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

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

PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Fed. R. Civ. P. 56, Plaintiffs move for partial summary judgment on the following claims:

- Claims against the Section 1557 Gender Identity Mandate:
  - Claim One: Administrative Procedure Act;
  - Claim Two: First Amendment Free Speech;
  - Claim Three: Religious Freedom Restoration Act;
  - Claim Four: First Amendment Free Exercise of Religion;
- Claim Six against the Grants Gender Identity Mandate (Administrative Procedure Act, Free Speech, RFRA, and Free Exercise);
- Claim Seven against the Delay of the Sunset Rule (Administrative Procedure Act, Regulatory Flexibility Act).

Attached to this motion is Plaintiffs' brief in support, which through citation to the record and the law shows that there is no genuine dispute as to any material fact and the movants are entitled to judgment as a matter of law. Plaintiffs also filed a consent motion to exceed the page limits for that brief (ECF No. 26).

Plaintiffs seek the following relief from the Court granting this motion:

- Declaratory relief that the Section 1557 Gender Identity Mandate, the Grants Gender Identity Mandate, and the Delay Rule of the SUNSET Rule (as described in the brief in support) are unlawful, set aside, and vacated;
- Permanent injunctive relief against Defendants' enforcement or implementation of the Section 1557 Gender Identity Mandate, the Grants Gender Identity Mandate, or the Delay Rule of the SUNSET Rule;
- Compelling agency action unlawfully withheld under the APA, requiring HHS to allow the 2021 repeal of the Grants Gender Identity Mandate to go into effect.

Pursuant to this Court's rules and procedures Plaintiffs will email a proposed form of order to the Court and to Counsel for Defendants.

Respectfully submitted, this 7th day of January 2022.

s/ Matthew S. Bowman
MATTHEW S. BOWMAN
DC Bar No. 993261
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
mbowman@ADFlegal.org

RYAN L. BANGERT*
TX Bar No. 24045446
JONATHAN A. SCRUGGS
TN Bar No. 25679
ALLIANCE DEFENDING FREEDOM
15100 N 90th Street
Scottsdale, AZ 85260

ANTHONY J. BILLER*
NC Bar No. 24,117
ENVISAGE LAW
2601 Oberlin Rd., NW, Ste. 100
Raleigh, NC 27608
Telephone: (919) 414–0313
Facsimile: (919) 782–0452
ajbiller@envisage.law

**Admitted pro hac vice*

Telephone: (480) 444-0020
Facsimile: (480) 444-0028
rbangert@ADFlegal.org
jscruggs@ADFlegal.org

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that I served this motion with the Clerk of Court and all parties using the ECF system.

Dated: January 7, 2022

s/ Matthew S. Bowman

MATTHEW S. BOWMAN
DC Bar No. 993261
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
mbowman@ADFlegal.org

Counsel for Plaintiffs

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

PLAINTIFFS' BRIEF IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT

ORAL ARGUMENT REQUESTED

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CONCISE STATEMENT OF FACTUAL AND LEGAL GROUNDS

The federal government has mandated that doctors nationwide perform and affirm gender reversal surgeries—regardless of the doctors' medical judgment, conscientious objections, or religious beliefs. The U.S. Department of Health and Human Services (HHS) has also given doctors words they must speak: affirming gender identity even when it conflicts with biological sex; stating that sex can change; and affirming that a woman who identifies as a man (or vice versa) is really a man for medical purposes. The penalty for refusal is exclusion from nearly every medical facility or program in the nation, including programs as broad as Medicaid, Medicare, and health facilities receiving HHS grants such as hospitals, community health centers, treatment centers addressing COVID-19 or substance abuse or mental health, and research facilities, to name a few. HHS's gender-identity mandates apply to virtually every health care provider in America.

Plaintiffs are two medical associations that represent three thousand physicians and health professionals seeking to stop the government from threatening their members with crippling penalties under the mandates. With them is an individual doctor from Chattanooga, Dr. Jeanie Dassow, who works at health centers receiving HHS grants. These professionals treat patients with dignity and respect, regardless of their sex or internal sense of gender. They also provide medical care with the excellence and forthrightness people have relied on from doctors for centuries. It would contravene the sound medical judgment of these healthcare providers—not to mention their religious beliefs—to adhere to HHS's dictates. The Free Exercise Clause of the First Amendment and the Religious Freedom Restoration Act protect the religious doctors' objections to these mandates, the Free Speech Clause protects them from HHS's speech mandates, and the Administrative Procedure Act protects them from regulations that are unlawful or capricious.

HHS's remarkable assertion of federal power is without statutory authority. Though HHS claims that § 1557 of the Affordable Care Act (ACA) allows this imposition, that law indicates otherwise. The ACA uses "sex" as a biological, binary category: male or female. And of course, medicine must respect this scientific, biological reality. Sex is a key concept in the medical field; surgeries, treatments, and prescriptions differ between men and women. HHS likewise imposed a gender-identity mandate lacking statutory authority in its grants regulations at 45 C.F.R. § 75.300(c). Although in 2020 the Supreme Court decided *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), that case solely concerns hiring and firing under the employment law statute Title VII—it disavows applying to other laws or circumstances such as the practice of medicine.

Two courts in 2021 enjoined HHS's gender-identity mandate under the ACA. *Franciscan All. v. Becerra*, No. 7:16-CV-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113 (D.N.D. 2021). But HHS refuses to extend those protections to other doctors, or to protect doctors from its gender identity mandate applied through grants. HHS is also flouting regulatory reform laws that would have required HHS to periodically review and reconsider regulations such as these gender-identity mandates. In early 2021, HHS sidestepped the Administrative Procedure Act by issuing a unilateral "delay" of such a regulation.

Because this case involves purely legal issues raised by the regulations themselves and undisputed facts concerning Plaintiffs, Plaintiffs ask this Court for partial summary judgment encompassing several of their claims, which would provide them with adequate relief.[1]

[1] Plaintiffs seek summary judgment on the following claims:

- As to the Section 1557 Gender-Identity Mandate—Claim One: Administrative Procedure Act; Claim Two: First Amendment Free Speech; Claim Three: Religious Freedom Restoration Act; Claim Four: First Amendment Free Exercise of Religion.
- Claim Six against the Grants Gender-Identity Mandate (Administrative Procedure Act, Free Speech, RFRA, and Free Exercise);

BACKGROUND

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

The Patient Protection and Affordable Care Act (ACA) prohibits discrimination on the basis of race, sex, age, and disability in federal healthcare programs like Medicaid or CHIP. Pub. L. No. 111-148, 124 Stat. 119; 42 U.S.C. § 18116 (Section 1557 or § 1557). To accomplish this, Congress borrowed the definition of sex discrimination from "title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.)." *Id.* Both Title IX and the ACA use the term "sex" pervasively to reflect whether a person is a biological male or female. Neither § 1557 of the ACA nor Title IX address gender identity.

Late in President Obama's second term, HHS issued a rule arguing that § 1557 and Title IX *do* cover gender identity. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,375 (May 18, 2016); First Am. Compl. ("Compl.") ¶¶ 50–73, ECF No. 15. The agency said the rule required covered healthcare providers to perform gender interventions, even if those services were not medically necessary under traditional standards. It prohibited imposing a binary view of gender, *see* 81 Fed. Reg. at 31,435 n.263, or categorizing transition-related treatment as experimental, outdated, or not based on current standards of care, *id*. at 31,429, 31,435. It also prohibited limiting care for a person who identifies contrary to his or her biological sex to "health

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- Claim Seven against the Delay of the Sunset Rule (Administrative Procedure Act and Regulatory Flexibility Act).

Plaintiffs seek the following relief under these claims:

- Declaratory relief that the Section 1557 Gender-Identity Mandate, the Grants Gender-Identity Mandate, and the Delay Rule of the SUNSET Rule are held unlawful, set aside, and vacated;
- Permanent injunctive relief against Defendants' enforcement or implementation of the Section 1557 Gender-Identity Mandate, the Grants Gender-Identity Mandate, and the Delay Rule of the SUNSET Rule;
- An order compelling agency action unlawfully withheld under the APA, requiring HHS to allow the 2021 repeal of the Grants Gender-Identity Mandate (*see* 86 Fed. Reg. 2,257 (Jan. 12, 2021)) to go into effect.

services that are ordinarily or exclusively available to individuals of one sex." *Id.* at 31,471 (45 C.F.R. § 92.206).

These were not idle requirements. The ACA and the grant statutes provide broad enforcement mechanisms. They drive providers out of government healthcare programs. Compl. ¶¶ 272–92 (discussing enforcement and penalties of § 1557 and grants rules). A federal court preliminarily enjoined the gender-identity mandate language (and related abortion mandate language in the same rule), and said it vacated the language. *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928 (N.D. Tex. 2019). But when the Trump administration repealed the rule based on that ruling,[2] two other courts enjoined the repeal, *Walker v. Azar*, 480 F. Supp. 3d 417, 430 (E.D.N.Y. 2020), and *Whitman-Walker Clinic, Inc. v. HHS*, 485 F. Supp. 3d 1 (D.D.C. 2020), and then stated the gender identity language from the 2016 rule "will remain in effect." *See, e.g., Walker*, 480 F. Supp. 3d at 430; *see also id.* at 427 (holding that *Franciscan Alliance* did not vacate gender identity language from the sex stereotyping definition), and *Walker v. Azar*, No. 20-CV-2834, 2020 WL 6363970 at *4 (E.D.N.Y. Oct. 29, 2020) (also restoring the 2016 rule's language requiring gender transition insurance coverage).

In other words, the 2016 § 1557 rule's gender-identity mandate is in effect today. To confirm this fact, HHS itself declared on May 10, 2021, that it will fully enforce that mandate.[3] HHS adopted this posture, in the 2016 ACA Rule and its May 2021 insistence that it would enforce it, with zero exemptions for conscience protection or religious freedom. *See* 81 Fed. Reg. at 31,380. Also, *Whitman-Walker Clinic* enjoined the 2020 rule's attempt to insert the religious exemption

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

[3] *See* https://www.hhs.gov/about/news/2021/05/10/hhs-announces-prohibition-sex-discrimination-includes-discrimination-basis-sexual-orientation-gender-identity.html, later published at Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27,984, 27,985 (May 25, 2021).

from Title IX. 485 F. Supp. 3d at 64–65. And HHS recently repealed all religious exemptions to HHS's gender-identity mandate under its grants rule.[4]

Two courts in 2021 confirmed the fact that the 2016 § 1557 gender-identity mandate is fully in effect today with no religious exemptions. *Religious Sisters*, 513 F. Supp. 3d at 1127–31, 1153–54, judgment entered sub nom. The federal court in North Dakota declared that *Walker* and *Whitman-Walker* "reinstate[d] the prior definition of 'on the basis of sex' to include 'gender identity' and 'sex stereotyping.'" *Id.* at 1138. The federal court for the Northern District of Texas declared that "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." *Franciscan All.*, 2021 WL 3492338 at *9 (citations omitted). Both courts then enjoined the 2016 § 1557 gender-identity mandate, *but only as to the religious plaintiffs in those cases*, represented by associations of health care providers.[5]

The plaintiffs and their members here face the same mandate and need similar relief. The § 1557 mandate states that "discrimination" based on "gender identity" means an individual's "internal sense of gender, which may be male, female, neither, or a combination of male and female." 81 Fed. Reg. at 31,467. For HHS, the "gender identity spectrum includes an array of possible gender identities beyond male and female," and individuals with "non-binary gender identities are protected under the rule." *Id.* at 31,392, 31,384. Thus, a healthcare provider who provides drugs and medical procedures for reasons unrelated to gender-identity changes must also provide those same procedures to change someone's biological sex and refer patients to others to

[4] *See* Press Release, U.S. Department of Health and Human Services, HHS Takes Action to Prevent Discrimination and Strengthen Civil Rights (Nov. 18, 2021), https://www.hhs.gov/about/news/2021/11/18/hhs-takes-action-to-prevent-discrimination-and-strengthen-civil-rights.html ("HHS will not condone the blanket use of religious exemptions against any person or blank checks to allow discrimination.").

[5] For ease of reference, the gender identity provisions in effect from the 2016 ACA Rule; the May 10, 2021, Notice of Enforcement; and the penalties in the remaining portions of the 2020 ACA Rule for violating HHS's § 1557 regulations related to the ACA, are collectively called the "§ 1557 mandate."

receive those procedures. *See id*. at 31,429, 31,455. This means that a gynecologist that removes cancerous uteruses via hysterectomies would have to remove healthy uteruses for any woman who identifies as a man. *Id*.

II. HHS issues a second gender-identity mandate—the grants mandate.

In late 2016, HHS imposed *a parallel* overarching gender-identity mandate by placing limits on HHS grants. Health and Human Services Grants Regulation, 81 Fed. Reg. 89,393 (Dec. 12, 2016) (codified at 45 C.F.R. § 75.300(c) and (d)) (the 2016 grants mandate, or grants mandate). This grants mandate applies to all HHS grant recipients, including healthcare providers who work in programs that accept federal HHS grants. Thus, doctors practicing at community health centers or institutions receiving HHS grants are covered. 45 C.F.R. § 75.101.

The 2016 grants mandate turns on HHS's belief that it may impose such a rule as a matter of "public policy" (in contrast to statutory authority). For its authority, the agency relies not on any substantive statute, but solely on the multi-agency "housekeeping statute," 5 U.S.C. § 301, which merely allows department secretaries to direct internal agency operations. This is the statute passed to allow George Washington to set up his cabinet. "There is nothing in the legislative history to indicate that § 301 is a substantive grant of legislative power to promulgate rules." *Chrysler Corp. v. Brown*, 441 U.S. 281, 283 (1979).

Like the § 1557 mandate, the grants mandate provides no express religious exemptions. Rather, the grants mandate relies on a long-standing, more general discretionary provision that authorizes the Department to grant "[e]xceptions on a case-by-case basis for individual non-Federal entities." 45 C.F.R. § 75.102(b). And like the § 1557 mandate, the Trump administration attempted to repeal the grants mandate, but the Biden Administration and courts thwarted that repeal, leaving the grants mandate on the books today. The would-be repeal, *see* Health and Human Services Grants Regulation, 86 Fed. Reg. 2,257, 2,257 (Jan. 12, 2021) (the 2021 grants rule), never went into effect because of a federal court order to which HHS consented when the case was less than a month old, and which HHS has extended by stipulations ever since. *See Facing Foster Care in Alaska v. HHS*, No. 21-cv-00308, ECF Nos. 17, 18, 23 (D.D.C. Feb. 2, 2021). As noted above,

supra note 2, HHS also recently revoked all the religious exemptions that the Trump administration had promulgated in lieu of repealing the grants rule. The only thing HHS has left in place is a unilateral letter issued in 2019 stating that HHS is exercising discretion not to enforce the grants rule at this time—a letter HHS can revoke at any moment.[6]

III. HHS issues, and then delays, its mandated SUNSET review.

In 2021, HHS also published a final rule required by the Regulatory Flexibility Act (RFA), which provides for periodic review of agency regulations: the SUNSET Rule.[7] Under Section 610(a) of the RFA, HHS must "publish in the Federal Register a plan for the periodic review" of any rule with "a significant economic impact upon a substantial number of small entities." 5 U.S.C. §§ 602, 605, 610(a). SUNSET took the first step of requiring HHS to "assess" its regulatory corpus to determine whether its rules have a significant economic effect on a substantial number of small entities, and to review those rules through notice and comment at set deadlines. 86 Fed. Reg. at 5,750–64 (codifying 45 C.F.R. § 8.1(b)(1)). If the RFA-required steps are not taken, the rules automatically expire, including rules governing these plaintiffs.[8]

The SUNSET Rule was set to go into effect March 22, 2021. All of HHS's regulations involving hospitals, clinics, Medicare, Medicaid, CHIP, grants, health care rights of conscience, and more would have been reviewed. But citing a lawsuit filed three days before the deadline, HHS announced on its website that it would delay the SUNSET Rule for a year. In that case, HHS *stipulated* to a stay immediately upon filing of the suit on March 19, 2021—supposedly so that HHS would have time to rescind the SUNSET Rule. *County of Santa Clara v. HHS*, No. 5:21-cv-01655-BLF (N.D. Cal. filed Mar. 9, 2021). HHS cited 5 U.S.C. § 705 as its authority for the delay.

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[6] Notification of Nonenforcement of Health and Human Services Grants Regulation, 84 Fed. Reg. 63,809 (Nov. 19, 2019).
[7] Securing Updated and Necessary Statutory Evaluations Timely, 86 Fed. Reg. 5,694, 5,695–97 (Jan. 19, 2021) (SUNSET Rule)
[8] HHS admits that it is not—and likely has never been—in compliance with the RFA. 86 Fed. Reg.at 5,695–97.

That statute provides that "[w]hen an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review." *Id.*

But the delay announcement was too late. It was published on March 23—the day *after* the SUNSET Rule took effect on March 22. Securing Updated and Necessary Statutory Evaluations Timely; Administrative Delay of Effective Date; Correction, 86 Fed. Reg. 15,404 (March 23, 2021) (the Delay Rule). As a result, by the Delay Rule, HHS used a process involving no public comment to negate a rule issued after public comment, and using a statute (5 U.S.C. § 705) that only applies before a rule goes into effect to delay a rule after it went into effect. Both violations deprived plaintiffs of their rights under the APA.

IV. HHS's gender-identity mandates threaten career-ending penalties for doctors with medical, ethical, and religious objections to HHS's required practices.

Two medical associations—representing more than three thousand doctors—and a Tennessee OB-GYN (collectively, the "doctors"), now challenge both of HHS's gender-identity mandates (the § 1557 and grants mandates), and HHS's circumvention of the rule (the SUNSET Rule) that would have allowed the doctors to participate in regulatory review of the mandates. The gender-identity mandates require them to provide gender interventions and speak as if their patients' sex is their gender identity, regardless of the doctors' judgment, faith, or ethics. The doctors all have medical, ethical, or religious objections to HHS' requirements.[9]

Plaintiff American College of Pediatricians' members include more than six hundred pediatricians and other healthcare professionals. Van Meter Decl. ¶¶ 16–20, ECF No. 15-1. These members of ACPeds have deep, science-based concerns against transgender interventions; many members also have religious objections, but not all have religious objections. *Id*. ¶¶ 25–81.

Plaintiff Catholic Medical Association (CMA) is the largest association of Catholic individuals in healthcare, with approximately 2,500 members. Dickerson Decl. ¶ 3, ECF No. 15-

[9] A list of the specific objectional practices required by the HHS gender-identity mandates, as described in the complaint, may be found in at paragraph 131 of the First Amended Complaint, ECF No. 15.

2. CMA members share the scientific and clinical concerns of ACPeds members, as well as all sharing objections based on their Catholic religious beliefs. *Id*. ¶¶ 27–57, 147.

Plaintiff Jeanie Dassow, M.D., is a board-certified obstetrician and gynecologist in Chattanooga, Tennessee who specializes in adolescents and shares many of these positions. Dassow Decl. ¶¶ 3, 9–10, ECF No. 15-3. Although she is protected from the § 1557 mandate by being a member of an organization protected by the *Franciscan Alliance* injunction, she is subject to the separate grants mandate prohibiting gender identity nondiscrimination because she works at facilities receiving HHS grants, and she was deprived of procedural rights by the unlawful Delay Rule.

These doctors are subject to HHS's mandates. Most members provide medical care in health programs and activities receiving federal financial assistance from HHS under 42 U.S.C. § 18116, and some members provide medical care in programs or entities receiving grants from HHS governed by 45 C.F.R. § 75.300.[10] Dr. Dassow participates in both programs and grants covered by the mandates.[11] Were the doctors to comply with the government's gender-identity mandates, they would suffer immeasurable harm to their religious exercise and free speech rights, as well as harm to their patients' best interests.[12] The doctors would also incur compliance costs because they would have to change their policies, alter their speech, spend time and resources to plan for how they must either comply or risk loss of participation in federal programs, re-train staff, and engage in public education campaigns to mitigate the confusion caused by the mandates.[13] But if the doctors disregard the government's mandates, they risk the promised enforcement.[14]

The penalties for non-compliance are meant to ensure that the doctors are exiled from virtually all healthcare. *See* Compl. ¶¶ 50–73, 272–92 (discussing enforcement, penalties, and

[10] Van Meter Decl. ¶¶ 21–24, 97, 124, 126–27; Dickerson Decl. ¶¶ 7–8, 63–66.
[11] Dassow Decl. ¶¶ 12–17.
[12] Van Meter Decl. ¶¶ 144–48, 156–71; Dickerson Decl. ¶¶ 109–12; Dassow Decl. ¶¶ 41–43, 47.
[13] Van Meter Decl. ¶¶ 141–42; Dickerson Decl. ¶¶ 107–08; Dassow Decl. ¶ 46.
[14] Van Meter Decl. ¶ 135; Dickerson Decl. ¶ 101; Dassow Decl. ¶¶ 44–45.

burdens of § 1557 and grants rules); *see also* enforcement mechanisms at 18 U.S.C. §§ 287, 3486, 1001, 1035, 1347, 1516, 1518; 31 U.S.C. § 3729(a)(1);42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c); 45 C.F.R. §§ 80.6 to 80.11; 45 C.F.R. Pt. 81; 45 C.F.R. §§ 86.4, 92.4, 92.5, 92.301. They include not only expulsion from all health programs funded by HHS, such as Medicaid, Medicare, and countless grants programs, but also federal false-claims liability, with civil penalties up to $10,000 per false claim plus treble damages, 31 U.S.C. § 3729(a)(1), and "up to five years' imprisonment," 42 U.S.C. § 1320a-7b.

When the doctors are driven out of their practices, the public will lose a measure of access to care—especially underserved, rural, and low-income patients.[15] Plaintiffs are subject to the mandates now, and face penalties at any moment.[16] At the same time, the improper delay of the SUNSET Rule denied the doctors procedural rights concerning repeal or modification of mandates that apply to them.[17]

LEGAL STANDARD

Plaintiffs seek summary judgment under the familiar standard of Federal Rule of Civil Procedure 56: "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Based on the undisputed facts in the records, Plaintiffs are entitled to a permanent injunction to prevent HHS's enforcement of the § 1557 and grants rules that coerce doctors into offering, providing, and affirming gender interventions. Plaintiffs also seek an order declaring that the SUNSET Rule and its compliance deadlines have remained in effect since the original scheduled implementation date of March 22, 2021.

The standards for a permanent injunction parallel those for a preliminary injunction: "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial

[15] Van Meter Decl. ¶¶ 152–55; Dickerson Decl. ¶¶ 118–19, 154–56; Dassow Decl. ¶¶ 36, 44–45.
[16] Van Meter Decl. ¶ 134; Dickerson Decl. ¶ 100; Dassow Decl. ¶¶ 37, 48.
[17] Van Meter Decl. ¶ 173–78; Dickerson Decl. ¶ 158–64; Dassow Decl. ¶¶ 38–49.

harm to others; and (4) whether the public interest would be served by the issuance of an injunction." *Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 385 (6th Cir. 2020). When First Amendment concerns are at issue, "the crucial inquiry is usually whether the plaintiff has demonstrated a likelihood of success on the merits" because "the public interest and harm to the respective parties largely depend on the constitutionality of the" government action. *Bays v. City of Fairborn*, 668 F.3d 814, 819 (6th Cir. 2012). "The third and fourth factors . . . merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The standard for a permanent injunction is the same, except that the plaintiff must show actual success on the merits rather than a likelihood of success. *ACLU of Ky. v. McCreary Cnty.*, 607 F.3d 439, 445 (6th Cir. 2010).

SUMMARY OF ARGUMENT

The government's gender-identity mandates jeopardize doctors' free speech and religious rights, their careers, and their patients. Not only have these diktats arrived without public notice and comment—or any consideration of religious exemptions—HHS lacks the authority to make them. Yet the government has promised to enforce the § 1557 mandate, believes it is free to enforce the grants mandate at any time, and is unconcerned with the lack of protection for First Amendment rights posed by both. And in the meantime, the doctors have lost procedural protections against the agency's actions.

The doctors have causes of action for their claims because final agency actions are subject to review. HHS's actions are unlawful for the following statutory and constitutional reasons:

First, the gender-identity mandates contradict federal law. The ACA's sex discrimination provision does not address gender identity. Indeed, these mandates run contrary to the ACA itself, Title IX, and other statutes. Congress's prohibition on sex discrimination cannot be repurposed to coerce doctors' speech and services for gender "reassignment" surgeries.

Second, HHS's gender-identity mandates are arbitrary and capricious. The government relied on legally erroneous justifications and failed to sufficiently explain its changes in position.

Third, HHS's mandates violate the First Amendment's Free Speech Clause. The overbroad mandates censor speech based on content and viewpoint; they prohibit speech supporting the doctors' existing policies but allow—or require—speech affirming the government's preferred gender policies.

Fourth, HHS's mandates violate RFRA and the First Amendment's Free Exercise Clause. With no compelling interest, the mandates burden doctors by threatening to drive them out of healthcare if they do not violate their religious beliefs.

Fifth, HHS's 2021 Notice of Enforcement for the § 1557 mandate unlawfully skipped notice and comment, which the Administrative Procedure Act and HHS regulations require.

Sixth, HHS's refusal to follow the SUNSET Rule is unlawful.

This Court should thus enjoin the government's enforcement of its gender-identity mandates.

ARGUMENT

Under the APA, a reviewing court must "hold unlawful and set aside" agency action that is "without observance of procedure required by law," "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law," "contrary to constitutional right, power, privilege or immunity," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2). An agency acting ultra vires or unconstitutionally is also subject to prospective injunctive relief. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–90, 693 (1949).

HHS's mandates and the delay of its review regulations violate these APA provisions and many other laws. This Court should hold HHS's actions unlawful and set them aside. 5 U.S.C. §§ 705–06. No procedural issue precludes this Court's review.

I. Plaintiffs' Claims Are Justiciable.

Plaintiffs have standing—and their challenges are ripe—because the government's interpretation and enforcement of federal law is currently forcing the doctors to either abandon their religious beliefs and medical ethics or risk devastating government penalties. U.S. CONST.

art. III, § 2. HHS's gender-identity mandates add a new protected class to federal law and bind HHS to enforce this interpretation. The mandates are thus final agency actions subject to review, and an injunction would redress the threatened injury of their enforcement. Two federal district courts have agreed, not only finding standing to challenge the § 1557 gender-identity mandate, but issuing permanent injunctive relief against it. *Franciscan Alliance*, 2021 WL 3492338; *Religious Sisters*, 513 F. Supp. 3d 1113.

To establish standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561 (1992)).

A. The APA provides judicial review and protects procedural rights.

The final regulations that Plaintiffs are challenging have already caused "legal wrong[s]" that trigger judicial review under the Administrative Procedure Act, 5 U.S.C. § 702. HHS finalized those rules, the rules encompass the doctors, and the rules changed the doctors' legal rights and responsibilities in ways the doctors contend is unlawful (which, as to standing, the Court must assume is true). Legal wrong is an injury under Article III: "the injury required by Art. III may exist solely by virtue of statutes creating legal rights, the invasion of which creates standing." *Lujan*, 504 U.S. at 578 (cleaned up). Here the injury cognizable under Article III and the APA is twofold: Defendants' final regulations literally changed the plaintiff doctors' rights (adding non-discrimination obligations and penalties) in a way the unregulated general public is not affected, and Defendants also deprived Plaintiffs of procedural rights under the APA such as the right to comment on rules before they are changed (as was lacking in the Delay Rule). The Supreme Court has also recently acknowledged that violation of a personal right even without actual damages presents a cognizable injury. *Uzuegbunam v. Preczewski*, 141 S. Ct. 792, 798–800 (2021).

In APA challenges, moreover, the Supreme Court has made it clear that "parties need not await enforcement proceedings before challenging final agency action." *U.S. Army Corps of*

Eng'rs v. Hawkes Co., 136 S. Ct. 1807, 1815 (2016). Instead, the "APA provides for judicial review of all final agency actions, not just those that impose a self-executing sanction." *Sackett v. EPA*, 566 U.S. 120, 129 (2012); *see also Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (plaintiffs need not await "the consummation of threatened injury to obtain preventive relief.") Challenges to final regulations by regulated entities are commonplace without any individual enforcement action having been commenced, and the Sixth Circuit regularly proceeds to the merits in such cases. *See, e.g., Gun Owners of Am., Inc. v. Garland*, 19 F.4th 890, 897 (6th Cir. 2021); *Nat'l Cotton Council of Am. v. EPA*, 553 F.3d 927, 929 (6th Cir. 2009).

The government also imposed a separate, ongoing harm by depriving the doctors of the chance to advocate for their interests through public comment. Procedural injuries under the APA establish standing "without meeting all the normal standards for redressability and immediacy" if the procedure in question is "designed to protect some threatened concrete interest of plaintiffs." *Parsons v. U.S. Dep't of Justice*, 801 F.3d 701, 712 (6th Cir. 2015). Here the notice and comment provisions are designed to provide plaintiffs—doctors regulated by various HHS rules—with the concrete interest of being able to receive notice and opportunity to comment on HHS rules before those rules are changed. The Delay Rule changed the SUNSET Rule's effective date after the SUNSET Rule was in effect, and did so without affording plaintiffs an opportunity to comment on it. The SUNSET Rule afforded the doctors procedural rights to HHS review, and public comment opportunities, of regulations governing their behavior such as the Section 1557 and the grants rules. An association "can assert violation of the APA's notice-and-comment requirements, as those procedures are plainly designed to protect the sort of interest alleged." *Sierra Club v. EPA*, 699 F.3d 530, 533 (D.C. Cir. 2012); *see also Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (a regulated entity "can show a cognizable injury if it has been deprived of 'a procedural right to protect [its] concrete interests.'") (citation omitted).

B. The plaintiff doctors are the object of the government's regulations.

A plaintiff also has standing if it shows that "the plaintiff has suffered an injury, that the defendant's conduct likely caused the injury, and that the relief sought will likely redress the

injury." *Ass'n of Am. Physicians & Surgeons v. FDA*, No. 20-1784, 2021 WL 4097325, at *3 (6th Cir. Sept. 9, 2021). There "is ordinarily little question" about standing if an entity is the "object of the [challenged] action," such as an injury to the entity from the regulation. *Lujan*, 504 U.S. at 561–62. Entities are the object of a regulation (1) when "the regulation is directed at them in particular"; (2) when "it requires them to make significant changes in their everyday business practices"; and (3) when, "if they fail to observe the [new] rule they are quite clearly exposed to the imposition of strong sanctions." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 153–54 (1967). The plaintiff doctors meet these criteria.

First, defendants made clear in the Section 1557 and grants rules that the mandates apply to healthcare providers who receive federal financial assistance or grants. These mandates impose HHS's interpretation on the ACA, its regulations, and other federal statutes: those rules, in turn, prohibit medical policies and speech. The mandates bind HHS enforcers and covered doctors to follow these rules. *See* Compl. ¶¶ 50–73, 272–92 (discussing enforcement, penalties, and burdens of § 1557 and grants rules). The plaintiff doctors, for their part, engage in activities that the government finds to fall within the mandates. They refuse to engage in each objectional practice compelled by the mandates, including refusing to provide or refer for gender interventions, or to use speech affirming gender interventions (such as referring to biological males as females).[18]

Second, HHS makes the doctors transform their everyday healthcare practices, policies, and procedures, or else risk liability, investigation, and exclusion from federal programs.[19] The mandates force doctors to choose now between three injuries: (1) obey the government and abandon their medical and religious speech rights (as well as suffer financial loss by attempting compliance); (2) refuse the government and risk crippling penalties; or (3) cease providing healthcare in virtually any setting.

[18] Van Meter Decl. ¶ 155; Dickerson Decl. ¶ 69; Dassow Decl. ¶¶ 32.
[19] Van Meter Decl. ¶¶ 135–40; Dickerson Decl. ¶¶ 101–06, 142–43; Dassow Decl. ¶¶ 39–40, 44–45.

Third, the government's threatened sanctions are strong. The ACA and federal grant statutes provides broad enforcement mechanisms—including complaints, investigations, lawsuits, and prosecutions—all designed to drive out of healthcare programs any dissenting voices. *E.g.*, 18 U.S.C. §§ 287, 3486, 1001, 1035, 1347, 1516, 1518; 31 U.S.C. § 3729(a)(1); 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c); 45 C.F.R. §§ 80.6 to 80.11; 45 C.F.R. Pt. 81; 45 C.F.R. §§ 86.4, 92.4, 92.5, 92.301. Violators can face private lawsuits for damages and attorney's fees. 42 U.S.C. § 1988(b). They risk federal false-claims liability, including civil penalties up to $10,000 per false claim plus treble damages, 31 U.S.C. § 3729(a)(1), and "up to five years' imprisonment," 42 U.S.C. § 1320a-7b. Similar criminal penalties are at 18 U.S.C. §§ 287, 1001, 1035, 1347, 1516, 1518; 42 U.S.C. §§ 1320a-7b(a), 1320a-7b(c). The "threat" sufficient for standing "need not stem from a criminal action," *Kiser v. Reitz*, 765 F.3d 601, 609 (6th Cir. 2014), but here both civil and criminal penalties are in play. Any argument that this pre-enforcement case is not justiciable is "contrary to well-settled law and utterly inconsistent with the policies" underlying these precedents, which favor judicial resolution of disputes. *Peoples Rts. Org., Inc. v. City of Columbus*, 152 F.3d 522, 529–30 (6th Cir. 1998).

C. The doctors face a credible threat of enforcement, especially based on their Free Speech interests.

The doctors independently have pre-enforcement standing under Article III because the government threatens their free speech and religious exercise (under the First Amendment and RFRA). To prove injury-in-fact in a pre-enforcement suit, the regulated entities need only prove a "substantial risk" of HHS enforcers harming them. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159, 158 (2014). A pre-enforcement challenge is independently justiciable if the plaintiff intends to engage in an activity "arguably affected with a constitutional interest" but "arguably" proscribed by a statute, and "a substantial" or a "credible" threat of enforcement exists. *Id.* at 159, 160. Each factor is met here.

First, the doctors intend to engage in an activity "arguably affected with a constitutional interest" because the First Amendment protects doctors' statements about their medical policies

and speech. *See infra* Pt. V. They need not "first expose [themselves] to actual arrest or prosecution" to challenge laws deterring "the exercise of [their] constitutional rights." *Steffel v. Thompson*, 415 U.S. 452, 459 (1974).

Second, the doctors' speech and policies are more than "arguably proscribed" by the government's mandates—the 2016 ACA Rule itself gave examples about how speech and policies concerning medical treatment and pronouns are proscribed. HHS finds unlawful any distinctions involving gender identity, which necessarily includes the doctors' speech. Standing exists for pre-enforcement review when plaintiffs "believed [they] were covered by the statute and testified that costly compliance measures would be necessary." *SBA List*, 573 U.S. at 159, 160.

Third, the gender-identity mandates chill the speech of ACPeds' and CMA's members and Dr. Dassow.[20] This naturally results from the mandates' threat of penalties and enforcement if doctors say anything that could be perceived as disagreeing with to gender identity or transition practices or ideology. The doctors need not succumb to government censorship and cease speaking to be allowed to challenge these mandates, needing only show a substantial risk that the harm will occur, *SBA List*, 573 U.S. at 158 (cleaned-up), not a "literal[] certain[ty]" of future harm, *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013).

Fourth, the doctors face far more than a "credible threat of enforcement." HHS itself announced its firm intention to fully enforce its Section 1557 gender-identity mandate on May 10, 2021, and it withdrew all its religious exemptions to the grants mandate on November 18, 2021 while insisting on that mandate's importance. HHS also has a history of enforcement of the § 1557 mandate: in 2016 multiple complaints were filed against religious entities for refusing to provide gender transition services—and HHS investigated such claims.[21] Where the government has an

[20] See Compl. ¶¶ 220, 270, 400, 416; Van Meter Decl. ¶¶ 159, 165; Dickerson Decl. ¶¶ 123, 129, 145; Dassow Decl. ¶ 42.

[21] See *Conforti v. St. Joseph's Healthcare System, Inc.*, No. 2:17-cv-00050, 2017 WL 67114, at ¶ 81 (D.N.J. Jan. 5, 2017) (HHS investigating claim against Catholic hospital for not performing gender transition surgery); Admin. Compl., *ACLU v. Ascension Health*, U.S. Dep't of Health & Human Servs., Office for Civil Rights (Oct. 25, 2016), *available at* https://perma.cc/26A8-7G95.

enforcement history, makes a strong statement of enforcement intention, and refuses "explicitly disavow[] enforcing [its law] in the future," the court will take the government at its word that it will enforce. *Green Party of Tenn. v. Hargett*, 791 F.3d 684, 696 (6th Cir. 2015); *see also Platt v. Bd. of Comm'rs on Grievances & Discipline of Ohio Sup. Ct.* , 769 F.3d 447, 452 (6th Cir. 2014) (same). The government has also recently refused to disavow enforcement in *Franciscan Alliance* and *Religious Sisters*, and counsel for the government indicated it will oppose injunctive relief here.

HHS's Notice of Non-Enforcement of the grants mandate does not negate the doctors' substantial risk of its enforcement. That notice is not a disavowal, but a mere discretionary decision not to enforce for the moment, and HHS can revoke it at any moment. A regulated entity has standing to defend itself from laws arguably restraining speech even when those statutes have never been enforced. *Epperson v. Arkansas*, 393 U.S. 97, 98 (1968) (challenge to 40-year-old statute that had never been enforced); *Holder v. Humanitarian Law Project*, 561 U.S. 1, 16 (2010) (standing even though government had only prosecuted "several" others under law); *Babbitt*, 442 U.S. at 302 (standing to challenge provision that "has not yet been applied and may never be applied"). HHS's recently repeated insistence on enforcing its gender identity mandates provides enough "evidence to establish that [plaintiffs'] challenge is capable of repetition yet evading review. Thus, the district court properly exercise[s] jurisdiction." *Graveline v. Benson*, 992 F.3d 524, 533–34 (6th Cir. 2021); *see also Stilwell v. Office of Thrift Supervision*, 569 F.3d 514, 518 (D.C. Cir. 2009) (finding it "more than a little ironic that [government] would suggest Petitioners lack standing and then, later in the same brief, label [Petitioners] as a prime example of . . . the very problem the Rule was intended to address") (cleaned up).

Here, the doctors wish to keep using their best medical, ethical, and religious judgments in speaking and giving information to patients; the doctors have been mandated to offer transgender procedures or referrals and change their policies now; they are at risk of a request for an objectionable practice from any patient at any moment of practice. Van Meter Decl. ¶ 134; Dickerson Decl. ¶ 100; Dassow Decl. ¶¶ 37, 48. The doctors thus face an imminent risk of incurring

liability and a substantial risk of enforcement against them, which creates a concrete injury-in-fact. *Cutshall v. Sundquist*, 193 F.3d 466, 471–72 (6th Cir. 1999) (standing for sex offender to challenge state law allowing disclosure of personal information if requested by local officials even though offender did not identify any pending request for information).

D. The doctors' claims are ripe.

For the same reasons, this case also presents ripe, purely legal questions. In pre-enforcement First Amendment cases, the line between "standing and ripeness . . . has evaporated." *Winter v. Wolnitzek*, 834 F.3d 681, 687 (6th Cir. 2016). Pre-enforcement cases are ripe when there is a threatened imminent injury-in-fact under the factors for free-speech cases. *Platt*, 769 F.3d at 451.

Further factual development thus is unnecessary here and would not "significantly advance [the court's] ability to deal with the legal issues presented." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 812 (2003) (citation omitted); *Abbott Lab'ys*, 387 U.S. at 149–54. The government has said in rulemaking what it finds to violate the law. The complaint and declarations provide detailed facts—including detailed descriptions of the doctors' policies and ongoing speech, as well as the basis for their medical, conscientious, and religious objections. Any remaining future contingencies do not affect the legal questions before the court, *Nat'l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 691–92 (2d Cir. 2013), especially not the overbreadth challenge that does not depend on particular facts.

The plaintiffs thus have standing even if they have never been prosecuted or threatened with prosecution. *McGlone v. Bell*, 681 F.3d 718, 729 (6th Cir. 2012). "[W]here threatened action by *government* is concerned, we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat ...." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128–29 (2007). For this reason, in reviewing federal agency action, "parties need not await enforcement proceedings before challenging final agency action where such proceedings carry the risk of serious criminal and civil penalties." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016) (cleaned up). Agency action is "immediately reviewable," even if

the order correctly implemented a statutory requirement and even if it "would have effect" only "when a particular action was brought." *Id*. The "APA provides for judicial review of all final agency actions, not just those that impose a self-executing sanction." *Sackett v. EPA*, 566 U.S. 120, 129 (2012).

E. This case meets the requirements for individual and associational standing.

Standing exists for each challenged agency action, either individually or through associational standing.

1. Dr. Dassow and the medical associations have individual standing to challenge the grants mandate and the delay of the SUNSET Rule.

First, the individual plaintiffs have standing to challenge the grants mandate and the Delay Rule, independent of associational standing. "At least one plaintiff must have standing to seek each form of relief requested in the complaint." *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 137 S. Ct. 1645, 1651 (2017). But "only one plaintiff needs to have standing in order for [a] suit to move forward." *Parsons v. U.S. Dep't of Just.*, 801 F.3d 701, 710 (6th Cir. 2015).

Under this one-plaintiff rule, Dr. Dassow has standing to challenge the grants mandate. Dassow Decl. ¶¶ 12–17, 32. This Court thus has jurisdiction on this basis alone to hear all Plaintiffs' claims on the grants mandate, including those of the associations' members. So the Court need not examine associational standing separately for the grants mandate claims.

Likewise, the individual plaintiffs have standing to challenge the Delay Rule, separate from any associational standing. The medical associations are small entities that, on their own behalf, have standing to challenge the delay of the SUNSET Rule under all causes of action. Dr. Dassow also has standing to challenge that delay under the remaining causes of action. This Court thus has jurisdiction on this basis alone to hear all Plaintiffs' claims against the delay of the SUNSET Rule, including those of the associations' members, with no need to examine associational standing to challenge the Delay Rule.

2. The medical associations have associational standing to challenge each mandate.

The medical associations also have associational standing to challenge on behalf of their members the § 1557 mandate, as well as to challenge the grants mandate and the delay of the SUNSET Rule. "An organization may sue on behalf of its members if it shows that: (1) its 'members would otherwise have standing to sue in their own right'; (2) the 'interests' that the suit 'seeks to protect are germane to the organization's purpose'; and (3) 'neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.'" *Ass'n of Am. Physicians & Surgeons*, 2021 WL 4097325, at *3 (quoting *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). To meet this standard, an "organization must . . . identify . . . a member who has suffered (or is about to suffer) a concrete and particularized injury from the defendant's conduct." *Ass'n of Am. Physicians & Surgeons,* 2021 WL 4097325, at *8. Plaintiffs ACPeds and CMA have associational standing under each of these three criteria.

First, their members would have standing to sue. The associations represent more than three thousand healthcare providers nationwide, all of whom object to providing gender transition services or referring patients for such services. Van Meter Decl. ¶¶ 18, 155; Dickerson Decl. ¶¶ 3, 69.

Second, the interests that the suit seeks to protect are germane to the organization's purpose. The medical organizations' purposes include ensuring high-quality healthcare for all people, and both organizations' official positions are against gender interventions. Van Meter Decl. ¶¶ 16–20, 25–81; Dickerson Decl. ¶¶ 27–57, 147.

Third, neither the claims asserted, nor the relief requested require the participation of individual members in the lawsuit. The issues here are purely legal, the views of the members are established, and the effect on virtually all doctors is the same. Van Meter Decl. ¶¶ 21–24, 91–131, 135–40, 141–42, 144–48, 152–71; Dickerson Decl. ¶¶ 7–8, 63–66, 71, 101–08, 109–12, 118–19,142–43, 154–56.

The associations have also identified members who have suffered or are about to suffer a concrete and particularized injury from the Defendants' conduct. Each declaration outlines several

named and unnamed members subject to the mandates who are not in compliance and who share the organization's objections to the mandates' requirements. Van Meter Decl. ¶¶ 91–131; Dickerson Decl. ¶¶ 76–98. Each doctor is subject to being driven out of healthcare unless they abandon their medical judgment or religious beliefs. Van Meter Decl. ¶¶ 135–40, 152–55; Dickerson Decl. ¶¶ 101–06, 118–19, 142–43, 154–56. And finally, Plaintiffs have sued "the entity that would cause this harm," namely HHS, as the government enforcer of these mandates. *Ass'n of Am. Physicians & Surgeons*, 2021 WL 4097325, at *10.

F. *Bostock* does not affect standing.

Bostock limited its holding to Title VII, and it said it was not interpreting any "other laws" like the ACA; the holding did not encompass spaces such as doctor-patient conversations and healthcare facilities. 140 S. Ct. at 1753. Unsurprisingly, it cannot affect the standing analysis here. Interpreting other federal statutes to encompass gender identity is, at minimum, an extension of *Bostock* beyond its self-imposed boundaries. That means the new threat of government enforcement here is traceable to HHS's actions, not *Bostock*. And because HHS's mandates extend precedent to mandate new legal obligations, it is reviewable final agency action anyway.

In all events, an agency cannot avoid judicial review by claiming that its new legal standard was obvious in the statute all along. After all, the whole point of APA review is to see whether an agency improperly read "substantive changes into the regulation under the guise of interpretation." *Children's Health Care v. Centers for Medicare & Medicaid Servs.*, 900 F.3d 1022, 1026 (8th Cir. 2018). That is why, if the government requires "its reviewing agents to utilize a different standard of review" or imposes "a presumption of invalidity when reviewing certain operations, its measures would surely require notice and comment"—"as well as close scrutiny to insure that it was consistent with the agency's statutory mandate." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1051 (D.C. Cir. 1987). When an agency uses informal guidance to change its position, its reference to statutory authority does not make the action any less final. *Texas v. United States*, 201 F. Supp. 3d 810, 827–31 (N.D. Tex. 2016) (holding the government's informal Title IX Dear Colleague letter to be final agency action subject to judicial review).

No case holds that a final agency action cannot be challenged if the agency claims that a statute required the action. Unlike in *California v. Texas*, 141 S. Ct. 2104, 2115, 2119 (2021), HHS has always said that it can enforce these provisions—including retroactively—and bring their harsh penalties to bear. Under this inquiry, the doctors' asserted injuries from the threat of government enforcement are easily traceable to the government enforcement officials, so enjoining government enforcement would redress this threat. *Telescope Media Grp. v. Lucero*, 936 F.3d 740, 749 (8th Cir. 2019).

Nor is it the case that an injury is not redressable because private parties could seek to enforce the same interpretation on the doctors through private causes of action. The possibility of other enforcers does not undermine relief against government enforcement officials. *281 Care Comm. v. Arneson*, 638 F.3d 621, 631 (8th Cir. 2011). To the contrary, standing is "bolstered" when the "authority to file a complaint" "is not limited to a prosecutor or an agency," *SBA List*, 573 U.S. at 164, or if "any person . . . may initiate enforcement," *Platt*, 769 F.3d at 452; *see also Woodhull Freedom Found. v. United States*, 948 F.3d 363, 373 (D.C. Cir. 2020) (private right of action bolstered standing under SBA List). The availability of a private cause of action thus "cut[s] decisively" in favor of justiciability. *Chelsey Nelson Photography LLC v. Louisville/Jefferson Cnty. Metro Gov't*, 479 F. Supp. 3d 543, 551 (W.D. Ky. 2020). A favorable judgment would relieve the doctors of a real government enforcement threat, which is enough—a judgment need not negate every injury from every non-governmental source to be proper. *Minn. Citizens Concerned for Life v. FEC*, 113 F.3d 129, 131 (8th Cir. 1997). And enjoining this interpretation would benefit the parties vis-à-vis third-party enforcers, too, by providing guiding precedent. *Bostock* is no obstacle to standing here.

II. Plaintiffs have causes of action under both the APA and general principles of equity.

A. The APA provides judicial review for final agency actions.

The APA allows a person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" to seek judicial review of that action. 5 U.S.C. § 702. It provides a "strong presumption favoring judicial review of administrative action." *Salinas v.*

United States R.R. Ret. Bd., 141 S. Ct. 691, 698 (2021) (citation omitted). Defendants are agencies subject to the APA. 5 U.S.C. § 701(b); 5 U.S.C. § 551(1). An agency action that "has the effect of committing the agency itself to a view of the law that, in turn, forces the plaintiff either to alter its conduct, or expose itself to potential liability" is thus reviewable. *EEOC*, 933 F.3d at 446 (citation omitted). The doctors thus have causes of action under the APA because the agency has made a decision so that "rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997).

Under this precedent, each mandate constitutes final agency action. The government bound itself and its grantees to a legal interpretation, and each rule reflects a view that the ACA or other laws give no "discretion to depart from the standards in specific applications," *U.S. Tel. Ass'n v. FCC*, 28 F.3d 1232, 1234 (D.C. Cir. 1994). The doctors "have 'reasonably [been] led to believe that failure to conform will bring adverse consequences.'" *Iowa League of Cities v. EPA*, 711 F.3d 844, 864 (8th Cir. 2013). A mandate that enforces a legal standard necessarily affects regulated entities—otherwise there would be nothing to enforce.

For much the same reasons, the mandates are "rules" subject to APA review. A rule, under 5 U.S.C. § 551(4), is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." The mandates meet this definition. They generally adopt a gender identity standard nationwide and they express a future effect to protect this class—in so doing, the mandates implement, interpret, and prescribe law and policy prohibiting gender identity discrimination. The mandates thus "encode[] a substantive value judgment [and] put[] a stamp of approval or disapproval on a given type of behavior." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987).

The Delay Rule is also subject to judicial review under the APA and RFA. The Delay Rule is definitive and determines the rights of persons, and it has been declared and treated as law. The delay affects the rights or obligations of the agency, the regulated parties, and the public by suspending the SUNSET Rule's effects and public comments. Leaving legal obligations in place creates legal consequences. The Delay Rule is thus a final agency action, a legislative or

substantive rule, 5 U.S.C. § 551(4), and constitutes "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court," 5 U.S.C. § 704. Plaintiffs ACPeds and CMA also bring their claims against the Delay Rule under the judicial review provision of the RFA. 5 U.S.C. § 611.

B. Exceptions to judicial review are inapplicable here.

"The APA establishes a basic presumption of judicial review for one suffering legal wrong because of agency action. That presumption can be rebutted by a showing that the relevant statute precludes review, or that the agency action is committed to agency discretion by law." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020) (cleaned up). But neither exception applies here. No statute prohibits judicial review and creating new protected classes under federal civil rights laws is not "committed to agency discretion by law." 5 U.S.C. § 701(a)(2).

Although "an agency's decision not to institute enforcement proceedings" is often not reviewable, the mandates are not "a non-enforcement policy." *Regents*, 140 S. Ct. at 1905–07. The announcement or rescission of any program for conferring affirmative relief is an action that provides a focus for judicial review. *Id.* Even if statutory "provisions leave much to [enforcement] discretion" in individual cases, that discretion cannot be unbounded. *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2568 (2019). In short, because there is a "meaningful standard by which to judge [Defendants'] action," the mandates are reviewable. *Id.*

C. The government's unlawful acts are also reviewable as a matter of equity.

Distinct from the APA, courts of equity have the power to set aside ultra vires and unconstitutional federal actions. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–90, 693 (1949). The "Supreme Court has long recognized that injunctive relief" apart from the APA can "be available to test the legality of administrative action." 33 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FED. PRAC. & PROC. JUD. REVIEW § 8304 (2d ed. 2021). And the government in past cases has conceded that there is "an implied private right of action directly under the

Constitution to challenge governmental action . . . as a general matter." *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491, n.2 (2010).

The plaintiffs also seek review under *Larson*. *See, e.g.*, *Leal v. Azar*, No. 2:20-CV-185-Z, 2020 WL 7672177, at *6 (N.D. Tex. Dec. 23, 2020). This equitable cause of action provides prospective relief for a constitutional violation or ultra vires act committed by a federal official. *Green Valley Special Util. Dist. v. City of Schertz*, 969 F.3d 460, 475 (5th Cir. 2020) (en banc); *Simmat v. U.S. Bureau of Prisons*, 413 F.3d 1225, 1232–33 n.9 (10th Cir. 2005) (McConnell, J.) (allowing claim to proceed even though plaintiff "appear[ed] to concede that his claim d[id] not satisfy the APA's requirement of 'final agency action'"). Plaintiffs can bring a "non-statutory review action," and courts can review federal executive action that violates statutory commands. *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1327–32 (D.C. Cir. 1996). This avenue for relief does not depend on meeting the APA's technical requirements. *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 189–90 (D.C. Cir. 2006). Section 701's reviewability limitation does "not repeal the review of ultra vires actions recognized long before" the APA. *Reich*, 74 F.3d at 1328. Indeed, the government relies on equitable causes of action in its own pre-enforcement challenges. *See, e.g.*, Complaint, *United States v. Texas*, Civil No. 1:21-cv-796 ¶8 (W.D. Tex. filed Sept. 9, 2021).

III. HHS's gender-identity mandates conflict with federal law.

The gender-identity mandates exceed HHS's statutory authority under 5 U.S.C. § 706(2)(C) by expanding the definition of "sex" in the ACA to cover gender identity "discrimination." But no law makes gender identity a protected class in healthcare, and the clear-notice canon bars the government's new interpretation. Congress—not an executive agency—must decide major issues like requiring doctors nationwide to offer, refer for, and affirm gender interventions. Moreover, by incorporating all of Title IX, any regulation related to the ACA must also provide the same protections for religious freedoms. *See* 20 U.S.C. § 1681(a). The mandates fail to do this.

A. "Anti-discrimination" mandates based on gender identity are refuted by the text of both the Affordable Care Act and Title IX.

1. Examination of the text of the ACA shows that Congress did not give HHS authority to impose a gender-identity mandate. On the contrary, the statute uses sex as a binary term—as must be the case in the medical field.

In any question of statutory interpretation, the court begins with the "fundamental canon of statutory construction that words generally should be interpreted as taking their ordinary meaning at the time Congress enacted the statute." *New Prime Inc. v. Oliveira*, 139 S. Ct. 532, 539 (2019) (cleaned up). Here, the ordinary meaning of "sex" when Congress wrote the ACA refers to the biological binary of male and female—not to encompass the concept of gender identity. *See, e.g.*, 124 Stat. at 261, 334, 343, 551, 577, 650, 670, 785, 809, 873, 890, 966. This is confirmed throughout the statute. For instance, Section 3509 of the ACA includes the statute's only express references to the term "sex," and requires data to be collected and analyzed "by sex" 124 Stat. at 536-37. It says information must be given "on those areas in which differences between men and women exist." *Id*. at 536.

The text of the ACA includes other language showing Congress legislated using a binary sex construct. The statute is replete with references to "women," "mothers," and variants of the same. There are one hundred thirty-seven references to "women," twelve references to "woman," eight references to "mother" and "mothers," and ten references to "maternal." *See, e.g.*, 124 Stat. at 551 (referring to "pregnant women"); *id*. at 577 (providing reasonable break time for nursing mothers).

The ACA also incorporates a binary sex understanding of the biologically binary nuclear family in the ACA. For example, Congress defined a primary care provider as "a clinician" responsible for "providing preventive and health promotion services for men, women, and children of all ages." *Id*. at 650. Likewise, under Section 2951 of the ACA titled "Maternal, Infant, and Early Childhood Home Visitation Programs," Congress defined the term "eligible family" to include "a woman who is pregnant, and the father of the child if the father is available." *Id*. at 334, 343. So, too, a provision barring certain health insurance plans from requiring a referral for

obstetrics and gynecological care applies only to a "female participant, beneficiary, or enrollee" who seeks this care. *Id*. at 890 (emphasis added).

The ACA furthermore features the use of binary, gendered pronouns, rather than concepts of gender on a spectrum. The ACA's amendment to the Fair Labor Standards Act provides "a reasonable break time for an employee to express breast milk for her nursing child." 124 Stat. at 577. The ACA uses the sex binary "his or her" at least seven times. *Id*. at 261, 670, 785, 809, 837, 966, and 1003.

While Section 1557 says nothing about gender or gender identity, Congress was aware of the interpretation now advanced HHS, using the term "gender" elsewhere to mean something other than sex. For example, Section 5306 of the ACA conditions grants based on recipients showing participation of "different genders and sexual orientation" in their programs. 124 Stat. at 626. Congress had a chance to make § 1557 address gender identity, along with biological sex, but chose not to do so.

2. That "sex" was meant only to refer to the male/female distinction can be seen through Title IX as well. When drafting the ACA, rather than adopting any modern gender theory, Congress incorporated Title IX's prohibition on discrimination "on the basis of sex." Looking to that statute thus provides a helpful interpretive guide.

When Congress enacted Title IX in 1974, Congress understood "sex" as a biological binary and not inclusive of the gender identity spectrum offered now by HHS. Title IX does not itself define the term "sex" or "on the basis of sex." But, in common, ordinary usage, the word "sex" in 1972 meant biologically male or female, based on reproductive organs.[22] Even today, the American Psychiatric Association's most recent diagnostic manual—the DSM-5—likewise affirms that "sex" "refer[s] to the biological indicators of male and female." AMERICAN

[22] *E.g.*, *Sex*, WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE (College ed. 1962) ("either of the two divisions of organisms distinguished as male or female"); *Sex*, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (1st ed. 1969) ("[t]he property or quality by which organisms are classified according to their reproductive functions").

PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 451 (5th ed. 2013).

Various textual provisions of Title IX confirm that Congress used the term "sex" to reference the biological reality of a binary option rather than HHS's current construction. For instance, the statute refers to "the process of changing from being an institution which admits only students of one sex to being an institution which admits students of both sexes." 20 U.S.C. § 1681(a)(2). Likewise, Congress preserved association rights for organizations that "traditionally [have] been limited to persons of one sex." *Id.* § 1681(a)(6)(B). Congress did "not preclude father-son or mother-daughter activities at an educational institution, but if such activities are provided for students of *one* sex, opportunities for reasonably comparable activities shall be provided for students of *the other* sex." *Id.* § 1681(a)(8) (emphases added). Title IX likewise says it does not prohibit an educational institution "from maintaining separate living facilities for the different sexes." *Id.* § 1686.

Rather than understanding sex as a concept involving a spectrum, Title IX refers to "men's" and "women's" associations and organizations for "boys" and "girls" where "membership . . . has traditionally been limited to persons of one sex." *Id.* § 1681(a)(6)(B). Section 1681(a)(7)(A) also refers to "boys'" and "girls'" conferences. *Id.* § 1681(a)(7)(A). In many other instances, Title IX and its implementing regulations not only allow but may require consideration of a person's biological sex, whether male or female. *See, e.g.*, 20 U.S.C. §§ 1681(a), 1686; 34 C.F.R. §§ 106.32(b), 106.33, 106.34, 106.40, 106.41, 106.43. 106.52, 106.59, 106.61. For example, institutions "may provide separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex." 34 C.F.R. § 106.33. Title IX also prohibits pregnancy discrimination, *see* 34 C.F.R. § 106.40(b)(1), thus relying on pregnancy to be a *distinction* between two sexes. The ordinary meaning of Title IX in 1972 does not include the notion of a pregnant "man."

Contrastingly, Title IX includes no references to "gender" or "gender identity." It thus makes little sense to claim that the ACA forbids healthcare providers from doing what Title IX has

allowed for educational facilities for decades (including in healthcare settings). But making gender identity a protected class is a ban on single-sex healthcare programs and facilities. And under the gender-identity mandates, doctors must now place males who identify as female in female treatment groups or communal hospital rooms, and vice versa. This conflicts with Title IX.

Before this recent set of mandates, HHS long held an understanding of the text that treats "sex" based on biology rather than philosophy. HHS refers many times in its Title IX regulations to "members of one sex" and "members of the other sex." 45 C.F.R. § 86.7; *see* 45 C.F.R. § 86.1 et seq. For example, HHS's Title IX regulations provide an exception for "separation of students by sex within physical education classes or activities during participation in . . . sports . . . which involves bodily contact." 45 C.F.R. § 86.34(c). See also 45 C.F.R. § 86.34(e) (separated sexuality classes); 45 C.F.R. § 86.34(f) (separated choirs); 45 C.F.R. § 86.37(c)(2) (separate athletic scholarships).

3. The major questions doctrine buttresses this interpretation. In prohibiting sex discrimination in Title IX in 1972, Congress cannot be found to have overturned the longstanding practice that doctors treat patients by biological sex—Congress does not hide "elephants in mouseholes." *Wittmer v. Phillips 66 Co.*, 915 F.3d 328, 336 (5th Cir. 2019) (Ho, J., concurring) (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)). This sea change in medicine was not within the government's discretion under the ACA. It is "a question of deep 'economic and political significance'" that Congress did not "expressly" assign to the executive branch. *King v. Burwell*, 576 U.S. 473, 474 (2015). Under this substantive canon, Congress must speak clearly to grant powers of "vast 'economic and political significance.'" *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021).

HHS thus correctly concluded in the 2020 ACA Rule, after consideration of and responses to public comments, that the § 1557 mandate was unlawful and unwarranted. For example, the 2020 ACA Rule concluded:

- "'Sex' according to its original and ordinary public meaning refers to the biological binary of male and female."

- "Distinctions based on real differences between men and women do not turn into discrimination merely because an individual objects to those distinctions. Title IX does not require covered entities to eliminate reasonable distinctions on the basis of sex whenever an individual identifies with the other sex, or with no sex at all, or with some combination of the two sexes."

85 Fed. Reg. at 37,178-80, 37,183-86.

In short, because Title IX does not address gender identity, Section 1557 cannot be presumed to do so either.

B. The § 1557 mandate also conflicts with ACA provisions regarding access to healthcare and the protection of conscience rights.

The gender-identity mandate also conflicts in whole or in part with four other key provisions of the ACA.

First, HHS must include Title IX's religious exemptions in its § 1557 mandate. And it unlawfully failed to do so. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016) ("Congress intended to incorporate the entire statutory structure, including the . . . religious exemptions.").

Second, the § 1557 mandate goes against multiple parts of Section 1554 of the ACA. The statute prohibits "any regulation" that:

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114(1) – (6).

The § 1557 mandate violates parts (1), (2) and (6) of Section 1554 because it pressures ACPeds and CMA members out of federally funded health programs and the practice of healthcare. It violates parts (3) and (4) because it requires ACPeds and CMA members to speak in affirmance of gender identity, and refrain from speaking in accordance with a patient's biological sex and related medical needs. Finally, the § 1557 mandate violates part (5) because it requires ACPeds

and CMA members to deprive patients of *informed* consent and forces the doctors to violate their ethical standards.

Third, the § 1557 mandate conflicts with the ACA's conscience provisions. First, "[n]othing in [the ACA] shall be construed to have any effect on Federal laws regarding (i) conscience protection." 42 U.S.C. § 18023(c)(2). As noted previously, HHS's gender-identity mandates fail this test. Second, the § 1557 mandate violates the Church Amendments, 42 U.S.C. § 300a-7(d), which provide that "no individual shall be required to perform or assist . . . if his performance or assistance in . . . such program or activity would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(d).

Fourth, the § 1557 mandate violates laws that restrict Medicare to items and services "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). HHS admitted in the 2016 ACA rule that it required these gender interventions to be provided even if not medically necessary. 81 Fed. Reg. at 31,429, 31,455. Making federal programs pay for such interventions thus violates the law.

C. The grants mandate cannot be justified under the housekeeping statute.

The grants mandate likewise exceeds the authority of the sole statute it cited in support: 5 U.S.C. § 301. That statute bears none of the substantive weight HHS has placed upon it.

The 2016 grants mandate relied on the multi-agency "housekeeping statute," which states that an agency head may "prescribe regulations for the government of his Department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." *Id*. This law does not allow HHS to regulate anything outside an agency's internal functions. Housekeeping does not include "'substantive rules.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 310–11 (1979); *accord In re Bankers Tr. Co.*, 61 F.3d 465, 470 (6th Cir. 1995) (same).

HHS may try to justify the grants mandate under another statute. But such post hoc rationalization is not allowed under the APA. *Regents*, 140 S. Ct. at 1909-10. The only authority

for the mandate is HHS's bald claim that it may impose it as a matter of public policy. And an agency cannot "incorporate such a preference into the text of a federal statute." *14 Penn Plaza LLC v. Pyett*, 556 U.S. 247, 267 n.9 (2009). The grants mandate therefore falls.

D. A narrow interpretation is compelled by the Constitution's clear-notice canon.

A narrow interpretation of the ACA and the housekeeping statute is also compelled by the Constitution's clear-notice canon. The "clear notice" canon imposes "a particularly strict standard," *Port Auth. Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 305 (1990), on attempts to preempt State "police powers." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). These "police" powers include regulations over medicine, healthcare, education, and real estate, *Bond v. United States*, 572 U.S. 844, 858 (2014), or that impose grant conditions, *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 24 (1981). Unlike regular statutes, to invade the States' police powers, Congress must make "its intention" "'unmistakably clear in the language of the statute,'" *Gregory v. Ashcroft*, 501 U.S. 452, 460, 464 (1991) at the time of enactment, *Carcieri v. Salazar*, 555 U.S. 379, 388 (2009). Congress must make a "clear and manifest" statement by deliberating and resolving each specific term. *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 551 (1985). This cuts off "burden[s] of unspecified proportions and weight, to be revealed only through case-by-case adjudication," *Bd. of Educ. of Hendrick Hudson Cent. Sch. Dist., Westchester Cnty. v. Rowley*, 458 U.S. 176, 190 n.11 (1982). The federal government may not "surpris[e] participating States with post acceptance or 'retroactive' conditions." *Pennhurst*, 451 U.S. at 25.

The Supreme Court also applies this canon to protect private parties. Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (citation omitted) (striking down eviction 'moratorium').

The laws here displace traditional state regulations over medicine, real estate use and other aspects of liberty, affecting an "area[ ] of traditional state responsibility," *Bond*, 572 U.S. at 858. Thus, 'clear notice' is required about the scope of any intrusion. But *Congress* did not *unmistakably* address gender identity in the 2010 ACA, or the 1972 passage of Title IX, or in the

1790 or 1874 housekeeping statutes. Congress never unmistakably declared that doctors must provide gender transitions on demand, regardless of medical judgment or religious beliefs. The States had no understanding that accepting Medicare, Medicaid, or CHIP as payment for medical services would lead to these consequences. *See* Van Meter Decl. ¶ 155; Dickerson Decl. ¶ 69; Dassow Decl. ¶¶ 32. Congress did not "in fact face[], and intend[] to bring into issue," the mandate's particular disruption of state and private authority, and its impositions violate the clear notice rule. *United States v. Bass*, 404 U.S. 336, 349 (1971).

For these reasons, the mandate cannot receive deference under *Auer v. Robbins*, 519 U.S. 452 (1997). Not only is this not an interpretation of the agency's own regulations, there is no ambiguity for the agency to exploit. When an act is subject to "competing plausible interpretations," *Clark v. Martinez*, 543 U.S. 371, 381 (2005), the statute must be construed "to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score," *Almendarez-Torres v. United States*, 523 U.S. 224, 237−328 (1998) (citation omitted). Under these canons, any ambiguity requires adopting "the less expansive reading." *Kollaritsch v. Mich. State Univ. Bd. of Trustees*, 944 F.3d 613, 629 (6th Cir. 2019) (Thapar, J., concurring).

And even if the defects with HHS's rulemakings could be overcome, any application or enforcement of § 1557 to discrimination because of gender identity exceeds Congress's Article I enumerated powers and transgresses on the reserved powers of the State under the federal constitution's structural principles of federalism and the Tenth Amendment. U.S. CONST. art. I, § 8, cl. 1; *id.* amend. X. It effectively coerces or commandeers the States, including in grant conditions and in the States' historical and well-established regulation of healthcare, freedom of speech, conscience protection, and religious freedom. *New York v. United States*, 505 U.S. 144, 162 (1992).

E. *Bostock* cannot rescue the gender-identity mandates.

As much as the Administration might want it to, *Bostock* provides no support for HHS's broadening of the statute. *Bostock* itself rejected any claim that the "decision w[ould] sweep beyond Title VII to other federal or state laws that prohibit sex discrimination." 140 S. Ct. at 1753.

The Court stated that "none of these other laws are before us; we have not had the benefit of adversarial testing about the meaning of their terms, and we do not prejudge any such question today." *Id.* And even under Title VII, the Court did "not purport to address bathrooms, locker rooms, or anything else of the kind," such as intimate settings in medicine. *Id.* The Court was also "deeply concerned with preserving" the constitutional and statutory rights of religious institutions. *Id.* at 1753–54.

But if these limits were not there, *Bostock* would still not support the § 1557 mandate. *Bostock* considers gender identity relevant only if it is part of "sex" discrimination, such as when an employer fires an employee for conduct or personal attributes on these bases that it would tolerate in a person of the opposite biological sex. *Bostock*, 140 S. Ct. at 1741–42. Sex discrimination is not the same under the text of Title IX, where sex not only can but must be considered, yet doing so does not constitute illegal discrimination. If the government's theory of sex discrimination were correct, every medical procedure that merely considers sex would be illegal under Section 1557. No court has applied the ACA that way, and for the same reason courts refuse to apply Title VII caselaw to Title IX where sex *must* be considered. *See Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021) ("it does not follow that principles announced in the Title VII context automatically apply in the Title IX context."); *Miami Univ. Wrestling Club v. Miami Univ.*, 302 F.3d 608, 615 (6th Cir. 2002) (considering it well-established that classification by gender is not a per se violation of Title IX).

The same is true for the doctors' speech. If doctors refer to all patients by the correct sex, they do not discriminate against any patient by sex. Doctors who code, chart, and treat all patients, male or female, by biological sex do not discriminate against men or women. Likewise, doctors do not discriminate by sex if they give full information warning about the risks and permanent effects of gender interventions to all patients of both sexes.

IV. HHS's gender-identity mandates are arbitrary and capricious.

On top of contradicting the law, HHS's gender-identity mandates must be set aside because they are arbitrary, capricious, and an abuse of discretion under 5 U.S.C. § 706(2)(A).

Agency action is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The arbitrary and capricious nature of HHS's gender-identity mandates are apparent as a matter of law for two reasons.

First, HHS's May 10, 2021 announcement that it would fully enforce the 2016 § 1557 gender-identity mandate is entirely premised on the legally false view that under *Bostock* Title IX and § 1557 prohibit gender identity discrimination. 86 Fed. Reg. 27,984–85. The substance of this error is discussed in Part III above, including that *Bostock* disavowed its application to this context. HHS's enforcement of the § 1557 gender-identity mandate is therefore arbitrary and capricious. In the grants mandate, HHS relied erroneously on the housekeeping statute for its statutory authority, which does not authorize the imposition of substantive non-discrimination requirements, discussed above in part II.

Second, HHS's enforcement of the § 1557 gender-identity mandate is arbitrary and capricious because it is a change in position from the view HHS took in the preamble of HHS's 2020 rule repealing the § 1557 gender-identity mandate, but HHS did not discuss, much less thoroughly and sufficiently explain, why it was changing its position once again concerning those issues to reverse course in such a radical way. "[A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change." *State Farm*, 463 U.S. at 42. When an agency changes course in rules or enforcement, it must also consider "legitimate reliance" on past policies and legitimate alternative policies. *Regents*, 140 S. Ct. at 1910–15. HHS did none of this in taking its current course to enforce the 2016 § 1557 gender-identity mandate. In 2020 HHS conceded that its 2016 decision was unjustified, "erroneous," and, "at a minimum," lacked a "scientific and medical consensus to support" it. 85 Fed. Reg. at 37,161–62, 37,187. HHS also concluded gender transition interventions—which it now mandates by objecting doctors—had a

"lack of high-quality scientific evidence" in support. *Id*. HHS took the public position that medical distinctions based on biological sex were reasonable, there was no sufficient statutory or policy reason to impose the 2016 gender-identity mandate under the ACA, that "[p]ronouns are not stereotypes," and that the government's alleged interests were "based largely on unsubstantiated hypothetical scenarios." *Id.* at 37,177–92. It is arbitrary and capricious for HHS to enforce the § 1557 gender-identity mandate without a thorough reconsideration of these and related issues.

The rationale of HHS return to the 2016 rule is based on the new administration's political reasons, not a reasoned analysis of law and policy. *See* 86 Fed. Reg. at 27,985 & n.7 (relying on Department of Justice memorandum that implements Executive Order 13,988, which requires agencies to comply with President Biden's "policy" that gender identity discrimination be prohibited under all civil rights laws). Changing position for policy reasons without a reasoned explanation of the agency's changes in position is impermissible. *See Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575–76 (2019). An agency fails its duty of reasoned decision making when it changes course without offering the reasons why it was changing its legal view, without examining the evidence before the agency, without examining religious exemptions, and without addressing reliance interests or legitimate alternatives. *Regents*, 140 S. Ct. at 1910–15 (invalidating rescission of a previous administration's immigration policies). Agency action, however, must rest on more than a belief that one part of the previous policy was unlawful. *Id.* at 1909–10. HHS failed to provide a suitable rationale for its abrupt change because it impermissibly placed dispositive weight on an incorrect legal interpretation of *Bostock* and on a freestanding desire to change policy without doing the work to explain changes in position, reliance interests, and alternatives. *Id*.

V. HHS's gender-identity mandates violate the freedom of speech.

The government's mandates also violate the First Amendment's Free Speech Clause by censoring and compelling doctors' speech by content and viewpoint. U.S. CONST., amend. I. Under the Free Speech Clause, the government may not restrict speech because of its content or viewpoint. *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015). But these mandates force doctors to communicate—on pain of losing their careers—a message they believe is false: that

gender identity, rather than biological reality, shapes and defines an individual's sex. The mandates thus violate doctors' First and Fifth Amendment rights facially and as-applied. None of these restrictions advance a compelling governmental interest nor are they narrowly tailored. This is therefore an unconstitutional condition on the receipt of federal funding, causing a deprivation without due process of law.

A. HHS seeks to impose unconstitutional content and viewpoint rules on doctors based on a political agenda that harms both the speakers and the listeners. Patients have a right to know the facts regarding documented harms associated with gender interventions, as well as the permanence of a decision to follow through with a gender transition. In the past, the doctors have conveyed such medical advice to their patients and their families. But HHS wants to interfere with the doctor-patient relationship, telling doctors what they can and cannot say about gender identity.

Consider statements that HHS censors doctors from making. By creating liability for what the government considers a hostile environment, disparate impact, or unlawful patterns or practices, HHS's mandates prevent doctors from:

- refusing to provide, refer for, or affirm gender interventions;
- having full and frank conversations about the risks of—and alternatives to—gender interventions;
- describing patients according to biological sex in medical records;
- using biologically correct medical screening questions;
- recommending treatment for patients' medical needs according to their biological sex;
- prescribing or offering participation in single-sex programs—including breastfeeding or mental health support groups—or facilities divided by biological sex—such as hospital rooms, showers, and bathrooms, and
- using a patient's biologically correct pronouns.

Doctors are also compelled to offer and refer for these interventions, even if no patient has asked for them. HHS prohibits doctors' speech that announces or affirms a policy that patients are treated

based on what their biological sex is—even if endangers patients with incorrect and confusing advice, records, or treatment.

At the same time the mandates require that doctors police their speech about transgender treatments. Doctors can tell a patient that they have, or prefer to have, healthcare practices affirming gender identity; they cannot tell a patient that they have, or prefer to have, healthcare practices based on biological sex.

The mandates also compel doctors' speech. Doctors must adopt and express views supportive of a patient's self-professed gender identity, even if contrary to biological sex. HHS compels doctors to:

- refer for and affirm gender interventions;
- describe patients in biologically inaccurate ways in medical records;
- use biologically incorrect medical screening questions;
- recommend treatment for patients' medical needs according to gender identity, even if that means ignoring a patient's true medical needs;
- inform biological males that they are welcome to participate in single-sex programs and enter facilities designated for women, and
- speak and write a person's "preferred pronoun," in doctor-patient communications, even if that pronoun differs from biological sex.

81 Fed. Reg. at 31,406. Thus, a doctor would have to call a biological male a female, or vice versa, and use any of the countless pronouns upon demand.

HHS also orders doctors to revise their written policies to affirm and offer gender transition services—regardless of the provider's religious beliefs, medical judgment, or ethical concerns. *See, e.g.*, 2016 ACA Rule, 81 Fed. Reg. at 31,455 ("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." (emphasis added)).

HHS also requires doctors to certify that they have policies complying with the § 1557 mandate, such as HHS's Form 690 requirement to assure compliance, or statements required to be made in award applications, notices of awards, or applications to qualify as providers in Medicaid, Medicare, or CHIP. Covered entities must also, as a condition of any application for Federal financial assistance, "submit an assurance, on a form specified by the Director [of the Department's Office for Civil Rights], that the entity's health programs or activities will be operated in compliance with section 1557 and this part," meaning the HHS regulations including the operative portions of the 2016 ACA Rule. 45 C.F.R. § 92.4(a); 81 Fed. Reg. at 31,392, 31,442, 31,468. Covered entities further must post notices about compliance with the 2016 ACA Rule in conspicuous locations, and HHS provided a sample notice to be posted. 81 Fed. Reg. at 31,472; 45 C.F.R. § 92, App. A. In addition, OCR can demand that covered entities record and submit compliance reports. 81 Fed. Reg. at 31,439, 31,472.

The Free Speech Clause protects healthcare professionals. *Nat'l Inst. of Fam. & Life Advocs. (NIFLA) v. Becerra*, 138 S. Ct. 2361, 2371-72 (2018). This is especially important in the medical field where biological sex can be important to treatment. Open communication in healthcare is "critical" because "[d]octors help patients make deeply personal decisions," and yet "[t]hroughout history, governments have manipulated the content of doctor-patient discourse to increase state power and suppress minorities." *Id*. at 2374. It is thus essential in the medical context that doctors have the freedom to maintain "good-faith disagreements, both with each other and with the government, on many topics in their respective fields. . . . [P]eople lose when the government is the one deciding which ideas should prevail." *Id*. at 2374–75. The government cannot be allowed to "suppress unpopular ideas or information" and impose its own views of proper healthcare. *Id*. at 2373–76.; *see also Conant v. Walters*, 309 F.3d 629, 636 (9th Cir. 2002) ("An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients.").

These First Amendment interests also implicate the doctors' rights to expressive association (or freedom of assembly). With the threat of driving them out of the healthcare field,

HHS compels the doctors to participate in facilities, programs, and other healthcare-related endeavors contrary to their religious beliefs and expressive identities—and to associate with messages on these topics about which they disagree.[23]

HHS may try to claim that this doctor-patient speech is unprotected because HHS considers it to be "discrimination." This argument fails, however, because no historical evidence or tradition finds doctors' policies and speech to be categorically unprotected. Indeed, far from "unprotected," speech about gender identity receives strong protection. *Loudoun Cnty. Sch. Bd. v. Cross*, No. 210584, slip op. at *9–10 (Va. Aug. 30, 2021). That is because frank discussion about "gender identity" plainly falls within the realm of protected speech as it is a "sensitive political topic[]" and "undoubtedly" a matter of "profound value and concern to the public." *Janus v. AFSCME Council 31*, 138 S. Ct. 2448, 2476 (2018). (internal citation omitted)[24]

As discussed above, HHS is not justified in requiring the doctors to provide gender transition procedures, and consequently, HHS is also prohibited from requiring them to speak about or in favor of those procedures. In addition, much of the compelled speech such as requiring doctors to use pronouns preferred by patients is unrelated to the provision of medical procedures as such. Therefore, the speech requirements within the gender identity mandates cannot be characterized as merely speech incidental to a legitimate mandate of conduct. HHS has said that categorizing gender transition services as "experimental" "is outdated and not based on current standards of care." 81 Fed. Reg. at 31,435. HHS thus demands that doctors alter their published

[23] The religious doctors' "First Amendment interests are *especially* strong" because their healthcare policies and speech—including the use of pronouns—derive from their core religious beliefs and protected exercise. *Meriwether*, 992 F.3d at 509 (emphasis added).

[24] Even unprotected or lesser-protected commercial speech is still shielded from viewpoint and content discrimination, which apply here. *Matal v. Tam*, 137 S. Ct. 1744, 1767–69 (2017). (agreeing that lower scrutiny did not apply to viewpoint-based restrictions on commercial speech); *Wandering Dago, Inc. v. Destito*, 879 F.3d 20, 39 (2d Cir. 2018) (interpreting *Matal* this way); *accord R.A.V. v. City of St. Paul*, 505 U.S. 377, 389 (1992) ("State may not prohibit only that commercial advertising that depicts men in a demeaning fashion."). When there is a commercial aspect to speech, that speech does not "retain[ ] its commercial character when it is inextricably intertwined with otherwise fully protected speech." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988).

policies. This is direct speech regulation forbidden by the Constitution. *See Bigelow v. Virginia*, 421 U.S. 809, 822 (1975) (invalidating restriction on abortion advertisement because "the activity advertised pertained to constitutional interests").

B. Because the government seeks to regulate speech by content and viewpoint, the mandates are subject to strict scrutiny, with its compelling interest and narrow tailoring requirements. *Reed*, 135 S. Ct. at 2227–30. This is a "stringent standard." *NIFLA*, 138 S. Ct. at 2371. HHS must prove that it has a compelling interest of the highest order in prohibiting objecting doctors from being excused from its mandates.

The Sixth Circuit has ruled that pronoun usage requirements violate the First Amendment. *Meriwether*, 992 F.3d at 510. Far from being "always" a "compelling interest," this interest is "comparatively weak" in the context of pronouns. *Id.* There is no government interest requiring either censoring doctors or compelling them to express views contrary to their best medical judgment or faith. In fact, the opposite is true—the government's only compelling interest should be in having doctors speak accurately to patients about biological realities. The government cannot plausibly maintain that speech that Congress had always allowed in healthcare is now suddenly not only prohibited but prohibited as an interest "of the highest order." *Reagan Nat'l Advert. of Austin, Inc. v. City of Austin*, 972 F.3d 696, 710 (5th Cir. 2020). And because the ACA and the housekeeping statute do not prohibit discrimination based on gender identity, they do not create or support any government interest in these mandates.

The government also lacks a compelling interest in ensuring that patients never hear views that they do not share. "[R]egulating speech because it is discriminatory or offensive is not a compelling state interest." *Telescope Media*, 936 F.3d at 755. The government, of course, lacks any legitimate objective "to produce speakers free" from bias. *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 578–79 (1995). As a result, a non-discrimination "interest is not sufficiently overriding as to justify compelling" speech. *Brush & Nib Studio, LC v. City of Phoenix*, 448 P.3d 890, 914–15 (Ariz. 2019).

At the same time, the government's alleged interest could be achieved in more narrowly tailored ways. Patients can visit many other doctors. Furthermore, as shown below, these mandates contain many religious-targeted exemptions, inconsistencies, and known alternatives. As it stands, though, HHS's mandates are overbroad because "'a substantial number' of [these] applications are unconstitutional, 'judged in relation to the statute's plainly legitimate sweep,'" *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449, n.6 (2008) .

In sum, the government is in no place to dictate the standard of care for highly debatable and evolving medical procedures, as HHS admitted only last year. 85 Fed. Reg. at 37,187 (quoting 81 Fed. Reg. at 31,429). If a healthcare provider recognizes the reality of a biological binary of sex, she ought to be able to speak to patients in accordance with her best medical judgment (not to mention her religious beliefs). HHS is not mandating anti-discrimination as much as a new orthodoxy. *Contra Ward v. Polite*, 667 F.3d 727, 735 (6th Cir. 2012). This brushes aside the thousands of doctors—including the Plaintiffs—across the country who wish to communicate their medical views based on biological sex rather than gender identity. This Court thus should enter facial relief that would "reach beyond the particular circumstances," *John Doe No. 1 v. Reed*, 561 U.S. 186, 194 (2010), to prevent HHS from imposing speech restrictions on any healthcare providers who practice medicine based on biological sex.

VI. HHS's Gender-identity mandates Violate RFRA and the Free Exercise Clause.

The HHS gender-identity mandates also violate the Religious Freedom Restoration Act (RFRA) and the First Amendment's Free Exercise Clause. RFRA prohibits HHS from substantially burdening a person's exercise of religion, unless the agency can prove that the burden is the least restrictive means of furthering a compelling government interest. 42 U.S.C. § 2000bb-1(a). The First Amendment also requires "the most rigorous of scrutiny" of any law that burdens religious practice with a rule that is not neutral and generally applicable. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993).

The mandates violate RFRA and the Free Exercise Clause for three reasons: (1) doctors exercise their religion when they decline to offer, refer for, or speak about gender interventions

contrary to their faith; (2) the mandates here substantially burden that exercise; and (3) the government lacks a compelling interest furthered by the least restrictive means. Strict scrutiny applies because the exemption-riddled mandates are not generally applicable or neutral.[25]

A. Doctors' healthcare decisions involve the exercise of religion.

RFRA defines "exercise of religion" to include "any exercise of religion, whether or not compelled by, or central to, a system of religious belief." 42 U.S.C. §§ 2000bb-2(4), 2000cc-5(7)(A). 'Exercise' involves "belief[,] profession [and] the performance of (or abstention from) physical acts.'" *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 710 (2014).

The religious doctors exercise their religion by serving low-income and underserved populations in health programs and activities funded by HHS, such as Medicaid, Medicare, CHIP, and federally qualified health centers.[26] They also exercise their religion when they decide—because of their religious beliefs about sex—to exclude offering, referring for, or affirming gender interventions. And they exercise their religion by offering frank medical advice about their medical, ethical, and religious positions on gender transitions. They also exercise their religion by not affirming false gender narratives, such as by using inaccurate pronouns or by mis-coding patients in charts and records.[27] But the religious doctors' sincerely held religious beliefs prohibit them offering or otherwise facilitating gender transition interventions, including from engaging in or facilitating in the "objectionable practices" mentioned previously.[28]

B. The gender-identity mandates substantially burden the doctors' exercise of religion.

The government substantially burdens the exercise of religion when: (1) non-compliance would have "substantial adverse practical consequences" on the party exercising its religion, or (2)

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[25] CMA asserts this claim on behalf of its members against both mandates, ACPeds brings it on behalf of its religious members against both mandates, and Dr. Dassow brings it for herself against the grants mandate. Compl. ¶¶ 425, 447, 485.
[26] Van Meter Decl. ¶¶ 152–55; Dickerson Decl. ¶¶ 118–19, 154–56; Dassow Decl. ¶¶ 4–7, 36.
[27] Van Meter Decl. ¶¶ 37, 41, 161; Dickerson Decl. ¶¶ 68–70; Dassow Decl. ¶¶ 32, 35–39.
[28] The CMA members' sincerely held religious beliefs also prohibit them performing, offering, facilitating, or referring for intentional sterilization procedures. Dickerson Decl. ¶ 35.

compliance would "cause the objecting party to violate its religious beliefs, as it sincerely understands them." *Religious Sisters*, 513 F. Supp. 3d at 1147. Courts do not decide whether a religious belief is "reasonable" or second-guess "important question[s] of religion and moral philosophy." *Hobby Lobby*, 573 U.S. at 686.

Complying with the mandates violates the sincerely held religious beliefs of the religious doctors. They believe that God purposefully created persons either as a male or female, that one's God-given sex is immutable and unchangeable, and that they cannot pay for, provide, perform, refer for, offer, or facilitate access to gender transition services.[29] In past cases, the government did not even dispute "that the current Section 1557 regulatory scheme threatens to burden Christian Plaintiffs' religious exercise in the same way as the 2016 scheme." *Franciscan All., Inc. v. Becerra*, No. 7:16-CV-00108-O, 2021 WL 3492338, at *10 (N.D. Tex. Aug. 9, 2021).

This is enough for the mandates to be subject to strict scrutiny under RFRA. As the Supreme Court said in *Bostock v. Clayton County*, "[b]ecause RFRA operates as a kind of super statute, displacing the normal operation of other federal laws, it might supersede [a statute's] commands in appropriate cases." 140 S. Ct. 1731, 1754 (2020).

The mandates are also subject to strict scrutiny under the Free Exercise Clause because they are neither generally applicable nor neutral. First, the § 1557 mandate exempts many entities. It excludes the government's own healthcare programs, such as the military's TRICARE health insurance; it incorporates the exemptions listed in Title VI, VII, IX, and various other statutes, 45 C.F.R. § 92.6; and it excludes healthcare providers that are not "principally" providing healthcare or those that do not receive Federal funds. 45 C.F.R. § 92.3(b). Second, the grants mandate is subject to categorical and discretionary individualized exemptions under 45 C.F.R. § 75.102, rendering it not generally applicable under *Fulton v. City of Philadelphia*, 141 S. Ct. 1868, 1877–79 (2021). It is also subject to a history in the previous administration where it was formally not enforced and exemptions were granted.

[29] Van Meter Decl. ¶¶ 25–81, 155; Dickerson Decl. ¶¶ 27–57, 69, 147; Dassow Decl. ¶¶ 32, 35.

1. The gender-identity mandates do not further a compelling governmental interest.

HHS must prove that it has a compelling interest in applying the mandates to the religious doctors—"the particular claimant[s] whose sincere exercise of religion is being substantially burdened." *Hobby Lobby*, 573 U.S. at 726 (quoting *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430–31 (2006)).

The government cannot satisfy this burden. Here, "[t]he creation of a system of exceptions . . . undermines the [government's] contention that its nondiscrimination- policies can brook no departures." *Fulton*, 141 S. Ct. at 1882. The government grants exemptions to many people, but not for doctors with religious objections. Under the First Amendment and RFRA, that should be the end of the mandates.

Nor does HHS have any valid interest—let alone a compelling one—in mandating that third parties offer, refer for, or affirm another person's gender intervention surgeries and procedures. A broadly stated interest "in ensuring nondiscriminatory access to healthcare" is not enough. *Religious Sisters*, 513 F. Supp. 3d at 1148. Instead, courts must "scrutinize the asserted harm of granting specific exemptions to particular religious claimants and to look to the marginal interest in enforcing the challenged government action in that particular context." *Id*. (quoting *Holt v. Hobbs*, 574 U.S. 352, 363 (2015)). Tellingly, in past cases, HHS never argued that exempting the plaintiffs would harm the government's interests. *Id*.; *Franciscan All.*, 2021 WL 3492338 at *10 (noting that the "government asserts no harm in granting specific exemptions to Christian Plaintiffs").

So too here. The government's "broadly formulated," *O Centro*, 546 U.S. at 431, and generic interests in access to healthcare are not compelling enough to justify the infringement of the doctors' religious beliefs. There is no harm to any purported governmental interest in granting these doctors an exemption, especially with so many other providers available. Van Meter Decl. ¶ 172; Dickerson Decl. ¶ 157; Dassow Decl. ¶ 50. If anything, the government has a much stronger interest in strengthening relationships with faith-based providers and groups, so that the government promotes new providers and avoids reductions in care for poor and rural underserved

communities.[30] The history of exemptions offered to the grants mandate in the previous administration, and HHS's own statements in its 2020 Rule that the gender-identity mandate under Section 1557 were not justified,[31] severely undermine any claim by the government that it has a compelling interest to enforce these mandates. In the 2020 Rule, for example, HHS took the public position that medical distinctions based on biological sex were reasonable, there was no sufficient statutory or policy reason to impose the 2016 gender-identity mandate under the ACA, that "[p]ronouns are not stereotypes," and that the government's alleged interests were "based largely on unsubstantiated hypothetical scenarios."[32] A compelling interest is not one that can flip flop from being an interest of the highest order, to being unsubstantiated, and then to being compelling again in a span of four years. The mandates thus fail strict scrutiny.

2. The gender-identity mandates are not the least restrictive means of furthering any governmental interest.

Even assuming HHS had a legitimate interest furthered by the mandates, "the government must come forward with the evidence to show that its policies are the only feasible means . . . to achieve its compelling interest." *Religious Sisters*, 513 F. Supp. 3d at 1148 (cleaned up). If it can "achieve its interests in a manner that does not burden religion, it must do so." *Fulton*, 141 S. Ct. at 1881.

No evidence shows that anyone has been prevented from obtaining gender transition interventions. There is every indication that the number of providers is sufficient, without forcing individual doctors to violate their consciences. *See Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 693 (N.D. Tex. 2016). The previous administration offered multiple state-wide religious exemptions to the grants mandate, and there is no evidence that persons were denied services as a result. As noted above, HHS itself declared in 2020 that allegations of denial of services due to transgender status were largely based on unsubstantiated hypothetical scenarios. Because the

[30] Van Meter Decl. ¶¶ 152–71; Dickerson Decl. ¶¶ 118–19, 137–57; Dassow Decl. ¶¶ 4–7, 36, 41–45, 47.
[31] *See* 85 Fed. Reg. at 37,161–62, 37,177–92.
[32] *Id.* at 37,177–92.

government has no compelling interest in denying exemptions, and because its purported interests are being furthered without burdening religious exercise, it cannot force religious doctors to violate their consciences. *Fulton*, 141 S. Ct. at 1881.

VII. HHS's 2021 ACA Notice of Enforcement is a substantive rule that unlawfully skipped notice and comment.

According to HHS and two courts, the 2016 ACA Rule's gender identity language remains in effect (and so can be challenged by Plaintiffs). But, if the 2016 ACA Rule's was vacated in *Franciscan Alliance*, HHS's May 10, 2021, Notice of Enforcement was itself a new substantive and legislative rule that required notice and comment under the APA. 5 U.S.C. § 553.

When an agency binds itself to a legal standard, leaving officials no enforcement discretion to disregard the theory of liability, the agency creates a legislative or substantive rule and must do so only through notice and comment. *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987). An agency "can't evade its notice-and-comment obligations" where its action "established or changed a 'substantive legal standard.'" *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810, 1817 (2019). Likewise, 45 C.F.R. §§ 1.2, 1.3, 1.4 would in any event have required notice and comment. *Voyageurs Region Nat'l Park Ass'n v. Lujan*, 966 F.2d 424, 428 (8th Cir. 1992).

Thus, to reimpose the 2016 gender-identity mandate under § 1557, if it had been vacated, requires notice and comment. But HHS has not done this.

VIII. HHS is denying plaintiffs the benefit of SUNSET Rule review of the gender-identity mandates and conscience protection rules through its unlawful delay rule.

HHS has also deprived the doctors of their right to participate in notice and comment processes by which HHS is supposed to assess and review these rules. The SUNSET Rule requires retrospective review of HHS rules with a significant economic effect on a substantial number of small entities under the factors outlined in the Regulatory Flexibility Act, 5 U.S.C. § 610(b) (RFA)—including the mandates that affect ACPeds and CMA. HHS's release of a final rule ("Delay Rule") purporting to delay the SUNSET Rule by one year was ineffective because it violated the APA procedural safeguards; disregarded the RFA's review requirements; and failed the APA's requirements of reasoned decision making. This Court should thus declare that the

SUNSET Rule has been in effect since its originally scheduled effective date, restoring the ability of doctors to participate in regulatory review of burdensome regulations like the mandates.

A. HHS's Delay Rule violates the APA's procedural safeguards.

Under the APA, agency rules do not go into effect for thirty days after publication and all substantive rules are subject to notice and comment. 5 U.S.C. § 553(b)–(d). HHS's Delay Rule violates both requirements.

First, the Delay Rule violates the constraint that agency action is not final until published in the Federal Register. An agency "shall separately state and currently publish in the Federal Register" its rules, 5 U.S.C. § 552(a)(1); all "substantive rules of general applicability adopted as authorized by law" must be published in the Federal Register, *id.*; and unless there is a finding of good cause to waive this specific requirement, the "required publication" of a rule may not be less than 30 days before a rule's effective date, 5 U.S.C. § 553(d).

The SUNSET Rule states an effective date of March 22, 2021. 86 Fed. Reg. at 5,694. HHS posted an unpublished version of the Delay Rule online on March 19, 2021,[33] but the Delay Rule did not publish in the Federal Register until March 23, 2021 (86 Fed. Reg. at 15,404). HHS therefore claims that a website posting delayed the SUNSET Rule without the need to publish that delay in the Federal Register before the regulation went into effect. This is incorrect under the APA. Delaying a duly-enacted substantive regulation is itself a substantive regulation, and therefore the delay is not effective until publication. *Nat. Res. Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009) ("Agencies must publish substantive rules in the Federal Register to give them effect."). Indeed, it is a "basic tenet of administrative law, set out by the APA," that regulations do not take effect or have any legal effect until they are published in the Federal Register. *Nat. Res. Def. Council v. NHTSA*, 894 F.3d 95, 106 (2d Cir. 2018). When an agency purports to delay the effective dates of a prior final rule, "Congress intended for publication to be the operative event." *Id*. Before publication, an action is not final, and the agency may change it

[33] *See* https://public-inspection.federalregister.gov/2021-05907.pdf.

without new notice or comment; after that point, it is final, and an agency can only change it after new notice and comment. *Humane Soc'y of the U.S. v. U.S. Dep't of Agric.*, 474 F. Supp. 3d 320, 330 (D.D.C. 2020). What is more, "publication" in the Federal Register requires more than mere "filing" the document for publication; it requires actual publication. *Rowell v. Andrus*, 631 F.2d 699, 704 (10th Cir. 1980).

Second, the Delay Rule must be set aside because it is a legislative or substantive rule that unlawfully skipped notice and comment under the APA. 5 U.S.C. § 553. Any agency action delaying the effective date or compliance dates of a prior rule is itself a new substantive rule, is subject to judicial review, and requires notice and comment. *See, e.g., Pineros y Campesinos Unidos del Noroeste v. Pruitt*, 293 F. Supp. 3d 1062, 1066 (N.D. Cal. 2018); *Open Communities All. v. Carson*, 286 F. Supp. 3d 148, 163, 174 (D.D.C. 2017). The same is even more true for attempts to change compliance dates. *Becerra v. U.S. Dep't of Interior*, 276 F. Supp. 3d 953, 964 (N.D. Cal. 2017). Removing the possibility of forced compliance with regulations, as well as leaving in place legal obligations, creates legal consequences. *Clean Air Council v. Pruitt*, 862 F.3d 1, 6–7 (D.C. Cir. 2017). Stays issued under § 705 are not "committed to agency discretion by law" and are thus subject to judicial review for procedural propriety, legal authority, and arbitrariness and capriciousness. *Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 144 (S.D.N.Y. 2019). An agency must take comments on the same questions on which it bases its delay. *State v. Bureau of Land Mgmt.*, 286 F. Supp. 3d 1054, 1072 (N.D. Cal. 2018). If changes to effective dates were not final rules, "an agency could guide a future rule through the rulemaking process, promulgate a final rule, and then effectively repeal it, simply by indefinitely postponing its operative date," even though the "APA specifically provides that the repeal of a rule is rulemaking subject to rulemaking procedures." *Nat. Res. Def. Council, Inc. v. U.S. EPA*, 683 F.2d 752, 762 (3d Cir. 1982). For this reason, "an order delaying the rule's effective date" is "tantamount to amending or revoking a rule." *Clean Air Council*, 862 F.3d at 6. The Delay Rule thus amounts to the promulgation of a regulation. *Env't Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 813 (D.C. Cir. 1983). A rule such as the Delay Rule "represents the final agency position on this

issue, has the status of law, and has an immediate and direct effect on the parties," leaving "no difficulty concluding that the Secretary has issued a final decision" subject to APA review. *See Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 823 F.2d 608, 614–15 & n.5 (D.C. Cir. 1987).

That delay has substantive effects on regulated entities because it removes procedural opportunities for public participation on set deadlines. The Plaintiffs, for example, have been deprived of the procedural protections of the SUNSET Rule with regard to how those procedural protections apply to the § 1557 mandate and the grants mandate, as well as other rules protecting conscientious objections in health care settings, *see* 45 C.F.R. Pt. 88. The Delay Rule thus is exactly the kind of binding rule Congress insisted must be issued only after public notice and an opportunity to comment.

Because HHS never undertook notice and comment for its delay of the SUNSET Rule, nor did HHS make any express finding of good cause to skip any of these procedures under the APA or its own regulations, the Delay Rule is without procedure required by law under the APA. A "new administration's simple desire to have time to review, and possibly revise or repeal, its predecessor's regulations falls short of th[e] exacting standard" for when notice and comment can be ignored. *Pineros y Campesinos Unidos del Noroeste*, 293 F. Supp. 3d at 1067.

B. HHS lacked authority to issue the Delay Rule.

In enacting the Delay Rule, HHS invoked 5 U.S.C. § 705 as its authority to stay the final, published SUNSET Rule. HHS did not meet Section 705's requirements.

First, HHS could not issue a delay of the SUNSET Rule because Section 705 does not allow an agency to delay the compliance dates of a prior, already-effective, already-published rule. Instead, it only allows an agency to delay the effective date of a published rule. "The plain language of the statute authorizes postponement of the 'effective date,' not 'compliance dates.'" *State v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1118—20 (N.D. Cal. 2017) (quoting 5 U.S.C. § 705). Because the SUNSET Rule took effect on March 22, 2021, before HHS published the Delay Rule on March 23, 2021, authority is lacking for issuing the Delay Rule.

Second, HHS did not satisfy the standard under 5 U.S.C. § 705 that "justice so require[d]" the agency to "postpone the effective date of action taken by it, pending judicial review." To "justify a stay under § 705, an agency must do more than pay lip service to the pending litigation, or merely assert, without any specificity, that the litigation raises serious questions concerning the validity of certain provisions of the rule." *Bauer v. DeVos*, 325 F. Supp. 3d 74, 107 (D.D.C. 2018) (cleaned up). "Most significantly, the relevant equitable considerations . . . must be tied to the underlying litigation." *Id.* at 106. Section 705 cannot be used "simply because litigation in the court of appeals happens to be pending." *U.S. Dep't of Energy*, 362 F. Supp. 3d at 150. The desire to reconsider a rule is also not an appropriate factor because it is "unrelated to the pending [court] case and are thus beyond the scope of the relevant § 705 considerations." *Id*. So, too, the "mere fact that parties would avoid the costs of complying . . . is plainly insufficient to support a § 705 stay." *Id*. at 107–08.

These insufficient reasons are precisely the ones cited by HHS in support of its Delay Rule. HHS stated that (1) "the Court may find merit in some of Plaintiffs' claims"; (2) "that Plaintiffs' allegations of harm are credible"; (3) "that the balance of equities and the public interest warrant postponement"; (4) and that the SUNSET Rule "could create significant obligations for HHS, cause confusion for the public, including Plaintiffs, and may lead to compliance costs." 86 Fed. Reg. at 15,405. HHS also said that "HHS is unaware of any benefits from the implementation of the SUNSET final rule that would be significantly curtailed from a stay of its effective date." *Id*. HHS also questioned whether the SUNSET Rule "is consistent with the policies and goals of the current administration." 86 Fed. Reg. at 15,405. HHS's rationale for the Delay Rule thus amounts to mere disagreement with the rule—an insufficient reason for a Section 705 stay. Moreover, all of the policy issues raised by HHS in the Delay Rule were already overruled by HHS in issuing the SUNSET Rule. 86 Fed. Reg. at 5,704–5,750. Finally, the claim that a delay was required for "judicial review" of the SUNSET Rule was pretextual for giving time to repeal the SUNSET Rule, not obtain a ruling. A § 705 stay is pretextual "where the parties are content to keep the case indefinitely on hold." *U.S. Dep't of Energy*, 362 F. Supp. 3d at 150–51. HHS's stay was entered

so it could begin "rulemaking repealing the SUNSET Rule." Stipulated Request, *Cnty. of Santa Clara v. U.S. Dep't of Health and Human Servs.* No. 5:21-cv-01655-BLF, ECF No.32 (N.D. Cal. July 30, 2021).

C. HHS's Delay Rule flouts the Regulatory Flexibility Act.

The Delay Rule (and associated pretextual litigation) also violates section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 610. Section 3(a) of the RFA requires a published "plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities." 5 U.S.C. § 610(a). It must "provide for the review" within ten years. *Id*. HHS has not provided a way to comply with the RFA, and HHS has admitted that it has not yet complied with the RFA. This matches HHS's admission that prior plans did not meet this requirement either. *See* 86 Fed. Reg. at 5,696, 5,738 (collecting examples of HHS's failure to review regulations despite statutory mandates). HHS identified no other "plan" for periodic review which meets the requirements of 5 U.S.C. § 610(a).

IX. Relief declaring the rules are unlawful, and setting aside and vacating them, is appropriate.

Anytime "a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated." *ACLU of Ky. v. McCreary Cty., Ky.*, 354 F.3d 438, 445 (6th Cir. 2003). The doctors' loss of their freedom "for even minimal periods of time" is irreparable injury. *Elrod v. Burns*, 427 U.S. 347, 373 (1976).

Under § 706 of the APA, the court must hold unlawful and set aside agency action subject to the flaws described here, vacating the rules. When "regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioner is proscribed." *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998). The statute gives courts no discretion to do otherwise. *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 848 (D.C. Cir. 1987).

And given that the agency has shown that vacatur will not suffice to deter its illegal conduct, injunctive relief is necessary. Injunctive relief is a standard remedy in these cases. *See*

Texas v. United States, 809 F.3d 134, 187–88 (5th Cir. 2015). The "scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

HHS's determination to find any means to impose its gender-identity mandates on as many people as possible makes both the vacatur and injunctive relief appropriate here. That is the lesson of *Franciscan Alliance*, in which the court denied injunctive relief beyond vacatur as unnecessary, because it assumed HHS would comply with the court's vacatur, only to find later that HHS claimed that it need not comply, necessitating a permanent injunction. *Franciscan Alliance v. Becerra*, No. 7:16-CV-00108-O, 2021 WL 3492338 (N.D. Tex. Aug. 9, 2021). That is also the lesson of *Religious Sisters*, in which the court attempted out of judicial comity to avoid any issues beyond RFRA, and in which it strictly limited its relief to the religious plaintiffs before it. 513 F. Supp. 3d at 1143–45. Emboldened, HHS announced its enforcement of the gender-identity mandates on the rest of the public, including other religious providers, and would grant no religious exemptions unless ordered by a court after all appeals are exhausted. May 10, 2021, Notice of Enforcement. Now, HHS openly intends to recodify and expand all its gender-identity mandates in the next year, seemingly to obviate just these RFRA injunctions.[34]

HHS furthermore intends to *expand* these mandates, to force all religious doctors and hospitals to perform abortions. In August 2021, HHS told the *Whitman-Walker* court that the plaintiffs in that case are "participating in the agency's reconsideration proceedings" and, as evidence, HHS attached a 74-page policy dossier from them advocating "a number of policies it believes should replace the 2020 Rule." HHS Opposition to Lifting Stay, *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.* No. 1:20-cv-01630-JEB, ECF No. 75 at *9 (D.D.C.

[34] *See* Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, available at https://public-inspection.federalregister.gov/2021-28317.pdf (restoring gender identity mandate in ACA plans despite attempted removal by 2020 § 1557 rule); *see also* Office of Information and Regulatory Affairs, "Nondiscrimination in Health Programs and Activities," available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0945-AA17 (describing HHS plans to re-codify gender identity mandate in § 1557 regulations in 2022).

filed Aug. 13, 2021). This detailed blueprint uses expansive language and re-imposes aggressive gender-identity mandates, removes all religious-freedom protections, and reinstates a requirement to provide and pay for abortions. *Id.* (citing Exh. 2 of the same filing).

Nor does HHS intend to enforce RFRA or the First Amendment on itself. At Defendant Pino's recommendation, HHS ended any enforcement by the HHS Office for Civil Rights of religious liberty and constitutional protections. HHS also will not issue new waivers for any religious objections. So rather than voluntarily applying a RFRA decision beyond the parties to a case to similarly situated parties, HHS will force each religious provider into years of litigation—unless this Court issues a nationwide injunction.

As HHS has shown, narrow injunctions will not stop its determined efforts to control the speech and faith of doctors nationwide.

CONCLUSION

For these reasons, Plaintiffs ask this Court to grant their motion for partial summary judgment, issue declaratory relief and enjoin HHS from enforcing its gender-identity mandates.

Respectfully submitted, this 7th day of January 2022.

s/ Matthew S. Bowman

MATTHEW S. BOWMAN
DC Bar No. 993261
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690
Facsimile: (202) 347-3622
mbowman@ADFlegal.org

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

ANTHONY J. BILLER*
NC Bar No. 24,117
ENVISAGE LAW
2601 Oberlin Rd., NW, Ste. 100
Raleigh, NC 27608
Telephone: (919) 414–0313
Facsimile: (919) 782–0452
ajbiller@envisage.law

**Admitted pro hac vice*

rbangert@ADFlegal.org
jscruggs@ADFlegal.org

Counsel for Plaintiffs