No. 21-1890

United States Court of Appeals for the Eighth Circuit

THE RELIGIOUS SISTERS OF MERCY, ET AL.,
Plaintiffs-Appellees,
v.
XAVIER BECERRA, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court
for the District of North Dakota
No. 3:16-cv-00386

Answering Brief of Plaintiffs-Appellees The Religious Sisters of Mercy, Sacred Heart Mercy Health Care Center, SMP Health System, and University of Mary

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SUMMARY OF THE CASE

The U.S. Department of Health and Human Services (HHS) currently requires all recipients of federal healthcare funding to perform and provide insurance coverage for gender-transition procedures, or else face liability for "sex" discrimination. Plaintiffs are Catholic healthcare providers who are subject to this requirement and who challenged it as a violation of the Religious Freedom Restoration Act (RFRA). The district court held that this requirement violates RFRA and enjoined HHS from enforcing it against Plaintiffs.

HHS now appeals. It does not dispute the merits of the district court's RFRA analysis. It argues only that the district court erred by finding that Plaintiffs demonstrated standing, ripeness, and irreparable harm.

Plaintiffs agree that oral argument would aid in the consideration of this appeal and that twenty minutes per side is appropriate.

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INTRODUCTION

This lawsuit began in 2016, when HHS announced it would enforce Section 1557 of the Affordable Care Act to require almost every doctor and hospital in the country, including Plaintiffs, to perform and insure gender-transition procedures or else be liable for "sex" discrimination. Religious doctors and hospitals challenged this action as a violation of the Religious Freedom Restoration Act (RFRA), and two federal courts, including the court below, agreed. These courts reasoned that forcing religious doctors to perform gender transitions in violation of conscience substantially burdened their religious exercise, and that HHS failed strict scrutiny because it has "many less restrictive alternatives" of furthering its goals. A801.

On appeal, HHS doesn't dispute the merits of this RFRA ruling. It argues only that this lawsuit is "premature." Br.1. Although HHS gives this argument three different labels—"standing," "ripeness," or lack of "irreparable injury"—it is really just one argument: Plaintiffs can't bring a lawsuit until they are subject to "specific enforcement activity undertaken by HHS." Br.30.

But this argument flies in the face of the well-settled doctrine of "pre-enforcement challenges"—as the district court rightly held. To bring a pre-enforcement challenge, a plaintiff need not show that it "was subject to past enforcement." Br.20. It need only show (1) that it intends to engage in conduct "arguably affected with a constitutional interest"; (2) that

its conduct is "arguably proscribed" by law; and (3) that there exists a "credible threat" of enforcement. *SBA List v. Driehaus*, 573 U.S. 149, 159, 162 (2014). Those elements are easily met here.

First, Plaintiffs seek to practice medicine consistent with their religious beliefs, including by refraining from harmful gender transitions. This is core First Amendment activity "affected with a constitutional interest"—as HHS doesn't dispute.

Second, Plaintiffs' conduct is "arguably proscribed" in three ways. It is proscribed by HHS's 2016 Rule, which expressly forbids Plaintiffs' conduct and remains in effect. It is proscribed by HHS's 2020 Rule, which incorporates *Bostock*'s holding that "sex" discrimination includes discrimination based on "transgender status." *Bostock v. Clayton County*, 140 S.Ct. 1731, 1741 (2020). And it is proscribed by HHS's current interpretation of Section 1557 itself, independent of any rule. This interpretation has been applied by multiple courts, which have refused to dismiss lawsuits against religious hospitals and insurance plans for declining to perform or insure gender transitions. And it has been confirmed by HHS, which just issued a Notification of Enforcement stating that it would enforce Section 1557 to prohibit "gender identity" discrimination.

Third, Plaintiffs face a "credible threat" of prosecution. As this Court has explained, if a plaintiff's conduct is arguably proscribed by law—as it is here—this Court "will assume a credible threat of prosecution," *St. Paul Area Chamber of Com. v. Gaertner*, 439 F.3d 481, 486 (8th Cir. 2006)

(quoting *N.H. Right to Life Pol. Action Comm. v. Gardner*, 99 F.3d 8, 15 (1st Cir. 1996)), except in "extreme cases approaching desuetude," *281 Care Comm. v. Arneson*, 638 F.3d 621, 628 (8th Cir. 2011). Here, Section 1557 is far from desuetude. It was recently enacted and has been the subject of two rulemakings in five years. HHS has said it will "vigorously enforce" it, A785, including in a recent Notification of Enforcement inviting the public to file complaints. And it is the basis of multiple *current* lawsuits seeking to force religious organizations to perform and insure gender transitions. As the district court held, this "is more than sufficient to establish a credible threat of enforcement." A785.

HHS's main response is to say that Plaintiffs still can't sue because HHS has not, "to date," evaluated whether RFRA "might apply to [protect] religious entities," so HHS "might" not enforce Section 1557 against them. Br.16. But that is cold comfort. The whole point of a pre-enforcement challenge is that "a plaintiff need not wait for an actual prosecution or enforcement action before challenging a law's constitutionality." *Telescope Media v. Lucero*, 936 F.3d 740 (8th Cir. 2019). And this Court has held that even a sworn disavowal of "present" intent not to enforce doesn't defeat standing, because "changes in leadership" could generate a different result. *United Food & Commercial Workers Int'l Union v. IBP, Inc.*, 857 F.2d 422, 429-30 (8th Cir. 1988).

Here, HHS has expressly *refused* to disavow enforcement. It has opposed Plaintiffs' RFRA claims in court. It has refused to adopt a religious

exemption in its regulations. President Biden campaigned on a promise to enforce Section 1557 by "revers[ing]" "religious exemptions" for "medical providers." A738. Asked point blank by the Fifth Circuit if it would disavow enforcement against religious plaintiffs, HHS said no: "[Q.] Are you able to tell us that … you're not going to enforce? [A.] No your honor." Oral Arg. at 15:46-19:27, *Franciscan All. v. Azar*, No. 20-10093 (5th Cir. Mar. 3, 2021). In fact, HHS sought to modify the injunction in this very case because it worried it would be held in "contempt" for enforcing Section 1557 against a religious organization, only to discover later that it was a member of Plaintiff Catholic Benefits Association. SA721. That is a straightforward admission that Plaintiffs face a credible threat of enforcement, and it is more than enough to establish standing.

Lacking any valid argument under the *Driehaus* factors, HHS tries to rebrand its standing argument as an argument against ripeness or irreparable harm. But its rebranding fails. The case is ripe because the issues are purely legal, as HHS admitted below, and because withholding review would force Plaintiffs to choose between violating their religious beliefs or risking multimillion-dollar penalties. And Plaintiffs face irreparable harm because, as this Circuit has held, the loss of First Amendment rights protected by RFRA is per se irreparable harm.

* * *

At bottom, this is a simple appeal. It is undisputed that Plaintiffs are subject to Section 1557 because they receive federal healthcare funding.

HHS interprets Section 1557 to prohibit Plaintiffs' conduct. And Plaintiffs face a credible threat of enforcement—both as a matter of law, and as confirmed by HHS's refusal to provide a religious exemption; by its public promise of vigorous enforcement; by its public solicitation of complaints; by its refusal to disavow enforcement against religious organizations; and by its request to modify the injunction so it won't be held in contempt if it unwittingly prosecutes Plaintiffs' members. That is more than enough to satisfy the elements of a pre-enforcement challenge, and the district court should be affirmed.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331. Judgment was entered on February 19, 2021. Defendants noticed this appeal on April 20, 2021. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court properly held that Plaintiffs have standing, where Plaintiffs' conduct violates HHS's current interpretation of Section 1557 of the Affordable Care Act, and Plaintiffs face a credible threat of enforcement. *See Driehaus*, 573 U.S. 149; *Telescope Media*, 936 F.3d 740; *281 Care*, 638 F.3d 621.

2. Whether the district court properly held that this case was ripe, where Plaintiffs must either violate their religious beliefs or face civil liability, loss of federal funding, and criminal penalties. *See Iowa League of Cities v. EPA*, 711 F.3d 844 (8th Cir. 2013); *Minn. Citizens Concerned for Life, Inc. v. FEC*, 113 F.3d 129 (8th Cir. 1997).

3. Whether the district court abused its discretion by finding irreparable harm, where Plaintiffs succeeded under RFRA, and courts have repeatedly held that the loss of RFRA rights is irreparable harm. *See Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63 (2020); *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927 (8th Cir. 2015); *Minn. Citizens Concerned for Life, Inc. v. Swanson*, 692 F.3d 864 (8th Cir. 2012) (en banc).

STATEMENT OF THE CASE

A. Plaintiffs

Plaintiffs are four Catholic organizations devoted to providing healthcare and education to the underserved consistent with their religious beliefs.

The Religious Sisters of Mercy are Catholic nuns devoted to works of mercy, including offering healthcare to the underserved. A100¶2.[1] Each Sister has chosen to follow Jesus Christ by taking a lifetime vow to serve the poor and sick by caring for the whole person, ministering to physical, psychological, intellectual, and spiritual woundedness. A100¶4. The Sisters seek "to bring about that profound and extensive healing which is a continuation of the work of redemption." A100-01¶4. Consistent with this mission, some Sisters serve as licensed healthcare professionals in healthcare facilities throughout the country. A101¶5-6.

The Sisters also operate **Sacred Heart Mercy Health Care Center**, a nonprofit health clinic. A101¶6. Sacred Heart furthers the Sisters' mission to care for the elderly and the poor by serving Medicare and Medicaid patients and by providing low-cost or free care to the uninsured. A102¶8. Some of the Sisters work in the clinic as doctors, nurses, or other

[1] Citations to HHS's Appendix are abbreviated A___. Citations to Plaintiffs' Appendix are abbreviated SA___.

healthcare professionals. A101¶6. Sacred Heart shares the Sisters' beliefs and follows the U.S. Conference of Catholic Bishops' Ethical and Religious Directives for Catholic Health Care Services. *Id.*

SMP Health System is a nonprofit Catholic health system headquartered in North Dakota and founded and sponsored by the Sisters of Mary of the Presentation. A108¶3. The Sisters of Mary of the Presentation are an international religious community who believe that Catholic healthcare services are ecclesial in nature, mandated by the Church to carry on the healing ministry of Jesus. A284-88. As part of that healing ministry, SMP Health provides healthcare throughout North Dakota, including in critical-access hospitals, clinics, long-term care facilities, and senior housing. A108¶3. It has a special emphasis on caring for the poor and elderly, including Medicare and Medicaid patients. A108-09¶4. SMP Health shares the beliefs of the Sisters of Mary of the Presentation and follows the Ethical and Religious Directives for Catholic Health Care Services. A109¶5.

University of Mary is a Catholic, Benedictine university headquartered in North Dakota. The University infuses all its programs with Christian, Catholic, Benedictine values to prepare its students to be ethical leaders. A115¶6. As is fundamental to its mission, the University upholds Catholic teaching in all its programs. *Id.* The University is sub-

ject to HHS's interpretations of Section 1557 because it operates a student health clinic and offers a nursing program that receives HHS funding. A115-16¶¶8, 10.

Like the Catholic Church they serve, these Plaintiffs believe that every man and woman is created in God's image and reflects God's image in unique and uniquely dignified ways. A102¶9; A109¶6; A116¶9. In providing medical services, Plaintiffs serve everyone in need, including transgender individuals. A102¶7; A126-27¶4. They also believe that gender-transition procedures can be deeply harmful to patients; thus, they do not perform or provide insurance coverage for those procedures, which would violate their religious beliefs and medical judgment. A102-04¶¶9-18; A110-11¶¶8, 11; A116¶¶9-13; A122¶¶9-11; A127¶5.

B. The Affordable Care Act and Section 1557

Congress enacted the statutes collectively known as the "Affordable Care Act" or ACA in 2010. At issue here is Section 1557 of the ACA, which prohibits "discrimination under[] any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a).

Section 1557 does not itself specify the grounds on which discrimination is prohibited. Instead, it incorporates the "ground[s] prohibited" under four other federal statutes: Title VI (race), Title IX (sex), the ADA

(age), and "section 794 of Title 29" (disability). *Id.* Section 1557 thus prohibits sex discrimination by incorporating Title IX's prohibition on sex discrimination.

C. The 2016 Rule

Following Section 1557's enactment, a number of transgender individuals filed complaints against both state-run and religious healthcare providers for declining to perform or insure gender-transition procedures, alleging such conduct constituted "sex" discrimination under Section 1557. *See, e.g., Cruz v. Zucker*, 116 F. Supp. 3d 334 (S.D.N.Y. 2015); Compl. ¶80, *Conforti v. St. Joseph's Healthcare Sys., Inc.*, No. 2:17-cv-00050, 2017 WL 67114 (D.N.J. Jan. 5, 2017) (HHS complaint filed Dec. 11, 2015). HHS ultimately agreed with this novel interpretation of Section 1557, and in May 2016 promulgated a rule interpreting Section 1557 to prohibit gender-identity discrimination. 81 Fed. Reg. 31,376 (May 18, 2016) (the "2016 Rule").

The 2016 Rule applies to any "entity that operates a health program or activity, any part of which receives Federal financial assistance." *Id.* at 31,466. "Federal financial assistance" is defined to include "any grant, loan, credit, subsidy, contract … or any other arrangement" by which the federal government makes funds or property available. *Id.* at 31,467. Thus, by HHS's own estimate, the 2016 Rule applies to almost every healthcare provider in the country—including over 133,000 health care

facilities (such as hospitals and clinics) and "almost all licensed physicians"—because almost all accept some form of federal funding, such as Medicare or Medicaid. *Id.* at 31,445-46.

The 2016 Rule prohibits discrimination "on the basis of … sex," defines "sex" to include "gender identity," and defines "gender identity" as an individual's "internal sense of gender, which may be male, female, neither, or a combination of male and female." *Id.* at 31,467. According to HHS, this means covered entities must perform gender-transition procedures (such as hysterectomies, mastectomies, hormone treatments, plastic surgery, and other treatments designed to alter a patient's body in response to gender dysphoria) or else be liable for "discrimination."

As HHS explains: "A provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals." *Id.* at 31,455. In other words, if a gynecologist performs a hysterectomy for a woman with uterine cancer, she must do the same for a woman who wants to remove a healthy uterus to transition to living as a man—or else be liable for "sex" discrimination. HHS says this reasoning applies to the full "range of transition-related services"; it "is not limited to surgical treatments and may include, but is not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual." *Id.* at 31,435-36.

The 2016 Rule also interprets Section 1557 to require covered entities to pay for medical transition procedures in their health-insurance plans. "A covered entity shall not, in providing or administering health-related insurance … [h]ave or implement a categorical coverage exclusion or limitation for all health services related to gender transition." *Id.* at 31,471-72. According to HHS, this means that a plan excluding "coverage for all health services related to gender transition is unlawful on its face." *Id.* at 31,429. In addition, if a doctor concludes a hysterectomy "is medically necessary to treat gender dysphoria," the patient's employer would be required to cover that procedure on the same basis that it would cover a hysterectomy for other conditions (like cancer). *Id.*

If a covered entity violates Section 1557, it is subject to the same penalties that accompany a violation of Title IX. 42 U.S.C. § 18116(a). These include the loss of potentially millions in federal funding from Medicare and Medicaid, civil enforcement proceedings, debarment from doing business with the federal government, false-claims liability, lawsuits for damages and attorneys' fees, and criminal penalties. A757; *see also* 81 Fed. Reg. at 31,440, 31,472.

HHS adopted this novel interpretation of Section 1557 despite "significant disagreement within the medical community" on the "necessity and efficacy" of gender-transition procedures. *Gibson v. Collier*, 920 F.3d 212, 216, 224 (5th Cir. 2019); *Smith v. Rasmussen*, 249 F.3d 755, 760-61 (8th Cir. 2001) (recognizing "the lack of consensus in the medical community"

regarding "sex reassignment surgery"). And HHS did this even though HHS's own medical experts recommended against mandating coverage of gender-reassignment surgery in Medicare—concluding after "a thorough review of the clinical evidence" that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria," and that some studies "reported harms." SA62; *see* SA212.

Lastly, despite the blanket religious exemption for religious organizations in Title IX, 20 U.S.C. § 1681(a)(3), HHS "decided against including a blanket religious exemption in the final rule." 81 Fed. Reg. at 31,376.

D. Lawsuits against HHS

Multiple plaintiffs challenged HHS's interpretation of Section 1557. On November 6, 2016, Plaintiffs and the State of North Dakota filed this suit, alleging HHS had violated, among other things, the APA, the First Amendment, RFRA, and the Spending Clause. In December 2016, another suit was filed in the same District, *Catholic Benefits Ass'n v. Burwell*, No. 16-cv-432, which challenged not only HHS's interpretation of Section 1557 but also EEOC's interpretation of Title VII.[2] These two suits were consolidated in the district court. Also in 2016, a coalition of States, religious hospitals, and religious healthcare professionals sued HHS in

[2] Because Plaintiffs' suit challenges only HHS's application of Section 1557, this brief doesn't address EEOC or Title VII.

Franciscan All., Inc. v. Burwell, No. 16-cv-108 (N.D. Tex. filed Aug. 23, 2016).

Franciscan proceeded first, and on December 31, 2016—the day before the challenged portions of the Rule took effect—the district court entered a nationwide preliminary injunction barring HHS from enforcing the ban on "gender identity" discrimination. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 670 (N.D. Tex. 2016). The court held HHS's "implement[ation] of Section 1557" likely violated RFRA by "plac[ing] substantial pressure on [plaintiffs] to perform and cover transition and abortion procedures" and by not satisfying strict scrutiny. *Id.* at 671, 691-93. The court also held HHS likely violated the APA by defining "sex" discrimination to include "gender identity" discrimination and by refusing to incorporate Title IX's religious exemption. *Id.* at 687-91.

Meanwhile, the district court here issued orders staying enforcement of the 2016 Rule against Plaintiffs. SA298. The court noted that the *Franciscan* court had issued a nationwide injunction prohibiting HHS from enforcing the 2016 Rule and found the order "thorough and well-reasoned." SA299. Following these decisions, both this case and *Franciscan* were stayed so HHS could consider further rulemaking.

In December 2018, following 17 months of inaction, the *Franciscan* court lifted its stay. And in October 2019, the *Franciscan* court granted summary judgment for the plaintiffs. *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019). The court found "no reason to depart from

its" preliminary-injunction analysis on the merits, holding that the 2016 Rule violated both RFRA and the APA. *Id.* at 942. However, the court concluded that the proper remedy was vacatur of "the unlawful portions of" the 2016 Rule, "not a permanent injunction." *Id.* at 944-45; *see* Order at 2, *Franciscan*, No. 16-cv-108 (N.D. Tex. Nov. 21, 2019), ECF 182 (vacating the 2016 Rule "insofar as [it] defines '*On the basis of sex*' to include gender identity and termination of pregnancy"). HHS did not appeal the court's ruling on the merits. But the plaintiffs appealed the denial of injunctive relief to the Fifth Circuit.

E. The 2020 Rule and *Bostock*

On June 12, 2020, HHS issued a new Section 1557 rule. 85 Fed. Reg. 37,160 (June 19, 2020) ("the 2020 Rule"). The 2020 Rule omitted the 2016 Rule's definition of "sex" discrimination but didn't replace it with a new definition. Instead, the 2020 Rule reasoned that the Supreme Court's then-forthcoming decision in *Bostock* would "have ramifications for the definition of 'on the basis of sex' under Title IX," so repealing the prior definition would permit "application of the [*Bostock*] Court's construction." *Id.* at 37,168, 37,178. The 2020 Rule also stated it "shall be construed consistently with," *inter alia*, Title IX's religious exemption, *id.* at 37,243, but suggested that, to the extent it applied, the exemption would cover only "[a]ny *educational operation* of an entity … control[led] by a religious organization," *id.* at 37,207 (emphasis added).

Three days later, the Supreme Court decided *Bostock*. 140 S.Ct. 1731 (2020). The Court held that when "an employer … fires someone simply for being homosexual or transgender," the employer has "discriminated against that individual 'because of such individual's sex.'" *Id.* at 1753. The Court explained, however, that it was "deeply concerned with preserving the promise of the free exercise of religion," and noted that RFRA is a "super statute" that "might supersede … in appropriate cases" an otherwise-applicable ban on gender-identity discrimination. *Id.* at 1754. In dissent, Justices Alito and Thomas explained that application of *Bostock*'s reasoning to Section 1557 could "threaten freedom of religion" by requiring "employers and healthcare providers" like Plaintiffs "to pay for or to perform" "sex reassignment procedures" contrary to "their deeply held religious beliefs." *Id.* at 1778, 1781-82 (Alito, J., dissenting).

F. Lawsuits Challenging the 2020 Rule

After *Bostock*, various plaintiffs filed five lawsuits against HHS, challenging the 2020 Rule and seeking restoration of the 2016 Rule. *See Whitman-Walker Clinic, Inc. v. HHS*, No. 20-cv-01630 (D.D.C. filed June 22, 2020); *Walker v. Azar*, No. 20-cv-02834 (E.D.N.Y. filed June 26, 2020); *BAGLY v. HHS*, No. 20-cv-11297 (D. Mass. filed July 9, 2020); *Washington v. HHS*, No. 20-cv-01105 (W.D. Wash. filed July 16, 2020); *New York v. HHS*, No. 20-cv-05583 (S.D.N.Y. filed July 20, 2020).

HHS defended against these suits on the ground that the 2020 Rule, interpreted "in light of *Bostock*," likely imposed the same prohibition on

gender-identity discrimination as did the 2016 Rule. Resp. to Show Cause Order at 6-7, *Washington v. HHS*, No. 20-1105 (W.D. Wash. Aug. 26, 2020), ECF 71 ("*Washington* Resp."). In one case, for example, HHS stated that, due to *Bostock*, efforts to apply Section 1557 to prohibit "gender identity" discrimination are "*more likely* to bear fruit under the 2020 Rule than under the 2016 Rule." Mem. in Supp. of MTD at 14, *BAGLY*, No. 20-11297 (D. Mass. Oct. 14, 2020), ECF 22 ("*BAGLY* Memo"). One district court agreed with HHS's argument and dismissed the case for lack of standing, reasoning that under *Bostock*, the 2020 Rule may already "in fact, extend protection against discrimination to LGBTQ individuals via the [2020] Rule's incorporation of Title IX by reference." *Washington v. HHS*, 482 F. Supp. 3d 1104, 1115 (W.D. Wash. 2020).

In two other cases, however, the district courts entered "overlapping injunctions," *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1, 60 (D.D.C. 2020) (cleaned up), preventing the 2020 Rule "from becoming operative" and reinstating portions of the 2016 Rule, *Walker v. Azar*, 480 F. Supp. 3d 417, 420 (E.D.N.Y. 2020).

In *Walker*, the court initially said it had "no power to revive a rule vacated" by the *Franciscan* court. *Id.* at 427. Nevertheless, the court "predict[ed] that either the district court or some higher authority w[ould] revisit the vacatur," and then specifically held that portions of the 2016 Rule the *Franciscan* court had vacated—including "the definitions of 'on

the basis of sex,' 'gender identity,' and 'sex stereotyping'"—"remain in effect." *Id.* at 427, 430.

The *Whitman-Walker* court indicated that a portion of the 2016 Rule purportedly not vacated by *Franciscan*—namely, the provision defining "sex" to include "sex stereotyping"—independently prohibits "[d]iscrimination based on … gender identity." 485 F. Supp. 3d at 38, 42. The court therefore enjoined the 2020 Rule's repeal of this portion of the 2016 Rule in light of *Bostock*, "le[aving] … the 2016 Rule's prohibition on … sex stereotyping" in effect. *Id.* at 26, 64. The *Whitman-Walker* court also enjoined the 2020 Rule to whatever extent it incorporated Title IX's religious exemption, *id.* at 43-46, even though the *Franciscan* court had held that the 2016 Rule was arbitrary and capricious for *not* incorporating that exemption, *Franciscan*, 227 F. Supp. 3d at 689-91.

G. The District Court's Decision

On November 6, 2020, following *Walker* and *Whitman-Walker*'s reinstatement of the 2016 Rule, Plaintiffs filed an unopposed motion to lift the stay in this case, which was granted. Plaintiffs and North Dakota then filed an amended complaint and motion for partial summary judgment. A25, A95. As relevant here, Plaintiffs sought a permanent injunction under RFRA prohibiting HHS from enforcing Section 1557 to compel them to perform or insure gender-transition procedures in violation of conscience. SA551. Plaintiffs requested relief before January 20, 2021, noting that the incoming Biden Administration had promised to enforce

Section 1557 on behalf of "the LGBTQ+ community" and "reverse" "religious exemptions" for "medical providers." A738. North Dakota also requested a permanent injunction under the Spending Clause. SA593-96.

On January 19, 2021, the district court issued a 57-page opinion granting in part and denying in part Plaintiffs' motions for partial summary judgment. A809. The court first considered whether Plaintiffs had standing to bring a pre-enforcement challenge to Section 1557—specifically, whether Plaintiffs had shown an intent to engage in conduct (1) "arguably affected with a constitutional interest," (2) "arguably proscribe[d]" by statute, and (3) subject to "a credible threat of prosecution." A782-85 (internal quotations omitted).

First, the court held that Plaintiffs' conduct "implicates constitutional interests" because their "refusal to perform or cover gender-transition procedures is predicated on an exercise of their religious beliefs protected by the First Amendment." A782. HHS did not dispute this point.

Second, the court held that Plaintiffs' conduct is "arguably proscribe[d]" by Section 1557 and HHS's rules. Specifically, their conduct is currently proscribed under the 2016 Rule, because the "overlapping preliminary injunctions" in *Walker* and *Whitman-Walker* "reinstate[d]" that rule and "enjoined incorporation of the Title IX religious exemption." A783. It is also proscribed by the 2020 Rule interpreted under *Bostock*—as "HHS admit[s]" and recent "[c]ase law vindicates." A783-84. And given *Bostock*, Plaintiffs' conduct "arguably falls within the ambit of Section

1557" itself, regardless of the governing HHS rule. A783-84. Thus, there is "a clear path for the Plaintiffs to incur liability." A783.

Lastly, the court determined "a credible threat of enforcement" exists because "the plain text" of Section 1557 "expose[s] the Plaintiffs to liability," and "there is no 'evidence—via official policy or a long history of disuse—that authorities' have 'actually' refused to enforce" the statute." A784 (quoting *Jones v. Jegley*, 947 F.3d 1100, 1104 (8th Cir. 2020)). Rather, "HHS has undertaken two rulemakings to refine enforcement parameters" and "vowed in the 2020 Rule's preamble to 'vigorously enforce the prohibitions on discrimination based on … sex.'" A784-85 (quoting 85 Fed. Reg. at 37,175). This is "more than sufficient to establish a credible threat of enforcement." A785.

The court also held that the case was ripe for adjudication. The court found the issues fit for judicial resolution, because they "present 'purely legal questions' … and need no additional factual development." A795. And the court found that withholding judicial review would impose hardship on Plaintiffs, because "Plaintiffs must either alter their policies" in violation of conscience "or risk the loss of critical federal healthcare funding along with potential civil and criminal penalties." A795-96.

Turning to the merits, the court held HHS had violated RFRA. By attempting to compel Plaintiffs "to perform or cover gender-transition procedures," on pain of "losing millions of dollars in federal healthcare funding and incurring civil and criminal liability," HHS had "indisputably"

imposed a substantial burden on Plaintiffs' religious exercise. A798-99 (quoting *Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 937 (8th Cir. 2015), *vacated on other grounds, HHS v. CNS Int'l Ministries*, No. 15-775, 2016 WL 2842448 (May 16, 2016)). And HHS did not even "attempt" to demonstrate that this burden was the least restrictive means of furthering a compelling governmental interest. A800.

Nor, as the court explained, could it. In the 2016 Rule, HHS asserted a generalized interest in "ensuring nondiscriminatory access to healthcare." A800 (citing 81 Fed. Reg. at 31,380). But in applying RFRA, "the Supreme Court has instructed [courts] to look 'beyond broadly formulated interests'" and instead "'scrutinize the asserted harm of granting specific exemptions to particular religious claimants.'" A800 (quoting *Gonzales v. O Centro Espírita Beneficente União do Vegetal*, 546 U.S. 418, 431 (2006); *Holt v. Hobbs*, 574 U.S. 352, 363 (2015)). Here, "[n]either HHS nor the EEOC has articulated how granting specific exemptions for the Catholic Plaintiffs will harm the asserted interests in preventing discrimination." A800. Additionally, "the government's own healthcare programs" do not require the provision of gender-transition procedures, which creates "serious doubts that a compelling interest exists." *Id.*

HHS also "fail[ed] to meet the rigors of the least-restrictive means test," because HHS "possess[es] many less restrictive alternatives." A800-01. One "straightforward" alternative "'would be for the Government to assume the cost of providing' gender-transition procedures for

those 'unable to obtain them under their health-insurance policies due to their employers' religious objections.'" A801 (quoting *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 728 (2015)). "Other options include providing 'subsidies, reimbursements, tax credits, or tax deductions to employees' or paying for services 'at community health centers, public clinics, and hospitals with income-based support.'" A801 (quoting *Sharpe Holdings*, 801 F.3d at 945). "ACA exchanges offer yet another viable alternative," and "if broadening access to gender-transition procedures themselves is the goal, then the government could assist transgender individuals in finding and paying for transition procedures available from the growing number of healthcare providers who offer and specialize in those services." A801-02 (cleaned up). Because HHS has "not shown that these alternatives are infeasible," it "fail[ed] to demonstrate that [its] policies use the least restrictive means to burden the Catholic Plaintiffs' exercise of religion." A802 (quoting *Sharpe Holdings*, 801 F.3d at 945).

After concluding that Plaintiffs established success on the merits, the court analyzed the remaining injunction factors. The court held Plaintiffs established irreparable harm because a "RFRA violation is comparable to the deprivation of a First Amendment right," which under Eighth Circuit precedent is "sufficient to show irreparable harm." A808 (citing *Child Evangelism Fellowship of Minn. v. Minneapolis Special Sch. Dist. No. 1*, 690 F.3d 996, 1000 (8th Cir. 2012)). The court also found "[t]he balance of harms tilts decisively in [Plaintiffs'] favor," because "they will either

be 'forced to violate their sincerely held religious beliefs' … 'or to incur severe monetary penalties for refusing to comply.'" A808 (quoting *Sharpe Holdings*, 801 F.3d at 945). Lastly, the court concluded an injunction protecting Plaintiffs' free-exercise rights is in the public interest. A808 (citing *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020)). Because all four injunctive factors favored Plaintiffs, the court permanently enjoined HHS from enforcing Section 1557 to require Plaintiffs or their members to perform or insure gender-transition procedures. A809-10.

The district court, however, did not accept some of Plaintiffs' and North Dakota's arguments. The court rejected North Dakota's Spending Clause claim on the merits, holding that Section 1557 unambiguously informed North Dakota it could be held liable for gender-identity discrimination. A804. And although Plaintiffs had also challenged HHS's application of Section 1557 to the extent it would require them to perform and insure abortions, the Court found they lacked standing to press this claim, reasoning that unlike with gender transitions, Section 1557, "[a]s interpreted today, … does not proscribe refusal to perform or insure abortions." A779.[3]

On February 16, 2021, HHS filed a motion to modify the court's injunction. SA717. Despite its prior claim that Plaintiffs and their members faced no risk of enforcement under Section 1557, HHS now claimed that

[3] Neither Plaintiffs nor North Dakota cross-appealed, so the Spending Clause and abortion issues are not before this Court.

it was at "risk of violating the [court's] Order" and being found in "contempt" because it might unwittingly enforce Section 1557 against a member of Plaintiff Catholic Benefits Association (CBA) without knowing the entity belonged to CBA. SA721-22. To address this concern, HHS proposed modifying the injunction to clarify that if HHS takes "any of the prohibited actions against a CBA member" for "failure to perform or provide insurance coverage for gender-transition procedures," then the member may "notify" HHS of its membership in CBA, and HHS "will not proceed further to enforce Section 1557" against them. *Id.* This, HHS said, would "provid[e] necessary protection so that [HHS] may otherwise carry out [its] statutory obligations without risk of violating the [court's] Order." SA722.

Plaintiffs consented to this request, SA730, and the proposed language was added to the injunction. A815. Plaintiffs also voluntarily dismissed their remaining claims, the court entered final judgment, and HHS appealed.

H. Subsequent Developments

The day after the district court's order, on his first day in office, President Biden issued an Executive Order declaring the new Administration's policy that "[p]eople should be able to access healthcare … without being subjected to sex discrimination," and that "[u]nder *Bostock*'s reasoning, laws that prohibit sex discrimination—including Title IX…—prohibit discrimination on the basis of gender identity." Exec. Order No.

13,988, 86 Fed. Reg. 7023 (Jan. 20, 2021). The Order announced the Administration's policy "to fully enforce … laws that prohibit discrimination on the basis of gender identity." *Id.* And it ordered HHS and other agencies, "as soon as practicable," to consider taking "new agency actions … fully implementing th[is] policy." *Id.* at 7023-24.

Accordingly, on May 10, 2021, HHS issued a Notification of Interpretation and Enforcement ("Notification of Enforcement") stating that, "beginning today," HHS "will interpret and enforce Section 1557[]" to prohibit "discrimination on the basis of gender identity." 86 Fed. Reg. 27,984, 27,985 (May 25, 2021). HHS said this interpretation will "guide [HHS] in processing complaints and conducting investigations," and HHS will enforce this prohibition via "Title IX's enforcement procedures." *Id.* at 27,984-85. And HHS concluded by inviting members of the public who "believe that a covered entity violated" the prohibition on gender-identity discrimination to "file a complaint" with HHS. *Id.* at 27,985.

Meanwhile, the Fifth Circuit held oral argument in the *Franciscan* appeal. There, the Court specifically asked HHS if it would disavow enforcement of Section 1557 against the religious plaintiffs, but HHS refused: "[Q.] Are you able to tell us that … you're not going to enforce? [A.] No your honor." Oral Arg. at 15:46-19:27, *Franciscan All., Inc. v. Azar*, No. 20-10093 (5th Cir. Mar. 3, 2021).

The Fifth Circuit then remanded the case, noting that "the legal landscape ha[d] shifted considerably"—citing the 2020 Rule, *Bostock*, the

Walker and *Whitman-Walker* injunctions, and the new Administration's actions. *Franciscan All., Inc. v. Becerra*, 843 Fed. App'x 662, 662-63 (5th Cir. 2021). It directed the district court to reconsider whether, in addition to vacatur of the 2016 Rule, a permanent injunction was needed. *Id.*

In August 2021, the district court in *Franciscan* granted a permanent injunction. *Franciscan All., Inc. v. Becerra*, No. 16-cv-108, 2021 WL 3492338 (N.D. Tex., Aug. 9, 2021). The court held the case was justiciable because HHS could "enforce[] Section 1557 against Christian Plaintiffs in the same religion-burdening way as the 2016 Rule," and "the current regulatory scheme for Section 1557 clearly prohibits Plaintiffs' conduct, thus[] putting them to the impossible choice of either defying federal law and risking serious financial and civil penalties, or else violating their religious beliefs." *Id.* at *8-9 (cleaned up). The court also held that injunctive relief was warranted because Section 1557 "forces Christian Plaintiffs to face civil penalties or to perform gender-transition procedures and abortions contrary to their religious beliefs—a quintessential irreparable injury." *Id.* at *10.

STANDARD OF REVIEW

"This court reviews de novo standing and ripeness determinations, and grants of summary judgment." *City of Kennett v. EPA*, 887 F.3d 424, 430 (8th Cir. 2018). A "district court's issuance of a permanent injunction" is reviewed "for abuse of discretion." *Kennedy Bldg. Assocs. v. CBS Corp.*, 576 F.3d 872, 876 (8th Cir. 2009).

SUMMARY OF ARGUMENT

I. The district court correctly held Plaintiffs have standing to bring a pre-enforcement challenge. To bring a pre-enforcement challenge "a plaintiff need not wait for an actual prosecution or enforcement action." *Telescope Media*, 936 F.3d at 749. Instead, a plaintiff need only show: (1) that plaintiff intends to engage in "conduct arguably affected with a constitutional interest"; (2) that this "conduct is arguably proscribed by" the challenged law; and (3) that there exists "a credible threat of enforcement." *Driehaus*, 573 U.S. at 161-67 (cleaned up). As the district court found, all three elements are easily satisfied here.

First, Plaintiffs' conduct is "affected with a constitutional interest" because their refusal to perform or insure gender transitions is an exercise of their religious beliefs protected by the First Amendment and RFRA. HHS doesn't dispute this point.

Second, Plaintiffs' conduct isn't just "arguably proscribed," but *actually* proscribed by HHS in three respects. It is proscribed by the 2016 Rule as revived in litigation; by the 2020 Rule as interpreted under *Bostock*; and by Section 1557 itself, independent of any rule. This understanding of the law has been advanced by HHS in litigation, confirmed by its recent Notification of Enforcement, and adopted by multiple courts in cases involving Catholic organizations like Plaintiffs.

Third, Plaintiffs face a "credible threat of enforcement." *Driehaus*, 573 U.S. at 164-67. This requirement follows as a matter of law from the first

two, except in "extreme cases approaching desuetude." *281 Care*, 638 F.3d at 628. Here, Section 1557 is far from defunct. HHS has vowed to vigorously enforce it, has conducted multiple rulemakings, and has issued a Notification of Enforcement soliciting public complaints. Beyond that, controlling precedent says even a sworn disavowal of present intent to prosecute doesn't eliminate the threat of prosecution. *United Food*, 857 F.2d at 429-30. Here, HHS has done the opposite: It has repeatedly *refused* to disavow enforcement against religious plaintiffs, and it told the district court it was at risk of "contempt" under the injunction precisely because it anticipates enforcing Section 1557 against religious organizations. SA721.

II. The district court also correctly held this case is ripe. A case is ripe when (1) the issues are fit for judicial decision and (2) withholding court review would result in hardship for plaintiffs. *Pub. Water Supply Dist. No. 10 v. City of Peculiar*, 345 F.3d 570, 572-73 (8th Cir. 2003). Here, the issues are fit for judicial decision because the legality of HHS's actions is "largely a legal question," *281 Care*, 638 F.3d at 631—as even HHS admitted below. SA640 n.1. And withholding review would result in hardship for Plaintiffs, because they "must either immediately alter their behavior" in violation of conscience "or play an expensive game of Russian roulette with" multimillion-dollar HHS penalties. *Iowa League of Cities*, 711 F.3d at 868.

III. Finally, the district court did not abuse its discretion in concluding Plaintiffs face irreparable injury. It is blackletter law that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Diocese of Brooklyn*, 141 S.Ct. at 67 (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality)). And courts have repeatedly applied this principle to RFRA, because "RFRA protects First Amendment free-exercise rights." *Korte v. Sebelius*, 735 F.3d 654, 666 (7th Cir. 2013). Thus, a violation of RFRA constitutes irreparable harm.

ARGUMENT

I. The district court correctly held Plaintiffs have standing.

Standing requires "(1) an injury in fact; (2) a causal connection between the injury and the challenged law; and (3) that a favorable decision is likely to redress the[] injury." *Telescope Media*, 936 F.3d at 749. HHS doesn't dispute causation or redressability; thus, "the only real question is whether [Plaintiffs] have suffered an injury in fact." *Id*. Plaintiffs meet this requirement.

A. Plaintiffs have suffered an injury-in-fact.

"When a statute is challenged by a party who is a target or object of the statute's prohibitions, 'there is ordinarily little question that the [statute] has caused him injury.'" *Gaertner*, 439 F.3d at 485 (quoting *Minn. Citizens*, 113 F.3d at 131). That is this case. It's undisputed that

Plaintiffs run "health program[s]" that "receiv[e] Federal financial assistance," 42 U.S.C. § 18116(a), and are therefore the "object" of Section 1557. It's also undisputed that Plaintiffs are "covered entities" under HHS's 2016 and 2020 Rules and are therefore the "object" of those Rules. 81 Fed. Reg. at 31,466; 85 Fed. Reg. at 37,226, 37,244. Thus, they presumptively have standing to sue.

Moreover, it's settled law that "a plaintiff need not wait for an actual prosecution or enforcement action before challenging a law's constitutionality." *Telescope Media*, 936 F.3d at 749. Rather, a "plaintiff satisfies the injury-in-fact requirement where he alleges 'an intention to engage in a course of conduct [1] arguably affected with a constitutional interest, but [2] proscribed by a statute, and [3] there exists a credible threat of prosecution thereunder.'" *Driehaus*, 573 U.S. at 159.

That, too, is this case, as the district court correctly concluded. A782-85. Plaintiffs are engaged in conduct affected with a constitutional interest—the practice of medicine and provision of health insurance in accordance with their religious beliefs, which forbid performing or insuring gender transitions. That conduct is expressly proscribed under HHS's interpretation of Section 1557. Accordingly, if Plaintiffs adhere to their beliefs, they are subject to multimillion-dollar financial penalties, debarment from doing business with the federal government, False Claims Act lawsuits, criminal penalties, private lawsuits, and "future enforcement actions brought by" HHS. *Alexis Bailly Vineyard v. Harrington*, 931 F.3d

774, 777 (8th Cir. 2019); *see* A757. Thus, Plaintiffs easily satisfy the injury-in-fact requirement for standing to sue.

1. Applying the first *Driehaus* factor, Plaintiffs' conduct is "arguably affected with a constitutional interest." *Driehaus*, 573 U.S. at 161. Plaintiffs' refusal to perform or pay for gender transitions is religious exercise protected by RFRA and the First Amendment. SA640 n.1; SA808 (collecting cases analogizing RFRA to a constitutional right). And Plaintiffs' desire to engage in First Amendment-protected conduct "means that their other claims are affected with a constitutional interest too, regardless of the precise legal theory." *Telescope Media*, 936 F.3d at 750. HHS doesn't contest this factor.

2. Second, Plaintiffs' conduct is "arguably proscribed" by law. *Driehaus*, 573 U.S. at 163. Indeed, it is triply proscribed: by the 2016 Rule, the 2020 Rule, and Section 1557 itself.

2016 Rule. HHS doesn't dispute that Plaintiffs' conduct is proscribed by the 2016 Rule. This Rule formally interprets Section 1557 to prohibit discrimination based on "gender identity" and "sex stereotyping," and states that categorical refusals to perform or insure gender transitions—which is precisely what Plaintiffs do—are "unlawful on [their] face." 81 Fed. Reg. at 31,467, 31,429; *id.* at 31,435-36, 31,455 (providers must perform transition procedures if they would perform similar procedures for other purposes); *id.* at 31,392 (forbidden "sex stereotype" "include[s] the

expectation that individuals consistently identify with only one of two genders").

In response, HHS says the 2020 Rule "rescinded" the 2016 Rule's definition of "sex" discrimination. Br.23. But as the district court found, this attempted rescission was *unsuccessful*. A783. Instead, two federal courts enjoined the relevant portions of the 2020 Rule and held that the 2016 "definitions … *remain in effect*." *Walker*, 480 F. Supp. 3d at 430 (emphasis added); *see also Whitman-Walker*, 485 F. Supp. 3d at 26-27, 64; *accord Hammons v. Univ. of Md. Med. Sys. Corp.*, No. 20-2088, 2021 WL 3190492, at *16 (D. Md. July 28, 2021) ("those 'regulatory changes' have been enjoined" (citing *Walker* and *Whitman-Walker*)).

Specifically, *Walker* enjoined the 2020 Rule's "repeal of the 2016 definition of discrimination on the basis of sex," such that, "[a]s a result," the 2016 Rule's "definitions of 'on the basis of sex,' 'gender identity,' and 'sex stereotyping'" "remain in effect." 480 F. Supp. 3d at 430. And *Whitman-Walker* revived the 2016 Rule's definition of "sex" discrimination to include "sex stereotyping"—which, it reasoned, would also prohibit "gender identity" discrimination, since the latter "often cannot be meaningfully separated from" the former. 485 F. Supp. 3d at 26-27, 38, 64. Thus, despite the attempted repeal, Plaintiffs remain subject to provisions of the 2016 Rule prohibiting "gender identity" discrimination—and thus, ac-

cording to HHS itself, they must "revise [their] polic[ies] to provide [transition] procedures" or face multimillion-dollar penalties. 81 Fed. Reg. at 31,455.

2020 Rule. The district court also held that, "even without the injunctions" reviving the 2016 Rule, Plaintiffs still face "potential consequences from the 2020 Rule." A783. Specifically, while the 2020 Rule omits any definition of "sex" discrimination, it states that "the [Supreme] Court's construction" of sex discrimination in *Bostock* will control. 85 Fed. Reg. at 37,168, 37,178. And in *Bostock*, the Supreme Court held that a prohibition on "sex" discrimination *does* encompass discrimination based on "transgender status." *Bostock*, 140 S.Ct. at 1741. Thus, the 2020 Rule, read in light of *Bostock*, *itself* prohibits gender-identity discrimination—and so proscribes Plaintiffs' conduct in the same way as the 2016 Rule.

HHS's own position in the cases challenging the 2020 Rule confirms as much. HHS defended the 2020 Rule on the ground that "in light of *Bostock*," covered entities may interpret the 2020 Rule to impose the same "sex"-discrimination requirements as the 2016 Rule. *Washington* Resp. at 6-7; *see Washington*, 482 F. Supp. 3d at 1114-15 (adopting HHS's argument). Indeed, HHS stated that efforts to apply Section 1557 to prohibit "gender identity" discrimination are now even "*more likely* to bear fruit under the 2020 Rule than under the 2016 Rule." *BAGLY* Memo at 14 (emphasis added). And HHS recently told the Second Circuit that pro-

viders would be "run[ning a] risk" in declining to perform gender-transition procedures under the 2020 Rule. HHS Br. at 23, *Walker v. Cochran*, No. 20-3580 (2d Cir. Feb. 19, 2021), ECF 46. This is exactly the sort of risk that justifies a pre-enforcement lawsuit like this one.[4]

Section 1557. Finally, regardless of the applicable Rule, Plaintiffs' conduct is also arguably proscribed by Section 1557 itself, which HHS can enforce directly without even promulgating a rule. *See* 42 U.S.C. § 18116(c) (HHS "*may* promulgate regulations to implement this section." (emphasis added)). Even before *Bostock*, multiple courts had held Section 1557 prohibits "gender identity" discrimination, and therefore permits lawsuits against healthcare providers who decline to perform or insure gender transitions. *See, e.g., Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 952-53 (D. Minn. 2018); *Prescott v. Rady Children's Hosp.-San Diego*, 265 F. Supp. 3d 1090, 1098-1100 (S.D. Cal. 2017). After *Bostock*,

[4] HHS says the 2020 Rule included a "provision … incorporating Title IX's religious exemption," Br.29, but it doesn't argue that this provision defeats standing. That is because the alleged provision was enjoined in *Whitman-Walker*—and "HHS cannot defeat standing with a wink and a nod to a regulatory interpretation that another court has enjoined." A787. In any event, the 2020 Rule *refused* to "craft a religious exemption to Section 1557," merely reciting the existence of one in Title IX. 85 Fed. Reg. at 37,207, 37,243. And HHS suggested the scope of any exemption would be limited to religious organizations' "educational operation[s]," 85 Fed. Reg. at 37,207—a limitation that wouldn't protect Plaintiffs even if the alleged exemption weren't enjoined. SA571, 591-93.

these lawsuits have multiplied—with at least two more courts now holding that Section 1557 prohibits specifically *Catholic* insurance plans and healthcare providers (like Plaintiffs) from declining to facilitate gender transitions. This includes paying for a mastectomy on a 15-year-old biological girl (*C.P. ex rel Pritchard v. Blue Cross Blue Shield of Ill.*, No. 20-cv-06145, 2021 WL 1758896, at *1-2, 4-5 (W.D. Wash. May 4, 2021)), and performing a hysterectomy on a biological female's "otherwise healthy" uterus (*Hammons*, 2021 WL 3190492, at *2-3). In other words, these courts have held that conduct identical to Plaintiffs' is not only *arguably* proscribed by Section 1557, but *actually* proscribed—making it unmistakable that this *Driehaus* factor is met.

Since the district court's decision, HHS has only confirmed this point. On May 10, 2021, HHS issued a Notification of Enforcement stating that it agrees with these courts: "Consistent with the Supreme Court's decision in *Bostock*," Section 1557 "prohibits" "discrimination on the basis of gender identity." 86 Fed. Reg. 27,985. And in June, DOJ filed a brief explaining at length the Administration's view that it is both gender-identity discrimination and sex stereotyping to permit medical treatments for non-transition purposes while prohibiting them for transition purposes, Statement of Interest at 7-9, *Brandt v. Rutledge*, No. 4:21-cv-00450 (E.D. Ark. June 17, 2021), ECF 19—as Plaintiffs do. These actions simply con-

firm what the district court already concluded: Plaintiffs' conduct remains "arguably … within the ambit of Section 1557" under HHS's "prevailing interpretations of Section 1557." A784, A798.

3. Third, Plaintiffs face a credible threat of prosecution. If Plaintiffs are engaged in conduct arguably proscribed by law, a credible threat of prosecution is typically assumed as a matter of law, except in "extreme cases approaching desuetude." *281 Care*, 638 F.3d at 628. That is, "as long as there is no 'evidence—via official policy or a long history of disuse—that authorities' have 'actually' refused to enforce a statute, a plaintiff's fear of prosecution for illegal activity is objectively reasonable." *Jones*, 947 F.3d at 1104 (quoting *281 Care*, 638 F.3d at 628). In fact, if a "non-moribund" law "facially restrict[s] expressive activity by the class to which the plaintiff belongs"—as here—"courts will *assume* a credible threat of prosecution in the absence of *compelling contrary evidence*." *Gaertner*, 439 F.3d at 486 (emphasis added).

Here, Section 1557 is far from moribund. It was enacted only eleven years ago and is the subject of two major rulemakings in the last five years. Br.15-16. In comparison, this Court found the law in *281 Care* non-moribund when it was adopted twenty-three years earlier (which the Court called "comparatively recently") "and was amended fewer than five years before this suit was filed." 638 F.3d at 628. Beyond that, HHS issued a Notification of Enforcement just this year, inviting the public to file complaints and stating it would "enforce Section 1557's prohibition

on discrimination on the basis of sex to include … discrimination on the basis of gender identity." 86 Fed. Reg. at 27,985. And there are multiple private lawsuits *pending today* seeking to enforce Section 1557 against religious organizations identically situated to Plaintiffs. *Supra* at 35-36. Under this Court's precedents, this "is more than sufficient to establish a credible threat of enforcement." A785; *accord Alexis*, 931 F.3d at 778 ("[W]hen a course of action is within the plain text of a statute, a 'credible threat of prosecution' exists.").

Even if Plaintiffs needed to show more, other factors confirm the threat. First, as in *Driehaus*, "there is a history of past enforcement." 573 U.S. at 164. Upon promulgating the 2016 Rule, HHS received a complaint against one Catholic hospital, *see* SA679 n.1; indicated it would investigate another Catholic hospital for refusing to perform a gender-transition surgery, *Conforti*, 2017 WL 67114 ¶81; and investigated the State of Texas for maintaining the same policies, *see* SA679 n.2—and the only reason it didn't do more is that the relevant portions of the 2016 Rule were enjoined on a nationwide basis on the eve of their effective date, *Franciscan*, 227 F. Supp. 3d 660.

Next, under *Driehaus*, the credibility of the threat is "bolstered" if private parties can file complaints. 573 U.S. at 164-65. This Court said the same thing in *281 Care*, where it noted plaintiffs' "reasonable worry" that "other complainants—including their political opponents who are free to

file complaints under the statute—will interpret the[ir] actions as violating the statute." 638 F.3d at 630; *Balogh v. Lombardi*, 816 F.3d 536, 542 (8th Cir. 2016) ("[A] credible threat that private parties will enforce a statute may also satisfy the injury-in-fact requirement." (cleaned up)).

So too here. In fact, HHS has *solicited* complaints specifically with respect to "gender identity" discrimination. 86 Fed. Reg. at 27,985. It has already received at least two complaints against Catholic hospitals—one from the ACLU, and one from Lambda Legal. SA679 n.1; *Conforti*, 2017 WL 67114 ¶¶80-81. And multiple parties and activist groups have not only filed complaints with HHS, but also sued covered entities directly under Section 1557 for declining to perform or insure gender transitions, *see, e.g.*, *Cruz*, 116 F. Supp. 3d 334; *Tovar*, 342 F. Supp. 3d 947—including, specifically, Catholic religious organizations like Plaintiffs, *Hammons*, 2021 WL 3190492, at *1 (Catholic hospital); *Conforti*, 2017 WL 67114 (same); *see also Pritchard*, 2021 WL 1758896, at *1 (administrator of Catholic employer's plan); *cf.* Compl. at 39, *Whitman-Walker*, No. 20-cv-1630 (D.D.C. June 22, 2020), ECF 1 (seeking to require all "hospitals and health care systems" to perform gender-transition procedures—"religiously affiliated" or otherwise).

Even where the government has "*never* prosecuted anyone under the [challenged statute] or made any public statements threatening to do so," this Court has also found a credible threat of enforcement if the defendant refuses to "disavow[] an intent to enforce the statute[] in the future."

Gaertner, 439 F.3d at 485 (emphasis added; cleaned up). And even a sworn disavowal of "present" intent doesn't suffice, since "changes in leadership" could generate a different result. *United Food*, 857 F.2d at 429-30; *cf. Rodgers v. Bryant*, 942 F.3d 451, 455 (8th Cir. 2019) ("[I]n-court assurances do not rule out the possibility that it will change its mind and enforce the law more aggressively in the future.").

Here, HHS has never disavowed an intention (present or future) to enforce Section 1557, much less submitted sworn testimony to that effect. To the contrary, HHS promised "robust enforcement of Section 1557" in the 2016 Rule, 81 Fed. Reg. at 31,440; it vowed in the 2020 Rule to "vigorously enforce [Section 1557's] prohibitions on discrimination based on … sex," 85 Fed. Reg. at 37,175; the Biden Administration campaigned on enforcing Section 1557 on behalf of "the LGBTQ+ community" and "revers[ing]" "religious exemptions" for "medical providers," A738; President Biden issued a day-one Executive Order declaring that *Bostock* prohibits "discrimination on the basis of gender identity" in "healthcare," 86 Fed. Reg. 7023; and HHS has issued a Notification of Enforcement stating its intent to "enforce" Section 1557 specifically with respect to "gender identity" discrimination and inviting complaints. 86 Fed. Reg. at 27,985. Perhaps most telling of all, HHS was asked point blank during the Fifth Circuit's oral argument in *Franciscan* if it would disavow enforcement against religious objectors and answered, "No your honor." Oral Arg. at 15:46-19:27, *Franciscan*, No. 20-10093 (5th Cir. Mar. 3, 2021).

Far from disavowing enforcement, HHS has *in this litigation* represented that it expects to enforce Section 1557 against religious entities like Plaintiffs. Specifically, after the district court entered its injunction, HHS moved to modify it, stating that HHS was at "risk of violating the [court's] Order" and being found in "contempt" because it might enforce Section 1557 against one of Plaintiff CBA's members without knowing it was a member of CBA. SA721-22. To address this concern, HHS asked for (and received) language clarifying that HHS would not be held in contempt for "enforc[ing] Section 1557" against a CBA member for "failure to perform or provide insurance coverage for gender-transition procedures," as long as HHS stopped its enforcement action after the member notified HHS of its membership. *Id.* But if HHS worries that it will unwittingly enforce Section 1557 against religious organizations in *violation* of the district court's injunction, then Plaintiffs obviously face a credible threat of enforcement *absent* an injunction. In short, this is a straightforward admission that Plaintiffs face a credible threat of enforcement.

B. HHS's counterarguments fail.

HHS offers several counterarguments on appeal, none persuasive.

First, HHS says "it is not enough [to show] that Section 1557 'arguably proscribes'" Plaintiffs' conduct. Br.25. Indeed, it says the mere fact the district court used the "arguably proscribes" "language" "underscores the

speculative nature of plaintiffs' injuries." *Id.* But the "arguably proscribed" language is a direct quote from *Driehaus*, where the Supreme Court said courts must assess whether plaintiffs' conduct "is 'arguably proscribed' by the law" they are challenging. 573 U.S. at 162. This Court and others have repeatedly used the same language. *See also, e.g.*, *Turtle Island Foods, SPC v. Thompson*, 992 F.3d 694, 700 (8th Cir. 2021); *Woodhull Freedom Found. v. United States*, 948 F.3d 363, 371-73 (D.C. Cir. 2020); *Kiser v. Reitz*, 765 F.3d 601, 608 (6th Cir. 2014).

HHS cites no case applying *Driehaus* differently. *Cf.* Br.25. Indeed, all authority we know of is to the contrary. *See, e.g.*, *Speech First, Inc. v. Fenves*, 979 F.3d 319, 332 n.10 (5th Cir. 2020) (rejecting argument "that the 'relevant inquiry is whether the policy actually prohibits the speech in question'" because under *Driehaus*, "the question is simply whether speech is 'arguably … proscribed by' the challenged policies"); *281 Care*, 638 F.3d at 627-30 (plaintiff need not concede actual proscription because it is "objectively reasonable" for protected conduct to be "chilled" when it is arguably proscribed by statute); *Majors v. Abell*, 317 F.3d 719, 721 (7th Cir. 2003) (same). Thus, far from indicating "the speculative nature of plaintiffs' injuries," Br.25, the district court's use of this language simply shows it followed settled law.

Next, HHS argues that Plaintiffs have suffered no injury-in-fact because the 2020 Rule "rescinded" the 2016 Rule's prohibition on gender-

identity discrimination, so no law or regulation currently prohibits Plaintiffs' conduct. Br.22-23. But this argument is triply flawed, for reasons already explained. First, the 2016 Rule has been revived by other litigation, and its provisions "remain in effect." *Walker*, 480 F. Supp. 3d at 430; *Whitman-Walker*, 485 F. Supp. 3d at 26-27, 38, 64. Second, regardless of the 2016 Rule, the 2020 Rule, as HHS interprets it under *Bostock*, has the same effect. 85 Fed. Reg. at 37,168, 37,178. And third, multiple courts, along with HHS in its own Notification of Enforcement, have concluded Section 1557 itself imposes the same requirement, independent of any HHS regulation, *see supra* at 35-36. So there remains "a clear path for the Plaintiffs to incur liability under Section 1557," with or without the 2016 Rule. A783.

Resisting this analysis, HHS says *Walker* and *Whitman-Walker* revived only the "sex stereotyping," not the "gender identity," portions of the 2016 Rule, and thus the district court's opinion "rests on [an] erroneous factual premise[]." Br.26. But the *Walker* opinion expressly revived the 2016 Rule's "definitions of 'on the basis of sex,' '*gender identity*,' *and* 'sex stereotyping,'" 480 F. Supp. 3d at 430 (emphasis added)—so the district court simply took *Walker* at its word. A783. In any event, this dispute is irrelevant. Both *Walker* and *Whitman-Walker* were premised on the notion that gender-identity discrimination is "inherently" a form of sex stereotyping. *Walker*, 480 F. Supp. 3d at 427; *see Whitman-Walker*, 485 F. Supp. 3d at 38. So if the "sex stereotyping" provision of the 2016

Rule has been revived (as all parties agree), then so has the 2016 Rule's prohibition on categorically refusing to perform or insure gender transitions—a point HHS doesn't contest.

Nor does HHS even mention the most analogous body of precedent, which the district court discussed at length: the widespread RFRA litigation challenging HHS's "contraceptive mandate." A786-87; *see generally Little Sisters of the Poor v. Pennsylvania*, 140 S.Ct. 2367, 2372-73 (2020). There, as here, the Obama Administration issued regulations applying the ACA to require coverage of religiously objectionable medical services. *Id.* at 2373-75. There, as here, many courts (including this Court) held the requirement violated RFRA. *See Sharpe Holdings*, 801 F.3d at 945-46. So there, as here, the Trump Administration issued new regulations attempting to repeal the mandate. *See Sharpe Holdings, Inc. v. HHS*, No. 12-CV-92, 2018 WL 1520031, at *2 (E.D. Mo. Mar. 28, 2018). But there, as here, the new regulations were themselves enjoined by two other district courts as violating the APA, thus bringing the mandate back "in[to] effect." *Id.* (internal quotation marks omitted).

Accordingly, there, as here, religious objectors pressed forward in their lawsuits challenging the mandate. *See id.* And *not one* of those cases was dismissed for lack of standing. Rather, over a dozen courts across the country, including two in this Circuit, issued permanent injunctions barring HHS's enforcement of the statute—and HHS never even *contested* justiciability. *See id.* (following injunctions against new regulations, "the

government … dropped its mootness challenge"); *see also Christian Emps. All. v. Azar*, No. 3:16-cv-00309, 2019 WL 2130142 (D.N.D. May 15, 2019); SA686 n.3 (collecting cases). As the district court concluded—and as HHS simply ignores—"the similar posture in [the contraceptive-mandate] cases reinforces the conclusion" that this case is justiciable, A787, and supports the same relief.

In fact, recent developments make the justiciability question even simpler here than in the contraceptive-mandate cases. Here, not only has the 2016 Rule been revived by other litigation, but HHS has issued a Notification of Enforcement *affirmatively reimposing* that Rule's requirements. So compared with the contraceptive-mandate litigation, this is an easy case.

Unable to deny this fact, HHS admits it "has now taken the position that sex discrimination includes gender-identity discrimination under Section 1557." Br.24. But it says the Notification can't "demonstrate standing" because it was issued after the filing of the operative complaint. Br.22-23.

But Plaintiffs don't argue that the Notification *confers* standing; it simply *confirms* what was already true at the time of filing—that under *Bostock*, HHS's "prevailing interpretations of Section 1557" covered gender-identity discrimination. A.783-84, 798-99; *see* 86 Fed. Reg. at 27,985 (Notification was issued "consistent with the Supreme Court's decision in *Bostock*"); *see also Hammons*, 2021 WL 3190492, at *17 (Notification is

"beside the point, as *Bostock* already made clear that the position stated in HHS's interpretation was already binding law"). In any event, in evaluating standing for pre-enforcement challenges, both the Supreme Court and this Court have routinely looked to post-litigation statements to determine whether the defendant has disavowed enforcement, *see, e.g.*, *Driehaus*, 573 U.S. at 165 (citing oral-argument transcript); *United Food*, 857 F.2d at 429 (citing post-litigation affidavits)—and the Notification (among other evidence) shows HHS has done the opposite.

Falling back, HHS asserts that even if it *does* interpret Section 1557 to prohibit gender-identity discrimination, and even if HHS and multiple courts have said this means entities like Plaintiffs must perform and insure gender-transition procedures, Plaintiffs still can't sue because HHS hasn't "initiated any enforcement activity against" them or sent them a "targeted threat of future enforcement." Br.20, 24.

But this simply misstates the law. Plaintiffs of course don't have to wait for HHS to *initiate* enforcement activity; that's the whole point of a *pre*-enforcement challenge. *See Telescope Media*, 936 F.3d at 749; *accord, e.g.*, *Jones*, 947 F.3d at 1104 (this Court has "repeatedly rejected the argument that a plaintiff must risk prosecution before challenging a statute under the First Amendment" (collecting cases)). Nor must Plaintiffs show HHS specifically threatened *them*; they just need to show the law arguably proscribes protected conduct "by the class to which [they] belong[]." *Gaertner*, 439 F.3d at 486; *see also id.* at 485-87 (standing found

"[a]lthough Appellants have [not] been threatened by Appellees with prosecution"). In these circumstances, this Court recently reiterated, "[a] formal threat … is not required." *Animal Legal Def. Fund v. Vaught*, No. 20-1538, 2021 WL 3482998, at *3 (8th Cir. Aug. 9, 2021).

HHS's caselaw doesn't show otherwise. HHS cites *Iowa Right to Life Committee, Inc. v. Tooker*, Br.24, but that case found no credible threat of enforcement because, on certification, an "Iowa Supreme Court[] opinion ma[de] clear" that plaintiffs weren't covered by the relevant Iowa statute—unsurprisingly rendering them without standing to sue. 717 F.3d 576, 585-86 (8th Cir. 2013). Meanwhile, in *Hughes v. City of Cedar Rapids* (*see* Br.22), the plaintiff wasn't challenging any law arguably proscribing his conduct; he was challenging one of the city's *means of enforcing* its traffic laws, which he couldn't allege would be "imminent[ly]" used against him. 840 F.3d 987, 991-92 (8th Cir. 2016).[5]

Finally, HHS claims Plaintiffs lack standing because HHS says it "will comply with [RFRA]"; and although HHS "has not to date evaluated whether" RFRA provides an exemption from Section 1557, it "*might* apply to [protect] religious entities." Br.16 (emphasis added). But this

[5] Lacking support from this Circuit, HHS reaches for *Lopez v. Candaele*, 630 F.3d 775 (9th Cir. 2010). But even *Lopez* is inapposite. There, the plaintiff failed to show that the challenged policy "even arguably applies to his past or intended future" conduct, *id.* at 790—which is exactly what Plaintiffs *have* shown here.

made-for-litigation "assurance" doesn't even rise to the level of assurances this Court has rejected in other cases. The government in *Rodgers* promised "it would *never* enforce its anti-loitering law" against non-harassing panhandlers like the plaintiffs. 942 F.3d at 455 (emphasis added). The government in *Alexis* showed that it had already granted numerous exemptions and "has *never* yet denied one." 931 F.3d at 778 (emphasis added). And the government in *United Food* provided sworn affidavits promising it had "no 'present plan'" to enforce the law against plaintiffs. 857 F.2d at 429.

Yet this Court found standing each time. In *Rodgers*, it said the government's "in-court assurances do not rule out the possibility that it will change its mind and enforce the law more aggressively in the future." 942 F.3d at 455. In *Alexis*, it said the past grant of exemptions provided "no reason to think that the [government] would be willing or able to grant a perpetual exception" requested by plaintiffs. 931 F.3d at 778. And in *United Food*, it said the sworn affidavits offered "'no more than a hesitant, qualified, equivocal and discretionary present intention not to prosecute,' the clear implication of which was that the state's position could well change." 857 F.2d at 429.

Here, HHS hasn't even offered an "equivocal" statement of "present intention not to prosecute." *Id.* It says only that it hasn't, "to date," "evaluated" RFRA. But that is just another way of saying it hasn't "rule[d] out

such prosecution." *United Food*, 857 F.2d at 427. In fact, HHS has repeatedly rejected any "blanket religious exemption." 81 Fed. Reg. at 31,376; *see* 85 Fed. Reg. at 37,207 ("This final rule does not craft a religious exemption to Section 1557."). President Biden vowed to "reverse" "religious exemptions" for "medical providers," A738; HHS has received and promised investigation of complaints against Catholic hospitals, SA679 n.1; *Conforti*, 2017 WL 67114 ¶¶80-81; it refused the Fifth Circuit's express invitation to disavow enforcement against religious entities; and it asked the district court to revise its injunction so it wouldn't face contempt for anticipated enforcement against religious entities, SA721. Under *Rodgers*, *Alexis*, and *United Food*, this is an *a fortiori* case.

Indeed, if merely reciting a boilerplate intention to "comply with RFRA" defeated standing, no plaintiff could ever bring a pre-enforcement RFRA challenge—because RFRA, by its own terms, already applies to all federal law. *Little Sisters of the Poor*, 140 S.Ct. at 2383 (citing 42 U.S.C. § 2000bb-3(a)). Yet courts across the country have resolved scores of pre-enforcement RFRA challenges. *E.g.*, *Hobby Lobby*, 573 U.S. 682. As the district court explained, "[s]imply repeating what the statute already commands does not diminish the possibility that HHS will review the Catholic Plaintiffs' 'individualized and fact specific' RFRA concerns and then decide to pursue enforcement anyway," A787—any more than the defendants' promising broadly that they intended to "comply with the

First Amendment" would have defeated standing in, *e.g.*, *Driehaus*, *Telescope Media*, or *281 Care*. *See also Speech First*, 979 F.3d at 333-34 (defendant's "paeans to … freedom of speech" do not "detract[] from the likelihood that [its] policies arguably cover [the plaintiff's] intended speech").

In short, Plaintiffs have standing, and the district court's decision should be affirmed.

II. The district court correctly held this case is ripe.

The district court also correctly held this case is ripe. In assessing ripeness, courts consider two factors: "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Public Water Supply*, 345 F.3d at 572-73 (cleaned up). Here, the district court correctly concluded both factors are easily satisfied.[6]

A. This case is fit for judicial decision.

"Fitness for judicial decision means, most often, that the issue is legal rather than factual." *Minn. Citizens*, 113 F.3d at 132. Here, the district court correctly held that this case "present[s] 'purely legal questions.'"

[6] The Supreme Court has suggested that when plaintiffs establish standing, courts *cannot* decline to exercise jurisdiction under the prudential ripeness doctrine, because doing so would be in "tension with … the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." *Driehaus*, 573 U.S. at 157 n.5. (quoting *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014)) (cleaned up). Nonetheless, analyzing ripeness here produces the same result: The Court has jurisdiction.

A795. HHS interprets Section 1557 to prohibit gender-identity discrimination, and thus to prohibit categorical refusals to perform gender-transition procedures. This prohibition applies to Plaintiffs because they receive federal healthcare funding. Thus, the only question is a legal one: "whether the challenged interpretations of federal law violate [RFRA]." A795. Indeed, HHS *admitted* in the district court "that the issues in these cases are purely legal." SA640 n.1.

HHS now tries to walk that back, claiming its "challenged interpretation" of Section 1557 is "purely hypothetical." Br.33. But there is nothing hypothetical about it. The "challenged interpretation" is embodied in the 2016 Rule, the 2020 Rule, and the Notification of Enforcement, all of which say that Section 1557 prohibits gender-identity discrimination. And the 2016 Rule explains exactly what that means: a provider who would perform a procedure for non-transition purposes must perform similar procedures for transition purposes, 81 Fed. Reg. at 31,455, and categorical refusals to perform or insure gender-transition procedures are "unlawful on [their] face," *id.* at 31,429.

Indeed, the only thing "hypothetical" is HHS's suggestion that it might, perhaps, in the future decide that its interpretation of Section 1557 violates RFRA. But again, HHS has not "to date" exempted Plaintiffs or any other religious organizations. Br.16. And its actions show the

opposite: an intent to enforce Section 1557 against all covered entities, including religious ones.[7]

Alternatively, HHS accuses the district court of conducting a "vague merits analysis that reached out to address arguments that HHS previously made in defending" the 2016 Rule. Br.32. But there are two good reasons the court addressed HHS's arguments on the 2016 Rule. First, that Rule is still operative, given the injunctions in *Walker* and *Whitman-Walker*. Br.26. And second, HHS failed to make any argument on the merits of the RFRA claim here—meaning its 2016 arguments are the best example of its RFRA defense. Indeed, it would be perverse if HHS could strategically offer no merits argument in the district court, and then use its own lack of argument to claim the case is unripe.

At bottom, HHS's ripeness argument is simply a repackaging of its standing argument—and fails for the same reasons. As this Court has explained, "in many cases, ripeness coincides squarely with standing's injury in fact prong." *Iowa League of Cities*, 711 F.3d at 870. And ripeness, like standing, "do[es] not require parties to operate beneath the

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[7] HHS also suggests "the RFRA analysis may be different" depending on which transition procedure is at issue, which it says cuts against ripeness. Br.34. But Plaintiffs demonstrated below that being forced to perform or insure *any* transition procedure would substantially burden their religious exercise. A798-99. So if HHS wanted to distinguish between procedures, the time to do so was at the district court—where under RFRA, it had the burden of proving a compelling reason to force Plaintiffs to perform some or all of these procedures. 42 U.S.C. § 2000bb-1(b). But HHS said nothing of the sort and didn't appeal the merits ruling.

sword of Damocles until the threatened harm actually befalls them." *Id.* at 867. Accordingly, Plaintiffs' claims are fit for review. *See also 281 Care*, 638 F.3d at 627-28, 631 (case was fit for review where the challenged statute, "by its very existence, chill[ed] the exercise of the Plaintiffs' First Amendment rights") (internal quotation marks omitted).

B. Plaintiffs would suffer hardship absent court review.

The hardship factor also favors Plaintiffs. This factor "asks whether delayed review 'inflicts significant practical harm' on the plaintiffs." *Parrish v. Dayton*, 761 F.3d 873, 875 (8th Cir. 2014) (quoting *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998)). Practical harm includes "both financial[]" harms and harms suffered due to "uncertainty-induced behavior modification." *Iowa League of Cities*, 711 F.3d at 867. And hardship is easily established if the government action "chills protected First Amendment activity." *Minn. Citizens*, 113 F.3d at 132.

The district court held that "[p]ractical harm is manifest here because the Plaintiffs must either alter their policies for providing and covering gender-transition procedures" or "risk the loss of critical federal healthcare funding along with potential civil and criminal penalties." A795-96. That is correct.

As in this Court's precedents, "[d]elayed judicial resolution" here would "increase the parties' uncertainty" and "require [plaintiffs] to gamble millions of dollars on an uncertain legal foundation." *Neb. Pub. Power Dist. v. MidAm. Energy Co.*, 234 F.3d 1032, 1039 (8th Cir. 2000). And "the

size of the threatened harm" also favors Plaintiffs, *Iowa League of Cities*, 711 F.3d at 867, since they risk "losing millions of dollars in federal healthcare funding and incurring civil and criminal liability." A798.

In response, HHS says "mere uncertainty" doesn't constitute hardship for ripeness purposes. Br.33, 34 (quoting *Nat'l Park Hosp. Ass'n v. DOI*, 538 U.S. 803, 811 (2003)). But this case isn't about "mere uncertainty"; HHS's actions also cause "practical harm." *Id.* at 810-811; *see Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1140 (D.C. Cir. 2010) (distinguishing *National Park* on this ground). For one thing, HHS's interpretation of Section 1557 "chills" Plaintiffs' religious exercise, which is "protected First Amendment activity." *Minn. Citizens*, 113 F.3d at 132. Moreover, Plaintiffs "must either immediately alter their behavior" by changing their policies "or play an expensive game of Russian roulette" and risk millions of dollars of federal healthcare funding. *Iowa League of Cities*, 711 F.3d at 868.

Indeed, the harm Plaintiffs face isn't static but *increasing* as this case proceeds. Plaintiffs must certify their compliance with Section 1557 on a rolling basis, *see* 45 C.F.R. §§ 86.4, 92.4—and every certification HHS later decides to treat as "false" will trigger false-claims liability, "exposing [them] to civil penalties," treble damages, and the possibility of "up to five years' imprisonment." A757 n.1. Thus, Plaintiffs can't just sit back and wait until HHS decides to enforce.

Alternatively, HHS says Plaintiffs face no hardship because they "could raise these same RFRA arguments in" future enforcement proceedings. Br.33. But if this made a case unripe, plaintiffs could *never* bring a pre-enforcement challenge—which is obviously not the law. *Iowa League of Cities*, 711 F.3d at 867.

HHS's cases fail to prove otherwise. In *Ohio Forestry*, the Supreme Court *distinguished* unripe cases from situations where the government pressured a plaintiff to "modify [his] behavior" "to avoid future adverse consequences"—as, for example, when "agency regulations can sometimes force immediate compliance through fear of future sanctions." 523 U.S. at 734. Such cases present no ripeness barriers, *id.* (collecting cases), and that is this case.

Colwell v. HHS is similarly inapposite. There, the Ninth Circuit held the case unripe because the challenged regulation was ambiguous and appeared simultaneously "not mandatory" and "mandatory"—something HHS doesn't argue here. 558 F.3d 1112, 1125-27 (9th Cir. 2009). And *Colwell* concluded the plaintiffs didn't face substantial hardship because the underlying statute didn't permit "any fines by HHS" or "financial liability to private parties." *Id.* at 1129. Indeed, the regulations did "not contemplate any kind of financial sanction other than termination of federal funding." *Id.* Here, by contrast, HHS may enforce Section 1557 not only through termination of funding, but also through "civil enforcement proceedings, debarment from doing business with the federal government,

lawsuits under the False Claims Act, … criminal penalties[, and] a private right of action for damages and attorney's fees." A757. *Colwell* therefore doesn't apply, and this case is ripe.

III. The district court correctly found irreparable harm.

The district court also properly found that Plaintiffs face irreparable harm. Of the four injunction factors—(1) success on the merits, (2) threat of irreparable harm, (3) balance of harms, and (4) public interest—HHS disputes only irreparable harm. Br.50. And this is an "equitable" issue reviewed "for abuse of discretion." *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 316 (8th Cir. 2009).

The district court didn't abuse its discretion here. The Supreme Court has repeatedly held that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Diocese of Brooklyn*, 141 S.Ct. at 67 (cleaned up). Lower courts have repeatedly applied this principle to RFRA, because "RFRA protects First Amendment free-exercise rights." *Korte*, 735 F.3d at 666; *see also, e.g.*, *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1146 (10th Cir. 2013), *aff'd*, 573 U.S. 682 (2014) ("[O]ur case law analogizes RFRA to a constitutional right."); *Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 298 (5th Cir. 2012) (similar). Thus, as the district court found, "intrusion upon the Catholic Plaintiffs' exercise of religion is sufficient to show irreparable harm." A808.

HHS doesn't even mention the district court's analysis. Nor does it address these cases. It simply repeats its justiciability argument, claiming there is no irreparable harm because it hasn't yet "sought to enforce Section 1557" against Plaintiffs. Br.50. But that argument fails for the same reasons its justiciability argument fails.

In fact, the district court's finding of irreparable harm isn't just supported by this Court's precedent. *See, e.g.*, *Swanson*, 692 F.3d at 870 ("When a plaintiff has shown a likely violation of his or her First Amendment rights, the other requirements for obtaining a preliminary injunction are generally deemed to have been satisfied."); *Child Evangelism Fellowship*, 690 F.3d at 1000 (meritorious First Amendment claim is "likely enough, standing alone, to establish irreparable harm."); *Sharpe Holdings*, 801 F.3d at 945 (success on the merits of RFRA is "the most significant factor in determining" injunctive relief). It's supported by the result in *every* case in which the Supreme Court has found a violation of RFRA, and over a dozen cases in the analogous contraceptive-mandate context—all of which resulted in injunctions. *See, e.g., Hobby Lobby*, 573 U.S. at 692, 701-04; *O Centro*, 546 U.S. at 427; *Sharpe Holdings*, 801 F.3d at 945-46. The same result is appropriate here.

CONCLUSION

The district court's judgment should be affirmed.

Respectfully submitted,

/s/ Luke W. Goodrich

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CERTIFICATE OF COMPLIANCE

I hereby certify that the following statements are true:

1. This brief complies with the type-volume limitations imposed by Federal Rule of Appellate Procedure 32(a)(7)(B)(i). It contains 12,974 words, excluding the parts of the brief exempted by Federal Rule 32(f).
2. This brief complies with the typeface and typestyle requirements of Federal Rule 32(a)(5) and 32(a)(6). It has been prepared in a proportionally-spaced typeface using Microsoft Office Word 2019 in 14-point Century Schoolbook font.
3. This brief complies with the electronic filing requirements of Eighth Circuit Rule 28A(h). The latest version of Windows Defender has been run on the files containing the electronic version of this brief and the addendum and no virus has been detected.

Executed this 3rd day of September, 2021.

/s/ Luke W. Goodrich
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CERTIFICATE OF SERVICE

I certify that on the date indicated below, I filed the foregoing document with the Clerk of the Court, using the CM/ECF system, which will automatically send notification and a copy of the brief to the counsel of record for the parties. I further certify that all parties to this case are represented by counsel of record who are CM/ECF participants.

Executed this 3rd day of September, 2021.

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