

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

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

Plaintiffs,

v.

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

Defendants.

No. 1:21-cv-00195-TRM-SKL

**MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS FIRST AMENDED COMPLAINT**

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INTRODUCTION

In this lawsuit, Plaintiffs challenge a supposed mandate that Defendant U.S. Department of Health and Human Services (“HHS”) has not in fact imposed, they challenge a regulation that HHS has stated publicly that it will not enforce, and they argue that a since-rescinded regulation that has now been rescinded should have gone into effect sooner. None of these challenges presents a case or controversy under Article III.

First, Plaintiffs challenge a supposed “gender identity mandate,” *e.g.*, Am. Compl. ¶ 39.a, that they claim HHS has imposed under Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116, a statute that prohibits discrimination on a variety of grounds (including sex) in federally funded health programs. Plaintiffs claim HHS has mandated that healthcare providers perform all kinds of gender transition services, even providers who have religious objections. Plaintiffs’ claim begins from a false premise: HHS has not imposed such a mandate. Tellingly, Plaintiffs cannot point to a *single* instance in which HHS has enforced such a “mandate,” nor can it identify any operative HHS regulations or guidance reflecting this so-called “gender identity mandate.”

To be sure, HHS has made clear that Section 1557’s prohibition on sex discrimination extends to gender-identity discrimination. But that is little more than an application of the Supreme Court’s reasoning that “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.” *Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1741 (2020). HHS has not issued regulations stating that the specific policies and actions identified by Plaintiffs fall within the scope of unlawful gender-identity discrimination, and HHS has consistently affirmed that the Religious Freedom Restoration Act (“RFRA”) and other religious defenses may be raised, on a case-by-case basis, to a charge of discrimination. The Supreme Court itself cautioned that determining what

“policies and practices” qualify as gender-identity discrimination, as well as how that proscription interacts with religious liberty laws, posed questions for “future cases.” *Id.* at 1753.

But this is not that future case. Plaintiffs do not present a concrete dispute between one of its member’s practices or beliefs and HHS’s enforcement actions; instead, they seek only to enjoin how HHS *might* interpret Section 1557 in the future and then *might* choose to enforce the law against Plaintiffs or their members. Such a conjectural theory of harm does not supply the “actual or imminent” injury required for Article III standing, *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 409 (2013), nor does it present the “concrete factual context” required for a ripe controversy, *Warshak v. United States*, 532 F.3d 521, 525 (6th Cir. 2008) (en banc).

Second, Plaintiffs challenge a 2016 HHS regulation concerning recipients of grants (the “2016 Grants Rule”), but HHS has expressly stated, in a notice published in the Federal Register, that it will not enforce the 2016 Grants Rule. Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809, 63,811 (Nov. 19, 2019). Plaintiffs accordingly cannot establish either that they have suffered any injury in fact to support standing or that their claims are ripe for adjudication. Plaintiffs’ alleged harm is entirely speculative. Indeed, two district courts recently dismissed similar challenges to the same rule based, respectively, on lack of standing and mootness. *See Vita Nuova, Inc. v. Azar*, 458 F. Supp. 3d 546, 558 (N.D. Tex. 2020); *Tex. Dep’t of Fam. & Protective Servs. v. Azar*, 476 F. Supp. 3d 570, 580 (S.D. Tex. 2020).

Third, Plaintiffs challenge HHS’s delay of effectiveness of a now-rescinded regulation called the SUNSET Rule. The SUNSET Rule would have required HHS to conduct periodic assessments and reviews of existing regulations, with the first reviews due in 2026. Prior to this lawsuit, HHS invoked its authority under 5 U.S.C. § 705 to postpone the SUNSET Rule’s March

2021 effective date. After Plaintiffs filed the Amended Complaint, however, HHS issued a new rule rescinding the SUNSET Rule. Plaintiffs challenge only the SUNSET Rule’s initial postponement, but now that HHS has rescinded the rule, a judicial opinion on the postponement’s lawfulness would be an advisory opinion with no practical effect on the parties. In any event, Plaintiffs lacked standing when they filed their claim because their claimed injury – the inability to participate in regulatory reviews due in 2026 – hardly qualified as “imminent.” *Clapper*, 568 U.S. at 409.

Because none of Plaintiffs’ claims presents a case or controversy under Article III, the Court should dismiss the First Amended Complaint for lack of subject-matter jurisdiction.¹

BACKGROUND

I. Statutory and Regulatory Background

A. Affordable Care Act § 1557

1. Section 1557

Section 1557 of the ACA prohibits, as relevant here, “any health program or activity” “receiving Federal financial assistance” from discriminating against an individual based on “ground[s] prohibited under” several other statutes. 42 U.S.C. § 18116(a). One of the referenced statutes is Title IX of the Education Amendments of 1972, which prohibits discrimination “on the basis of sex.” 20 U.S.C. § 1681(a).

2. 2016 Rule and Subsequent Litigation

In 2016, HHS promulgated a rule implementing the anti-discrimination requirements of Section 1557. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376

¹ Defendants also believe that Plaintiffs’ claims suffer from many defects on the merits. Given the plain jurisdictional defects in Plaintiffs’ claims, however, Defendants focus on jurisdictional issues in this motion.

(May 18, 2016) (“2016 Rule”). As relevant here, the 2016 Rule defined discrimination “on the basis of sex” to include discrimination on the basis of “gender identity.” *See id.* at 31,467. The 2016 Rule listed several practices that would be deemed discriminatory, including the categorical exclusion of providing or covering gender-transition services. *Id.* at 31,471-72. The 2016 Rule stated that the Rule’s “application shall not be required” insofar as it “would violate applicable Federal statutory protections for religious freedom and conscience.” 81 Fed. Reg. at 31,466.

Several lawsuits followed challenging the 2016 Rule. In December 2016, a district court issued a nationwide preliminary injunction enjoining HHS “from enforcing the [2016] Rule’s prohibition against discrimination on the basis of gender identity.” *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016). In 2019, the *Franciscan Alliance* court issued a final judgment vacating the 2016 Rule “insofar as the [2016] Rule define[d] ‘on the basis of sex’ to include gender identity.” Order at 2, *Franciscan All. Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019) (Civ. A. No. 7:16-cv-00108), ECF No. 182 (quotation marks omitted); *see also Franciscan All.*, 414 F. Supp. 3d at 941-946 (explaining court’s reasoning for vacating rule).

3. 2020 Rule and Subsequent Litigation

In June 2020, HHS finalized a new rule implementing Section 1557. *See* Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37,160 (June 19, 2020) (“2020 Rule”). As relevant here, the 2020 Rule rescinded the 2016 Rule’s provisions defining sex discrimination, including the portion regarding gender identity. *See id.* at 37,162-65. In place of those provisions, the 2020 Rule paraphrased the statutory language without adopting a new regulatory definition of sex discrimination. *See id.* at 37,178. In addition, the 2020 Rule stated that HHS interpreted the religious exemptions provided by Title IX to apply under Section 1557. *See id.* at 37,204-09. In the 2020 Rule’s

preamble, HHS explained that it did not believe that either Section 1557 or Title IX prohibited gender-identity discrimination. *See id.* at 37,162, 37,168, 37,183-86, 37,207.

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 Court held that Title VII’s prohibition of discrimination “because of . . . sex” includes discrimination because of sexual orientation and transgender status. *Id.* at 1737-1741.

Following *Bostock*, plaintiffs in several district courts challenged the 2020 Rule under the Administrative Procedure Act (APA). *See, e.g., Washington v. HHS*, No. 2:20-cv-1105 (W.D. Wash. July 16, 2020); *Whitman-Walker Clinic, Inc. v. HHS*, No. 1:20-cv-1630 (D.D.C. June 22, 2020); *Walker v. Azar*, No. 1:20-cv-2834 (E.D.N.Y. June 26, 2020). Two district courts issued preliminary injunctions barring HHS from enforcing its repeal of the 2016 regulatory definition of sex discrimination as including discrimination on the basis of sex stereotyping, and one court enjoined HHS from enforcing the 2020 Rule’s incorporation of Title IX’s religious exemption. *See Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 64 (D.D.C. 2020); *Walker v. Azar*, 480 F. Supp. 3d 417, 427 (E.D.N.Y. 2020); *Walker v. Azar*, No. 1:20-cv-2834, 2020 WL 6363970 (E.D.N.Y. Oct. 29, 2020). Both district courts acknowledged that their orders did not affect the *Franciscan Alliance* court’s vacatur of the 2016 Rule insofar as it construed § 1557 to prohibit gender-identity discrimination. *See Whitman-Walker*, 485 F. Supp. 3d at 14 (acknowledging *Franciscan Alliance* vacatur); *Walker*, 480 F. Supp. 3d at 427 (same).

4. *May 2021 Bostock Notification*

On May 10, 2021, HHS issued a notification to inform the public that, consistent with *Bostock* and Title IX, HHS would interpret and enforce Section 1557’s prohibition of sex discrimination as including discrimination based on sexual orientation and gender identity.

Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and

Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984 (May 25, 2021) (the “Notification”). HHS stated that “[t]his interpretation will guide [HHS Office of Civil Rights] in processing complaints and conducting investigations, but does not itself determine the outcome in any particular case or set of facts.” *Id.* at 27,985. The notification explicitly states that HHS “will comply with the Religious Freedom Restoration Act, 42 U.S.C. 2000bb *et seq.*, and all other legal requirements.” *Id.* (footnote omitted).

B. HHS’s Grants Rules

HHS has established a regulatory framework that governs the administration of federal financial assistance provided by the agency, whether via grants or cooperative agreements. As part of this framework, in 2016, HHS promulgated a rule that prohibited “discrimination in the administration of HHS programs and services based on non-merit factors such as . . . gender identity,” 45 C.F.R. § 75.300(c), and also required grant recipients to “treat as valid the marriages of same-sex couples,” *id.* § 75.300(d)² (collectively, the “2016 Grants Rule”); *see also* Health and Human Services Grants Regulation, 81 Fed. Reg. 89,393, 89,395 (Dec. 12, 2016) (promulgating 2016 Grants Rule).

Nine days after the 2016 Grants Rule became effective, a change in administrations occurred, after which “the Department and its grantmaking agencies did not make, and have not made, any concerted effort to obtain recipient compliance with” the rule. 86 Fed. Reg. 2,257, 2,273 (Jan. 12, 2021). In November 2019, HHS published a notification in the Federal Register that “the regulatory actions, promulgated through the December 12, 2016 final rules, 81 Fed. Reg. 89393, namely, the additions of . . . 75.300(c) and (d) . . . will not be enforced pending

² The provision of the 2016 Grants Rule concerning same-sex couples is not directly relevant to this action but is relevant to other litigation involving the 2016 Grants Rule, described *infra* pp. 26-27.

repromulgation.” Notification of Nonenforcement of Health and Human Services Grant Regulation, 84 Fed. Reg. 63,809, 63,811 (Nov. 19, 2019) (hereinafter “Notice of Nonenforcement”). Accordingly, HHS has never enforced the 2016 Grants Rule.

HHS subsequently issued a final rule on January 12, 2021, with an effective date of February 11, 2021, which eliminated the gender identity nondiscrimination requirement in HHS’s grants regulations. *See* 86 Fed. Reg. 2,257, 2,278 (“2021 Grants Rule”). As a result of litigation challenging the 2021 Grants Rule, its effective date was postponed on several occasions under 5 U.S.C. § 705. *See generally Facing Foster Care in Alaska v. HHS*, No. 1:21-cv-00308 (D.D.C. Feb. 2, 2021). Recently, HHS discovered anomalies in HHS’s review of the comments for the 2021 Grants Rule that led HHS to conclude that the rule was not promulgated in compliance with procedural requirements of the APA; HHS accordingly moved the *Facing Foster Care* court to remand the rule with vacatur, *Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 41 at 1 (D.D.C. June 17, 2022). In that motion, HHS reaffirmed the Notice of Nonenforcement, stating that “vacating the 2021 [Grants] Rule’s formal repeal of the 2016 [Grants] Rule will not cause disruption or change the status quo” because “the 2016 [Grants] Rule has never been enforced, and HHS has stated publicly that it will not enforce the 2016 [Grants] Rule pending promulgation of a new rule.” *Id.* at 8–9. The court granted the motion and vacated the 2021 Grants Rule. *See Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 44 (D.D.C. June 29, 2022).

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. 86 Fed. Reg. 5,694. The SUNSET Rule required HHS to conduct assessments or reviews of existing regulations, setting a deadline for such initial assessments or reviews of the later of five years

after the SUNSET Rule’s effective date or ten years after the promulgation of the regulation under review (therefore, the earliest possible deadline for any assessment or review was 2026); regulations not reviewed or assessed by those deadlines would automatically expire. *Id.* at 5,694.

On March 9, 2021, a lawsuit was filed challenging the SUNSET Rule under the APA. *County of Santa Clara v. HHS*, Case No. 5:21-cv-01655-BLF (N.D. Cal.). In response to the lawsuit, HHS twice delayed the SUNSET Rule’s effective date pursuant to 5 U.S.C. § 705. *See* 86 Fed. Reg. 15,404 (Mar. 23, 2021) (delaying effective date to March 22, 2022); 87 Fed. Reg. 12,399 (Mar. 4, 2022) (delaying effective date to September 22, 2022).

On May 27, 2022, HHS published a final rule “withdrawing the SUNSET final rule in its entirety,” effective July 26, 2022. 87 Fed. Reg. 32,246 (May 27, 2022). HHS explained that it was withdrawing the SUNSET Rule because, among other things, the SUNSET Rule would have had “considerable negative repercussions for a diverse array of stakeholders,” “gave insufficient weight” to comments that “raised compelling concerns that the SUNSET final rule would harm the public health and welfare,” “rested on flawed assumptions and analysis” that “likely underestimated to a significant degree the resources needed for the required undertaking,” and contained a regulation expiration provision that was “unsound and in our view unlawful.” *Id.* at 32,247-48, 32,280.

II. This Lawsuit

A. Plaintiffs’ Allegations

Plaintiffs are a physician, Jeanie Dassow, and two associations of healthcare professionals or providers: American College of Pediatricians (ACP) and Catholic Medical Association (CMA). Am. Compl. ¶¶ 14, 23, 32, ECF No. 15. ACP includes more than 600 healthcare professional members (“ACP Members”), *id.* ¶ 16, and CMA includes more than 2500 healthcare provider members (“CMA Members,” and collectively with ACP Members, the

“Members”), *id.* ¶ 194. Dassow and most Members provide medical care in health programs or activities receiving federal financial assistance, which would subject them to Section 1557. *Id.* ¶¶ 18, 27, 33. Dassow and some Members provide medical care in programs or entities receiving grants from HHS governed by HHS’s grants regulations. *Id.* ¶¶ 19, 28, 33.

Plaintiffs “have medical, ethical, or religious objections” to performing 22 activities related to gender transition (including providing puberty blockers, hormone therapy, and various surgeries for gender transition), which Plaintiffs call the “objectionable practices.” *Id.* ¶ 131. Plaintiffs assert that HHS has imposed a “gender identity mandate under Section 1557,” *id.* ¶ 39.a, under which “HHS requires” that they perform each of the “objectionable practices.” *Id.* ¶ 131. Plaintiffs “assum[e]” that the 2016 Rule’s provisions concerning gender identity are currently in effect and impose this mandate, but they suggest that the mandate may also derive from the Notification or from “Section 1557 itself.” *Id.* ¶ 82. Plaintiffs contend that the 2016 Grants Rule imposes a “second gender identity mandate on doctors who work in programs that receive grants from HHS.” *Id.* ¶ 39.b. Plaintiffs also assert that if HHS conducted assessments and reviews under the SUNSET Rule, they would submit comments on the 2016 Rule, the 2016 Grants Rule, and other rules. *Id.* ¶ 316.

B. Plaintiffs’ Claims

Plaintiffs bring five claims challenging the so-called “Section 1557 gender identity mandate,” claiming that this mandate violates the APA (Claim I), *id.* ¶¶ 352-83, First Amendment rights to freedom of speech and association (Claim II), *id.* ¶¶ 385-420, RFRA (Claim III), *id.* ¶¶ 422-442, the Free Exercise Clause (Claim IV), *id.* ¶¶ 444-459, and structural principles of federalism (Claim V), *id.* ¶¶ 461-476. Plaintiffs also challenge the so-called “Grants gender identity mandate,” claiming that it violates the APA, RFRA, the Free Exercise Clause, the Free Speech Clause, structural constitutional principles of federalism, the Spending

Clause, and the Tenth Amendment (Claim VI). *Id.* ¶¶ 478-517. Finally, Plaintiffs challenge the lawfulness of the delay of effectiveness of the SUNSET Rule (Claim VII). *Id.* ¶¶ 521-46.

Plaintiffs seek injunctive relief enjoining, vacating, or setting aside the challenged actions, and declaratory relief declaring the unlawfulness of the challenged actions. *See id.*, Prayer for Relief.

LEGAL STANDARD

A court lacks authority to adjudicate the merits of a plaintiff's claims unless it has subject-matter jurisdiction. *See, e.g., Sinochem Int'l Co. v. Malay. Int'l Shipping Corp.*, 549 U.S. 422, 430–31 (2007); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The plaintiff bears the burden of demonstrating subject matter jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Courts should “presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record.” *Renne v. Geary*, 501 U.S. 312, 316 (1991) (quotations omitted) (quoting *Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 546 (1986)).

“Where, as here, a case is at the pleading stage, the plaintiff must ‘clearly . . . allege facts demonstrating’ each element” of standing. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)). Standing is “the threshold question in every federal case.” *Warth*, 422 U.S. at 498; *see also Stalley v. Methodist Healthcare*, 517 F.3d 911, 916 (6th Cir. 2008) (stating that a dismissal for lack of standing is one for lack of subject matter jurisdiction under Rule 12(b)(1)); *Dealer Computer Services, Inc. v. Dub Herring Ford*, 547 F.3d 558, 560 (6th Cir. 2008) (same regarding ripeness); *Thompson v. DeWine*, 7 F.4th 521, 523 (6th Cir. 2021) (“if the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome, then the case is moot and the court has no jurisdiction”) (alterations and citations omitted).

ARGUMENT

“[N]o principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Clapper*, 568 U.S. at 408 (citation omitted). The case-or-controversy inquiry is “especially rigorous when reaching the merits of the dispute would force [a court] to decide whether an action taken by one of the other two branches of the Federal Government was” unlawful. *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997).

Where plaintiffs bring suit when no enforcement action has been taken against them, Article III doctrines of standing and ripeness are implicated. Under the doctrine of standing, a plaintiff must, *inter alia*, show it has suffered an injury that is “actual or imminent, not ‘conjectural’ or ‘hypothetical.’” *Susan B. Anthony List v. Driehaus (SBA List)*, 573 U.S. 149, 158 (2014) (quoting *Lujan*, 504 U.S. at 560). “[T]he Supreme Court has tightened the hatches on [the] requirement” for “imminent injury,” requiring a “certainly impending” injury, rather than a mere “allegation ‘of possible future injury.’” *Vonderhaar v. Vill. of Evandale, Ohio*, 906 F.3d 397, 401 (6th Cir. 2018) (quoting *Clapper*, 568 U.S. at 409). 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.’” *SBA List*, 573 U.S. at 159 (quoting *Babbitt v. Farm Workers*, 442 U.S. 289, 298 (1979)). But “[i]n the absence of contemporary enforcement, . . . a plaintiff claiming standing must show that the likelihood of future enforcement is ‘substantial.’” *California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

A plaintiff cannot satisfy Article III merely by alleging that it engages in conduct that it fears may violate federal law. *See, e.g., Clapper*, 568 U.S. at 410; *Zanders v. Swanson*, 573 F.3d 591, 594 (8th Cir. 2009); *Thomas v. Anchorage Equal Rights Comm’n*, 220 F.3d 1134, 1139 (9th

Cir. 2000). Likewise, “‘general threats by officials to enforce those laws which they are charged to administer’ do not create the necessary injury in fact” absent a more particularized basis for the plaintiff to fear enforcement. *Lopez v. Candaele*, 630 F.3d 775, 787 (9th Cir. 2010) (alteration omitted) (quoting *United Pub. Workers of Am. (C.I.O.) v. Mitchell*, 330 U.S. 75, 88 (1947)).

Lawsuits filed when there has been no enforcement action against plaintiffs also implicate the doctrine of ripeness. The ripeness doctrine seeks to prevent the adjudication of claims relating to “contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998) (citation omitted).

“The ripeness doctrine serves to ‘avoid[] . . . premature adjudication’ of legal questions and to prevent courts from ‘entangling themselves in abstract’ debates that may turn out differently in different settings.” *Warshak*, 532 F.3d at 525 (quoting *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 807 (2003)). The ripeness inquiry involves “two basic questions: (1) is the claim ‘fit[] . . . for judicial decision’ in the sense that it arises in a concrete factual context and concerns a dispute that is likely to come to pass? and (2) what is ‘the hardship to the parties of withholding court consideration’?”. *Id.* (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

Because federal courts “do not render advisory opinions,” *Golden v. Zwickler*, 394 U.S. 103, 108 (1969), they have “no authority to render a decision upon moot questions.” *United States v. City of Detroit*, 401 F.3d 448, 450 (6th Cir. 2005) (quoting *Cleveland Branch, N.A.A.C.P. v. City of Parma*, 263 F.3d 513, 530 (6th Cir. 2001)). “A case becomes moot—and therefore no longer a ‘Case’ or ‘Controversy’ for purposes of Article III—‘when the issues

presented are no longer “live” or the parties lack a legally cognizable interest in the outcome.””
Already, LLC v. Nike, Inc., 568 U.S. 85, 91 (2013).

Adherence to those principles ensures that federal courts remain within their assigned role in our system of separated powers. Yet Plaintiffs’ claims violate each of these principles. Plaintiffs lack standing for their Section 1557 claims because they challenge a mandate HHS has not imposed. Their claims present, at most, a speculative challenge to future legal interpretations and enforcement positions they predict HHS will take. Their Section 1557 claims are also unripe because HHS is still developing its legal interpretation of Section 1557, and any future dispute will hinge on concrete facts that have yet to be developed. Plaintiffs similarly lack standing or ripeness to challenge the 2016 Grants Rule, given HHS’s notice that it will not enforce that regulation. Finally, Plaintiffs suffered no imminent injury from the delay of the SUNSET Rule (which set deadlines for regulatory reviews no earlier than 2026), and their challenge is moot now that the SUNSET Rule has been rescinded.

I. The Court Lacks Jurisdiction Over Plaintiffs’ Section 1557 Claims

A. Plaintiffs Lack Standing To Challenge A Supposed Section 1557 Mandate that HHS Has Not Imposed

Plaintiffs lack standing to bring their Section 1557 claims for the simple reason that they seek to challenge the lawfulness of a position that HHS has not taken. Plaintiffs challenge the so-called “Section 1557 Gender Identity Mandate,” *e.g.*, Am. Compl. ¶¶ 87, 89, and ask this Court to declare this mandate unlawful and set it aside, *id.*, Prayer For Relief, § A. Plaintiffs claim that this mandate “requires” all doctors subject to Section 1557 to perform 22 practices and procedures related to gender transition, *id.* ¶ 131, with no religious exemptions available, *id.* ¶¶ 89-90. The First Amended Complaint essentially portrays HHS as having issued a binding regulation called the “Gender Identity Mandate” with 22 subsections listing the specific

procedures that all doctors must perform, and a separate section rejecting any religious exemptions. In fact, there is no such regulation.

Plaintiffs “proceed[] under the assumption” that the 2016 Rule’s provisions concerning gender identity are still in effect and impose the alleged gender identity mandate. But in 2019, the *Franciscan Alliance* court vacated the 2016 Rule “insofar as the [2016] Rule define[d] ‘on the basis of sex’ to include gender identity.” Order at 2, *Franciscan All. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019) (No. 7:16-cv-00108), ECF No. 182 (quotation marks omitted). The 2016 Rule’s gender identity provisions are therefore no longer in effect.

Plaintiffs contend that two subsequent district court decisions that enjoined parts of the 2020 Rule “restore[d] the 2016 ACA Rule’s gender identity language,” Am. Compl. ¶ 82, but that is incorrect. Both district courts recognized that they could not, and did not, revive a vacated regulation. The *Walker* court agreed with HHS that “it has no power to revive a rule vacated by another district court” and therefore “cannot revive the ‘gender identity’” language from the 2016 Rule. 480 F. Supp. 3d at 427 (citation omitted). The *Whitman-Walker* court similarly recognized that the *Franciscan Alliance* court’s “vacatur . . . renders the Court powerless to revive” the 2016 Rule’s gender identity provisions. 485 F. Supp. 3d at 26. As the court further explained, after the *Franciscan Alliance* vacatur, “the 2016 Rule’s original prohibition on discrimination based on gender identity was no longer part of the regulation. As a result, even if this Court were to grant Plaintiffs their desired relief and enjoin HHS from enforcing its repeal of the 2016 definition, the resulting regulation would not contain any language barring gender-identity discrimination.” *Id.*

HHS has taken the consistent position in litigation that the 2016 Rule’s gender identity provisions are no longer in effect³ and has not taken any action to enforce those provisions since their vacatur. To the extent there is any ambiguity in the *Walker* and *Whitman-Walker* orders, they should be read to avoid a conflict with the *Franciscan Alliance* vacatur order for reasons of comity. *Cf. Feller v. Brock*, 802 F.2d 722, 727-28 (4th Cir. 1986) (“Prudence requires that whenever possible, coordinate courts should avoid issuing conflicting orders.”); *Colby v. J.C. Penney Co.*, 811 F.2d 1119, 1124 (7th Cir. 1987) (same). Accordingly, Plaintiffs can suffer no injury from a rule that has been vacated and that HHS is not enforcing.

Plaintiffs further contend that HHS’s *Bostock* Notification imposes the “gender identity mandate,” Am. Compl. ¶ 82, but Plaintiffs misinterpret the Notification. HHS merely expressed the general point that sex discrimination includes discrimination on the basis of “sexual orientation” or “gender identity,” 86 Fed. Reg. at 27,984, which followed directly from *Bostock*’s reasoning that “it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex.” *Bostock*, 140 S. Ct. at 1741. The Notification did not define what gender identity discrimination means in the context of specific treatment decisions, nor did it conclude that providers were required to perform any specific procedure. *See* 86 Fed. Reg. at 27,985 (Notification “does not itself determine the outcome in any particular case or set of facts”). The Notification further assured that in applying Section 1557, HHS “will comply with the [RFRA] and all other legal requirements.” *Id.* Accordingly, Plaintiffs’ allegation that “HHS takes the position that RFRA provides no

³ *See, e.g., Religious Sisters of Mercy v. Becerra*, Brief for Appellants at 26, No. 21-1890 (8th Cir. filed June 16, 2021) (explaining that *Walker* and *Whitman-Walker* “did not affect the *Franciscan Alliance* district court’s vacatur of the 2016 Rule”).

exemption” for those with a religious objection to providing gender transition services, is baseless. Am. Compl. ¶ 90.

Moreover, the Notification is not a binding regulation. It is a general policy statement that does not impose legal obligations on Plaintiffs or anyone else. As then-Judge Kavanaugh explained, “When the agency applies [a general statement of] policy in a particular situation, it must be prepared to support the policy just as if the policy statement had never been issued.” *Nat. Mining Ass’n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014) (Kavanaugh, J.) (quoting *Pac. Gas & Elec. Co. v. Fed. Power Comm’n*, 506 F.2d 33, 38 (D.C. Cir. 1974)). Therefore, the Notification does not “mandate” anything, and Plaintiffs are not injured by it.

Plaintiffs are left with the argument that HHS may in the future conclude that “Section 1557 itself” contains the “gender identity mandate,” Am. Compl. ¶ 82, and may enforce this mandate against Plaintiffs. But Plaintiffs fail to meet the rigorous requirements for standing to challenge a hypothetical future enforcement action. “In the absence of contemporary enforcement, . . . a plaintiff claiming standing must show that the likelihood of future enforcement is ‘substantial.’” *California v. Texas*, 141 S. Ct. at 2114 (quoting *SBA List*, 573 U.S. at 164); *see also Vonderhaar*, 906 F.3d at 401 (“allegation ‘of possible future injury’ is not enough”) (quoting *Clapper*, 568 U.S. at 409).

Plaintiffs fail to make that showing of a substantial likelihood of future enforcement. Plaintiffs do not allege that HHS has ever enforced Section 1557 to require any provider, let alone Plaintiffs, to provide gender transition services. Nor do Plaintiffs allege that HHS has threatened any Plaintiff or Member with enforcement. *See Steffel v. Thompson*, 415 U.S. 452, 459 (1974) (plaintiff had standing where he was twice instructed that if he did not cease challenged conduct, he would be prosecuted). Indeed, HHS has not taken the legal position that

Plaintiffs ascribe to the agency, that Section 1557 requires providers, including those with religious objections, to perform each of the 22 so-called “objectionable practices.” Am. Compl. ¶¶ 89-90, 131.

Further demonstrating the lack of substantial threat of enforcement, Plaintiff Dassow and the vast majority of the Members (all 2500 CMA Members and some of the 600 ACP Members, including each Member named in the Complaint) claim to have religious objections to providing gender transition services. *See* Am. Compl. ¶¶ 147, 219, 222, 225, 237, 258. RFRA prohibits the federal government from “substantially burden[ing] a person’s exercise of religion even if the burden results from a rule of general applicability,” unless the federal government demonstrates that the burden “is the least restrictive means of furthering” “a compelling governmental interest.” 42 U.S.C. § 2000bb-1(a), (b)(2); *see also Bostock*, 140 S. Ct. at 1754 (“RFRA operates as a kind of super statute, displacing the normal operation of other federal laws,” which “might supersede” antidiscrimination laws in “appropriate cases”). If a Plaintiff or Member asserted a religious objection to an enforcement proceeding under RFRA, HHS would apply RFRA’s test to that objection, considering the facts of that case.

The availability of RFRA renders the risk of future injury speculative because the prospect that Section 1557 will be enforced against Plaintiffs unlawfully hinges on the supposition that HHS will wrongfully reject a religious objection when a Plaintiff or Member is entitled to one. Since it issued its first Section 1557 rule in 2016, HHS has consistently maintained that to the extent it enforces Section 1557, it will do so in compliance with RFRA. *See* 2016 Rule, 81 Fed. Reg. at 31,380 (“application of RFRA is the proper means to evaluate any religious concerns about the application of Section 1557 requirements”); *id.* at 31,466 (“application” of 2016 Rule’s requirements “shall not be required” where it “would violate

applicable Federal statutory protections for religious freedom and conscience”); Notification, 86 Fed. Reg. at 27,985 (HHS “will comply with” RFRA). There is no cause to doubt HHS’s commitment to faithfully apply RFRA and other conscience protections in enforcing Section 1557, particularly because Plaintiffs point to no example of HHS having enforced Section 1557 to require a provider with a religious objection to provide gender transition services. *See Irwin v. Tenn. Valley Auth.*, No. 3:12-cv-35, 2013 WL 3968553, at *2 (E.D. Tenn. July 31, 2013) (“government actor[s]” are “entitled to a presumption of good faith”).

In sum, HHS has not imposed the “Section 1557 Gender Identity Mandate” that Plaintiffs claim injures them. The prospect that HHS will impose such a mandate in the future and enforce it against Plaintiffs is too speculative to meet the strictures of Article III standing.

B. Plaintiffs’ Section 1557 Claims Do Not Present A Ripe Controversy

Plaintiffs’ Section 1557 claims are unripe for similar reasons to those that Plaintiffs lack standing: Their claim depends on speculation about “contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas*, 523 U.S. at 300 (citation omitted).

Plaintiffs’ claimed injuries hinge on the contingency that HHS will take a legal position it has not yet taken and bring enforcement actions that HHS has not yet brought. Even if such contingencies came to pass, the contours of any future controversy would depend largely on future factual and legal developments that at this point are impossible to predict.

Here, Plaintiffs seek to “entangle” this Court in “abstract debates,” *Warshak*, 532 F.3d at 525 (citation omitted). A dispute is unripe where, as here, a plaintiff challenges legal positions the government has not actually taken, and the government’s legal position is subject to further development. For example, in *Kentucky Press Association, Inc. v. Kentucky*, 454 F.3d 505, 507 (6th Cir. 2006), a press association brought a First Amendment challenge to Kentucky statutes that the plaintiff contended denied the media any access to juvenile court proceedings. But the

dispute was unripe because the Kentucky courts had not interpreted the statutes, and “it [was] far from certain that Kentucky law actually closes juvenile proceedings and records entirely to the media.” *Id.* at 510. So too, here, it is far from certain that HHS would conclude that Section 1557 requires Plaintiffs to perform each of the gender transition services to which they object, particularly when many of them have religious objections.

A recent Fifth Circuit decision, *Walmart, Inc. v. U.S. Department of Justice*, 21 F.4th 300 (5th Cir. 2021), similarly shows that a legal challenge to positions the government has not taken does not present a ripe controversy. In that case, Walmart asked the court to issue nine declarations about the limits of pharmacists’ and distributors’ legal obligations under the Controlled Substances Act, but Walmart could not “point to any regulations or guidance documents” from the government taking a “contrary view on all these proposed declarations.” *Id.* at 306. Although the government had “taken positions similar to those that Walmart challenges,” there were “subtle differences,” showing that the government disagreed with only some of the positions Walmart advanced in its proposed declarations. *Id.* at 312. In dismissing Walmart’s lawsuit as unripe, the Fifth Circuit emphasized “the importance of an unequivocally expressed position by the government.” *Id.* “Because [Walmart] challenge[d] a series of positions that the government does not quite take, Walmart fail[ed] to show the ‘actual controversy’ that is needed for a declaratory judgment to be fit for judicial decision.” *Id.*

The same is true here. HHS has not imposed the challenged “Section 1557 Gender Identity Mandate,” nor has HHS taken the legal position attributed to it by Plaintiffs, that all providers must engage in each of the so-called “objectionable practices,” regardless of religious objection. To the contrary, HHS has made clear that whatever Section 1557 requires as a general matter, providers are entitled to religious exemptions when they meet the requirements of RFRA

or other statutes protecting religious exercise. *See supra*, pp. 16-17; *Walmart*, 21 F.4th at 312 (“Those discrepancies illustrate the peril of treating [Plaintiffs’] requested declarations as constituting a ripe case or controversy.”).

Further, HHS has not yet set forth its “unequivocally expressed position” about what Section 1557 requires in the context of providing particular treatments to transgender patients. *Id.* Underscoring that point, HHS intends to issue a Notice of Proposed Rulemaking (NPRM) in the near future, proposing a rule implementing Section 1557. *See* <https://www.reginfo.gov/public/do/eoDetails?rrid=234566>. (showing that HHS submitted a draft of the proposed rule to the Office of Information and Regulatory Affairs on March 22, 2022). Even when HHS issues the NPRM, it will be only a proposal, subject to change after HHS considers comments under the APA’s notice-and-comment procedures. 5 U.S.C. § 553. Given that HHS is engaged in the rulemaking process to interpret and implement Section 1557, HHS has not yet “unequivocally expressed” its legal “position” that would apply in any hypothetical future dispute with Plaintiffs. *Walmart*, 21 F.4th at 312.

Moreover, this case does not “arise[] in a concrete factual context,” as Article III requires. *Warshak*, 532 F.3d at 525. If HHS ever brought a Section 1557 enforcement action against a provider for failing to provide a gender transition service, the lawfulness of such an action would hinge on the case’s specific facts. For example, in cases evaluating claims of unlawful discrimination under federal civil rights law, courts generally allow a defendant “to articulate some legitimate, nondiscriminatory reason” for taking an action that would constitute *prima facie* discrimination. *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802 (1973). The outcome of any concrete dispute may depend on the nondiscriminatory reasons offered by the provider and the evidence supporting those reasons, as well as any evidence suggesting that such

reasons were a “pretext for . . . discrimination.” *Id.* at 804. A court cannot evaluate such questions in the abstract, without factual evidence.

In addition, in the event that a provider claimed a religious exemption under RFRA, HHS would need to apply RFRA’s test of determining whether enforcing Section 1557 was the least restrictive means of supporting a compelling government interest. 42 U.S.C. § 2000bb-1(b). The Supreme Court has counseled that RFRA’s test is necessarily fact-specific because it requires “application of the challenged law ‘to the person’—the particular claimant whose sincere exercise of religion is being substantially burdened.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430-431 (2006); *see also Ramirez v. Collier*, 142 S. Ct. 1264, 1281 (2022) (holding that the Religious Land Use and Institutionalized Persons Act, which applies RFRA’s religious exemption test in the prison context, “requires that courts take cases one at a time, considering only the particular claimant whose sincere exercise of religion is being substantially burdened”) (quoting *Holt v. Hobbs*, 574 U.S. 352, 363 (2015)). Yet this lawsuit improperly asks the Court to find, absent a developed factual record, that each of thousands of providers has a valid claim under RFRA for an exemption to whatever HHS might require in the future regarding gender transition services. Judicial review is properly deferred because “[t]he operation of [a] statute” would be “better grasped when viewed in light of a particular application.” *Texas*, 523 U.S. at 301.

Finally, Plaintiffs’ claims are unripe because “withholding court consideration” would not cause “hardship to the parties.” *Warshak*, 532 F.3d at 525. Plaintiffs claim that they must suffer through the choice of enduring government enforcement, providing services in conflict with their beliefs, or exiting the healthcare field. Am. Compl. ¶ 272. But that is a false choice because HHS has not threatened enforcement against Plaintiffs, nor have Plaintiffs shown that a

substantial risk of future enforcement exists. *See supra*, pp. 15-17. Even if HHS were to decide at some point to pursue action against Plaintiffs, Plaintiffs would still be many steps removed from losing federal funding. *See Colwell v. HHS*, 558 F.3d 1112, 1128 (9th Cir. 2009). First, HHS would be required to attempt to achieve informal or voluntary compliance. 45 C.F.R. § 80.8(c); *see id.* § 92.5(a). Second, there must be a formal adjudication and an administrative hearing. *Id.* § 80.8(c). Third, HHS must wait thirty days after providing a full written report to Congressional committees. *Id.* Finally, “[j]udicial review of any funding termination is available in an Article III court.” *Colwell*, 558 F.3d at 1128. Plaintiffs make no effort to explain why they would be harmed if this Court does not consider their abstract legal objections, when they do not allege that HHS has initiated an investigation or enforcement action against any of them.

C. Other District Court Decisions Granting Legal Relief Under Section 1557 Were Wrongly Decided

HHS acknowledges that three district courts have granted injunctive relief to plaintiffs that challenged HHS’s activities concerning gender identity under Section 1557. *See Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113 (D.N.D. 2021), *appeal filed*, No. 21-1890 (8th Cir. Apr. 21, 2021); *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361 (N.D. Tex. 2021), *appeal filed*, No. 21-11174 (5th Cir. Nov. 21, 2021); *Christian Emps. All. v. United States Equal Opportunity Comm’n*, No. 1:21-cv-195, 2022 WL 1573689 (D.N.D. May 16, 2022). However, these cases were wrongly decided and rest on several fundamental legal errors.⁴

⁴ The government appealed the *Religious Sisters of Mercy* injunctions to the Eighth Circuit. *Religious Sisters of Mercy v. Becerra*, No. 21-1890 (8th Cir.). That appeal is fully briefed and was argued on December 15, 2021. The government appealed the *Franciscan Alliance* injunction to the Fifth Circuit. *Franciscan Alliance, Inc. v. Becerra*, No. 21-11174 (5th Cir.). That appeal was fully briefed as of July 1, 2022, and oral argument is scheduled for August 4, 2022. The government is currently considering whether to appeal the injunction in *Christian*

Most significantly, each of these courts misconstrued the legal effect of past HHS actions to conclude that HHS had imposed a mandate, similar to what Plaintiffs allege here, that providers must perform all gender transition services regardless of religious objection. *See Franciscan Alliance*, 553 F. Supp. 3d at 374 (“the current regulatory scheme for Section 1557 ‘clearly prohibits’ Plaintiffs’” refusal to perform gender transition services); *Christian Emps. Alliance*, 2022 WL 1573689, at *8 (“Plaintiffs, compelled by fines and civil liability, must perform or provide coverage for gender transition procedures.”). These courts wrongly concluded that the 2016 Rule’s provisions regarding gender identity were still in effect (despite the *Franciscan Alliance* court’s vacatur of those provisions in 2019), *see Religious Sisters of Mercy*, 513 F. Supp. 3d at 1130, 1138; *Christian Emps. Alliance*, 2022 WL 1573689, at *5, or that HHS had effectively repromulgated the 2016 Rule through the Notification, *see Franciscan Alliance*, 553 F. Supp. 3d at 373; *Christian Emps. Alliance*, 2022 WL 1573689, at *5. In actuality, as described above, the 2016 Rule’s gender identity provisions were vacated by the *Franciscan Alliance* court in 2019. *See supra*, pp. 14-15. And the Notification was simply a guidance document that made the general point that sex discrimination includes gender identity discrimination under a straightforward reading of *Bostock*, without setting forth any specific requirements for provision of gender transition services, let alone doing so in a binding manner. *See supra*, pp. 15-16.

The courts’ misinterpretation of HHS’s past actions led those courts to conclude that the plaintiffs (medical providers, employers, or associations of medical providers and employers with religious objections to performing or covering gender transition services) had suffered an

Employers Alliance. The government’s arguments against these decisions are set forth in greater detail in the government’s appellate briefs in *Religious Sisters of Mercy* and *Franciscan Alliance*.

Article III injury because they were under the immediate threat of losing funding. *See Religious Sisters of Mercy*, 513 F. Supp. 3d at 1139; *Franciscan Alliance*, 553 F. Supp. 3d at 374; *Christian Emps. Alliance*, 2022 WL 1573689, at *8. In fact, HHS has never enforced Section 1557 to revoke the funding of a provider for failure to provide gender transition services, and has consistently maintained that it will abide by RFRA to the extent it does enforce Section 1557. *See supra*, pp. 16-17.

Finally, those courts failed to appreciate that the question whether Section 1557, as limited by RFRA, would require a provider to perform a gender transition service in any specific circumstance would depend on the applicable facts. *See Religious Sisters of Mercy*, 513 F. Supp. 3d at 1145 (“These cases present ‘purely legal questions’ . . . and need no factual development.”) (citation omitted); *Christian Emps. Alliance*, 2022 WL 1573689, at *8 (holding that it would be inappropriate to “[d]etermin[e] on a case-by-case basis if a religious exemption should apply”). Yet it is difficult to determine, absent a concrete set of facts, whether a provider’s refusal to perform a particular procedure constitutes sex discrimination, and if so, whether the provider is entitled to a religious exemption. *See supra*, pp. 20-21.

In sum, this Court should not follow these out-of-circuit district court decisions (two of which are currently pending appeals), and should instead dismiss Plaintiffs’ Section 1557 claims for lack of subject-matter jurisdiction.

II. Plaintiffs Lack Standing Or A Ripe Controversy To Challenge the 2016 Grants Rule, Which Is Subject To HHS’s Notice Of Nonenforcement

Plaintiffs lack standing to challenge the 2016 Grants Rule because the Notice of Nonenforcement, combined with HHS’s consistent history of nonenforcement, demonstrates the lack of a substantial threat that the 2016 Grants Rule will be enforced against Plaintiffs. An injury in fact must be “concrete, particularized, and actual or imminent.” *Clapper*, 568 U.S. at

409 (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010)). “Although imminence is concededly a somewhat elastic concept,” its purpose “is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending.” *Id.* (quoting *Lujan*, 504 U.S. at 565 n.2). A plaintiff “cannot file a lawsuit based on a ‘highly speculative fear’ that a law may harm them at some future date” because “[a]n allegation ‘of *possible* future injury’ is not enough” to establish an injury in fact. *Vonderhaar*, 906 F.3d at 401 (6th Cir. 2018) (quoting *Clapper*, 568 U.S. at 409-10). Rather, a plaintiff bringing a pre-enforcement challenge to a regulation must establish a credible threat that the regulation will be enforced against it. *See SBA List*, 573 U.S. at 158-59.

Here, Plaintiffs fail to show any credible threat of enforcement and instead allege only a “highly speculative fear” of “*possible* future injury.” *Vonderhaar*, 906 F.3d at 401 (quoting *Clapper*, 568 U.S. at 409–410). HHS has declared in the Federal Register that it will not enforce the 2016 Grants Rule pending promulgation of a new rule. HHS has not enforced the 2016 Grants Rule against anyone, let alone any Plaintiff, either before or since the Notice of Nonenforcement. Courts routinely dismiss challenges to rules in such cases when the government entity has made clear that it will not enforce the rule. *See, e.g., Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25, 36 (D.D.C. 2012) (holding plaintiff lacked standing to challenge rule where agency indicated it would not enforce the rule pending promulgation of a new rule); *Moore v. Brown*, 868 F.3d 398, 406-07 (5th Cir. 2017) (holding case moot after city wrote to plaintiff explaining that challenged rule would not be enforced against him); *Buscemi v. Bell*, 964 F.3d 252, 260 (4th Cir. 2020), *cert. denied sub nom. Kopitke v. Bell*, 141 S. Ct. 1388 (2021) (holding plaintiff lacked standing to challenge rule given defendant’s history of nonenforcement and “present assurances that it will not enforce” the rule); *see also Mink v. Suthers*, 482 F.3d

1244, 1255 (10th Cir. 2007) (holding plaintiff lacked standing when “district attorney publicly announced he would not prosecute,” and explaining that “standing is defeated when there is evidence the government will not enforce the challenged statute against the plaintiff”). This is so because “[w]ithout evidence to the contrary, [courts] assume that formally announced changes to official governmental policy are not mere litigation posturing.” *Sossamon v. Lone Star State of Texas*, 560 F.3d 316, 325 (5th Cir. 2009), *aff’d* 563 U.S. 277 (2011).

Despite HHS’s express statement of nonenforcement, Plaintiffs claim that HHS “could withdraw [the Notice of Nonenforcement] at any moment” and “may enforce the 2016 Grants Rule at any time.” Am. Compl. ¶¶ 108, 111. However, history shows consistent adherence to and reaffirmation of the Notice of Nonenforcement. It has now been nearly three years since the Notice of Enforcement and 18 months since the change in administrations, and HHS has retained the Notice of Enforcement in place and has not enforced the 2016 Grants Rule. Just last month, in a motion to vacate and remand the 2021 Grants Rule because of a recently discovered procedural anomaly, HHS stated that “vacating the 2021 [Grants] Rule’s formal repeal of the 2016 [Grants] Rule will not cause disruption or change the status quo” because “the 2016 [Grants] Rule has never been enforced, and HHS has stated publicly that it will not enforce the 2016 [Grants] Rule pending promulgation of a new rule.” *Facing Foster Care in Alaska*, No. 1:21-cv-00308, ECF No. 41 at 8-9 (D.D.C. June 17, 2022).

Two separate district courts recently held that the 2016 Grants Rule posed no imminent threat to the plaintiffs based, respectively, on lack of standing and mootness. *Cf. Sumpter v. Wayne Cnty.*, 868 F.3d 473, 490 (6th Cir. 2017) (explaining that “mootness is just ‘standing set in a time frame’” (quoting *U.S. Parole Comm’n v. Geraghty*, 445 U.S. 388, 397 (1980))). These are the only two courts to have considered challenges to the 2016 Grants Rule—or individually

to 45 C.F.R. § 75.300(c) or (d)—since HHS issued the Notice of Nonenforcement. First, in *Vita Nuova, Inc. v. Azar*, the district court held that the plaintiff-organization lacked standing to challenge § 75.300(d) because HHS “expressly disavowed enforcement of § 75.300(d)” by issuing the Notice of Nonenforcement. 458 F. Supp. 3d at 558 (declining to consider mootness in lieu of standing). The court explained that the plaintiff faced “little to no credible threat of enforcement related to § 75.300(d).” *Id.* (relying on *SBA List*, 573 U.S. at 159, 164-65). Similarly, in *Texas Department of Family and Protective Services v. Azar*, the district court found that a challenge to the 2016 Grants Rule was moot based in part on HHS’s subsequent issuance of the Notice of Nonenforcement. *See* 476 F. Supp. 3d at 580 (declining to consider standing in lieu of mootness).⁵ The court explained that even though HHS had not yet officially repealed the 2016 Grants Rule, the Notice of Nonenforcement “unequivocally states that [HHS] will not enforce the challenged provisions pending repromulgation.” *Id.* at 578.

The operative facts of both cases map cleanly onto this case: Plaintiffs filed suit despite HHS’s “unequivocal[] state[ment] that it will not enforce the challenged provisions pending repromulgation.” *Id.* As such, Plaintiffs face “no credible threat of enforcement related to” the 2016 Grants Rule. *Vita Nuova*, 458 F. Supp. 3d at 558. This is particularly true given that “[t]he Sixth Circuit has adhered to the principal [sic] that acts of voluntary cessation by government officials are treated with greater solicitude than similar acts taken by private parties.” *Hooper v.*

⁵ HHS had also granted the plaintiffs in *Texas Department of Family and Protective Services* an exemption from the 2016 Grants Rule. *See* 476 F. Supp. 3d at 580. But it makes no difference for comparative purposes that the plaintiffs in *Texas Department of Family and Protective Services* had a specific exemption in addition to the general Notice of Nonenforcement. The court’s decision in *Texas Department of Family and Protective Services* was not based exclusively on the exemption but rather on the broader fact that “the governmental entity has promised not to enforce the rule.” *Id.*

Morkle, 219 F.R.D. 120, 123 (S.D. Ohio 2003) (collecting cases); *see also Sossamon*, 560 F.3d at 325. Thus, in light of the Notice of Nonenforcement, Plaintiffs fail to establish an injury in fact.

For similar reasons, Plaintiffs' challenge to the 2016 Grants Rule is unripe. First, Plaintiffs' claims are not fit for judicial decision because they do not "arise[] in a concrete factual context," nor do they "concern[] a dispute that is likely to come to pass." *Warshak*, 532 F.3d at 525. Plaintiffs' claims are premised on the speculative, subjective fear that HHS will enforce a regulation that it has expressly and publicly declared that it will not enforce. That is insufficient to establish a ripe controversy. *See, e.g., Presbytery of N.J. of the Orthodox Presbyterian Church v. Florio*, 830 F. Supp. 241, 249 (D.N.J. 1993), *aff'd in relevant part*, 40 F.3d 1454 (3d Cir. 1994) (holding case unripe with respect to plaintiff-church because defendants "conceded that they will not enforce [the statute] against" plaintiff-church); *Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris*, 729 F.3d 937, 944 (9th Cir. 2013) ("[A] state official who contends that he or she will not enforce the law may challenge plaintiff's Article III standing based on 'an unripe controversy.'" (quoting *National Audubon Soc'y, Inc. v. Davis*, 307 F.3d 835, 847 (9th Cir. 2002))).

Second, Plaintiffs will suffer no hardship if the Court withholds consideration. Plaintiffs allege only hardship that would apply if HHS *were* currently or imminently enforcing the 2016 Grants Rule—which HHS is not. *See, e.g., Compl.* ¶¶ 130-271 (arguing that the 2016 Grants Rule forces Plaintiffs to violate their beliefs, lose funding, or cease providing services). Given that HHS has made clear that it will not enforce the 2016 Grants Rule, Plaintiffs fail to carry their burden of establishing jurisdiction. *See Lujan*, 504 U.S. at 561. Accordingly, Plaintiffs' claims are not ripe for review.

III. The Court Lacks Jurisdiction Over Plaintiffs' SUNSET Rule Claim

As noted earlier, Plaintiffs' SUNSET Rule claim seeks only to challenge the postponement of the regulation, but that regulation has now been rescinded. Plaintiffs' SUNSET Rule claim suffered from a lack of standing when filed, and it is moot now that the SUNSET Rule has been withdrawn.

Plaintiffs lack standing because they alleged no imminent injury caused by the SUNSET Rule's delay. Their only claimed injury is the inability to participate in reviews and assessments that HHS would have conducted under the SUNSET Rule. *See* Am. Compl. ¶¶ 316-19. But the first reviews and assessments were not due until "five calendar years after the year that [the SUNSET Rule] first becomes effective," 86 Fed. Reg. 5,694, which would have been 2026 if the rule had become effective on schedule in 2021. An injury that could not occur for years into the future is hardly "imminent." *Clapper*, 568 U.S. at 409; *see also Winebarger v. Pa. Higher Educ. Assistance Agency*, 411 F. Supp. 3d 1070, 1087 (C.D. Cal. 2019) ("when an injury is years away from materializing, the injury is not immediate") (citation omitted).

In any event, the Court need not decide whether Plaintiffs had standing to bring this claim when the First Amended Complaint was filed, because it is clearly moot now that HHS has withdrawn the SUNSET Rule. *See In re: 2016 Primary Election*, 836 F.3d 584, 587 (6th Cir. 2016) ("[f]ederal law does not provide any order" for sequencing resolution of standing and mootness issues). Plaintiffs' First Amended Complaint seeks only to challenge the postponement of the SUNSET Rule, not any of the other actions associated with the Rule. *See* Am. Compl. ¶ 521 (challenging the "Delay Rule," meaning HHS's postponement of the SUNSET Rule's effectiveness). Thus, even if Plaintiffs succeeded in setting aside the validity of the delays in the SUNSET Rule's effectiveness, that at most would have resulted in the SUNSET Rule being effective from March 2021 through its withdrawal in July 2022. But the SUNSET

Rule did not obligate HHS to conduct reviews or assessments of any regulation during that time frame, including as to the rulemakings on which Plaintiffs allege they would have liked to submit comments. *See* Am. Compl. ¶ 316. Accordingly, a ruling by this Court that the SUNSET Rule was improperly postponed before its ultimate withdrawal would not “make a difference to the legal interests of the parties.” *City of Detroit*, 401 F.3d at 451 (quoting *McPherson v. Michigan High Sch. Athletic Ass’n, Inc.*, 119 F.3d 453, 458 (6th Cir. 1997) (en banc)). Opining on the legality of delays in connection with a now-withdrawn regulation would not result in any meaningful relief to Plaintiffs, and therefore this claim likewise fails to present an Article III justiciable controversy.

CONCLUSION

The Court should grant Defendants’ Motion to Dismiss and dismiss the First Amended Complaint for lack of subject-matter jurisdiction.

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Respectfully submitted,

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