

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA**

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

MEMORANDUM OPINION

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

I. BACKGROUND

A. Section 1557 Implementing Regulations

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

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

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

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

i. 2016 Rule and Subsequent Litigation

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

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

Gender identity means an individual’s internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual’s sex assigned at birth. The way an individual expresses gender identity is frequently called “gender expression,” and may or may not conform to social stereotypes associated with a particular gender. A transgender individual is an individual whose gender identity is different from the sex assigned to that person at birth.

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

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

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

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

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

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

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

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

As a result, the court in *Franciscan Alliance II* vacated relevant portions of the 2016 Rule¹—defining sex discrimination to include gender-identity and termination-of-pregnancy discrimination—and remanded the rule to HHS for further consideration in light of the opinion.

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

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

ii. 2020 Rule and Subsequent Litigation

a. 2020 Rule

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

(a) . . . [A]n individual shall not, on any of the grounds set forth in paragraph (b) of this section, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the Department under such Title; or under any program or activity administered by any entity established under such Title.

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

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

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

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

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

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

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

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

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

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

b. *Walker*

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

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

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

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

Homes, Inc., 884 F.3d 560 (6th Cir. 2018), that because transgender people are “inherently ‘gender non-conforming[,]’ . . . an employer cannot discriminate on the basis of transgender status without imposing its stereotypical notions of how sexual organs and gender identity ought to align.” *Harris Funeral Homes*, 884 F.3d 560 at 576 (citations omitted); *accord id.*.

Accordingly, the *Walker* court found that the plaintiffs’ injuries were redressable through the court’s injunction on the enforcement of the 2020 Rule because the 2016 Rule’s unvacated ban on sex-stereotyping also embodied a ban on gender-identity discrimination. 480 F. Supp. 3d at 427, 430. Ultimately, the *Walker* court ordered that “the definitions of ‘on the basis of sex,’² ‘gender identity,’ and ‘sex stereotyping’ currently set forth in 45 C.F.R. § 92.4 will remain in effect.” *Id.* at 430.

c. *Whitman-Walker Clinic*

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

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

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

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

d. *Religious Sisters of Mercy*

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

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

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

iii. May 2021 Bostock Notification and Subsequent Litigation

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

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

Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984-02, 27,984 (May 25, 2021) [hereinafter the “*Bostock* Notification”]. The *Bostock* Notification specified that “[i]n enforcing Section 1557, as stated above, OCR will comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.*, and all other legal requirements.” *Id.* at 27,985. The *Bostock* Notification also stated that HHS would comply with the applicable court orders regarding Section 1557 regulations, including *Franciscan Alliance II*, *Whitman-Walker Clinic*, *Walker*, and *Religious Sisters of Mercy*. *Id.* at 27,985 n.9–12.

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

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

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

On August 26, 2022, the Fifth Circuit issued an opinion on HHS’s appeal. *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 371 (5th Cir. 2022) [hereinafter “*Franciscan Alliance V*”].

The Fifth Circuit reversed in part, finding that the plaintiffs’ APA claim was moot:

Appellants are right that the APA claim is moot. When a challenged rule is replaced with a new rule, the case is moot so long as the change gives “the precise relief that petitioners requested.” The change will not moot the case if the “government repeals the challenged action and replaces it with something substantially similar.”

The 2020 Rule gave Franciscan Alliance the remedy an APA violation called for—vacatur of the 2016 Rule’s prohibition of discrimination on the basis of “termination of pregnancy” and “gender identity.” Franciscan Alliance’s APA claim sought nothing more. Nor could it have. Vacatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation.

True, the *Whitman* and *Whitman-Walker* cases “resurrected” most of the 2016 Rule, but those courts expressly disclaimed any intention of altering the two portions of the rule Franciscan Alliance’s APA claim takes issue with. It is also true that these injunctions and the agency’s threat to enforce Section 1557 harm *Franciscan Alliance* the same way the 2016 Rule’s termination of pregnancy and gender-identity clauses did (a topic discussed in more detail below). But those facts don’t make a difference. Franciscan Alliance cannot use the APA to vacate those injunctions or Section 1557. For Franciscan Alliance’s APA claim, then, the court is unable to provide relief beyond what the 2020 Rule already gave. The claim is therefore moot.

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

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

B. HHS Grants Rules

i. 2016 Grants Rule

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

(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as age, disability, sex, race, color, national origin, religion, gender identity, or sexual orientation. Recipients must comply with this public policy requirement in the administration of programs supported by HHS awards.

(d) In accordance with the Supreme Court decisions in *United States v. Windsor* and in *Obergefell v. Hodges*, all recipients must treat as valid the marriages of same-sex couples. This does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

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

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

ii. Notification of Nonenforcement

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

iii. 2021 Grants Rule and Subsequent Litigation

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

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

(c) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services, to the extent doing so is prohibited by federal statute.

(d) HHS will follow all applicable Supreme Court decisions in administering its award programs.

Id.

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

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

C. SUNSET Rule

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

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

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

D. This Litigation

i. The Plaintiffs

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

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

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

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

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

ii. The Allegations

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

- a. Prescribing puberty blockers off-label from the FDA-approved indication to treat gender dysphoria and initiate or further transition in adults and children;
- b. Prescribing hormone therapies off-label from the FDA-approved indication to treat gender dysphoria in all adults and children;
- c. Providing other continuing interventions to further gender transitions ongoing in both adults and minors;
- d. Performing hysterectomies or mastectomies on healthy women who believe themselves to be men;
- e. Removing the non-diseased ovaries of healthy women who believe themselves to be men;
- f. Removing the testicles of healthy men who believe themselves to be women;
- g. Performing a process called "de-gloving" to remove the skin of a man's penis and use it to create a faux vaginal opening;
- h. Remove vaginal tissue from women to facilitate the creation of a faux or cosmetic penis;
- i. Performing or participating in any combination of the above mutilating cosmetic procedures, or similar surgeries, to place a patient somewhere along the socially constructed gender identity spectrum;
- j. Offering to perform, provide, or prescribe any and all such interventions, procedures, services, or drugs;
- k. Referring patients for any and all such interventions, procedures, services, or

drugs;

- l. Ending or modifying their policies, procedures, and practices of not offering to perform or prescribe these procedures, drugs, and interventions;
- m. Saying in their professional opinions that these gender intervention procedures are the standard of care, are safe, are beneficial, are not experimental, or should otherwise be recommended;
- n. Treating patients according to gender identity and not sex;
- o. Expressing views on gender interventions that they do not share;
- p. Saying that sex or gender is nonbinary or on a spectrum;
- q. Using language affirming any self-professed gender identity;
- r. Using patients' preferred pronouns according to gender identity, rather than using no pronouns or using pronouns based on biological sex;
- s. Creating medical records and coding patients and services according to gender identity not biological sex;
- t. Providing the government assurances of compliance, providing compliance reports, and posting notices of compliance in prominent physical locations, if the 2016 ACA Rule's interpretation of the term sex governs these documents;
- u. Refraining from expressing their medical, ethical, or religious views, options, and opinions to patients when those views disagree with gender identity theory or transitions; and
- v. Allowing patients to access single-sex programs and facilities, such as mental health therapy groups, breastfeeding support groups, postpartum support groups, educational sessions, changing areas, restrooms, communal showers, and other single-sex programs and spaces, by gender identity and not by biological sex.

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

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

in effect insofar as it does not incorporate Title IX’s religious exemption. (*Id.* at 14.) They also allege that, even if *Walker* and *Whitman-Walker Clinic* did not restore gender-identity discrimination to the 2016 Rule’s definition of sex discrimination, HHS has nevertheless concluded that those courts did so, and is enforcing Section 1557 accordingly, as evidenced by the May 2021 *Bostock* Notification. (*Id.* at 15.) Plaintiffs refer to the collective effect of the rules, the subsequent litigation, and the *Bostock* Notification as “the Section 1557 Gender-Identity Mandate.” (*Id.* at 16.)

Plaintiffs also allege the 2016 Grants Rule imposes an independent, “second gender identity mandate on doctors who work in programs that receive grants from HHS.” (*Id.* at 7.) Therefore, even though Dr. Dassow is protected under *Franciscan Alliance*’s injunction from HHS enforcing Section 1557, which might otherwise require her to engage in the “objectionable practices,” Plaintiffs allege Dr. Dassow is not protected from enforcement of the 2016 Grants Rule. (*Id.* at 40.) For this reason, Plaintiffs claim, Dr. Dassow is still effectively barred from discriminating on the basis of gender identity. (*Id.*)

Finally, Plaintiffs allege in their amended complaint, which was filed before HHS withdrew the SUNSET Rule, that the delay of the SUNSET Rule’s effective date harmed them because it delayed the time in which Plaintiffs could have participated in HHS’s reassessment process under the rule for the 2016 Rule and 2016 Grants Rule. (*Id.* at 47–50.)

iii. The Claims

Plaintiffs assert seven claims for relief: (1) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates the APA; (2) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates their freedom of speech and association pursuant to the First and Fifth Amendments to the U.S.

Constitution; (3) CMA on behalf of its members and ACPeds on behalf of its religious members allege that the Section 1557 Gender-Identity Mandate violates the Religious Freedom Restoration Act; (4) CMA on behalf of its members and ACPeds on behalf of its religious members allege that the Section 1557 Gender-Identity Mandate violates their free exercise of religion pursuant to the First and Fifth Amendments to the U.S. Constitution; (5) ACPeds and CMA allege on behalf of their members that the Section 1557 Gender-Identity Mandate violates the “structural principles of federalism” and exceeds Congress’s Article I enumerated powers; (6) all Plaintiffs allege that the Grants Gender-Identity Mandate violates the APA, RFRA, Free Exercise Clause, Free Speech Clause, the “structural principles of federalism” and exceeds Congress’s Article I enumerated powers; and (7) all Plaintiffs allege that the delay of the SUNSET Rule’s effective date violates the APA and RFA. (Doc. 15, at 53–79.) Defendants moved to dismiss this case, contending that “[n]one of these challenges presents a case or controversy under Article III” because Plaintiffs either lack standing or do not present a ripe controversy. (Doc. 52, at 9.)

II. STANDARD OF REVIEW

The case-or-controversy requirement of Article III, Section 2 mandates that a plaintiff have standing in order to sue. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). To have standing, a plaintiff must have “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Daunt v. Benson*, 956 F.3d 396, 417 (6th Cir. 2020) (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338, (2016)). An injury, for standing purposes, means the “invasion of a legally protected interest which is (a) concrete and particularized, and (b) ‘actual or imminent.’” *Id.* (quoting *Lujan*, 504 U.S. at 560). “For an injury to be ‘particularized,’ it ‘must

affect the plaintiff in a personal and individual way.” *Spokeo*, 578 U.S. at 339 (quoting *Lujan*, 504 U.S. at 560). A “concrete” injury in fact does not have to be tangible, but it must be “‘real,’ and not ‘abstract.’” *Id.* at 340. Further, “[w]here plaintiffs seek to establish standing based on an imminent injury, the Supreme Court has explained ‘that “threatened injury must be *certainly impending* to constitute injury in fact,” and that “[a]llegations of *possible* future injury” are not sufficient.’” *Galaria v. Nationwide Mut. Ins. Co.*, 663 F. App’x 384, 388 (6th Cir. 2016) (quoting *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013) (emphasis in original)).

The plaintiff bears the burden of showing that standing exists. *Id.* at 387 (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)). When a case is at the pleading stage, the plaintiff must clearly allege facts demonstrating each element of standing. *See Spokeo*, 578 U.S. at 338 (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). In a pre-enforcement suit, “a plaintiff satisfies the injury-in-fact requirement [of the standing inquiry] where he alleges ‘an intention to engage in a course of conduct arguably affected with a constitutional interest, but [arguably] proscribed by a statute, and there exists a credible threat of prosecution thereunder.’” *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014) (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)).

III. ANALYSIS

Here, Plaintiffs have declared, on behalf of themselves or their members, an intention to refrain from engaging in the twenty-two “objectionable practices” related to medical gender-transition services and allege that doing so is arguably affected with a constitutional interest, namely, freedom of speech and association, free exercise of religion, and the structural principles of federalism. (Doc. 15, at 53–70.) Although Plaintiffs bring additional claims, such as their claim that the 2016 Rule and Notification violate the APA, “their other claims are affected with a

constitutional interest too, regardless of the precise legal theory” because they intend to engage in arguably protected *conduct*. *Religious Sisters of Mercy*, 513 F. Supp. 3d at 1138 (quoting *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 750 (8th Cir. 2019)); *see also Susan B. Anthony List*, 573 U.S. at 161. Thus, standing turns on whether Plaintiffs’ anticipated course of conduct is proscribed by statute and, if so, whether there is a credible threat of prosecution. *See Susan B. Anthony List*, 573 U.S. at 159.

A. Section 1557 Gender-Identity-Mandate Claims

i. Whether the Intended Course of Conduct is Proscribed by Statute

In support of standing, Plaintiffs allege that their refusal to perform the objectionable practices is proscribed by Section 1557. (Doc. 55, at 17.) HHS argues that it has not taken the position that Section 1557 mandates physicians in programs receiving federal funding to perform the objectionable practices, because the gender-identity provision of the 2016 Rule was vacated in *Franciscan Alliance II* and the *Bostock* Notification is nonbinding guidance. (*Id.* at 11, 22.) HHS’s arguments fall short of demonstrating that Plaintiffs’ proposed course of conduct is not proscribed by statute.

First, although the provision defining sex discrimination as including gender-identity discrimination was vacated in *Franciscan Alliance II*, the *Walker* and *Whitman-Walker Clinic* courts found that, regardless of *Franciscan Alliance II*, entities receiving federal funding would still be barred from discrimination against transgender individuals under the 2016 Rule’s ban on sex-stereotyping, and these courts enjoined the repeal of that provision. *See Whitman-Walker Clinic*, 485 F. Supp. 3d. at 64; *Walker*, 480 F. Supp. 3d at 430. Therefore, HHS’s operative Section 1557 regulations at least arguably bar discrimination against transgender patients as a form of sex discrimination under the statute. Additionally, Plaintiffs’ refusal to engage in the

“objectionable practices” would arguably amount to such sex discrimination. As the *Religious Sisters of Mercy* court found, “[c]onstruing the same definitions [in the 2016 Rule] that now control once again, HHS previously classified the categorical refusal to perform or cover gender-transition procedures as unlawfully discriminatory.” 513 F. Supp. 3d at 1138 (citing the 2016 Rule, 81 Fed. Reg. at 31,471–72 (formerly codified at 45 C.F.R. §§ 92.206, 92.207(b)(4)-(5))).

Second, regardless of the operative regulations or whether the *Bostock* Notification is binding, if Title IX, as incorporated by Section 1557, is interpreted such that its definition of sex discrimination includes gender-identity discrimination, Plaintiffs’ proposed course of conduct is “arguably proscribed by statute.” See *Susan B. Anthony List*, 573 U.S. at 159. Following the Supreme Court’s decision in *Bostock*, the reasoning of which some courts have since held applies equally to Title IX, Plaintiffs’ proposed discrimination against transgender patients is at least arguably proscribed. See, e.g., *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 593 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021). The Sixth Circuit held, before *Bostock* was even decided, that a school seeking to discriminate against a transgender student was not likely to succeed on the merits of its claims,³ because Title IX prohibits discrimination based on sex-stereotyping and gender nonconformity. *Dodds v. United*

³ This case came before the Sixth Circuit on appeal of a district court’s preliminary injunction ordering a school district to permit an eleven-year-old transgender girl to use the girls’ restroom. *Dodds v. United States Dep’t of Educ.*, 845 F.3d 217, 220 (6th Cir. 2016). The Sixth Circuit denied the school district’s motion to stay the injunction pending appeal. *Id.* at 222. Therefore, the Sixth Circuit did not conclusively hold that discrimination against transgender individuals would constitute sex discrimination under Title IX; rather, it held the school district did not show a likelihood of success on appeal because “settled law in this Circuit” reflected that “[s]ex stereotyping based on a person’s gender non-conforming behavior is impermissible discrimination.” *Id.* at 221 (quoting *Smith v. City of Salem*, 378 F.3d 566, 575 (6th Cir. 2004)). Therefore, while the precedent is not affirmatively dispositive of whether Title IX prohibits discrimination against transgender individuals, this Court is bound by its reasoning, and it supports the notion that Section 1557, by incorporating Title IX, at least arguably proscribes Plaintiffs’ proposed conduct. See *id.*

States Dep't of Educ., 845 F.3d 217, 221 (6th Cir. 2016). Therefore, Plaintiffs' proposed conduct of refusing to engage in the objectionable practices is at least arguably proscribed by Section 1557.

ii. *Whether There Exists a Credible Threat of Prosecution*

a. Other Circuits' Jurisprudence

Whether Plaintiffs face a “credible threat of prosecution” under Section 1557, however, is a distinct inquiry. Plaintiffs argue that it is “not plausible that these doctors lack standing to bring a challenge that was successful in three other courts.” (Doc. 55, at 17.) However, the two district courts that have heard similar challenges and found standing for physicians and healthcare-provider entities were the Northern District of Texas and the District of North Dakota—courts outside the Sixth Circuit whose opinions were instead predicated on precedents of the Fifth and Eighth Circuit, respectively. *Franciscan All. I*, 227 F. Supp. 3d at 678–80; *Religious Sisters*, 513 F. Supp. 3d at 1133; *Christian Emp. Alliance*, No. 1:21-cv-195, 2022 WL 1573689, at *1 (D.N.D. May 16, 2022). The Sixth Circuit's jurisprudence on standing, in particular, the issue of whether there exists a credible threat of prosecution, bears considerable differences from the Fifth and Eighth Circuit's.

The Fifth Circuit upheld the district court's finding that the plaintiffs had standing in *Franciscan Alliance V*, relying in part on its decision in *Speech First, Inc. v. Fenves*, 979 F.3d 319, 336 (5th Cir. 2020), *as revised* (Oct. 30, 2020). *Franciscan All. V*, 47 F.4th at 377. In *Speech First*, the Fifth Circuit held that the plaintiffs had standing despite the defendant's “disavowals of any future intention to enforce the policies contrary to the First Amendment,” because the mere “existence of the [defendant's] policies” and the fact that the plaintiffs fell within a class whose speech was “arguably restricted” rendered the threat of future enforcement

substantial. 979 F.3d at 336–38. The Fifth Circuit held, “[w]here the policy remains non-moribund, the claim is that the policy causes self-censorship among those who are subject to it, and the students’ speech is arguably regulated by the policy, there is standing.” *Id.* at 336–37 (citation omitted).

Similarly, the Eighth Circuit has held that “when a course of action is within the plain text of a statute, a ‘credible threat of prosecution’ exists.” *Alexis Bailly Vineyard, Inc. v. Harrington*, 931 F.3d 774, 778 (8th Cir. 2019) (citing *North Dakota v. Heydinger*, 825 F.3d 912, 917 (8th Cir. 2016)). The *Religious Sisters of Mercy* court relied on this Eighth Circuit holding to find the plaintiffs had standing to challenge the Section 1557 Gender Identity Mandate. *Religious Sisters of Mercy*, 513 F. Supp. 3d at 1139 (citing *id.*). But the Sixth Circuit requires more. *See infra* Section III.A.ii.b–c.

b. Sixth Circuit Jurisprudence: *McKay* Factors

In the Sixth Circuit, “[t]he mere *possibility* of prosecution,” such as the plaintiff’s intended course of action falling within the plain text of a non-moribund statute, “does not amount to a ‘credible threat’ of prosecution. Instead, the threat of prosecution must be *certainly impending* to constitute injury in fact.” *Daly v. McGuffey*, No. 21-3266, 2021 WL 7543815, at *2–3 (6th Cir. Nov. 15, 2021) (internal quotation marks omitted) (emphasis in original) (quoting *Crawford v. U.S. Dep’t of Treasury*, 868 F.3d 438, 454 (6th Cir. 2017)) (citing *Nat’l Rifle Ass’n of Am. v. Magaw*, 132 F.3d 272, 293 (6th Cir. 1997); *Fieger v. Mich. Sup. Ct.*, 553 F.3d 955, 967 (6th Cir. 2009)). In fact, the Sixth Circuit applies a factor test, first articulated in *McKay v. Federspiel*, 823 F.3d 862 (6th Cir. 2016) and known as the “*McKay* factors,” to determine whether an alleged threat of prosecution is credible:

Various factors inform our analysis of whether there is a credible threat of prosecution sufficient to confer standing: (1) “a history of past enforcement

against the plaintiffs or others”; (2) “enforcement warning letters sent to the plaintiffs regarding their specific conduct”; (3) “an attribute of the challenged statute that makes enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action”; and (4) the “defendant’s refusal to disavow enforcement of the challenged statute against a particular plaintiff.”

Online Merchs. Guild v. Cameron, 995 F.3d 540, 550 (6th Cir. 2021) (quoting *McKay*, 823 F.3d at 869). “These *McKay* factors are not exhaustive, nor must each be established,” but plaintiffs must “point to some combination” of the factors to demonstrate a credible threat of enforcement. *Id.*; *McKay*, 823 F.3d at 869; *Plunderbund Media, L.L.C. v. DeWine*, 753 F. App’x 362, 366, 372 (6th Cir. 2018) (holding that plaintiffs failed to allege a “factual, non-conjectural basis for their fear of prosecution” where plaintiffs did not show a history of enforcement against them, there was no feature of the statute making enforcement easier, and the statute did not clearly apply to plaintiffs); *W.O. v. Beshear*, 459 F. Supp. 3d 833, 841 (E.D. Ky. 2020) (citing *Plunderbund*, 753 F. App’x at 367) (finding plaintiffs lacked standing where, on a motion for preliminary injunction, “even construed in the light most favorable to Plaintiffs, they fail to provide any allegation or point to any evidence which would establish any of these ‘*McKay* factors.’”); *Block v. Canepa*, No. 20-cv-3686, 2021 WL 1909650, at *3 (S.D. Ohio May 12, 2021) (“Courts find a credible threat exists when some combination of these factors are present.”).

Plaintiffs can point to no facts relating to any of these factors to support their contention that they face a credible threat of prosecution under Section 1557. (See generally Doc. 15.) First, there is no history of enforcement against the plaintiffs or others. Plaintiffs allege, “[u]pon information and belief, OCR is now actively investigating, enforcing, and implementing an interpretation of Section 1557 and HHS regulations under which sex discrimination includes gender identity and sex stereotyping.” (*Id.* at 16.) But Plaintiffs do not set forth any facts to support such an inference beyond the mere existence of the *Walker* and *Whitman Walker Clinic*

injunctions and the *Bostock* Notification.⁴ See *Bickerstaff v. Lucarelli*, 830 F.3d 388, 396 (6th Cir. 2016) (“[W]e need not accept as true any conclusory legal allegations that do not include specific facts necessary to establish the cause of action. The plaintiff’s complaint instead must contain either direct or inferential allegations with respect to all material elements necessary to sustain a recovery under some viable legal theory.”) (internal quotation marks and citations omitted). Plaintiffs certainly have not alleged HHS has any history of enforcing Section 1557 against them. (See generally Doc. 15.) Even if HHS were enforcing Section 1557 against other entities, Plaintiffs still would not meet their burden to establish a credible threat of prosecution, because they must allege that the “same conduct” in which Plaintiffs intend to engage “has drawn enforcement actions or threats of enforcement in the past.” *Kiser v. Reitz*, 765 F.3d 601, 609 (6th Cir. 2014) (citing *Steffel*, 415 U.S. at 459); see also *Doe v. Yost*, No. 3:20-cv-10, 2021 WL 1185807, at *3 (S.D. Ohio Mar. 30, 2021) (finding the plaintiff failed to establish a credible threat of prosecution where her conduct was not sufficiently similar to the previous conduct that had triggered prosecutions under the same statute). Plaintiffs make no allegations regarding what type of conduct has drawn or is drawing enforcement actions under Section 1557, much less that the refusal to perform gender-transition services for medical, ethical, and religious reasons has precipitated enforcement actions. (See Doc. 15.)

Second, Plaintiffs also did not allege that they have received any enforcement warning letters from HHS regarding their refusal to perform gender-transition services. (See generally Doc. 15.) Plaintiffs nonetheless contend that the *Bostock* Notification is evidence that HHS has

⁴ Consistent Plaintiffs’ failure to assert these facts, HHS represented in its memorandum in support of its motion to dismiss that “HHS has never enforced Section 1557 to revoke the funding of a provider for failure to provide gender-transition services . . . ,” and Plaintiffs did not dispute this in their response. (Doc. 52, at 24–25, 32; see generally Doc. 55; Doc. 57, at 5.)

“expressed a credible threat of enforcing the § 1557 mandate” because it states that it was issued “to inform the public that, consistent with [*Bostock*], beginning May 10, 2021, [HHS] will interpret and enforce section 1557 of the Affordable Care Act prohibition on discrimination on the basis of sex to include: Discrimination on the basis of sexual orientation; and discrimination on the basis of gender identity.” *Bostock* Notification, 86 Fed. Reg. at 27,984; (Doc. 55, at 28). But the *Bostock* Notification says nothing about whether this interpretation would require anyone, much less Plaintiffs, to engage in the objectionable practices, and it explicitly states both that the *Bostock* Notification “does not itself determine the outcome in any particular case or set of facts,” and that “OCR will comply with [RFRA] and all other legal requirements.” *Bostock* Notification, 86 Fed. Reg. at 27,984, 27,985. In *McKay*, the plaintiff argued that signs posted, which stated that violation of the challenged provisions “may result in contempt sanctions[,]” gave rise to a threat of enforcement. 823 F.3d at 869. The Sixth Circuit held that the signs did not weigh in favor of finding a credible threat of enforcement against the plaintiff, because “the signs in the present case address the general public, not McKay specifically or any of his past conduct, and the signs also reference the possibility of an exemption by judicial permission.” *Id.* at 869–870. Similarly, here, the *Bostock* Notification does not support either of the *McKay* factors (history of past enforcement or enforcement warning letters sent to the plaintiffs regarding their specific conduct), because the *Bostock* Notification is explicitly addressed to the public, not to Plaintiffs, and it references the possibility for RFRA exemptions. *See id.*

Third, there is no feature of Section 1557 that makes it easier to enforce against Plaintiffs, such as a citizen-enforcement provision. To the contrary, HHS’s enforcement process under Section 1557 is lengthier than those of commonly challenged state civil and criminal statutes that are often examined for standing. *See, e.g., Plunderbund*, 753 F. App’x at 371 (holding plaintiffs

did not have standing to challenge a state criminal law prohibiting “telecommunication . . . with purpose to abuse, threaten, or harass another person” and no feature of the law made it easier to enforce, because “[o]nly law enforcement officials can investigate a claim of telecommunications or cyber-harassment, and only prosecutors can bring charges.”). HHS’s enforcement process offers regulated entities many procedural protections prior to any funding loss. *See Colwell v. Dep’t of Health & Hum. Servs.*, 558 F.3d 1112, 1128–29 (9th Cir. 2009) (finding plaintiffs’ claims unripe) (“If HHS initiates compliance proceedings against Plaintiffs based on the 2003 Policy Guidance, Plaintiffs will have an opportunity to challenge the Policy Guidance on the same legal bases on which they rely in the suit now before us.”). HHS would first be required to attempt to achieve voluntary or informal compliance with the regulated entity. 45 C.F.R. § 80.8(c). Then, there must be a formal adjudication and an administrative hearing finding noncompliance with a regulation. *Id.* After that, HHS must submit to the House and Senate committees having legislative jurisdiction over the programs at issue a full written report of the circumstances and grounds for such an action and wait an additional thirty days before terminating funding. *Id.* Finally, any enforcement under Section 1557 is subject to judicial review in an Article III court. 42 U.S.C. § 18116 (“The enforcement mechanisms provided for and available under such title VI, title IX, section 794, or such Age Discrimination Act shall apply for purposes of violations of [Section 1557].”); 20 U.S.C. § 1683 (“Any department or agency action taken pursuant to [Title IX] shall be subject to such judicial review as may otherwise be provided by law for similar action taken by such department or agency on other grounds.”); *Tennessee v. United States Dep’t of Educ.*, No. 3:21-cv-308, 2022 WL 2791450, at *18 (E.D. Tenn. July 15, 2022) (“The right to judicial review under the APA extends to agency actions ‘except to the extent that—(1) statutes preclude judicial review; or (2) agency action is

committed to agency discretion by law.”).

At each point in any putative enforcement process, Plaintiffs would be able to raise the same claims they now raise (well before any enforcement action has been taken), and HHS or the reviewing court would be able to determine the merits of their claims with the benefit of further factual development, such as the nondiscriminatory reasons offered by the provider for the refusal to perform a specific medical procedure, evidence supporting those reasons, any evidence suggesting that such reasons were pretextual, and the provider’s entitlement to a religious exemption. *See Ky. Press Ass’n, Inc. v. Kentucky*, 454 F.3d 505, 509 (6th Cir. 2006) (“Ripeness is a justiciability doctrine designed ‘to prevent the courts, through premature adjudication, from entangling themselves in abstract disagreements.’”) (quoting *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580 (1985)); *Hallandale Pro. Fire Fighters Loc. 2238 v. City of Hallandale*, 922 F.2d 756, 760 (11th Cir. 1991) (“Because both standing and ripeness analyses look to the existence of actual injury to the plaintiff caused by the alleged wrong, they overlap to some degree and often collapse into each other.”).

Finally, Plaintiff has not alleged HHS’s “refusal to disavow enforcement” against them. *See McKay*, 823 F.3d at 869. HHS has not taken *any* position, whatsoever, on enforcement against these Plaintiffs, besides its assurance in the *Bostock* Notification that it will comply with the *Franciscan Alliance* injunction, which precludes enforcement of Section 1557 against Dr. Jeannie Dassow, and potentially other Plaintiffs who are members of both ACPeds or CMA and CMDA, the organization protected from enforcement in *Franciscan Alliance*. *See Franciscan All. V.*, 47 F.4th at 379–80 (affirming injunction against enforcement of Section 1557 in a way that would require CMDA members to perform gender-transition services); *Bostock* Notification, 86 Fed. Reg. at 27,985 n.9–12 (assuring regulated entities that HHS would comply applicable

court orders, including *Franciscan Alliance*); (Doc. 15-3, at 3, 9; Doc. 52, at 26, 28, 32; Doc. 57, at 8). This does not amount to a “refusal to disavow enforcement.” *McKay*, 823 F.3d at 869 (emphasis added); *Thiede v. Burcroff*, No. 16-13650, 2018 WL 465968, at *14 (E.D. Mich. Jan. 18, 2018) (“And he does not credibly allege that Defendants have refused to disavow enforcement of Policy #34. (Contrary to Plaintiff’s assertion [], silence as to enforcement of Policy #34 does not amount to a refusal to disavow enforcement.)”) (parenthetical in original). Indeed, HHS’s consistent position has been that any enforcement would depend on the particular facts of the action, including the nondiscriminatory reasons for refusing to offer a specific service and the applicability of RFRA and other legal requirements. (Doc. 52, at 26, 28, 32; Doc. 57, at 8); *Bostock* Notification 86 Fed. Reg. at 27,985 (The *Bostock* Notification “does not itself determine the outcome in any particular case or set of facts.”). Accepting as true Plaintiffs’ allegations that they have nondiscriminatory scientific and medical concerns regarding the objectionable practices and that RFRA protects them from engaging in the objectionable practices, HHS’s position can hardly be construed as a “refusal to disavow enforcement” against Plaintiffs. (See Doc. 15, at 2, 26, 33–34, 63–66.)

Therefore, Plaintiffs have not alleged that they face “some combination” of *McKay* factors so as to establish that they face a credible threat of prosecution or that their alleged injury is “certainly impending.” See *Daly*, 2021 WL 7543815, at *2–3. To the contrary, the *McKay* factors weigh against Plaintiffs’ standing given that Plaintiffs have received no enforcement warning letters, the features of the statute make it considerably arduous for HHS to enforce, and HHS has not refused to disavow enforcement of the statute against Plaintiffs. The Sixth Circuit has “declined to find a credible threat of prosecution—and, thus, declined to find pre-enforcement standing—where,” as here, “plaintiffs have failed to show such a combination and

where ‘the record is silent as to whether the [defendants] threatened to punish or would have punished’ a plaintiff for proposed conduct that might violate the challenged policy or statute.” *McKay*, 823 F.3d at 869 (quoting *Morrison v. Bd. of Educ. of Boyd Cnty.*, 521 F.3d 602, 611 (6th Cir. 2008)) (alteration in original).

c. Availability of Exemptions

The *McKay* factors, however, are “not exhaustive.” *Online Merch. Guild*, 995 F.3d at 550. From the Court’s review of the amended complaint, Plaintiffs do not allege any other feature of Section 1557 that would render their injuries “certainly impending.” (*See generally* Doc. 15.) Further, in addition to the *McKay* factors, the availability of a religious exemption to protect Plaintiffs from enforcement cuts against any argument that they face a credible threat of prosecution. *See Ky. Press Ass’n*, 454 F.3d at 509. *Kentucky Press Association* stands for the proposition that, where plaintiffs’ intended conduct is arguably restricted by a policy, but it contains a vague exemption, by which the plaintiffs are arguably protected from enforcement of the policy, the plaintiffs do not have standing until the exemption has been interpreted so as not to protect them:

[T]hat the Kentucky courts would deny [the Kentucky Press Association] the access it seeks is far from certain. K.R.S. § 610.070(3) allows a judge to grant access to juvenile proceedings to “such persons admitted as the judge shall find have a direct interest in the case or in the work of the court,” and under K.R.S. § 610.340(1)(a) juvenile records may be disclosed to “persons authorized to attend a juvenile court hearing pursuant to KRS 610.070” and when “ordered by the court for good cause.” The Kentucky courts could reasonably interpret these provisions to allow for limited access to juvenile proceedings by the media, which arguably has a “direct interest in the . . . work of the court.”⁵

⁵ The Court notes that this holding goes to ripeness, a justiciability doctrine that is distinct from standing. *Ky. Press Ass’n*, 454 F.3d at 509. However, “[t]here is unquestionably some overlap between ripeness and standing. When the injury alleged is not actual but merely threatened, standing and ripeness become more difficult to distinguish.” *Airline Professionals Association of the International Brotherhood of Teamsters, Local 1224CIO v. Airborne, Inc.*, 332 F.3d 983,

Ky. Press Ass’n, 454 F.3d at 509.

This Sixth Circuit precedent stands in opposition to the Fifth Circuit precedent in *Speech First*, which held that a vague exemption that could arguably protect the plaintiffs from enforcement is not sufficient to defeat standing when the plaintiffs’ intended conduct was still “arguably restricted.” In *Franciscan Alliance V*, the Fifth Circuit relied on *Speech First* to determine that HHS’s promise to comply with RFRA and all other legal requirements was insufficient to defeat standing, because the plaintiffs’ conduct was still “arguably” restricted, and the exemption had not been interpreted such that the scope of liability was knowable. 47 F.4th. at 377 (quoting *Speech First*, 979 F.3d. at 338). In the Sixth Circuit, the fact that there exists an exemption to enforcement, under which Plaintiffs are arguably protected from enforcement of

988 (6th Cir. 2003) (internal citation omitted) (citing *Warth v. Seldin*, 422 U.S. 490, 499 n.10 (1975) (“The standing question thus bears close affinity to questions of ripeness—whether the harm asserted has matured sufficiently to warrant judicial intervention.”)). The first factor in the ripeness inquiry is “the likelihood that the harm alleged by the plaintiffs will ever come to pass,” which overlaps with whether there is a credible threat of prosecution so as to render ripeness precedents useful analysis under this prong of the standing inquiry. *See, e.g., id.*; *Ky. Press Ass’n*, 454 F.3d at 509. Nonetheless, to the extent Plaintiffs would contend this exemption analysis would only apply to ripeness, not standing, the Court would find that their claims are unripe as much as they lack standing. In addition to the unlikelihood that the injury would ever come to pass in light of the RFRA exemption and the lack of threatened or actual enforcement, the other two factors of the ripeness inquiry weigh against finding Plaintiffs’ claims to be ripe. *See Ky. Press Ass’n*, 454 F.3d at 509. The second prong is “whether the factual record is sufficiently developed to produce a fair adjudication of the merits of the parties’ respective claims,” which, as discussed, it is not here because there are no facts alleged regarding a particular patient, seeking a particular medical procedure, with their medical provider giving particular reasons, whether discriminatory or nondiscriminatory, for their refusal to perform the procedure. *See id.*; *supra* Section III.A.ii.b. The third ripeness factor is “the hardship to the parties if judicial relief is denied at this stage in the proceedings.” *Ky. Press Ass’n*, 454 F.3d at 509. In this case, there is little to no hardship to the parties because Plaintiffs could raise these exact same claims, albeit in a more developed factual context, at any point after HHS initiated some kind of enforcement proceeding against them—even if HHS merely sends an enforcement-warning letter to them. *See supra* Section III.A.ii.b.; 45 C.F.R. § 80.8(c). Therefore the Court also finds Plaintiffs’ claims unripe.

Section 1557, and the fact that the exemption has not yet been interpreted so as not to provide such protection, cuts against standing under *Kentucky Press Association*.

In this case, HHS represents that it

has consistently stated that it will abide by RFRA in any enforcement of Section 1557, has never enforced Section 1557 to require a provider with a religious objection to perform gender transition services, and has recently proposed a robust procedural mechanism to protect providers' rights under RFRA and other religious freedom laws.

(Doc. 57, at 7.) The regulatory record supports this contention. The 2016 Rule stated that “[i]nsofar as the application of any requirement under this part would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.” 2016 Rule, 81 Fed. Reg. at 31,466. The *Bostock* Notification further assured that in applying Section 1557, HHS “will comply with the [RFRA] and all other legal requirements.” *Bostock* Notification, 86 Fed. Reg. at 27,985. Most recently, HHS issued a notice of proposed rulemaking that would interpret Section 1557 to prohibit gender-identity discrimination, but it would not require regulated entities to provide any specific services if the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service and proposes a process for covered entities to assert claims for religious exemptions. *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824-01, 47,828 (Aug. 4, 2022) (“[T]he Department proposes to adopt a process by which recipients may inform the Department of their views that the application of a specific provision or provisions of this part to them would violate Federal conscience or religious freedom laws, so that the Department may, as appropriate, make a determination that recipients are exempt from, or entitled to a modification of the application of, a provision or provisions of this part.”). Under *Kentucky Press Association*, the availability of a religious-freedom exemption to HHS’s enforcement of Section 1557 cuts against the credibility

of any threat of enforcement in this case.⁶ 454 F.3d at 509; *cf. Miller v. City of Wickliffe*, 852 F.3d 497, 506 (6th Cir. 2017) (holding plaintiffs did not have standing where they “were not required to censor themselves, at this point, to avoid violating the Ordinance. Instead, plaintiffs needed only to apply for a license to discover whether they could open their businesses.”).

Additionally, in *R.K. v. Lee*, No. 22-5004, slip op. at 4 (6th Cir. Nov. 18, 2022), the Sixth Circuit held that the plaintiffs, students with disabilities that make them particularly susceptible to COVID-19, failed to show that a Tennessee statute prohibiting schools from mandating face

⁶ However, there are some Plaintiffs, the non-religious members of ACPeds, who have only ethical, scientific, or medical objections to the objectionable practices, rather than religious objections. (*See* Doc. 15-1, at 5, 10.) As such, the non-religious members of ACPeds may not be entitled to a religious exemption under RFRA from enforcement of Section 1557 against them. But even without the availability of a religious exemption, the non-religious Plaintiffs still have not met their burden to show standing, because they did not allege a credible threat of enforcement under the *McKay* factors. *See supra* Section III.A.ii.b. Additionally, not only has HHS consistently stated that its enforcement decisions would depend on the fact-specific RFRA analysis for religious providers, but also that its enforcement decisions would depend on nondiscriminatory reasons given for a refusal to perform a service, such as a bona fide treatment decision based on scientific and medical concerns. (Doc. 52, at 28–29; Doc. 57, at 4.) This position is also supported by the regulatory record. In HHS’s recent notice of proposed rulemaking to replace the 2016 Rule, the proposed replacement rule would “not require health care professionals to perform services outside of their normal specialty area,” and further would “not compel a provider to prescribe a specific treatment that the provider decides not to offer after making a nondiscriminatory bona fide treatment decision.” *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. at 47,867.

For example, a family practice covered by the rule would not be required to provide transition-related surgery where surgical care is not within its normal area of practice. Nor would the proposed rule require a pediatrician to prescribe hormone blockers for a prepubescent gender-nonconforming minor if that health care provider concluded, pursuant to a nondiscriminatory bona fide treatment decision, that social transition was the clinically indicated next step for that child.

Id. HHS’s position that its enforcement decisions will account for the bona fide, nondiscriminatory reasons for refusing specific treatments, therefore, weighs against finding a credible threat of prosecution for the non-religious Plaintiffs who allege that they have scientific and medical objections to engaging in the objectionable practices. Considering this and considering that the non-religious Plaintiffs also failed to demonstrate the presence of any of the *McKay* factors, they have not shown a credible threat of prosecution under Section 1557.

masks concretely injured them. Central to the Sixth Circuit’s reasoning was the fact that the statute contains an exception that allows students to request a reasonable accommodation, such as requiring any students within a six-foot bubble of the accommodated student to wear a face covering provided by the school. *Id.* “Equally significant is plaintiffs’ failure to test the practical effect of the Act by seeking an accommodation; instead, they filed this suit on the heels of the Act’s passage.” *Id.* Similarly, in this case, Plaintiffs did not test the practical effect of the 2016 Rule by seeking a fact-specific religious exemption from HHS; instead, they filed this suit. (*See generally* Doc. 15.) Therefore, not only does the availability of an exemption that arguably protects Plaintiffs from enforcement cut against standing under *Kentucky Press Association*, but the fact that Plaintiffs did not test the practical effect of such an exemption by requesting coverage before filing this suit also undermines any argument that they have suffered a concrete injury under the Section 1557 Gender Identity Mandate. *See R.K. v. Lee*, No. 22-5004, slip op. at 4.

Given Plaintiffs’ failure to allege any of the *McKay* factors, the availability of a religious exemption by which they are arguably protected from enforcement, which has not yet been interpreted otherwise, the fact that Plaintiffs filed this lawsuit before seeking an exemption, and the Supreme Court’s mandate that the standing inquiry is “especially rigorous when reaching the merits of the dispute would force [a court] to decide the constitutionality of an action taken by one of the other two branches of the Federal Government,” the Court finds Plaintiffs have not established standing as to their claims. *See Raines v. Byrd*, 521 U.S. 811, 811 (1997). Accordingly, the Court lacks jurisdiction to hear their claims and will **GRANT** Defendants’ motion to dismiss (Doc. 52) as to Plaintiffs’ Section 1557 claims.

B. 2016 Grants Rule Claims

Plaintiffs also lack standing to bring their claims against the 2016 Grants Rule. Plaintiffs do not allege that HHS has any history of enforcing the 2016 Grants Rule against them or others, or that Plaintiffs have received any sort of enforcement warning regarding the 2016 Grants Rule. Indeed, the history of enforcement under the 2016 Grants Rule is even more barren than that of Section 1557 because the presidential administration changed eight days after the rule first became effective, resulting in HHS never having enforced the 2016 Grants Rule against *anyone* for *any* form of discrimination. *See* 2021 Grants Rule, 86 Fed. Reg. at 2,273. Plaintiffs also fail to allege that the 2016 Grants Rule has any feature making enforcement easier or more likely, such as a citizen enforcement provision. (*See generally* Doc. 15.) Indeed, like Section 1557, the administrative enforcement process is lengthier than a typical state statute, even one without a citizen-enforcement provision, and subject to judicial review. *See* Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 79 Fed. Reg. at 75,919.

Further, while HHS was “silent” on whether it would enforce Section 1557 against Plaintiffs, which did not amount to a refusal to disavow enforcement against them, HHS went a step further for the 2016 Grants Rule by *expressly disavowing* any enforcement against Plaintiffs, or any other regulated entity, in the Notification of Nonenforcement. Notification of Nonenforcement, 84 Fed. Reg. at 63,809-01. Two other district courts, which follow the Fifth Circuit’s more permissive standing doctrines, *see supra* Section III.A.ii.a., c., have found that plaintiffs had no standing to challenge the 2016 Grants Rule in light of this express disavowal of enforcement. *Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546, 558 (N.D. Tex. 2020) (“Defendants

have expressly disavowed enforcement of § 75.300(d). With the limited authority to file suit, this means Vita Nuova stands a negligible chance of being prosecuted under § 75.300(d). Because there exists little to no credible threat of enforcement related to 45 C.F.R. § 75.300(d), Vita Nuova’s second claim cannot survive Defendants’ Motion to Dismiss.”); *Tex. Dep’t of Fam. & Protective Servs. v. Azar*, 476 F. Supp. 3d 570, 578 (S.D. Tex. 2020) (finding the plaintiffs lacked standing because “HHS unequivocally states that it will not enforce the challenged provisions pending repromulgation”). Plaintiffs argue that they are no longer protected by the Notification of Nonenforcement since the 2016 Grants Rule is no longer pending repromulgation, because HHS repromulgated the rule already with the 2021 Grants Rule but then voluntarily vacated it. (Doc. 55, at 26–27.) Not only is this argument a reach because HHS still has not effectively promulgated a replacement rule and so is still “pending repromulgation,” but also, even if the Court accepted such an argument, it still would not render HHS’s actions a “refusal to disavow enforcement” against Plaintiffs under the *McKay* factors. Therefore, Plaintiffs also lack standing as to their 2016 Grants Rule claims, so Defendants’ motion to dismiss will be **GRANTED**.

C. SUNSET Rule Claims

In their response to Defendants’ motion to dismiss, Plaintiffs represent that “[b]ecause HHS repealed the SUNSET Rule through rulemaking earlier this year, Plaintiffs do not oppose dismissal of Claim Seven of their Amended Complaint. Plaintiffs reserve the possibility of bringing claims related to that rule in the future, and so ask that the dismissal be without prejudice.” (Doc. 55, at 13.) In their reply brief, Defendants do not oppose Plaintiffs’ request that their SUNSET Rule claims be dismissed without prejudice. (*See generally* Doc. 57.) Therefore, the motion to dismiss is **GRANTED** with respect to Plaintiffs’ SUNSET Rule claims,

which will be **DISMISSED WITHOUT PREJUDICE**. See *Walther v. Fla. Tile, Inc.*, 776 F. App'x 310, 315 (6th Cir. 2019) (“Whether voluntary dismissal should be granted under Rule 41(a)(2) is within the sound discretion of the district court. The primary purpose of Rule 41(a)(2)’s requirement of a court order is to protect the nonmovant from unfair treatment. ‘[A]n abuse of discretion is found only where the defendant would suffer plain legal prejudice as a result of a dismissal without prejudice, as opposed to facing the mere prospect of a second lawsuit.’” (citing *Grover by Grover v. Eli Lilly & Co.*, 33 F.3d 716, 718 (6th Cir. 1994)) (internal citations omitted)).

IV. CONCLUSION

For these reasons, the Court **GRANTS** Defendants’ motion to dismiss (Doc. 52). Plaintiffs’ claims are **DISMISSED WITHOUT PREJUDICE**.⁷

AN APPROPRIATE JUDGMENT SHALL ENTER.

/s/ Travis R. McDonough

**TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE**

⁷“Traditionally, when courts find that they lack standing and therefore must dismiss a case due to lack of subject matter jurisdiction, they dismiss the case without prejudice because they did not reach the merits of the Plaintiff’s claim.” *Thompson v. Equifax Info. Servs., L.L.C.*, 441 F. Supp. 3d 533, 547 n.7 (E.D. Mich. 2020) (citing *Thompson v. Love’s Travel Stops & Country Stores, Inc.*, 748 F. App’x. 6, 11 (6th Cir. 2018)).