protect the doctors, and therefore no credible threat of enforcement exists. As noted, however, the government refuses to exempt these doctors, and has revoked all other religious exemptions it had provided under these mandates.[36]

These mandates have no religious exemptions in their text. In the 2020 rule, HHS did try to affirm the application of religious exemptions including the Title IX religious exemption governing § 1557, because § 1557 derives from the Title IX statute. But the *Whitman-Walker Clinic* court issued a nationwide injunction eliminating that exemption. 485 F. Supp. 3d at 64. Because the 2016 ACA Rule had none of these protections, they are still absent.

Moreover, this month HHS published a proposed rule in which it takes the position that the Title IX religious exemption does not apply to § 1557, thereby

---

[34] *Franciscan All.*, No. 7:16-cv-00108-O, ECF No. 208 at 4 (filed Sept. 13, 2021).

[35] *Christian Emps. All.*, No. 1:21-cv-00195-DMT-CRH, ECF No. 43 (filed June 6, 2022); *Religious Sisters*, No. 3:16-cv-00386-PDW-ARS, ECF No. 130 (filed Feb. 16, 2021).

[36] In addition, some of the doctors object based on non-religious reasons. *See* Van Meter Decl. ¶¶ 29, 86. As a result, the existence of religious freedom exemptions cannot negate the threat of enforcement to all the doctors here.

precluding any suggestion by the government that HHS might credit the doctors with that exemption here.[37] As the *Franciscan Alliance* court stated, "the facts suggest a threat well beyond the 'mere risk that [HHS might] repeat its allegedly wrongful conduct' of the enforcement of Section 1557 against Christian Plaintiffs." 553 F. Supp. 3d at 374 (quoting *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 286 (5th Cir. 2012)).

The government argues that somehow RFRA itself precludes this suit, because since RFRA *might* protect the doctors it is unclear whether they face a threat of enforcement. This position is untenable for several reasons. Initially, the injury standard asks whether the statutes or regulations "arguably" apply to the doctors, not whether they apply *if* one considers superseding laws like the First Amendment or RFRA. *See Susan B. Anthony List*, 573 U.S. at 160. If it were true that such laws prevent credible threats of enforcement, there would have been no standing to bring the Free Speech Clause challenge in *Susan B. Anthony List*. But this is the wrong inquiry. The question is whether mandates themselves encompass the doctors' behavior, not the mandates as superseded by other laws, since the merits of this case is about whether other laws supersede those mandates.

The government's view of standing would negate RFRA's text. RFRA says a person can raise "*a claim* or defense in a judicial proceeding and obtain appropriate relief against a government." 42 U.S.C. § 2000bb-1 (emphasis added). The outcome of such a RFRA claim would be to mandate an exemption, exactly as happened in *Religious Sisters*, *Franciscan Alliance*, and *Christian Employers Alliance*. But the government's view would negate the ability to bring a RFRA "claim" before enforcement, making RFRA into no more than a "defense."

---

[37] Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47,824, 47,839–40 (Aug. 4, 2022).

Previous RFRA litigation renders the government's position untenable. Besides the three rulings just mentioned, a decade of litigation over other ACA mandates show that plaintiffs can raise and win RFRA claims even if no enforcement occurs. Most circuit courts and the Supreme Court considered pre-enforcement challenges to an HHS rule issued under the ACA that required employers to cover contraceptives in their employee health insurance plans. The Supreme Court ultimately granted RFRA relief in those cases. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). But not one of the plaintiffs in those cases had been subject to a specific complaint or enforcement procedure by HHS. Even where the courts of appeals disagreed on the *merits* of those RFRA claims, they ruled the parties had *standing* to bring pre-enforcement challenges. *Compare, e.g.*, *Dordt College v. Burwell*, 801 F.3d 946 (8th Cir. 2015) (ruling in favor of RFRA claims) *with Autocam Corp. v. Sebelius*, 730 F.3d 618, 622 (6th Cir. 2013) ("Autocam has standing to challenge the mandate in its corporate capacity, and we concur in that conclusion."). Across nearly every circuit, courts handled scores of RFRA challenges to HHS's contraceptive mandate. No court adopted the government's view that RFRA precludes jurisdiction to challenge a regulatory mandate before the government investigates a complaint on specific facts.

Nor are these mandates any different. The gender identity mandates prohibit certain conduct, including all categorical exclusions or limitations on providing gender transition services, as being "unlawful on [their] face." 81 Fed. Reg. at 31,429. The doctors here engage in that conduct and corresponding speech. There is no uncertainty about the fact that HHS's mandates prohibit what these doctors say and do. The doctors therefore have standing to ask the Court for a RFRA exemption before enforcement occurs, just like the Supreme Court allowed the litigants in *Hobby Lobby* to request, and just as Judges Atchley, Welte, O'Connor, and Traynor allowed other

challengers to request relief from gender identity mandates under § 1557 and Title IX.

The government's view would turn RFRA into a statute that prohibits claims rather than authorizing them. But in RFRA Congress acknowledged that sometimes the government imposes mandates violating religious liberty, and therefore litigants need the ability to sue for relief. Religious persons can sue under RFRA because they are injured by the government action they are challenging *until* they obtain a RFRA injunction from a court. The Court might agree or disagree with the plaintiff on the merits, but that plaintiff has standing to sue.

The Court should not adopt the government's novel and peculiar reading of RFRA. It would allow the Executive Branch to impose whatever substantial burdens on religion it wants to impose, without having to comply with RFRA in the first place, or needing to defend against judicial review afterward. HHS unilaterally revoked all RFRA exemptions and reversed its position on whether Title IX's religious exemption applies. Now it asks this Court to deny review of its rules. The government's view would turn RFRA into a sword against religious believers instead of a shield against government overreach. The doctors have standing to bring claims under RFRA.

5. The APA provides for judicial review of agency action.

The APA allows litigants to challenge "legal wrong[s]" imposed by an agency. 5 U.S.C. § 702. HHS finalized the 2016 and 2020 rules and issued its May 2021 enforcement policy. Those rules encompass the doctors, and they changed the doctors' legal rights and responsibilities in ways the doctors contend is unlawful. Assuming, as the Court must, that the doctors are right about the illegal effect of those rules, the doctors have standing to challenge the legal wrongs these rules imposed on them.

Legal wrong is an injury under Article III: "the injury required by Art. III may exist solely by virtue of statutes creating legal rights, the invasion of which creates

standing." *Lujan*, 504 U.S. at 578 (cleaned up). Here HHS's final regulations in 2016, and if the Court interprets it so, in 2020 and in the 2021 notice of enforcement, changed the doctors' rights (adding non-discrimination obligations and penalties) in a way the unregulated general public is not affected. The Supreme Court has recently acknowledged that violation of a personal right even without actual damages presents a cognizable injury. *Uzuegbunam v. Preczewski*, 141 S. Ct. 792, 798–800 (2021). Likewise, the "APA provides for judicial review of all final agency actions, not just those that impose a self-executing sanction." *Sackett v. EPA*, 566 U.S. 120, 129 (2012); *see also U.S. Army Corps of Eng'rs*, 136 S. Ct. at 1815 ("parties need not await enforcement proceedings before challenging final agency action."); *Babbitt*, 442 U.S. at 298 (plaintiffs need not await "the consummation of threatened injury to obtain preventive relief.")

Challenges to final regulations by regulated entities are commonplace even with no individual enforcement first occurring. The Sixth Circuit regularly proceeds to the merits in such cases. *See, e.g.*, *Gun Owners of Am.*, 19 F.4th at 897; *Nat'l Cotton Council of Am.*, 553 F.3d at 929.

B. The doctors have shown causation and redressability.

This case also meets the remaining two requirements of standing: causation and redressability. Because the doctors' injury stems from the two gender identity mandates, there is a direct causal relationship between their injuries and HHS's actions (or, alternatively, the § 1557 statute itself). An injunction against the gender identity mandates would redress the injuries, as it did in other courts.

III. The doctors' claims are ripe.

The government disputes the ripeness of the doctors' claims, somehow contending that HHS has not taken a position on the gender identity mandate. Gov. Br. at 18. This contradicts HHS's repeated statements cited above, insisting there is

a gender identity mandate under § 1557 and that HHS is actively enforcing it. In this respect, the government seems to be creating confusion about the source of the mandate to contend no mandate exists, even as HHS tells the public and regulated health providers that they must comply with it or face penalties.

In support of its ripeness argument, the government cites *Kentucky Press Association, Inc. v. Kentucky*, 454 F.3d 505, 507 (6th Cir. 2006), in which the court reasoned it was "far from certain" that a Kentucky statute applied to free speech activities. *Id.* at 510. But unlike in that case, HHS has indeed taken a position on this rule: it insists § 1557 prohibits gender identity discrimination. It said so in its 2016 ACA Rule, whose language remains in effect as explained above. It said so in the Federal Register in May 2021, and in subsequent press and guidance documents, insisting it is enforcing this mandate. There is nothing uncertain about whether HHS is imposing a ban on gender identity discrimination under § 1557.

The government also contends, as noted above, that RFRA somehow undermines ripeness. In this respect the government overlooks the nationwide injunction by the *Whitman-Walker Clinic* court against the religious exemptions that would have been in the 2020 § 1557 rule. As the court explained in *Religious Sisters of Mercy*, "[w]ith the religious exemption enjoined too, a clear path for the Plaintiffs to incur liability under Section 1557 emerges." 513 F. Supp. 3d at 1138.

The government contends that because HHS has not yet enforced any regulations against the doctors personally, they do not know the exact and contextual treatment that HHS would require, and therefore lack the concrete facts Article III requires for ripeness. Gov. Br. at 20. Moreover, the government states that even on enforcement, administrative steps occur such as a hearing and written report. *Id.* at 21–22. But the doctors have plausibly alleged that they engage in conduct prohibited by HHS's bans on gender identity discrimination in health care, as discussed above. This Court must accept those facts as true, not deny them and then conclude the facts

are unclear. "'[J]ust because a plaintiff's claim might fail on the merits does not deprive the plaintiff of standing to assert it.'" *Barber v. Charter Twp. of Springfield*, 31 F.4th 382, 390 (6th Cir. 2022) (quoting *CHKRS, LLC v. City of Dublin*, 984 F.3d 483, 489 (6th Cir. 2021)). The injury-in-fact requirement simply establishes that plaintiffs have a "personal stake in the outcome of the controversy." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). The doctors' personal stake is evident, in that they categorically oppose providing or speaking in favor of gender transition interventions, and HHS's gender identity mandates regulate their conduct.

The notion that a plaintiff must wait until enforcement for her claim to be ripe contradicts precedent. The Supreme Court has held that "parties need not await enforcement proceedings before challenging final agency action where such proceedings carry the risk of serious criminal and civil penalties." *U.S. Army Corps of Engr's*, 136 S. Ct. at 1815. "[W]here threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat . . . ." *MedImmune, Inc. v. Genetech, Inc.*, 549 U.S. 118, 128–29 (2007). The Sixth Circuit likewise insists that a "[p]laintiff is not required to 'first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights.'" *McGlone v. Bell*, 681 F.3d 718, 730 (6th Cir. 2012) (quoting *Steffel v. Thompson*, 415 U.S. 452, 459 (1974)).

Judge Atchley's ruling in *Tennessee v. United States Department of Education*, No. 3:21-CV-308, 2022 WL 2791450 at *9–10, is instructive. There, the government argued that Tennessee's claims were not ripe because the Department of Education had not enforced the provision, but the Court held that the "argument ignores a long line of precedent allowing pre-enforcement judicial review of agency actions." *Id.* at *9.

Finally, in pre-enforcement First Amendment cases, the line between "standing and ripeness . . . has evaporated." *Winter v. Wolnitzek*, 834 F.3d 681, 687 (6th Cir. 2016). When there is a threatened imminent injury in fact under the factors for free speech cases, pre-enforcement claims are ripe. *Platt*, 769 F.3d at 451. For the reasons previously explained, Plaintiffs suffer imminent injury-in-fact as well as a credible threat of enforcement. Further development of the facts is not required because the doctors have provided detailed facts of their policies and ongoing speech, along with the basis for their various objections.

CONCLUSION

The government would deprive the doctors of their day in court—an opportunity three other courts gave to similar associations of health care providers. This Court should deny the government's motion to dismiss, and allow this case to proceed to the merits.[38]

[38] As noted above, *supra* Background section IV, Plaintiffs do not oppose dismissal of their Claim Seven pertaining to the SUNSET Rule, but ask that the dismissal be without prejudice.

Respectfully submitted this 18th day of August, 2022.

By: /s/ Matthew S. Bowman

ANTHONY J. BILLER*
NC Bar No. 24,117
ENVISAGE LAW
2061 Oberlin Road NW, Suite 100
Raleigh, NC 27608
Telephone: (919) 414-0313
Facsimile: (919) 782-0452
ajbiller@envisage.law

MATTHEW BOWMAN
DC Bar No. 490159
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
mbowman@ADFlegal.org

RYAN L. BANGERT*
TX Bar No. 24045446
JONATHAN SCRUGGS
TN Bar No. 25679
ALLIANCE DEFENDING FREEDOM
15100 N. 90th Street
Scottsdale, AZ 85260
Telephone: (480) 444-0020
Facsimile: (480) 444-0028
rbangert@ADFlegal.org
jscruggs@ADFlegal.org

JULIE M. BLAKE*
VA BAR NO. 97891
ALLIANCE DEFENDING FREEDOM
44180 Riverside Parkway
Lansdowne, Virginia 20176
Telephone: (571) 707-4655
Facsimile: (571) 707-4790
jblake@ADFlegal.org

Counsel for Plaintiffs American College of Pediatricians, et al.
**Admitted pro hac vice*

CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States District Court Eastern District of Tennessee by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Matthew S. Bowman
MATTHEW S. BOWMAN